Are you participating in any other research studies? _____ Yes _____No

INTRODUCTION TO RESEARCH STUDIES

You are invited to voluntarily participate in a research study of an experimental drug called Remetinostat (also known as SHP-141) to treat early stage basal cell carcinomas (BCCs). This study is being conducted by Kavita Sarin, MD, PhD, at the Stanford Cancer Center.

You were selected as a possible participant in this study because you have a skin cancer, known as basal cell carcinoma (BCC), and at least 1 lesion (tumor site) is 5 mm in size or greater (about or more than ⅛ inch), and is being biopsied as a part of your regular medical care.

This document is to be used as a guide for a discussion between you and your Study Doctor and the study team. This form, called an informed consent document, was designed to help you understand why this study is being done; what part of the study is "research" or "experimental;" what will be asked of you if you choose to participate; possible risks; any inconveniences or discomforts you may experience; and other important information. This form may also be helpful as a reference if you choose to participate, as a reminder of what your role in the study is, and who to contact if you have questions at any time during your participation. You are urged to discuss any and all questions you have about this study with members of the study team. If you wish, you can also discuss this study and your role with your family doctor or medical provider.

PURPOSE OF RESEARCH

The study team hopes to learn if there is any beneficial effect of Remetinostat at the doses to be used in this study, and if Remetinostat is safe to use at those doses.

"Phase 2" means the study will include assessments of how well the Remetinostat works in treating your cancer.

The study team hopes to learn if 6 weeks of topical Remetinostat applied 3 times a day will slow the growth of BCCs. We also hope to learn if topical Remetinostat will affect a biomarker called "Gli" that is known to be involved in BCC development. A "biomarker" is a biological marker that we can measure to assess a medical condition or disease such as BCC.

It is hoped that Remetinostat could be used in the future to treat or prevent BCCs.

Your regular medical care for a BCC would include surgical removal of the site of the cancer. The current standard anti-BCC treatment for your lesion includes drugs like Efudex (also known as Fluorouracil) and Aldara (also known as Imiquimod). Using these therapies, some patients with BCCs receive treatment benefit, but are not cured of their disease. Your regular medical care would also include skin checks every 3 to 6 months;

biopsies of lesions; and surgical removal of additional BCC lesions as they are identified. We are requesting that you delay removal of your BCC lesion by up to 12 weeks while you participate in our study. BCCs are typically slow-growing cancers. Delaying removal by up to 12 weeks should not have a significant effect on your BCC. Regular medical care for BCC would be to schedule the surgery within a week or several weeks.

The use of Remetinostat in this research study is investigational ("experimental"). The word "investigational" means that Remetinostat is not approved by the US Food and Drug Administration (FDA) for use in the United States to treat BCCs. This study is being conducted under an application submitted to FDA, called an "Investigational New Drug Application" or "IND."

Remetinostat will be provided by the drug manufacturer, Medivir AB.

If you decide to terminate your participation in this study, you should notify Dr. Kavita Sarin at [redacted]

This research study is looking for up to 30 people with early stage BCC, of which at least 10 people are planned to participate in the optional biopsy study. Stanford University expects to enroll research study participants until data on 30 tumors has been collected.

VOLUNTARY PARTICIPATION

Your participation in this study is entirely voluntary. Your decision not to participate will not have any negative effect on you or your medical care. You can decide to participate now, but withdraw your consent later and stop being in the study without any loss of benefits or medical care to which you are entitled.

DURATION OF STUDY INVOLVEMENT

It is planned that each participant will take part in this study for about 8 weeks. This is a 2-year study with 6 weeks of active treatment where we will collect medical information for each participant.

PROCEDURES

It may be harmful to enter this study while receiving some medications; therefore, you will be excluded if you are taking certain medications. Your Study Doctor will review your medications and let you know.

Research studies are usually dividing into at least 3 parts, typically consisting of:

1. Testing to see if you are eligible to participate in the study ("Screening");
2. Testing during study treatment to monitor your health and the effects of the study treatment ("Study Evaluation Procedures"); and

3. Testing after your treatment is complete ("Follow-up"). Testing/procedures for each of these parts are described separately below.

