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CONSENT TO TAKE PART IN A RESEARCH STUDY

TITLE: Randomized Comparison of Combination Azithromycin and Hydroxychloroquine vs. Hydroxychloroquine Alone for the Treatment of Confirmed COVID-19

PROTOCOL NO.: [redacted]

PRINICIPAL INVESTIGATOR: [redacted]

[redacted]

STUDY SITES

[redacted]

STUDY SUMMARY: This consent form is part of an informed consent process for a research study and it will provide information that will help you decide whether you want to take part in this study. It is your choice to take part or not.

The purpose of the research is to determine if azithromycin combined with hydroxychloroquine is better than hydroxychloroquine alone for treating patients with symptoms consistent with COVID-19. Azithromycin is approved by the Food and Drug Administration (FDA) for the treatment of infections. Hydroxychloroquine is approved by the FDA for the treatment of malaria and auto-immune diseases (lupus, rheumatoid arthritis). The use of hydroxychloroquine and the combination of azithromycin and hydroxychloroquine is experimental and has not been approved by FDA for the treatment of COVID-19. If you take part in this research study, you will be asked to sign this document and go through pre-study laboratory and medical [redacted]

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to take part in the study. If you are eligible to take part, you will receive the study treatment, undergo laboratory tests, and study procedures at specific time points during the study. After you complete the study treatment, you will have end of study laboratory and medical tests.

As part of this study, you will receive one of the following treatments: 1) Azithromycin and Hydroxychloroquine; 2) Hydroxychloroquine alone; or 3) placebo pill for 6 days followed by Hydroxychloroquine. Treatment will continue for 10 days.

Possible harms or burdens of taking part in the study may have side effects from the study treatment such as nausea, vomiting, diarrhea, stomach pain or irregular or slow heart rate. You may feel discomfort and/or pain during some of the tests or procedures in the study. Your condition may not improve and could even worsen if you take part in this study. Possible benefits of taking part may be improvement in your condition. Information learned from the study may help other people in the future. However, it is possible that you will not receive any direct personal benefit from taking part in this study.

Your alternative to taking part in the research study is not to take part in it and pursue other available treatment options as described above after talking with your physician.

The information in this consent form will provide more details about the research study and what will be asked of you if you choose to take part in it. If you have any questions now or during the study, if you choose to take part, you should feel free to ask them and should expect to be given answers you completely understand. After all of your questions have been answered and you wish to take part in the research study, you will be asked to sign this consent form. You are not giving up any of your legal rights by agreeing to take part in this research or by signing this consent form.

WHO IS CONDUCTING THIS STUDY?

[redacted] the Principal Investigator of this research study. A Principal Investigator has the overall responsibility for the conduct of the research. However, often other individuals are part of the research team.

[redacted]

[redacted] Investigator or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

Sponsor of the Study

[redacted]

[redacted] THIS STUDY BEING DONE?

Coronavirus disease 2019 (COVID-19) is a respiratory illness that can spread from person to person. The virus that causes COVID-19 is a novel coronavirus that was first identified during an investigation into an outbreak in Wuhan, China.

There is no specific antiviral treatment for COVID-19.

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The purpose of the research is to determine if hydroxychloroquine combined with azithromycin is better for treating COVID-19 than hydroxychloroquine alone. The study will also determine if the combination of hydroxychloroquine and azithromycin reduces the viral load when compared to hydroxychloroquine alone after taking the study treatment for six days. Viral load is the total amount of virus a person has inside of them.

The combination of hydroxychloroquine and azithromycin has not been approved by the FDA for the treatment of COVID-19 and is experimental in this study.

Since we do not know which study treatment is better, we will compare the study arms. Arm 1 and Arm 2 will be compared to Arm 3, which receives placebo and hydroxychloroquine. The use of a placebo will is being done to learn which of the two study treatment works better to treat COVID-19 and reduces viral load after six days of study treatment.

A computer will assign you to one of the arms (groups) in the study. This is called randomization and is done by chance like the flipping of a coin. Neither you nor the study doctor will choose what treatment you get. You will not be told if you have been assigned to Arm 2 or Arm 3; however, your study doctor will know. The arms are:

Arm 1	Arm 2	Arm 3
• Hydroxychloroquine 200 mg taken by mouth three (3) times a day for 10 days • Azithromycin 500 mg taken by mouth on Day 1, followed by • Azithromycin 250 mg taken by mouth once a day for four (4) days.	• Hydroxychloroquine 200 mg taken by mouth three (3) times a day for 10 days	• Placebo pill Days 1-6. • Hydroxychloroquine 200 mg by mouth three (3) times a day for 10 days

Hydroxychloroquine is approved by the Food and Drug Administration (FDA) for either prevention or treatment of certain types of malaria and autoimmune disease, such as lupus and rheumatoid arthritis. Hydroxychloroquine has not been approved for the treatment of COVID-19. It has been used experimentally to treat certain people with COVID-19, including hospitalized patients.

