

MEDICAL RECORD	CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY • Adult Patient or •Parent, for Minor Patient
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INSTITUTE: National Institute of Arthritis and Musculoskeletal and Skin Diseases

STUDY NUMBER: 13-AR-0071 PRINCIPAL INVESTIGATOR: Edward Cowen, M.D. M.H.S.

STUDY TITLE: A Phase 2 Study of Anakinra in Inflammatory Pustular Dermatoses: Evaluation of Therapeutic Efficacy and Validation of Pathogenic Mechanisms

Continuing Review Approved by the IRB on 06/10/19

Amendment Approved by the IRB on 12/26/18 (M)

Date posted to web: 06/18/19

Standard

INTRODUCTION

We invite you to take part in a research study at the National Institutes of Health (NIH).

First, we want you to know that:

Taking part in NIH research is entirely voluntary.

You may choose not to take part, or you may withdraw from the study at any time. In either case, you will not lose any benefits to which you are otherwise entitled. However, to receive care at the NIH, you must be taking part in a study or be under evaluation for study participation.

You may receive no benefit from taking part. The research may give us knowledge that may help people in the future.

Second, some people have personal, religious or ethical beliefs that may limit the kinds of medical or research treatments they would want to receive (such as blood transfusions). If you have such beliefs, please discuss them with your NIH doctors or research team before you agree to the study.

Now we will describe this research study. Before you decide to take part, please take as much time as you need to ask any questions and discuss this study with anyone at NIH, or with family, friends or your personal physician or other health professional.

Why is this study being done?

Patients with inflammatory pustular skin disease may have some of the following problems: painful or itchy skin rashes, irritation of the eyes, mouth sores, joint pain, fevers and fatigue. Medicines used to treat inflammatory pustular skin disease include acitretin, cyclosporine, methotrexate, adalimumab, etanercept, psoralen plus ultraviolet A (PUVA), prednisone and

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colchicine. Despite these medications, patients often still have active disease. Most of the medicines used to treat inflammatory pustular skin disease suppress the immune system. If you use these medicines for a long time, you may experience bad side effects including increased risk for infections, liver problems, kidney problems, high blood pressure, weight gain, osteoporosis, endocrine problems and mood disturbances. Since the available medicines are not always helpful and may have side effects, we are interested in learning whether new medicines may be helpful with fewer side effects.

Inflammatory pustular skin diseases fall under a category of diseases called “autoinflammatory diseases.” Autoinflammatory diseases are conditions with episodes of inflammation such as fever, rash, or joint swelling. IL-1 is a name for a small protein that is produced in the body and may be important in causing the inflammation seen in pustular skin disease. Some autoinflammatory diseases are well-treated with medications that block the action of IL-1. IL-1 blocking agents are very helpful as standard of care treatment for other autoinflammatory diseases. Anakinra is an FDA-approved medication that works by blocking IL-1 and has been effective in the treatment of some inflammatory conditions, such as rheumatoid arthritis. Anakinra has not been studied for use in patients with pustular skin disease and is, therefore, considered an experimental treatment in this study. We would like to study whether anakinra will be effective in treating your pustular disease.

Why are you being asked to participate in this study?

You have been invited to participate in this study because you have a pustular skin disease.

How many people will take part in this study?

Up to 30 participants will take part in this study. The study will take place at the NIH and the University of California, San Francisco.

Description of Research Study

This will be a 16-week study. While on treatment, you will be evaluated at the NIH at Weeks 4, 8, 12 and 16. The first dose of anakinra will be administered under supervision in clinic during your NIH visit. You will then start self-injecting anakinra 100 mg daily. You will be evaluated at the NIH at Week 4 (after one month of treatment). Depending upon your evaluation, you may continue injecting 100mg daily for the remainder of the study or have your dose increased to 200mg daily. Depending on how your skin disease is responding to therapy, you may be evaluated at the NIH again at Week 8 (after two months of treatment). Based on the physician's evaluation of you at that time, you may stay at the 200mg daily dose for the remainder of the study or have your dose increased to 300mg daily if you weigh more than 75 kilograms (or 165 pounds). You will continue to take the injections for up to 12 weeks, provided that you do not develop side effects that would require stopping the medication, and you continue to meet the

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NIH 2514-1, Consent to Participate in A Clinical Research Study

NIH 2514-2, Minor Patient's Assent to Participate In A Clinical Research Study

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study criteria. If you have side effects related to anakinra during the study, you will be evaluated by a physician and your dose of anakinra may be stopped or reduced.