Some of these examinations, tests, or procedures may be part of your regular medical care, and/or and may be done even if you do not join the study. If you have had some of them recently, they may not need to be repeated.

Before you join this study, Kavita Sarin, MD, PhD, and her research study team will review this document with you and ask you to sign this informed consent document. After you have signed this document, and received a signed copy, the study will begin with a Screening Visit.

All the procedures listed below are research-related and not part of your regular medical care, with the exception of the planned removal of your BCC at week 8 of the study.

Screening Visit:

Location: The location of the study visits will be at one of the following:

Stanford Medicine Outpatient Center
450 Broadway St; Pavilion B
Redwood City, CA 94063

Dermatology Clinic at Portola Valley
3240 Alpine Road
Portola Valley, CA 94028

Stanford Skin Care Center
900 Blake Wilbur Drive,
Palo Alto, CA 94304

Contact the study team at [redacted] regarding your Study Visit at any of these locations.

Screening Visit:

If you choose to participate, the first activity will be "Screening." During the Screening Visit, you will be asked to have the following tests and activities or assessments;

- The Study Doctor will perform a physical exam to include recording your height, weight and vital signs (blood pressure, pulse rate and temperature). She will review your current medications and medical history. She will also collect some general information about you e.g., age; gender; race.
- You will be asked how well you are able to perform normal daily living activities (such as bathing; driving; shopping; working; etc.).
- A blood sample (2 to 3 teaspoons) may be taken for a serum pregnancy test (if you are a woman who can become pregnant). The pregnancy test must be negative within 1 day before the 1st dose of study drug.
- A serum pregnancy test if you are a woman of child-bearing potential.

The Study Doctor will determine if you are eligible to join the study based on the information collected at this visit.

Women of Childbearing Potential

If you are pregnant or currently breast-feeding, you may not participate in this study. It is not known whether Remetinostat is safe for the fetus (unborn child) or a breast-fed baby.

Visit 1:

- The Study Doctor will go over this consent form and perform a physical exam to include recording your weight and vital signs, as described above.
- You will be asked how well you are able to perform normal daily living activities, as described above.
- She will review your current medications, past medical history
- Your BCC(s) will be measured and photographed.
- A small sample of your BCC may be collected, typically by slicing off a small piece (a "shave biopsy"), for biomarker testing. This biopsy is optional.

Drug treatment: You will be instructed to apply topical 1% Remetinostat to individual BCCs 3 times a day for 6 weeks. You will cover the treated BCCs with a sticky strip bandage, such as a Band-Aid.

Study Drug Application Diary

You will be provided with a diary to record when you apply the Study Drug. This is important because it allows the study team to understand how often participants are applying the medication to their cancer(s). You will be asked to fill out this diary for the full duration of time you are applying the Study Drug.

We may contact you weekly by phone to see how you are doing.

Phone Call (Week 2)

- Someone from the treatment team will call you to check compliance with medication application, drug application method, Adverse Events, and any changes in the medications you take.

Visit 2 (Week 4):

- The Study Doctor will perform a physical exam to include recording of your weight and vital signs, as described above.
- You will be asked how well you are able to perform normal daily living activities, as described above.
- She will review your current medications and any side effects or symptoms you may have experienced with the study drug.
- Your BCC(s) will be measured and photographed.
- Your medication diary will be reviewed

Phone Call (Week 6)

- Someone from the treatment team will call you to check compliance with medication application, drug application method, Adverse Events, and any changes in the medications you take.
- You will be reminded to stop the study drug at this time.

Visit 3 (Week 8):

- The Study Doctor will perform a physical exam to include recording of your weight and vital signs, as described above.
- You will be asked how well you are able to perform normal daily living activities, as described above.
- She will review your current medications and any side effects or symptoms you may have experienced.
- Your BCC(s) will be measured and photographed.
- The tumor may be surgically removed at week 8 per regular medical care for BCCs.
- We may temporarily stop or reduce the duration of your treatment if your lesions become irritated from the Remetinostat
- You will apply your last dose of Remetinostat 30 mins before your BCC is surgically removed.
- However, if your surgery has not yet been scheduled, you will be asked to continue treatment until your surgery for a maximum of 4 weeks.

