# Informed Consent Form

**Participant Name: _____ Participant Number: _____**

**STUDY TITLE: Self-administered Intralesional Injections of Triamcinolone for Acne Vulgaris**

**STUDY NUMBER: ATM-2301**

| **INVESTIGATOR:** | **CONTACT PHONE:** | **SPONSOR** |
|---|---|---|
| Dr. Sunil Dhawan | 510-797-4111 | ACOM Labs, Inc. |

## INTRODUCTION

You are being invited to participate in a research study. This consent form is only part of the process of informed consent. It should give you the basic idea of what the research is about and what your participation will involve. If you would like more detail about something mentioned here, or information not included here, you should feel free to ask. Please take as long as you need to read this form carefully and to understand any accompanying information. After reading this information sheet, take time to think about this research study and discuss it with anyone you want to. You are entirely free to decide to accept or refuse to participate in this study. If you decide to participate, please sign and date this informed consent form. You will be given a copy of this information and consent form once signed.

## PURPOSE OF THE STUDY

The purpose of this study is to investigate the safety of self-administered injections of triamcinolone into acne lesions using an injection assistance device (i.e., an Intradermal Needle Adaptor). The study will also assess how acne lesions respond to these injections.

Triamcinolone is a type of corticosteroid that is commonly used to treat acne lesions by intralesional injections (i.e., injection of triamcinolone directly into the acne lesion). A total of 0.10 mL of triamcinolone (at a concentration of 1.0% to 2.5%) will be injected into at least one, and up to three of your inflammatory acne lesions. Triamcinolone has already been approved by the FDA for intralesional injections.

The injection assistance device is a hand-held adaptor to an intradermal safety needle and syringe designed to allow individuals to safely and consistently self-administer intralesional injections.

A total of 150 participants of any gender, 18 years of age or older will take part in this study, which will be conducted at doctor-supervised clinical settings.

The study is sponsored and financed by ACOM Labs, Inc. It has been reviewed and approved by an Independent Review Board (Veritas IRB).

## PROCEDURES

Your participation will last up to 14 days, during which there will be one visit at the study site and 13 days of remote follow-up. After the first study visit, you will submit photos and complete surveys via a photography app installed on your cell phone at 24 hours, 48 hours, 72 hours, Day 7, and Day 14. You may also submit photos on additional days and opt in to having additional photos taken by the study team at study site or a location of your convenience.

At Visit 1, if you are eligible to participate in the study, you will download the study photography app, take baseline photographs, and self-administer study injections into up to 3 inflammatory acne lesions.

All study participants will receive study treatment. Study treatment will be provided to you at no charge.

**To participate in this study, you must agree to the following:**

- You must review and sign this informed consent form and a Health Insurance Portability and Accountability Act (HIPAA) release. If you live in California, you will also be asked to sign the California Experimental Research Subject's Bill of Rights. In order to participate in this study, you must also sign the photography/video release section of this informed consent form which allows photographs/video of your acne vulgaris affected areas to be used for the research purposes of this study. All your questions should be answered before signing these forms. Also, if you agree, the study doctor will inform your primary physician (if you have one) about your participation in the study to ensure that you have adequate medical follow-up during and after this study.
- You must follow the study instructions and those of your study doctor. This includes taking all follow-up images using the study photography app and provided "ring-light" (an attachment for your cell phone), completing all surveys during the follow-up period and reporting any changes in how you feel to the study doctor.
- The photography app that will be used in this study is called "appiell" and is currently available on the Apple App Store and Google Play. Please note that that the app may ask you to consent to the use of the app, and that the privacy policy of the app may differ from what is included in the informed consent documentation for the study.
- Current acne treatment: If you are currently using acne medication you can continue to do so. You will not be required to stop taking such treatment but will need to continue using your medication at the current dosage and frequency.
- Pregnancy: You cannot participate in this study if you are pregnant. If you are a female and are able to become pregnant, you must perform a urine pregnancy test to confirm that you are not pregnant.
- If you discontinue study participation early (for any reason), you will be invited to be contacted by the study doctor for a follow-up (telephone) to ensure that you are not experiencing side effects.