You will be asked to record the severity of rash, pustules, itching, skin pain, joint pain, fevers, your overall well-being, doses of medications and the side effects you are experiencing in a log (or diary). You will be asked to return the log to the clinical staff each time you visit the NIH Clinical Center.

You will also be required to have weekly telephone assessments with our research staff for the entire duration of the study so that we can monitor your skin disease on anakinra therapy. See the schedule below.

Study time point	Event
Start of study: Day 1	NIH Clinic visit: Initiate anakinra, first dose will be administered under supervision in clinic
Weeks 1, 2, 3	Telephone assessment
Week 4	NIH Clinic visit: Return for follow-up evaluations
Weeks 5, 6, 7	Telephone assessment
Week 8	NIH Clinic visit: Return for follow-up evaluations
Weeks 9, 10, 11	Telephone assessment
Week 12	NIH Clinic visit: Return for final NIH for follow-up evaluations
Weeks 13, 14, 15	Telephone assessment
Week 16	NIH Clinic visit: Complete study follow-up period, including a post-treatment safety visit & evaluations

The maximum duration of your involvement on this trial will be up to 1 month after your last dose of study medication. In all treatment groups, your final study visit will occur 30 days after the final dose of study medication. This will take approximately two days and will be a full NIH study visit including a physical exam and laboratory studies. The purpose of this visit is to

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determine your level of disease activity and to check for any side effects that may be related to the study medication.

If your pustular disease improves with anakinra therapy during this trial and you wish to continue therapy, we will try to help you obtain this drug after your active treatment on the study ends. However, we cannot guarantee that you will be able to obtain anakinra after your active treatment on the study ends.

A maximum of 30 subjects with inflammatory pustular skin disease will participate in this study. The maximum amount of time possible to be in the study is 4 months; however your participation may be shorter, depending on your response to anakinra.

Therapies that you may be taking which can compound the immunosuppressive effect of anakinra will be discontinued. Phototherapy must be discontinued 2 weeks prior to beginning anakinra. You may not be on other biologic agents while on anakinra. If you have used biologic agents in the past, we will advise you as to the duration of time needed between stopping that medication and beginning anakinra. If you have been treated with canakinumab in the past, we will need to wait 12 months after your last dose before we can begin anakinra. If you are taking any other immunosuppressants or medications for your skin disease, the doses of these medications must remain stable in the 2 weeks prior to study initiation and during the study. You are ineligible to participate in this study if you have received any live vaccines in the last 3 months. You may not receive any live vaccines while you are enrolled in this study.

While you are taking anakinra, it is important that you contact the study investigators before beginning any new prescription medicine, over-the-counter drug, supplement and/or herbal medicine.

Evaluations:

Before you begin the study, we will need to confirm that you have an inflammatory pustular skin disease. At a minimum, this study will require the collection of blood specimens and clinical data, which we will describe further in this consent. The purpose of this baseline visit is to perform all clinical evaluations of your pustular skin disease and evaluate your eligibility for this trial. We will perform routine urine and blood tests. If you have not had a prior skin biopsy showing that you have an inflammatory pustular skin disease, we will need to perform one to confirm this condition. We will need to give you a chest x-ray and administer a tuberculin positive protein derivative (PPD) test or a blood test called the Quantiferon TB gold to make sure you have no evidence of tuberculosis. Once these tests have been completed and we have confirmed that you have an inflammatory pustular skin disease, we will begin the study. You will continue to have regular visits at the NIH (described below) while you remain on study.

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You will be given the chance to decide whether you would like to participate in the examinations listed below as "optional" at the time of each procedure.

Examinations can include the following:

History and Physical Examination:

A summary of your medical record will be requested from your physician when you are initially referred to the NIH. In addition, we will review your medical history with you and you will have a detailed physical examination. If you have had prior biopsies done, we may also ask your permission to have these sent for further evaluation at the NIH.

Blood and Urine Tests:

During your visits, blood will be drawn from a vein in your arm for autoinflammatory and autoimmune studies, screening for viruses and other routine tests. Also, every month additional blood will be drawn to monitor your progress on anakinra and for research purposes to study the biology of inflammatory pustular skin disease and the effects of the study medication. Routine urine tests and a pregnancy test for females of childbearing potential will be done.

