VIII. Sample Forms

Informed Consent Form
Case Report Forms
Questionnaires
Daily Diary

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INTEGREVIEW IRB
FEBRUARY 20, 2016

INFORMED CONSENT DOCUMENT
AGREEMENT TO BE IN A RESEARCH STUDY

NAME OF TESTING COMPANY:	Thomas J. Stephens & Associates, Inc.
NUMBER AND TITLE OF STUDY:	C16-CD020 (GLI.04.SPR.US10354); "A Multi-Center Clinical Trial to Evaluate the Efficacy of Two Acne Treatments"
NAME OF PERSON IN CHARGE OF THE RESEARCH STUDY (STUDY DOCTOR/INVESTIGATOR):	Lily Jiang, Ph.D.
TELEPHONE NUMBER(S), DAYTIME:	972-392-1529
AFTER HOURS:	469-766-4781

INTRODUCTION

You are being invited to volunteer for a clinical research study. You must read and sign this form before you agree to take part in this study. This form will give you more information about this study. Please ask as many questions as you need to before you decide if you want to be in the study. You should not sign this form if you have any questions that have not been answered.

Thomas J. Stephens & Associates, Inc., a contract research organization, is being paid by the sponsor (the company paying for this study) to conduct this research study.

You must be honest with the Investigator about your health history or it may not be safe for you to be in this study.

PURPOSE OF THE STUDY

The purpose of this study is to evaluate the efficiency of 2 acne treatments for 24 weeks of use in adult men and women with mild to moderate facial acne, at least 5 inflammatory lesions, and at least 10 – 100 non-inflammatory lesions.

HOW LONG THE STUDY WILL LAST AND HOW MANY PEOPLE WILL BE IN THE STUDY

This study will last 24 weeks and have up to 8 visits. At least 100 subjects, men and women between the ages of 21-45, are expected to complete this study, with at least 50 subjects completed per cell. Each site is to enroll no more than 40 subjects, with at least 100 subjects expected to complete when combined.

TO BE IN THIS STUDY

You must:

- Be a man or woman age 21 to 45 years at the time of enrollment.
- Have mild to moderate acne on the face as determined by the Investigator or designee.
- Have at least 5 inflammatory lesions as determined by the Investigator or designee.
- Have 10 – 100 non-inflammatory lesions as determined by the Investigator or designee.
- Be willing to use the test products as instructed for 24 weeks.

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- Be willing and able to comply with all of the time commitments and procedural requirements of the clinical trial protocol.
- Be willing to provide written informed consent including photo release, Health Insurance Portability and Accountability Act (HIPAA), and be able to read, speak, write, understand English and be willing to share personal information and data, as verified by signing a written authorization at the screening.
- Be willing to withhold all facial treatments during the course of the study including botulinum toxin, injectable fillers, microdermabrasion, IPL, peels, facials, laser treatments and tightening treatments. Waxing and threading is allowed but not facial laser hair removal.
- Males must be regular shavers and willing to shave on the day of the study visits (prior to clinic visits).
- Women of child bearing potential must be willing to take a urine pregnancy test prior to study enrollment, at week 24, and when deemed appropriate by the Investigator and/or Sponsor.
- Individuals of child bearing potential must use an acceptable method of contraception throughout the study. Acceptable methods of birth control include:
    - Oral and other system contraceptives. Individuals must be on a stable use for 3 months prior to study enrollment. Individuals on oral contraceptives must not alter their use, including dose or regimen for the duration of the study
    - Double barrier
    - Bilateral tubal ligation (tubes tied)
    - Partner vasectomy
    - Abstinence
- Be willing to follow study requirements and report any changes in health status or medications, side effect symptoms, or reactions immediately.
- Be stable on any medication you are taking for at least 30 days

YOU CANNOT BE ON THE STUDY

If you:

- Have been diagnosed with allergies to topical acne products.
- Have a condition and/or disease of the skin that the Investigator deems inappropriate for participation.
- Are a woman who is breastfeeding, pregnant, or planning to become pregnant during the study.
- Have pre-existing or dormant dermatologic conditions on the face (e.g., psoriasis, rosacea, eczema, seborrheic dermatitis, severe excoriations etc.) which in the opinion of the Investigator could interfere with the outcome of the study.
- Have a history of immunosuppression/immune deficiency disorders (including HIV infection or AIDS) or currently using immunosuppressive medications (e.g., azathioprine, belimumab, cyclophosphamide, Enbrel, Imuran, Humira, mycophenolate mofetil, methotrexate, prednisone, Remicade, Stelara.).
- Have an uncontrolled disease such as asthma, diabetes, hypertension, hyperthyroidism, or hypothyroidism. Individuals having multiple health conditions may be excluded from participation even if the conditions are controlled by diet, medication, etc. at the Investigator's discretion.
- Are currently participating in another facial usage study or have participated in a clinical trial within 4 weeks prior to inclusion into the study.
- Have a history of skin cancer on the face within the past 5 years.
- Have any planned surgeries and/or invasive medical procedures during the course of the study.

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- Have started hormone replacement therapies (HRT) or hormones for birth control less than 3 months prior to study entry or plan on starting, stopping, or changing doses of HRT or hormones for birth control during the study.
- Have facial sunburn or excessive tanned facial skin or are not willing to avoid daily sun exposure on the face and the use of tanning beds or sunless tanning products for the duration of the study.
- Have severe acne, acne conglobata, multiple nodules or cysts (more than 2).
- Are currently taking a natural or prescription testosterone blocker (e.g. saw palmetto, blask cohosh, chaste tree, chasteberry, spironolactone, drospirenone, progestins).
- Are currently on a testosterone booster or prescription testosterone (e.g. DHEA, tribulus, testosterone cypionate, testosterone enanthate, Sustanon, testosterone propionate, testosterone phenylpropriate, Omnadren etc.).
- Are currently taking or have taken within the last 30 days oral or topical prescription medications for acne such as Doxycycline, Minocycline, Clindamycin, Bactrim, Tetracycline, Erythromycin, Vibramycin and topical tretinoin (Retin A, Renova, Adapalene, Tazarotene), Azelaic acid, benzoyl peroxide, Dapsone, Sodium sulfacetamide, Differin, Epiduo.
- Have used oral isotretinoin (Accutane) within the past 6-months.
- Are routinely using (3x a week or more) topical over-the-counter (OTC) acne product (e.g. benzoyl peroxide, salicylic acid, alpha hydroxyl, beta hydroxyl and/or poly-hydroxy products or medicated cleansers, wipes, masks, scrubs, gels and creams) within 14 days of the study entry.
- Are using or have used any systemic medication considered to affect the course of acne, specifically, but not exclusively antibiotics or steroids within the last 30 days prior to entry into the study.
- Have excessive facial hair, including beard, mustache or goatee, or scars, which could interfere with evaluations as determined by the Investigator or designee.

WHAT WILL HAPPEN DURING THE STUDY

***Visit 1: Screening (* Visit 1 {*Screening*} AND Visit 2 {*Baseline*} may be combined into 1 Visit)**

You will:

- Be given an IRB-approved Informed Consent Form (ICF), to read and sign. You will be given enough time to read the informed consent, and ask questions about the study, and sign 2 copies of this consent form. (1 for clinic records, 1 for your records)
- Be given an eligibility and health questionnaire to complete, and assigned a screening number.
- Will acclimate for 15 minutes in a room at 68-75^{0}F and 35-65% humidity.
- Will be screened by the Investigator or designee to see if you qualify for the study.
- If you do qualify for the study, you will:
    - Take a urine pregnancy test (females of child-bearing potential)
    - Have a dermatologist confirm your eligibility
    - Schedule your next appointment.

***Visit 2: Baseline**

- Be asked if you have experienced any changes in your health since the previous visit.
- Will acclimate for 15 minutes in a room at 68-75^{0}F and 35-65% humidity.
- Be screened by the Investigator or designee to see if you still qualify for the study.
- Have your health and eligibility re-reviewed.

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- If you still qualify for the study you will:
    - Be assigned a subject number
    - Have photos taken of your face
    - Be randomly assigned to receive one of the test products & supporting facial cleanser, moisturizer & facial SPF 30
    - Be provided verbal and written usage instructions, and a daily diary to record product use
    - Schedule your next appointment

Visits 3, 4 (Week 1, Week 2)

- Be asked if you have experienced any changes in your health since the previous visit.
- Will acclimate for 15 minutes in a room at 68-75^{0}F and 35-65% humidity.
- Have your face examined by the Investigator or designee
- Complete a self-assessment questionnaire
- Have your diary collected and reviewed for compliance, and returned to you. At week 2, your diary will be retained by the testing facility and you will be given a new diary
- Have your product collected, weighed, and returned to you
- Schedule your next appointment

Visits 5, 6 (Week 6, Week 12)

- Be asked if you have experienced any changes in your health since the previous visit.
- Will acclimate for 15 minutes in a room at 68-75^{0}F and 35-65% humidity.
- Have your face examined by the Investigator or designee
- Have photos taken of your face
- Complete a self-assessment questionnaire
- Have your diary collected and reviewed for compliance, and retained by the testing facility and you will be given a new diary.
- Have your product collected, weighed, and retained. New products will be dispensed as necessary.
- Schedule your next appointment

Visit 7 (Week 18)

- Be asked if you have experienced any changes in your health since the previous visit.
- Have your diary collected and reviewed for compliance, and retained by the testing facility and you will be given a new diary.
- Have your product collected, weighed, and returned to you
- Schedule your next appointment

Visit 8 (Week 24)

- Be asked if you have experienced any changes in your health since the previous visit.
- Take a urine pregnancy test (females of child-bearing potential).
- Will acclimate for 15 minutes in a room at 68-75^{0}F and 35-65% humidity.
- Have your face examined by the Investigator or designee
- Have photos taken of your face
- Complete a self-assessment questionnaire
- Have your diary collected and reviewed for compliance, and retained by the testing facility.
- Have your product collected, weighed, and retained by the testing facility.

Do not give the study product to other people and keep it out of the reach of children.

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RISKS OR DISCOMFORTS

If you do not understand what any of these side effects mean, please ask the investigator or study staff to explain these terms to you.

Because the study products are investigational, all of their side effects may not be known. There may be rare and unknown side effects. Some of these may be life threatening.

Possible risks associated with the product are, as with any other cosmetic and OTC products, signs of irritation including:

- Itching
- Burning
- Stinging
- Rash or other allergic reaction
- Tingling
- Scaling/Dryness
- Redness

In some cases, it is possible for a subject to develop allergic reactions to the test material(s). This risk is increased for individuals with a history of allergies, and individuals with asthma and/or a history of hives may also be affected. Symptoms include rash, hives, and itching.

You must tell the Investigator or study staff about all side effects that you have. If you are not honest about your side effects, it may not be safe for you to stay in the study.

BIRTH CONTROL, DANGERS OF PREGNANCY AND BREASTFEEDING

If you are a female, you must not get pregnant while in this study. The only certain way to not get pregnant is to not have sex. If you are a female and choose to have sex, you must use a type of birth control.

Even if you use birth control during the study, there is a chance you could become pregnant. If you are pregnant or become pregnant during the study, test products or procedures may involve unforeseeable risks to the unborn baby.

A pregnancy test can be wrong. If you become pregnant during the study, stop using the test products and call/inform the Investigator at once.

You cannot be in the study if you are breastfeeding. It is not known whether the test products are safe for breast fed babies. Therefore if you are breastfeeding a child then it may not be safe for you to participate in the study.

POSSIBLE BENEFITS OF THE STUDY

You will not get any medical benefit from being in this study, and there is no promise that your condition (acne) will get better. It might stay the same or it might get worse. Your participation will provide information that may help others. There may be other marketed products that claim to have similar benefits.

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OTHER OPTIONS TO PARTICIPATING IN THE STUDY

Since this study is for research only, the only other choice would be not to be in the study.

STUDY AND TEST PRODUCT CONFIDENTIALITY

To participate in this study, you must agree to keep any information relating to the design, identity or use of these test product samples confidential.

On rare occasions, the sponsor may allow the testing company to disclose to you the name of the test products if you are not given this information during the study. This information is typically not provided until the end of the study or after the test products have been released for sale to the public. The study doctor or study staff will notify you if the sponsor allows us to give you this information.

DISCLOSURE AGREEMENT

This section explains how personal health information collected about you for the study may be used. Your personal health information includes, but is not limited to, information that was collected for your entry into the study and information that is collected during the study. The purpose of collecting this information is to allow the study staff and the Investigator to conduct the study, to evaluate the sponsor's study products and to analyze the study results.

You may decide not to give permission for the release of your personal health information for the study. In that case, you will not be able to participate in the study. This is because the study staff and/or the Investigator would not be able to collect the information needed to evaluate the sponsor's study products.

People who may inspect your personal and health information includes the Investigator, the Institutional Review Board, IntegReview IRB, FDA and other regulatory authorities from the United States or other countries, the study sponsor and people that work with the sponsor which includes, monitoring committees, contract research organizations, and consultants who have contracts with the company to do the study and review the study results. These reviews are done to check on the quality of the study and also for other purposes allowed by law.

The results of the study may be published in a medical book or journal, or presented at meetings for educational purposes. Neither your name, nor any other personal health information that specifically identifies you, will be used in those materials or presentations.

You may ask the Investigator to see and copy your personal health information related to the study. You may also ask the Investigator to correct any study related information about you that is wrong. You may have to wait until the end of the study to see your study records, so that the study can be organized properly.

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This permission to share your personal health information for this study does not have an expiration date. If you no longer want to share your personal health information, you may cancel your permission at any time by writing to the study staff and/or the Investigator at the address below:

Thomas J. Stephens & Associates, Inc.
1801 North Glenville Drive, Suite 200
Richardson, TX 75081

If you cancel your permission after you have started in the study, the study staff and the Investigator will stop collecting your personal health information. Although they will stop collecting new information about you, they will need to use the information they have already collected to evaluate the study results. If you start the study and then cancel your permission, you will not be able to continue to participate in the study. This is because the study staff and/or the Investigator would not be able to collect the information needed to evaluate the study.

Thomas J. Stephens & Associates and the sponsor will make every effort to keep your personal health information private. But after the study staff or the Investigator share your personal health information from the study, federal privacy laws may not keep it private. There might be laws in your state or other federal laws that would protect the privacy of this information.

CONFIDENTIALITY

Your records of being in this study will be kept private except when ordered by law. The following people will have access to your study records:

- The Investigator
- Sponsor company or research institution [including monitor(s) and auditor(s)]
- Other country, state or federal regulatory agencies
- IntegReview IRB

The Institutional Review Board (IRB), IntegReview, and accrediting agencies may inspect and copy your records, which may have your name on them. Therefore, total confidentiality cannot be guaranteed. If the study results are presented at meetings or printed in publications, your name will not be used.

IN CASE OF STUDY RELATED INJURY

Side effects or complications, both foreseeable and unforeseeable, are possible in any research study without any fault to you, the Investigator, the study site, or the study sponsor. If you get hurt or sick as a direct result of being in this study, the sponsor will pay the costs of reasonable medical treatment. To ask questions about this, talk to the Investigator or study staff.

The sponsor's policy does not offer compensation for other expenses. Be aware that your health care payer/insurer might not cover the costs of study-related injuries or illnesses.

Unreimbursed medical expenses not covered by insurance or other third party coverage will be reimbursed by the sponsor for medical treatment for any injury that, in the opinion of the study doctor and the sponsor, is directly caused by the investigational product or by procedures required by the study protocol which would not have been performed as part of your regular medical care.

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LEGAL RIGHTS

You will not lose any of your legal rights by signing this consent form.

CONTACT INFORMATION

If you have questions, concerns, or complaints about this study or to report a study related injury, contact:

Lily Jiang, Ph.D.
972-392-1529 daytime telephone number
469-766-4781 after hours number

If you are unable to reach anyone at the number(s) listed above and you need medical attention, please go to the nearest emergency room.

If you do not want to talk to the Investigator or study staff, if you have concerns or complaints about the research, or to ask questions about your rights as a study subject you may contact IntegReview. IntegReview's policy indicates that all concerns/complaints are to be submitted in writing for review at a convened IRB meeting to:

Mailing Address:	OR	Email Address:
Chairperson IntegReview IRB 3815 S. Capital of Texas Highway Suite 320 Austin, TX 78704		integreview@integreview.com

If you are unable to provide your concerns/complaints in writing or if this is an emergency situation regarding subject safety, contact our office at:

512-326-3001 or
toll free at 1-877-562-1589
between 8 a.m. and 5 p.m. Central Time

IntegReview has approved the information in this consent form and has given approval for the Investigator to do the study. This does not mean IntegReview has approved your being in the study. You must consider the information in this consent form for yourself and decide if you want to be in this study.

PAYMENT FOR BEING IN THE STUDY

You may receive up to $575.00 for being in the study. You will be paid per completed visit as follows:

Visit	Compensation (amount)
Screening/Baseline (Visit 1)	$40.00
Week 1 (Visit 2)	$60.00
Week 2 (Visit 3)	$65.00
Week 6 (Visit 4)	$75.00
Week 12 (Visit 5)	$90.00

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Week 18 (Visit 6)	$95.00
Week 24 (Visit 7)	$150.00

If you choose to leave or are withdrawn from the study for any reason before finishing all visits you will be paid for each completed visit. You will receive payment within 2 weeks of final study visit.

If you do not qualify for any reason, you will be paid $20.00, which will be mailed to you within 2 weeks of the baseline study visit.

If you are paid $600.00 or more by Thomas J. Stephens & Associates, Inc. in a calendar year, those payments will be reported to the Internal Revenue Service via form 1099-MISC. As required by tax laws, if you withhold your social security number, Thomas J. Stephens & Associates, Inc. is required to withhold 28% of your payment for tax purposes. In this case a form 1099-MISC will be sent to you reporting your withholding.

VOLUNTEERING TO BE IN THE STUDY

It is your choice if you want to be in the study. No one can force you to be in the study. You may not want to be in this study or you may leave the study at any time without penalty or loss of benefits to which you are otherwise entitled.

The Investigator, the sponsor company, or IntegReview may take you out of the study without your permission, at any time, for the following reasons:

- If you do not follow the Investigator's instructions
- If we find out you should not be in the study
- If the study is stopped
- If it becomes harmful to your health

If you leave the study or if you are taken out of the study, you may be asked to return for a final visit to have some end of study evaluations or tests. If information generated from this study is published or presented, your identity will not be revealed. If you leave the study, no more information about you will be collected for this study. However, all of the information you gave us before you left the study will still be used.

NEW FINDINGS

If there is new information or any significant new findings that could relate to your willingness to continue participation we will tell you. You can then decide if you still want to be in the study.

THE REASON FOR INSTITUTIONAL REVIEW BOARDS AND INFORMED CONSENT

What is a consent form?
The informed consent document contains information required by federal regulations. The informed consent document must be approved by an Institutional Review Board (IRB).

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What is an Institutional Review Board (IRB)?
An Institutional Review Board (IRB) is a group of people that reviews research studies. The main goal of this review is to protect the rights and well being of the human subjects participating in research studies.

IntegReview, the IRB for this study
IntegReview is an IRB whose board members provide IRB services across the United States, Canada, Japan and Latin America.

To meet requirements of the law, the IntegReview Boards currently include:

- Doctors
- Pharmacists
- Nurses
- Toxicologists (people who study the harmful effects of chemicals)
- Other specialists
- Others who do not have a background in science/medicine

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AGREEMENT TO BE IN THE STUDY

This consent form contains important information to help you decide if you want to be in the study. If you have any questions that are not answered in this consent form, ask one of the study staff.

Please answer **YES** or **NO** to the following questions:

A. Is this document in a language you understand? _____

B. Do you understand the information in this consent form? _____

C. Have you been given enough time to ask questions and talk about the study? _____

D. Have all of your questions been answered to your satisfaction? _____

E. Do you think you received enough information about the study? _____

F. Do you volunteer to be in this study of your own free will and without being pressured by the Investigator or study staff? _____

G. Do you know that you can leave the study at any time without giving a reason and without affecting your health care? _____

H. Do you know that your health records from this study may be reviewed by the sponsor company and by government authorities? _____

I. Do you know that you cannot be in another study while you are in this study? _____

IF YOU ANSWERED "NO" TO ANY OF THE ABOVE QUESTIONS,
OR YOU ARE UNABLE TO ANSWER ANY OF THE ABOVE QUESTIONS,
YOU SHOULD NOT SIGN THIS CONSENT FORM.

_____
Printed Name of Adult Study Subject

_____
Signature of Adult Study Subject Date

_____
Printed Name of Person Explaining Consent Form

_____
Signature of Person Explaining Consent Form Date

You will be given a signed and dated copy of this consent form to keep.

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Authorization and Release Form

I hereby for good and valuable consideration grant to Thomas J. Stephens & Associates, the study sponsor and their respective affiliates, agencies, agents, employees, and assigns (collectively, "Authorized Entities"), the unrestricted, royalty free, irrevocable and perpetual right and permission to reproduce, distribute, broadcast and/or otherwise use for advertising and other commercial/noncommercial purposes: (i) my name, likeness, image, video, and any other biographical or personal information ("Personal Content"); and (ii) any statement or endorsement, or any portions thereof ("Testimonial(s)"), made by me relating to the study sponsor's products ("Products"), in any and all media now known or later developed, worldwide in perpetuity, without further compensation or approval by me.

I hereby assign to the Authorized Entities all of my world-wide right, title and interest, including my copyright interests and all renewals, reissues and extensions thereof, in and to the Personal Content and Testimonial(s), including without limitation, any photographic portraits, sound recordings and video performances of and/or by me in connection with the Personal Content and/or Testimonial(s).

I am at least 21 years of age, and competent to contract in my own name. I have read and understand this Authorization and Release.

_____
Printed Name of Adult Study Subject

_____
Signature of Adult Study Subject Date

_____
Printed Name of Person Explaining Release Form

_____
Signature of Person Explaining Release Form Date

Copy of consent form given to subject on _____ (date) by _____ (initials)

You will be given a signed and dated copy of this consent form to keep.

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AUTHORIZATION TO USE AND DISCLOSE PERSONAL HEALTH INFORMATION FOR RESEARCH

THIS SECTION DESCRIBES YOUR RIGHTS AND HOW PERSONAL HEALTH INFORMATION COLLECTED ABOUT YOU DURING THIS STUDY MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

The United States government has issued a privacy rule to protect the privacy rights of patients. This rule was issued under a law called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The Privacy Rule is designed to protect the confidentiality of your personal health information. The document you are reading, called an "Authorization," describes your rights and explains how your health information will be used and disclosed (shared).

Federal law requires hospitals, researchers and health care providers to protect the privacy of information that identifies you and relates to your past, present and future physical and mental health or conditions.

All information collected during the study will be retained by the study doctor and the Study Sponsor, except as required by law. Information from this study will be given to the sponsor. "Sponsor" includes any persons or companies, which are contracted by the sponsor to have access to the research information during and after the study. The information will also be given to the U.S. Food and Drug Administration (FDA). Study records which identify you and the consent form signed by you will be inspected and/or copied for research or regulatory purposes by:

- Sponsor
- Agents for the sponsor
- The US Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies
- IntegReview IRB

Because of the need to release information to these parties, absolute confidentiality cannot be guaranteed. The results of this research study may be presented at meetings or in publications; however, your identity will not be disclosed in those presentations.

For purposes of study reporting, you will be identified by your initials and code numbers only. However, your name, date of birth, address, and phone number will be kept on record by the study doctor in case you need to be contacted in the future about this study.

After your personal health information is disclosed to the Study Sponsor, the results of the study may be reanalyzed at a later date and may be combined with the results of other studies. The Study Sponsor and people who work with the Study Sponsor may use the results of this study for other research purposes, including:

- Developing a better understanding of the disease;
- Improving the design of future actual use trials

After the study staff or the study doctor discloses your personal health information to others, it could be re-disclosed and no longer protected by federal privacy laws.

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This permission to share your personal health information for this study does not have an expiration date. If you do not withdraw this Authorization in writing, it will remain in effect indefinitely. Your study doctor will keep this Authorization for at least 6 years. If you no longer want to share your personal health information, you may cancel your permission at any time by writing to the study staff and/or the study doctor at the address below:

Thomas J. Stephens & Associates, Inc.
1801 North Glenville Drive, Suite 200
Richardson, TX 75081

You have the right to see and get a copy of your records related to the study for as long as the study doctor has this information. However, by signing this Authorization you agree that you might not be able to review or receive some of your records related to the study until after the study has been completed.

If you cancel your permission after you have started in the study, the study staff and the study doctor will stop collecting your personal health information unless the information concerns an adverse event (a bad effect) related to the study. If an adverse event occurs, your entire medical record may be reviewed. All information that has already been collected for study purposes, and any new information about an adverse event related to the study, will be sent to the study sponsor. Although they will stop collecting new information about you, they will need to use the information they have already collected to evaluate the study results. If you start the study and then cancel your permission, you will not be able to continue to participate in the study. This is because the study staff and/or the study doctor would not be able to collect the information needed to evaluate the study results.

If you withdraw from the study but do not withdraw your Authorization, new personal health information may be collected until this study ends.

You may decide not to give permission for the release of your personal health information for this study. In that case, you will not be able to participate. This is because the study staff and study doctor would not be able to collect the information needed to evaluate the study results.

At the completion of the study, you have the right to access your protected health information that is created during this research study that relates to your treatment or to payment, provided such information is not exempted under certain laws and regulations. To request this information, please contact the study doctor at the address listed above.

Your Right to Access Health Information

Subject to certain exceptions prescribed by law, you have a right to request access to the health information that we hold about you and to request changes if your health information is incorrect or incomplete. Any request for access or corrections should be made to the principal doctor conducting this study.

Your records obtained while you are in this trial, as well as related health records, will remain strictly confidential at all times. However, these will need to be made available to others working on the Sponsor's behalf, the Independent Ethics Committee members and Medicines Regulatory Authorities.

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By signing the consent form you agree to this access for the current trial and any further research that may be done. However, the Sponsor will take steps to protect your personal information and will not include your name on any sponsor forms, reports, publications, or in any future disclosures. If you withdraw from the study, we will no longer collect your personal information, but we may need to continue to use information already collected.

Personal data which may be sensitive (e.g., date of birth) will be collected and processed, but only for research purposes in connection with this trial.

The trial data will be sent around the world, but you will not be referred to by name or identified in any report or publication nor could the data be traced back to you. Your data may be transferred to a country that does not have the same level of personal data protection as within the United States. However, The Sponsor maintains high standards of confidentiality and protection.

The Sponsor (who will control the use of the data) will take steps to ensure your personal data is protected.

By taking part in this trial you agree not to restrict the use of any data even if you withdraw from the trial and agree to the transfer of your personal data to other Sponsor companies and to Medicines Regulatory Authorities both within and outside of Europe.

_____

Printed Name of Adult Study Subject

_____

Signature of Adult Study Subject Date

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SEPTEMBER 16, 2016

INFORMED CONSENT DOCUMENT
AGREEMENT TO BE IN A RESEARCH STUDY

NAME OF TESTING COMPANY:	Thomas J. Stephens & Associates, Inc.
NUMBER AND TITLE OF STUDY:	C16-CD020 (GLI.04.SPR.US10354); "A Multi-Center Clinical Trial to Evaluate the Efficacy of Two Acne Treatments"
NAME OF PERSON IN CHARGE OF THE RESEARCH STUDY (STUDY DOCTOR/INVESTIGATOR):	Lily Jiang, Ph.D.
TELEPHONE NUMBER(S), DAYTIME:	972-392-1529
AFTER HOURS:	469-766-4781

INTRODUCTION

You are being invited to volunteer for a clinical research study. You must read and sign this form before you agree to take part in this study. This form will give you more information about this study. Please ask as many questions as you need to before you decide if you want to be in the study. You should not sign this form if you have any questions that have not been answered.

Thomas J. Stephens & Associates, Inc., a contract research organization, is being paid by the sponsor (the company paying for this study) to conduct this research study.

You must be honest with the Investigator about your health history or it may not be safe for you to be in this study.

PURPOSE OF THE STUDY

The purpose of this study is to evaluate the efficiency of 2 acne treatments for 24 weeks of use in adult men and women with mild to moderate facial acne, at least 5 inflammatory lesions, and at least 10 – 100 non-inflammatory lesions.

HOW LONG THE STUDY WILL LAST AND HOW MANY PEOPLE WILL BE IN THE STUDY

This study will last 24 weeks and have up to 8 visits. At least 100 subjects, men and women between the ages of 21-45, are expected to complete this study, with at least 50 subjects completed per cell.

TO BE IN THIS STUDY

You must:

- Be a man or woman age 21 to 45 years at the time of enrollment.
- Have mild to moderate acne on the face as determined by the Investigator or designee.
- Have at least 5 inflammatory lesions as determined by the Investigator or designee.
- Have 10 – 100 non-inflammatory lesions as determined by the Investigator or designee.
- Be willing to use the test products as instructed for 24 weeks.
- Be willing and able to comply with all of the time commitments and procedural requirements of the clinical trial protocol.

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- Be willing to provide written informed consent including photo release, Health Insurance Portability and Accountability Act (HIPAA), and be able to read, speak, write, understand English and be willing to share personal information and data, as verified by signing a written authorization at the screening.
- Be willing to withhold all facial treatments during the course of the study including botulinum toxin, injectable fillers, microdermabrasion, IPL, peels, facials, laser treatments and tightening treatments. Waxing and threading is allowed but not facial laser hair removal.
- Males must be regular shavers and willing to shave on the day of the study visits (prior to clinic visits).
- Women of child bearing potential must be willing to take a urine pregnancy test prior to study enrollment, at week 24, and when deemed appropriate by the Investigator and/or Sponsor.
- Individuals of child bearing potential must use an acceptable method of contraception throughout the study. Acceptable methods of birth control include:
    - Oral and other system contraceptives. Individuals must be on a stable use for 3 months prior to study enrollment. Individuals on oral contraceptives must not alter their use, including dose or regimen for the duration of the study
    - Double barrier
    - Bilateral tubal ligation (tubes tied)
    - Partner vasectomy
    - Abstinence
- Be willing to follow study requirements and report any changes in health status or medications, side effect symptoms, or reactions immediately.
- Be stable on any medication you are taking for at least 30 days

YOU CANNOT BE ON THE STUDY

If you:

- Have been diagnosed with allergies to topical acne products.
- Have a condition and/or disease of the skin that the Investigator deems inappropriate for participation.
- Are a woman who is breastfeeding, pregnant, or planning to become pregnant during the study.
- Have pre-existing or dormant dermatologic conditions on the face (e.g., psoriasis, rosacea, eczema, seborrheic dermatitis, severe excoriations etc.) which in the opinion of the Investigator could interfere with the outcome of the study.
- Have a history of immunosuppression/immune deficiency disorders (including HIV infection or AIDS) or currently using immunosuppressive medications (e.g., azathioprine, belimumab, cyclophosphamide, Enbrel, Imuran, Humira, mycophenolate mofetil, methotrexate, prednisone, Remicade, Stelara.).
- Have an uncontrolled disease such as asthma, diabetes, hypertension, hyperthyroidism, or hypothyroidism. Individuals having multiple health conditions may be excluded from participation even if the conditions are controlled by diet, medication, etc. at the Investigator's discretion.
- Are currently participating in another facial usage study or have participated in a clinical trial within 4 weeks prior to inclusion into the study.
- Have a history of skin cancer on the face within the past 5 years.
- Have any planned surgeries and/or invasive medical procedures during the course of the study.
- Have started hormone replacement therapies (HRT) or hormones for birth control less than 3 months prior to study entry or plan on starting, stopping, or changing doses of HRT or hormones for birth control during the study.

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- Have facial sunburn or excessive tanned facial skin or are not willing to avoid daily sun exposure on the face and the use of tanning beds or sunless tanning products for the duration of the study.
- Have severe acne, acne conglobata, multiple nodules or cysts (more than 2).
- Are currently taking a natural or prescription testosterone blocker (e.g. saw palmetto, blask cohosh, chaste tree, chasteberry, spironolactone, drospirenone, progestins).
- Are currently on a testosterone booster or prescription testosterone (e.g. DHEA, tribulus, testosterone cypionate, testosterone enanthate, Sustanon, testosterone propionate, testosterone phenylpropriate, Omnadren etc.).
- Are currently taking or have taken within the last 30 days oral or topical prescription medications for acne such as Doxycycline, Minocycline, Clindamycin, Bactrim, Tetracycline, Erythromycin, Vibramycin and topical tretinoin (Retin A, Renova, Adapalene, Tazarotene), Azelaic acid, benzoyl peroxide, Dapsone, Sodium sulfacetamide, Differin, Epiduo.
- Have used oral isotretinoin (Accutane) within the past 6-months.
- Are routinely using (3x a week or more) topical over-the-counter (OTC) acne product (e.g. benzoyl peroxide, salicylic acid, alpha hydroxyl, beta hydroxyl and/or poly-hydroxy products or medicated cleansers, wipes, masks, scrubs, gels and creams) within 14 days of the study entry.
- Are using or have used any systemic medication considered to affect the course of acne, specifically, but not exclusively antibiotics or steroids within the last 30 days prior to entry into the study.
- Have excessive facial hair, including beard, mustache or goatee, or scars, which could interfere with evaluations as determined by the Investigator or designee.

WHAT WILL HAPPEN DURING THE STUDY

***Visit 1: Screening (* Visit 1 {*Screening*} AND Visit 2 {*Baseline*} may be combined into 1 Visit)**

You will:

- Be given an IRB-approved Informed Consent Form (ICF), to read and sign. You will be given enough time to read the informed consent, and ask questions about the study, and sign 2 copies of this consent form. (1 for clinic records, 1 for your records)
- Be given an eligibility and health questionnaire to complete, and assigned a screening number.
- Will acclimate for 15 minutes in a room at 68-75^{0}F and 35-65% humidity.
- Will be screened by the Investigator or designee to see if you qualify for the study.
- If you do qualify for the study, you will:
    - Take a urine pregnancy test (females of child-bearing potential)
    - Have a dermatologist confirm your eligibility
    - Schedule your next appointment.

***Visit 2: Baseline**

- Be asked if you have experienced any changes in your health since the previous visit.
- Will acclimate for 15 minutes in a room at 68-75^{0}F and 35-65% humidity.
- Be screened by the Investigator or designee to see if you still qualify for the study.
- Have your health and eligibility re-reviewed.
- If you still qualify for the study you will:
    - Be assigned a subject number
    - Have photos taken of your face

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- Be randomly assigned to receive one of the test products & supporting facial cleanser, moisturizer & facial SPF 30
- Be provided verbal and written usage instructions, and a daily diary to record product use
- Schedule your next appointment

Visits 3, 4 (Week 1, Week 2)

- Be asked if you have experienced any changes in your health since the previous visit.
- Will acclimate for 15 minutes in a room at 68-75^{0}F and 35-65% humidity.
- Have your face examined by the Investigator or designee
- Complete a self-assessment questionnaire
- Have your diary collected and reviewed for compliance, and returned to you. At week 2, your diary will be retained by the testing facility and you will be given a new diary
- Have your product collected, weighed, and returned to you
- Schedule your next appointment

Visits 5, 6 (Week 6, Week 12)

- Be asked if you have experienced any changes in your health since the previous visit.
- Will acclimate for 15 minutes in a room at 68-75^{0}F and 35-65% humidity.
- Have your face examined by the Investigator or designee
- Have photos taken of your face
- Complete a self-assessment questionnaire
- Have your diary collected and reviewed for compliance, and retained by the testing facility and you will be given a new diary.
- Have your product collected, weighed, and retained. New products will be dispensed as necessary.
- Schedule your next appointment

Visit 7 (Week 18)

- Be asked if you have experienced any changes in your health since the previous visit.
- Have your diary collected and reviewed for compliance, and retained by the testing facility and you will be given a new diary.
- Have your product collected, weighed, and returned to you
- Schedule your next appointment

Visit 8 (Week 24)

- Be asked if you have experienced any changes in your health since the previous visit.
- Take a urine pregnancy test (females of child-bearing potential).
- Will acclimate for 15 minutes in a room at 68-75^{0}F and 35-65% humidity.
- Have your face examined by the Investigator or designee
- Have photos taken of your face
- Complete a self-assessment questionnaire
- Have your diary collected and reviewed for compliance, and retained by the testing facility.
- Have your product collected, weighed, and retained by the testing facility.

Do not give the study product to other people and keep it out of the reach of children.

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RISKS OR DISCOMFORTS

If you do not understand what any of these side effects mean, please ask the investigator or study staff to explain these terms to you.

Because the study products are investigational, all of their side effects may not be known. There may be rare and unknown side effects. Some of these may be life threatening.

Possible risks associated with the product are, as with any other cosmetic and OTC products, signs of irritation including:

- Itching
- Burning
- Stinging
- Rash or other allergic reaction
- Tingling
- Scaling/Dryness
- Redness

In some cases, it is possible for a subject to develop allergic reactions to the test material(s). This risk is increased for individuals with a history of allergies, and individuals with asthma and/or a history of hives may also be affected. Symptoms include rash, hives, and itching.

You must tell the Investigator or study staff about all side effects that you have. If you are not honest about your side effects, it may not be safe for you to stay in the study.

BIRTH CONTROL, DANGERS OF PREGNANCY AND BREASTFEEDING

If you are a female, you must not get pregnant while in this study. The only certain way to not get pregnant is to not have sex. If you are a female and choose to have sex, you must use a type of birth control.

Even if you use birth control during the study, there is a chance you could become pregnant. If you are pregnant or become pregnant during the study, test products or procedures may involve unforeseeable risks to the unborn baby.

A pregnancy test can be wrong. If you become pregnant during the study, stop using the test products and call/inform the Investigator at once.

You cannot be in the study if you are breastfeeding. It is not known whether the test products are safe for breast fed babies. Therefore if you are breastfeeding a child then it may not be safe for you to participate in the study.

POSSIBLE BENEFITS OF THE STUDY

You will not get any medical benefit from being in this study, and there is no promise that your condition (acne) will get better. It might stay the same or it might get worse. Your participation will provide information that may help others. There may be other marketed products that claim to have similar benefits.

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OTHER OPTIONS TO PARTICIPATING IN THE STUDY

Since this study is for research only, the only other choice would be not to be in the study.

STUDY AND TEST PRODUCT CONFIDENTIALITY

To participate in this study, you must agree to keep any information relating to the design, identity or use of these test product samples confidential.

On rare occasions, the sponsor may allow the testing company to disclose to you the name of the test products if you are not given this information during the study. This information is typically not provided until the end of the study or after the test products have been released for sale to the public. The study doctor or study staff will notify you if the sponsor allows us to give you this information.

DISCLOSURE AGREEMENT

This section explains how personal health information collected about you for the study may be used. Your personal health information includes, but is not limited to, information that was collected for your entry into the study and information that is collected during the study. The purpose of collecting this information is to allow the study staff and the Investigator to conduct the study, to evaluate the sponsor's study products and to analyze the study results.

You may decide not to give permission for the release of your personal health information for the study. In that case, you will not be able to participate in the study. This is because the study staff and/or the Investigator would not be able to collect the information needed to evaluate the sponsor's study products.

People who may inspect your personal and health information includes the Investigator, the Institutional Review Board, IntegReview IRB, FDA and other regulatory authorities from the United States or other countries, the study sponsor and people that work with the sponsor which includes, monitoring committees, contract research organizations, and consultants who have contracts with the company to do the study and review the study results. These reviews are done to check on the quality of the study and also for other purposes allowed by law.

The results of the study may be published in a medical book or journal, or presented at meetings for educational purposes. Neither your name, nor any other personal health information that specifically identifies you, will be used in those materials or presentations.

You may ask the Investigator to see and copy your personal health information related to the study. You may also ask the Investigator to correct any study related information about you that is wrong. You may have to wait until the end of the study to see your study records, so that the study can be organized properly.

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This permission to share your personal health information for this study does not have an expiration date. If you no longer want to share your personal health information, you may cancel your permission at any time by writing to the study staff and/or the Investigator at the address below:

Thomas J. Stephens & Associates, Inc.
1801 North Glenville Drive, Suite 200
Richardson, TX 75081

If you cancel your permission after you have started in the study, the study staff and the Investigator will stop collecting your personal health information. Although they will stop collecting new information about you, they will need to use the information they have already collected to evaluate the study results. If you start the study and then cancel your permission, you will not be able to continue to participate in the study. This is because the study staff and/or the Investigator would not be able to collect the information needed to evaluate the study.

Thomas J. Stephens & Associates and the sponsor will make every effort to keep your personal health information private. But after the study staff or the Investigator share your personal health information from the study, federal privacy laws may not keep it private. There might be laws in your state or other federal laws that would protect the privacy of this information.