**Visit 1 (Day 1- Baseline):** This visit will last about 90 minutes and will take place at the study doctor's office.

- You will review and sign this Informed Consent form.
- The study doctor will determine if you are eligible to participate in this study.
- You will download a study-specific photography phone app and create an account.
- Your medical history, current medical conditions, and medication use will be reviewed.
- A urine pregnancy test will be performed if you are a woman of childbearing potential. If you are pregnant, you will not be enrolled into the study. The study doctor will assess the severity and general appearance of your acne.
- The study doctor will assess the size, severity and general appearance of the acne lesions that will be injected.

- Before the injection, you will be asked how painful are the acne lesions that will be injected, and the study team will take photographs of your acne lesions. You will also take photographs of your acne lesions using the photography phone app and ring-light.
- The study team will then guide you to self-inject the triamcinolone into at least one, and up to three of your acne lesions using the study device. The study team will record a video of the injection procedure for at least one of the acne lesions.
- Once the Intradermal Needled Adapter has been positioned over a lesion, the self-injection itself will take approximately 2-3 seconds.
- After the injection, you will be asked about how you are feeling and if you experienced any side effects, as well as the level of pain associated with each injection.
- The study team will take photographs of your treated acne lesions. You will also take photographs of your acne lesions using the study phone app

**Remote Follow-up Visits (24hrs, 48hrs, 72hrs, Day 7 and Day 14):** Each remote follow-up visit will take about 15 minutes and will utilize the photography app and ring-light provided by the study team.

- You will be asked via questionnaire sent to your phone if you experienced any side effects or used any new medications or treatments since the last visit.
- You will be asked via questionnaire sent to your phone how painful your treated acne lesions are as well as how satisfied you are with the study treatment.
- You will take and submit photographs of your treated acne lesions via the photography app. Prior to taking photographs you will place a numbered sticker beside the lesion to identify which lesion it is. Additionally, you will place three stickers on the face that indicate size and dimension (i.e., a sticker of a tiny ruler).
- The study doctor will remotely assess the size, severity and general appearance of the acne lesions that were injected using the submitted photographs.

Rather than using the photography app, you have the option of in-person photography for the Follow-up Visits at 24hrs, 48hrs, 72hrs, Day 7 and Day 14. Each optional in-person photography visit would last about 30 minutes and will take place at the study site or a location of your convenience.

- If you elect to participate in this additional opt-in photography, you will coordinate time and place of photography with a study team member at Visit 1.
- A member of the study team will take photographs of your treated acne lesions at the time and place decided upon at Visit 1.

**STUDY EXIT:** Before exiting the study, the study doctor will make sure that if you experienced any side effects, these are appropriately resolved. If all side effects have resolved, your study participation will be considered fully completed and you will exit the study. If a side effect(s) has not yet resolved, the study doctor may need to contact you or ask you to return at a later date so that he/she can collect final data on the side effect(s) and make sure that you are OK.

## EXCLUSIONS

Since there may be unknown risks to pregnant women, their unborn children and breastfed infants, you will be excluded from the study if you are pregnant. If you are able to become pregnant

you must have a urine pregnancy test before receiving study product. If you are pregnant, you will not be allowed to receive treatment with the study product.

If you are able to become pregnant you must have a urine pregnancy test before receiving study product. If you are pregnant, you will not be allowed to receive treatment with the study product. You must use a medically acceptable method of contraception throughout the study. Medically acceptable methods of contraception are hormonal methods (contraceptive pill or implant), an intrauterine device (IUD), barrier method such as diaphragm plus spermicide, condom plus spermicide, or vasectomized partner(s). Barrier methods must be in use at least 14 days prior to injection, hormonal methods and IUDs must be in use at least 90 days prior to study product injection. Females of childbearing potential who are not sexually active or who have a male partner who has had a vasectomy at least 3 months prior to receiving treatment (or who has a confirmed '0' sperm count) are not required to use an additional reliable method of contraception.