Blood collection: Blood collection will typically be from a vein in your arm, using a blood collection needle. This is called venipuncture. Standard clean techniques ("aseptic") will be used. Your blood samples will not be stored but sent to the Stanford Clinical Laboratory. These samples will be labeled with your name, date of birth and MRN. About 2 to 3 teaspoons (10 to 15 mL) of blood will be collected. :

Tumor biopsy: A sample of tissue that is taken from your body for laboratory testing, such as a sample of your BBC tumor, is called a "biopsy." If a screening biopsy is collected, a thin slice from the top of the BCC lesion it will cut off with a special cutting instrument. This type of biopsy is called a "shave" biopsy. No sutures or stiches are required after this type of biopsy.

Tissue Sampling for Laboratory Research Tests

Research using tissues, such as from your tumor or a blood sample, is an important way to try to understand human disease. A sample of tissue that is taken from your body for laboratory testing, such as from skin or a tumor, is called a "biopsy."

Biopsy samples of tumor tissue may be taken by cutting out the entire tumor or by taking a small sample using a special curved blade.

_____ I consent to optional biopsy for biomarker testing

_____ I do not consent to optional biopsy for biomarker testing

Your tissue samples will be stored in a secure location at Stanford University labeled with your initials, date of removal and a unique code number. Only the Study Doctor and her research team will be able to identify you and link your sample to your medical record. Analysis on your tissue samples will be conducted at Stanford and/or by the study sponsor, Medivir.

You have the right to refuse to allow your tissues to be studied now or saved for future study. You may withdraw from this study at any time. The Study Doctors might retain the identified samples, eg, as part of your routine clinical care, but not for additional research.

_____ I consent to allow my tissues to be saved for future research

_____ I do not consent to allow my tissues to be saved for future research

Phone Call (end of study – Week 12):

You will be contacted by phone to review any residual side effects or symptoms you may have experienced.

Adverse event (or side effects) monitoring will be performed as part of the procedures described above. During the treatment period, the Study Doctors will monitor you for any potential side effects. If the side effects are severe, the Study Doctors may withdraw your medication completely.

If, at any time, you have any symptom; side effect; or injury affecting you physically or mentally during the study, **you should tell the Study Doctors or nurses right away**, even if you do not think it was caused by the study medication.

If you have to go to the hospital for any reason, please tell the hospital staff that you are participating on a research study and give them the contact information for the study team. You may be provided with a card with the study team contact information, similar to the one represented below.

PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

- Follow the instructions of the Study Doctor and study staff.
- Apply the study drug as instructed. Apply your last dose 30 mins before your BCC(s) is surgically removed.
- Keep your study appointments. If it is necessary to miss an appointment, please contact the Study Doctor or research study staff to reschedule as soon as you know you will miss the appointment.
- Tell the Study Doctor or research study staff about any side effects, doctor visits, or hospitalizations that you may have.
- Tell the Study Doctor or research staff if you believe you might be pregnant or if your partner becomes pregnant.
- Keep the study drug refrigerated and in a safe place, away from children and for your use only.
- Ask questions as you think of them.
- Tell the Study Doctor or research staff if you change your mind about staying in the study.

Women of Childbearing Potential: If you are a woman who is able to become pregnant, it is expected that you will use an effective method of birth control to prevent exposing a fetus to a potentially dangerous agent with unknown risk. If you are pregnant or currently breast feeding, you may not participate in this study. You understand that if you are pregnant, if you become pregnant, or if you are breast-feeding during this study, you or your child may be exposed to an unknown risk.

In order to confirm that you are not pregnant (to the extent medically possible), you agree to choose to have a pregnancy test done before beginning this research study.

You must agree to avoid sexual intercourse or use a birth control method judged to be effective by the Study Doctor and which will not interfere with the proposed investigation. You must accept the risk that pregnancy could still result despite the responsible use of reliable method of birth control. You agree to notify the Study Doctor as soon as possible of any failure of proper use of your birth control method, or if you become pregnant, either of which may result in your being withdrawn from the study.

If you are a man participating in this study and your partner is able to become pregnant, you and your partner must use adequate contraception while you are participating in the study and for 3 months after stopping treatment. Your doctor will discuss with you what methods of birth control are considered adequate. You should inform your study doctor if your partner becomes pregnant during the study or within 3 months of stopping treatment.