Azithromycin is approved by the FDA for the treatment of many types of infections caused by bacteria, such as respiratory infections, skin infections, ear infections, eye infections, and sexually transmitted diseases.

Placebo if you are assigned to Arm 3 you will receive a placebo pill for Days 1-6. On Day 6, you will have blood drawn to check your viral load. If you still have symptoms, you will receive the study drug hydroxychloroquine for 10 days. A placebo pill does not have any drug or medicine in it. It will look and taste like hydroxychloroquine. Researchers use a placebo to see if the study drug works better than not taking anything.

[redacted]

[redacted]

WHO MAY TAKE PART IN THIS STUDY AND WHO MAY NOT?

If you decide to take part in this study and sign this consent form, you will have some procedures done to see if you are eligible. You may take part in this study if:

- You are 18 years of age or older.
- You have been diagnosed with SARS-CoV-2 infection and exhibiting COVID-19 symptoms.

You may not take part in this study if:

- You are pregnant or breast-feeding.
- You are not able to tolerate oral medications.
- You have a known allergy or bad reactions to either azithromycin or hydroxychloroquine sulfate.

WHY HAVE I BEEN ASKED TO TAKE PART IN THIS STUDY?

You are being asked to take part in this study because you have symptoms of COVID-19.

HOW LONG WILL THE STUDY TAKE AND HOW MANY SUBJECTS WILL TAKE PART?

You will be one of about 160 subjects to be enrolled in this study at the [redacted] Institute of [redacted] r 10 days and will remain on the study for follow-up for 6 months after treatment completion.

WHAT WILL I BE ASKED TO DO IF I TAKE PART IN THIS STUDY?

If you agree to take part in this study, you will first sign this consent form. Before you are enrolled in the study, you will have *"Screening Visit Procedures"* to determine if you are eligible for the study. These exams, tests or procedures are being performed because you are taking part in this research study. You or your health insurance provider will not be billed for the costs of these tests or procedures.

<u>Screening Visit Procedures will include:</u>

- Read and if you agree to take part in this study, sign this informed consent and the member of the study team will sign. You will receive a copy of the signed and dated consent for your records.
- Physical examination
- Vital signs (blood pressure, heart rate, temperature)
- Demographic data (age, gender, race and ethnicity)
- Questions about your past medical history
- Review the medications you are currently taking
- Review of your COVID-19 symptoms
- An Electrocardiogram (ECG) (An ECG is a test which measures the electrical activity of your heart to show whether or not it is working normally)
- Urine or blood (about 2 teaspoons) for a pregnancy test
- Blood will be drawn from a vein in your arm:

[redacted]

[redacted]

- About 2 teaspoons will be drawn from a vein in your arm to check how your body stores iron, check for blood clots and check your heart function
- About 3 teaspoons will be collected for this research study.

- You will be asked to complete a questionnaire about COVID-19 symptoms
- You will be given education on how to complete the pill diary, and temperature log.

If you are an inpatient, the following will occur:

- Read and if you agree to take part in this study, sign this informed consent and the member of the study team will sign. You will receive a copy of the signed and dated consent for your records.
- Your medical record will be reviewed by a member of the research team and the following information will be collected for the research study:
  - The results of the physical examination
  - Vital signs (blood pressure, heart rate, temperature)
  - Demographic data (age, gender, race and ethnicity)
  - Information about your past medical history
  - The medications you are currently taking
  - A Review of your COVID-19 symptoms
- The following procedures will be performed:
  - An Electrocardiogram (ECG) (An ECG is a test which measures the electrical activity of your heart to show whether or not it is working normally)
  - Saliva and throat swab will be collected for the research study
  - Blood will be drawn from a vein in your arm:
    - About 2 teaspoons will be drawn from a vein in your arm to check how your body stores iron, check for blood clots and check your heart function
    - About 3 teaspoons will be collected for this research study.
    - If you are a woman who could become pregnant, your doctor will perform a blood pregnancy test.
- You will be asked to complete a questionnaire about COVID-19 symptoms

Treatment Period

If the "Screening Visit Procedures" show you are eligible to enter this study and you agree to take part you will be randomized (like the flipping of a coin) to one of three of the Arms (groups). Neither you nor the study doctor will choose what treatment you will get. You will not be told which arm you have been assigned to the Arm 3, however, your study doctor will know.