CONFIDENTIALITY

Your records of being in this study will be kept private except when ordered by law. The following people will have access to your study records:

- The Investigator
- Sponsor company or research institution [including monitor(s) and auditor(s)]
- Other country, state or federal regulatory agencies
- IntegReview IRB

The Institutional Review Board (IRB), IntegReview, and accrediting agencies may inspect and copy your records, which may have your name on them. Therefore, total confidentiality cannot be guaranteed. If the study results are presented at meetings or printed in publications, your name will not be used.

IN CASE OF STUDY RELATED INJURY

Side effects or complications, both foreseeable and unforeseeable, are possible in any research study without any fault to you, the Investigator, the study site, or the study sponsor. If you get hurt or sick as a direct result of being in this study, the sponsor will pay the costs of reasonable medical treatment. To ask questions about this, talk to the Investigator or study staff.

The sponsor's policy does not offer compensation for other expenses. Be aware that your health care payer/insurer might not cover the costs of study-related injuries or illnesses.

Unreimbursed medical expenses not covered by insurance or other third party coverage will be reimbursed by the sponsor for medical treatment for any injury that, in the opinion of the study doctor and the sponsor, is directly caused by the investigational product or by procedures required by the study protocol which would not have been performed as part of your regular medical care.

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LEGAL RIGHTS

You will not lose any of your legal rights by signing this consent form.

CONTACT INFORMATION

If you have questions, concerns, or complaints about this study or to report a study related injury, contact:

Lily Jiang, Ph.D.
972-392-1529 daytime telephone number
469-766-4781 after hours number

If you are unable to reach anyone at the number(s) listed above and you need medical attention, please go to the nearest emergency room.

If you do not want to talk to the Investigator or study staff, if you have concerns or complaints about the research, or to ask questions about your rights as a study subject you may contact IntegReview. IntegReview's policy indicates that all concerns/complaints are to be submitted in writing for review at a convened IRB meeting to:

Mailing Address:	OR	Email Address:
Chairperson IntegReview IRB 3815 S. Capital of Texas Highway Suite 320 Austin, TX 78704		integreview@integreview.com

If you are unable to provide your concerns/complaints in writing or if this is an emergency situation regarding subject safety, contact our office at:

512-326-3001 or
toll free at 1-877-562-1589
between 8 a.m. and 5 p.m. Central Time

IntegReview has approved the information in this consent form and has given approval for the Investigator to do the study. This does not mean IntegReview has approved your being in the study. You must consider the information in this consent form for yourself and decide if you want to be in this study.

PAYMENT FOR BEING IN THE STUDY

You may receive up to $575.00 for being in the study. You will be paid per completed visit as follows:

Visit	Compensation (amount)
Screening/Baseline (Visit 1)	$40.00
Week 1 (Visit 2)	$60.00
Week 2 (Visit 3)	$65.00
Week 6 (Visit 4)	$75.00
Week 12 (Visit 5)	$90.00

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VERSION CONTROL
clw/master: 2-17-16 snb/site: 2-20-16 rss/master: 9-16-16

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Week 18 (Visit 6)	$95.00
Week 24 (Visit 7)	$150.00

If you choose to leave or are withdrawn from the study for any reason before finishing all visits you will be paid for each completed visit. You will receive payment within 2 weeks of final study visit.

If you do not qualify for any reason, you will be paid $20.00, which will be mailed to you within 2 weeks of the baseline study visit.

If you are paid $600.00 or more by Thomas J. Stephens & Associates, Inc. in a calendar year, those payments will be reported to the Internal Revenue Service via form 1099-MISC. As required by tax laws, if you withhold your social security number, Thomas J. Stephens & Associates, Inc. is required to withhold 28% of your payment for tax purposes. In this case a form 1099-MISC will be sent to you reporting your withholding.

VOLUNTEERING TO BE IN THE STUDY

It is your choice if you want to be in the study. No one can force you to be in the study. You may not want to be in this study or you may leave the study at any time without penalty or loss of benefits to which you are otherwise entitled.

The Investigator, the sponsor company, or IntegReview may take you out of the study without your permission, at any time, for the following reasons:

- If you do not follow the Investigator's instructions
- If we find out you should not be in the study
- If the study is stopped
- If it becomes harmful to your health

If you leave the study or if you are taken out of the study, you may be asked to return for a final visit to have some end of study evaluations or tests. If information generated from this study is published or presented, your identity will not be revealed. If you leave the study, no more information about you will be collected for this study. However, all of the information you gave us before you left the study will still be used.

NEW FINDINGS

If there is new information or any significant new findings that could relate to your willingness to continue participation we will tell you. You can then decide if you still want to be in the study.

THE REASON FOR INSTITUTIONAL REVIEW BOARDS AND INFORMED CONSENT

What is a consent form?
The informed consent document contains information required by federal regulations. The informed consent document must be approved by an Institutional Review Board (IRB).

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What is an Institutional Review Board (IRB)?
An Institutional Review Board (IRB) is a group of people that reviews research studies. The main goal of this review is to protect the rights and well being of the human subjects participating in research studies.

IntegReview, the IRB for this study
IntegReview is an IRB whose board members provide IRB services across the United States, Canada, Japan and Latin America.

To meet requirements of the law, the IntegReview Boards currently include:

- Doctors
- Pharmacists
- Nurses
- Toxicologists (people who study the harmful effects of chemicals)
- Other specialists
- Others who do not have a background in science/medicine

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AGREEMENT TO BE IN THE STUDY

This consent form contains important information to help you decide if you want to be in the study. If you have any questions that are not answered in this consent form, ask one of the study staff.

Please answer **YES** or **NO** to the following questions:

A. Is this document in a language you understand? _____

B. Do you understand the information in this consent form? _____

C. Have you been given enough time to ask questions and talk about the study? _____

D. Have all of your questions been answered to your satisfaction? _____

E. Do you think you received enough information about the study? _____

F. Do you volunteer to be in this study of your own free will and without being pressured by the Investigator or study staff? _____

G. Do you know that you can leave the study at any time without giving a reason and without affecting your health care? _____

H. Do you know that your health records from this study may be reviewed by the sponsor company and by government authorities? _____

I. Do you know that you cannot be in another study while you are in this study? _____

IF YOU ANSWERED "NO" TO ANY OF THE ABOVE QUESTIONS,
OR YOU ARE UNABLE TO ANSWER ANY OF THE ABOVE QUESTIONS,
YOU SHOULD NOT SIGN THIS CONSENT FORM.

_____
Printed Name of Adult Study Subject

_____
Signature of Adult Study Subject Date

_____
Printed Name of Person Explaining Consent Form

_____
Signature of Person Explaining Consent Form Date

You will be given a signed and dated copy of this consent form to keep.

THIS IS AN IMPORTANT DOCUMENT - KEEP FOR FUTURE REFERENCE

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Authorization and Release Form

I hereby for good and valuable consideration grant to Thomas J. Stephens & Associates, the study sponsor and their respective affiliates, agencies, agents, employees, and assigns (collectively, "Authorized Entities"), the unrestricted, royalty free, irrevocable and perpetual right and permission to reproduce, distribute, broadcast and/or otherwise use for advertising and other commercial/noncommercial purposes: (i) my name, likeness, image, video, and any other biographical or personal information ("Personal Content"); and (ii) any statement or endorsement, or any portions thereof ("Testimonial(s)"), made by me relating to the study sponsor's products ("Products"), in any and all media now known or later developed, worldwide in perpetuity, without further compensation or approval by me.

I hereby assign to the Authorized Entities all of my world-wide right, title and interest, including my copyright interests and all renewals, reissues and extensions thereof, in and to the Personal Content and Testimonial(s), including without limitation, any photographic portraits, sound recordings and video performances of and/or by me in connection with the Personal Content and/or Testimonial(s).

I am at least 21 years of age, and competent to contract in my own name. I have read and understand this Authorization and Release.

_____
Printed Name of Adult Study Subject

_____
Signature of Adult Study Subject Date

_____
Printed Name of Person Explaining Release Form

_____
Signature of Person Explaining Release Form Date

Copy of consent form given to subject on _____ (date) by _____ (initials)

You will be given a signed and dated copy of this consent form to keep.

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AUTHORIZATION TO USE AND DISCLOSE PERSONAL HEALTH INFORMATION FOR RESEARCH

THIS SECTION DESCRIBES YOUR RIGHTS AND HOW PERSONAL HEALTH INFORMATION COLLECTED ABOUT YOU DURING THIS STUDY MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

The United States government has issued a privacy rule to protect the privacy rights of patients. This rule was issued under a law called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The Privacy Rule is designed to protect the confidentiality of your personal health information. The document you are reading, called an "Authorization," describes your rights and explains how your health information will be used and disclosed (shared).

Federal law requires hospitals, researchers and health care providers to protect the privacy of information that identifies you and relates to your past, present and future physical and mental health or conditions.

All information collected during the study will be retained by the study doctor and the Study Sponsor, except as required by law. Information from this study will be given to the sponsor. "Sponsor" includes any persons or companies, which are contracted by the sponsor to have access to the research information during and after the study. The information will also be given to the U.S. Food and Drug Administration (FDA). Study records which identify you and the consent form signed by you will be inspected and/or copied for research or regulatory purposes by:

- Sponsor
- Agents for the sponsor
- The US Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies
- IntegReview IRB

Because of the need to release information to these parties, absolute confidentiality cannot be guaranteed. The results of this research study may be presented at meetings or in publications; however, your identity will not be disclosed in those presentations.

For purposes of study reporting, you will be identified by your initials and code numbers only. However, your name, date of birth, address, and phone number will be kept on record by the study doctor in case you need to be contacted in the future about this study.

After your personal health information is disclosed to the Study Sponsor, the results of the study may be reanalyzed at a later date and may be combined with the results of other studies. The Study Sponsor and people who work with the Study Sponsor may use the results of this study for other research purposes, including:

- Developing a better understanding of the disease;
- Improving the design of future actual use trials

After the study staff or the study doctor discloses your personal health information to others, it could be re-disclosed and no longer protected by federal privacy laws.

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This permission to share your personal health information for this study does not have an expiration date. If you do not withdraw this Authorization in writing, it will remain in effect indefinitely. Your study doctor will keep this Authorization for at least 6 years. If you no longer want to share your personal health information, you may cancel your permission at any time by writing to the study staff and/or the study doctor at the address below:

Thomas J. Stephens & Associates, Inc.
1801 North Glenville Drive, Suite 200
Richardson, TX 75081

You have the right to see and get a copy of your records related to the study for as long as the study doctor has this information. However, by signing this Authorization you agree that you might not be able to review or receive some of your records related to the study until after the study has been completed.

If you cancel your permission after you have started in the study, the study staff and the study doctor will stop collecting your personal health information unless the information concerns an adverse event (a bad effect) related to the study. If an adverse event occurs, your entire medical record may be reviewed. All information that has already been collected for study purposes, and any new information about an adverse event related to the study, will be sent to the study sponsor. Although they will stop collecting new information about you, they will need to use the information they have already collected to evaluate the study results. If you start the study and then cancel your permission, you will not be able to continue to participate in the study. This is because the study staff and/or the study doctor would not be able to collect the information needed to evaluate the study results.

If you withdraw from the study but do not withdraw your Authorization, new personal health information may be collected until this study ends.

You may decide not to give permission for the release of your personal health information for this study. In that case, you will not be able to participate. This is because the study staff and study doctor would not be able to collect the information needed to evaluate the study results.

At the completion of the study, you have the right to access your protected health information that is created during this research study that relates to your treatment or to payment, provided such information is not exempted under certain laws and regulations. To request this information, please contact the study doctor at the address listed above.

Your Right to Access Health Information

Subject to certain exceptions prescribed by law, you have a right to request access to the health information that we hold about you and to request changes if your health information is incorrect or incomplete. Any request for access or corrections should be made to the principal doctor conducting this study.

Your records obtained while you are in this trial, as well as related health records, will remain strictly confidential at all times. However, these will need to be made available to others working on the Sponsor's behalf, the Independent Ethics Committee members and Medicines Regulatory Authorities.

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SEPTEMBER 16, 2016**

By signing the consent form you agree to this access for the current trial and any further research that may be done. However, the Sponsor will take steps to protect your personal information and will not include your name on any sponsor forms, reports, publications, or in any future disclosures. If you withdraw from the study, we will no longer collect your personal information, but we may need to continue to use information already collected.

Personal data which may be sensitive (e.g., date of birth) will be collected and processed, but only for research purposes in connection with this trial.

The trial data will be sent around the world, but you will not be referred to by name or identified in any report or publication nor could the data be traced back to you. Your data may be transferred to a country that does not have the same level of personal data protection as within the United States. However, The Sponsor maintains high standards of confidentiality and protection.

The Sponsor (who will control the use of the data) will take steps to ensure your personal data is protected.

By taking part in this trial you agree not to restrict the use of any data even if you withdraw from the trial and agree to the transfer of your personal data to other Sponsor companies and to Medicines Regulatory Authorities both within and outside of Europe.

_____

Printed Name of Adult Study Subject

_____

Signature of Adult Study Subject Date

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FEBRUARY 29, 2016

INFORMED CONSENT DOCUMENT
AGREEMENT TO BE IN A RESEARCH STUDY

NAME OF TESTING COMPANY:	Thomas J. Stephens & Associates, Inc.
NUMBER AND TITLE OF STUDY:	C16-CD020 (GLI.04.SPR.US10354); "A Multi-Center Clinical Trial to Evaluate the Efficacy of Two Acne Treatments"
NAME OF PERSON IN CHARGE OF THE RESEARCH STUDY (STUDY DOCTOR/INVESTIGATOR):	Kun Qian, M.D.
TELEPHONE NUMBER(S), DAYTIME:	719-637-2828
AFTER HOURS:	719-471-1763

INTRODUCTION

You are being invited to volunteer for a clinical research study. You must read and sign this form before you agree to take part in this study. This form will give you more information about this study. Please ask as many questions as you need to before you decide if you want to be in the study. You should not sign this form if you have any questions that have not been answered.

Thomas J. Stephens & Associates, Inc., a contract research organization, is being paid by the sponsor (the company paying for this study) to conduct this research study.

You must be honest with the Investigator about your health history or it may not be safe for you to be in this study.

PURPOSE OF THE STUDY

The purpose of this study is to evaluate the efficiency of 2 acne treatments for 24 weeks of use in adult men and women with mild to moderate facial acne, at least 5 inflammatory lesions, and at least 10 – 100 non-inflammatory lesions.

HOW LONG THE STUDY WILL LAST AND HOW MANY PEOPLE WILL BE IN THE STUDY

This study will last 24 weeks and have up to 8 visits. At least 100 subjects, men and women between the ages of 21-45, are expected to complete this study, with at least 50 subjects completed per cell. Each site is to enroll no more than 40 subjects, with at least 100 subjects expected to complete when combined.

TO BE IN THIS STUDY

You must:

- Be a man or woman age 21 to 45 years at the time of enrollment.
- Have mild to moderate acne on the face as determined by the Investigator or designee.
- Have at least 5 inflammatory lesions as determined by the Investigator or designee.
- Have 10 – 100 non-inflammatory lesions as determined by the Investigator or designee.
- Be willing to use the test products as instructed for 24 weeks.

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- Be willing and able to comply with all of the time commitments and procedural requirements of the clinical trial protocol.
- Be willing to provide written informed consent including photo release, Health Insurance Portability and Accountability Act (HIPAA), and be able to read, speak, write, understand English and be willing to share personal information and data, as verified by signing a written authorization at the screening.
- Be willing to withhold all facial treatments during the course of the study including botulinum toxin, injectable fillers, microdermabrasion, IPL, peels, facials, laser treatments and tightening treatments. Waxing and threading is allowed but not facial laser hair removal.
- Males must be regular shavers and willing to shave on the day of the study visits (prior to clinic visits).
- Women of child bearing potential must be willing to take a urine pregnancy test prior to study enrollment, at week 24, and when deemed appropriate by the Investigator and/or Sponsor.
- Individuals of child bearing potential must use an acceptable method of contraception throughout the study. Acceptable methods of birth control include:
    - Oral and other system contraceptives. Individuals must be on a stable use for 3 months prior to study enrollment. Individuals on oral contraceptives must not alter their use, including dose or regimen for the duration of the study
    - Double barrier
    - Bilateral tubal ligation (tubes tied)
    - Partner vasectomy
    - Abstinence
- Be willing to follow study requirements and report any changes in health status or medications, side effect symptoms, or reactions immediately.
- Be stable on any medication you are taking for at least 30 days

YOU CANNOT BE ON THE STUDY

If you:

- Have been diagnosed with allergies to topical acne products.
- Have a condition and/or disease of the skin that the Investigator deems inappropriate for participation.
- Are a woman who is breastfeeding, pregnant, or planning to become pregnant during the study.
- Have pre-existing or dormant dermatologic conditions on the face (e.g., psoriasis, rosacea, eczema, seborrheic dermatitis, severe excoriations etc.) which in the opinion of the Investigator could interfere with the outcome of the study.
- Have a history of immunosuppression/immune deficiency disorders (including HIV infection or AIDS) or currently using immunosuppressive medications (e.g., azathioprine, belimumab, cyclophosphamide, Enbrel, Imuran, Humira, mycophenolate mofetil, methotrexate, prednisone, Remicade, Stelara.).
- Have an uncontrolled disease such as asthma, diabetes, hypertension, hyperthyroidism, or hypothyroidism. Individuals having multiple health conditions may be excluded from participation even if the conditions are controlled by diet, medication, etc. at the Investigator's discretion.
- Are currently participating in another facial usage study or have participated in a clinical trial within 4 weeks prior to inclusion into the study.
- Have a history of skin cancer on the face within the past 5 years.
- Have any planned surgeries and/or invasive medical procedures during the course of the study.

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- Have started hormone replacement therapies (HRT) or hormones for birth control less than 3 months prior to study entry or plan on starting, stopping, or changing doses of HRT or hormones for birth control during the study.
- Have facial sunburn or excessive tanned facial skin or are not willing to avoid daily sun exposure on the face and the use of tanning beds or sunless tanning products for the duration of the study.
- Have severe acne, acne conglobata, multiple nodules or cysts (more than 2).
- Are currently taking a natural or prescription testosterone blocker (e.g. saw palmetto, blask cohosh, chaste tree, chasteberry, spironolactone, drospirenone, progestins).
- Are currently on a testosterone booster or prescription testosterone (e.g. DHEA, tribulus, testosterone cypionate, testosterone enanthate, Sustanon, testosterone propionate, testosterone phenylpropriate, Omnadren etc.).
- Are currently taking or have taken within the last 30 days oral or topical prescription medications for acne such as Doxycycline, Minocycline, Clindamycin, Bactrim, Tetracycline, Erythromycin, Vibramycin and topical tretinoin (Retin A, Renova, Adapalene, Tazarotene), Azelaic acid, benzoyl peroxide, Dapsone, Sodium sulfacetamide, Differin, Epiduo.
- Have used oral isotretinoin (Accutane) within the past 6-months.
- Are routinely using (3x a week or more) topical over-the-counter (OTC) acne product (e.g. benzoyl peroxide, salicylic acid, alpha hydroxyl, beta hydroxyl and/or poly-hydroxy products or medicated cleansers, wipes, masks, scrubs, gels and creams) within 14 days of the study entry.
- Are using or have used any systemic medication considered to affect the course of acne, specifically, but not exclusively antibiotics or steroids within the last 30 days prior to entry into the study.
- Have excessive facial hair, including beard, mustache or goatee, or scars, which could interfere with evaluations as determined by the Investigator or designee.

WHAT WILL HAPPEN DURING THE STUDY

***Visit 1: Screening (* Visit 1 {*Screening*} AND Visit 2 {*Baseline*} may be combined into 1 Visit)**

You will:

- Be given an IRB-approved Informed Consent Form (ICF), to read and sign. You will be given enough time to read the informed consent, and ask questions about the study, and sign 2 copies of this consent form. (1 for clinic records, 1 for your records)
- Be given an eligibility and health questionnaire to complete, and assigned a screening number.
- Will acclimate for 15 minutes in a room at 68-75^{0}F and 35-65% humidity.
- Will be screened by the Investigator or designee to see if you qualify for the study.
- If you do qualify for the study, you will:
    - Take a urine pregnancy test (females of child-bearing potential)
    - Have a dermatologist confirm your eligibility
    - Schedule your next appointment.

***Visit 2: Baseline**

- Be asked if you have experienced any changes in your health since the previous visit.
- Will acclimate for 15 minutes in a room at 68-75^{0}F and 35-65% humidity.
- Be screened by the Investigator or designee to see if you still qualify for the study.
- Have your health and eligibility re-reviewed.

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- If you still qualify for the study you will:
    - Be assigned a subject number
    - Have photos taken of your face
    - Be randomly assigned to receive one of the test products & supporting facial cleanser, moisturizer & facial SPF 30
    - Be provided verbal and written usage instructions, and a daily diary to record product use
    - Schedule your next appointment

Visits 3, 4 (Week 1, Week 2)

- Be asked if you have experienced any changes in your health since the previous visit.
- Will acclimate for 15 minutes in a room at 68-75^{0}F and 35-65% humidity.
- Have your face examined by the Investigator or designee
- Complete a self-assessment questionnaire
- Have your diary collected and reviewed for compliance, and returned to you. At week 2, your diary will be retained by the testing facility and you will be given a new diary
- Have your product collected, weighed, and returned to you
- Schedule your next appointment

Visits 5, 6 (Week 6, Week 12)

- Be asked if you have experienced any changes in your health since the previous visit.
- Will acclimate for 15 minutes in a room at 68-75^{0}F and 35-65% humidity.
- Have your face examined by the Investigator or designee
- Have photos taken of your face
- Complete a self-assessment questionnaire
- Have your diary collected and reviewed for compliance, and retained by the testing facility and you will be given a new diary.
- Have your product collected, weighed, and retained. New products will be dispensed as necessary.
- Schedule your next appointment

Visit 7 (Week 18)

- Be asked if you have experienced any changes in your health since the previous visit.
- Have your diary collected and reviewed for compliance, and retained by the testing facility and you will be given a new diary.
- Have your product collected, weighed, and returned to you
- Schedule your next appointment

Visit 8 (Week 24)

- Be asked if you have experienced any changes in your health since the previous visit.
- Take a urine pregnancy test (females of child-bearing potential).
- Will acclimate for 15 minutes in a room at 68-75^{0}F and 35-65% humidity.
- Have your face examined by the Investigator or designee
- Have photos taken of your face
- Complete a self-assessment questionnaire
- Have your diary collected and reviewed for compliance, and retained by the testing facility.
- Have your product collected, weighed, and retained by the testing facility.

Do not give the study product to other people and keep it out of the reach of children.

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RISKS OR DISCOMFORTS

If you do not understand what any of these side effects mean, please ask the investigator or study staff to explain these terms to you.

Because the study products are investigational, all of their side effects may not be known. There may be rare and unknown side effects. Some of these may be life threatening.

Possible risks associated with the product are, as with any other cosmetic and OTC products, signs of irritation including:

- Itching
- Burning
- Stinging
- Rash or other allergic reaction
- Tingling
- Scaling/Dryness
- Redness

In some cases, it is possible for a subject to develop allergic reactions to the test material(s). This risk is increased for individuals with a history of allergies, and individuals with asthma and/or a history of hives may also be affected. Symptoms include rash, hives, and itching.

You must tell the Investigator or study staff about all side effects that you have. If you are not honest about your side effects, it may not be safe for you to stay in the study.

BIRTH CONTROL, DANGERS OF PREGNANCY AND BREASTFEEDING

If you are a female, you must not get pregnant while in this study. The only certain way to not get pregnant is to not have sex. If you are a female and choose to have sex, you must use a type of birth control.

Even if you use birth control during the study, there is a chance you could become pregnant. If you are pregnant or become pregnant during the study, test products or procedures may involve unforeseeable risks to the unborn baby.

A pregnancy test can be wrong. If you become pregnant during the study, stop using the test products and call/inform the Investigator at once.

You cannot be in the study if you are breastfeeding. It is not known whether the test products are safe for breast fed babies. Therefore if you are breastfeeding a child then it may not be safe for you to participate in the study.

POSSIBLE BENEFITS OF THE STUDY

You will not get any medical benefit from being in this study, and there is no promise that your condition (acne) will get better. It might stay the same or it might get worse. Your participation will provide information that may help others. There may be other marketed products that claim to have similar benefits.

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OTHER OPTIONS TO PARTICIPATING IN THE STUDY

Since this study is for research only, the only other choice would be not to be in the study.

STUDY AND TEST PRODUCT CONFIDENTIALITY

To participate in this study, you must agree to keep any information relating to the design, identity or use of these test product samples confidential.

On rare occasions, the sponsor may allow the testing company to disclose to you the name of the test products if you are not given this information during the study. This information is typically not provided until the end of the study or after the test products have been released for sale to the public. The study doctor or study staff will notify you if the sponsor allows us to give you this information.

DISCLOSURE AGREEMENT

This section explains how personal health information collected about you for the study may be used. Your personal health information includes, but is not limited to, information that was collected for your entry into the study and information that is collected during the study. The purpose of collecting this information is to allow the study staff and the Investigator to conduct the study, to evaluate the sponsor's study products and to analyze the study results.

You may decide not to give permission for the release of your personal health information for the study. In that case, you will not be able to participate in the study. This is because the study staff and/or the Investigator would not be able to collect the information needed to evaluate the sponsor's study products.

People who may inspect your personal and health information includes the Investigator, the Institutional Review Board, IntegReview IRB, FDA and other regulatory authorities from the United States or other countries, the study sponsor and people that work with the sponsor which includes, monitoring committees, contract research organizations, and consultants who have contracts with the company to do the study and review the study results. These reviews are done to check on the quality of the study and also for other purposes allowed by law.

The results of the study may be published in a medical book or journal, or presented at meetings for educational purposes. Neither your name, nor any other personal health information that specifically identifies you, will be used in those materials or presentations.

You may ask the Investigator to see and copy your personal health information related to the study. You may also ask the Investigator to correct any study related information about you that is wrong. You may have to wait until the end of the study to see your study records, so that the study can be organized properly.

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This permission to share your personal health information for this study does not have an expiration date. If you no longer want to share your personal health information, you may cancel your permission at any time by writing to the study staff and/or the Investigator at the address below:

Thomas J. Stephens & Associates, Inc.
5050 Edison Ave., Suite 202
Colorado Springs, CO 80915

If you cancel your permission after you have started in the study, the study staff and the Investigator will stop collecting your personal health information. Although they will stop collecting new information about you, they will need to use the information they have already collected to evaluate the study results. If you start the study and then cancel your permission, you will not be able to continue to participate in the study. This is because the study staff and/or the Investigator would not be able to collect the information needed to evaluate the study.

Thomas J. Stephens & Associates and the sponsor will make every effort to keep your personal health information private. But after the study staff or the Investigator share your personal health information from the study, federal privacy laws may not keep it private. There might be laws in your state or other federal laws that would protect the privacy of this information.

CONFIDENTIALITY

Your records of being in this study will be kept private except when ordered by law. The following people will have access to your study records:

- The Investigator
- Sponsor company or research institution [including monitor(s) and auditor(s)]
- Other country, state or federal regulatory agencies
- IntegReview IRB

The Institutional Review Board (IRB), IntegReview, and accrediting agencies may inspect and copy your records, which may have your name on them. Therefore, total confidentiality cannot be guaranteed. If the study results are presented at meetings or printed in publications, your name will not be used.

IN CASE OF STUDY RELATED INJURY

Side effects or complications, both foreseeable and unforeseeable, are possible in any research study without any fault to you, the Investigator, the study site, or the study sponsor. If you get hurt or sick as a direct result of being in this study, the sponsor will pay the costs of reasonable medical treatment. To ask questions about this, talk to the Investigator or study staff.

The sponsor's policy does not offer compensation for other expenses. Be aware that your health care payer/insurer might not cover the costs of study-related injuries or illnesses.

Unreimbursed medical expenses not covered by insurance or other third party coverage will be reimbursed by the sponsor for medical treatment for any injury that, in the opinion of the study doctor and the sponsor, is directly caused by the investigational product or by procedures required by the study protocol which would not have been performed as part of your regular medical care.

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LEGAL RIGHTS

You will not lose any of your legal rights by signing this consent form.

CONTACT INFORMATION

If you have questions, concerns, or complaints about this study or to report a study related injury, contact:

Kun Qian, M.D.
719-637-2828 daytime telephone number
719-471-1763 after hours number

If you are unable to reach anyone at the number(s) listed above and you need medical attention, please go to the nearest emergency room.

If you do not want to talk to the Investigator or study staff, if you have concerns or complaints about the research, or to ask questions about your rights as a study subject you may contact IntegReview. IntegReview's policy indicates that all concerns/complaints are to be submitted in writing for review at a convened IRB meeting to:

Mailing Address:	OR	Email Address:
Chairperson IntegReview IRB 3815 S. Capital of Texas Highway Suite 320 Austin, TX 78704		integreview@integreview.com

If you are unable to provide your concerns/complaints in writing or if this is an emergency situation regarding subject safety, contact our office at:

512-326-3001 or
toll free at 1-877-562-1589
between 8 a.m. and 5 p.m. Central Time

IntegReview has approved the information in this consent form and has given approval for the Investigator to do the study. This does not mean IntegReview has approved your being in the study. You must consider the information in this consent form for yourself and decide if you want to be in this study.

PAYMENT FOR BEING IN THE STUDY

You may receive up to $575.00 for being in the study. You will be paid per completed visit as follows:

Visit	Compensation (amount)
Visit 1	$40.00
Visit 2	$60.00
Visit 3	$65.00
Visit 4	$75.00
Visit 5	$90.00

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Visit 6	$95.00
Visit 7	$150.00

If you choose to leave or are withdrawn from the study for any reason before finishing all visits you will be paid for each completed visit. You will receive payment within 2 weeks of final study visit.

If you do not qualify for any reason, you will be paid $20.00, which will be mailed to you within 2 weeks of the baseline study visit.

If you are paid $600.00 or more by Thomas J. Stephens & Associates, Inc. in a calendar year, those payments will be reported to the Internal Revenue Service via form 1099-MISC. As required by tax laws, if you withhold your social security number, Thomas J. Stephens & Associates, Inc. is required to withhold 28% of your payment for tax purposes. In this case a form 1099-MISC will be sent to you reporting your withholding.

VOLUNTEERING TO BE IN THE STUDY

It is your choice if you want to be in the study. No one can force you to be in the study. You may not want to be in this study or you may leave the study at any time without penalty or loss of benefits to which you are otherwise entitled.

The Investigator, the sponsor company, or IntegReview may take you out of the study without your permission, at any time, for the following reasons:

- If you do not follow the Investigator's instructions
- If we find out you should not be in the study
- If the study is stopped
- If it becomes harmful to your health

If you leave the study or if you are taken out of the study, you may be asked to return for a final visit to have some end of study evaluations or tests. If information generated from this study is published or presented, your identity will not be revealed. If you leave the study, no more information about you will be collected for this study. However, all of the information you gave us before you left the study will still be used.

NEW FINDINGS

If there is new information or any significant new findings that could relate to your willingness to continue participation we will tell you. You can then decide if you still want to be in the study.

THE REASON FOR INSTITUTIONAL REVIEW BOARDS AND INFORMED CONSENT

What is a consent form?
The informed consent document contains information required by federal regulations. The informed consent document must be approved by an Institutional Review Board (IRB).

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What is an Institutional Review Board (IRB)?
An Institutional Review Board (IRB) is a group of people that reviews research studies. The main goal of this review is to protect the rights and well being of the human subjects participating in research studies.

IntegReview, the IRB for this study
IntegReview is an IRB whose board members provide IRB services across the United States, Canada, Japan and Latin America.

To meet requirements of the law, the IntegReview Boards currently include:

- Doctors
- Pharmacists
- Nurses
- Toxicologists (people who study the harmful effects of chemicals)
- Other specialists
- Others who do not have a background in science/medicine

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AGREEMENT TO BE IN THE STUDY

This consent form contains important information to help you decide if you want to be in the study. If you have any questions that are not answered in this consent form, ask one of the study staff.

Please answer **YES** or **NO** to the following questions:

A. Is this document in a language you understand? _____

B. Do you understand the information in this consent form? _____

C. Have you been given enough time to ask questions and talk about the study? _____

D. Have all of your questions been answered to your satisfaction? _____

E. Do you think you received enough information about the study? _____

F. Do you volunteer to be in this study of your own free will and without being pressured by the Investigator or study staff? _____

G. Do you know that you can leave the study at any time without giving a reason and without affecting your health care? _____

H. Do you know that your health records from this study may be reviewed by the sponsor company and by government authorities? _____

I. Do you know that you cannot be in another study while you are in this study? _____

IF YOU ANSWERED "NO" TO ANY OF THE ABOVE QUESTIONS,
OR YOU ARE UNABLE TO ANSWER ANY OF THE ABOVE QUESTIONS,
YOU SHOULD NOT SIGN THIS CONSENT FORM.

_____
Printed Name of Adult Study Subject

_____
Signature of Adult Study Subject Date

_____
Printed Name of Person Explaining Consent Form

_____
Signature of Person Explaining Consent Form Date

You will be given a signed and dated copy of this consent form to keep.

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Authorization and Release Form

I hereby for good and valuable consideration grant to Thomas J. Stephens & Associates, the study sponsor and their respective affiliates, agencies, agents, employees, and assigns (collectively, "Authorized Entities"), the unrestricted, royalty free, irrevocable and perpetual right and permission to reproduce, distribute, broadcast and/or otherwise use for advertising and other commercial/noncommercial purposes: (i) my name, likeness, image, video, and any other biographical or personal information ("Personal Content"); and (ii) any statement or endorsement, or any portions thereof ("Testimonial(s)"), made by me relating to the study sponsor's products ("Products"), in any and all media now known or later developed, worldwide in perpetuity, without further compensation or approval by me.

I hereby assign to the Authorized Entities all of my world-wide right, title and interest, including my copyright interests and all renewals, reissues and extensions thereof, in and to the Personal Content and Testimonial(s), including without limitation, any photographic portraits, sound recordings and video performances of and/or by me in connection with the Personal Content and/or Testimonial(s).

I am at least 21 years of age, and competent to contract in my own name. I have read and understand this Authorization and Release.

_____
Printed Name of Adult Study Subject

_____
Signature of Adult Study Subject Date

_____
Printed Name of Person Explaining Release Form

_____
Signature of Person Explaining Release Form Date

Copy of consent form given to subject on _____ (date) by _____ (initials)

You will be given a signed and dated copy of this consent form to keep.

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AUTHORIZATION TO USE AND DISCLOSE PERSONAL HEALTH INFORMATION FOR RESEARCH

THIS SECTION DESCRIBES YOUR RIGHTS AND HOW PERSONAL HEALTH INFORMATION COLLECTED ABOUT YOU DURING THIS STUDY MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

The United States government has issued a privacy rule to protect the privacy rights of patients. This rule was issued under a law called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The Privacy Rule is designed to protect the confidentiality of your personal health information. The document you are reading, called an "Authorization," describes your rights and explains how your health information will be used and disclosed (shared).

Federal law requires hospitals, researchers and health care providers to protect the privacy of information that identifies you and relates to your past, present and future physical and mental health or conditions.

All information collected during the study will be retained by the study doctor and the Study Sponsor, except as required by law. Information from this study will be given to the sponsor. "Sponsor" includes any persons or companies, which are contracted by the sponsor to have access to the research information during and after the study. The information will also be given to the U.S. Food and Drug Administration (FDA). Study records which identify you and the consent form signed by you will be inspected and/or copied for research or regulatory purposes by:

- Sponsor
- Agents for the sponsor
- The US Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies
- IntegReview IRB

Because of the need to release information to these parties, absolute confidentiality cannot be guaranteed. The results of this research study may be presented at meetings or in publications; however, your identity will not be disclosed in those presentations.

For purposes of study reporting, you will be identified by your initials and code numbers only. However, your name, date of birth, address, and phone number will be kept on record by the study doctor in case you need to be contacted in the future about this study.

After your personal health information is disclosed to the Study Sponsor, the results of the study may be reanalyzed at a later date and may be combined with the results of other studies. The Study Sponsor and people who work with the Study Sponsor may use the results of this study for other research purposes, including:

- Developing a better understanding of the disease;
- Improving the design of future actual use trials

After the study staff or the study doctor discloses your personal health information to others, it could be re-disclosed and no longer protected by federal privacy laws.

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INTEGREVIEW IRB
FEBRUARY 29, 2016**

This permission to share your personal health information for this study does not have an expiration date. If you do not withdraw this Authorization in writing, it will remain in effect indefinitely. Your study doctor will keep this Authorization for at least 6 years. If you no longer want to share your personal health information, you may cancel your permission at any time by writing to the study staff and/or the study doctor at the address below:

Thomas J. Stephens & Associates, Inc.
5050 Edison Ave., Suite 202
Colorado Springs, CO 80915

You have the right to see and get a copy of your records related to the study for as long as the study doctor has this information. However, by signing this Authorization you agree that you might not be able to review or receive some of your records related to the study until after the study has been completed.

If you cancel your permission after you have started in the study, the study staff and the study doctor will stop collecting your personal health information unless the information concerns an adverse event (a bad effect) related to the study. If an adverse event occurs, your entire medical record may be reviewed. All information that has already been collected for study purposes, and any new information about an adverse event related to the study, will be sent to the study sponsor. Although they will stop collecting new information about you, they will need to use the information they have already collected to evaluate the study results. If you start the study and then cancel your permission, you will not be able to continue to participate in the study. This is because the study staff and/or the study doctor would not be able to collect the information needed to evaluate the study results.

If you withdraw from the study but do not withdraw your Authorization, new personal health information may be collected until this study ends.

You may decide not to give permission for the release of your personal health information for this study. In that case, you will not be able to participate. This is because the study staff and study doctor would not be able to collect the information needed to evaluate the study results.

At the completion of the study, you have the right to access your protected health information that is created during this research study that relates to your treatment or to payment, provided such information is not exempted under certain laws and regulations. To request this information, please contact the study doctor at the address listed above.

Your Right to Access Health Information

Subject to certain exceptions prescribed by law, you have a right to request access to the health information that we hold about you and to request changes if your health information is incorrect or incomplete. Any request for access or corrections should be made to the principal doctor conducting this study.

Your records obtained while you are in this trial, as well as related health records, will remain strictly confidential at all times. However, these will need to be made available to others working on the Sponsor's behalf, the Independent Ethics Committee members and Medicines Regulatory Authorities.

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FEBRUARY 29, 2016**

By signing the consent form you agree to this access for the current trial and any further research that may be done. However, the Sponsor will take steps to protect your personal information and will not include your name on any sponsor forms, reports, publications, or in any future disclosures. If you withdraw from the study, we will no longer collect your personal information, but we may need to continue to use information already collected.

Personal data which may be sensitive (e.g., date of birth) will be collected and processed, but only for research purposes in connection with this trial.

The trial data will be sent around the world, but you will not be referred to by name or identified in any report or publication nor could the data be traced back to you. Your data may be transferred to a country that does not have the same level of personal data protection as within the United States. However, The Sponsor maintains high standards of confidentiality and protection.

The Sponsor (who will control the use of the data) will take steps to ensure your personal data is protected.

By taking part in this trial you agree not to restrict the use of any data even if you withdraw from the trial and agree to the transfer of your personal data to other Sponsor companies and to Medicines Regulatory Authorities both within and outside of Europe.

_____

Printed Name of Adult Study Subject

_____

Signature of Adult Study Subject Date

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SEPTEMBER 16, 2016

INFORMED CONSENT DOCUMENT
AGREEMENT TO BE IN A RESEARCH STUDY

NAME OF TESTING COMPANY:	Thomas J. Stephens & Associates, Inc.
NUMBER AND TITLE OF STUDY:	C16-CD020 (GLI.04.SPR.US10354); "A Multi-Center Clinical Trial to Evaluate the Efficacy of Two Acne Treatments"
NAME OF PERSON IN CHARGE OF THE RESEARCH STUDY (STUDY DOCTOR/INVESTIGATOR):	Kun Qian, M.D.
TELEPHONE NUMBER(S), DAYTIME:	719-637-2828
AFTER HOURS:	719-471-1763

INTRODUCTION

You are being invited to volunteer for a clinical research study. You must read and sign this form before you agree to take part in this study. This form will give you more information about this study. Please ask as many questions as you need to before you decide if you want to be in the study. You should not sign this form if you have any questions that have not been answered.

Thomas J. Stephens & Associates, Inc., a contract research organization, is being paid by the sponsor (the company paying for this study) to conduct this research study.