Biopsy of the skin (optional):

All patients with pustular skin disease must have a biopsy to confirm this diagnosis. If a biopsy has not been previously obtained, then a skin biopsy at the NIH will be performed. The biopsy will be used to confirm your diagnosis, and if possible, a portion of the biopsy specimen obtained will be used for research studies evaluating certain proteins that may be present in the skin. If a biopsy has been previously obtained, then skin biopsy at the NIH is optional and will be obtained for research purposes only. If a decision is made to perform a biopsy, the full procedure, medical reasons for doing it and all its risks and benefits will be explained to you by the treating physician who will perform the biopsy.

Chest X-ray:

A chest x-ray uses radiation to takes pictures of the heart, lungs, airway, blood vessels and the bones of the spine and chest. You may be asked to remove your clothes and wear a gown during this test. You will need to stand very still in order not to blur the x-ray picture and may be asked to hold your breath for a few seconds while the x-ray is being taken.

PET Scan (optional):

Positron emission tomography (PET) scan is a test that uses radioactive glucose (sugar) and a computer to create images of how organs and tissues in the body are functioning. Abnormal cells in the body use glucose at a different rate than normal cells and this allows the scanner to create a detailed picture of how your body is working.

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CT Scan (optional):

A computerized tomography (CT) scan is an X-ray procedure where a high-speed computer is used to make multiple images or pictures of your body. You will be asked to lie still on a table and at time may have to hold your breath for a few seconds in order to avoid blurring the pictures. You may hear a slight buzzing, clicking and/or whirring sounds as the CT scanner moves around your body. You will receive information on how to get ready for this procedure.

MRI Scan (optional):

This study may use magnetic resonance imaging (MRI) to look at the joints. Magnetic resonance imaging is a type of scan that uses magnetic fields and radio waves to make a picture of the joints in order to better understand the cause of any symptoms you might have in that location.

Specialty Consultations:

You may also be evaluated by different specialists. Their evaluations will be used in evaluating other signs and symptoms relating to your pustular skin disease and if there is response to therapy. The specialty consultations are:

- Rheumatologist (Muscle and Joint Specialist)
- Ophthalmologist (Eye Specialist)- optional
- Cardiologist (Heart Specialist)- optional
- Gastroenterologist (Specialist of the esophagus, stomach, intestines and liver)- optional

These consultants and specialists will be provided by the NIH Clinical Center.

Questionnaires:

We also want to know about the effect that your illness has on behavior and everyday activities. These questionnaires are called the Quality of Life (QOL) Assessments. It will take about 60 minutes to complete QOL assessment questions. These questionnaires will be performed at the time you enroll on study and at weeks 4, 8, 12 and 16. The following testing will be done:

Short Form-36 (SF-36): Self-reported questionnaire with 36 items to evaluate eight domains of physical and mental health. Can be completed in 10 minutes.

Dermatology Life Quality Index (DLQI): Self-reported questionnaire with 10 items to evaluate skin-related quality of life. Can be completed in 5 minutes.

Pruritus Visual Analog Scale: Self-reported instrument ranging from 0-10 which measures degree of itching. Can be completed in less than 1 minute.

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Pain Visual Analog Scale: Self-reported instrument ranging from 0-10 which measures degree of pain. Can be completed in less than 1 minute.

Overall Disease Severity Visual Analog Scale: Self-reported instrument ranging from 0-10 which measures overall disease severity. Can be completed in less than 1 minute.

Health Assessment Questionnaire: Self-reported questionnaire to evaluate ability to function in daily life. Can be completed in 5 minutes.

Collection of this information is authorized under 42 USC 285. The primary use of the information you provide is to assess your health and quality of life. The information may be disclosed to clinicians and researchers for research purposes and to monitor personnel to assure that safety standards are maintained. Submission of this information is voluntary. NIH Privacy Act Systems of Record Notice (SORN) Number: [09-25-0200](#).

Photographs (optional):

At your baseline visit and at weeks 4, 8, 12 and 16, your study doctor may recommend that pictures are taken of your face and body to document how your skin disease responds to therapy.