The research nurse will review the study drug instructions with you.

[redacted]

[redacted]

Arm 1	Arm 2	Arm 3
• Hydroxychloroquine 200 mg taken by mouth three (3) times a day for 10 days • Azithromycin 500 mg taken by mouth on Day 1, followed by • Azithromycin 250 mg taken by mouth once a day for four (4) days.	• Hydroxychloroquine 200 mg taken by mouth three (3) times a day for 10 days	• Placebo pill Days 1-6. • Hydroxychloroquine 200 mg by mouth three (3) times a day for 10 days

Treatment Period – For study participants randomized to Arm 1 and Arm 2:
Days 1 – 10

- Take your study drug as prescribed.
- A research nurse will collect the following information by phone or in person:
  - Complete follow-up COVID signs and symptoms questionnaire
  - Review your temperature log
  - Review of your pill diary
  - Review of any side-effects you may have had
  - Record standard of care treatments and/or procedures prescribed
- **If you are an inpatient, you will be asked to complete the questionnaire. The hospital staff will give you the study medication. A member of the research team will review your medical record and collect the following information:**
  - Your daily temperatures
  - The times you received the study drug
  - Review of any side-effects you may have had
  - Record standard of care treatments and/or procedures prescribed

Arm 1 and Arm 2: During the study treatment period, the following tests and procedures will be done on the days listed below:

Day 3, Day 6 and Day 10

You will return to the study site and the follow tests and procedures will be done:

- Repeat physical examination
- Blood (about 2 teaspoons) will be drawn from a vein in your arm to check how your body stores iron, check for blood clots and check your heart function (Day 6 only)
- Blood (about 3-1/2 teaspoons) will be drawn for the research study (Day 3 and Day 6 only)
- Saliva and throat swab will be collected for the research study
- Review your temperature log
- Review of your pill diary
- Complete follow-up COVID-19 signs and symptoms questionnaire

[redacted]

[redacted]

- **If you are an inpatient, the hospital staff will draw blood from a vein for the blood tests and the research study and swab your nose and throat to collect the specimen for the research study. You will be asked to complete the COVID-19 symptom questionnaire. A member of the research team will review your medical record and collect the following information:**
    - Your daily temperatures
    - The times you received the study medication
    - Review of any side-effects you may have had
    - Record standard of care treatments and/or procedures prescribed

Day 11-20 – Daily Follow-up

- A research nurse will collect the following information by phone or in person:
    - Review of symptoms
    - Review your temperature log
    - Review of your pill diary
    - Adverse events
    - Record standard of care treatments and/or procedures prescribed

Treatment Period – For study participants randomized to Arm 3:

Days 1-5

- Take the placebo pill
- Complete follow-up COVID-19 signs and symptoms questionnaire
- A research nurse will collect the following information by phone or in person:
    - Review your temperature log
    - Review of any side-effects you may have had
    - Record standard of care treatments and/or procedures prescribed
- **You will be asked to complete the COVID-19 symptom questionnaire. A member of the research team will review your medical record and collect the following information:**
    - Your daily temperatures
    - Review of any side-effects you may have had
    - Record standard of care treatments and/or procedures prescribed

Day 3

You will return to the study site and have the following tests and procedures:

- Complete follow-up COVID-19 signs and symptoms questionnaire
- A research nurse will collect the following information by phone or in person:
    - Review your temperature log
    - Review of any side-effects you may have had
    - Record standard of care treatments and/or procedures prescribed
- Blood (about 3-1/2 teaspoons) will be drawn for the research study
- Saliva and throat swab will be collected for the research study

[redacted]

[redacted]

- **If you are an inpatient, the hospital staff will draw blood from a vein for the blood tests and the research study and swab your nose and throat to collect the specimen for the research study. You will be asked to complete the COVID-19 symptom questionnaire. A member of the research team will review your medical record and collect the following information:**
    - Your daily temperatures
    - Review of any side-effects you may have had
    - Record standard of care treatments and/or procedures prescribed

Day 6

You will return to the study site. If you continue to have symptoms of COVID-19, you will receive the study treatment Hydroxychloroquine sulfate to begin at home. The research nurse will review with you how to take the medication. You will receive a pill diary to write down the times you take the study medication.