You understand that you should not be enrolled into this study if you are pregnant. If you become pregnant during the study and you choose to continue the pregnancy, you must immediately inform the study doctor. If you agree, you will give Dr. Sunil Dhawan access to your and/or your infant's medical records for the time of pregnancy and for at least 8 weeks following delivery if you become pregnant during the study.

## PARTICIPATION AND TERMINATION

Your participation in this study is voluntary. You may refuse to participate. If you choose to participate, you can change your mind at any time and withdraw from the study. Refusal to participate or withdrawal from the study will not compromise your ongoing or future medical care or benefits to which you are otherwise entitled at this office. If you do participate and your symptoms do not improve, or if you have an adverse experience, you can withdraw from the study at any time. Your doctor will then treat your condition appropriately.

If you do withdraw from the study, all data collect up until your withdrawal will be maintained in the database, but new data will not be collected.

If you experience any study-related illness or injury, necessary medical treatment will be available to you at no additional cost. You will not waive any of your legal rights by signing this consent form. If you experience an injury, illness or side effect, you should contact: Dr. Sunil Dhawan 24 hours a day at: 510-797-4111.

Your participation in this study can also be terminated, without your consent, by the study doctor if it is determined to be in your best interest or if you fail to follow the study doctor's instructions. Specific reasons why you may be removed from this study without your consent include but are not limited to the following:

- A condition or circumstance exists that may jeopardize your welfare or study integrity.
- Your failure to follow the instructions of the study doctor.
- The study is stopped by the sponsor or doctor participating in the study prior to completion.

## RISKS

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. If necessary, the study doctor may give you medicines to help lessen side effects. You will not be responsible for the potential costs associated with any treatment of side effects.

You should talk to your study doctor about any side-effects you experience while taking part in the study.

***Possible risks associated with the Study Treatment:*** Intralesional injection of triamcinolone may produce side effects. Typical side effects reported for are usually limited to the injection site and may include pain due to injection, flushing, change in skin pigmentation, bruising, shiny-appearing skin, redness, and/or thinning of skin.

***Unknown risks:*** The possibility of unknown risks exists. The study product may have side effects that no one yet knows of, and the fetus of a pregnant woman or the infant of a nursing woman becomes at risk as well.

***Allergic reactions:*** The study product may have a potential risk of an allergic reaction. Allergic reactions may vary from mild (rash, hives, itching) to severe reactions such as anaphylaxis. Signs that you may be having a severe allergic reaction are difficulty breathing, wheezing when you breathe, sudden change in blood pressure (making you feel dizzy or lightheaded), swelling around the mouth, throat or eyes, fast pulse, rash or itching, and sweating. Severe allergic reactions could result in permanent disability or death. You should get medical help and contact the study doctor or staff if you have any of these or any other side effects during the study.

***Breach of Confidentiality***: Any records that could identify you will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available.

***New information:*** Your study doctor or study staff will let you know if any significant new findings or additional information becomes available during the course of this study, which may affect your willingness to continue participating in this study.

## BENEFITS

You may or may not benefit from participating in this research study. The purpose of this study is to determine the safety of self-administered injections of triamcinolone into acne lesions using an injection assistance device.

Such benefits may include improvement of the acne lesions that have been injected; however, this is not guaranteed. It is possible that you receive no benefit. The results of this study may be useful in the development of a new therapy for others with similar conditions.

## ALTERNATIVE THERAPY

If you decide not to participate, or if you withdraw from this study before it is completed, a variety of alternative therapies are available to treat your acne lesions such as cosmetic and/or over the counter (OTC) products, topical treatments for acne (e.g., retinoids, antibiotics, corticosteroids, etc.), as well as intralesional injection of triamcinolone (i.e., the drug that is being used in this study). You are encouraged to discuss alternative treatments with the study doctor if you would like. You also have the option of not receiving any treatment.