You must be honest with the Investigator about your health history or it may not be safe for you to be in this study.

PURPOSE OF THE STUDY

The purpose of this study is to evaluate the efficiency of 2 acne treatments for 24 weeks of use in adult men and women with mild to moderate facial acne, at least 5 inflammatory lesions, and at least 10 – 100 non-inflammatory lesions.

HOW LONG THE STUDY WILL LAST AND HOW MANY PEOPLE WILL BE IN THE STUDY

This study will last 24 weeks and have up to 8 visits. At least 100 subjects, men and women between the ages of 21-45, are expected to complete this study, with at least 50 subjects completed per cell.

TO BE IN THIS STUDY

You must:

- Be a man or woman age 21 to 45 years at the time of enrollment.
- Have mild to moderate acne on the face as determined by the Investigator or designee.
- Have at least 5 inflammatory lesions as determined by the Investigator or designee.
- Have 10 – 100 non-inflammatory lesions as determined by the Investigator or designee.
- Be willing to use the test products as instructed for 24 weeks.
- Be willing and able to comply with all of the time commitments and procedural requirements of the clinical trial protocol.

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- Be willing to provide written informed consent including photo release, Health Insurance Portability and Accountability Act (HIPAA), and be able to read, speak, write, understand English and be willing to share personal information and data, as verified by signing a written authorization at the screening.
- Be willing to withhold all facial treatments during the course of the study including botulinum toxin, injectable fillers, microdermabrasion, IPL, peels, facials, laser treatments and tightening treatments. Waxing and threading is allowed but not facial laser hair removal.
- Males must be regular shavers and willing to shave on the day of the study visits (prior to clinic visits).
- Women of child bearing potential must be willing to take a urine pregnancy test prior to study enrollment, at week 24, and when deemed appropriate by the Investigator and/or Sponsor.
- Individuals of child bearing potential must use an acceptable method of contraception throughout the study. Acceptable methods of birth control include:
    - Oral and other system contraceptives. Individuals must be on a stable use for 3 months prior to study enrollment. Individuals on oral contraceptives must not alter their use, including dose or regimen for the duration of the study
    - Double barrier
    - Bilateral tubal ligation (tubes tied)
    - Partner vasectomy
    - Abstinence
- Be willing to follow study requirements and report any changes in health status or medications, side effect symptoms, or reactions immediately.
- Be stable on any medication you are taking for at least 30 days

YOU CANNOT BE ON THE STUDY

If you:

- Have been diagnosed with allergies to topical acne products.
- Have a condition and/or disease of the skin that the Investigator deems inappropriate for participation.
- Are a woman who is breastfeeding, pregnant, or planning to become pregnant during the study.
- Have pre-existing or dormant dermatologic conditions on the face (e.g., psoriasis, rosacea, eczema, seborrheic dermatitis, severe excoriations etc.) which in the opinion of the Investigator could interfere with the outcome of the study.
- Have a history of immunosuppression/immune deficiency disorders (including HIV infection or AIDS) or currently using immunosuppressive medications (e.g., azathioprine, belimumab, cyclophosphamide, Enbrel, Imuran, Humira, mycophenolate mofetil, methotrexate, prednisone, Remicade, Stelara.).
- Have an uncontrolled disease such as asthma, diabetes, hypertension, hyperthyroidism, or hypothyroidism. Individuals having multiple health conditions may be excluded from participation even if the conditions are controlled by diet, medication, etc. at the Investigator's discretion.
- Are currently participating in another facial usage study or have participated in a clinical trial within 4 weeks prior to inclusion into the study.
- Have a history of skin cancer on the face within the past 5 years.
- Have any planned surgeries and/or invasive medical procedures during the course of the study.
- Have started hormone replacement therapies (HRT) or hormones for birth control less than 3 months prior to study entry or plan on starting, stopping, or changing doses of HRT or hormones for birth control during the study.

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- Have facial sunburn or excessive tanned facial skin or are not willing to avoid daily sun exposure on the face and the use of tanning beds or sunless tanning products for the duration of the study.
- Have severe acne, acne conglobata, multiple nodules or cysts (more than 2).
- Are currently taking a natural or prescription testosterone blocker (e.g. saw palmetto, blask cohosh, chaste tree, chasteberry, spironolactone, drospirenone, progestins).
- Are currently on a testosterone booster or prescription testosterone (e.g. DHEA, tribulus, testosterone cypionate, testosterone enanthate, Sustanon, testosterone propionate, testosterone phenylpropriate, Omnadren etc.).
- Are currently taking or have taken within the last 30 days oral or topical prescription medications for acne such as Doxycycline, Minocycline, Clindamycin, Bactrim, Tetracycline, Erythromycin, Vibramycin and topical tretinoin (Retin A, Renova, Adapalene, Tazarotene), Azelaic acid, benzoyl peroxide, Dapsone, Sodium sulfacetamide, Differin, Epiduo.
- Have used oral isotretinoin (Accutane) within the past 6-months.
- Are routinely using (3x a week or more) topical over-the-counter (OTC) acne product (e.g. benzoyl peroxide, salicylic acid, alpha hydroxyl, beta hydroxyl and/or poly-hydroxy products or medicated cleansers, wipes, masks, scrubs, gels and creams) within 14 days of the study entry.
- Are using or have used any systemic medication considered to affect the course of acne, specifically, but not exclusively antibiotics or steroids within the last 30 days prior to entry into the study.
- Have excessive facial hair, including beard, mustache or goatee, or scars, which could interfere with evaluations as determined by the Investigator or designee.

WHAT WILL HAPPEN DURING THE STUDY

***Visit 1: Screening (* Visit 1 {*Screening*} AND Visit 2 {*Baseline*} may be combined into 1 Visit)**

You will:

- Be given an IRB-approved Informed Consent Form (ICF), to read and sign. You will be given enough time to read the informed consent, and ask questions about the study, and sign 2 copies of this consent form. (1 for clinic records, 1 for your records)
- Be given an eligibility and health questionnaire to complete, and assigned a screening number.
- Will acclimate for 15 minutes in a room at 68-75^{0}F and 35-65% humidity.
- Will be screened by the Investigator or designee to see if you qualify for the study.
- If you do qualify for the study, you will:
    - Take a urine pregnancy test (females of child-bearing potential)
    - Have a dermatologist confirm your eligibility
    - Schedule your next appointment.

***Visit 2: Baseline**

- Be asked if you have experienced any changes in your health since the previous visit.
- Will acclimate for 15 minutes in a room at 68-75^{0}F and 35-65% humidity.
- Be screened by the Investigator or designee to see if you still qualify for the study.
- Have your health and eligibility re-reviewed.
- If you still qualify for the study you will:
    - Be assigned a subject number
    - Have photos taken of your face

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- Be randomly assigned to receive one of the test products & supporting facial cleanser, moisturizer & facial SPF 30
- Be provided verbal and written usage instructions, and a daily diary to record product use
- Schedule your next appointment

Visits 3, 4 (Week 1, Week 2)

- Be asked if you have experienced any changes in your health since the previous visit.
- Will acclimate for 15 minutes in a room at 68-75^{0}F and 35-65% humidity.
- Have your face examined by the Investigator or designee
- Complete a self-assessment questionnaire
- Have your diary collected and reviewed for compliance, and returned to you. At week 2, your diary will be retained by the testing facility and you will be given a new diary
- Have your product collected, weighed, and returned to you
- Schedule your next appointment

Visits 5, 6 (Week 6, Week 12)

- Be asked if you have experienced any changes in your health since the previous visit.
- Will acclimate for 15 minutes in a room at 68-75^{0}F and 35-65% humidity.
- Have your face examined by the Investigator or designee
- Have photos taken of your face
- Complete a self-assessment questionnaire
- Have your diary collected and reviewed for compliance, and retained by the testing facility and you will be given a new diary.
- Have your product collected, weighed, and retained. New products will be dispensed as necessary.
- Schedule your next appointment

Visit 7 (Week 18)

- Be asked if you have experienced any changes in your health since the previous visit.
- Have your diary collected and reviewed for compliance, and retained by the testing facility and you will be given a new diary.
- Have your product collected, weighed, and returned to you
- Schedule your next appointment

Visit 8 (Week 24)

- Be asked if you have experienced any changes in your health since the previous visit.
- Take a urine pregnancy test (females of child-bearing potential).
- Will acclimate for 15 minutes in a room at 68-75^{0}F and 35-65% humidity.
- Have your face examined by the Investigator or designee
- Have photos taken of your face
- Complete a self-assessment questionnaire
- Have your diary collected and reviewed for compliance, and retained by the testing facility.
- Have your product collected, weighed, and retained by the testing facility.

Do not give the study product to other people and keep it out of the reach of children.

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RISKS OR DISCOMFORTS

If you do not understand what any of these side effects mean, please ask the investigator or study staff to explain these terms to you.

Because the study products are investigational, all of their side effects may not be known. There may be rare and unknown side effects. Some of these may be life threatening.

Possible risks associated with the product are, as with any other cosmetic and OTC products, signs of irritation including:

- Itching
- Burning
- Stinging
- Rash or other allergic reaction
- Tingling
- Scaling/Dryness
- Redness

In some cases, it is possible for a subject to develop allergic reactions to the test material(s). This risk is increased for individuals with a history of allergies, and individuals with asthma and/or a history of hives may also be affected. Symptoms include rash, hives, and itching.

You must tell the Investigator or study staff about all side effects that you have. If you are not honest about your side effects, it may not be safe for you to stay in the study.

BIRTH CONTROL, DANGERS OF PREGNANCY AND BREASTFEEDING

If you are a female, you must not get pregnant while in this study. The only certain way to not get pregnant is to not have sex. If you are a female and choose to have sex, you must use a type of birth control.

Even if you use birth control during the study, there is a chance you could become pregnant. If you are pregnant or become pregnant during the study, test products or procedures may involve unforeseeable risks to the unborn baby.

A pregnancy test can be wrong. If you become pregnant during the study, stop using the test products and call/inform the Investigator at once.

You cannot be in the study if you are breastfeeding. It is not known whether the test products are safe for breast fed babies. Therefore if you are breastfeeding a child then it may not be safe for you to participate in the study.

POSSIBLE BENEFITS OF THE STUDY

You will not get any medical benefit from being in this study, and there is no promise that your condition (acne) will get better. It might stay the same or it might get worse. Your participation will provide information that may help others. There may be other marketed products that claim to have similar benefits.

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OTHER OPTIONS TO PARTICIPATING IN THE STUDY

Since this study is for research only, the only other choice would be not to be in the study.

STUDY AND TEST PRODUCT CONFIDENTIALITY

To participate in this study, you must agree to keep any information relating to the design, identity or use of these test product samples confidential.

On rare occasions, the sponsor may allow the testing company to disclose to you the name of the test products if you are not given this information during the study. This information is typically not provided until the end of the study or after the test products have been released for sale to the public. The study doctor or study staff will notify you if the sponsor allows us to give you this information.

DISCLOSURE AGREEMENT

This section explains how personal health information collected about you for the study may be used. Your personal health information includes, but is not limited to, information that was collected for your entry into the study and information that is collected during the study. The purpose of collecting this information is to allow the study staff and the Investigator to conduct the study, to evaluate the sponsor's study products and to analyze the study results.

You may decide not to give permission for the release of your personal health information for the study. In that case, you will not be able to participate in the study. This is because the study staff and/or the Investigator would not be able to collect the information needed to evaluate the sponsor's study products.

People who may inspect your personal and health information includes the Investigator, the Institutional Review Board, IntegReview IRB, FDA and other regulatory authorities from the United States or other countries, the study sponsor and people that work with the sponsor which includes, monitoring committees, contract research organizations, and consultants who have contracts with the company to do the study and review the study results. These reviews are done to check on the quality of the study and also for other purposes allowed by law.

The results of the study may be published in a medical book or journal, or presented at meetings for educational purposes. Neither your name, nor any other personal health information that specifically identifies you, will be used in those materials or presentations.

You may ask the Investigator to see and copy your personal health information related to the study. You may also ask the Investigator to correct any study related information about you that is wrong. You may have to wait until the end of the study to see your study records, so that the study can be organized properly.

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This permission to share your personal health information for this study does not have an expiration date. If you no longer want to share your personal health information, you may cancel your permission at any time by writing to the study staff and/or the Investigator at the address below:

Thomas J. Stephens & Associates, Inc.
5050 Edison Ave., Suite 202
Colorado Springs, CO 80915

If you cancel your permission after you have started in the study, the study staff and the Investigator will stop collecting your personal health information. Although they will stop collecting new information about you, they will need to use the information they have already collected to evaluate the study results. If you start the study and then cancel your permission, you will not be able to continue to participate in the study. This is because the study staff and/or the Investigator would not be able to collect the information needed to evaluate the study.

Thomas J. Stephens & Associates and the sponsor will make every effort to keep your personal health information private. But after the study staff or the Investigator share your personal health information from the study, federal privacy laws may not keep it private. There might be laws in your state or other federal laws that would protect the privacy of this information.

CONFIDENTIALITY

Your records of being in this study will be kept private except when ordered by law. The following people will have access to your study records:

- The Investigator
- Sponsor company or research institution [including monitor(s) and auditor(s)]
- Other country, state or federal regulatory agencies
- IntegReview IRB

The Institutional Review Board (IRB), IntegReview, and accrediting agencies may inspect and copy your records, which may have your name on them. Therefore, total confidentiality cannot be guaranteed. If the study results are presented at meetings or printed in publications, your name will not be used.

IN CASE OF STUDY RELATED INJURY

Side effects or complications, both foreseeable and unforeseeable, are possible in any research study without any fault to you, the Investigator, the study site, or the study sponsor. If you get hurt or sick as a direct result of being in this study, the sponsor will pay the costs of reasonable medical treatment. To ask questions about this, talk to the Investigator or study staff.

The sponsor's policy does not offer compensation for other expenses. Be aware that your health care payer/insurer might not cover the costs of study-related injuries or illnesses.

Unreimbursed medical expenses not covered by insurance or other third party coverage will be reimbursed by the sponsor for medical treatment for any injury that, in the opinion of the study doctor and the sponsor, is directly caused by the investigational product or by procedures required by the study protocol which would not have been performed as part of your regular medical care.

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LEGAL RIGHTS

You will not lose any of your legal rights by signing this consent form.

CONTACT INFORMATION

If you have questions, concerns, or complaints about this study or to report a study related injury, contact:

Kun Qian, M.D.
719-637-2828 daytime telephone number
719-471-1763 after hours number

If you are unable to reach anyone at the number(s) listed above and you need medical attention, please go to the nearest emergency room.

If you do not want to talk to the Investigator or study staff, if you have concerns or complaints about the research, or to ask questions about your rights as a study subject you may contact IntegReview. IntegReview's policy indicates that all concerns/complaints are to be submitted in writing for review at a convened IRB meeting to:

Mailing Address:	OR	Email Address:
Chairperson IntegReview IRB 3815 S. Capital of Texas Highway Suite 320 Austin, TX 78704		integreview@integreview.com

If you are unable to provide your concerns/complaints in writing or if this is an emergency situation regarding subject safety, contact our office at:

512-326-3001 or
toll free at 1-877-562-1589
between 8 a.m. and 5 p.m. Central Time

IntegReview has approved the information in this consent form and has given approval for the Investigator to do the study. This does not mean IntegReview has approved your being in the study. You must consider the information in this consent form for yourself and decide if you want to be in this study.

PAYMENT FOR BEING IN THE STUDY

You may receive up to $575.00 for being in the study. You will be paid per completed visit as follows:

Visit	Compensation (amount)
Visit 1	$40.00
Visit 2	$60.00
Visit 3	$65.00
Visit 4	$75.00
Visit 5	$90.00

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Visit 6	$95.00
Visit 7	$150.00

If you choose to leave or are withdrawn from the study for any reason before finishing all visits you will be paid for each completed visit. You will receive payment within 2 weeks of final study visit.

If you do not qualify for any reason, you will be paid $20.00, which will be mailed to you within 2 weeks of the baseline study visit.

If you are paid $600.00 or more by Thomas J. Stephens & Associates, Inc. in a calendar year, those payments will be reported to the Internal Revenue Service via form 1099-MISC. As required by tax laws, if you withhold your social security number, Thomas J. Stephens & Associates, Inc. is required to withhold 28% of your payment for tax purposes. In this case a form 1099-MISC will be sent to you reporting your withholding.

VOLUNTEERING TO BE IN THE STUDY

It is your choice if you want to be in the study. No one can force you to be in the study. You may not want to be in this study or you may leave the study at any time without penalty or loss of benefits to which you are otherwise entitled.

The Investigator, the sponsor company, or IntegReview may take you out of the study without your permission, at any time, for the following reasons:

- If you do not follow the Investigator's instructions
- If we find out you should not be in the study
- If the study is stopped
- If it becomes harmful to your health

If you leave the study or if you are taken out of the study, you may be asked to return for a final visit to have some end of study evaluations or tests. If information generated from this study is published or presented, your identity will not be revealed. If you leave the study, no more information about you will be collected for this study. However, all of the information you gave us before you left the study will still be used.

NEW FINDINGS

If there is new information or any significant new findings that could relate to your willingness to continue participation we will tell you. You can then decide if you still want to be in the study.

THE REASON FOR INSTITUTIONAL REVIEW BOARDS AND INFORMED CONSENT

What is a consent form?
The informed consent document contains information required by federal regulations. The informed consent document must be approved by an Institutional Review Board (IRB).

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What is an Institutional Review Board (IRB)?
An Institutional Review Board (IRB) is a group of people that reviews research studies. The main goal of this review is to protect the rights and well being of the human subjects participating in research studies.

IntegReview, the IRB for this study
IntegReview is an IRB whose board members provide IRB services across the United States, Canada, Japan and Latin America.

To meet requirements of the law, the IntegReview Boards currently include:

- Doctors
- Pharmacists
- Nurses
- Toxicologists (people who study the harmful effects of chemicals)
- Other specialists
- Others who do not have a background in science/medicine

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AGREEMENT TO BE IN THE STUDY

This consent form contains important information to help you decide if you want to be in the study. If you have any questions that are not answered in this consent form, ask one of the study staff.

Please answer **YES** or **NO** to the following questions:

A. Is this document in a language you understand? _____

B. Do you understand the information in this consent form? _____

C. Have you been given enough time to ask questions and talk about the study? _____

D. Have all of your questions been answered to your satisfaction? _____

E. Do you think you received enough information about the study? _____

F. Do you volunteer to be in this study of your own free will and without being pressured by the Investigator or study staff? _____

G. Do you know that you can leave the study at any time without giving a reason and without affecting your health care? _____

H. Do you know that your health records from this study may be reviewed by the sponsor company and by government authorities? _____

I. Do you know that you cannot be in another study while you are in this study? _____

IF YOU ANSWERED "NO" TO ANY OF THE ABOVE QUESTIONS,
OR YOU ARE UNABLE TO ANSWER ANY OF THE ABOVE QUESTIONS,
YOU SHOULD NOT SIGN THIS CONSENT FORM.

_____
Printed Name of Adult Study Subject

_____
Signature of Adult Study Subject Date

_____
Printed Name of Person Explaining Consent Form

_____
Signature of Person Explaining Consent Form Date

You will be given a signed and dated copy of this consent form to keep.

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Authorization and Release Form

I hereby for good and valuable consideration grant to Thomas J. Stephens & Associates, the study sponsor and their respective affiliates, agencies, agents, employees, and assigns (collectively, "Authorized Entities"), the unrestricted, royalty free, irrevocable and perpetual right and permission to reproduce, distribute, broadcast and/or otherwise use for advertising and other commercial/noncommercial purposes: (i) my name, likeness, image, video, and any other biographical or personal information ("Personal Content"); and (ii) any statement or endorsement, or any portions thereof ("Testimonial(s)"), made by me relating to the study sponsor's products ("Products"), in any and all media now known or later developed, worldwide in perpetuity, without further compensation or approval by me.

I hereby assign to the Authorized Entities all of my world-wide right, title and interest, including my copyright interests and all renewals, reissues and extensions thereof, in and to the Personal Content and Testimonial(s), including without limitation, any photographic portraits, sound recordings and video performances of and/or by me in connection with the Personal Content and/or Testimonial(s).

I am at least 21 years of age, and competent to contract in my own name. I have read and understand this Authorization and Release.

_____
Printed Name of Adult Study Subject

_____
Signature of Adult Study Subject Date

_____
Printed Name of Person Explaining Release Form

_____
Signature of Person Explaining Release Form Date

Copy of consent form given to subject on _____ (date) by _____ (initials)

You will be given a signed and dated copy of this consent form to keep.

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AUTHORIZATION TO USE AND DISCLOSE PERSONAL HEALTH INFORMATION FOR RESEARCH

THIS SECTION DESCRIBES YOUR RIGHTS AND HOW PERSONAL HEALTH INFORMATION COLLECTED ABOUT YOU DURING THIS STUDY MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

The United States government has issued a privacy rule to protect the privacy rights of patients. This rule was issued under a law called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The Privacy Rule is designed to protect the confidentiality of your personal health information. The document you are reading, called an "Authorization," describes your rights and explains how your health information will be used and disclosed (shared).

Federal law requires hospitals, researchers and health care providers to protect the privacy of information that identifies you and relates to your past, present and future physical and mental health or conditions.

All information collected during the study will be retained by the study doctor and the Study Sponsor, except as required by law. Information from this study will be given to the sponsor. "Sponsor" includes any persons or companies, which are contracted by the sponsor to have access to the research information during and after the study. The information will also be given to the U.S. Food and Drug Administration (FDA). Study records which identify you and the consent form signed by you will be inspected and/or copied for research or regulatory purposes by:

- Sponsor
- Agents for the sponsor
- The US Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies
- IntegReview IRB

Because of the need to release information to these parties, absolute confidentiality cannot be guaranteed. The results of this research study may be presented at meetings or in publications; however, your identity will not be disclosed in those presentations.

For purposes of study reporting, you will be identified by your initials and code numbers only. However, your name, date of birth, address, and phone number will be kept on record by the study doctor in case you need to be contacted in the future about this study.

After your personal health information is disclosed to the Study Sponsor, the results of the study may be reanalyzed at a later date and may be combined with the results of other studies. The Study Sponsor and people who work with the Study Sponsor may use the results of this study for other research purposes, including:

- Developing a better understanding of the disease;
- Improving the design of future actual use trials

After the study staff or the study doctor discloses your personal health information to others, it could be re-disclosed and no longer protected by federal privacy laws.

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INTEGREVIEW IRB
SEPTEMBER 16, 2016**

This permission to share your personal health information for this study does not have an expiration date. If you do not withdraw this Authorization in writing, it will remain in effect indefinitely. Your study doctor will keep this Authorization for at least 6 years. If you no longer want to share your personal health information, you may cancel your permission at any time by writing to the study staff and/or the study doctor at the address below:

Thomas J. Stephens & Associates, Inc.
5050 Edison Ave., Suite 202
Colorado Springs, CO 80915

You have the right to see and get a copy of your records related to the study for as long as the study doctor has this information. However, by signing this Authorization you agree that you might not be able to review or receive some of your records related to the study until after the study has been completed.

If you cancel your permission after you have started in the study, the study staff and the study doctor will stop collecting your personal health information unless the information concerns an adverse event (a bad effect) related to the study. If an adverse event occurs, your entire medical record may be reviewed. All information that has already been collected for study purposes, and any new information about an adverse event related to the study, will be sent to the study sponsor. Although they will stop collecting new information about you, they will need to use the information they have already collected to evaluate the study results. If you start the study and then cancel your permission, you will not be able to continue to participate in the study. This is because the study staff and/or the study doctor would not be able to collect the information needed to evaluate the study results.

If you withdraw from the study but do not withdraw your Authorization, new personal health information may be collected until this study ends.

You may decide not to give permission for the release of your personal health information for this study. In that case, you will not be able to participate. This is because the study staff and study doctor would not be able to collect the information needed to evaluate the study results.

At the completion of the study, you have the right to access your protected health information that is created during this research study that relates to your treatment or to payment, provided such information is not exempted under certain laws and regulations. To request this information, please contact the study doctor at the address listed above.

Your Right to Access Health Information

Subject to certain exceptions prescribed by law, you have a right to request access to the health information that we hold about you and to request changes if your health information is incorrect or incomplete. Any request for access or corrections should be made to the principal doctor conducting this study.

Your records obtained while you are in this trial, as well as related health records, will remain strictly confidential at all times. However, these will need to be made available to others working on the Sponsor's behalf, the Independent Ethics Committee members and Medicines Regulatory Authorities.

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By signing the consent form you agree to this access for the current trial and any further research that may be done. However, the Sponsor will take steps to protect your personal information and will not include your name on any sponsor forms, reports, publications, or in any future disclosures. If you withdraw from the study, we will no longer collect your personal information, but we may need to continue to use information already collected.

Personal data which may be sensitive (e.g., date of birth) will be collected and processed, but only for research purposes in connection with this trial.

The trial data will be sent around the world, but you will not be referred to by name or identified in any report or publication nor could the data be traced back to you. Your data may be transferred to a country that does not have the same level of personal data protection as within the United States. However, The Sponsor maintains high standards of confidentiality and protection.

The Sponsor (who will control the use of the data) will take steps to ensure your personal data is protected.

By taking part in this trial you agree not to restrict the use of any data even if you withdraw from the trial and agree to the transfer of your personal data to other Sponsor companies and to Medicines Regulatory Authorities both within and outside of Europe.

_____

Printed Name of Adult Study Subject

_____

Signature of Adult Study Subject Date

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FEBRUARY 25, 2016

INFORMED CONSENT DOCUMENT
AGREEMENT TO BE IN A RESEARCH STUDY

NAME OF TESTING COMPANY:	Thomas J. Stephens & Associates, Inc.
NUMBER AND TITLE OF STUDY:	C16-CD020 (GLI.04.SPR.US10354); "A Multi-Center Clinical Trial to Evaluate the Efficacy of Two Acne Treatments"
NAME OF PERSON IN CHARGE OF THE RESEARCH STUDY (STUDY DOCTOR/INVESTIGATOR):	Edward Lain, MD
TELEPHONE NUMBER(S), DAYTIME:	512-279-2545
AFTER HOURS:	512-844-4500

INTRODUCTION

You are being invited to volunteer for a clinical research study. You must read and sign this form before you agree to take part in this study. This form will give you more information about this study. Please ask as many questions as you need to before you decide if you want to be in the study. You should not sign this form if you have any questions that have not been answered.

Thomas J. Stephens & Associates, Inc., a contract research organization, is being paid by the sponsor (the company paying for this study) to conduct this research study.

You must be honest with the Investigator about your health history or it may not be safe for you to be in this study.

PURPOSE OF THE STUDY

The purpose of this study is to evaluate the efficiency of 2 acne treatments for 24 weeks of use in adult men and women with mild to moderate facial acne, at least 5 inflammatory lesions, and at least 10 – 100 non-inflammatory lesions.

HOW LONG THE STUDY WILL LAST AND HOW MANY PEOPLE WILL BE IN THE STUDY

This study will last 24 weeks and have up to 8 visits. At least 100 subjects, men and women between the ages of 21-45, are expected to complete this study, with at least 50 subjects completed per cell. Each site is to enroll no more than 40 subjects, with at least 100 subjects expected to complete when combined.

TO BE IN THIS STUDY

You must:

- Be a man or woman age 21 to 45 years at the time of enrollment.
- Have mild to moderate acne on the face as determined by the Investigator or designee.
- Have at least 5 inflammatory lesions as determined by the Investigator or designee.
- Have 10 – 100 non-inflammatory lesions as determined by the Investigator or designee.
- Be willing to use the test products as instructed for 24 weeks.

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- Be willing and able to comply with all of the time commitments and procedural requirements of the clinical trial protocol.
- Be willing to provide written informed consent including photo release, Health Insurance Portability and Accountability Act (HIPAA), and be able to read, speak, write, understand English and be willing to share personal information and data, as verified by signing a written authorization at the screening.
- Be willing to withhold all facial treatments during the course of the study including botulinum toxin, injectable fillers, microdermabrasion, IPL, peels, facials, laser treatments and tightening treatments. Waxing and threading is allowed but not facial laser hair removal.
- Males must be regular shavers and willing to shave on the day of the study visits (prior to clinic visits).
- Women of child bearing potential must be willing to take a urine pregnancy test prior to study enrollment, at week 24, and when deemed appropriate by the Investigator and/or Sponsor.
- Individuals of child bearing potential must use an acceptable method of contraception throughout the study. Acceptable methods of birth control include:
    - Oral and other system contraceptives. Individuals must be on a stable use for 3 months prior to study enrollment. Individuals on oral contraceptives must not alter their use, including dose or regimen for the duration of the study
    - Double barrier
    - Bilateral tubal ligation (tubes tied)
    - Partner vasectomy
    - Abstinence
- Be willing to follow study requirements and report any changes in health status or medications, side effect symptoms, or reactions immediately.
- Be stable on any medication you are taking for at least 30 days

YOU CANNOT BE ON THE STUDY

If you:

- Have been diagnosed with allergies to topical acne products.
- Have a condition and/or disease of the skin that the Investigator deems inappropriate for participation.
- Are a woman who is breastfeeding, pregnant, or planning to become pregnant during the study.
- Have pre-existing or dormant dermatologic conditions on the face (e.g., psoriasis, rosacea, eczema, seborrheic dermatitis, severe excoriations etc.) which in the opinion of the Investigator could interfere with the outcome of the study.
- Have a history of immunosuppression/immune deficiency disorders (including HIV infection or AIDS) or currently using immunosuppressive medications (e.g., azathioprine, belimumab, cyclophosphamide, Enbrel, Imuran, Humira, mycophenolate mofetil, methotrexate, prednisone, Remicade, Stelara.).
- Have an uncontrolled disease such as asthma, diabetes, hypertension, hyperthyroidism, or hypothyroidism. Individuals having multiple health conditions may be excluded from participation even if the conditions are controlled by diet, medication, etc. at the Investigator's discretion.
- Are currently participating in another facial usage study or have participated in a clinical trial within 4 weeks prior to inclusion into the study.
- Have a history of skin cancer on the face within the past 5 years.
- Have any planned surgeries and/or invasive medical procedures during the course of the study.

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- Have started hormone replacement therapies (HRT) or hormones for birth control less than 3 months prior to study entry or plan on starting, stopping, or changing doses of HRT or hormones for birth control during the study.
- Have facial sunburn or excessive tanned facial skin or are not willing to avoid daily sun exposure on the face and the use of tanning beds or sunless tanning products for the duration of the study.
- Have severe acne, acne conglobata, multiple nodules or cysts (more than 2).
- Are currently taking a natural or prescription testosterone blocker (e.g. saw palmetto, blask cohosh, chaste tree, chasteberry, spironolactone, drospirenone, progestins).
- Are currently on a testosterone booster or prescription testosterone (e.g. DHEA, tribulus, testosterone cypionate, testosterone enanthate, Sustanon, testosterone propionate, testosterone phenylpropriate, Omnadren etc.).
- Are currently taking or have taken within the last 30 days oral or topical prescription medications for acne such as Doxycycline, Minocycline, Clindamycin, Bactrim, Tetracycline, Erythromycin, Vibramycin and topical tretinoin (Retin A, Renova, Adapalene, Tazarotene), Azelaic acid, benzoyl peroxide, Dapsone, Sodium sulfacetamide, Differin, Epiduo.
- Have used oral isotretinoin (Accutane) within the past 6-months.
- Are routinely using (3x a week or more) topical over-the-counter (OTC) acne product (e.g. benzoyl peroxide, salicylic acid, alpha hydroxyl, beta hydroxyl and/or poly-hydroxy products or medicated cleansers, wipes, masks, scrubs, gels and creams) within 14 days of the study entry.
- Are using or have used any systemic medication considered to affect the course of acne, specifically, but not exclusively antibiotics or steroids within the last 30 days prior to entry into the study.
- Have excessive facial hair, including beard, mustache or goatee, or scars, which could interfere with evaluations as determined by the Investigator or designee.

WHAT WILL HAPPEN DURING THE STUDY

***Visit 1: Screening (* Visit 1 {*Screening*} AND Visit 2 {*Baseline*} may be combined into 1 Visit)**

You will:

- Be given an IRB-approved Informed Consent Form (ICF), to read and sign. You will be given enough time to read the informed consent, and ask questions about the study, and sign 2 copies of this consent form. (1 for clinic records, 1 for your records)
- Be given an eligibility and health questionnaire to complete, and assigned a screening number.
- Will acclimate for 15 minutes in a room at 68-75^{0}F and 35-65% humidity.
- Will be screened by the Investigator or designee to see if you qualify for the study.
- If you do qualify for the study, you will:
    - Take a urine pregnancy test (females of child-bearing potential)
    - Have a dermatologist confirm your eligibility
    - Schedule your next appointment.

***Visit 2: Baseline**

- Be asked if you have experienced any changes in your health since the previous visit.
- Will acclimate for 15 minutes in a room at 68-75^{0}F and 35-65% humidity.
- Be screened by the Investigator or designee to see if you still qualify for the study.
- Have your health and eligibility re-reviewed.

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- If you still qualify for the study you will:
    - Be assigned a subject number
    - Have photos taken of your face
    - Be randomly assigned to receive one of the test products & supporting facial cleanser, moisturizer & facial SPF 30
    - Be provided verbal and written usage instructions, and a daily diary to record product use
    - Schedule your next appointment

Visits 3, 4 (Week 1, Week 2)

- Be asked if you have experienced any changes in your health since the previous visit.
- Will acclimate for 15 minutes in a room at 68-75^{0}F and 35-65% humidity.
- Have your face examined by the Investigator or designee
- Complete a self-assessment questionnaire
- Have your diary collected and reviewed for compliance, and returned to you. At week 2, your diary will be retained by the testing facility and you will be given a new diary
- Have your product collected, weighed, and returned to you
- Schedule your next appointment

Visits 5, 6 (Week 6, Week 12)

- Be asked if you have experienced any changes in your health since the previous visit.
- Will acclimate for 15 minutes in a room at 68-75^{0}F and 35-65% humidity.
- Have your face examined by the Investigator or designee
- Have photos taken of your face
- Complete a self-assessment questionnaire
- Have your diary collected and reviewed for compliance, and retained by the testing facility and you will be given a new diary.
- Have your product collected, weighed, and retained. New products will be dispensed as necessary.
- Schedule your next appointment

Visit 7 (Week 18)

- Be asked if you have experienced any changes in your health since the previous visit.
- Have your diary collected and reviewed for compliance, and retained by the testing facility and you will be given a new diary.
- Have your product collected, weighed, and returned to you
- Schedule your next appointment

Visit 8 (Week 24)

- Be asked if you have experienced any changes in your health since the previous visit.
- Take a urine pregnancy test (females of child-bearing potential).
- Will acclimate for 15 minutes in a room at 68-75^{0}F and 35-65% humidity.
- Have your face examined by the Investigator or designee
- Have photos taken of your face
- Complete a self-assessment questionnaire
- Have your diary collected and reviewed for compliance, and retained by the testing facility.
- Have your product collected, weighed, and retained by the testing facility.

Do not give the study product to other people and keep it out of the reach of children.

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RISKS OR DISCOMFORTS

If you do not understand what any of these side effects mean, please ask the investigator or study staff to explain these terms to you.

Because the study products are investigational, all of their side effects may not be known. There may be rare and unknown side effects. Some of these may be life threatening.

Possible risks associated with the product are, as with any other cosmetic and OTC products, signs of irritation including:

- Itching
- Burning
- Stinging
- Rash or other allergic reaction
- Tingling
- Scaling/Dryness
- Redness

In some cases, it is possible for a subject to develop allergic reactions to the test material(s). This risk is increased for individuals with a history of allergies, and individuals with asthma and/or a history of hives may also be affected. Symptoms include rash, hives, and itching.

You must tell the Investigator or study staff about all side effects that you have. If you are not honest about your side effects, it may not be safe for you to stay in the study.

BIRTH CONTROL, DANGERS OF PREGNANCY AND BREASTFEEDING

If you are a female, you must not get pregnant while in this study. The only certain way to not get pregnant is to not have sex. If you are a female and choose to have sex, you must use a type of birth control.

Even if you use birth control during the study, there is a chance you could become pregnant. If you are pregnant or become pregnant during the study, test products or procedures may involve unforeseeable risks to the unborn baby.

A pregnancy test can be wrong. If you become pregnant during the study, stop using the test products and call/inform the Investigator at once.

You cannot be in the study if you are breastfeeding. It is not known whether the test products are safe for breast fed babies. Therefore if you are breastfeeding a child then it may not be safe for you to participate in the study.

POSSIBLE BENEFITS OF THE STUDY

You will not get any medical benefit from being in this study, and there is no promise that your condition (acne) will get better. It might stay the same or it might get worse. Your participation will provide information that may help others. There may be other marketed products that claim to have similar benefits.

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OTHER OPTIONS TO PARTICIPATING IN THE STUDY

Since this study is for research only, the only other choice would be not to be in the study.

STUDY AND TEST PRODUCT CONFIDENTIALITY

To participate in this study, you must agree to keep any information relating to the design, identity or use of these test product samples confidential.

On rare occasions, the sponsor may allow the testing company to disclose to you the name of the test products if you are not given this information during the study. This information is typically not provided until the end of the study or after the test products have been released for sale to the public. The study doctor or study staff will notify you if the sponsor allows us to give you this information.

DISCLOSURE AGREEMENT

This section explains how personal health information collected about you for the study may be used. Your personal health information includes, but is not limited to, information that was collected for your entry into the study and information that is collected during the study. The purpose of collecting this information is to allow the study staff and the Investigator to conduct the study, to evaluate the sponsor's study products and to analyze the study results.

You may decide not to give permission for the release of your personal health information for the study. In that case, you will not be able to participate in the study. This is because the study staff and/or the Investigator would not be able to collect the information needed to evaluate the sponsor's study products.

People who may inspect your personal and health information includes the Investigator, the Institutional Review Board, IntegReview IRB, FDA and other regulatory authorities from the United States or other countries, the study sponsor and people that work with the sponsor which includes, monitoring committees, contract research organizations, and consultants who have contracts with the company to do the study and review the study results. These reviews are done to check on the quality of the study and also for other purposes allowed by law.

The results of the study may be published in a medical book or journal, or presented at meetings for educational purposes. Neither your name, nor any other personal health information that specifically identifies you, will be used in those materials or presentations.

You may ask the Investigator to see and copy your personal health information related to the study. You may also ask the Investigator to correct any study related information about you that is wrong. You may have to wait until the end of the study to see your study records, so that the study can be organized properly.

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This permission to share your personal health information for this study does not have an expiration date. If you no longer want to share your personal health information, you may cancel your permission at any time by writing to the study staff and/or the Investigator at the address below:

Austin Institute for Clinical Research, Inc.
302 N. Heatherwilde Blvd., Suite 300
Pflugerville, TX 78660

If you cancel your permission after you have started in the study, the study staff and the Investigator will stop collecting your personal health information. Although they will stop collecting new information about you, they will need to use the information they have already collected to evaluate the study results. If you start the study and then cancel your permission, you will not be able to continue to participate in the study. This is because the study staff and/or the Investigator would not be able to collect the information needed to evaluate the study.

Thomas J. Stephens & Associates and the sponsor will make every effort to keep your personal health information private. But after the study staff or the Investigator share your personal health information from the study, federal privacy laws may not keep it private. There might be laws in your state or other federal laws that would protect the privacy of this information.

CONFIDENTIALITY

Your records of being in this study will be kept private except when ordered by law. The following people will have access to your study records:

- The Investigator
- Sponsor company or research institution [including monitor(s) and auditor(s)]
- Other country, state or federal regulatory agencies
- IntegReview IRB

The Institutional Review Board (IRB), IntegReview, and accrediting agencies may inspect and copy your records, which may have your name on them. Therefore, total confidentiality cannot be guaranteed. If the study results are presented at meetings or printed in publications, your name will not be used.

IN CASE OF STUDY RELATED INJURY

Side effects or complications, both foreseeable and unforeseeable, are possible in any research study without any fault to you, the Investigator, the study site, or the study sponsor. If you get hurt or sick as a direct result of being in this study, the sponsor will pay the costs of reasonable medical treatment. To ask questions about this, talk to the Investigator or study staff.

The sponsor's policy does not offer compensation for other expenses. Be aware that your health care payer/insurer might not cover the costs of study-related injuries or illnesses.
Unreimbursed medical expenses not covered by insurance or other third party coverage will be reimbursed by the sponsor for medical treatment for any injury that, in the opinion of the study doctor and the sponsor, is directly caused by the investigational product or by procedures required by the study protocol which would not have been performed as part of your regular medical care.