You will also have the following tests and procedures:

- Complete follow-up COVID-19 signs and symptoms questionnaire
- Review your temperature log
- Review of any side-effects you may have had
- Record standard of care treatments and/or procedures prescribed
- Blood will be drawn from a vein in your arm:
    - About 2 teaspoons will be drawn from a vein in your arm to check how your body stores iron, check for blood clots and check your heart function
    - Blood (about 3-1/2 teaspoons) will be drawn for the research study
- Saliva and throat swab will be collected for the research study
- **If you are an inpatient, the hospital staff will give you the study medication and draw blood from a vein for the blood tests and the research study and swab your nose and throat to collect the specimen for the research study. You will be asked to complete the COVID-19 symptom questionnaire. A member of the research team will review your medical record and collect the following information:**
    - Your daily temperatures
    - Review of any side-effects you may have had
    - Record standard of care treatments and/or procedures prescribed

Day 10

You will return to the study site and the following tests and procedures will be done:

- Take the study medication as prescribed.
- Repeat physical exam
- Blood will (about 2 teaspoons) will be drawn from a vein in your arm to check how your body stores iron, check for blood clots and check your heart function
- Complete follow-up COVID-19 signs and symptoms questionnaire
- Review your temperature log
- Review of your pill diary

[redacted]

- Review of any side-effects you may have had
- Record standard of care treatments and/or procedures prescribed
- **If you are an inpatient, the hospital staff will give you the study medication and draw blood from a vein for the blood tests. You will be asked to complete the COVID-19 symptom questionnaire. A member of the research team will review your medical record and collect the following information:**
    - Your daily temperatures
    - The times you received the study medication
    - Review of any side-effects you may have had
    - Record standard of care treatments and/or procedures prescribed

Day 11-15

- Take the study medication as prescribed.
- Complete follow-up COVID-19 signs and symptoms questionnaire
- A research nurse will collect the following information by phone or in person:
    - Review your temperature log
    - Review of your pill diary
    - Review of any side-effects you may have had
    - Record standard of care treatments and/or procedures prescribed
- Record standard of care treatments and/or procedures prescribed
- **If you are an inpatient, the hospital staff will draw blood from a vein for the blood tests and the research study and swab your nose and throat to collect the specimen for the research study. You will be asked to complete the COVID-19 symptom questionnaire. A member of the research team will review your medical record and collect the following information:**
    - Your daily temperatures
    - The times you received the study medication
    - Review of any side-effects you may have had
    - Record standard of care treatments and/or procedures prescribed

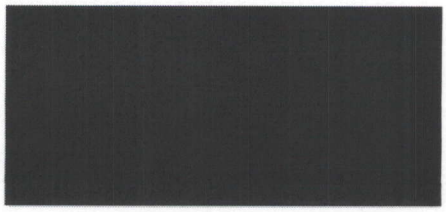
Day 16-20 – Daily Follow-up

- A research nurse will collect the following information by phone or in person:
    - Review your temperature log
    - Review of your pill diary
    - Review of any side-effects you may have had
    - Record standard of care treatments and/or procedures prescribed

Follow-up Period

The research nurse will call weekly for four (4) weeks after the last dose of the study medication to collect the following assessments:

- Review of symptoms
- Review of daily temperatures
- Adverse events



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- Record standard of care treatments and/or procedures prescribed

Monthly Follow-up for Six (6) Months

The next five (5) months the research nurse will call you once monthly after the last dose of the medication to collect the following assessments:

- Review of symptoms
- Review of daily temperatures
- Adverse events
- Record standard of care treatments and/or procedures prescribed

WHAT ARE THE RISKS OF HARM OR DISCOMFORTS I MIGHT EXPERIENCE IF I TAKE PART IN THIS STUDY?

You may have side effects while on this study. Everyone taking part in the study will be watched carefully for any side effects. However, doctors do not know all the side effect that may happen. Side effects may be mild or very serious. Your study doctor may give you medicines to help lessen side effects. Your study doctor may also decide that it is necessary to delay or stop the study treatment. Many side effects go away soon after you stop taking the drugs. In some cases, side effects can be serious, long lasting, or never go away. You should talk with your study doctor about any side effects you may have while taking part in the study.