Your doctor will discuss with you whether your preference for birth control is considered adequate.

WITHDRAWAL FROM THE STUDY

If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation at any time. Your decision will not affect your ability to receive medical care for your disease and you will not lose any benefits to which you would otherwise be entitled.

If you decide to withdraw your consent to participate in this study, you should notify Dr. Kavita Sarin at [redacted]. If you withdraw after starting treatment with the study drugs, your Study Doctor will need to check on your health status afterwards. If you do not want the Study Doctor to check on your health status after withdrawing from the study, you should say so. Any information collected before you withdraw will be kept and used to complete the research.

To help you safely finish your participation in the study, the Study Doctors may ask you to have more tests and you will be asked to come into the clinic for an End-of-Treatment Visit. The Study Doctor will discuss your treatment options with you at this time. If your participation in the study is ended, you must return all study-related supplies, including unused Study Drug.

The Study Doctor may also withdraw you from the study and the study medication may be stopped, without your consent for one or more of the following reasons:

- Your cancer gets worse.
- Failure to follow the instructions of the Study Doctor and/or study staff.
- The Study Doctor decides that continuing your participation could be harmful to you.
- Pregnancy
- You need treatment not allowed in the study.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

After you finish the study or stop taking the Study Drug for any other reason, you may continue to be checked regularly (physical exams; blood tests; tumor measurements; X-rays; other scans, etc.) if you continue to have significant side effects from the treatment. This is called follow-up. Your Study Doctor will follow your progress, in accordance with good medical care, for as long as it is felt to be necessary by both you and the Study Doctor, unless you ask otherwise. Many if not all of these procedures will

be part of your regular continued medical care. In addition, further treatment outside the study will be discussed with you.

POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES

There are risks, discomforts, and inconveniences associated with any research study. These deserve careful thought. You should talk with the Study Doctor if you have any questions.

Risks from Remetinostat (SHP-141)

The main remetinostat treatment-related AEs were skin findings including irritation, dermatitis, erythema, dry skin, rash, exfoliation, skin lesion, inflammation, pain, paraesthesia, erythema, pruritus, infection, application site reaction, skin papilloma which resolved on reducing the frequency of remetinostat application or stopping application for short periods of up to 2 weeks.

The effect of Remetinostat in pregnancy has not been studied. Similarly, excretion of Remetinostat into breast milk has not been examined. Therefore, pregnant and lactating women are excluded from clinical trials at this time.

Risks from Topical Treatments

Many drugs that are administered topically can cause irritation and/or inflammation of the skin. This may be due to the ingredients the drug is mixed in, or the drug itself.

Allergic reactions

Sometimes people have allergic reactions to drugs. Although unlikely, especially for an application to a small area of skin, if you have a very bad allergic reaction, you could die. Some things that happen during an allergic reaction that could be a sign or symptom of a life-threatening allergic reaction (anaphylaxis) are:

- Rash
- Having a hard time breathing (shortness of breath)
- Wheezing when you breathe
- Sudden drop in blood pressure
- Swelling around the mouth, throat, or eyes
- Fast pulse
- Sweating

You should get medical help and notify the Study Doctor or study staff if you experience any of these or any other side effects during the study.

Risks of giving blood (venipuncture)

The Study Doctor or study staff will take your blood by sticking a needle in your arm. Some problems you might have from this are pain, bruising, dizziness and infection.

Risks for Women of Childbearing Potential

If you are a woman, you cannot be in this study if you are pregnant. Woman should not breastfeed a baby while in this study. You must not become pregnant during the study or within 3 months of stopping treatment.

If you are pregnant or nursing while receiving Remetinostat, there may be risks to the fetus or nursing child. Nobody knows what these risks are right now. Some drugs cause premature (early) birth or birth defects.

All historically documented and confirmed post-menopausal women (women who no longer have menstrual periods), surgically sterile women, or women using a medically acceptable form of birth control will be considered for participation in the study. All women who can have children will have a serum pregnancy test as part of the screening visit. If you have a positive pregnancy test, you will not be able to enter in the study.

The only certain way to prevent pregnancy is to not have sex. If you are a woman who can have children, the study staff will talk to you about birth control you must use during the study.