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LEGAL RIGHTS

You will not lose any of your legal rights by signing this consent form.

CONTACT INFORMATION

If you have questions, concerns, or complaints about this study or to report a study related injury, contact:

Edward Lain, MD
512-279-2545 daytime telephone number
512-844-4500 after hours number

If you are unable to reach anyone at the number(s) listed above and you need medical attention, please go to the nearest emergency room.

If you do not want to talk to the Investigator or study staff, if you have concerns or complaints about the research, or to ask questions about your rights as a study subject you may contact IntegReview. IntegReview's policy indicates that all concerns/complaints are to be submitted in writing for review at a convened IRB meeting to:

Mailing Address:	OR	Email Address:
Chairperson IntegReview IRB 3815 S. Capital of Texas Highway Suite 320 Austin, TX 78704		integreview@integreview.com

If you are unable to provide your concerns/complaints in writing or if this is an emergency situation regarding subject safety, contact our office at:

512-326-3001 or
toll free at 1-877-562-1589
between 8 a.m. and 5 p.m. Central Time

IntegReview has approved the information in this consent form and has given approval for the Investigator to do the study. This does not mean IntegReview has approved your being in the study. You must consider the information in this consent form for yourself and decide if you want to be in this study.

PAYMENT FOR BEING IN THE STUDY

You may receive up to $575.00 for being in the study. You will be paid per completed visit as follows:

Visit	Compensation (amount)
Screening/Baseline (Visit 1, 2)	$40.00
Visit 3	$60.00
Visit 4	$65.00
Visit 5	$75.00
Visit 6	$90.00

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Visit 7	$95.00
Visit 8	$150.00

If you choose to leave or are withdrawn from the study for any reason before finishing all visits you will be paid for each completed visit. You will receive payment at the end of each study visit.

If you do not qualify for any reason, you will be paid $20.00, which will be mailed to you within 2 weeks of the baseline study visit.

If you are paid $600.00 or more by Thomas J. Stephens & Associates, Inc. in a calendar year, those payments will be reported to the Internal Revenue Service via form 1099-MISC. As required by tax laws, if you withhold your social security number, Thomas J. Stephens & Associates, Inc. is required to withhold 28% of your payment for tax purposes. In this case a form 1099-MISC will be sent to you reporting your withholding.

VOLUNTEERING TO BE IN THE STUDY

It is your choice if you want to be in the study. No one can force you to be in the study. You may not want to be in this study or you may leave the study at any time without penalty or loss of benefits to which you are otherwise entitled.

The Investigator, the sponsor company, or IntegReview may take you out of the study without your permission, at any time, for the following reasons:

- If you do not follow the Investigator's instructions
- If we find out you should not be in the study
- If the study is stopped
- If it becomes harmful to your health

If you leave the study or if you are taken out of the study, you may be asked to return for a final visit to have some end of study evaluations or tests. If information generated from this study is published or presented, your identity will not be revealed. If you leave the study, no more information about you will be collected for this study. However, all of the information you gave us before you left the study will still be used.

NEW FINDINGS

If there is new information or any significant new findings that could relate to your willingness to continue participation we will tell you. You can then decide if you still want to be in the study.

THE REASON FOR INSTITUTIONAL REVIEW BOARDS AND INFORMED CONSENT

What is a consent form?
The informed consent document contains information required by federal regulations. The informed consent document must be approved by an Institutional Review Board (IRB).

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What is an Institutional Review Board (IRB)?
An Institutional Review Board (IRB) is a group of people that reviews research studies. The main goal of this review is to protect the rights and well being of the human subjects participating in research studies.

IntegReview, the IRB for this study
IntegReview is an IRB whose board members provide IRB services across the United States, Canada, Japan and Latin America.

To meet requirements of the law, the IntegReview Boards currently include:

- Doctors
- Pharmacists
- Nurses
- Toxicologists (people who study the harmful effects of chemicals)
- Other specialists
- Others who do not have a background in science/medicine

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AGREEMENT TO BE IN THE STUDY

This consent form contains important information to help you decide if you want to be in the study. If you have any questions that are not answered in this consent form, ask one of the study staff.

Please answer **YES** or **NO** to the following questions:

A. Is this document in a language you understand? _____

B. Do you understand the information in this consent form? _____

C. Have you been given enough time to ask questions and talk about the study? _____

D. Have all of your questions been answered to your satisfaction? _____

E. Do you think you received enough information about the study? _____

F. Do you volunteer to be in this study of your own free will and without being pressured by the Investigator or study staff? _____

G. Do you know that you can leave the study at any time without giving a reason and without affecting your health care? _____

H. Do you know that your health records from this study may be reviewed by the sponsor company and by government authorities? _____

I. Do you know that you cannot be in another study while you are in this study? _____

IF YOU ANSWERED "NO" TO ANY OF THE ABOVE QUESTIONS,
OR YOU ARE UNABLE TO ANSWER ANY OF THE ABOVE QUESTIONS,
YOU SHOULD NOT SIGN THIS CONSENT FORM.

_____
Printed Name of Adult Study Subject

_____
Signature of Adult Study Subject Date

_____
Printed Name of Person Explaining Consent Form

_____
Signature of Person Explaining Consent Form Date

You will be given a signed and dated copy of this consent form to keep.

THIS IS AN IMPORTANT DOCUMENT - KEEP FOR FUTURE REFERENCE

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Authorization and Release Form

I hereby for good and valuable consideration grant to Thomas J. Stephens & Associates, the study sponsor and their respective affiliates, agencies, agents, employees, and assigns (collectively, "Authorized Entities"), the unrestricted, royalty free, irrevocable and perpetual right and permission to reproduce, distribute, broadcast and/or otherwise use for advertising and other commercial/noncommercial purposes: (i) my name, likeness, image, video, and any other biographical or personal information ("Personal Content"); and (ii) any statement or endorsement, or any portions thereof ("Testimonial(s)"), made by me relating to the study sponsor's products ("Products"), in any and all media now known or later developed, worldwide in perpetuity, without further compensation or approval by me.

I hereby assign to the Authorized Entities all of my world-wide right, title and interest, including my copyright interests and all renewals, reissues and extensions thereof, in and to the Personal Content and Testimonial(s), including without limitation, any photographic portraits, sound recordings and video performances of and/or by me in connection with the Personal Content and/or Testimonial(s).

I am at least 21 years of age, and competent to contract in my own name. I have read and understand this Authorization and Release.

_____
Printed Name of Adult Study Subject

_____
Signature of Adult Study Subject Date

_____
Printed Name of Person Explaining Release Form

_____
Signature of Person Explaining Release Form Date

Copy of consent form given to subject on _____ (date) by _____ (initials)

You will be given a signed and dated copy of this consent form to keep.

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AUTHORIZATION TO USE AND DISCLOSE PERSONAL HEALTH INFORMATION FOR RESEARCH

THIS SECTION DESCRIBES YOUR RIGHTS AND HOW PERSONAL HEALTH INFORMATION COLLECTED ABOUT YOU DURING THIS STUDY MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

The United States government has issued a privacy rule to protect the privacy rights of patients. This rule was issued under a law called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The Privacy Rule is designed to protect the confidentiality of your personal health information. The document you are reading, called an "Authorization," describes your rights and explains how your health information will be used and disclosed (shared).

Federal law requires hospitals, researchers and health care providers to protect the privacy of information that identifies you and relates to your past, present and future physical and mental health or conditions.

All information collected during the study will be retained by the study doctor and the Study Sponsor, except as required by law. Information from this study will be given to the sponsor. "Sponsor" includes any persons or companies, which are contracted by the sponsor to have access to the research information during and after the study. The information will also be given to the U.S. Food and Drug Administration (FDA). Study records which identify you and the consent form signed by you will be inspected and/or copied for research or regulatory purposes by:

- Sponsor
- Agents for the sponsor
- The US Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies
- IntegReview IRB

Because of the need to release information to these parties, absolute confidentiality cannot be guaranteed. The results of this research study may be presented at meetings or in publications; however, your identity will not be disclosed in those presentations.

For purposes of study reporting, you will be identified by your initials and code numbers only. However, your name, date of birth, address, and phone number will be kept on record by the study doctor in case you need to be contacted in the future about this study.

After your personal health information is disclosed to the Study Sponsor, the results of the study may be reanalyzed at a later date and may be combined with the results of other studies. The Study Sponsor and people who work with the Study Sponsor may use the results of this study for other research purposes, including:

- Developing a better understanding of the disease;
- Improving the design of future actual use trials

After the study staff or the study doctor discloses your personal health information to others, it could be re-disclosed and no longer protected by federal privacy laws.

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This permission to share your personal health information for this study does not have an expiration date. If you do not withdraw this Authorization in writing, it will remain in effect indefinitely. Your study doctor will keep this Authorization for at least 6 years. If you no longer want to share your personal health information, you may cancel your permission at any time by writing to the study staff and/or the study doctor at the address below:

Austin Institute for Clinical Research, Inc.
302 N. Heatherwilde Blvd., Suite 300
Pflugerville, TX 78660

You have the right to see and get a copy of your records related to the study for as long as the study doctor has this information. However, by signing this Authorization you agree that you might not be able to review or receive some of your records related to the study until after the study has been completed.

If you cancel your permission after you have started in the study, the study staff and the study doctor will stop collecting your personal health information unless the information concerns an adverse event (a bad effect) related to the study. If an adverse event occurs, your entire medical record may be reviewed. All information that has already been collected for study purposes, and any new information about an adverse event related to the study, will be sent to the study sponsor. Although they will stop collecting new information about you, they will need to use the information they have already collected to evaluate the study results. If you start the study and then cancel your permission, you will not be able to continue to participate in the study. This is because the study staff and/or the study doctor would not be able to collect the information needed to evaluate the study results.

If you withdraw from the study but do not withdraw your Authorization, new personal health information may be collected until this study ends.

You may decide not to give permission for the release of your personal health information for this study. In that case, you will not be able to participate. This is because the study staff and study doctor would not be able to collect the information needed to evaluate the study results.

At the completion of the study, you have the right to access your protected health information that is created during this research study that relates to your treatment or to payment, provided such information is not exempted under certain laws and regulations. To request this information, please contact the study doctor at the address listed above.

Your Right to Access Health Information

Subject to certain exceptions prescribed by law, you have a right to request access to the health information that we hold about you and to request changes if your health information is incorrect or incomplete. Any request for access or corrections should be made to the principal doctor conducting this study.

Your records obtained while you are in this trial, as well as related health records, will remain strictly confidential at all times. However, these will need to be made available to others working on the Sponsor's behalf, the Independent Ethics Committee members and Medicines Regulatory Authorities.

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By signing the consent form you agree to this access for the current trial and any further research that may be done. However, the Sponsor will take steps to protect your personal information and will not include your name on any sponsor forms, reports, publications, or in any future disclosures. If you withdraw from the study, we will no longer collect your personal information, but we may need to continue to use information already collected.

Personal data which may be sensitive (e.g., date of birth) will be collected and processed, but only for research purposes in connection with this trial.

The trial data will be sent around the world, but you will not be referred to by name or identified in any report or publication nor could the data be traced back to you. Your data may be transferred to a country that does not have the same level of personal data protection as within the United States. However, The Sponsor maintains high standards of confidentiality and protection.

The Sponsor (who will control the use of the data) will take steps to ensure your personal data is protected.

By taking part in this trial you agree not to restrict the use of any data even if you withdraw from the trial and agree to the transfer of your personal data to other Sponsor companies and to Medicines Regulatory Authorities both within and outside of Europe.

_____

Printed Name of Adult Study Subject

_____

Signature of Adult Study Subject Date

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INFORMED CONSENT DOCUMENT
AGREEMENT TO BE IN A RESEARCH STUDY

NAME OF TESTING COMPANY:	Austin Institute for Clinical Research, Inc.
NUMBER AND TITLE OF STUDY:	C16-CD020 (GLI.04.SPR.US10354); "A Multi-Center Clinical Trial to Evaluate the Efficacy of Two Acne Treatments"
NAME OF PERSON IN CHARGE OF THE RESEARCH STUDY (STUDY DOCTOR/INVESTIGATOR):	Edward Lain, MD
TELEPHONE NUMBER(S), DAYTIME:	512-279-2545
AFTER HOURS:	512-844-4500

INTRODUCTION

You are being invited to volunteer for a clinical research study. You must read and sign this form before you agree to take part in this study. This form will give you more information about this study. Please ask as many questions as you need to before you decide if you want to be in the study. You should not sign this form if you have any questions that have not been answered.

Austin Institute for Clinical Research, Inc. is being paid by the sponsor (the company paying for this study) to conduct this research study.

You must be honest with the Investigator about your health history or it may not be safe for you to be in this study.

PURPOSE OF THE STUDY

The purpose of this study is to evaluate the efficiency of 2 acne treatments for 24 weeks of use in adult men and women with mild to moderate facial acne, at least 5 inflammatory lesions, and at least 10 – 100 non-inflammatory lesions.

HOW LONG THE STUDY WILL LAST AND HOW MANY PEOPLE WILL BE IN THE STUDY

This study will last 24 weeks and have up to 8 visits. At least 100 subjects, men and women between the ages of 21-45, are expected to complete this study, with at least 50 subjects completed per cell. Each site is to enroll no more than 40 subjects, with at least 100 subjects expected to complete when combined.

TO BE IN THIS STUDY

You must:

- Be a man or woman age 21 to 45 years at the time of enrollment.
- Have mild to moderate acne on the face as determined by the Investigator or designee.
- Have at least 5 inflammatory lesions as determined by the Investigator or designee.
- Have 10 – 100 non-inflammatory lesions as determined by the Investigator or designee.
- Be willing to use the test products as instructed for 24 weeks.

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- Be willing and able to comply with all of the time commitments and procedural requirements of the clinical trial protocol.
- Be willing to provide written informed consent including photo release, Health Insurance Portability and Accountability Act (HIPAA), and be able to read, speak, write, understand English and be willing to share personal information and data, as verified by signing a written authorization at the screening.
- Be willing to withhold all facial treatments during the course of the study including botulinum toxin, injectable fillers, microdermabrasion, IPL, peels, facials, laser treatments and tightening treatments. Waxing and threading is allowed but not facial laser hair removal.
- Males must be regular shavers and willing to shave on the day of the study visits (prior to clinic visits).
- Women of child bearing potential must be willing to take a urine pregnancy test prior to study enrollment, at week 24, and when deemed appropriate by the Investigator and/or Sponsor.
- Individuals of child bearing potential must use an acceptable method of contraception throughout the study. Acceptable methods of birth control include:
    - Oral and other system contraceptives. Individuals must be on a stable use for 3 months prior to study enrollment. Individuals on oral contraceptives must not alter their use, including dose or regimen for the duration of the study
    - Double barrier
    - Bilateral tubal ligation (tubes tied)
    - Partner vasectomy
    - Abstinence
- Be willing to follow study requirements and report any changes in health status or medications, side effect symptoms, or reactions immediately.
- Be stable on any medication you are taking for at least 30 days

YOU CANNOT BE ON THE STUDY

If you:

- Have been diagnosed with allergies to topical acne products.
- Have a condition and/or disease of the skin that the Investigator deems inappropriate for participation.
- Are a woman who is breastfeeding, pregnant, or planning to become pregnant during the study.
- Have pre-existing or dormant dermatologic conditions on the face (e.g., psoriasis, rosacea, eczema, seborrheic dermatitis, severe excoriations etc.) which in the opinion of the Investigator could interfere with the outcome of the study.
- Have a history of immunosuppression/immune deficiency disorders (including HIV infection or AIDS) or currently using immunosuppressive medications (e.g., azathioprine, belimumab, cyclophosphamide, Enbrel, Imuran, Humira, mycophenolate mofetil, methotrexate, prednisone, Remicade, Stelara.).
- Have an uncontrolled disease such as asthma, diabetes, hypertension, hyperthyroidism, or hypothyroidism. Individuals having multiple health conditions may be excluded from participation even if the conditions are controlled by diet, medication, etc. at the Investigator's discretion.
- Are currently participating in another facial usage study or have participated in a clinical trial within 4 weeks prior to inclusion into the study.
- Have a history of skin cancer on the face within the past 5 years.
- Have any planned surgeries and/or invasive medical procedures during the course of the study.

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- Have started hormone replacement therapies (HRT) or hormones for birth control less than 3 months prior to study entry or plan on starting, stopping, or changing doses of HRT or hormones for birth control during the study.
- Have facial sunburn or excessive tanned facial skin or are not willing to avoid daily sun exposure on the face and the use of tanning beds or sunless tanning products for the duration of the study.
- Have severe acne, acne conglobata, multiple nodules or cysts (more than 2).
- Are currently taking a natural or prescription testosterone blocker (e.g. saw palmetto, blask cohosh, chaste tree, chasteberry, spironolactone, drospirenone, progestins).
- Are currently on a testosterone booster or prescription testosterone (e.g. DHEA, tribulus, testosterone cypionate, testosterone enanthate, Sustanon, testosterone propionate, testosterone phenylpropriate, Omnadren etc.).
- Are currently taking or have taken within the last 30 days oral or topical prescription medications for acne such as Doxycycline, Minocycline, Clindamycin, Bactrim, Tetracycline, Erythromycin, Vibramycin and topical tretinoin (Retin A, Renova, Adapalene, Tazarotene), Azelaic acid, benzoyl peroxide, Dapsone, Sodium sulfacetamide, Differin, Epiduo.
- Have used oral isotretinoin (Accutane) within the past 6-months.
- Are routinely using (3x a week or more) topical over-the-counter (OTC) acne product (e.g. benzoyl peroxide, salicylic acid, alpha hydroxyl, beta hydroxyl and/or poly-hydroxy products or medicated cleansers, wipes, masks, scrubs, gels and creams) within 14 days of the study entry.
- Are using or have used any systemic medication considered to affect the course of acne, specifically, but not exclusively antibiotics or steroids within the last 30 days prior to entry into the study.
- Have excessive facial hair, including beard, mustache or goatee, or scars, which could interfere with evaluations as determined by the Investigator or designee.

WHAT WILL HAPPEN DURING THE STUDY

***Visit 1: Screening (* Visit 1 {*Screening*} AND Visit 2 {*Baseline*} may be combined into 1 Visit)**

You will:

- Be given an IRB-approved Informed Consent Form (ICF), to read and sign. You will be given enough time to read the informed consent, and ask questions about the study, and sign 2 copies of this consent form. (1 for clinic records, 1 for your records)
- Be given an eligibility and health questionnaire to complete, and assigned a screening number.
- Will acclimate for 15 minutes in a room at 68-75^{0}F and 35-65% humidity.
- Will be screened by the Investigator or designee to see if you qualify for the study.
- If you do qualify for the study, you will:
    - Take a urine pregnancy test (females of child-bearing potential)
    - Have a dermatologist confirm your eligibility
    - Schedule your next appointment.

***Visit 2: Baseline**

- Be asked if you have experienced any changes in your health since the previous visit.
- Will acclimate for 15 minutes in a room at 68-75^{0}F and 35-65% humidity.
- Be screened by the Investigator or designee to see if you still qualify for the study.
- Have your health and eligibility re-reviewed.

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- If you still qualify for the study you will:
    - Be assigned a subject number
    - Have photos taken of your face
    - Be randomly assigned to receive one of the test products & supporting facial cleanser, moisturizer & facial SPF 30
    - Be provided verbal and written usage instructions, and a daily diary to record product use
    - Schedule your next appointment

Visits 3, 4 (Week 1, Week 2)

- Be asked if you have experienced any changes in your health since the previous visit.
- Will acclimate for 15 minutes in a room at 68-75^{0}F and 35-65% humidity.
- Have your face examined by the Investigator or designee
- Complete a self-assessment questionnaire
- Have your diary collected and reviewed for compliance, and returned to you. At week 2, your diary will be retained by the testing facility and you will be given a new diary
- Have your product collected, weighed, and returned to you
- Schedule your next appointment

Visits 5, 6 (Week 6, Week 12)

- Be asked if you have experienced any changes in your health since the previous visit.
- Will acclimate for 15 minutes in a room at 68-75^{0}F and 35-65% humidity.
- Have your face examined by the Investigator or designee
- Have photos taken of your face
- Complete a self-assessment questionnaire
- Have your diary collected and reviewed for compliance, and retained by the testing facility and you will be given a new diary.
- Have your product collected, weighed, and retained. New products will be dispensed as necessary.
- Schedule your next appointment

Visit 7 (Week 18)

- Be asked if you have experienced any changes in your health since the previous visit.
- Have your diary collected and reviewed for compliance, and retained by the testing facility and you will be given a new diary.
- Have your product collected, weighed, and returned to you
- Schedule your next appointment

Visit 8 (Week 24)

- Be asked if you have experienced any changes in your health since the previous visit.
- Take a urine pregnancy test (females of child-bearing potential).
- Will acclimate for 15 minutes in a room at 68-75^{0}F and 35-65% humidity.
- Have your face examined by the Investigator or designee
- Have photos taken of your face
- Complete a self-assessment questionnaire
- Have your diary collected and reviewed for compliance, and retained by the testing facility.
- Have your product collected, weighed, and retained by the testing facility.

Do not give the study product to other people and keep it out of the reach of children.

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RISKS OR DISCOMFORTS

If you do not understand what any of these side effects mean, please ask the investigator or study staff to explain these terms to you.

Because the study products are investigational, all of their side effects may not be known. There may be rare and unknown side effects. Some of these may be life threatening.

Possible risks associated with the product are, as with any other cosmetic and OTC products, signs of irritation including:

- Itching
- Burning
- Stinging
- Rash or other allergic reaction
- Tingling
- Scaling/Dryness
- Redness

In some cases, it is possible for a subject to develop allergic reactions to the test material(s). This risk is increased for individuals with a history of allergies, and individuals with asthma and/or a history of hives may also be affected. Symptoms include rash, hives, and itching.

You must tell the Investigator or study staff about all side effects that you have. If you are not honest about your side effects, it may not be safe for you to stay in the study.

BIRTH CONTROL, DANGERS OF PREGNANCY AND BREASTFEEDING

If you are a female, you must not get pregnant while in this study. The only certain way to not get pregnant is to not have sex. If you are a female and choose to have sex, you must use a type of birth control.

Even if you use birth control during the study, there is a chance you could become pregnant. If you are pregnant or become pregnant during the study, test products or procedures may involve unforeseeable risks to the unborn baby.

A pregnancy test can be wrong. If you become pregnant during the study, stop using the test products and call/inform the Investigator at once.

You cannot be in the study if you are breastfeeding. It is not known whether the test products are safe for breast fed babies. Therefore if you are breastfeeding a child then it may not be safe for you to participate in the study.

POSSIBLE BENEFITS OF THE STUDY

You will not get any medical benefit from being in this study, and there is no promise that your condition (acne) will get better. It might stay the same or it might get worse. Your participation will provide information that may help others. There may be other marketed products that claim to have similar benefits.

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OTHER OPTIONS TO PARTICIPATING IN THE STUDY

Since this study is for research only, the only other choice would be not to be in the study.

STUDY AND TEST PRODUCT CONFIDENTIALITY

To participate in this study, you must agree to keep any information relating to the design, identity or use of these test product samples confidential.

On rare occasions, the sponsor may allow the testing company to disclose to you the name of the test products if you are not given this information during the study. This information is typically not provided until the end of the study or after the test products have been released for sale to the public. The study doctor or study staff will notify you if the sponsor allows us to give you this information.

DISCLOSURE AGREEMENT

This section explains how personal health information collected about you for the study may be used. Your personal health information includes, but is not limited to, information that was collected for your entry into the study and information that is collected during the study. The purpose of collecting this information is to allow the study staff and the Investigator to conduct the study, to evaluate the sponsor's study products and to analyze the study results.

You may decide not to give permission for the release of your personal health information for the study. In that case, you will not be able to participate in the study. This is because the study staff and/or the Investigator would not be able to collect the information needed to evaluate the sponsor's study products.

People who may inspect your personal and health information includes the Investigator, the Institutional Review Board, IntegReview IRB, FDA and other regulatory authorities from the United States or other countries, the study sponsor and people that work with the sponsor which includes, monitoring committees, contract research organizations, and consultants who have contracts with the company to do the study and review the study results. These reviews are done to check on the quality of the study and also for other purposes allowed by law.

The results of the study may be published in a medical book or journal, or presented at meetings for educational purposes. Neither your name, nor any other personal health information that specifically identifies you, will be used in those materials or presentations.

You may ask the Investigator to see and copy your personal health information related to the study. You may also ask the Investigator to correct any study related information about you that is wrong. You may have to wait until the end of the study to see your study records, so that the study can be organized properly.

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This permission to share your personal health information for this study does not have an expiration date. If you no longer want to share your personal health information, you may cancel your permission at any time by writing to the study staff and/or the Investigator at the address below:

Austin Institute for Clinical Research, Inc.
302 N. Heatherwilde Blvd., Suite 300
Pflugerville, TX 78660

If you cancel your permission after you have started in the study, the study staff and the Investigator will stop collecting your personal health information. Although they will stop collecting new information about you, they will need to use the information they have already collected to evaluate the study results. If you start the study and then cancel your permission, you will not be able to continue to participate in the study. This is because the study staff and/or the Investigator would not be able to collect the information needed to evaluate the study.

Austin Institute for Clinical Research, Inc. and the sponsor will make every effort to keep your personal health information private. But after the study staff or the Investigator share your personal health information from the study, federal privacy laws may not keep it private. There might be laws in your state or other federal laws that would protect the privacy of this information.

CONFIDENTIALITY

Your records of being in this study will be kept private except when ordered by law. The following people will have access to your study records:

- The Investigator
- Sponsor company or research institution [including monitor(s) and auditor(s)]
- Other country, state or federal regulatory agencies
- IntegReview IRB

The Institutional Review Board (IRB), IntegReview, and accrediting agencies may inspect and copy your records, which may have your name on them. Therefore, total confidentiality cannot be guaranteed. If the study results are presented at meetings or printed in publications, your name will not be used.

IN CASE OF STUDY RELATED INJURY

Side effects or complications, both foreseeable and unforeseeable, are possible in any research study without any fault to you, the Investigator, the study site, or the study sponsor. If you get hurt or sick as a direct result of being in this study, the sponsor will pay the costs of reasonable medical treatment. To ask questions about this, talk to the Investigator or study staff.

The sponsor's policy does not offer compensation for other expenses. Be aware that your health care payer/insurer might not cover the costs of study-related injuries or illnesses.

Unreimbursed medical expenses not covered by insurance or other third party coverage will be reimbursed by the sponsor for medical treatment for any injury that, in the opinion of the study doctor and the sponsor, is directly caused by the investigational product or by procedures required by the study protocol which would not have been performed as part of your regular medical care.

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LEGAL RIGHTS

You will not lose any of your legal rights by signing this consent form.

CONTACT INFORMATION

If you have questions, concerns, or complaints about this study or to report a study related injury, contact:

Edward Lain, MD
512-279-2545 daytime telephone number
512-844-4500 after hours number

If you are unable to reach anyone at the number(s) listed above and you need medical attention, please go to the nearest emergency room.

If you do not want to talk to the Investigator or study staff, if you have concerns or complaints about the research, or to ask questions about your rights as a study subject you may contact IntegReview. IntegReview's policy indicates that all concerns/complaints are to be submitted in writing for review at a convened IRB meeting to:

Mailing Address:	OR	Email Address:
Chairperson IntegReview IRB 3815 S. Capital of Texas Highway Suite 320 Austin, TX 78704		integreview@integreview.com

If you are unable to provide your concerns/complaints in writing or if this is an emergency situation regarding subject safety, contact our office at:

512-326-3001 or
toll free at 1-877-562-1589
between 8 a.m. and 5 p.m. Central Time

IntegReview has approved the information in this consent form and has given approval for the Investigator to do the study. This does not mean IntegReview has approved your being in the study. You must consider the information in this consent form for yourself and decide if you want to be in this study.

PAYMENT FOR BEING IN THE STUDY

You may receive up to $575.00 for being in the study. You will be paid per completed visit as follows:

Visit	Compensation (amount)
Screening/Baseline (Visit 1, 2)	$40.00
Visit 3	$60.00
Visit 4	$65.00
Visit 5	$75.00
Visit 6	$90.00

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Visit 7	$95.00
Visit 8	$150.00

If you choose to leave or are withdrawn from the study for any reason before finishing all visits you will be paid for each completed visit. You will receive payment at the end of each study visit.

If you do not qualify for any reason, you will be paid $20.00, which will be mailed to you within 2 weeks of the baseline study visit.

If you are paid $600.00 or more by Austin Institute for Clinical Research, Inc. in a calendar year, those payments will be reported to the Internal Revenue Service via form 1099-MISC. As required by tax laws, if you withhold your social security number, Austin Institute for Clinical Research, Inc. is required to withhold 28% of your payment for tax purposes. In this case a form 1099-MISC will be sent to you reporting your withholding.

VOLUNTEERING TO BE IN THE STUDY

It is your choice if you want to be in the study. No one can force you to be in the study. You may not want to be in this study or you may leave the study at any time without penalty or loss of benefits to which you are otherwise entitled.

The Investigator, the sponsor company, or IntegReview may take you out of the study without your permission, at any time, for the following reasons:

- If you do not follow the Investigator's instructions
- If we find out you should not be in the study
- If the study is stopped
- If it becomes harmful to your health

If you leave the study or if you are taken out of the study, you may be asked to return for a final visit to have some end of study evaluations or tests. If information generated from this study is published or presented, your identity will not be revealed. If you leave the study, no more information about you will be collected for this study. However, all of the information you gave us before you left the study will still be used.

NEW FINDINGS

If there is new information or any significant new findings that could relate to your willingness to continue participation we will tell you. You can then decide if you still want to be in the study.

THE REASON FOR INSTITUTIONAL REVIEW BOARDS AND INFORMED CONSENT

What is a consent form?
The informed consent document contains information required by federal regulations. The informed consent document must be approved by an Institutional Review Board (IRB).

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What is an Institutional Review Board (IRB)?
An Institutional Review Board (IRB) is a group of people that reviews research studies. The main goal of this review is to protect the rights and well being of the human subjects participating in research studies.

IntegReview, the IRB for this study
IntegReview is an IRB whose board members provide IRB services across the United States, Canada, Japan and Latin America.

To meet requirements of the law, the IntegReview Boards currently include:

- Doctors
- Pharmacists
- Nurses
- Toxicologists (people who study the harmful effects of chemicals)
- Other specialists
- Others who do not have a background in science/medicine

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AGREEMENT TO BE IN THE STUDY

This consent form contains important information to help you decide if you want to be in the study. If you have any questions that are not answered in this consent form, ask one of the study staff.

Please answer **YES** or **NO** to the following questions:

A. Is this document in a language you understand? _____

B. Do you understand the information in this consent form? _____

C. Have you been given enough time to ask questions and talk about the study? _____

D. Have all of your questions been answered to your satisfaction? _____

E. Do you think you received enough information about the study? _____

F. Do you volunteer to be in this study of your own free will and without being pressured by the Investigator or study staff? _____

G. Do you know that you can leave the study at any time without giving a reason and without affecting your health care? _____

H. Do you know that your health records from this study may be reviewed by the sponsor company and by government authorities? _____

I. Do you know that you cannot be in another study while you are in this study? _____

IF YOU ANSWERED "NO" TO ANY OF THE ABOVE QUESTIONS,
OR YOU ARE UNABLE TO ANSWER ANY OF THE ABOVE QUESTIONS,
YOU SHOULD NOT SIGN THIS CONSENT FORM.

_____
Printed Name of Adult Study Subject

_____
Signature of Adult Study Subject Date

_____
Printed Name of Person Explaining Consent Form

_____
Signature of Person Explaining Consent Form Date

You will be given a signed and dated copy of this consent form to keep.

THIS IS AN IMPORTANT DOCUMENT - KEEP FOR FUTURE REFERENCE

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Authorization and Release Form

I hereby for good and valuable consideration grant to Austin Institute for Clinical Research, Inc., the study sponsor and their respective affiliates, agencies, agents, employees, and assigns (collectively, "Authorized Entities"), the unrestricted, royalty free, irrevocable and perpetual right and permission to reproduce, distribute, broadcast and/or otherwise use for advertising and other commercial/noncommercial purposes: (i) my name, likeness, image, video, and any other biographical or personal information ("Personal Content"); and (ii) any statement or endorsement, or any portions thereof ("Testimonial(s)"), made by me relating to the study sponsor's products ("Products"), in any and all media now known or later developed, worldwide in perpetuity, without further compensation or approval by me.

I hereby assign to the Authorized Entities all of my world-wide right, title and interest, including my copyright interests and all renewals, reissues and extensions thereof, in and to the Personal Content and Testimonial(s), including without limitation, any photographic portraits, sound recordings and video performances of and/or by me in connection with the Personal Content and/or Testimonial(s).

I am at least 21 years of age, and competent to contract in my own name. I have read and understand this Authorization and Release.

_____
Printed Name of Adult Study Subject

_____
Signature of Adult Study Subject Date

_____
Printed Name of Person Explaining Release Form

_____
Signature of Person Explaining Release Form Date

Copy of consent form given to subject on _____ (date) by _____ (initials)

You will be given a signed and dated copy of this consent form to keep.

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AUTHORIZATION TO USE AND DISCLOSE PERSONAL HEALTH INFORMATION FOR RESEARCH

THIS SECTION DESCRIBES YOUR RIGHTS AND HOW PERSONAL HEALTH INFORMATION COLLECTED ABOUT YOU DURING THIS STUDY MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

The United States government has issued a privacy rule to protect the privacy rights of patients. This rule was issued under a law called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The Privacy Rule is designed to protect the confidentiality of your personal health information. The document you are reading, called an "Authorization," describes your rights and explains how your health information will be used and disclosed (shared).

Federal law requires hospitals, researchers and health care providers to protect the privacy of information that identifies you and relates to your past, present and future physical and mental health or conditions.

All information collected during the study will be retained by the study doctor and the Study Sponsor, except as required by law. Information from this study will be given to the sponsor. "Sponsor" includes any persons or companies, which are contracted by the sponsor to have access to the research information during and after the study. The information will also be given to the U.S. Food and Drug Administration (FDA). Study records which identify you and the consent form signed by you will be inspected and/or copied for research or regulatory purposes by:

- Sponsor
- Agents for the sponsor
- The US Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies
- IntegReview IRB

Because of the need to release information to these parties, absolute confidentiality cannot be guaranteed. The results of this research study may be presented at meetings or in publications; however, your identity will not be disclosed in those presentations.

For purposes of study reporting, you will be identified by your initials and code numbers only. However, your name, date of birth, address, and phone number will be kept on record by the study doctor in case you need to be contacted in the future about this study.

After your personal health information is disclosed to the Study Sponsor, the results of the study may be reanalyzed at a later date and may be combined with the results of other studies. The Study Sponsor and people who work with the Study Sponsor may use the results of this study for other research purposes, including:

- Developing a better understanding of the disease;
- Improving the design of future actual use trials

After the study staff or the study doctor discloses your personal health information to others, it could be re-disclosed and no longer protected by federal privacy laws.

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FEBRUARY 29, 2016**

This permission to share your personal health information for this study does not have an expiration date. If you do not withdraw this Authorization in writing, it will remain in effect indefinitely. Your study doctor will keep this Authorization for at least 6 years. If you no longer want to share your personal health information, you may cancel your permission at any time by writing to the study staff and/or the study doctor at the address below:

Austin Institute for Clinical Research, Inc.
302 N. Heatherwilde Blvd., Suite 300
Pflugerville, TX 78660

You have the right to see and get a copy of your records related to the study for as long as the study doctor has this information. However, by signing this Authorization you agree that you might not be able to review or receive some of your records related to the study until after the study has been completed.

If you cancel your permission after you have started in the study, the study staff and the study doctor will stop collecting your personal health information unless the information concerns an adverse event (a bad effect) related to the study. If an adverse event occurs, your entire medical record may be reviewed. All information that has already been collected for study purposes, and any new information about an adverse event related to the study, will be sent to the study sponsor. Although they will stop collecting new information about you, they will need to use the information they have already collected to evaluate the study results. If you start the study and then cancel your permission, you will not be able to continue to participate in the study. This is because the study staff and/or the study doctor would not be able to collect the information needed to evaluate the study results.

If you withdraw from the study but do not withdraw your Authorization, new personal health information may be collected until this study ends.

You may decide not to give permission for the release of your personal health information for this study. In that case, you will not be able to participate. This is because the study staff and study doctor would not be able to collect the information needed to evaluate the study results.

At the completion of the study, you have the right to access your protected health information that is created during this research study that relates to your treatment or to payment, provided such information is not exempted under certain laws and regulations. To request this information, please contact the study doctor at the address listed above.

Your Right to Access Health Information

Subject to certain exceptions prescribed by law, you have a right to request access to the health information that we hold about you and to request changes if your health information is incorrect or incomplete. Any request for access or corrections should be made to the principal doctor conducting this study.

Your records obtained while you are in this trial, as well as related health records, will remain strictly confidential at all times. However, these will need to be made available to others working on the Sponsor's behalf, the Independent Ethics Committee members and Medicines Regulatory Authorities.

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By signing the consent form you agree to this access for the current trial and any further research that may be done. However, the Sponsor will take steps to protect your personal information and will not include your name on any sponsor forms, reports, publications, or in any future disclosures. If you withdraw from the study, we will no longer collect your personal information, but we may need to continue to use information already collected.

Personal data which may be sensitive (e.g., date of birth) will be collected and processed, but only for research purposes in connection with this trial.

The trial data will be sent around the world, but you will not be referred to by name or identified in any report or publication nor could the data be traced back to you. Your data may be transferred to a country that does not have the same level of personal data protection as within the United States. However, The Sponsor maintains high standards of confidentiality and protection.

The Sponsor (who will control the use of the data) will take steps to ensure your personal data is protected.

By taking part in this trial you agree not to restrict the use of any data even if you withdraw from the trial and agree to the transfer of your personal data to other Sponsor companies and to Medicines Regulatory Authorities both within and outside of Europe.

_____

Printed Name of Adult Study Subject

_____

Signature of Adult Study Subject Date

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INFORMED CONSENT DOCUMENT
AGREEMENT TO BE IN A RESEARCH STUDY

NAME OF TESTING COMPANY:	Austin Institute for Clinical Research, Inc.
NUMBER AND TITLE OF STUDY:	C16-CD020 (GLI.04.SPR.US10354); "A Multi-Center Clinical Trial to Evaluate the Efficacy of Two Acne Treatments"
NAME OF PERSON IN CHARGE OF THE RESEARCH STUDY (STUDY DOCTOR/INVESTIGATOR):	Edward Lain, MD
TELEPHONE NUMBER(S), DAYTIME:	512-279-2545
AFTER HOURS:	512-844-4500

INTRODUCTION

You are being invited to volunteer for a clinical research study. You must read and sign this form before you agree to take part in this study. This form will give you more information about this study. Please ask as many questions as you need to before you decide if you want to be in the study. You should not sign this form if you have any questions that have not been answered.

Austin Institute for Clinical Research, Inc. is being paid by the sponsor (the company paying for this study) to conduct this research study.

You must be honest with the Investigator about your health history or it may not be safe for you to be in this study.

PURPOSE OF THE STUDY

The purpose of this study is to evaluate the efficiency of 2 acne treatments for 24 weeks of use in adult men and women with mild to moderate facial acne, at least 5 inflammatory lesions, and at least 10 – 100 non-inflammatory lesions.

HOW LONG THE STUDY WILL LAST AND HOW MANY PEOPLE WILL BE IN THE STUDY

This study will last 24 weeks and have up to 8 visits. At least 100 subjects, men and women between the ages of 21-45, are expected to complete this study, with at least 50 subjects completed per cell.

TO BE IN THIS STUDY

You must:

- Be a man or woman age 21 to 45 years at the time of enrollment.
- Have mild to moderate acne on the face as determined by the Investigator or designee.
- Have at least 5 inflammatory lesions as determined by the Investigator or designee.
- Have 10 – 100 non-inflammatory lesions as determined by the Investigator or designee.
- Be willing to use the test products as instructed for 24 weeks.
- Be willing and able to comply with all of the time commitments and procedural requirements of the clinical trial protocol.