Possible Side Effects of Azithromycin

Common

- Nausea
- Vomiting
- Diarrhea
- Loss of appetite
- Stomach pain, indigestion
- Itching or rash

Rare but serious

- Irregular or slow heart rate
- Fluttering in your chest
- Shortness of breath
- Sudden dizziness (like you might pass out)
- Muscle aches and pains

Possible Side Effects of Hydroxychloroquine

Common

- Skin changes, including a bleaching of hair, changes in skin pigment
- Nausea
- Vomiting
- Diarrhea
- Muscle weakness (lack of strength)
- Low red blood cell counts (which make you feel tired or weak)
- Low platelet counts (which may make you more likely to bruise or bleed)
- Headaches

[redacted]

[redacted]

- Dizziness
- Eye problems, including abnormal color vision

Rare but serious

- Eye problems, including blurred vision, double vision, problems to the retina (flashing lights, reading difficulties)
- Pruritus (itching)
- Rash
- Heart rhythm change (your hear beat may be irregular or beat to fast or too slow)

Risks of Blood Draws

If a blood sample is taken from you, there are few risks of harm. Possible effects from drawing a blood sample include mild pain, bruising and infection at the site of needle insertion. Fainting or light-headedness can sometimes occur, but usually last only a few minutes. Infection is rare.

Reproductive Risks of Harm

Women of childbearing potential

Females of childbearing potential should use reliable methods of contraception from the time of screening until 4 weeks after discontinuing study treatment. Acceptable methods of contraception include abstinence, tubal ligation, combined oral, transdermal or intra-vaginal hormonal contraceptives, medroxyprogesterone injections (e.g., Depo-Provera), copper-banded intra-uterine devices, hormone impregnated intra-uterine systems and vasectomised partners. All methods of contraception (with the exception of total abstinence) should be used in combination with the use of a condom by their male sexual partner for intercourse.

Males

Male patients must use a condom during sexual intercourse with all sexual partners including a pregnant female partner during the study and for 4 weeks after discontinuing study treatment. However, where a sexual partner of a male participant is a woman of childbearing potential who is not using effective contraception, men must use a condom during sexual intercourse during the study and for 6 months after discontinuing study treatment. Male patients should avoid procreation during the trial and for 6 months after discontinuing study treatment.

ARE THERE ANY BENEFITS TO ME IF I CHOOSE TO TAKE PART IN THIS STUDY?

The benefits of taking part in this study may be an improvement of your condition. However, it is possible that you will not receive any direct benefit from taking part in this study. Information learned from this study may help other people in the future.

WHAT ARE MY ALTERNATIVES IF I DO NOT WANT TO TAKE PART IN THIS STUDY?

Your alternative is not to take part in this study. You may receive supportive care outside of this study.

HOW WILL I KNOW IF NEW INFORMATION IS LEARNED THAT MAY AFFECT WHETHER I AM WILLING TO STAY IN THE STUDY?

During the study, your study doctor will update you on if your disease is progressing, stable or getting better. During the course of the study, you will be updated about any other new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

[redacted]

[redacted]

WILL I RECEIVE THE RESULTS OF THE RESEARCH?

In general, we will not give you any individual results from the study except the details that pertain to your condition. You will receive the COVID-19 results. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence. For example, 'unusual findings on the blood test that we think you should discuss with your doctor.

WILL THERE BE ANY COST TO ME TO TAKE PART IN THIS STUDY?

The drugs used in this study are commercially available. The study drugs will be provided at no charge by the Rutgers Cancer Institute of New Jersey. You and/or your health insurance company will not be billed for the cost of any research procedures, which are conducted as part of this study.

If you are hospitalized and being treated for COVID-19 symptoms, this is standard of care. You and/or your health insurance will be responsible for the cost of the hospitalization, standard of care tests and/or procedures and any co-pays related to your hospitalization or emergency department visit.

You will be responsible for any co-payments due for office visits, co-insurances and deductibles due on any tests and/or procedures that are required and considered standard care for the treatment of COVID-19 symptoms.

WILL I BE PAID TO TAKE PART IN THIS STUDY?

You will not be paid to take part in this study.

HOW WILL INFORMATION ABOUT ME BE KEPT PRIVATE OR CONFIDENTIAL?

All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed.

Information about your condition and treatment will be collected from your medical record for the study. The information will be with a study identification number and stored in a secured electronic file. The electronic file is password protected and accessible only to authorized study personnel.