Birth Control

If you are a woman who is breast-feeding or pregnant, you may not take part in the study because we don't know how this medicine would affect your baby or your unborn child. If you are a woman who can become pregnant, or are the partner of a woman who can become pregnant, you will need to practice an effective form of birth control before starting study treatment, during study treatment, and for 1 month after you finish study treatment. If you think that you or your partner is pregnant, you should tell your study doctor or nurse at once.

Effective forms of birth control include:

- abstinence
- intrauterine device (IUD)
- hormonal [birth control pills, injections, or implants]
- tubal ligation
- vasectomy

Risks or Discomforts of Participation**What side effects or risks can I expect from being in this study?**

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, doctors don't know all the side effects that may occur.

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Side effects may be mild or very serious. Many side effects go away soon after you stop taking anakinra. In some cases, side effects can be serious, or long lasting.

Anakinra:**Likely**

- Redness and pain at the site where the medicine is injected
- Cough
- Cold
- Bacterial skin infections
- Lung infection, pneumonia
- Diarrhea
- Bone and joint infections
- Reaction of the immune system
- Headache
- Nausea
- Stomach pain
- Sinusitis

Less Likely

- Low blood counts

Rare but Serious

- Rare bacterial, fungal (a form of yeast or mold), or viral infections
- Anaphylaxis (serious or life-threatening allergic reaction characterized by itchy rash, facial and throat swelling, and low blood pressure)

In studies using anakinra for patients with rheumatoid arthritis, patients had increased rates of cancers of the lymph nodes, breast, respiratory tract and digestive system as compared with the general population. However, rheumatoid arthritis patients have an increased risk of cancer in general, and the rates of cancer seen in anakinra patients were about the same as what we expect to see in rheumatoid arthritis patients who are not taking anakinra. Therefore, it is not clear what role anakinra plays in the development of cancer.

Anakinra has not been systematically studied in patients with pustular skin diseases, so we do not know if anakinra use is associated with increased cancer risk in patients with these conditions.

Tissue biopsy:

Skin biopsy (optional): Pain at the biopsy site should be minimal and bleeding and infections are rare. Biopsy wounds heal with a very small, nearly unnoticeable scar, but sometimes a raised scar (keloid) or visible lump may result. However, the biopsy will be taken from a place on your body that is not easily seen. The numbing medicine is used to reduce the discomfort of the

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biopsies, however, there is minimal burning discomfort caused by the injection of the numbing medicine and the discomfort may not be eliminated completely. You may experience discomfort and mild tenderness at the biopsy site for up to 1 week. You may develop a bruise around the biopsy site, which usually disappears in one to two weeks. In rare cases, allergic reactions to the numbing medication have been reported. Please contact one of the investigators if you ever have had an allergic reaction to any medications or anesthetic agents in the past or after this procedure.

Imaging ProceduresPET/CT Scan (optional)

This research study involves exposure to radiation from up to 2 FDG PET CT scans of 10 mCi each. The radiation exposure from each FDG PET CT is equivalent to the radiation from about 6 chest x-rays. The amount of radiation you will receive in this study is 2.6 rem which is below the guideline of 5 rem in adults per year allowed for research subjects by the NIH Radiation Safety Committee. The average person in the United States receives a radiation exposure of 0.3 rem per year from natural sources, such as the sun, outer space, and the earth's air and soil. This radiation exposure is not required for your medical care and is for research purposes only. If you would like more information about radiation, please ask the investigator for a copy of the pamphlet, An Introduction to Radiation for NIH Research Subjects.

While there is no direct evidence that the amount of exposure received from participating in this study is harmful, there is indirect evidence it may not be completely safe. There may be a very slight increase in the risk of cancer.

Please tell your doctor if you have had any radiation exposure in the past year, either from other research studies or from medical tests or care, so we can make sure that you will not receive too much radiation. Radiation exposure includes x-rays taken in radiology departments, cardiac catheterization, and fluoroscopy as well as nuclear medicine scans in which radioactive materials were injected into your body.

If you are pregnant you will not be permitted to participate in this research study. If you are breast feeding and the protocol involves injection of radioactive material you will not be permitted to participate. It is best to avoid radiation exposure to unborn or nursing infants since they are more sensitive to radiation than adults.

MRI (optional)

MRI has been used for over 20 years in hospitals around the world. There are no known long-term risks or consequences of MRI scans. Since you may feel extra warmth from the scanner, please report any sensation of heat during the test. During the scan, it is possible that you may experience something called "peripheral nerve stimulation." This usually takes the form of a mild

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sensation in the skin like a vibration. If you feel pain or a twitch in the muscle, you should report it to the person performing the scan. Some individuals may feel claustrophobic (confined) in the scanner.