Even if you use a medically proven birth control method, there is a chance you could still become pregnant. Some types of birth control will not work when you are taking certain drugs.

If you think you are pregnant during the study or become pregnant within 3 months of stopping treatment, you must tell the Study Doctor immediately. Women who become pregnant during the study will have to leave the study. If you become pregnant, you will be removed from the study. The study doctor or study staff may ask for information about the pregnancy and the birth of the baby. The study doctor will share this information with the sponsor and the IRB (a group of people who review research studies to protect the rights and welfare of research participants).

POTENTIAL BENEFITS

Use of Remetinostat (SHP-141) is this study may help reduce your BCC lesion(s). It is not known whether being in this study will help you, since Remetinostat (SHP-141) has not been used in treatment of BCC before. Your BCC might not get better or may even get worse while you are in the study. However, information from this study might help researchers determine how to treat BCC patients in the future.

We cannot and do not guarantee or promise that you will receive any benefits from this study.

ALTERNATIVES

You do not have to be in this study to receive treatment for your cancer. Instead of taking part in this study, you may choose to receive treatment with other cancer drugs or have immediate surgical treatment. Your study doctor will discuss the risks and benefits of other treatments with you.

The Study Doctors will discuss with you the risks and benefits of these alternatives, including which other treatments might be suitable for you.

If you decide that you do not wish to take part in this study and wish to pursue any of these, or other alternatives, this will not change your regular medical care or the other treatment choices in any way.

PARTICIPANT'S RIGHTS

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction.

If you decide not to participate, tell the Study Doctor. You will still receive care for your disease and will not lose any benefits to which you would otherwise be entitled.

You will be told of any significant new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study. After you hear about this information, you have the right to withdraw from the program.

ClinicalTrials.gov

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by US 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.

CONFIDENTIALITY

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed except as authorized by you or as required by law. However, there is always some risk that even de-identified information might be re-identified.

Patient information may be provided to Federal and other regulatory agencies as required. The US FDA, for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

The purpose of this research study is to obtain data or information on the safety and effectiveness of Remetinostat; the results will be provided to the sponsor, the Food and Drug Administration and other federal and regulatory agencies as required.

CERTIFICATE OF CONFIDENTIALITY

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

Authorization To Use Your Health Information For Research Purposes

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will my health information be utilized in the study?

The primary purpose of this study is to determine if 6 weeks of topical Remetinostat applied three times daily will suppress Basal Cell Carcinoma. If you choose to participate, the study staff will obtain personal information about you for research purposes. This may include medical and research records that may identify you and that may describe your health. The Study Doctor and research staff may obtain and give out records about your study visits, physical exams, medical history, telephone calls, laboratory results, other test results and response to study treatment including side effects, medications, and study drug you received.

Do I have to sign this authorization form?

You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study including receiving any research-related treatment. Signing the form is not a condition for receiving any medical care outside the study.

If I sign, can I revoke it or withdraw from the research later?

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (eg, necessary to maintain integrity of research). If you wish to

revoke your authorization for the research use or disclosure of your health information in this study, you must write to:

Kavita Sarin, MD, PhD
Dermatology - North Campus
450 Broadway St

Redwood City, CA 94063

What Personal Information Will Be Obtained, Used or Disclosed?
Your health information related to this study may be used or disclosed in connection with this research study, including, but not limited to information related to your medical condition, blood tests, pathology, EKG, physical exam, current medications, side effects, and photos of lesions and medical imaging results. The researchers will also get information from your medical record (including hospital records from the Stanford Healthcare and your referring physician's records).

Who May Use or Disclose the Information?
The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Study Doctor, Kavita Sarin, MD, PhD
- Research Staff
- The Stanford University Administrative Panel on Human Subjects in Medical Research; the Stanford Data and Safety Monitoring Committee (DSMC); and/or any other unit of Stanford University as necessary

Who May Receive or Use the Information?
The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- Medivir AB or their representatives
- The American Skin Association
- The Food and Drug Administration (FDA) and/or other state or international regulatory authorities

- The Office for Human Research Protections (OHRP) in the US Department of Health and Human Services (DHHS)

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?
Your authorization for the use and/or disclosure of your health information will end on 31 December 2032 or when the research project ends, whichever is earlier.