## COSTS AND COMPENSATION

You are not responsible for any costs for the required study visits, examinations, procedures, and study product.

You will receive $100.00 for participating in visit 1 and will receive $40.00 for each remote follow-up you complete by taking photographs and answering surveys in the app (up to a maximum of $300.00). If you choose to participate in the optional in-person photography, $40.00 will be paid for each visit (up to a maximum of $300.00) to help defray the costs for your participation in this study. These funds will be paid at the end of your participation in the study. or timepoint. These payments are for your time, travel expenses, and inconvenience.

If you choose to leave or are withdrawn from the study for any reason before finishing all visits, your compensation will be prorated for the visits and procedures you have completed.

## INVESTIGATOR PAYMENT

ACOM Labs, Inc., the manufacturer of the self-administered injection device, is funding the study and will pay the study doctor for their time spent on the study. This disclosure is made so that you can decide if this relationship will affect your willingness to participate in the study.

## CONFIDENTIALITY

Any information that identifies you with respect to this research study will be kept confidential.

Information in your medical records (including your identity and contact information) relating to this study will be kept as confidential as possible under applicable laws and regulations and will not be made publicly available. If the results of the trial are published, your identity will remain confidential. Any information about you that is sent out the clinic will be coded; this means that it will not be identified by name, but only with the coded number assigned to you for this trial.

However, by signing this consent form, you allow access to your medical records. Your medical records identifying you may be reviewed by ACOM Labs, inc. (Study Sponsor, Manufacturer of the injection assistance device), ethica CRO Inc. (the company managing this study), and/or representatives of Veritas IRB. These individuals may directly access your original medical records to verify that research procedures were correctly followed and the accuracy of the data. The confidential nature of your medical information will be respected. Although different measures (as described above) are taken to keep your information and medical records as private as possible, your privacy cannot be 100% guaranteed or protected because it may not be possible to entirely de-identify your photos.

Regarding the photographs/videos of your acne lesions, you may be recognizable. The photographs/videos will be used only for the purposes to which you agreed on the “Photography/Video Release” section of this form. The Sponsor will not make any link whatsoever between your name and your images when using them.

With your permission, the study Sponsor would like to contact you after completion of this study to discuss your study experience, your personal experience with acne and to discuss your opinion regarding the Sponsor's products, including the device used in this trial. In order to contact you, you will need to share your name and contact information with the study Sponsor requires your permission. You can provide your permission by completing the “Post-Study Follow-up” section of this form.

The data from this study will be used for the research related to this study. It may additionally be used to support future research studies and/or to support marketing of a product. The information collected during this study will be kept on file for a maximum of 10 years after the end of the study (even if you withdraw from the study) as any data collected up to the time of your study exit will remain in the trial database and be included in the data analysis.

All data generated by this study, including data related to your participation in the study, will be stored by ethica CRO Inc. using a secure and password protected server located in Canada. Your individual data will be identified by a unique study identification number only (i.e., no personal information). Any paper records will be stored at the office of your study doctor in a secure locked room and/ or file cabinet.

You have the right to access your study records. You can request a copy of this information from your study doctor.

By signing this document, you consent to such review, inspection, and disclosure.

## CONTACT

If you have any questions regarding this study, your participation in it, if a research-related injury arises, or if you want to voice concerns or complaints for any reason, you should contact Dr. Sunil Dhawan at 510-797-4111.