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- Be willing to provide written informed consent including photo release, Health Insurance Portability and Accountability Act (HIPAA), and be able to read, speak, write, understand English and be willing to share personal information and data, as verified by signing a written authorization at the screening.
- Be willing to withhold all facial treatments during the course of the study including botulinum toxin, injectable fillers, microdermabrasion, IPL, peels, facials, laser treatments and tightening treatments. Waxing and threading is allowed but not facial laser hair removal.
- Males must be regular shavers and willing to shave on the day of the study visits (prior to clinic visits).
- Women of child bearing potential must be willing to take a urine pregnancy test prior to study enrollment, at week 24, and when deemed appropriate by the Investigator and/or Sponsor.
- Individuals of child bearing potential must use an acceptable method of contraception throughout the study. Acceptable methods of birth control include:
    - Oral and other system contraceptives. Individuals must be on a stable use for 3 months prior to study enrollment. Individuals on oral contraceptives must not alter their use, including dose or regimen for the duration of the study
    - Double barrier
    - Bilateral tubal ligation (tubes tied)
    - Partner vasectomy
    - Abstinence
- Be willing to follow study requirements and report any changes in health status or medications, side effect symptoms, or reactions immediately.
- Be stable on any medication you are taking for at least 30 days

YOU CANNOT BE ON THE STUDY

If you:

- Have been diagnosed with allergies to topical acne products.
- Have a condition and/or disease of the skin that the Investigator deems inappropriate for participation.
- Are a woman who is breastfeeding, pregnant, or planning to become pregnant during the study.
- Have pre-existing or dormant dermatologic conditions on the face (e.g., psoriasis, rosacea, eczema, seborrheic dermatitis, severe excoriations etc.) which in the opinion of the Investigator could interfere with the outcome of the study.
- Have a history of immunosuppression/immune deficiency disorders (including HIV infection or AIDS) or currently using immunosuppressive medications (e.g., azathioprine, belimumab, cyclophosphamide, Enbrel, Imuran, Humira, mycophenolate mofetil, methotrexate, prednisone, Remicade, Stelara.).
- Have an uncontrolled disease such as asthma, diabetes, hypertension, hyperthyroidism, or hypothyroidism. Individuals having multiple health conditions may be excluded from participation even if the conditions are controlled by diet, medication, etc. at the Investigator's discretion.
- Are currently participating in another facial usage study or have participated in a clinical trial within 4 weeks prior to inclusion into the study.
- Have a history of skin cancer on the face within the past 5 years.
- Have any planned surgeries and/or invasive medical procedures during the course of the study.
- Have started hormone replacement therapies (HRT) or hormones for birth control less than 3 months prior to study entry or plan on starting, stopping, or changing doses of HRT or hormones for birth control during the study.

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- Have facial sunburn or excessive tanned facial skin or are not willing to avoid daily sun exposure on the face and the use of tanning beds or sunless tanning products for the duration of the study.
- Have severe acne, acne conglobata, multiple nodules or cysts (more than 2).
- Are currently taking a natural or prescription testosterone blocker (e.g. saw palmetto, blask cohosh, chaste tree, chasteberry, spironolactone, drospirenone, progestins).
- Are currently on a testosterone booster or prescription testosterone (e.g. DHEA, tribulus, testosterone cypionate, testosterone enanthate, Sustanon, testosterone propionate, testosterone phenylpropriate, Omnadren etc.).
- Are currently taking or have taken within the last 30 days oral or topical prescription medications for acne such as Doxycycline, Minocycline, Clindamycin, Bactrim, Tetracycline, Erythromycin, Vibramycin and topical tretinoin (Retin A, Renova, Adapalene, Tazarotene), Azelaic acid, benzoyl peroxide, Dapsone, Sodium sulfacetamide, Differin, Epiduo.
- Have used oral isotretinoin (Accutane) within the past 6-months.
- Are routinely using (3x a week or more) topical over-the-counter (OTC) acne product (e.g. benzoyl peroxide, salicylic acid, alpha hydroxyl, beta hydroxyl and/or poly-hydroxy products or medicated cleansers, wipes, masks, scrubs, gels and creams) within 14 days of the study entry.
- Are using or have used any systemic medication considered to affect the course of acne, specifically, but not exclusively antibiotics or steroids within the last 30 days prior to entry into the study.
- Have excessive facial hair, including beard, mustache or goatee, or scars, which could interfere with evaluations as determined by the Investigator or designee.

WHAT WILL HAPPEN DURING THE STUDY

***Visit 1: Screening (* Visit 1 {*Screening*} AND Visit 2 {*Baseline*} may be combined into 1 Visit)**

You will:

- Be given an IRB-approved Informed Consent Form (ICF), to read and sign. You will be given enough time to read the informed consent, and ask questions about the study, and sign 2 copies of this consent form. (1 for clinic records, 1 for your records)
- Be given an eligibility and health questionnaire to complete, and assigned a screening number.
- Will acclimate for 15 minutes in a room at 68-75^{0}F and 35-65% humidity.
- Will be screened by the Investigator or designee to see if you qualify for the study.
- If you do qualify for the study, you will:
    - Take a urine pregnancy test (females of child-bearing potential)
    - Have a dermatologist confirm your eligibility
    - Schedule your next appointment.

***Visit 2: Baseline**

- Be asked if you have experienced any changes in your health since the previous visit.
- Will acclimate for 15 minutes in a room at 68-75^{0}F and 35-65% humidity.
- Be screened by the Investigator or designee to see if you still qualify for the study.
- Have your health and eligibility re-reviewed.
- If you still qualify for the study you will:
    - Be assigned a subject number
    - Have photos taken of your face

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- Be randomly assigned to receive one of the test products & supporting facial cleanser, moisturizer & facial SPF 30
- Be provided verbal and written usage instructions, and a daily diary to record product use
- Schedule your next appointment

Visits 3, 4 (Week 1, Week 2)

- Be asked if you have experienced any changes in your health since the previous visit.
- Will acclimate for 15 minutes in a room at 68-75^{0}F and 35-65% humidity.
- Have your face examined by the Investigator or designee
- Complete a self-assessment questionnaire
- Have your diary collected and reviewed for compliance, and returned to you. At week 2, your diary will be retained by the testing facility and you will be given a new diary
- Have your product collected, weighed, and returned to you
- Schedule your next appointment

Visits 5, 6 (Week 6, Week 12)

- Be asked if you have experienced any changes in your health since the previous visit.
- Will acclimate for 15 minutes in a room at 68-75^{0}F and 35-65% humidity.
- Have your face examined by the Investigator or designee
- Have photos taken of your face
- Complete a self-assessment questionnaire
- Have your diary collected and reviewed for compliance, and retained by the testing facility and you will be given a new diary.
- Have your product collected, weighed, and retained. New products will be dispensed as necessary.
- Schedule your next appointment

Visit 7 (Week 18)

- Be asked if you have experienced any changes in your health since the previous visit.
- Have your diary collected and reviewed for compliance, and retained by the testing facility and you will be given a new diary.
- Have your product collected, weighed, and returned to you
- Schedule your next appointment

Visit 8 (Week 24)

- Be asked if you have experienced any changes in your health since the previous visit.
- Take a urine pregnancy test (females of child-bearing potential).
- Will acclimate for 15 minutes in a room at 68-75^{0}F and 35-65% humidity.
- Have your face examined by the Investigator or designee
- Have photos taken of your face
- Complete a self-assessment questionnaire
- Have your diary collected and reviewed for compliance, and retained by the testing facility.
- Have your product collected, weighed, and retained by the testing facility.

Do not give the study product to other people and keep it out of the reach of children.

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RISKS OR DISCOMFORTS

If you do not understand what any of these side effects mean, please ask the investigator or study staff to explain these terms to you.

Because the study products are investigational, all of their side effects may not be known. There may be rare and unknown side effects. Some of these may be life threatening.

Possible risks associated with the product are, as with any other cosmetic and OTC products, signs of irritation including:

- Itching
- Burning
- Stinging
- Rash or other allergic reaction
- Tingling
- Scaling/Dryness
- Redness

In some cases, it is possible for a subject to develop allergic reactions to the test material(s). This risk is increased for individuals with a history of allergies, and individuals with asthma and/or a history of hives may also be affected. Symptoms include rash, hives, and itching.

You must tell the Investigator or study staff about all side effects that you have. If you are not honest about your side effects, it may not be safe for you to stay in the study.

BIRTH CONTROL, DANGERS OF PREGNANCY AND BREASTFEEDING

If you are a female, you must not get pregnant while in this study. The only certain way to not get pregnant is to not have sex. If you are a female and choose to have sex, you must use a type of birth control.

Even if you use birth control during the study, there is a chance you could become pregnant. If you are pregnant or become pregnant during the study, test products or procedures may involve unforeseeable risks to the unborn baby.

A pregnancy test can be wrong. If you become pregnant during the study, stop using the test products and call/inform the Investigator at once.

You cannot be in the study if you are breastfeeding. It is not known whether the test products are safe for breast fed babies. Therefore if you are breastfeeding a child then it may not be safe for you to participate in the study.

POSSIBLE BENEFITS OF THE STUDY

You will not get any medical benefit from being in this study, and there is no promise that your condition (acne) will get better. It might stay the same or it might get worse. Your participation will provide information that may help others. There may be other marketed products that claim to have similar benefits.

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OTHER OPTIONS TO PARTICIPATING IN THE STUDY

Since this study is for research only, the only other choice would be not to be in the study.

STUDY AND TEST PRODUCT CONFIDENTIALITY

To participate in this study, you must agree to keep any information relating to the design, identity or use of these test product samples confidential.

On rare occasions, the sponsor may allow the testing company to disclose to you the name of the test products if you are not given this information during the study. This information is typically not provided until the end of the study or after the test products have been released for sale to the public. The study doctor or study staff will notify you if the sponsor allows us to give you this information.

DISCLOSURE AGREEMENT

This section explains how personal health information collected about you for the study may be used. Your personal health information includes, but is not limited to, information that was collected for your entry into the study and information that is collected during the study. The purpose of collecting this information is to allow the study staff and the Investigator to conduct the study, to evaluate the sponsor's study products and to analyze the study results.

You may decide not to give permission for the release of your personal health information for the study. In that case, you will not be able to participate in the study. This is because the study staff and/or the Investigator would not be able to collect the information needed to evaluate the sponsor's study products.

People who may inspect your personal and health information includes the Investigator, the Institutional Review Board, IntegReview IRB, FDA and other regulatory authorities from the United States or other countries, the study sponsor and people that work with the sponsor which includes, monitoring committees, contract research organizations, and consultants who have contracts with the company to do the study and review the study results. These reviews are done to check on the quality of the study and also for other purposes allowed by law.

The results of the study may be published in a medical book or journal, or presented at meetings for educational purposes. Neither your name, nor any other personal health information that specifically identifies you, will be used in those materials or presentations.

You may ask the Investigator to see and copy your personal health information related to the study. You may also ask the Investigator to correct any study related information about you that is wrong. You may have to wait until the end of the study to see your study records, so that the study can be organized properly.

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This permission to share your personal health information for this study does not have an expiration date. If you no longer want to share your personal health information, you may cancel your permission at any time by writing to the study staff and/or the Investigator at the address below:

Austin Institute for Clinical Research, Inc.
302 N. Heatherwilde Blvd., Suite 300
Pflugerville, TX 78660

If you cancel your permission after you have started in the study, the study staff and the Investigator will stop collecting your personal health information. Although they will stop collecting new information about you, they will need to use the information they have already collected to evaluate the study results. If you start the study and then cancel your permission, you will not be able to continue to participate in the study. This is because the study staff and/or the Investigator would not be able to collect the information needed to evaluate the study.

Austin Institute for Clinical Research, Inc. and the sponsor will make every effort to keep your personal health information private. But after the study staff or the Investigator share your personal health information from the study, federal privacy laws may not keep it private. There might be laws in your state or other federal laws that would protect the privacy of this information.

CONFIDENTIALITY

Your records of being in this study will be kept private except when ordered by law. The following people will have access to your study records:

- The Investigator
- Sponsor company or research institution [including monitor(s) and auditor(s)]
- Other country, state or federal regulatory agencies
- IntegReview IRB

The Institutional Review Board (IRB), IntegReview, and accrediting agencies may inspect and copy your records, which may have your name on them. Therefore, total confidentiality cannot be guaranteed. If the study results are presented at meetings or printed in publications, your name will not be used.

IN CASE OF STUDY RELATED INJURY

Side effects or complications, both foreseeable and unforeseeable, are possible in any research study without any fault to you, the Investigator, the study site, or the study sponsor. If you get hurt or sick as a direct result of being in this study, the sponsor will pay the costs of reasonable medical treatment. To ask questions about this, talk to the Investigator or study staff.

The sponsor's policy does not offer compensation for other expenses. Be aware that your health care payer/insurer might not cover the costs of study-related injuries or illnesses.

Unreimbursed medical expenses not covered by insurance or other third party coverage will be reimbursed by the sponsor for medical treatment for any injury that, in the opinion of the study doctor and the sponsor, is directly caused by the investigational product or by procedures required by the study protocol which would not have been performed as part of your regular medical care.

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LEGAL RIGHTS

You will not lose any of your legal rights by signing this consent form.

CONTACT INFORMATION

If you have questions, concerns, or complaints about this study or to report a study related injury, contact:

Edward Lain, MD
512-279-2545 daytime telephone number
512-844-4500 after hours number

If you are unable to reach anyone at the number(s) listed above and you need medical attention, please go to the nearest emergency room.

If you do not want to talk to the Investigator or study staff, if you have concerns or complaints about the research, or to ask questions about your rights as a study subject you may contact IntegReview. IntegReview's policy indicates that all concerns/complaints are to be submitted in writing for review at a convened IRB meeting to:

Mailing Address:	OR	Email Address:
Chairperson IntegReview IRB 3815 S. Capital of Texas Highway Suite 320 Austin, TX 78704		integreview@integreview.com

If you are unable to provide your concerns/complaints in writing or if this is an emergency situation regarding subject safety, contact our office at:

512-326-3001 or
toll free at 1-877-562-1589
between 8 a.m. and 5 p.m. Central Time

IntegReview has approved the information in this consent form and has given approval for the Investigator to do the study. This does not mean IntegReview has approved your being in the study. You must consider the information in this consent form for yourself and decide if you want to be in this study.

PAYMENT FOR BEING IN THE STUDY

You may receive up to $575.00 for being in the study. You will be paid per completed visit as follows:

Visit	Compensation (amount)
Screening/Baseline (Visit 1, 2)	$40.00
Visit 3	$60.00
Visit 4	$65.00
Visit 5	$75.00
Visit 6	$90.00

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Visit 7	$95.00
Visit 8	$150.00

If you choose to leave or are withdrawn from the study for any reason before finishing all visits you will be paid for each completed visit. You will receive payment at the end of each study visit.

If you do not qualify for any reason, you will be paid $20.00, which will be mailed to you within 2 weeks of the baseline study visit.

If you are paid $600.00 or more by Austin Institute for Clinical Research, Inc. in a calendar year, those payments will be reported to the Internal Revenue Service via form 1099-MISC. As required by tax laws, if you withhold your social security number, Austin Institute for Clinical Research, Inc. is required to withhold 28% of your payment for tax purposes. In this case a form 1099-MISC will be sent to you reporting your withholding.

VOLUNTEERING TO BE IN THE STUDY

It is your choice if you want to be in the study. No one can force you to be in the study. You may not want to be in this study or you may leave the study at any time without penalty or loss of benefits to which you are otherwise entitled.

The Investigator, the sponsor company, or IntegReview may take you out of the study without your permission, at any time, for the following reasons:

- If you do not follow the Investigator's instructions
- If we find out you should not be in the study
- If the study is stopped
- If it becomes harmful to your health

If you leave the study or if you are taken out of the study, you may be asked to return for a final visit to have some end of study evaluations or tests. If information generated from this study is published or presented, your identity will not be revealed. If you leave the study, no more information about you will be collected for this study. However, all of the information you gave us before you left the study will still be used.

NEW FINDINGS

If there is new information or any significant new findings that could relate to your willingness to continue participation we will tell you. You can then decide if you still want to be in the study.

THE REASON FOR INSTITUTIONAL REVIEW BOARDS AND INFORMED CONSENT

What is a consent form?
The informed consent document contains information required by federal regulations. The informed consent document must be approved by an Institutional Review Board (IRB).

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What is an Institutional Review Board (IRB)?
An Institutional Review Board (IRB) is a group of people that reviews research studies. The main goal of this review is to protect the rights and well being of the human subjects participating in research studies.

IntegReview, the IRB for this study
IntegReview is an IRB whose board members provide IRB services across the United States, Canada, Japan and Latin America.

To meet requirements of the law, the IntegReview Boards currently include:

- Doctors
- Pharmacists
- Nurses
- Toxicologists (people who study the harmful effects of chemicals)
- Other specialists
- Others who do not have a background in science/medicine

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AGREEMENT TO BE IN THE STUDY

This consent form contains important information to help you decide if you want to be in the study. If you have any questions that are not answered in this consent form, ask one of the study staff.

Please answer **YES** or **NO** to the following questions:

A. Is this document in a language you understand? _____

B. Do you understand the information in this consent form? _____

C. Have you been given enough time to ask questions and talk about the study? _____

D. Have all of your questions been answered to your satisfaction? _____

E. Do you think you received enough information about the study? _____

F. Do you volunteer to be in this study of your own free will and without being pressured by the Investigator or study staff? _____

G. Do you know that you can leave the study at any time without giving a reason and without affecting your health care? _____

H. Do you know that your health records from this study may be reviewed by the sponsor company and by government authorities? _____

I. Do you know that you cannot be in another study while you are in this study? _____

IF YOU ANSWERED "NO" TO ANY OF THE ABOVE QUESTIONS,
OR YOU ARE UNABLE TO ANSWER ANY OF THE ABOVE QUESTIONS,
YOU SHOULD NOT SIGN THIS CONSENT FORM.

_____
Printed Name of Adult Study Subject

_____
Signature of Adult Study Subject Date

_____
Printed Name of Person Explaining Consent Form

_____
Signature of Person Explaining Consent Form Date

You will be given a signed and dated copy of this consent form to keep.

THIS IS AN IMPORTANT DOCUMENT - KEEP FOR FUTURE REFERENCE

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Authorization and Release Form

I hereby for good and valuable consideration grant to Austin Institute for Clinical Research, Inc., the study sponsor and their respective affiliates, agencies, agents, employees, and assigns (collectively, "Authorized Entities"), the unrestricted, royalty free, irrevocable and perpetual right and permission to reproduce, distribute, broadcast and/or otherwise use for advertising and other commercial/noncommercial purposes: (i) my name, likeness, image, video, and any other biographical or personal information ("Personal Content"); and (ii) any statement or endorsement, or any portions thereof ("Testimonial(s)"), made by me relating to the study sponsor's products ("Products"), in any and all media now known or later developed, worldwide in perpetuity, without further compensation or approval by me.

I hereby assign to the Authorized Entities all of my world-wide right, title and interest, including my copyright interests and all renewals, reissues and extensions thereof, in and to the Personal Content and Testimonial(s), including without limitation, any photographic portraits, sound recordings and video performances of and/or by me in connection with the Personal Content and/or Testimonial(s).

I am at least 21 years of age, and competent to contract in my own name. I have read and understand this Authorization and Release.

_____
Printed Name of Adult Study Subject

_____
Signature of Adult Study Subject Date

_____
Printed Name of Person Explaining Release Form

_____
Signature of Person Explaining Release Form Date

Copy of consent form given to subject on _____ (date) by _____ (initials)

You will be given a signed and dated copy of this consent form to keep.

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SEPTEMBER 16, 2016

AUTHORIZATION TO USE AND DISCLOSE PERSONAL HEALTH INFORMATION FOR RESEARCH

THIS SECTION DESCRIBES YOUR RIGHTS AND HOW PERSONAL HEALTH INFORMATION COLLECTED ABOUT YOU DURING THIS STUDY MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

The United States government has issued a privacy rule to protect the privacy rights of patients. This rule was issued under a law called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The Privacy Rule is designed to protect the confidentiality of your personal health information. The document you are reading, called an "Authorization," describes your rights and explains how your health information will be used and disclosed (shared).

Federal law requires hospitals, researchers and health care providers to protect the privacy of information that identifies you and relates to your past, present and future physical and mental health or conditions.

All information collected during the study will be retained by the study doctor and the Study Sponsor, except as required by law. Information from this study will be given to the sponsor. "Sponsor" includes any persons or companies, which are contracted by the sponsor to have access to the research information during and after the study. The information will also be given to the U.S. Food and Drug Administration (FDA). Study records which identify you and the consent form signed by you will be inspected and/or copied for research or regulatory purposes by:

- Sponsor
- Agents for the sponsor
- The US Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies
- IntegReview IRB

Because of the need to release information to these parties, absolute confidentiality cannot be guaranteed. The results of this research study may be presented at meetings or in publications; however, your identity will not be disclosed in those presentations.

For purposes of study reporting, you will be identified by your initials and code numbers only. However, your name, date of birth, address, and phone number will be kept on record by the study doctor in case you need to be contacted in the future about this study.

After your personal health information is disclosed to the Study Sponsor, the results of the study may be reanalyzed at a later date and may be combined with the results of other studies. The Study Sponsor and people who work with the Study Sponsor may use the results of this study for other research purposes, including:

- Developing a better understanding of the disease;
- Improving the design of future actual use trials

After the study staff or the study doctor discloses your personal health information to others, it could be re-disclosed and no longer protected by federal privacy laws.

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This permission to share your personal health information for this study does not have an expiration date. If you do not withdraw this Authorization in writing, it will remain in effect indefinitely. Your study doctor will keep this Authorization for at least 6 years. If you no longer want to share your personal health information, you may cancel your permission at any time by writing to the study staff and/or the study doctor at the address below:

Austin Institute for Clinical Research, Inc.
302 N. Heatherwilde Blvd., Suite 300
Pflugerville, TX 78660

You have the right to see and get a copy of your records related to the study for as long as the study doctor has this information. However, by signing this Authorization you agree that you might not be able to review or receive some of your records related to the study until after the study has been completed.

If you cancel your permission after you have started in the study, the study staff and the study doctor will stop collecting your personal health information unless the information concerns an adverse event (a bad effect) related to the study. If an adverse event occurs, your entire medical record may be reviewed. All information that has already been collected for study purposes, and any new information about an adverse event related to the study, will be sent to the study sponsor. Although they will stop collecting new information about you, they will need to use the information they have already collected to evaluate the study results. If you start the study and then cancel your permission, you will not be able to continue to participate in the study. This is because the study staff and/or the study doctor would not be able to collect the information needed to evaluate the study results.

If you withdraw from the study but do not withdraw your Authorization, new personal health information may be collected until this study ends.

You may decide not to give permission for the release of your personal health information for this study. In that case, you will not be able to participate. This is because the study staff and study doctor would not be able to collect the information needed to evaluate the study results.

At the completion of the study, you have the right to access your protected health information that is created during this research study that relates to your treatment or to payment, provided such information is not exempted under certain laws and regulations. To request this information, please contact the study doctor at the address listed above.

Your Right to Access Health Information

Subject to certain exceptions prescribed by law, you have a right to request access to the health information that we hold about you and to request changes if your health information is incorrect or incomplete. Any request for access or corrections should be made to the principal doctor conducting this study.

Your records obtained while you are in this trial, as well as related health records, will remain strictly confidential at all times. However, these will need to be made available to others working on the Sponsor's behalf, the Independent Ethics Committee members and Medicines Regulatory Authorities.

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By signing the consent form you agree to this access for the current trial and any further research that may be done. However, the Sponsor will take steps to protect your personal information and will not include your name on any sponsor forms, reports, publications, or in any future disclosures. If you withdraw from the study, we will no longer collect your personal information, but we may need to continue to use information already collected.

Personal data which may be sensitive (e.g., date of birth) will be collected and processed, but only for research purposes in connection with this trial.

The trial data will be sent around the world, but you will not be referred to by name or identified in any report or publication nor could the data be traced back to you. Your data may be transferred to a country that does not have the same level of personal data protection as within the United States. However, The Sponsor maintains high standards of confidentiality and protection.

The Sponsor (who will control the use of the data) will take steps to ensure your personal data is protected.

By taking part in this trial you agree not to restrict the use of any data even if you withdraw from the trial and agree to the transfer of your personal data to other Sponsor companies and to Medicines Regulatory Authorities both within and outside of Europe.

_____
Printed Name of Adult Study Subject

_____
Signature of Adult Study Subject Date

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VERSION CONTROL

clw/master: 2-17-16 snb/site: 2-25-16 clw/site: 2-29-16 rss/master: 9-16-16

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FEBRUARY 25, 2016

INFORMED CONSENT DOCUMENT
AGREEMENT TO BE IN A RESEARCH STUDY

NAME OF TESTING COMPANY:	RCTS, Inc.,
NUMBER AND TITLE OF STUDY:	C16-CD020 (GLI.04.SPR.US10354); "A Multi-Center Clinical Trial to Evaluate the Efficacy of Two Acne Treatments"
NAME OF PERSON IN CHARGE OF THE RESEARCH STUDY (INVESTIGATOR):	Barry T. Reece, M.S., M.B.A. Principal Investigator
MEDICAL INVESTIGATORS:	Raymond L. Garcia, M.D. Board Certified Dermatologist **G**ene Ream, M.D. Board Certified Dermatologist
TELEPHONE NUMBER(S), DAYTIME: **AFTER HOURS:**	972-871-7578 972-841-2916 (Emergencies Only, Cell Phone Number)

INTRODUCTION

You are being invited to volunteer for a clinical research study. You must read and sign this form before you agree to take part in this study. This form will give you more information about this study. Please ask as many questions as you need to before you decide if you want to be in the study. You should not sign this form if you have any questions that have not been answered.

RCTS, Inc., a contract research organization, is being paid by the sponsor (the company paying for this study) to conduct this research study.

You must be honest with the Investigator about your health history or it may not be safe for you to be in this study.

PURPOSE OF THE STUDY

The purpose of this study is to evaluate the efficiency of 2 acne treatments for 24 weeks of use in adult men and women with mild to moderate facial acne, at least 5 inflammatory lesions, and at least 10 – 100 non-inflammatory lesions.

HOW LONG THE STUDY WILL LAST AND HOW MANY PEOPLE WILL BE IN THE STUDY

This study will last 24 weeks and have up to 8 visits. At least 100 subjects, men and women between the ages of 21-45, are expected to complete this study, with at least 50 subjects completed per cell. Each site is to enroll no more than 40 subjects, with at least 100 subjects expected to complete when combined.

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TO BE IN THIS STUDY

You must:

- Be a man or woman age 21 to 45 years at the time of enrollment.
- Have mild to moderate acne on the face as determined by the Investigator or designee.
- Have at least 5 inflammatory lesions as determined by the Investigator or designee.
- Have 10 – 100 non-inflammatory lesions as determined by the Investigator or designee.
- Be willing to use the test products as instructed for 24 weeks.
- Be willing and able to comply with all of the time commitments and procedural requirements of the clinical trial protocol.
- Be willing to provide written informed consent including photo release, Health Insurance Portability and Accountability Act (HIPAA), and be able to read, speak, write, understand English and be willing to share personal information and data, as verified by signing a written authorization at the screening.
- Be willing to withhold all facial treatments during the course of the study including botulinum toxin, injectable fillers, microdermabrasion, IPL, peels, facials, laser treatments and tightening treatments. Waxing and threading is allowed but not facial laser hair removal.
- Males must be regular shavers and willing to shave on the day of the study visits (prior to clinic visits).
- Women of child bearing potential must be willing to take a urine pregnancy test prior to study enrollment, at week 24, and when deemed appropriate by the Investigator and/or Sponsor.
- Individuals of child bearing potential must use an acceptable method of contraception throughout the study. Acceptable methods of birth control include:
    - Oral and other system contraceptives. Individuals must be on a stable use for 3 months prior to study enrollment. Individuals on oral contraceptives must not alter their use, including dose or regimen for the duration of the study
    - Double barrier
    - Bilateral tubal ligation (tubes tied)
    - Partner vasectomy
    - Abstinence
- Be willing to follow study requirements and report any changes in health status or medications, side effect symptoms, or reactions immediately.
- Be stable on any medication you are taking for at least 30 days

YOU CANNOT BE ON THE STUDY

If you:

- Have been diagnosed with allergies to topical acne products.
- Have a condition and/or disease of the skin that the Investigator deems inappropriate for participation.
- Are a woman who is breastfeeding, pregnant, or planning to become pregnant during the study.
- Have pre-existing or dormant dermatologic conditions on the face (e.g., psoriasis, rosacea, eczema, seborrheic dermatitis, severe excoriations etc.) which in the opinion of the Investigator could interfere with the outcome of the study.
- Have a history of immunosuppression/immune deficiency disorders (including HIV infection or AIDS) or currently using immunosuppressive medications (e.g., azathioprine, belimumab,

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cyclophosphamide, Enbrel, Imuran, Humira, mycophenolate mofetil, methotrexate, prednisone, Remicade, Stelara.).

- Have an uncontrolled disease such as asthma, diabetes, hypertension, hyperthyroidism, or hypothyroidism. Individuals having multiple health conditions may be excluded from participation even if the conditions are controlled by diet, medication, etc. at the Investigator's discretion.
- Are currently participating in another facial usage study or have participated in a clinical trial within 4 weeks prior to inclusion into the study.
- Have a history of skin cancer on the face within the past 5 years.
- Have any planned surgeries and/or invasive medical procedures during the course of the study.
- Have started hormone replacement therapies (HRT) or hormones for birth control less than 3 months prior to study entry or plan on starting, stopping, or changing doses of HRT or hormones for birth control during the study.
- Have facial sunburn or excessive tanned facial skin or are not willing to avoid daily sun exposure on the face and the use of tanning beds or sunless tanning products for the duration of the study.
- Have severe acne, acne conglobata, multiple nodules or cysts (more than 2).
- Are currently taking a natural or prescription testosterone blocker (e.g. saw palmetto, blask cohosh, chaste tree, chasteberry, spironolactone, drospirenone, progestins).
- Are currently on a testosterone booster or prescription testosterone (e.g. DHEA, tribulus, testosterone cypionate, testosterone enanthate, Sustanon, testosterone propionate, testosterone phenylpropriate, Omnadren etc.).
- Are currently taking or have taken within the last 30 days oral or topical prescription medications for acne such as Doxycycline, Minocycline, Clindamycin, Bactrim, Tetracycline, Erythromycin, Vibramycin and topical tretinoin (Retin A, Renova, Adapalene, Tazarotene), Azelaic acid, benzoyl peroxide, Dapsone, Sodium sulfacetamide, Differin, Epiduo.
- Have used oral isotretinoin (Accutane) within the past 6-months.
- Are routinely using (3x a week or more) topical over-the-counter (OTC) acne product (e.g. benzoyl peroxide, salicylic acid, alpha hydroxyl, beta hydroxyl and/or poly-hydroxy products or medicated cleansers, wipes, masks, scrubs, gels and creams) within 14 days of the study entry.
- Are using or have used any systemic medication considered to affect the course of acne, specifically, but not exclusively antibiotics or steroids within the last 30 days prior to entry into the study.
- Have excessive facial hair, including beard, mustache or goatee, or scars, which could interfere with evaluations as determined by the Investigator or designee.

WHAT WILL HAPPEN DURING THE STUDY

***Visit 1: Screening (* Visit 1 {*Screening*} AND Visit 2 {*Baseline*} may be combined into 1 Visit)**

You will:

- Be given an IRB-approved Informed Consent Form (ICF), to read and sign. You will be given enough time to read the informed consent, and ask questions about the study, and sign 1 copy of this consent form and be given a signed photocopy to keep for your records.
- Be given an eligibility and health questionnaire to complete, and assigned a screening number.
- Will acclimate for 15 minutes in a room at 68-75^{0}F and 35-65% humidity.
- Will be screened by the Investigator or designee to see if you qualify for the study.
- If you do qualify for the study, you will:
    - Take a urine pregnancy test (females of child-bearing potential)

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- Have a trained evaluator confirm your eligibility
- Schedule your next appointment.

***Visit 2: Baseline**

- Be asked if you have experienced any changes in your health since the previous visit.
- Will acclimate for 15 minutes in a room at 68-75^{0}F and 35-65% humidity.
- Be screened by the Investigator or designee to see if you still qualify for the study.
- Have your health and eligibility re-reviewed.
- If you still qualify for the study you will:
  - Be assigned a subject number
  - Have photos taken of your face
  - Be randomly assigned to receive one of the test products & supporting facial cleanser, moisturizer & facial SPF 30
  - Be provided verbal and written usage instructions, and a daily diary to record product use
  - Schedule your next appointment

Visits 3, 4 (Week 1, Week 2)

- Be asked if you have experienced any changes in your health since the previous visit.
- Will acclimate for 15 minutes in a room at 68-75^{0}F and 35-65% humidity.
- Have your face examined by the Investigator or designee
- Complete a self-assessment questionnaire
- Have your diary collected and reviewed for compliance, and returned to you. At week 2, your diary will be retained by the testing facility and you will be given a new diary
- Have your product collected, weighed, and returned to you
- Schedule your next appointment

Visits 5, 6 (Week 6, Week 12)

- Be asked if you have experienced any changes in your health since the previous visit.
- Will acclimate for 15 minutes in a room at 68-75^{0}F and 35-65% humidity.
- Have your face examined by the Investigator or designee
- Have photos taken of your face
- Complete a self-assessment questionnaire
- Have your diary collected and reviewed for compliance, and retained by the testing facility and you will be given a new diary.
- Have your product collected, weighed, and retained. New products will be dispensed as necessary.
- Schedule your next appointment

Visit 7 (Week 18)

- Be asked if you have experienced any changes in your health since the previous visit.
- Have your diary collected and reviewed for compliance, and retained by the testing facility and you will be given a new diary.
- Have your product collected, weighed, and returned to you
- Schedule your next appointment

Visit 8 (Week 24)

- Be asked if you have experienced any changes in your health since the previous visit.
- Take a urine pregnancy test (females of child-bearing potential).

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- Will acclimate for 15 minutes in a room at 68-75^{0}F and 35-65% humidity.
- Have your face examined by the Investigator or designee
- Have photos taken of your face
- Complete a self-assessment questionnaire
- Have your diary collected and reviewed for compliance, and retained by the testing facility.
- Have your product collected, weighed, and retained by the testing facility.

Do not give the study product to other people and keep it out of the reach of children.

RISKS OR DISCOMFORTS

If you do not understand what any of these side effects mean, please ask the investigator or study staff to explain these terms to you.

Because the study products are investigational, all of their side effects may not be known. There may be rare and unknown side effects. Some of these may be life threatening.

Possible risks associated with the product are, as with any other cosmetic and OTC products, signs of irritation including:

- Itching
- Burning
- Stinging
- Rash or other allergic reaction
- Tingling
- Scaling/Dryness
- Redness

In some cases, it is possible for a subject to develop allergic reactions to the test material(s). This risk is increased for individuals with a history of allergies, and individuals with asthma and/or a history of hives may also be affected. Symptoms include rash, hives, and itching.

You must tell the Investigator or study staff about all side effects that you have. If you are not honest about your side effects, it may not be safe for you to stay in the study.

BIRTH CONTROL, DANGERS OF PREGNANCY AND BREASTFEEDING

If you are a female, you must not get pregnant while in this study. The only certain way to not get pregnant is to not have sex. If you are a female and choose to have sex, you must use a type of birth control.

Even if you use birth control during the study, there is a chance you could become pregnant. If you are pregnant or become pregnant during the study, test products or procedures may involve unforeseeable risks to the unborn baby.

A pregnancy test can be wrong. If you become pregnant during the study, stop using the test products and call/inform the Investigator at once.

You cannot be in the study if you are breastfeeding. It is not known whether the test products are safe for breast fed babies. Therefore if you are breastfeeding a child then it may not be safe for you to participate in the study.

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POSSIBLE BENEFITS OF THE STUDY

You will not get any medical benefit from being in this study, and there is no promise that your condition (acne) will get better. It might stay the same or it might get worse. Your participation will provide information that may help others. There may be other marketed products that claim to have similar benefits.

OTHER OPTIONS TO PARTICIPATING IN THE STUDY

Since this study is for research only, the only other choice would be not to be in the study.

STUDY AND TEST PRODUCT CONFIDENTIALITY

To participate in this study, you must agree to keep any information relating to the design, identity or use of these test product samples confidential.

On rare occasions, the sponsor may allow the testing company to disclose to you the name of the test products if you are not given this information during the study. This information is typically not provided until the end of the study or after the test products have been released for sale to the public. The study doctor or study staff will notify you if the sponsor allows us to give you this information.

DISCLOSURE AGREEMENT

This section explains how personal health information collected about you for the study may be used. Your personal health information includes, but is not limited to, information that was collected for your entry into the study and information that is collected during the study. The purpose of collecting this information is to allow the study staff and the Investigator to conduct the study, to evaluate the sponsor's study products and to analyze the study results.

You may decide not to give permission for the release of your personal health information for the study. In that case, you will not be able to participate in the study. This is because the study staff and/or the Investigator would not be able to collect the information needed to evaluate the sponsor's study products.

People who may inspect your personal and health information includes the Investigator, the Institutional Review Board, IntegReview IRB, FDA and other regulatory authorities from the United States or other countries, the study sponsor and people that work with the sponsor which includes, monitoring committees, contract research organizations, and consultants who have contracts with the company to do the study and review the study results. These reviews are done to check on the quality of the study and also for other purposes allowed by law.

The results of the study may be published in a medical book or journal, or presented at meetings for educational purposes. Neither your name, nor any other personal health information that specifically identifies you, will be used in those materials or presentations.

You may ask the Investigator to see and copy your personal health information related to the study. You may also ask the Investigator to correct any study related information about you that is wrong. You may have to wait until the end of the study to see your study records, so that the study can be organized properly.

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This permission to share your personal health information for this study does not have an expiration date. If you no longer want to share your personal health information, you may cancel your permission at any time by writing to the study staff and/or the Investigator at the address below:

Barry T. Reece
3207 Esters Road
Irving, Texas 75062

If you cancel your permission after you have started in the study, the study staff and the Investigator will stop collecting your personal health information. Although they will stop collecting new information about you, they will need to use the information they have already collected to evaluate the study results. If you start the study and then cancel your permission, you will not be able to continue to participate in the study. This is because the study staff and/or the Investigator would not be able to collect the information needed to evaluate the study.

RCTS, Inc., and the sponsor will make every effort to keep your personal health information private. But after the study staff or the Investigator share your personal health information from the study, federal privacy laws may not keep it private. There might be laws in your state or other federal laws that would protect the privacy of this information.

CONFIDENTIALITY

Your records of being in this study will be kept private except when ordered by law. The following people will have access to your study records:

- The Investigator
- Sponsor company or research institution [including monitor(s) and auditor(s)]
- Other country, state or federal regulatory agencies
- IntegReview IRB

The Institutional Review Board (IRB), IntegReview, and accrediting agencies may inspect and copy your records, which may have your name on them. Therefore, total confidentiality cannot be guaranteed. If the study results are presented at meetings or printed in publications, your name will not be used.

IN CASE OF STUDY RELATED INJURY

Side effects or complications, both foreseeable and unforeseeable, are possible in any research study without any fault to you, the Investigator, the study site, or the study sponsor. If you get hurt or sick as a direct result of being in this study, the sponsor will pay the costs of reasonable medical treatment. To ask questions about this, talk to the Investigator or study staff.

The sponsor's policy does not offer compensation for other expenses. Be aware that your health care payer/insurer might not cover the costs of study-related injuries or illnesses.
Unreimbursed medical expenses not covered by insurance or other third party coverage will be reimbursed by the sponsor for medical treatment for any injury that, in the opinion of the study doctor and the sponsor, is directly caused by the investigational product or by procedures required by the study protocol which would not have been performed as part of your regular medical care.

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LEGAL RIGHTS

You will not lose any of your legal rights by signing this consent form.

CONTACT INFORMATION

If you have questions, concerns, or complaints about this study or to report a study related injury, contact:

Barry T. Reece
972-871-7578 daytime telephone number
972-841-2916 after hours number (cell phone)

If you are unable to reach anyone at the number(s) listed above and you need medical attention, please go to the nearest emergency room.

If you do not want to talk to the Investigator or study staff, if you have concerns or complaints about the research, or to ask questions about your rights as a study subject you may contact IntegReview. IntegReview's policy indicates that all concerns/complaints are to be submitted in writing for review at a convened IRB meeting to:

Mailing Address:	OR	Email Address:
Chairperson IntegReview IRB 3815 S. Capital of Texas Highway Suite 320 Austin, TX 78704		integreview@integreview.com

If you are unable to provide your concerns/complaints in writing or if this is an emergency situation regarding subject safety, contact our office at:

512-326-3001 or
toll free at 1-877-562-1589
between 8 a.m. and 5 p.m. Central Time

IntegReview has approved the information in this consent form and has given approval for the Investigator to do the study. This does not mean IntegReview has approved your being in the study. You must consider the information in this consent form for yourself and decide if you want to be in this study.