Will access to my medical record be limited during the study?
To maintain the integrity of this research study, you may not have access to any health information developed as part of this study until it is completed. At that point, you would have access to such health information if it was used to make a medical or billing decision about you (eg, if included in your official medical record).

_____ _____
Signature of Adult Participant Date

_____
Printed Name of Adult Participant

NOTE: If using the Short Form Consent process for informed consent in another language pursuant to an "Alteration of HIPAA Authorization," the participant should not sign the HIPAA "Authorization To Use Your Health Information For Research Purposes" above.

FINANCIAL CONSIDERATIONS

Costs

If you participate in this study, the study will pay for those services, supplies, procedures, and care associated with this study that are not a part of your routine medical care. However, there may be additional costs to you. These include basic expenses like transportation and the personal time it will take to come to the Study Visits.

You and/or your health insurance must pay for services, supplies, procedures, and care that are required during this study for routine medical care. **You will also be responsible for any co-payments and/or deductibles as required by your insurance**. Participation in this study is not a substitute for health insurance.

Payments

You will not be paid to participate in this research study. There is no reimbursement offered for any expenses related to your participation in this study.

Funding Source

This study is funded in part by Medivir, AB, the company who owns the study drug Remetinostat. The Stanford Dermatology Department is also partially funding this study. The National Institutes of Health are providing additional financial support for this study.

Consultative or Financial Relationships

None

COMPENSATION for Research-Related Injury

All forms of medical diagnosis and treatment – whether routine or experimental – involve some risk of injury. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the Study Doctor and the research study team will assist you in obtaining appropriate medical treatment. In the event that you have an injury or illness that is directly caused by your participation in this study, reimbursement for all related costs of care first will be sought from your insurer, managed care plan, or other benefits program. If costs of care related to such an injury are not covered by your insurer, managed care plan or other benefits program, you may be responsible for these costs. If you are unable to pay for such costs, the Study Doctor will assist you in applying for supplemental benefits and explain how to apply for patient financial assistance from the hospital. **You will be responsible for any associated co-payments or deductibles as required by your insurance.**

You do not waive any liability rights for personal injury by signing this form.

CONTACT INFORMATION

Questions, Concerns, Complaints, or to Report an Injury or Side Effect: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Study Doctor, Kavita Sarin, MD, PhD, at [redacted]You should also contact her at any time if you feel you have been hurt by being a part of this study.

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

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at [redacted] or toll-free at 1-[redacted] . You can also write to the Stanford IRB, Stanford University, 1705 El Camino Real, Palo Alto, CA 94306.

Alternate Contact: If you cannot reach the Study Doctor, please contact study coordinator at [redacted]

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

As a research participant you have the following rights. These rights include but are not limited to the participant's right to:

- Be informed of the nature and purpose of the experiment;
- Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- Be given a description of any attendant discomforts and risks reasonably expected;
- Be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- Be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
- Be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
- Be given an opportunity to ask questions concerning the experiment or the procedures involved;
- Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;

- Be given a copy of the signed and dated consent form; and
- Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

Signing your name means you agree to be in this study and that you will receive a copy of this signed and dated consent form.

_____ _____
Signature of Adult Participant Date

_____
Printed Name of Adult Participant

_____ _____
Signature of Person Obtaining Consent (POC) Date

_____
Printed Name of POC

The following witness line is to be signed only if the consent is provided as a summary form and accompanied by a short-form foreign language informed consent document.

_____ _____
Signature of witness Date

_____
Printed name of witness
(eg, staff, translator/interpreter, family member)

The translated short form must be signed and dated by **BOTH** the participant **AND** the witness.

The English consent form (“referred to as the "Summary Form" in the regulations”):

- Must be signed by **BOTH** the witness **AND** the Person Obtaining Consent (POC).
- The non-English speaking participant does **NOT** sign the English consent.
- The non-English speaking participant should **NOT** sign the HIPAA participant line.
- If the participant is non-English speaking, the POC must ensure that any questions or options presented by the consent form are documented and initialed by the POC on the Summary Form, per the participant's wishes, as they are understood during the consent process.