This study has been reviewed and approved by Veritas Independent Review Board (IRB). If you have any questions about your rights as a research participant or the study doctor's responsibilities, you may contact the Manager of the Veritas Independent Review Board 24 hours per day and 7 days per week at 1-866-384-4221. An IRB is a group of scientific and non-scientific individuals who perform the initial and ongoing ethical review of the research study with the participant's rights and welfare in mind. If you have any study-related comments, complaints or concerns you should first contact the study doctor. Please call the IRB if you need to speak to a person independent from the study doctor and research staff, and/or if the study doctor and research staff could not be reached.

## HIPAA AUTHORIZATION

**(Patient Authorization for use and disclosure of Personal Health Information in Research)**

I agree to permit:

(a) Dr. Sunil Dhawan at Center for Dermatology Clinical Research Inc ("**Researchers**"),
(b) My doctors and my other health care providers ("**Providers**")
to use and disclose (release) health information about me as described below.

**1. The health information that may be used and disclosed includes:**

(a) all information collected during the research described in the Informed Consent Form for the study and
(b) de-identified health information in my medical records that is relevant to the study.

**2. The Providers may disclose health information in my medical records to:**

(a) the Researchers;
(b) the company that manufactured the product to be studied, ACOM Labs, inc., and its agents and contractors (together "Company") for any research related to this study only, including analysis of the trial findings, and to conduct additional research using such protected de-identified health information, and
(c) representatives of government agencies, review boards, and other persons who watch over the safety, effectiveness, and conduct of research.

**3. The Researchers may:**

(a) use and share my de-identified health information among themselves, with the Company, and with other participating researchers and laboratories to conduct the study, and
(b) disclose my de-identified health information to representatives of government agencies, review boards, and other persons who watch over the safety, effectiveness, and conduct of research.

**4. The Researchers may** use and share my de-identified health information as permitted by the Informed Consent Form.

**5. Once my health information has been disclosed,** federal privacy laws may no longer protect it from further disclosure.

**6. Please note that:**

(a) You do not have to sign this Authorization, but if you do not, you will not be able to participate in the study.
*(b)* You may change your mind and revoke (take back) this Authorization at any time and for any reason. To revoke this Authorization, you must write to Dr. Sunil Dhawan, Center for Dermatology Clinical Research, Inc, 2557 Mowry Ave, Suite 34, Fremont, CA 94538. However, if you revoke this Authorization, you will not be allowed to continue taking part in the study. Also, even if you revoke this Authorization, your Providers, the Researchers, and the Company may continue to use and disclose the information they have already collected to protect the integrity of the research or as permitted by the Informed Consent Form.

**7. This Authorization does not have an expiration (ending) date**

_____

**Participant's Printed Name** Signature Date

_____

**Person Explaining Consent Printed Name** Signature Date

## CONSENT

**IF YOU WANT TO PARTICIPATE IN THIS STUDY, please read and sign the following pages and, if applicable, the California Experimental Research Subject's Bill of Rights.**

I have read this form, and I have been able to ask questions about this study. The study doctor or study staff has talked with me about this study and they have answered all my questions. I voluntarily agree to be in this study.

By signing this form, I have not given up any of my legal rights as a research participant. The informed consent requirements in these regulations are not intended to preempt any applicable Federal, State, or local laws that require additional information to be disclosed for informed consent to be legally effective. Nothing in these regulations is intended to limit the authority of a physician to provide emergency medical care to the extent the physician is permitted to do so under applicable Federal, State, or local law.

You will receive a fully signed copy of this consent form for your records, and in California, a copy of the Experimental Research Subject's Bill of Rights.

**Participant:**

_____

Printed Name Signature Date

**Person Obtaining Consent (e.g., Study Nurse, Investigator):**

I attest that the above-named participant had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to participate in this study.

_____

Printed Name Signature Date

## INVESTIGATOR STATEMENT

I certify that I or my representative have explained to the above-named participant the nature and implications of this research study. I have answered all of the participant's questions and have encouraged him or her to ask any additional questions at any time during the course of the study.