Photographs (optional)

Taking pictures of the face and body may be embarrassing to some patients. These photographs may be published in medical journals, without identifying the patient.

Potential Benefits of Participation**Are there benefits to taking part in this study?**

The potential benefit of this treatment is that it might improve your pustular skin disease and may lead to a reduction in related symptoms. We hope that you will get personal medical benefit from taking part in this study, but we cannot be certain. Because there is not much information about the drug's effect on your skin disease, we do not know if you will benefit from taking part in this study, although the knowledge gained from this study may help others in the future who have a similar skin condition. Your participation in this study will also allow us to learn more about pustular skin diseases.

Alternative Approaches or Treatments**What other choices do I have if I do not take part in this study?**

Instead of being in this study, you have these options:

- Getting treatment or care for your skin without being in a study
- Taking part in another study
- Opting for no treatment

Please talk to your doctor about these and other options.

Research Subject's Rights**What are the costs of taking part in this study?**

If you choose to take part in the study, the following will apply, in keeping with the NIH policy:

- You will receive study treatment at no charge to you. This may include surgery, medicines, laboratory testing, x-rays or scans done at the Clinical Center, National Institutes of Health (NIH), or arranged for you by the research team to be done outside the Clinical Center, NIH if the study related treatment is not available at the NIH.
- There are limited funds available to cover the cost of some tests and procedures performed outside the Clinical Center, NIH. You may have to pay for these costs if they are not covered by your insurance company.

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- Medicines that are not part of the study treatment will not be provided or paid for by the Clinical Center, NIH.
- Once you have completed taking part in the study, medical care will no longer be provided by the Clinical Center, NIH. If your pustular disease improves with anakinra therapy during this trial and you wish to continue therapy, we will try to help you obtain this drug after your active treatment on the study ends. However, we cannot guarantee that you will be able to obtain anakinra after your active treatment on the study ends.

A description of this clinical trial will be available on <http://www.Clinicaltrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most the Web site will include a summary of the results. You can search this Web site at any time.

Will your medical information be kept private?

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The National Cancer Institute (NCI) and other government agencies, like the Food and Drug Administration (FDA), which are involved in keeping research safe for people.
- National Institutes of Health Intramural Institutional Review Board
- Qualified representatives from the Swedish Orphan Biovitrum, the pharmaceutical company who produces Anakinra.

Stopping Therapy

Your doctor may decide to stop your therapy for the following reasons:

- if he/she believes that it is in your best interest
- if your disease flares during treatment
- if you have side effects from the treatment that your doctor thinks are too severe
- if new information shows that another treatment would be better for you
- you request to withdraw from therapy

In this case, you will be informed of the reason therapy is being stopped.

You can stop taking part in the study at any time. However, if you decide to stop taking part in the study, we would like you to talk to the study doctor and your regular doctor first.

If you decide at any time to withdraw your consent to participate in the trial, we will not collect any additional medical information about you. If you leave the trial, any remaining samples of

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yours that have been obtained for the study can be destroyed. However, the samples and data generated from the samples that have already been distributed to other researchers or placed in the research databases **cannot** be withdrawn.

Certificate of Confidentiality

To help us protect your privacy, we have obtained a Certificate of Confidentiality. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

You should also know that there are several circumstances in which the Certificate does not provide coverage. These include when information:

- will be used for auditing or program evaluation internally by the NIH; or
- must be disclosed to meet the legal requirements of the federal Food and Drug Administration (FDA).
- is necessary for your medical treatment and you have consented to this disclosure;
- is for other research.

In addition, identifiable, sensitive information protected by this Certificate cannot be admissible as evidence or used for any purpose in any action, suit, or proceeding without your consent.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

The Certificate of Confidentiality will not protect against the required reporting by hospital staff of information on suspected child abuse, reportable communicable diseases, and/or possible threat of harm to self or others.

Conflict of Interest

The National Institutes of Health (NIH) reviews NIH staff researchers at least yearly for conflicts of interest. This process is detailed in a Protocol Review Guide. You may ask your research team for a copy of the Protocol Review Guide or for more information. Members of the research team who do not work for NIH are expected to follow these guidelines but they do not need to report their personal finances to the NIH.