If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

If you agree to be in this study, health data that identifies you will be kept confidential. Unless required by law, only those listed below will have direct access to your medical and study records to check the study information:

- the study doctor and staff
- [redacted]

[redacted]

[redacted]

- Government regulatory agencies throughout the world (such as the FDA).

A description of this clinical trial will be available on ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

WHAT WILL HAPPEN TO MY INFORMATION OR BIOSPECIMENS COLLECTED FOR THIS RESEARCH AFTER THE STUDY IS OVER?

The information or biospecimens collected for this research may be used by or distributed to investigators for other research after obtaining additional informed consent from you. Please refer to "CONSENT ADDENDA: Request to Store Tissue and/or Health Information for Future Research Use".

At the conclusion of the trial, the Principal Investigator will notify the [redacted]y Cell and [redacted]

WHAT WILL HAPPEN IF I AM INJURED DURING THIS STUDY?

Subjects in this study will be exposed to certain risks of personal injury in addition to those associated with standard forms of treatment as described under "What risks can I expect from taking part in this study?" In addition, it is possible that during the course of this study, new adverse effects that result in personal injury may be discovered. The University RWJ Barnabas Health will make appropriate referrals for medical and/or dental treatment for subjects who sustain personal injuries or illnesses as a direct consequence of participation in the research. The subject's health insurance carrier or other third-party payer will be billed for the cost of this treatment; provided that the University shall not submit to federally funded programs, e.g., Medicare, Medicaid or CHAMPUS, for reimbursement first if submission to such programs is prohibited by law. No financial compensation will be provided by the [redacted] Health and no other type of assistance is available from the University [redacted]. However, by signing this form, you are not giving up any legal rights to seek further compensation.

WHAT WILL HAPPEN IF I DO NOT WISH TO TAKE PART IN THE STUDY OR IF I LATER DECIDE NOT TO STAY IN THE STUDY?

It is your choice whether to take part in the research. You may choose to take part, not to take part or you may change your mind and withdraw from the study at any time.

If you do not want to enter the study or decide to stop taking part, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

[redacted]

[redacted]

[redacted]

Any data that has already been sent for analysis cannot be withdrawn because there may not be any identifiers with the data.

At any time, the study doctor can take you out of this study if it would not be in your best interest to stay in it. Your study doctor can stop treatment even if you are willing to stay in the study if medically indicated.
If you decide to withdraw from the study for any reason, you may be asked to return for at least one additional visit for safety reasons.

WHO CAN I CONTACT IF I HAVE QUESTIONS?

[redacted]

PERMISSION (Authorization) TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY

Information about you and your health is personal and private, so this information generally cannot be used in research without your written permission. The next few paragraphs tell you about how researchers want to use and share your health information in this research study. Your information will only be used as described here or as allowed or required by law. Ask questions if you do not understand any part of the research or the use of your health information. If you sign this consent form, you agree to let the researchers use your information in the research and share it with others as described below.

What is the purpose of the research and how will my information be used?

You are being invited to take part in this research study, which is described at the beginning of this form. The purpose of collecting and using your health information for this study is to help researchers answer the questions that are being asked in the research.

What information about me will be used?

- All information in your medical record
- Hospital discharge summaries
- Laboratory, x-rays, CT scans and test results
- Medical history or treatment
- Medications

[redacted]

[redacted]

- Laboratory/diagnostic tests or imaging
- Operative reports (about a surgery)
- Emergency Medicine reports

Who will see my medical information?
Your privacy is very important to us and the researchers will make every effort to protect it. Your information may be given out if required by law. For example, certain states require doctors to report to health boards if they find a disease like tuberculosis. However, the researchers will do their best to make sure that any information that is released will not identify you. Some of your health information, and/or information about your specimen, from this study will be kept in a central database for research. Your name or contact information will not be put in the database.

There are organizations that may inspect your records. These organizations are required to make sure your information is kept private, unless required by law to provide information. Some of these organizations are:

- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services
- The Food and Drug Administration

Who May Use, Share or Receive My Information?
The research team may use or share your information collected or created for this study with the following people and institutions:

- [redacted]

[redacted] that receive your information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, if permitted by the laws governing them.

Will I Be Able To Review My Research Record While The Research Is Ongoing?
No. We are not able to share information in the research records with you until the study is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research study.

Do I Have To Give My Permission?
No. You do not have to permit use of your information. But, if you do not give permission, you cannot take part in this study. (Saying no does not stop you from getting medical care or other benefits you are eligible for outside of this study.)

[redacted]