**Investigator/Delegate:**

_____

Printed Name Signature Date

## CONTACT WITH YOUR PRIMARY PHYSICIAN

I, the undersigned, confirm that:

☐ **I HAVE A PRIMARY PHYSICIAN AND**

☐ Agree that the study doctor contact my primary physician to inform him/her of my participation in the study ATM-2301.

☐ Disagree that the study doctor contact my primary physician to inform him/her of my participation in the study ATM-2301.

☐ **I DO NOT HAVE A PRIMARY PHYSICIAN**

**Participant:**

_____

Printed Name Signature Date

**Person Obtaining Consent (e.g., Study Nurse, Investigator):**

_____

Printed Name Signature Date

## PHOTOGRAPHY / VIDEO RELEASE

You confirm voluntarily consenting to the taking, copyright, and use of your pictures/videos of your acne lesions. As the acne lesions will be on your face, you may be identifiable. These photos/videos will be used only for the research purposes of the study (e.g., photographic record of improvement and/or healing of the treated acne lesions, video recording of the injection procedure). You will not be able to participate if you do not consent to your pictures/videos being taken for research purposes.

**YES NO**

☐ ☐ **I CONSENT TO HAVING PHOTOGRAPHS/VIDEOS OF MY ACNE LESIONS TAKEN FOR THIS STUDY**

There are other uses for your photographs/videos (e.g., publications, promotion of the study product, etc.). Please check the "Yes" box for the categories for which you give consent and the "No" box for the categories for which you do not give consent. You do not have to give consent to either of these two categories to participate in the study.

**YES NO**

☐ ☐ FOR EDUCATION, PUBLICATIONS, INFORMATIONAL PURPOSES, OR RESEARCH ASSOCIATED WITH THIS STUDY

☐ ☐ FOR GENERAL ADVERTISING, PUBLICITY, AND PROMOTIONAL PURPOSES AND

- ☐ *I permit the photography of my whole face without the application of "eye bars" (i.e., black bar covering eyes*
- ☐ *I permit the photography of my whole face only with the application of "eye bars"*

By signing this release, you do not forfeit any of your legal rights. It is within your rights to revoke this authorization for future uses at any time.

**Participant:**

_____

Printed Name Signature Date

**Person Obtaining Consent (e.g., Study Nurse, Investigator):**

_____

Printed Name Signature Date

## PREGNANCY FOLLOW-UP

**Only to be completed by females of child-bearing potential**

**I, the undersigned, confirm that:**

☐ I **agree** to give Dr. Sunil Dhawan access to my and/or my infant's medical records for the time of pregnancy and for at least 8 weeks following delivery if I become pregnant during the study ATM-2301

☐ I **disagree** to give Dr. Sunil Dhawan access to my and/or my infant's medical records for the time of pregnancy and for at least 8 weeks following delivery if I become pregnant during the study ATM-2301

**Participant:**

| Printed Name | Signature | Date |
|---|---|---|

**Person Obtaining Consent (e.g., Study Nurse, Investigator):**

| Printed Name | Signature | Date |
|---|---|---|

## POST-STUDY FOLLOW-UP

You confirm voluntarily consenting to sharing your name and contact information with the Study sponsor and permit the Sponsor to contact you after you complete the study in order to discuss with you your study experience, your personal experience with acne and to discuss your opinion regarding the Sponsor's products, including the device used in this trial.

| YES | NO | |
|---|---|---|
| ☐ | ☐ | **I CONSENT TO HAVING MY NAME AND CONTACT INFORMATION BEING SHARED WITH THE STUDY SPONSOR AFTER I COMPETE THIS CLINICAL STUDY IN ORDER TO DISCUSS MY STUDY EXPERIENCE, MY PERSONAL EXPERIENCE WITH ACNE AND TO DISCUSS MY OPINION REGARDING THE SPONSOR'S PRODUCTS** |

**Participant:**

_____

Printed Name Signature Date

**Person Obtaining Consent (e.g., Study Nurse, Investigator):**

_____

Printed Name Signature Date