PAYMENT FOR BEING IN THE STUDY

You may receive up to $600.00 for being in the study. You will be paid per completed visit as follows:

Visit	Compensation (amount)
Visit 1: Screening	$25.00
Visit 2: Baseline	$50.00
Visit 3: Week 1	$50.00
Visit 4: Week 2	$50.00
Visit 5: Week 6	$50.00

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Visit 6: Week 12	$50.00
Visit 7: Week 18	$50.00
Visit 8: Week 24	$50.00
Bonus for completing all visits:	$225.00

If you choose to leave or are withdrawn from the study for any reason before finishing all visits you will be paid for each completed visit. You will receive payment on the originally scheduled last day of the study.

If you are paid $600.00 or more by RCTS, Inc., in a calendar year, those payments will be reported to the Internal Revenue Service via form 1099-MISC. As required by tax laws, if you withhold your social security number, RCTS, Inc. is required to withhold 28% of your payment for tax purposes. In this case a form 1099-MISC will be sent to you reporting your withholding.

VOLUNTEERING TO BE IN THE STUDY

It is your choice if you want to be in the study. No one can force you to be in the study. You may not want to be in this study or you may leave the study at any time without penalty or loss of benefits to which you are otherwise entitled.

The Investigator, the sponsor company, or IntegReview may take you out of the study without your permission, at any time, for the following reasons:

- If you do not follow the Investigator's instructions
- If we find out you should not be in the study
- If the study is stopped
- If it becomes harmful to your health

If you leave the study or if you are taken out of the study, you may be asked to return for a final visit to have some end of study evaluations or tests. If information generated from this study is published or presented, your identity will not be revealed. If you leave the study, no more information about you will be collected for this study. However, all of the information you gave us before you left the study will still be used.

NEW FINDINGS

If there is new information or any significant new findings that could relate to your willingness to continue participation we will tell you. You can then decide if you still want to be in the study.

THE REASON FOR INSTITUTIONAL REVIEW BOARDS AND INFORMED CONSENT

What is a consent form?
The informed consent document contains information required by federal regulations. The informed consent document must be approved by an Institutional Review Board (IRB).

What is an Institutional Review Board (IRB)?
An Institutional Review Board (IRB) is a group of people that reviews research studies. The main goal of this review is to protect the rights and well being of the human subjects participating in research studies.

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IntegReview, the IRB for this study
IntegReview is an IRB whose board members provide IRB services across the United States, Canada, Japan and Latin America.

To meet requirements of the law, the IntegReview Boards currently include:

- Doctors
- Pharmacists
- Nurses
- Toxicologists (people who study the harmful effects of chemicals)
- Other specialists
- Others who do not have a background in science/medicine

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AGREEMENT TO BE IN THE STUDY

This consent form contains important information to help you decide if you want to be in the study. If you have any questions that are not answered in this consent form, ask one of the study staff.

Please answer **YES** or **NO** to the following questions:

A. Is this document in a language you understand? _____

B. Do you understand the information in this consent form? _____

C. Have you been given enough time to ask questions and talk about the study? _____

D. Have all of your questions been answered to your satisfaction? _____

E. Do you think you received enough information about the study? _____

F. Do you volunteer to be in this study of your own free will and without being pressured by the Investigator or study staff? _____

G. Do you know that you can leave the study at any time without giving a reason and without affecting your health care? _____

H. Do you know that your health records from this study may be reviewed by the sponsor company and by government authorities? _____

I. Do you know that you cannot be in another study while you are in this study? _____

IF YOU ANSWERED "NO" TO ANY OF THE ABOVE QUESTIONS,
OR YOU ARE UNABLE TO ANSWER ANY OF THE ABOVE QUESTIONS,
YOU SHOULD NOT SIGN THIS CONSENT FORM.

_____
Printed Name of Adult Study Subject

_____
Signature of Adult Study Subject Date

_____
Printed Name of Person Explaining Consent Form

_____
Signature of Person Explaining Consent Form Date

You will be given a signed and dated copy of this consent form to keep.

THIS IS AN IMPORTANT DOCUMENT - KEEP FOR FUTURE REFERENCE

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Authorization and Photographic Release Form

I hereby for good and valuable consideration grant to RCTS, Inc., the study sponsor and their respective affiliates, agencies, agents, employees, and assigns (collectively, "Authorized Entities"), the unrestricted, royalty free, irrevocable and perpetual right and permission to reproduce, distribute, broadcast and/or otherwise use for advertising and other commercial/noncommercial purposes: (i) my name, likeness, image, video, and any other biographical or personal information ("Personal Content"); and (ii) any statement or endorsement, or any portions thereof ("Testimonial(s)"), made by me relating to the study sponsor's products ("Products"), in any and all media now known or later developed, worldwide in perpetuity, without further compensation or approval by me.

I hereby assign to the Authorized Entities all of my world-wide right, title and interest, including my copyright interests and all renewals, reissues and extensions thereof, in and to the Personal Content and Testimonial(s), including without limitation, any photographic portraits, sound recordings and video performances of and/or by me in connection with the Personal Content and/or Testimonial(s).

I am at least 21 years of age, and competent to contract in my own name. I have read and understand this Authorization and Release.

_____
Printed Name of Adult Study Subject

_____
Signature of Adult Study Subject Date

_____
Printed Name of Person Explaining Release Form

_____
Signature of Person Explaining Release Form Date

Copy of consent form given to subject on _____ (date) by _____ (initials)

You will be given a signed and dated copy of this consent form to keep.

APPROVED BY
INTEGREVIEW IRB
FEBRUARY 25, 2016

AUTHORIZATION TO USE AND DISCLOSE PERSONAL HEALTH INFORMATION FOR RESEARCH

THIS SECTION DESCRIBES YOUR RIGHTS AND HOW PERSONAL HEALTH INFORMATION COLLECTED ABOUT YOU DURING THIS STUDY MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

The United States government has issued a privacy rule to protect the privacy rights of patients. This rule was issued under a law called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The Privacy Rule is designed to protect the confidentiality of your personal health information. The document you are reading, called an "Authorization," describes your rights and explains how your health information will be used and disclosed (shared).

Federal law requires hospitals, researchers and health care providers to protect the privacy of information that identifies you and relates to your past, present and future physical and mental health or conditions.

All information collected during the study will be retained by the study doctor and the Study Sponsor, except as required by law. Information from this study will be given to the sponsor. "Sponsor" includes any persons or companies, which are contracted by the sponsor to have access to the research information during and after the study. The information will also be given to the U.S. Food and Drug Administration (FDA). Study records which identify you and the consent form signed by you will be inspected and/or copied for research or regulatory purposes by:

- Sponsor
- Agents for the sponsor
- The US Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies
- IntegReview IRB

Because of the need to release information to these parties, absolute confidentiality cannot be guaranteed. The results of this research study may be presented at meetings or in publications; however, your identity will not be disclosed in those presentations.

For purposes of study reporting, you will be identified by your initials and code numbers only. However, your name, date of birth, address, and phone number will be kept on record by the study doctor in case you need to be contacted in the future about this study.

After your personal health information is disclosed to the Study Sponsor, the results of the study may be reanalyzed at a later date and may be combined with the results of other studies. The Study Sponsor and people who work with the Study Sponsor may use the results of this study for other research purposes, including:

- Developing a better understanding of the disease;
- Improving the design of future actual use trials

After the study staff or the study doctor discloses your personal health information to others, it could be re-disclosed and no longer protected by federal privacy laws.

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This permission to share your personal health information for this study does not have an expiration date. If you do not withdraw this Authorization in writing, it will remain in effect indefinitely. Your study doctor will keep this Authorization for at least 6 years. If you no longer want to share your personal health information, you may cancel your permission at any time by writing to the study staff and/or the study doctor at the address below:

RCTS, Inc.,
3207 Esters Road
Irving, Texas, 75062

You have the right to see and get a copy of your records related to the study for as long as the study doctor has this information. However, by signing this Authorization you agree that you might not be able to review or receive some of your records related to the study until after the study has been completed.

If you cancel your permission after you have started in the study, the study staff and the study doctor will stop collecting your personal health information unless the information concerns an adverse event (a bad effect) related to the study. If an adverse event occurs, your entire medical record may be reviewed. All information that has already been collected for study purposes, and any new information about an adverse event related to the study, will be sent to the study sponsor. Although they will stop collecting new information about you, they will need to use the information they have already collected to evaluate the study results. If you start the study and then cancel your permission, you will not be able to continue to participate in the study. This is because the study staff and/or the study doctor would not be able to collect the information needed to evaluate the study results.

If you withdraw from the study but do not withdraw your Authorization, new personal health information may be collected until this study ends.

You may decide not to give permission for the release of your personal health information for this study. In that case, you will not be able to participate. This is because the study staff and study doctor would not be able to collect the information needed to evaluate the study results.

At the completion of the study, you have the right to access your protected health information that is created during this research study that relates to your treatment or to payment, provided such information is not exempted under certain laws and regulations. To request this information, please contact the study doctor at the address listed above.

Your Right to Access Health Information

Subject to certain exceptions prescribed by law, you have a right to request access to the health information that we hold about you and to request changes if your health information is incorrect or incomplete. Any request for access or corrections should be made to the principal doctor conducting this study.

Your records obtained while you are in this trial, as well as related health records, will remain strictly confidential at all times. However, these will need to be made available to others working on the Sponsor's behalf, the Independent Ethics Committee members and Medicines Regulatory Authorities.

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By signing the consent form you agree to this access for the current trial and any further research that may be done. However, the Sponsor will take steps to protect your personal information and will not include your name on any sponsor forms, reports, publications, or in any future disclosures. If you withdraw from the study, we will no longer collect your personal information, but we may need to continue to use information already collected.

Personal data which may be sensitive (e.g., date of birth) will be collected and processed, but only for research purposes in connection with this trial.

The trial data will be sent around the world, but you will not be referred to by name or identified in any report or publication nor could the data be traced back to you. Your data may be transferred to a country that does not have the same level of personal data protection as within the United States. However, The Sponsor maintains high standards of confidentiality and protection.

The Sponsor (who will control the use of the data) will take steps to ensure your personal data is protected.

By taking part in this trial you agree not to restrict the use of any data even if you withdraw from the trial and agree to the transfer of your personal data to other Sponsor companies and to Medicines Regulatory Authorities both within and outside of Europe.

_____

Printed Name of Adult Study Subject

_____

Signature of Adult Study Subject Date

APPROVED BY
INTEGREVIEW IRB
SEPTEMBER 16, 2016

INFORMED CONSENT DOCUMENT
AGREEMENT TO BE IN A RESEARCH STUDY

NAME OF TESTING COMPANY:	RCTS, Inc.,
NUMBER AND TITLE OF STUDY:	C16-CD020 (GLI.04.SPR.US10354); "A Multi-Center Clinical Trial to Evaluate the Efficacy of Two Acne Treatments"
NAME OF PERSON IN CHARGE OF THE RESEARCH STUDY (INVESTIGATOR):	Barry T. Reece, M.S., M.B.A. Principal Investigator
MEDICAL INVESTIGATORS:	Raymond L. Garcia, M.D. Board Certified Dermatologist **G**ene Ream, M.D. Board Certified Dermatologist
TELEPHONE NUMBER(S), DAYTIME: **AFTER HOURS:**	972-871-7578 972-841-2916 (Emergencies Only, Cell Phone Number)

INTRODUCTION

You are being invited to volunteer for a clinical research study. You must read and sign this form before you agree to take part in this study. This form will give you more information about this study. Please ask as many questions as you need to before you decide if you want to be in the study. You should not sign this form if you have any questions that have not been answered.

RCTS, Inc., a contract research organization, is being paid by the sponsor (the company paying for this study) to conduct this research study.

You must be honest with the Investigator about your health history or it may not be safe for you to be in this study.

PURPOSE OF THE STUDY

The purpose of this study is to evaluate the efficiency of 2 acne treatments for 24 weeks of use in adult men and women with mild to moderate facial acne, at least 5 inflammatory lesions, and at least 10 – 100 non-inflammatory lesions.

HOW LONG THE STUDY WILL LAST AND HOW MANY PEOPLE WILL BE IN THE STUDY

This study will last 24 weeks and have up to 8 visits. At least 100 subjects, men and women between the ages of 21-45, are expected to complete this study, with at least 50 subjects completed per cell.

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TO BE IN THIS STUDY

You must:

- Be a man or woman age 21 to 45 years at the time of enrollment.
- Have mild to moderate acne on the face as determined by the Investigator or designee.
- Have at least 5 inflammatory lesions as determined by the Investigator or designee.
- Have 10 – 100 non-inflammatory lesions as determined by the Investigator or designee.
- Be willing to use the test products as instructed for 24 weeks.
- Be willing and able to comply with all of the time commitments and procedural requirements of the clinical trial protocol.
- Be willing to provide written informed consent including photo release, Health Insurance Portability and Accountability Act (HIPAA), and be able to read, speak, write, understand English and be willing to share personal information and data, as verified by signing a written authorization at the screening.
- Be willing to withhold all facial treatments during the course of the study including botulinum toxin, injectable fillers, microdermabrasion, IPL, peels, facials, laser treatments and tightening treatments. Waxing and threading is allowed but not facial laser hair removal.
- Males must be regular shavers and willing to shave on the day of the study visits (prior to clinic visits).
- Women of child bearing potential must be willing to take a urine pregnancy test prior to study enrollment, at week 24, and when deemed appropriate by the Investigator and/or Sponsor.
- Individuals of child bearing potential must use an acceptable method of contraception throughout the study. Acceptable methods of birth control include:
    - Oral and other system contraceptives. Individuals must be on a stable use for 3 months prior to study enrollment. Individuals on oral contraceptives must not alter their use, including dose or regimen for the duration of the study
    - Double barrier
    - Bilateral tubal ligation (tubes tied)
    - Partner vasectomy
    - Abstinence
- Be willing to follow study requirements and report any changes in health status or medications, side effect symptoms, or reactions immediately.
- Be stable on any medication you are taking for at least 30 days

YOU CANNOT BE ON THE STUDY

If you:

- Have been diagnosed with allergies to topical acne products.
- Have a condition and/or disease of the skin that the Investigator deems inappropriate for participation.
- Are a woman who is breastfeeding, pregnant, or planning to become pregnant during the study.
- Have pre-existing or dormant dermatologic conditions on the face (e.g., psoriasis, rosacea, eczema, seborrheic dermatitis, severe excoriations etc.) which in the opinion of the Investigator could interfere with the outcome of the study.

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- Have a history of immunosuppression/immune deficiency disorders (including HIV infection or AIDS) or currently using immunosuppressive medications (e.g., azathioprine, belimumab, cyclophosphamide, Enbrel, Imuran, Humira, mycophenolate mofetil, methotrexate, prednisone, Remicade, Stelara.).
- Have an uncontrolled disease such as asthma, diabetes, hypertension, hyperthyroidism, or hypothyroidism. Individuals having multiple health conditions may be excluded from participation even if the conditions are controlled by diet, medication, etc. at the Investigator's discretion.
- Are currently participating in another facial usage study or have participated in a clinical trial within 4 weeks prior to inclusion into the study.
- Have a history of skin cancer on the face within the past 5 years.
- Have any planned surgeries and/or invasive medical procedures during the course of the study.
- Have started hormone replacement therapies (HRT) or hormones for birth control less than 3 months prior to study entry or plan on starting, stopping, or changing doses of HRT or hormones for birth control during the study.
- Have facial sunburn or excessive tanned facial skin or are not willing to avoid daily sun exposure on the face and the use of tanning beds or sunless tanning products for the duration of the study.
- Have severe acne, acne conglobata, multiple nodules or cysts (more than 2).
- Are currently taking a natural or prescription testosterone blocker (e.g. saw palmetto, blask cohosh, chaste tree, chasteberry, spironolactone, drospirenone, progestins).
- Are currently on a testosterone booster or prescription testosterone (e.g. DHEA, tribulus, testosterone cypionate, testosterone enanthate, Sustanon, testosterone propionate, testosterone phenylpropriate, Omnadren etc.).
- Are currently taking or have taken within the last 30 days oral or topical prescription medications for acne such as Doxycycline, Minocycline, Clindamycin, Bactrim, Tetracycline, Erythromycin, Vibramycin and topical tretinoin (Retin A, Renova, Adapalene, Tazarotene), Azelaic acid, benzoyl peroxide, Dapsone, Sodium sulfacetamide, Differin, Epiduo.
- Have used oral isotretinoin (Accutane) within the past 6-months.
- Are routinely using (3x a week or more) topical over-the-counter (OTC) acne product (e.g. benzoyl peroxide, salicylic acid, alpha hydroxyl, beta hydroxyl and/or poly-hydroxy products or medicated cleansers, wipes, masks, scrubs, gels and creams) within 14 days of the study entry.
- Are using or have used any systemic medication considered to affect the course of acne, specifically, but not exclusively antibiotics or steroids within the last 30 days prior to entry into the study.
- Have excessive facial hair, including beard, mustache or goatee, or scars, which could interfere with evaluations as determined by the Investigator or designee.

WHAT WILL HAPPEN DURING THE STUDY

***Visit 1: Screening (* Visit 1 {*Screening*} AND Visit 2 {*Baseline*} may be combined into 1 Visit)**

You will:

- Be given an IRB-approved Informed Consent Form (ICF), to read and sign. You will be given enough time to read the informed consent, and ask questions about the study, and sign 1 copy of this consent form and be given a signed photocopy to keep for your records.
- Be given an eligibility and health questionnaire to complete, and assigned a screening number.
- Will acclimate for 15 minutes in a room at 68-75^{0}F and 35-65% humidity.
- Will be screened by the Investigator or designee to see if you qualify for the study.

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- If you do qualify for the study, you will:
    - Take a urine pregnancy test (females of child-bearing potential)
    - Have a trained evaluator confirm your eligibility
    - Schedule your next appointment.

***Visit 2: Baseline**

- Be asked if you have experienced any changes in your health since the previous visit.
- Will acclimate for 15 minutes in a room at 68-75^{0}F and 35-65% humidity.
- Be screened by the Investigator or designee to see if you still qualify for the study.
- Have your health and eligibility re-reviewed.
- If you still qualify for the study you will:
    - Be assigned a subject number
    - Have photos taken of your face
    - Be randomly assigned to receive one of the test products & supporting facial cleanser, moisturizer & facial SPF 30
    - Be provided verbal and written usage instructions, and a daily diary to record product use
    - Schedule your next appointment

Visits 3, 4 (Week 1, Week 2)

- Be asked if you have experienced any changes in your health since the previous visit.
- Will acclimate for 15 minutes in a room at 68-75^{0}F and 35-65% humidity.
- Have your face examined by the Investigator or designee
- Complete a self-assessment questionnaire
- Have your diary collected and reviewed for compliance, and returned to you. At week 2, your diary will be retained by the testing facility and you will be given a new diary
- Have your product collected, weighed, and returned to you
- Schedule your next appointment

Visits 5, 6 (Week 6, Week 12)

- Be asked if you have experienced any changes in your health since the previous visit.
- Will acclimate for 15 minutes in a room at 68-75^{0}F and 35-65% humidity.
- Have your face examined by the Investigator or designee
- Have photos taken of your face
- Complete a self-assessment questionnaire
- Have your diary collected and reviewed for compliance, and retained by the testing facility and you will be given a new diary.
- Have your product collected, weighed, and retained. New products will be dispensed as necessary.
- Schedule your next appointment

Visit 7 (Week 18)

- Be asked if you have experienced any changes in your health since the previous visit.
- Have your diary collected and reviewed for compliance, and retained by the testing facility and you will be given a new diary.
- Have your product collected, weighed, and returned to you
- Schedule your next appointment

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Visit 8 (Week 24)

- Be asked if you have experienced any changes in your health since the previous visit.
- Take a urine pregnancy test (females of child-bearing potential).
- Will acclimate for 15 minutes in a room at 68-75^{0}F and 35-65% humidity.
- Have your face examined by the Investigator or designee
- Have photos taken of your face
- Complete a self-assessment questionnaire
- Have your diary collected and reviewed for compliance, and retained by the testing facility.
- Have your product collected, weighed, and retained by the testing facility.

Do not give the study product to other people and keep it out of the reach of children.

RISKS OR DISCOMFORTS

If you do not understand what any of these side effects mean, please ask the investigator or study staff to explain these terms to you.

Because the study products are investigational, all of their side effects may not be known. There may be rare and unknown side effects. Some of these may be life threatening.

Possible risks associated with the product are, as with any other cosmetic and OTC products, signs of irritation including:

- Itching
- Burning
- Stinging
- Rash or other allergic reaction
- Tingling
- Scaling/Dryness
- Redness

In some cases, it is possible for a subject to develop allergic reactions to the test material(s). This risk is increased for individuals with a history of allergies, and individuals with asthma and/or a history of hives may also be affected. Symptoms include rash, hives, and itching.

You must tell the Investigator or study staff about all side effects that you have. If you are not honest about your side effects, it may not be safe for you to stay in the study.

BIRTH CONTROL, DANGERS OF PREGNANCY AND BREASTFEEDING

If you are a female, you must not get pregnant while in this study. The only certain way to not get pregnant is to not have sex. If you are a female and choose to have sex, you must use a type of birth control.

Even if you use birth control during the study, there is a chance you could become pregnant. If you are pregnant or become pregnant during the study, test products or procedures may involve unforeseeable risks to the unborn baby.

A pregnancy test can be wrong. If you become pregnant during the study, stop using the test products and call/inform the Investigator at once.

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You cannot be in the study if you are breastfeeding. It is not known whether the test products are safe for breast fed babies. Therefore if you are breastfeeding a child then it may not be safe for you to participate in the study.

POSSIBLE BENEFITS OF THE STUDY

You will not get any medical benefit from being in this study, and there is no promise that your condition (acne) will get better. It might stay the same or it might get worse. Your participation will provide information that may help others. There may be other marketed products that claim to have similar benefits.

OTHER OPTIONS TO PARTICIPATING IN THE STUDY

Since this study is for research only, the only other choice would be not to be in the study.

STUDY AND TEST PRODUCT CONFIDENTIALITY

To participate in this study, you must agree to keep any information relating to the design, identity or use of these test product samples confidential.

On rare occasions, the sponsor may allow the testing company to disclose to you the name of the test products if you are not given this information during the study. This information is typically not provided until the end of the study or after the test products have been released for sale to the public. The study doctor or study staff will notify you if the sponsor allows us to give you this information.

DISCLOSURE AGREEMENT

This section explains how personal health information collected about you for the study may be used. Your personal health information includes, but is not limited to, information that was collected for your entry into the study and information that is collected during the study. The purpose of collecting this information is to allow the study staff and the Investigator to conduct the study, to evaluate the sponsor's study products and to analyze the study results.

You may decide not to give permission for the release of your personal health information for the study. In that case, you will not be able to participate in the study. This is because the study staff and/or the Investigator would not be able to collect the information needed to evaluate the sponsor's study products.

People who may inspect your personal and health information includes the Investigator, the Institutional Review Board, IntegReview IRB, FDA and other regulatory authorities from the United States or other countries, the study sponsor and people that work with the sponsor which includes, monitoring committees, contract research organizations, and consultants who have contracts with the company to do the study and review the study results. These reviews are done to check on the quality of the study and also for other purposes allowed by law.

The results of the study may be published in a medical book or journal, or presented at meetings for educational purposes. Neither your name, nor any other personal health information that specifically identifies you, will be used in those materials or presentations.

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You may ask the Investigator to see and copy your personal health information related to the study. You may also ask the Investigator to correct any study related information about you that is wrong. You may have to wait until the end of the study to see your study records, so that the study can be organized properly.

This permission to share your personal health information for this study does not have an expiration date. If you no longer want to share your personal health information, you may cancel your permission at any time by writing to the study staff and/or the Investigator at the address below:

Barry T. Reece
3207 Esters Road
Irving, Texas 75062

If you cancel your permission after you have started in the study, the study staff and the Investigator will stop collecting your personal health information. Although they will stop collecting new information about you, they will need to use the information they have already collected to evaluate the study results. If you start the study and then cancel your permission, you will not be able to continue to participate in the study. This is because the study staff and/or the Investigator would not be able to collect the information needed to evaluate the study.

RCTS, Inc., and the sponsor will make every effort to keep your personal health information private. But after the study staff or the Investigator share your personal health information from the study, federal privacy laws may not keep it private. There might be laws in your state or other federal laws that would protect the privacy of this information.

CONFIDENTIALITY

Your records of being in this study will be kept private except when ordered by law. The following people will have access to your study records:

- The Investigator
- Sponsor company or research institution [including monitor(s) and auditor(s)]
- Other country, state or federal regulatory agencies
- IntegReview IRB

The Institutional Review Board (IRB), IntegReview, and accrediting agencies may inspect and copy your records, which may have your name on them. Therefore, total confidentiality cannot be guaranteed. If the study results are presented at meetings or printed in publications, your name will not be used.

IN CASE OF STUDY RELATED INJURY

Side effects or complications, both foreseeable and unforeseeable, are possible in any research study without any fault to you, the Investigator, the study site, or the study sponsor. If you get hurt or sick as a direct result of being in this study, the sponsor will pay the costs of reasonable medical treatment. To ask questions about this, talk to the Investigator or study staff.

The sponsor's policy does not offer compensation for other expenses. Be aware that your health care payer/insurer might not cover the costs of study-related injuries or illnesses.

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Unreimbursed medical expenses not covered by insurance or other third party coverage will be reimbursed by the sponsor for medical treatment for any injury that, in the opinion of the study doctor and the sponsor, is directly caused by the investigational product or by procedures required by the study protocol which would not have been performed as part of your regular medical care.

LEGAL RIGHTS

You will not lose any of your legal rights by signing this consent form.

CONTACT INFORMATION

If you have questions, concerns, or complaints about this study or to report a study related injury, contact:

Barry T. Reece
972-871-7578 daytime telephone number
972-841-2916 after hours number (cell phone)

If you are unable to reach anyone at the number(s) listed above and you need medical attention, please go to the nearest emergency room.

If you do not want to talk to the Investigator or study staff, if you have concerns or complaints about the research, or to ask questions about your rights as a study subject you may contact IntegReview. IntegReview's policy indicates that all concerns/complaints are to be submitted in writing for review at a convened IRB meeting to:

Mailing Address:	OR	Email Address:
Chairperson IntegReview IRB 3815 S. Capital of Texas Highway Suite 320 Austin, TX 78704		integreview@integreview.com

If you are unable to provide your concerns/complaints in writing or if this is an emergency situation regarding subject safety, contact our office at:

512-326-3001 or
toll free at 1-877-562-1589
between 8 a.m. and 5 p.m. Central Time

IntegReview has approved the information in this consent form and has given approval for the Investigator to do the study. This does not mean IntegReview has approved your being in the study. You must consider the information in this consent form for yourself and decide if you want to be in this study.

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PAYMENT FOR BEING IN THE STUDY

You may receive up to $600.00 for being in the study. You will be paid per completed visit as follows:

Visit	Compensation (amount)
Visit 1: Screening	$25.00
Visit 2: Baseline	$50.00
Visit 3: Week 1	$50.00
Visit 4: Week 2	$50.00
Visit 5: Week 6	$50.00
Visit 6: Week 12	$50.00
Visit 7: Week 18	$50.00
Visit 8: Week 24	$50.00
Bonus for completing all visits:	$225.00

If you choose to leave or are withdrawn from the study for any reason before finishing all visits you will be paid for each completed visit. You will receive payment on the originally scheduled last day of the study.

If you are paid $600.00 or more by RCTS, Inc., in a calendar year, those payments will be reported to the Internal Revenue Service via form 1099-MISC. As required by tax laws, if you withhold your social security number, RCTS, Inc. is required to withhold 28% of your payment for tax purposes. In this case a form 1099-MISC will be sent to you reporting your withholding.

VOLUNTEERING TO BE IN THE STUDY

It is your choice if you want to be in the study. No one can force you to be in the study. You may not want to be in this study or you may leave the study at any time without penalty or loss of benefits to which you are otherwise entitled.

The Investigator, the sponsor company, or IntegReview may take you out of the study without your permission, at any time, for the following reasons:

- If you do not follow the Investigator's instructions
- If we find out you should not be in the study
- If the study is stopped
- If it becomes harmful to your health

If you leave the study or if you are taken out of the study, you may be asked to return for a final visit to have some end of study evaluations or tests. If information generated from this study is published or presented, your identity will not be revealed. If you leave the study, no more information about you will be collected for this study. However, all of the information you gave us before you left the study will still be used.

NEW FINDINGS

If there is new information or any significant new findings that could relate to your willingness to continue participation we will tell you. You can then decide if you still want to be in the study.

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THE REASON FOR INSTITUTIONAL REVIEW BOARDS AND INFORMED CONSENT

What is a consent form?
The informed consent document contains information required by federal regulations. The informed consent document must be approved by an Institutional Review Board (IRB).

What is an Institutional Review Board (IRB)?
An Institutional Review Board (IRB) is a group of people that reviews research studies. The main goal of this review is to protect the rights and well being of the human subjects participating in research studies.
IntegReview, the IRB for this study
IntegReview is an IRB whose board members provide IRB services across the United States, Canada, Japan and Latin America.

To meet requirements of the law, the IntegReview Boards currently include:

- Doctors
- Pharmacists
- Nurses
- Toxicologists (people who study the harmful effects of chemicals)
- Other specialists
- Others who do not have a background in science/medicine

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AGREEMENT TO BE IN THE STUDY

This consent form contains important information to help you decide if you want to be in the study. If you have any questions that are not answered in this consent form, ask one of the study staff.

Please answer **YES** or **NO** to the following questions:

A. Is this document in a language you understand? _____

B. Do you understand the information in this consent form? _____

C. Have you been given enough time to ask questions and talk about the study? _____

D. Have all of your questions been answered to your satisfaction? _____

E. Do you think you received enough information about the study? _____

F. Do you volunteer to be in this study of your own free will and without being pressured by the Investigator or study staff? _____

G. Do you know that you can leave the study at any time without giving a reason and without affecting your health care? _____

H. Do you know that your health records from this study may be reviewed by the sponsor company and by government authorities? _____

I. Do you know that you cannot be in another study while you are in this study? _____

IF YOU ANSWERED "NO" TO ANY OF THE ABOVE QUESTIONS,
OR YOU ARE UNABLE TO ANSWER ANY OF THE ABOVE QUESTIONS,
YOU SHOULD NOT SIGN THIS CONSENT FORM.

_____
Printed Name of Adult Study Subject

_____
Signature of Adult Study Subject Date

_____
Printed Name of Person Explaining Consent Form

_____
Signature of Person Explaining Consent Form Date

You will be given a signed and dated copy of this consent form to keep.

THIS IS AN IMPORTANT DOCUMENT - KEEP FOR FUTURE REFERENCE

APPROVED BY
INTEGREVIEW IRB
SEPTEMBER 16, 2016

Authorization and Photographic Release Form

I hereby for good and valuable consideration grant to RCTS, Inc., the study sponsor and their respective affiliates, agencies, agents, employees, and assigns (collectively, "Authorized Entities"), the unrestricted, royalty free, irrevocable and perpetual right and permission to reproduce, distribute, broadcast and/or otherwise use for advertising and other commercial/noncommercial purposes: (i) my name, likeness, image, video, and any other biographical or personal information ("Personal Content"); and (ii) any statement or endorsement, or any portions thereof ("Testimonial(s)"), made by me relating to the study sponsor's products ("Products"), in any and all media now known or later developed, worldwide in perpetuity, without further compensation or approval by me.

I hereby assign to the Authorized Entities all of my world-wide right, title and interest, including my copyright interests and all renewals, reissues and extensions thereof, in and to the Personal Content and Testimonial(s), including without limitation, any photographic portraits, sound recordings and video performances of and/or by me in connection with the Personal Content and/or Testimonial(s).

I am at least 21 years of age, and competent to contract in my own name. I have read and understand this Authorization and Release.

_____
Printed Name of Adult Study Subject

_____
Signature of Adult Study Subject Date

_____
Printed Name of Person Explaining Release Form

_____
Signature of Person Explaining Release Form Date

Copy of consent form given to subject on _____ (date) by _____ (initials)

You will be given a signed and dated copy of this consent form to keep.

APPROVED BY
INTEGREVIEW IRB
SEPTEMBER 16, 2016

AUTHORIZATION TO USE AND DISCLOSE PERSONAL HEALTH INFORMATION FOR RESEARCH

THIS SECTION DESCRIBES YOUR RIGHTS AND HOW PERSONAL HEALTH INFORMATION COLLECTED ABOUT YOU DURING THIS STUDY MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

The United States government has issued a privacy rule to protect the privacy rights of patients. This rule was issued under a law called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The Privacy Rule is designed to protect the confidentiality of your personal health information. The document you are reading, called an "Authorization," describes your rights and explains how your health information will be used and disclosed (shared).

Federal law requires hospitals, researchers and health care providers to protect the privacy of information that identifies you and relates to your past, present and future physical and mental health or conditions.

All information collected during the study will be retained by the study doctor and the Study Sponsor, except as required by law. Information from this study will be given to the sponsor. "Sponsor" includes any persons or companies, which are contracted by the sponsor to have access to the research information during and after the study. The information will also be given to the U.S. Food and Drug Administration (FDA). Study records which identify you and the consent form signed by you will be inspected and/or copied for research or regulatory purposes by:

- Sponsor
- Agents for the sponsor
- The US Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies
- IntegReview IRB

Because of the need to release information to these parties, absolute confidentiality cannot be guaranteed. The results of this research study may be presented at meetings or in publications; however, your identity will not be disclosed in those presentations.

For purposes of study reporting, you will be identified by your initials and code numbers only. However, your name, date of birth, address, and phone number will be kept on record by the study doctor in case you need to be contacted in the future about this study.

After your personal health information is disclosed to the Study Sponsor, the results of the study may be reanalyzed at a later date and may be combined with the results of other studies. The Study Sponsor and people who work with the Study Sponsor may use the results of this study for other research purposes, including:

- Developing a better understanding of the disease;
- Improving the design of future actual use trials

After the study staff or the study doctor discloses your personal health information to others, it could be re-disclosed and no longer protected by federal privacy laws.

**APPROVED BY
INTEGREVIEW IRB
SEPTEMBER 16, 2016**

This permission to share your personal health information for this study does not have an expiration date. If you do not withdraw this Authorization in writing, it will remain in effect indefinitely. Your study doctor will keep this Authorization for at least 6 years. If you no longer want to share your personal health information, you may cancel your permission at any time by writing to the study staff and/or the study doctor at the address below:

RCTS, Inc.,
3207 Esters Road
Irving, Texas, 75062

You have the right to see and get a copy of your records related to the study for as long as the study doctor has this information. However, by signing this Authorization you agree that you might not be able to review or receive some of your records related to the study until after the study has been completed.

If you cancel your permission after you have started in the study, the study staff and the study doctor will stop collecting your personal health information unless the information concerns an adverse event (a bad effect) related to the study. If an adverse event occurs, your entire medical record may be reviewed. All information that has already been collected for study purposes, and any new information about an adverse event related to the study, will be sent to the study sponsor. Although they will stop collecting new information about you, they will need to use the information they have already collected to evaluate the study results. If you start the study and then cancel your permission, you will not be able to continue to participate in the study. This is because the study staff and/or the study doctor would not be able to collect the information needed to evaluate the study results.

If you withdraw from the study but do not withdraw your Authorization, new personal health information may be collected until this study ends.

You may decide not to give permission for the release of your personal health information for this study. In that case, you will not be able to participate. This is because the study staff and study doctor would not be able to collect the information needed to evaluate the study results.

At the completion of the study, you have the right to access your protected health information that is created during this research study that relates to your treatment or to payment, provided such information is not exempted under certain laws and regulations. To request this information, please contact the study doctor at the address listed above.

Your Right to Access Health Information

Subject to certain exceptions prescribed by law, you have a right to request access to the health information that we hold about you and to request changes if your health information is incorrect or incomplete. Any request for access or corrections should be made to the principal doctor conducting this study.

Your records obtained while you are in this trial, as well as related health records, will remain strictly confidential at all times. However, these will need to be made available to others working on the Sponsor's behalf, the Independent Ethics Committee members and Medicines Regulatory Authorities.

**APPROVED BY
INTEGREVIEW IRB
SEPTEMBER 16, 2016**

By signing the consent form you agree to this access for the current trial and any further research that may be done. However, the Sponsor will take steps to protect your personal information and will not include your name on any sponsor forms, reports, publications, or in any future disclosures. If you withdraw from the study, we will no longer collect your personal information, but we may need to continue to use information already collected.

Personal data which may be sensitive (e.g., date of birth) will be collected and processed, but only for research purposes in connection with this trial.

The trial data will be sent around the world, but you will not be referred to by name or identified in any report or publication nor could the data be traced back to you. Your data may be transferred to a country that does not have the same level of personal data protection as within the United States. However, The Sponsor maintains high standards of confidentiality and protection.

The Sponsor (who will control the use of the data) will take steps to ensure your personal data is protected.

By taking part in this trial you agree not to restrict the use of any data even if you withdraw from the trial and agree to the transfer of your personal data to other Sponsor companies and to Medicines Regulatory Authorities both within and outside of Europe.

_____

Printed Name of Adult Study Subject

_____

Signature of Adult Study Subject Date

Source Documents			
Galderma	Study # C16-CD020	INVESTIGTOR NAME To be added per site	Subject Initials Subject Number

Visit 1 –Baseline (Day 1)

INCLUSION CRITERIA		
	Yes	No*
1. Is a man or woman between the ages of 21 and 45 years of age at the time of enrollment.	☐	☐
2. Has mild to moderate acne (score of 2-3 on FDA Investigator's Global Assessment Scale) on the face.	☐	☐
3. Have at least 5 inflammatory lesions.	☐	☐
4. Have 10 – 100 non-inflammatory lesions.	☐	☐
5. Is willing to use the test products as instructed for 24 weeks.	☐	☐
6. Has a Fitzpatrick skin type I-VI	☐	☐
7. Is willing and able to comply with all of the time commitments and procedural requirements of the clinical trial protocol.	☐	☐
8. Is willing to provide written informed consent including photo release, Health Insurance Portability and Accountability Act (HIPAA), and is able to read, speak, write, understand English and is willing to share personal information and data, as verified by signing a written authorization at the screening	☐	☐
9. Is willing to withhold all facial treatments during the course of the study including botulinum toxin, injectable fillers, microdermabrasion, IPL, peels, facials, laser treatments and tightening treatments. Waxing and threading is allowed but not facial laser hair removal.	☐	☐
10. If male, who is a regular shaver and willing to shave on the day of the study visits (prior to clinic visits).	☐	☐
11. If a woman of child bearing potential, is willing to take a urine pregnancy test prior to study enrollment, at week 24, and when deemed appropriate by the Investigator and/or Sponsor.	☐	☐
12. Is of child bearing potential who uses an acceptable method of contraception throughout the study. Acceptable methods of birth control include • Oral and other system contraceptives. Individuals must be on a stable use for 3 months prior to study enrollment. Individuals on oral contraceptives must not alter their use, including dose or regimen for the duration of the study • Double barrier • Bilateral tubal ligation • Partner vasectomy • Abstinence	☐	☐
13. Is willing to follow study requirements and report any changes in health status or medications, adverse event symptoms, or reactions immediately.	☐	☐
14. Must be stable on any medication they are taking for at least 30 days	☐	☐
If any criterion is answered no, **DO NOT** enroll the subject.		