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Members of the research team working on this study may have up to \$15,000 of stock in the companies that make products used in this study. This is allowed under federal rules and is not a conflict of interest.

The Swedish Orphan Biovitrum is providing Anakinra for this study to NIH without charge, although it may also be purchased by the NIH pharmacy. No NIH investigator involved in this study receives payments or other benefits from any company whose drug, product or device is being tested. However, there are some non-NIH collaborators on this study who may receive payments or benefits, limited by the rules of their workplace.

Use of Specimens and Data for Future Research

To advance science, it is helpful for researchers to share information they get from studying human samples. They do this by putting it into one or more scientific databases, where it is stored along with information from other studies. A researcher who wants to study the information must apply to the database and be approved. Researchers use specimens and data stored in scientific databases to advance science and learn about health and disease.

We plan to keep some of your specimens and data that we collect and use them for future research and share them with other researchers. We will not contact you to ask about each of these future uses. These specimens and data will be stripped of identifiers such as name, address or account number, so that they may be used for future research on any topic and shared broadly for research purposes. Your specimens and data will be used for research purposes only and will not benefit you. It is also possible that the stored specimens and data may never be used. Results of research done on your specimens and data will not be available to you or your doctor. It might help people who have cancer and other diseases in the future.

If you do not want your stored specimens and data used for future research, please contact us in writing and let us know that you do not want us to use your specimens and/or data. Then any specimens that remain will be destroyed and your data will not be used for future research. However, it may not be possible to withdraw or delete materials or data once they have been shared with other researchers.

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OTHER PERTINENT INFORMATION

1. Confidentiality. When results of an NIH research study are reported in medical journals or at scientific meetings, the people who take part are not named and identified. In most cases, the NIH will not release any information about your research involvement without your written permission. However, if you sign a release of information form, for example, for an insurance company, the NIH will give the insurance company information from your medical record. This information might affect (either favorably or unfavorably) the willingness of the insurance company to sell you insurance.

The Federal Privacy Act protects the confidentiality of your NIH medical records. However, you should know that the Act allows release of some information from your medical record without your permission, for example, if it is required by the Food and Drug Administration (FDA), members of Congress, law enforcement officials, or authorized hospital accreditation organizations.

2. Policy Regarding Research-Related Injuries. The Clinical Center will provide short-term medical care for any injury resulting from your participation in research here. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the National Institutes of Health, the Clinical Center, or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

3. Payments. The amount of payment to research volunteers is guided by the National Institutes of Health policies. In general, patients are not paid for taking part in research studies at the National Institutes of Health. Reimbursement of travel and subsistence will be offered consistent with NIH guidelines.

4. Problems or Questions. If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigator, Edward W. Cowen, M.D., Building 10, Room 12N238, Telephone: 301-480-7196. You may also call the Clinical Center Patient Representative at 301-496-2626. If you have any questions about the use of your specimens and data for future research studies, you may also contact the Office of the Clinical Director, Telephone: 240-760-6070.

5. Consent Document. Please keep a copy of this document in case you want to read it again.

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COMPLETE APPROPRIATE ITEM(S) BELOW:			
<p>A. Adult Patient's Consent I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby consent to take part in this study.</p> <p>_____ Signature of Adult Patient/ Legal Representative</p> <p>_____ Date</p> <p>_____ Print Name</p>	<p>B. Parent's Permission for Minor Patient. I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby give permission for my child to take part in this study. (Attach NIH 2514-2, Minor's Assent, if applicable.)</p> <p>_____ Signature of Parent(s)/ Guardian</p> <p>_____ Date</p> <p>_____ Print Name</p>		
<p>C. Child's Verbal Assent (If Applicable) The information in the above consent was described to my child and my child agrees to participate in the study.</p> <p>_____ Signature of Parent(s)/Guardian</p> <p>_____ Date</p> <p>_____ Print Name</p>			
<p>THIS CONSENT DOCUMENT HAS BEEN APPROVED FOR USE FROM JUNE 10, 2019 THROUGH JUNE 24, 2020.</p>			
<p>_____ Signature of Investigator</p> <p>_____ Date</p> <p>_____ Print Name</p>	<p>_____ Signature of Witness</p> <p>_____ Date</p> <p>_____ Print Name</p>		