Visit 1 –Baseline (Day 1)

EXCLUSION CRITERIA

Source Documents			
Galderma	Study # C16-CD020	INVESTIGTOR NAME To be added per site	Subject Initials Subject Number

	Yes*	No
1. Has been diagnosed with allergies to topical acne products.	☐	☐
2. Has a condition and/or disease of the skin that the Investigator deems inappropriate for participation.	☐	☐
3. Is nursing, pregnant, or planning to become pregnant during the study.	☐	☐
4. Have pre-existing or dormant dermatologic conditions on the face (e.g., psoriasis, rosacea, eczema, seborrheic dermatitis, severe excoriations etc.) which in the opinion of the Investigator could interfere with the outcome of the study.	☐	☐
5. Has a history of immunosuppression/immune deficiency disorders (including (HIV infection or AIDS) or currently using immunosuppressive medications (e.g., azathioprine, belimumab, cyclophosphamide, Enbrel, Imuran, Humira, mycophenolate mofetil, methotrexate, prednisone, Remicade, Stelara.).	☐	☐
6. Has an uncontrolled disease such as asthma, diabetes, hypertension, hyperthyroidism, or hypothyroidism. Individuals having multiple health conditions may be excluded from participation even if the conditions are controlled by diet, medication, etc. at the Investigator's discretion.	☐	☐
7. Is currently participating in another facial usage study or has participated in a clinical trial at Stephens or at another research facility or doctor's office within 4 weeks prior to inclusion into the study.	☐	☐
8. Has a history of skin cancer within the past 5 years.	☐	☐
9. Has any planned surgeries and/or invasive medical procedures during the course of the study.	☐	☐
10. Has started hormone replacement therapies (HRT) or hormones for birth control less than 3 months prior to study entry or plans on starting, stopping, or changing doses of HRT or hormones for birth control during the study.	☐	☐
11. Has facial sunburn or excessive tanned facial skin or is not willing to avoid daily sun exposure on the face and the use of tanning beds or sunless tanning products for the duration of the study.	☐	☐
12. Has severe acne, acne conglobata, multiple nodules or cysts (more than 2).	☐	☐
13. Is currently taking a natural or prescription testosterone blocker (e.g. saw palmetto, blask cohosh, chaste tree, chasteberry, spironolactone, drospirenone, progestins).	☐	☐
14. Is currently on a testosterone booster or prescription testosterone (e.g. DHEA, tribulus, testosterone cypionate, testosterone enanthate, Sustanon, testosterone propionate, testosterone phenylpropriate, Omnadren etc.).	☐	☐
(CONTINUED ON NEXT PAGE)		

Source Documents			
Galderma	Study # C16-CD020	INVESTIGTOR NAME To be added per site	Subject Initials Subject Number

Visit 1 –Baseline

EXCLUSION CRITERIA (CONTINUED)		
	Yes*	No
15. Is currently taking or has taken within the last 30 days oral or topical prescription medications for acne such as Doxycycline, Minocycline, Clindamycin, Bactrim, Tetracycline, Erythromycin, Vibramycin and topical tretinoin.(Retin A Renova, Adapalene, Tazarotene), Azelaic acid, benzoyl peroxide, Dapsone, Sodium sulfacetamide, Differin, Epiduo.	☐	☐
16. Has used oral isotretinoin (Accutane) within the past 6-months.	☐	☐
17. Is routinely using (3x a week or more) topical OTC acne product (e.g. benzoyl peroxide, salicylic acid, alpha hydroxyl, beta hydroxyl and/or poly-hydroxy products or medicated cleansers, wipes, masks, scrubs, gels and creams) within 30 days of the study entry.	☐	☐
18. Is using or has used any systemic medication considered to affect the course of acne, specifically, but not exclusively antibiotics or steroids within the last 30 days prior to entry into the study.	☐	☐
19. Has excessive facial hair, including beard, mustache or goatee, or scars, which could interfere with evaluations by Investigator or designee.	☐	☐
*If any criterion is answered **Yes*, <u>DO NOT</u>** enroll the subject.		

Visit 1 – Baseline

INCLUSION/EXCLUSION

Is the subject eligible per Inclusion/Exclusion criteria?

☐ Yes

☐ No If no, please indicate which Inclusion/Exclusion criteria the subject did not meet and complete End of Study page:

Inclusion #_____ Exclusion #_____

Investigators review

I affirm that all required information has been reviewed by me, deemed accurate and complete and that the subject meets the inclusion/exclusion criteria, and is eligible to be enrolled in the study.

_____ _____-_____-_____

Investigator's Signature DD MMM YYYY

Source Documents			
Galderma	Study # C16-CD020	INVESTIGTOR NAME To be added per site	Subject Initials Subject Number

Visit 1 –Baseline (Day 1)

INCLUSION CRITERIA		
	Yes	No*
1. Is a man or woman between the ages of 21 and 45 years of age at the time of enrollment.	☐	☐
2. Has mild to moderate acne (score of 2-3 on FDA Investigator's Global Assessment Scale) on the face.	☐	☐
3. Have at least 5 inflammatory lesions.	☐	☐
4. Have 10 – 100 non-inflammatory lesions.	☐	☐
5. Is willing to use the test products as instructed for 24 weeks.	☐	☐
6. Has a Fitzpatrick skin type I-VI	☐	☐
7. Is willing and able to comply with all of the time commitments and procedural requirements of the clinical trial protocol.	☐	☐
8. Is willing to provide written informed consent including photo release, Health Insurance Portability and Accountability Act (HIPAA), and is able to read, speak, write, understand English and is willing to share personal information and data, as verified by signing a written authorization at the screening	☐	☐
9. Is willing to withhold all facial treatments during the course of the study including botulinum toxin, injectable fillers, microdermabrasion, IPL, peels, facials, laser treatments and tightening treatments. Waxing and threading is allowed but not facial laser hair removal.	☐	☐
10. If male, who is a regular shaver and willing to shave on the day of the study visits (prior to clinic visits).	☐	☐
11. If a woman of child bearing potential, is willing to take a urine pregnancy test prior to study enrollment, at week 24, and when deemed appropriate by the Investigator and/or Sponsor.	☐	☐
12. Is of child bearing potential who uses an acceptable method of contraception throughout the study. Acceptable methods of birth control include • Oral and other system contraceptives. Individuals must be on a stable use for 3 months prior to study enrollment. Individuals on oral contraceptives must not alter their use, including dose or regimen for the duration of the study • Double barrier • Bilateral tubal ligation • Partner vasectomy • Abstinence	☐	☐
13. Is willing to follow study requirements and report any changes in health status or medications, adverse event symptoms, or reactions immediately.	☐	☐
14. Must be stable on any medication they are taking for at least 30 days	☐	☐
If any criterion is answered no, **DO NOT** enroll the subject.		

Visit 1 –Baseline (Day 1)

EXCLUSION CRITERIA

Source Documents			
Galderma	Study # C16-CD020	INVESTIGTOR NAME To be added per site	Subject Initials Subject Number

	Yes*	No
1. Has been diagnosed with allergies to topical acne products.	☐	☐
2. Has a condition and/or disease of the skin that the Investigator deems inappropriate for participation.	☐	☐
3. Is nursing, pregnant, or planning to become pregnant during the study.	☐	☐
4. Have pre-existing or dormant dermatologic conditions on the face (e.g., psoriasis, rosacea, eczema, seborrheic dermatitis, severe excoriations etc.) which in the opinion of the Investigator could interfere with the outcome of the study.	☐	☐
5. Has a history of immunosuppression/immune deficiency disorders (including (HIV infection or AIDS) or currently using immunosuppressive medications (e.g., azathioprine, belimumab, cyclophosphamide, Enbrel, Imuran, Humira, mycophenolate mofetil, methotrexate, prednisone, Remicade, Stelara.).	☐	☐
6. Has an uncontrolled disease such as asthma, diabetes, hypertension, hyperthyroidism, or hypothyroidism. Individuals having multiple health conditions may be excluded from participation even if the conditions are controlled by diet, medication, etc. at the Investigator's discretion.	☐	☐
7. Is currently participating in another facial usage study or has participated in a clinical trial at Stephens or at another research facility or doctor's office within 4 weeks prior to inclusion into the study.	☐	☐
8. Has a history of skin cancer within the past 5 years.	☐	☐
9. Has any planned surgeries and/or invasive medical procedures during the course of the study.	☐	☐
10. Has started hormone replacement therapies (HRT) or hormones for birth control less than 3 months prior to study entry or plans on starting, stopping, or changing doses of HRT or hormones for birth control during the study.	☐	☐
11. Has facial sunburn or excessive tanned facial skin or is not willing to avoid daily sun exposure on the face and the use of tanning beds or sunless tanning products for the duration of the study.	☐	☐
12. Has severe acne, acne conglobata, multiple nodules or cysts (more than 2).	☐	☐
13. Is currently taking a natural or prescription testosterone blocker (e.g. saw palmetto, blask cohosh, chaste tree, chasteberry, spironolactone, drospirenone, progestins).	☐	☐
14. Is currently on a testosterone booster or prescription testosterone (e.g. DHEA, tribulus, testosterone cypionate, testosterone enanthate, Sustanon, testosterone propionate, testosterone phenylpropriate, Omnadren etc.).	☐	☐
(CONTINUED ON NEXT PAGE)		

Source Documents			
Galderma	Study # C16-CD020	INVESTIGTOR NAME To be added per site	Subject Initials Subject Number

Visit 1 –Baseline

EXCLUSION CRITERIA (CONTINUED)		
	Yes*	No
15. Is currently taking or has taken within the last 30 days oral or topical prescription medications for acne such as Doxycycline, Minocycline, Clindamycin, Bactrim, Tetracycline, Erythromycin, Vibramycin and topical tretinoin.(Retin A Renova, Adapalene, Tazarotene), Azelaic acid, benzoyl peroxide, Dapsone, Sodium sulfacetamide, Differin, Epiduo.	☐	☐
16. Has used oral isotretinoin (Accutane) within the past 6-months.	☐	☐
17. Is routinely using (3x a week or more) topical OTC acne product (e.g. benzoyl peroxide, salicylic acid, alpha hydroxyl, beta hydroxyl and/or poly-hydroxy products or medicated cleansers, wipes, masks, scrubs, gels and creams) within 30 days of the study entry.	☐	☐
18. Is using or has used any systemic medication considered to affect the course of acne, specifically, but not exclusively antibiotics or steroids within the last 30 days prior to entry into the study.	☐	☐
19. Has excessive facial hair, including beard, mustache or goatee, or scars, which could interfere with evaluations by Investigator or designee.	☐	☐
*If any criterion is answered **Yes*, <u>DO NOT</u>** enroll the subject.		

Visit 1 – Baseline

INCLUSION/EXCLUSION

Is the subject eligible per Inclusion/Exclusion criteria?

☐ Yes

☐ No If no, please indicate which Inclusion/Exclusion criteria the subject did not meet and complete End of Study page:

Inclusion #_____ Exclusion #_____

Investigators review

I affirm that all required information has been reviewed by me, deemed accurate and complete and that the subject meets the inclusion/exclusion criteria, and is eligible to be enrolled in the study.

_____ _____-_____-_____

Investigator's Signature DD MMM YYYY

Source Documents			
Galderma	Study # C16-CD020	INVESTIGTOR NAME Barry T. Reece (RCTS, Inc.)	Subject Initials Screening Number

Visit 1 –Screening/Baseline (Day 1)

INCLUSION CRITERIA		
	Yes	No*
1. Is a man or woman between the ages of 21 and 45 years of age at the time of enrollment.	☐	☐
2. Has mild to moderate acne (score of 2-3 on FDA Investigator's Global Assessment Scale) on the face.	☐	☐
3. Have at least 5 inflammatory lesions.	☐	☐
4. Have 10 – 100 non-inflammatory lesions.	☐	☐
5. Is willing to use the test products as instructed for 24 weeks.	☐	☐
6. Has a Fitzpatrick skin type I-VI	☐	☐
7. Is willing and able to comply with all of the time commitments and procedural requirements of the clinical trial protocol.	☐	☐
8. Is willing to provide written informed consent including photo release, Health Insurance Portability and Accountability Act (HIPAA), and is able to read, speak, write, understand English and is willing to share personal information and data, as verified by signing a written authorization at the screening	☐	☐
9. Is willing to withhold all facial treatments during the course of the study including botulinum toxin, injectable fillers, microdermabrasion, IPL, peels, facials, laser treatments and tightening treatments. Waxing and threading is allowed but not facial laser hair removal.	☐	☐
10. If male, who is a regular shaver and willing to shave on the day of the study visits (prior to clinic visits).	☐	☐
11. If a woman of child bearing potential, is willing to take a urine pregnancy test prior to study enrollment, at week 24, and when deemed appropriate by the Investigator and/or Sponsor.	☐	☐
12. Is of child bearing potential who uses an acceptable method of contraception throughout the study. Acceptable methods of birth control include • Oral and other system contraceptives. Individuals must be on a stable use for 3 months prior to study enrollment. Individuals on oral contraceptives must not alter their use, including dose or regimen for the duration of the study • Double barrier • Bilateral tubal ligation • Partner vasectomy • Abstinence	☐	☐
13. Is willing to follow study requirements and report any changes in health status or medications, adverse event symptoms, or reactions immediately.	☐	☐
14. Must be stable on any medication they are taking for at least 30 days	☐	☐
If any criterion is answered no, **DO NOT** enroll the subject.		

Source Documents			
Galderma	Study # C16-CD020	INVESTIGTOR NAME Barry T. Reece (RCTS, Inc.)	Subject Initials Screening Number

Visit 1 –Screening/Baseline (Day 1)

EXCLUSION CRITERIA		
	Yes*	No
1. Has been diagnosed with allergies to topical acne products.	☐	☐
2. Has a condition and/or disease of the skin that the Investigator deems inappropriate for participation.	☐	☐
3. Is nursing, pregnant, or planning to become pregnant during the study.	☐	☐
4. Have pre-existing or dormant dermatologic conditions on the face (e.g., psoriasis, rosacea, eczema, seborrheic dermatitis, severe excoriations etc.) which in the opinion of the Investigator could interfere with the outcome of the study.	☐	☐
5. Has a history of immunosuppression/immune deficiency disorders (including (HIV infection or AIDS) or currently using immunosuppressive medications (e.g., azathioprine, belimumab, cyclophosphamide, Enbrel, Imuran, Humira, mycophenolate mofetil, methotrexate, prednisone, Remicade, Stelara.).	☐	☐
6. Has an uncontrolled disease such as asthma, diabetes, hypertension, hyperthyroidism, or hypothyroidism. Individuals having multiple health conditions may be excluded from participation even if the conditions are controlled by diet, medication, etc. at the Investigator's discretion.	☐	☐
7. Is currently participating in another facial usage study or has participated in a clinical trial at this or at another research facility or doctor's office within 4 weeks prior to inclusion into the study.	☐	☐
8. Has a history of skin cancer within the past 5 years.	☐	☐
9. Has any planned surgeries and/or invasive medical procedures during the course of the study.	☐	☐
10. Has started hormone replacement therapies (HRT) or hormones for birth control less than 3 months prior to study entry or plans on starting, stopping, or changing doses of HRT or hormones for birth control during the study.	☐	☐
11. Has facial sunburn or excessive tanned facial skin or is not willing to avoid daily sun exposure on the face and the use of tanning beds or sunless tanning products for the duration of the study.	☐	☐
12. Has severe acne, acne conglobata, multiple nodules or cysts (more than 2).	☐	☐
13. Is currently taking a natural or prescription testosterone blocker (e.g. saw palmetto, blask cohosh, chaste tree, chasteberry, spironolactone, drospirenone, progestins).	☐	☐
14. Is currently on a testosterone booster or prescription testosterone (e.g. DHEA, tribulus, testosterone cypionate, testosterone enanthate, Sustanon, testosterone propionate, testosterone phenylpropriate, Omnadren etc.).	☐	☐
(CONTINUED ON NEXT PAGE)		

Source Documents			
Galderma	Study # C16-CD020	INVESTIGTOR NAME Barry T. Reece (RCTS, Inc.)	Subject Initials Screening Number

Visit 1 –Screening/Baseline

EXCLUSION CRITERIA (CONTINUED)		
	Yes*	No
15. Is currently taking or has taken within the last 30 days oral or topical prescription medications for acne such as Doxycycline, Minocycline, Clindamycin, Bactrim, Tetracycline, Erythromycin, Vibramycin and topical tretinoin.(Retin A Renova, Adapalene, Tazarotene), Azelaic acid, benzoyl peroxide, Dapsone, Sodium sulfacetamide, Differin, Epiduo.	☐	☐
16. Has used oral isotretinoin (Accutane) within the past 6-months.	☐	☐
17. Is routinely using (3x a week or more) topical OTC acne product (e.g. benzoyl peroxide, salicylic acid, alpha hydroxyl, beta hydroxyl and/or poly-hydroxy products or medicated cleansers, wipes, masks, scrubs, gels and creams) within 30 days of the study entry.	☐	☐
18. Is using or has used any systemic medication considered to affect the course of acne, specifically, but not exclusively antibiotics or steroids within the last 30 days prior to entry into the study.	☐	☐
19. Has excessive facial hair, including beard, mustache or goatee, or scars, which could interfere with evaluations by Investigator or designee.	☐	☐
*If any criterion is answered **Yes*, <u>DO NOT</u>** enroll the subject.		

Visit 1 – Screening/Baseline

INCLUSION/EXCLUSION

Is the subject eligible per Inclusion/Exclusion criteria?

☐ Yes

☐ No If no, please indicate which Inclusion/Exclusion criteria the subject did not meet and complete End of Study page:

Inclusion #_____ Exclusion #_____

Investigators review

I affirm that all required information has been reviewed by me, deemed accurate and complete and that the subject meets the inclusion/exclusion criteria, and is eligible to be enrolled in the study.

_____ _____-_____-_____

Investigator's Signature DD MMM YYYY

Source Documents			
Galderma	Study # C16-CD020	INVESTIGTOR NAME To be added per site SITE NUMBER To be added per site	Subject Initials Subject Number

Visit 1 –Screening Visit Date: _____-_____-_____
DD-MMM-YYYY

Check In Procedures
Has the subject cleansed their face and removed all makeup at least 30 minutes prior? ☐ Yes ☐ No (If no, subject needs to remove residual makeup and acclimate 20 minutes)
Acclimation
***Reminder:** Subject must acclimate for at least 15 minutes in temperature of 68-75°F and relative humidity range 35-65% before starting assessments, and photography procedures.
Acclimation start time :_____:_____ AM/PM | Acclimation end time :_____:_____ AM/PM
Technician initials:_____ Date(DD-MMM-YYYY):_____

Informed Consent/HIPAA/Photo Release		
Date & Time Consent Obtained	__ __ - __ __ __ - __ __ __ __ DD MMM YYYY	Time: __ __ : __ __ AM / PM
Date of HIPAA Authorization	__ __ - __ __ __ - __ __ __ __ DD MMM YYYY	

	YES	**NO**
Was consent obtained prior to any study related procedure?	☐	☐
Was the consent reviewed with the subject?	☐	☐
Was the subject allowed to ask questions and have them answered?	☐	☐
Did the subject receive a fully executed and signed copy of the consent?	☐	☐
Was the photo release signed?	☐	☐

Demographics		
Sex: ☐ Male ☐ Female	**Date of Birth:** _____ / _____ / _____ DD MMM YYYY	**Must be between 21 and 45 years of age.** **Age (Years):** ___ ___

Race:	**Ethnicity:**
☐American Indian/Alaskan Native ☐Asian ☐Black/African American ☐Native Hawaiian/ other Pacific Islander ☐White ☐Other: (specify) _____	☐ Hispanic or Latino ☐ Not Hispanic or Latino
Fitzpatrick Skin Type (Mark one): ☐ I ☐II ☐ III ☐ IV ☐V ☐VI	

Source Documents			
Galderma	Study # C16-CD020	INVESTIGTOR NAME To be added per site SITE NUMBER To be added per site	Subject Initials ☐☐☐ Subject Number ☐☐☐

All Visits

Medical History Page ☐ 1 ☐ 2 ☐3 ☐4 ☐5 ☐__ ☐ Last Page

☐ Check this box only if there is **NO recent and relevant** medical history and leave the form blank

Enter all recent/relevant past and/or concomitant medical conditions and past surgeries with an onset date prior to Screening. Enter only one condition or surgery per line. When entering a condition and a surgery related to that condition, use one line for the condition and one line for the surgery. Enter all medications taken within 6 months prior to Screening on the concomitant medication page.

A year is required for Date of Diagnosis/Surgery and Resolved. Enter UN for any unknown DD or MMM.

Condition/Diagnosis/Surgery	Date of Diagnosis/Surgery (DD-MMM-YYYY)	Date Resolved (DD-MMM-YYYY)	Ongoing	Physician's initials and date
	___ - ____ - ____ DD - MMM - YYYY	___ - ____ - ____ DD - MMM - YYYY	☐	
	___ - ____ - ____ DD - MMM - YYYY	___ - ____ - ____ DD - MMM - YYYY	☐	
	___ - ____ - ____ DD - MMM - YYYY	___ - ____ - ____ DD - MMM - YYYY	☐	
	___ - ____ - ____ DD - MMM - YYYY	___ - ____ - ____ DD - MMM - YYYY	☐	
	___ - ____ - ____ DD - MMM - YYYY	___ - ____ - ____ DD - MMM - YYYY	☐	
	___ - ____ - ____ DD - MMM - YYYY	___ - ____ - ____ DD - MMM - YYYY	☐	
	___ - ____ - ____ DD - MMM - YYYY	___ - ____ - ____ DD - MMM - YYYY	☐	
	___ - ____ - ____ DD - MMM - YYYY	___ - ____ - ____ DD - MMM - YYYY	☐	

Enter all medications taken within 6 months prior to Screening on the concomitant medication page.

Source Documents			
Galderma	Study # C16-CD020	INVESTIGTOR NAME To be added per site SITE NUMBER To be added per site	Subject Initials Subject Number

All Visits

MEDICATIONS

RECORD ANY MEDICATIONS INCLUDING PRESCRIPTION AND OTC DRUGS TAKEN REGURARLY, INTERMITTITENTLY OR ONE TIME ONLY TAKEN WITHIN 6 MONTHS PRIOR TO SIGING THE ICF UNTIL THE END OF THE STUDY. ***A year is required for Start Date. Enter UN for any unknown DD or MMM.***

Page ☐ 1 ☐ 2 ☐3 ☐4 ☐5 ☐__

Review for prohibited medications use for the last 6 months

☐ Last Page

☐ NONE USED/TAKEN (leave rest of the page blank)

Drug name (Generic or Brand name)	Indication	Used to treat an AE?	Dose	Frequency	Route*	Start Date Stop Date (DD-MMM-YYYY)	Ongoing	Physician's initials and date
		☐ Yes ☐ No				Start ___ ___- ___ ___ ___- ___ ___ ___ Stop ___ ___- ___ ___ ___- ___ ___ ___	☐	
		☐ Yes ☐ No				Start ___ ___- ___ ___ ___- ___ ___ ___ Stop ___ ___- ___ ___ ___- ___ ___ ___	☐	
		☐ Yes ☐ No				Start ___ ___- ___ ___ ___- ___ ___ ___ Stop ___ ___- ___ ___ ___- ___ ___ ___	☐	

*1=oral, 2=topical, 3=subcutaneous, 4=transdermal, 5=Intraocular,6=Intramuscular, 7=Inhalation, 8= Intralesion, 9=Intraperitoneal, 10=Intravenous, 11=Nasal, 12=Vaginal, 13=Rectal,14= Ophthalmic, 15=Unknown, 16=Other

Source Documents			
Galderma	Study # C16-CD020	INVESTIGTOR NAME To be added per site SITE NUMBER To be added per site	Subject Initials Subject Number

Visit 1 – Screening

Qualification Criteria		
Subject must have mild to moderate facial acne (score of 2-3 on FDA Investigator's Global Assessment Scale, at least 5 inflammatory lesions, and 10-100 non-inflammatory lesions		
Does the subject have mild to moderate facial acne?	☐ Yes Score: ___	☐ No
Does the subject have at least 5 inflammatory lesions?	☐ Yes (>5)	☐ No
Does the subject have 10 – 100 non-inflammatory lesions?	☐ Yes (10-100) *	☐ No
Technician initials:_____ Date(DD-MMM-YYYY):_____		

***Tolerability Instructions:** Local cutaneous tolerability will be evaluated by assessing the signs and symptoms of erythema, dryness, and scaling, and by subject reporting of the degree of stinging/burning on the global face (treatment area). (Half-point scores may be used as necessary to more accurately describe the skin condition): 0 = none, 1 = mild, 2 = moderate, 3 = severe

Parameter	**Global Face** **Enter 2 digits for all scores (ie 0.5, 1.0, 2.0)**				
Erythema			.		
Dryness			.		
Scaling			.		
Burning/Stinging			.		
Evaluator's initials:_____ Date(DD-MMM-YYYY):_____					

Source Documents			
Galderma	Study # C16-CD020	INVESTIGTOR NAME To be added per site SITE NUMBER To be added per site	Subject Initials ☐☐☐ Subject Number ☐☐☐

Visit 1 –Screening

INCLUSION CRITERIA	Yes	No*
1. Is a man or woman between the ages of 21 and 45 years of age at the time of enrollment.	☐	☐
2. Has mild to moderate acne (score of 2-3 on FDA Investigator's Global Assessment Scale) on the face.	☐	☐
3. Have at least 5 inflammatory lesions.	☐	☐
4. Have 10 – 100 non-inflammatory lesions.	☐	☐
5. Is willing to use the test products as instructed for 24 weeks.	☐	☐
6. Has a Fitzpatrick skin type I-VI	☐	☐
7. Is willing and able to comply with all of the time commitments and procedural requirements of the clinical trial protocol.	☐	☐
8. Is willing to provide written informed consent including photo release, Health Insurance Portability and Accountability Act (HIPAA), and is able to read, speak, write, understand English and is willing to share personal information and data, as verified by signing a written authorization at the screening	☐	☐
9. Is willing to withhold all facial treatments during the course of the study including botulinum toxin, injectable fillers, microdermabrasion, IPL, peels, facials, laser treatments and tightening treatments. Waxing and threading is allowed but not facial laser hair removal.	☐	☐
10. If male, who is a regular shaver and willing to shave on the day of the study visits (prior to clinic visits).	☐	☐
11. If a woman of child bearing potential, is willing to take a urine pregnancy test prior to study enrollment, at week 24, and when deemed appropriate by the Investigator and/or Sponsor.	☐	☐
12. Is of child bearing potential who uses an acceptable method of contraception throughout the study. Acceptable methods of birth control include • Oral and other system contraceptives. Individuals must be on a stable use for 3 months prior to study enrollment. Individuals on oral contraceptives must not alter their use, including dose or regimen for the duration of the study • Double barrier • Bilateral tubal ligation • Partner vasectomy • Abstinence	☐	☐
13. Is willing to follow study requirements and report any changes in health status or medications, adverse event symptoms, or reactions immediately.	☐	☐
14. Must be stable on any medication they are taking for at least 30 days	☐	☐
If any criterion is answered no, **DO NOT** enroll the subject.		

Source Documents			
Galderma	Study # C16-CD020	INVESTIGTOR NAME To be added per site SITE NUMBER To be added per site	Subject Initials Subject Number

Visit 1 –Screening

EXCLUSION CRITERIA	Yes*	No
1. Has been diagnosed with allergies to topical acne products.	☐	☐
2. Has a condition and/or disease of the skin that the Investigator deems inappropriate for participation.	☐	☐
3. Is nursing, pregnant, or planning to become pregnant during the study.	☐	☐
4. Have pre-existing or dormant dermatologic conditions on the face (e.g., psoriasis, rosacea, eczema, seborrheic dermatitis, severe excoriations etc.) which in the opinion of the Investigator could interfere with the outcome of the study.	☐	☐
5. Has a history of immunosuppression/immune deficiency disorders (including (HIV infection or AIDS) or currently using immunosuppressive medications (e.g., azathioprine, belimumab, cyclophosphamide, Enbrel, Imuran, Humira, mycophenolate mofetil, methotrexate, prednisone, Remicade, Stelara.).	☐	☐
6. Has an uncontrolled disease such as asthma, diabetes, hypertension, hyperthyroidism, or hypothyroidism. Individuals having multiple health conditions may be excluded from participation even if the conditions are controlled by diet, medication, etc. at the Investigator's discretion.	☐	☐
7. Is currently participating in another facial usage study or has participated in a clinical trial at Stephens or at another research facility or doctor's office within 4 weeks prior to inclusion into the study.	☐	☐
8. Has a history of skin cancer within the past 5 years.	☐	☐
9. Has any planned surgeries and/or invasive medical procedures during the course of the study.	☐	☐
10. Has started hormone replacement therapies (HRT) or hormones for birth control less than 3 months prior to study entry or plans on starting, stopping, or changing doses of HRT or hormones for birth control during the study.	☐	☐
11. Has facial sunburn or excessive tanned facial skin or is not willing to avoid daily sun exposure on the face and the use of tanning beds or sunless tanning products for the duration of the study.	☐	☐
12. Has severe acne, acne conglobata, multiple nodules or cysts (more than 2).	☐	☐
13. Is currently taking a natural or prescription testosterone blocker (e.g. saw palmetto, blask cohosh, chaste tree, chasteberry, spironolactone, drospirenone, progestins).	☐	☐
14. Is currently on a testosterone booster or prescription testosterone (e.g. DHEA, tribulus, testosterone cypionate, testosterone enanthate, Sustanon, testosterone propionate, testosterone phenylpropriate, Omnadren etc.).	☐	☐
(CONTINUED ON NEXT PAGE)		

Source Documents			
Galderma	Study # C16-CD020	INVESTIGTOR NAME To be added per site SITE NUMBER To be added per site	Subject Initials Subject Number

Source Documents			
Galderma	Study # C16-CD020	INVESTIGTOR NAME To be added per site SITE NUMBER To be added per site	Subject Initials Subject Number

Visit 1 –Screening

EXCLUSION CRITERIA CONTINUED	Yes*	No
15. Is currently taking or has taken within the last 30 days oral or topical prescription medications for acne such as Doxycycline, Minocycline, Clindamycin, Bactrim, Tetracycline, Erythromycin, Vibramycin and topical tretinoin.(Retin A Renova, Adapalene, Tazarotene), Azelaic acid, benzoyl peroxide, Dapsone, Sodium sulfacetamide, Differin, Epiduo.	☐	☐
16. Has used oral isotretinoin (Accutane) within the past 6-months.	☐	☐
17. Is routinely using (3x a week or more) topical OTC acne product (e.g. benzoyl peroxide, salicylic acid, alpha hydroxyl, beta hydroxyl and/or poly-hydroxy products or medicated cleansers, wipes, masks, scrubs, gels and creams) within 30 days of the study entry.	☐	☐
18. Is using or has used any systemic medication considered to affect the course of acne, specifically, but not exclusively antibiotics or steroids within the last 30 days prior to entry into the study.	☐	☐
19. Has excessive facial hair, including beard, mustache or goatee, or scars, which could interfere with evaluations by Investigator or designee.	☐	☐
*If any criterion is answered **Yes*, <u>DO NOT</u>** enroll the subject.		

Urine Pregnancy Test			
If the candidate subject qualifies and is female of child-bearing potential, conduct a urine pregnancy test. Candidate female subjects with negative results, females of non-child-bearing potential, or candidate males that qualify will proceed to the next step.			
Test Results	**Reason Not Applicable**	**Kit Lot #**	**Kit Expiration date**
☐ Neg ☐ Pos ☐N/A			
Technician initials:_____ Time: _____:_____AM/PM Date(DD-MMM-YYYY):_____ _			

Source Documents			
Galderma	Study # C16-CD020	INVESTIGTOR NAME To be added per site SITE NUMBER To be added per site	Subject Initials Subject Number

Visit 1 –Screening

INCLUSION/EXCLUSION
Is the subject eligible per Inclusion/Exclusion criteria? ☐ Yes ☐ No If no, please indicate which Inclusion/Exclusion criteria the subject did not meet and complete End of Study page: Inclusion #_____ Exclusion #_____

Investigators review
I affirm that all required information has been reviewed by me, deemed accurate and complete and that the subject meets the inclusion/exclusion criteria, and is eligible to be enrolled in the study. _____ _____-_____-_____ Investigator's Signature DD MMM YYYY

Source Documents			
Galderma	Study # C16-CD020	INVESTIGTOR NAME To be added per site SITE NUMBER To be added per site	Subject Initials Subject Number

Visit 2 –Baseline Visit Date: _____-_____-_____
DD-MMM-YYYY

Check In Procedures
Has the subject cleansed their face and removed all makeup at least 30 minutes prior? ☐ Yes ☐ No (If no, subject needs to remove residual makeup and acclimate 20 minutes)
Review of Adverse Events
Has the subject experienced an Adverse Events or medical problems since their last visit? ☐ Yes (If yes, record on AE page) ☐ No Has the subject started or discontinued any concomitant medication since their last visit? ☐ Yes (If yes, record on Medications page) ☐ No Has the subject had any procedures or treatments since their last visit? ☐ Yes (If yes, record on Medications page) ☐ No
Acclimation
***Reminder:** Subject must acclimate for at least 15 minutes in temperature of 68-75°F and relative humidity range 35-65% before starting assessments, and photography procedures.
Acclimation start time :_____:_____ AM/PM | Acclimation end time :_____:_____ AM/PM
Technician initials:_____ Date(DD-MMM-YYYY):_____

Qualification Criteria (confirm that subject still meets eligibility criteria)		
Subject must have mild to moderate facial acne (score of 2-3 on FDA Investigator's Global Assessment Scale, at least 5 inflammatory lesions, and 10-100 non-inflammatory lesions		
Does the subject have mild to moderate facial acne?	☐ Yes Score: ___	☐ No
Does the subject have at least 5 inflammatory lesions?	☐ Yes (>5) *	☐ No
Does the subject have 10 – 100 non-inflammatory lesions?	☐ Yes (10-100) *	☐ No
*If yes, please fill out lesion count on page 10		
Evaluator's initials:_____ Date(DD-MMM-YYYY):_____		

Source Documents			
Galderma	Study # C16-CD020	INVESTIGTOR NAME To be added per site SITE NUMBER To be added per site	Subject Initials Subject Number

Visit 2 –Baseline

Lesion Count

A trained grader will count and record the number of open comedones, closed comedones, papules, and pustules on each subject's face. Note that papules and pustules are classified as inflammatory acne lesions while open and closed comedones are classified as non-inflammatory lesions.
**Lesions on the nose, under the jaw line or along the hairline (including eye brows) will not be included in the counts.*

Parameter	Forehead Enter 2 digits for all scores (ie 05, 10, 20)	Left Cheek Enter 2 digits for all scores (ie 05, 10, 20)	Chin Enter 2 digits for all scores (ie 05, 10, 20)	Right Cheek Enter 2 digits for all scores (ie 05, 10, 20)	Total Enter 3 digits for all scores (ie 050, 099, 100)
Open Comedones					
Closed Comedones					
Papules					
Pustules					
Total					

Evaluator's initials:_____ Date(DD-MMM-YYYY):_____

Investigator's Global Assessment (IGA)

A trained grader will evaluate each subject's global face for Investigator's Global Improvement Assessment.

Scale:

0	Clear	No inflammatory or non-inflammatory lesions
1	Almost Clear	Rare non-inflammatory lesions with no more than one small inflammatory lesion
2	Mild	Greater than Grade 1, some non-inflammatory lesions with no more than a few inflammatory lesion (papules/pustules only, no nodular lesions)
3	Moderate	Greater than Grade 2, up to many non-inflammatory lesions and may have some inflammatory lesions, but no more than one small nodular lesion
4	Severe	Greater than Grade 3, up to many non-inflammatory and inflammatory lesions, but no more than a few nodular lesions

Parameter	Global Face Enter 1 digit for all scores (ie 1, 2, 3)
IGA	

Evaluator's initials:_____ Date(DD-MMM-YYYY):_____

Source Documents			
Galderma	Study # C16-CD020	INVESTIGTOR NAME To be added per site SITE NUMBER To be added per site	Subject Initials Subject Number

Visit 2 –Baseline

***Tolerability Instructions:** Local cutaneous tolerability will be evaluated by assessing the signs and symptoms of erythema, dryness, and scaling, and by subject reporting of the degree of stinging/burning on the global face (treatment area). (Half-point scores may be used as necessary to more accurately describe the skin condition): 0 = none, 1 = mild, 2 = moderate, 3 = severe

Parameter	**Global Face** **Enter 2 digits for all scores (ie 0.5, 1.0, 2.0)**
Erythema	.
Dryness	.
Scaling	.
Burning/Stinging	.

Evaluator's initials:_____ Date(DD-MMM-YYYY):_____

VISIA Imaging – 1 2 3 Stephens TX site only, delete if not needed

***Reminder:** Subject must have a clean face (no makeup) and all jewelry removed. Subject must be wearing a black or gray matte headband to keep hair away from the face. Subject must be wearing a black matte shirt or draped with a black or gray matte cloth to hide clothing. Subjects must have a neutral, non-smiling expression with their eyes gently closed in all pictures.

Please mark the box for each photo that was taken. If one was not taken, leave box unmarked.

Left View:	**Center View:**	**Right View:**
☐ Standard Lighting 1 (visible)	☐ Standard Lighting 1 (visible)	☐ Standard Lighting 1 (visible)
☐ Standard Lighting 2 (visible)	☐ Standard Lighting 2 (visible)	☐ Standard Lighting 2 (visible)
☐Cross Polarized	☐Cross Polarized	☐Cross Polarized
☐Parallel Polarized	☐Parallel Polarized	☐Parallel Polarized
☐ UV Fluorescence	☐ UV Fluorescence	☐UV Fluorescence

Seat height: _____ cm

Headrest: 1 2 3 (circle one)

Technician initials:_____ Time: _____:_____AM/PM Date(DD-MMM-YYYY):_____ _

Source Documents			
Galderma	Study # C16-CD020	INVESTIGTOR NAME To be added per site SITE NUMBER To be added per site	Subject Initials Subject Number

Visible Light Imaging (Beauty shot) **Stephens sites only, delete if not needed**

For subjects completing at sites 1 and 2 (Stephens' Texas and Colorado locations), digital images will be taken of each subject's face using visible light. Full-face images will be taken of each subject's center view. Subjects will not be wearing any headband or using any headrest/chinrest. Subjects will be instructed to adopt neutral, non-smiling expressions with their eyes open.

Please mark the box for each photo that was taken. If one was not taken, leave box unmarked.

Center View:	
☐ Visible light	Seat height: _____ Camera height: _____

Technician initials:_____ Time: _____:_____AM/PM Date(DD-MMM-YYYY):_____ _

Product Distribution		
Randomization Group: A / B (circle one)		
Was the subject provided instructions on how to properly use the study products?	☐ Yes	☐ No
Was the subject provided with a daily diary to record product application?	☐ Yes	☐ No
Was the subject instructed to bring back the dispensed study products at the next visit?	☐ Yes	☐ No

Technician initials:_____ Time: _____:_____AM/PM Date(DD-MMM-YYYY):_____ _

Source Documents			
Galderma	Study # C16-CD020	INVESTIGTOR NAME To be added per site SITE NUMBER To be added per site	Subject Initials Subject Number

Visit 3 – Week 1 Visit Date: _____-_____-_____
DD-MMM-YYYY

Check In Procedures
Has the subject cleansed their face and removed all makeup at least 30 minutes prior? ☐ Yes ☐ No (If no, subject needs to remove residual makeup and acclimate 20 minutes) Have the subject's test materials been visually inspected and weighed? **Record weights in Test Material Sheet** ☐ Yes ☐ No Has the subject's diary been reviewed for compliance? ☐ Yes ☐ No Has the subject been instructed to bring back the dispensed study products at the next visit? ☐ Yes ☐ No
Review of Adverse Events
Has the subject experienced an Adverse Events or medical problems since their last visit? ☐ Yes (If yes, record on AE page) ☐ No Has the subject started or discontinued any concomitant medication since their last visit? ☐ Yes (If yes, record on Medications page) ☐ No Has the subject had any procedures or treatments since their last visit? ☐ Yes (If yes, record on Medications page) ☐ No
Acclimation
***Reminder:** Subject must acclimate for at least 15 minutes in temperature of 68-75°F and relative humidity range 35-65% before starting assessments, and photography procedures.
Acclimation start time :_____:_____ AM/PM | Acclimation end time :_____:_____ AM/PM
Technician initials:_____ Date(DD-MMM-YYYY):_____

Source Documents			
Galderma	Study # C16-CD020	INVESTIGTOR NAME To be added per site SITE NUMBER To be added per site	Subject Initials Subject Number

Visit 3 – Week 1 Visit Date: _____-_____-_____
DD-MMM-YYYY

Lesion Count

A trained grader will count and record the number of open comedones, closed comedones, papules, and pustules on each subject's face. Note that papules and pustules are classified as inflammatory acne lesions while open and closed comedones are classified as non-inflammatory lesions.
**Lesions on the nose, under the jaw line or along the hairline (including eye brows) will not be included in the counts.*

Parameter	Forehead Enter 2 digits for all scores (ie 05, 10, 20)		Left Cheek Enter 2 digits for all scores (ie 05, 10, 20)		Chin Enter 2 digits for all scores (ie 05, 10, 20)		Right Cheek Enter 2 digits for all scores (ie 05, 10, 20)		Total Enter 3 digits for all scores (ie 050, 099, 100)		
Open Comedones											
Closed Comedones											
Papules											
Pustules											
Total											

Evaluator's initials:_____ Date(DD-MMM-YYYY):_____

Investigator's Global Assessment (IGA)

A trained grader will evaluate each subject's global face for Investigator's Global Improvement Assessment.

Scale:

0	Clear	No inflammatory or non-inflammatory lesions
1	Almost Clear	Rare non-inflammatory lesions with no more than one small inflammatory lesion
2	Mild	Greater than Grade 1, some non-inflammatory lesions with no more than a few inflammatory lesion (papules/pustules only, no nodular lesions)
3	Moderate	Greater than Grade 2, up to many non-inflammatory lesions and may have some inflammatory lesions, but no more than one small nodular lesion
4	Severe	Greater than Grade 3, up to many non-inflammatory and inflammatory lesions, but no more than a few nodular lesions

Parameter	Global Face Enter 1 digit for all scores (ie 1, 2, 3)		
IGA			

Evaluator's initials:_____ Date(DD-MMM-YYYY):_____

Source Documents			
Galderma	Study # C16-CD020	INVESTIGTOR NAME To be added per site SITE NUMBER To be added per site	Subject Initials Subject Number

Visit 3 – Week 1

***Tolerability Instructions:** Local cutaneous tolerability will be evaluated by assessing the signs and symptoms of erythema, dryness, and scaling, and by subject reporting of the degree of stinging/burning on the global face (treatment area). (Half-point scores may be used as necessary to more accurately describe the skin condition): 0 = none, 1 = mild, 2 = moderate, 3 = severe

Parameter	**Global Face** **Enter 2 digits for all scores (ie 0.5, 1.0, 2.0)**
Erythema	.
Dryness	.
Scaling	.
Burning/Stinging	.

Evaluator's initials:_____ Date(DD-MMM-YYYY):_____

Self-Assessment Questionnaire		
Has the subject completed the self-assessment questionnaire?	☐ Yes	☐ No

Technician initials:_____ Date(DD-MMM-YYYY):_____

Source Documents			
Galderma	Study # C16-CD020	INVESTIGTOR NAME To be added per site SITE NUMBER To be added per site	Subject Initials Subject Number

Visit 4 – Week 2 Visit Date: _____-_____-_____
DD-MMM-YYYY

Check In Procedures
Has the subject cleansed their face and removed all makeup at least 30 minutes prior? ☐ Yes ☐ No (If no, subject needs to remove residual makeup and acclimate 20 minutes) Have the subject's test materials been visually inspected and weighed? **Record weights in Test Material Sheet** ☐ Yes ☐ No Has the subject's diary been reviewed for compliance? ☐ Yes ☐ No Has the subject been instructed to bring back the dispensed study products at the next visit? ☐ Yes ☐ No
Review of Adverse Events
Has the subject experienced an Adverse Events or medical problems since their last visit? ☐ Yes (If yes, record on AE page) ☐ No Has the subject started or discontinued any concomitant medication since their last visit? ☐ Yes (If yes, record on Medications page) ☐ No Has the subject had any procedures or treatments since their last visit? ☐ Yes (If yes, record on Medications page) ☐ No
Acclimation
***Reminder:** Subject must acclimate for at least 15 minutes in temperature of 68-75°F and relative humidity range 35-65% before starting assessments, and photography procedures.
Acclimation start time :_____:_____ AM/PM | Acclimation end time :_____:_____ AM/PM
Technician initials:_____ Date(DD-MMM-YYYY):_____

Source Documents			
Galderma	Study # C16-CD020	INVESTIGTOR NAME To be added per site SITE NUMBER To be added per site	Subject Initials Subject Number

Visit 4 – Week 2

Lesion Count

A trained grader will count and record the number of open comedones, closed comedones, papules, and pustules on each subject's face. Note that papules and pustules are classified as inflammatory acne lesions while open and closed comedones are classified as non-inflammatory lesions.
**Lesions on the nose, under the jaw line or along the hairline (including eye brows) will not be included in the counts.*

Parameter	Forehead Enter 2 digits for all scores (ie 05, 10, 20)		Left Cheek Enter 2 digits for all scores (ie 05, 10, 20)		Chin Enter 2 digits for all scores (ie 05, 10, 20)		Right Cheek Enter 2 digits for all scores (ie 05, 10, 20)		Total Enter 3 digits for all scores (ie 050, 099, 100)		
Open Comedones											
Closed Comedones											
Papules											
Pustules											
Total											

Evaluator's initials:_____ Date(DD-MMM-YYYY):_____

Investigator's Global Assessment (IGA)

A trained grader will evaluate each subject's global face for Investigator's Global Improvement Assessment.

Scale:

0	Clear	No inflammatory or non-inflammatory lesions
1	Almost Clear	Rare non-inflammatory lesions with no more than one small inflammatory lesion
2	Mild	Greater than Grade 1, some non-inflammatory lesions with no more than a few inflammatory lesion (papules/pustules only, no nodular lesions)
3	Moderate	Greater than Grade 2, up to many non-inflammatory lesions and may have some inflammatory lesions, but no more than one small nodular lesion
4	Severe	Greater than Grade 3, up to many non-inflammatory and inflammatory lesions, but no more than a few nodular lesions

Parameter	Global Face Enter 1 digit for all scores (ie 1, 2, 3)		
IGA			

Evaluator's initials:_____ Date(DD-MMM-YYYY):_____

Source Documents			
Galderma	Study # C16-CD020	INVESTIGTOR NAME To be added per site SITE NUMBER To be added per site	Subject Initials Subject Number

Visit 4 – Week 2

***Tolerability Instructions:** Local cutaneous tolerability will be evaluated by assessing the signs and symptoms of erythema, dryness, and scaling, and by subject reporting of the degree of stinging/burning on the global face (treatment area). (Half-point scores may be used as necessary to more accurately describe the skin condition): 0 = none, 1 = mild, 2 = moderate, 3 = severe

Parameter	**Global Face** **Enter 2 digits for all scores (ie 0.5, 1.0, 2.0)**
Erythema	
Dryness	
Scaling	
Burning/Stinging	

Evaluator's initials:_____ Date(DD-MMM-YYYY):_____

Self-Assessment Questionnaire		
Has the subject completed the self-assessment questionnaire?	☐ Yes	☐ No

Technician initials:_____ Date(DD-MMM-YYYY):_____

Source Documents			
Galderma	Study # C16-CD020	INVESTIGTOR NAME To be added per site SITE NUMBER To be added per site	Subject Initials Subject Number

Visit 5 – Week 6 Visit Date: _____-_____-_____
DD-MMM-YYYY

Check In Procedures

Has the subject cleansed their face and removed all makeup at least 30 minutes prior?
☐ Yes ☐ No (If no, subject needs to remove residual makeup and acclimate 20 minutes)

Have the subject's test materials been visually inspected and weighed? **Record weights in Test Material Sheet**
☐ Yes ☐ No

Has the subject's diary been reviewed for compliance?
☐ Yes ☐ No

Has the subject been given a new diary?
☐ Yes ☐ No

Has the subject been instructed to bring back the dispensed study products at the next visit?
☐ Yes ☐ No

Review of Adverse Events

Has the subject experienced an Adverse Events or medical problems since their last visit?
☐ Yes (If yes, record on AE page) ☐ No

Has the subject started or discontinued any concomitant medication since their last visit?
☐ Yes (If yes, record on Medications page) ☐ No

Has the subject had any procedures or treatments since their last visit?
☐ Yes (If yes, record on Medications page) ☐ No

Acclimation

***Reminder:** Subject must acclimate for at least 15 minutes in temperature of 68-75°F and relative humidity range 35-65% before starting assessments, and photography procedures.

Acclimation start time :_____:_____ AM/PM	Acclimation end time :_____:_____ AM/PM

Technician initials:_____ Date(DD-MMM-YYYY):_____

Source Documents			
Galderma	Study # C16-CD020	INVESTIGTOR NAME To be added per site SITE NUMBER To be added per site	Subject Initials Subject Number

Visit 5 – Week 6

VISIA Imaging		
***Reminder:** Subject must have a clean face (no makeup) and all jewelry removed. Subject must be wearing a black or gray matte headband to keep hair away from the face. Subject must be wearing a black matte shirt or draped with a black or gray matte cloth to hide clothing. Subjects must have a neutral, non-smiling expression with their eyes gently closed in all pictures.		
Please mark the box for each photo that was taken. If one was not taken, leave box unmarked.		
Left View: ☐ Standard Lighting 1 (visible) ☐ Standard Lighting 2 (visible) ☐Cross Polarized ☐Parallel Polarized ☐ UV Fluorescence	**Center View:** ☐ Standard Lighting 1 (visible) ☐ Standard Lighting 2 (visible) ☐Cross Polarized ☐Parallel Polarized ☐ UV Fluorescence	**Right View:** ☐ Standard Lighting 1 (visible) ☐ Standard Lighting 2 (visible) ☐Cross Polarized ☐Parallel Polarized ☐ UV Fluorescence
Seat height: _____ cm	Headrest: 1 2 3 (circle one)	
Technician initials:_____ Time: _____:_____AM/PM Date(DD-MMM-YYYY):_____ _		

Source Documents			
Galderma	Study # C16-CD020	INVESTIGTOR NAME To be added per site SITE NUMBER To be added per site	Subject Initials Subject Number

Visit 5 – Week 6

Lesion Count

A trained grader will count and record the number of open comedones, closed comedones, papules, and pustules on each subject's face. Note that papules and pustules are classified as inflammatory acne lesions while open and closed comedones are classified as non-inflammatory lesions.
**Lesions on the nose, under the jaw line or along the hairline (including eye brows) will not be included in the counts.*

Parameter	Forehead Enter 2 digits for all scores (ie 05, 10, 20)		Left Cheek Enter 2 digits for all scores (ie 05, 10, 20)		Chin Enter 2 digits for all scores (ie 05, 10, 20)		Right Cheek Enter 2 digits for all scores (ie 05, 10, 20)		Total Enter 3 digits for all scores (ie 050, 099, 100)		
Open Comedones											
Closed Comedones											
Papules											
Pustules											
Total											

Evaluator's initials:_____ Date(DD-MMM-YYYY):_____

Investigator's Global Assessment (IGA)

A trained grader will evaluate each subject's global face for Investigator's Global Improvement Assessment.

Scale:

0	Clear	No inflammatory or non-inflammatory lesions
1	Almost Clear	Rare non-inflammatory lesions with no more than one small inflammatory lesion
2	Mild	Greater than Grade 1, some non-inflammatory lesions with no more than a few inflammatory lesion (papules/pustules only, no nodular lesions)
3	Moderate	Greater than Grade 2, up to many non-inflammatory lesions and may have some inflammatory lesions, but no more than one small nodular lesion
4	Severe	Greater than Grade 3, up to many non-inflammatory and inflammatory lesions, but no more than a few nodular lesions

Parameter	Global Face Enter 1 digit for all scores (ie 1, 2, 3)		
IGA			

Evaluator's initials:_____ Date(DD-MMM-YYYY):_____

Source Documents			
Galderma	Study # C16-CD020	INVESTIGTOR NAME To be added per site SITE NUMBER To be added per site	Subject Initials Subject Number

Visit 5 – Week 6

***Tolerability Instructions:** Local cutaneous tolerability will be evaluated by assessing the signs and symptoms of erythema, dryness, and scaling, and by subject reporting of the degree of stinging/burning on the global face (treatment area). (Half-point scores may be used as necessary to more accurately describe the skin condition): 0 = none, 1 = mild, 2 = moderate, 3 = severe

Parameter	**Global Face** **Enter 2 digits for all scores (ie 0.5, 1.0, 2.0)**
Erythema	
Dryness	
Scaling	
Burning/Stinging	

Technician initials:_____ Date (DD-MMM-YYYY):_____ _

Self-Assessment Questionnaire		
Has the subject completed the self-assessment questionnaire?	☐ Yes	☐ No

Technician initials:_____ Date(DD-MMM-YYYY):_____

Source Documents			
Galderma	Study # C16-CD020	INVESTIGTOR NAME To be added per site SITE NUMBER To be added per site	Subject Initials Subject Number

Follow-up Phone Call (between Week 6 and Week 12)

Review of Adverse Events

Has the subject experienced an Adverse Events or medical problems since their last visit?
☐ Yes (If yes, record on AE page) ☐ No

Has the subject started or discontinued any concomitant medication since their last visit?
☐ Yes (If yes, record on Medications page) ☐ No

Has the subject had any procedures or treatments since their last visit?
☐ Yes (If yes, record on Medications page) ☐ No

Does the subject have enough study product to until the next study visit?
☐ Yes ☐ No

Technician initials:_____ Date(DD-MMM-YYYY):_____

Source Documents			
Galderma	Study # C16-CD020	INVESTIGTOR NAME To be added per site SITE NUMBER To be added per site	Subject Initials Subject Number

Visit 6 – Week 12 Visit Date: _____-_____-_____
DD-MMM-YYYY

Check In Procedures

Has the subject cleansed their face and removed all makeup at least 30 minutes prior?
☐ Yes ☐ No (If no, subject needs to remove residual makeup and acclimate 20 minutes)

Have the subject's test materials been visually inspected and weighed? **Record weights in Test Material Sheet**
☐ Yes ☐ No

Has the subject's diary been reviewed for compliance?
☐ Yes ☐ No

Has the subject been given a new diary?
☐ Yes ☐ No

Has the subject been instructed to bring back the dispensed study products at the next visit?
☐ Yes ☐ No

Review of Adverse Events

Has the subject experienced an Adverse Events or medical problems since their last visit?
☐ Yes (If yes, record on AE page) ☐ No

Has the subject started or discontinued any concomitant medication since their last visit?
☐ Yes (If yes, record on Medications page) ☐ No

Has the subject had any procedures or treatments since their last visit?
☐ Yes (If yes, record on Medications page) ☐ No

Acclimation

***Reminder:** Subject must acclimate for at least 15 minutes in temperature of 68-75°F and relative humidity range 35-65% before starting assessments, and photography procedures.

Acclimation start time :_____:_____ AM/PM	Acclimation end time :_____:_____ AM/PM

Technician initials:_____ Date(DD-MMM-YYYY):_____

Source Documents			
Galderma	Study # C16-CD020	INVESTIGTOR NAME To be added per site SITE NUMBER To be added per site	Subject Initials Subject Number

Visit 6 – Week 12

VISIA Imaging		
***Reminder:** Subject must have a clean face (no makeup) and all jewelry removed. Subject must be wearing a black or gray matte headband to keep hair away from the face. Subject must be wearing a black matte shirt or draped with a black or gray matte cloth to hide clothing. Subjects must have a neutral, non-smiling expression with their eyes gently closed in all pictures.		
Please mark the box for each photo that was taken. If one was not taken, leave box unmarked.		
Left View: ☐ Standard Lighting 1 (visible) ☐ Standard Lighting 2 (visible) ☐Cross Polarized ☐Parallel Polarized ☐ UV Fluorescence	**Center View:** ☐ Standard Lighting 1 (visible) ☐ Standard Lighting 2 (visible) ☐Cross Polarized ☐Parallel Polarized ☐ UV Fluorescence	**Right View:** ☐ Standard Lighting 1 (visible) ☐ Standard Lighting 2 (visible) ☐Cross Polarized ☐Parallel Polarized ☐ UV Fluorescence
Seat height: _____ cm	Headrest: 1 2 3 (circle one)	
Technician initials:_____ Time: _____:_____AM/PM Date(DD-MMM-YYYY):_____ _		

Visible Light Imaging (Beauty shot) Stephens sites only, delete if not needed	
For subjects completing at sites 1 and 2 (Stephens' Texas and Colorado locations), digital images will be taken of each subject's face using visible light. Full-face images will be taken of each subject's center view. Subjects will not be wearing any headband or using any headrest/chinrest. Subjects will be instructed to adopt neutral, non-smiling expressions with their eyes open.	
Please mark the box for each photo that was taken. If one was not taken, leave box unmarked.	
Center View: ☐ Visible light	Seat height: _____ Camera height: _____
Technician initials:_____ Time: _____:_____AM/PM Date(DD-MMM-YYYY):_____ _	

Source Documents			
Galderma	Study # C16-CD020	INVESTIGTOR NAME To be added per site SITE NUMBER To be added per site	Subject Initials Subject Number

Visit 6 – Week 12

Lesion Count

A trained grader will count and record the number of open comedones, closed comedones, papules, and pustules on each subject's face. Note that papules and pustules are classified as inflammatory acne lesions while open and closed comedones are classified as non-inflammatory lesions.
**Lesions on the nose, under the jaw line or along the hairline (including eye brows) will not be included in the counts.*

Parameter	Forehead Enter 2 digits for all scores (ie 05, 10, 20)		Left Cheek Enter 2 digits for all scores (ie 05, 10, 20)		Chin Enter 2 digits for all scores (ie 05, 10, 20)		Right Cheek Enter 2 digits for all scores (ie 05, 10, 20)		Total Enter 3 digits for all scores (ie 050, 099, 100)		
Open Comedones											
Closed Comedones											
Papules											
Pustules											
Total											

Evaluator's initials:_____ Date(DD-MMM-YYYY):_____

Investigator's Global Assessment (IGA)

A trained grader will evaluate each subject's global face for Investigator's Global Improvement Assessment.

Scale:

0	Clear	No inflammatory or non-inflammatory lesions
1	Almost Clear	Rare non-inflammatory lesions with no more than one small inflammatory lesion
2	Mild	Greater than Grade 1, some non-inflammatory lesions with no more than a few inflammatory lesion (papules/pustules only, no nodular lesions)
3	Moderate	Greater than Grade 2, up to many non-inflammatory lesions and may have some inflammatory lesions, but no more than one small nodular lesion
4	Severe	Greater than Grade 3, up to many non-inflammatory and inflammatory lesions, but no more than a few nodular lesions

Parameter	Global Face Enter 1 digit for all scores (ie 1, 2, 3)		
IGA			

Evaluator's initials:_____ Date(DD-MMM-YYYY):_____

Source Documents			
Galderma	Study # C16-CD020	INVESTIGTOR NAME To be added per site SITE NUMBER To be added per site	Subject Initials Subject Number

Visit 6 – Week 12

***Tolerability Instructions:** Local cutaneous tolerability will be evaluated by assessing the signs and symptoms of erythema, dryness, and scaling, and by subject reporting of the degree of stinging/burning on the global face (treatment area). (Half-point scores may be used as necessary to more accurately describe the skin condition): 0 = none, 1 = mild, 2 = moderate, 3 = severe

Parameter	**Global Face** **Enter 2 digits for all scores (ie 0.5, 1.0, 2.0)**
Erythema	
Dryness	
Scaling	
Burning/Stinging	

Evaluator's initials:_____ Date(DD-MMM-YYYY):_____

Self-Assessment Questionnaire		
Has the subject completed the self-assessment questionnaire?	☐ Yes	☐ No

Technician initials:_____ Date(DD-MMM-YYYY):_____

Source Documents			
Galderma	Study # C16-CD020	INVESTIGTOR NAME To be added per site SITE NUMBER To be added per site	Subject Initials Subject Number

Visit 7 – Week 18 Visit Date: _____-_____-_____
DD-MMM-YYYY

Check In Procedures

Has the subject cleansed their face and removed all makeup at least 30 minutes prior?
☐ Yes ☐ No (If no, subject needs to remove residual makeup and acclimate 20 minutes)

Have the subject's test materials been visually inspected and weighed? **Record weights in Test Material Sheet**
☐ Yes ☐ No

Has the subject's diary been reviewed for compliance?
☐ Yes ☐ No

Has the subject been given a new diary?
☐ Yes ☐ No

Has the subject been instructed to bring back the dispensed study products at the next visit?
☐ Yes ☐ No

Review of Adverse Events

Has the subject experienced an Adverse Events or medical problems since their last visit?
☐ Yes (If yes, record on AE page) ☐ No

Has the subject started or discontinued any concomitant medication since their last visit?
☐ Yes (If yes, record on Medications page) ☐ No

Has the subject had any procedures or treatments since their last visit?
☐ Yes (If yes, record on Medications page) ☐ No

Technician initials:_____ Date(DD-MMM-YYYY):_____

Source Documents			
Galderma	Study # C16-CD020	INVESTIGTOR NAME To be added per site SITE NUMBER To be added per site	Subject Initials Subject Number

Visit 8 – Week 24 Visit Date: _____-_____-_____
DD-MMM-YYYY

Check In Procedures
Has the subject cleansed their face and removed all makeup at least 30 minutes prior? ☐ Yes ☐ No (If no, subject needs to remove residual makeup and acclimate 20 minutes) Have the subject's test materials been visually inspected and weighed? **Record weights in Test Material Sheet** ☐ Yes ☐ No Has the subject's diary been reviewed for compliance? ☐ Yes ☐ No
Review of Adverse Events
Has the subject experienced an Adverse Events or medical problems since their last visit? ☐ Yes (If yes, record on AE page) ☐ No Has the subject started or discontinued any concomitant medication since their last visit? ☐ Yes (If yes, record on Medications page) ☐ No Has the subject had any procedures or treatments since their last visit? ☐ Yes (If yes, record on Medications page) ☐ No
Acclimation
***Reminder:** Subject must acclimate for at least 15 minutes in temperature of 68-75°F and relative humidity range 35-65% before starting assessments, and photography procedures.
Acclimation start time :_____:_____ AM/PM | Acclimation end time :_____:_____ AM/PM
Technician initials:_____ Date(DD-MMM-YYYY):_____

Urine Pregnancy Test			
If the subject is a female of child-bearing potential, conduct a urine pregnancy test.			
Test Results	**Reason Not Applicable**	**Kit Lot #**	**Kit Expiration date**
☐ Neg ☐ Pos ☐ N/A			
Technician initials:_____ Time: _____:_____AM/PM Date(DD-MMM-YYYY):_____ _			

Source Documents			
Galderma	Study # C16-CD020	INVESTIGTOR NAME To be added per site SITE NUMBER To be added per site	Subject Initials Subject Number

Visit 8 – Week 24

VISIA Imaging		
***Reminder:** Subject must have a clean face (no makeup) and all jewelry removed. Subject must be wearing a black or gray matte headband to keep hair away from the face. Subject must be wearing a black matte shirt or draped with a black or gray matte cloth to hide clothing. Subjects must have a neutral, non-smiling expression with their eyes gently closed in all pictures.		
Please mark the box for each photo that was taken. If one was not taken, leave box unmarked.		
Left View: ☐ Standard Lighting 1 (visible) ☐ Standard Lighting 2 (visible) ☐Cross Polarized ☐Parallel Polarized ☐ UV Fluorescence	**Center View:** ☐ Standard Lighting 1 (visible) ☐ Standard Lighting 2 (visible) ☐Cross Polarized ☐Parallel Polarized ☐ UV Fluorescence	**Right View:** ☐ Standard Lighting 1 (visible) ☐ Standard Lighting 2 (visible) ☐Cross Polarized ☐Parallel Polarized ☐ UV Fluorescence
Seat height: _____ cm	Headrest: 1 2 3 (circle one)	
Technician initials:_____ Time: _____:_____AM/PM Date(DD-MMM-YYYY):_____ _		

Visible Light Imaging (Beauty shot) – Stephens sites only, delete if not needed	
For subjects completing at sites 1 and 2 (Stephens' Texas and Colorado locations), digital images will be taken of each subject's face using visible light. Full-face images will be taken of each subject's center view. Subjects will not be wearing any headband or using any headrest/chinrest. Subjects will be instructed to adopt neutral, non-smiling expressions with their eyes open.	
Please mark the box for each photo that was taken. If one was not taken, leave box unmarked.	
Center View: ☐ Visible light	Seat height: _____ Camera height: _____
Technician initials:_____ Time: _____:_____AM/PM Date(DD-MMM-YYYY):_____ _	

Source Documents			
Galderma	Study # C16-CD020	INVESTIGTOR NAME To be added per site SITE NUMBER To be added per site	Subject Initials Subject Number

Visit 8 – Week 24

Lesion Count

A trained grader will count and record the number of open comedones, closed comedones, papules, and pustules on each subject's face. Note that papules and pustules are classified as inflammatory acne lesions while open and closed comedones are classified as non-inflammatory lesions.
**Lesions on the nose, under the jaw line or along the hairline (including eye brows) will not be included in the counts.*

Parameter	Forehead Enter 2 digits for all scores (ie 05, 10, 20)		Left Cheek Enter 2 digits for all scores (ie 05, 10, 20)		Chin Enter 2 digits for all scores (ie 05, 10, 20)		Right Cheek Enter 2 digits for all scores (ie 05, 10, 20)		Total Enter 3 digits for all scores (ie 050, 099, 100)		
Open Comedones											
Closed Comedones											
Papules											
Pustules											
Total											

Evaluator's initials:_____ Date(DD-MMM-YYYY):_____

Investigator's Global Assessment (IGA)

A trained grader will evaluate each subject's global face for Investigator's Global Improvement Assessment.

Scale:

0	Clear	No inflammatory or non-inflammatory lesions
1	Almost Clear	Rare non-inflammatory lesions with no more than one small inflammatory lesion
2	Mild	Greater than Grade 1, some non-inflammatory lesions with no more than a few inflammatory lesion (papules/pustules only, no nodular lesions)
3	Moderate	Greater than Grade 2, up to many non-inflammatory lesions and may have some inflammatory lesions, but no more than one small nodular lesion
4	Severe	Greater than Grade 3, up to many non-inflammatory and inflammatory lesions, but no more than a few nodular lesions

Parameter	Global Face Enter 1 digit for all scores (ie 1, 2, 3)		
IGA			

Evaluator's initials:_____ Date (DD-MMM-YYYY):_____ _

Source Documents			
Galderma	Study # C16-CD020	INVESTIGTOR NAME To be added per site SITE NUMBER To be added per site	Subject Initials Subject Number

Visit 8 – Week 24

***Tolerability Instructions:** Local cutaneous tolerability will be evaluated by assessing the signs and symptoms of erythema, dryness, and scaling, and by subject reporting of the degree of stinging/burning on the global face (treatment area). (Half-point scores may be used as necessary to more accurately describe the skin condition): 0 = none, 1 = mild, 2 = moderate, 3 = severe

Parameter	**Global Face** **Enter 2 digits for all scores (ie 0.5, 1.0, 2.0)**
Erythema	.
Dryness	.
Scaling	.
Burning/Stinging	.

Evaluator's initials:_____ Date (DD-MMM-YYYY):_____ _

Self-Assessment Questionnaire		
Has the subject completed the self-assessment questionnaire?	☐ Yes	☐ No

Technician initials:_____ Date(DD-MMM-YYYY):_____

Source Documents			
Galderma	Study # C16-CD020	INVESTIGTOR NAME To be added per site SITE NUMBER To be added per site	Subject Initials Subject Number

Test Material Sheet

Kit #:_____ Date Dispensed: _____ Date Returned: _____	Pre-Weight	Week 1	Week 2	Week 6
Product: ☐A ☐B (check one)	g	g	g	g
Facial Cleanser	g	g	g	g
Moisturizing Lotion	g	g	g	g
Facial Moisturizer SPF 30	g	g	g	g
Staff Initials / Date				

Kit #:_____ Date Dispensed: _____ Date Returned: _____	Pre-Weight	Week 12
Product: ☐A ☐B (check one)	g	g
Facial Cleanser	g	g
Moisturizing Lotion	g	g
Facial Moisturizer SPF 30	g	g
Staff Initials / Date		

Kit #:_____ Date Dispensed: _____ Date Returned: _____	Pre-Weight	Week 18
Product: ☐A ☐B (check one)	g	g
Facial Cleanser	g	g
Moisturizing Lotion	g	g
Facial Moisturizer SPF 30	g	g
Staff Initials / Date		

Kit #:_____ Date Dispensed: _____ Date Returned: _____	Pre-Weight	Week 24
Product: ☐A ☐B (check one)	g	g
Facial Cleanser	g	g
Moisturizing Lotion	g	g
Facial Moisturizer SPF 30	g	g
Staff Initials / Date		

Kit #:_____ Date Dispensed: _____ Date Returned: _____	Pre-Weight	Unscheduled
Product: ☐A ☐B (check one)	g	g
Facial Cleanser	g	g
Moisturizing Lotion	g	g
Facial Moisturizer SPF 30	g	g
Staff Initials / Date		

Source Documents			
Galderma	Study # C16-CD020	INVESTIGTOR NAME To be added per site SITE NUMBER To be added per site	Subject Initials Subject Number

Adverse Events

FROM TIME CONSENTED UNTIL STUDY EXIT

Page ☐ 1 ☐ 2 ☐3 ☐4 ☐5 ☐__

☐ Last Page

Did the subject report any adverse events? ☐Yes (complete form) ☐No (if no, leave the rest of the form blank)

Adverse Event	**Onset Date** DD-MMM-YYY	**Cessation Date** DD-MMM-YYY	**Serious**	**Severity**	**Relation to Investigational product**	**Action Taken with Investigational Product**	**Treatment Taken** If yes, complete Concomitant medication form	**Outcome**
1.			☐No ☐Yes*	☐Mild ☐Moderate ☐Severe	☐Reasonable possibility ☐No Reasonable possibility	☐None ☐Modified Use ☐Interrupted ☐Discontinued ☐Not Applicable	☐No ☐Yes	☐Resolved ☐Ongoing ☐Fatal ☐Unknown
2.			☐No ☐Yes*	☐Mild ☐Moderate ☐Severe	☐Reasonable possibility ☐No Reasonable possibility	☐None ☐Modified Use ☐Interrupted ☐Discontinued ☐Not Applicable	☐No ☐Yes	☐Resolved ☐Ongoing ☐Fatal ☐Unknown
3.			☐No ☐Yes*	☐Mild ☐Moderate ☐Severe	☐Reasonable possibility ☐No Reasonable possibility	☐None ☐Modified Use ☐Interrupted ☐Discontinued ☐Not Applicable	☐No ☐Yes	☐Resolved ☐Ongoing ☐Fatal ☐Unknown
4.			☐No ☐Yes*	☐Mild ☐Moderate ☐Severe	☐Reasonable possibility ☐No Reasonable possibility	☐None ☐Modified Use ☐Interrupted ☐Discontinued ☐Not Applicable	☐No ☐Yes	☐Resolved ☐Ongoing ☐Fatal ☐Unknown

*Serious AEs only (must notify Sponsor within 24 hours):

☐Death
☐ Life Threatening
☐Inpatient Hospitalization
☐Prolonged Hospitalization
☐Persistent or Significant disability/incapacity
☐Congenital anomaly/birth defect
☐Other Medically Important Event

Source Documents			
Galderma	Study # C16-CD020	INVESTIGTOR NAME To be added per site SITE NUMBER To be added per site	Subject Initials Subject Number

END OF STUDY

Date of Completion or Discontinuation (DD-MMM-YYYY) _____-_____-_____

Did the subject complete through Visit 7? ☐ Yes ☐No

If NO, mark primary reason for premature withdrawal:

☐ Voluntary Withdrawal

☐ Death

☐ Pregnancy

☐ Investigator decision that it is not the best medical interest of the subject to continue participation in the investigation

☐ Adverse/ Serious Adverse Event #_____

☐ Subject not following required study procedures

☐ Requires disallowed Therapy

☐ Lost to Follow-up

☐ Occurrence of relevant exclusion Criteria

Source Documents			
Galderma	Study # C16-CD020	INVESTIGTOR NAME To be added per site SITE NUMBER To be added per site	Subject Initials Subject Number

Contact Log		
Initials of person contacting the subject	Date of contact (DD-MMM-YYYY)	Reason for contact with subject

Source Documents			
Galderma	Study # C16-CD020	INVESTIGTOR NAME To be added per site SITE NUMBER To be added per site	Subject Initials Subject Number

Notes Page

Source Documents			
Galderma	Study # C16-CD020	INVESTIGTOR NAME To be added per site	Subject Initials Subject Number

Week 1

Questions	1=Strongly Agree	2	3	4	5=Strongly Disagree
This treatment works faster than my previous acne treatment.					
I feel that this treatment deep cleans and unblocks my pores.					
I noticed an improvement in my acne.					
I have noticed I had fewer breakouts than my previous treatments.					
I saw improvement in the overall health of my skin since starting the regimen					
This regimen is easy to use every day.					
I liked the feel of this product.					

_____

Subject Initials and Date

Source Documents			
Galderma	Study # C16-CD020	INVESTIGTOR NAME To be added per site	Subject Initials Subject Number

Week 2

Questions	1=Strongly Agree	2	3	4	5=Strongly Disagree
My skin is clearer skin using this treatment					
This treatment works faster than my previous acne treatment.					
I feel that this treatment deep cleans and unblocks my pores.					
I noticed an improvement in my acne. Strongly agree to Strongly disagree					
I have noticed I had fewer breakouts than my previous treatments.					
The areas of my skin where I used to have acne is now clear and radiant after daily treatment.					

_____

Subject Initials and Date

Source Documents			
Galderma	Study # C16-CD020	INVESTIGTOR NAME To be added per site	Subject Initials Subject Number

Week 6

Questions	1=Strongly Agree	2	3	4	5=Strongly Disagree
My skin is clearer skin using this treatment					
I feel my skin is now clear					
The treatment helped to reduce redness and inflammation caused by my acne.					
I feel that this treatment deep cleans and unblocks my pores.					
This treatment visually minimized my pore size.					
This treatment reduces my acne without leaving behind dry, flakey skin.					
I have noticed I had fewer breakouts than my previous treatments.					
My skin looks better than before					
I saw improvement in the overall health of my skin since starting the regimen					
My skin looks noticeably smoother and healthier					
The areas of my skin where I used to have acne is now clear and radiant after daily treatment.					
I feel better about my skin since I've started the treatment regimen					
I feel more confident since I've started the treatment					
What is your overall satisfaction with the regimen?					
I have noticed a positive difference in the appearance of my skin with this regimen.					
This regimen is easy to use every day.					

Subject Initials and Date

Source Documents			
Galderma	Study # C16-CD020	INVESTIGTOR NAME To be added per site	Subject Initials Subject Number

Week 12

Questions	1=Strongly Agree	2	3	4	5=Strongly Disagree
I experienced noticeable improvement in my skin tone					
I experienced noticeable improvement in my skin texture					
I experienced noticeable improvement in my skin radiance					
My skin has a more youthful appearance					
My skin is clearer skin using this treatment					
I feel my skin is now clear					
This treatment is strong enough to give me clear, acne free skin.					
The treatment helped to reduce redness and inflammation caused by my acne.					
This treatment visually minimized my pore size.					
This treatment reduces my acne without leaving behind dry, flakey skin.					
I have noticed I had fewer breakouts than my previous treatments.					
My skin looks better than before					
This treatment breaks my cycle of acne and keeps my skin clear					
I saw improvement in the overall health of my skin since starting the regimen					
My skin looks noticeably smoother and healthier					
The areas of my skin where I used to have acne is now clear and radiant after daily treatment.					
I feel better about my skin since I've started the treatment regimen					
I feel more confident since I've started the treatment					

_____

Subject Initials and Date

Source Documents			
Galderma	Study # C16-CD020	INVESTIGTOR NAME To be added per site	Subject Initials Subject Number

Week 12 (cont.)

Questions	1=Strongly Agree	2	3	4	5=Strongly Disagree
Has your quality of life improved now that you have started using this product?					
What is your overall satisfaction with the regimen?					
I have noticed a positive difference in the appearance of my skin with this regimen.					
I would recommend this product to others.					
My acne is as clear as if I went to a doctor or received a prescription.					
I don't feel the need for a prescription after using this product.					
Do you feel this treatment is designed for you?					
Do you feel more positive and less frustrated about your acne and your skin since starting this treatment?					
Do you feel this treatment meets the needs of your skin?					

_____

Subject Initials and Date

Source Documents			
Galderma	Study # C16-CD020	INVESTIGTOR NAME To be added per site	Subject Initials Subject Number

Week 24

Questions	1=Strongly Agree	2	3	4	5=Strongly Disagree
I experienced noticeable improvement in my skin tone					
I experienced noticeable improvement in my skin texture					
I experienced noticeable improvement in my skin radiance					
My skin has a more youthful appearance					
My skin is clearer skin using this treatment					
I feel my skin is now clear					
This treatment is strong enough to give me clear, acne free skin.					
The treatment helped to reduce redness and inflammation caused by my acne.					
This treatment visually minimized my pore size.					
I noticed an improvement in my acne. Strongly agree to Strongly disagree					
This treatment reduces my acne without leaving behind dry, flakey skin.					
I have noticed I had fewer breakouts than my previous treatments.					
My skin looks better than before					
This treatment breaks my cycle of acne and keeps my skin clear					
I saw improvement in the overall health of my skin since starting the regimen					
The areas of my skin where I used to have acne is now clear and radiant after daily treatment.					
I feel better about my skin since I've started the treatment regimen					

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Subject Initials and Date

Source Documents			
Galderma	Study # C16-CD020	INVESTIGTOR NAME To be added per site	Subject Initials Subject Number

Week 24 (cont.)

Questions	1=Strongly Agree	2	3	4	5=Strongly Disagree
I feel more confident since I've started the treatment					
Has your quality of life improved now that you have started using this product?					
I would continue using this treatment beyond 24 weeks as a regular part of my skincare routine.					
What is your overall satisfaction with the regimen?					
I have noticed a positive difference in the appearance of my skin with this regimen.					
I would recommend this product to others.					
My acne is as clear as if I went to a doctor or received a prescription.					
I don't feel the need for a prescription after using this product.					
Do you feel this treatment is designed for you?					
Do you feel more positive and less frustrated about your acne and your skin since starting this treatment?					
Do you feel this treatment meets the needs of your skin?					

_____

Subject Initials and Date

Subject Initials: __ __ __

Subject Number:__ __ __

Sample Diary 1

Please record daily (in BLACK INK) the time you applied the product. DO NOT use pencil or white out, or draw arrows ↓ or quotation marks (" "). If you have any problems, please contact Miguel at **(972) 852-5880 immediately!**

USAGE INSTRUCTIONS:

- **Facial cleanser**: Massage a small amount onto wet skin. Rinse
- Dispense a nickel size amount of product and apply as a thin layer to the entire face or any other affected areas of the skin once daily, after washing gently with a mild soap-less cleanser and drying the area.
- **Moisturizing Lotion**: After applying the product, use moisturizer on the entire face. Apply daily to dry skin as needed or as directed by physician.
- **Facial Moisturizer SPF 30**: Apply lilberally 15 minutes before sun exposure. Use a water resistant sunscreen if swimming or sweating. Reapply at least every 2 hours.

Date	Day	Cleanser (✓)	Application Time	Moisturizer (✓)	SPF (✓)	Comments
5/6/2016 Visit 1	**Friday**					
5/7/2016	Saturday					
5/8/2016	Sunday					
5/9/2016	Monday					
5/10/2016	Tuesday					
5/11/2016	Wednesday					
5/12/2016	Thursday					
5/13/2016 Visit 2	**Friday**					
5/14/2016	Saturday					
5/15/2016	Sunday					
5/16/2016	Monday					
5/17/2016	Tuesday					
5/18/2016	Wednesday					
5/19/2016	Thursday					
5/20/2016 Visit 3	**Friday**					

Subject Initials: __ __ __

Subject Number:__ __ __

Sample Diary 2

Please record daily (in BLACK INK) the time you applied the product. DO NOT use pencil or white out, or draw arrows ↓ or quotation marks (" "). If you have any problems, please contact Miguel at (972) 852-5880 **immediately!**

USAGE INSTRUCTIONS:

- **Facial cleanser**: Massage a small amount onto wet skin. Rinse
- Clean the skin thoroughly before applying this product. Cover the entire affected area with a thin layer one to three times daily. Because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three daily if needed or as directed by a doctor. If bothersome dryness or peeling occurs, reduce application to once a day or every other day.
- **Moisturizing Lotion**: After applying the product, use moisturizer on the entire face. Apply daily to dry skin as needed or as directed by physician.
- **Facial Moisturizer SPF 30**: Apply lilberally 15 minutes before sun exposure. Use a water resistant sunscreen if swimming or sweating. Reapply at least every 2 hours.

Date	Day	Cleanser (✓)	Application Time			Moisturizer (✓)	SPF (✓)	Comments
			1	2	3			
5/6/2016 Visit 1	**Friday**							
5/7/2016	Saturday							
5/8/2016	Sunday							
5/9/2016	Monday							
5/10/2016	Tuesday							
5/11/2016	Wednesday							
5/12/2016	Thursday							
5/13/2016 Visit 2	**Friday**							
5/14/2016	Saturday							
5/15/2016	Sunday							
5/16/2016	Monday							
5/17/2016	Tuesday							
5/18/2016	Wednesday							
5/19/2016	Thursday							
5/20/2016 Visit 3	**Friday**							