Please check all that are applicable:

☐ I am an adult participant in this study.

Print your name here: _____

☐ I am the parent or guardian granting permission for a child in this study (the use of "you" refers to "your child" or "your ward.")

Print child's name here: _____

****

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

PURPOSE OF RESEARCH

You are invited to participate in a research study of chronic pruritus or long-lasting itch associated with epidermolysis bullosa (EB). We hope to learn if a research medication known as Serlopitant is effective and safe to use in patients with EB and chronic pruritus. You were selected as a possible participant in this study because you have been diagnosed with EB and chronic pruritus (itch).

Researchers want to find out more about an investigational drug called Serlopitant. An "investigational drug" is a drug that is being tested and is not approved for sale in the United States by the U.S. Food and Drug Administration (FDA).

In addition, this study will compare doses of Serlopitant (5 mg) with a placebo to see if taking Serlopitant is better than taking a placebo. The placebo is a tablet that looks like a drug but has no drug or other active ingredient in it. Be aware that this form refers to Serlopitant as "study drug."

If you decide to terminate your participation in this study, you should notify Dr. Albert Chiou at (650) 721-8418.

This research study is looking for 40 to 50 patients with EB and chronic itch. Enrollment will occur in the United States. Stanford University expects to enroll all research study participants.

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

This research study is expected to take approximately 16 weeks, with up to 4 weeks of screening, 8 weeks of active treatment, and a follow up period of 4 weeks. A washout period of at least 30 days may be required for patients currently taking medication that is not allowed during the study. Enrollment for the entire study may take up to 16 months. Stanford University will be responsible for analysis of study data.

If you decide to be in this study and the study doctor says you can be in the study, your participation will last up to 16 weeks.

You will visit the study center 2 times (Screening Visit and Month 2 after starting study medication) to have the procedures and tests described in this form. Your visits will be followed up by monthly calls (Month 1 and Month 3 after starting study medication) by a research coordinator or research team member in order to ask how you are doing and if you have any problems during the course of study. Ask the study doctor or study staff about your study visit schedule.

PROCEDURES

If you choose to participate, Dr. Chiou and his research study staff will start by screening you to see if you are eligible to participate in the study.

Phone Screen (Day -60 to -30)

- A member of the research team may call you to introduce this study.
- We will ask questions to determine your eligibility.
- If eligible and interested, you may give your contact information to us. A read-only version of this consent form and a medical release form (if you are not a Stanford patient) will be mailed to you.
- After the phone screen, we will review your medical history to make sure you meet eligibility requirements.
- If you meet study criteria, we will contact you to schedule a Screening Visit at Stanford.

Screening Visit (Day -30 at Stanford): screening procedures should be completed within 30 days prior to Baseline/Day 1 of study medication. This may be extended by at least 14 days if a medication washout is required. The following procedures are to be performed:

- The study information will be reviewed with you and written consent will be obtained.
- Inclusion/exclusion criteria will be reviewed in depth.
- Demographic and background information will be collected; this includes your age, gender, race and ethnicity.
- We will review your medical history including history of EB and allergies.
- Information on all concurrent medications will be collected.
- An abbreviated physical examination, including assessments of weight, height and skin will be performed.
- Vital signs (blood pressure, pulse, temperature) will also be recorded.
- If you are a female of childbearing potential, a urine sample will be collected for a pregnancy test.
- Blood (up to 2 tablespoons) and urine samples for safety testing will be collected.
- You will be provided with an itch diary where you will record your itch severity nightly until you receive the study medication in the mail. You will also receive a return envelope to send the itch diary back to us when you receive a new itch diary in the mail.
- Photographs: If you give the study center permission to take your photograph, a member of the study staff will take photos of the affected area. We will designate a target wound area and photograph it.
- Questionnaires: You will be asked to complete questionnaires about your quality of life, including your day to day activities. Questionnaires may be completed on paper or online.
- In the case that you are eligible, you will be instructed on how and when to take the study medication, which will be mailed to you.
- We will contact you when we can determine if you are eligible or not eligible for the study.

The screening period may be extended by at least 14 days if a washout from medications which are not allowed while on study is required. If you decide to be in this study, you may have to stop taking your regular medication during the entire study.

Make sure to tell the study staff about all of the medicines you take so you will know if any must be stopped. If you stop your regular medication to be on the study, your symptoms might come back or your health might get worse.

Any blood or urine samples taken during this study will not be saved for future research.

Baseline (Day 1 of treatment)

During the screening period, if the exams, tests and procedures show that you can be in the study, and you choose to take part, then you will be mailed home the study medication and an Itch Diary to record your itch score. The medication package will include detailed instructions on how and when to take the study medication. Once you receive a new Itch Diary, you will mail back the previous Itch Diary in the return envelope provided during the Screening Visit (if applicable).

Screening and Baseline visits may be combined. In this case you will be given an itch diary to record your nightly itch score for at least 7 days before starting Study Drug.

Eligible patients will be randomly (like tossing a coin) assigned to receive one of the two different patterns of therapy. There will be a 50% chance of receiving either pattern of therapy.

1. Approximately one half of the patients (20 -25) will receive Serlopitant: 5 mg once daily by mouth following a 3-tablet loading dose on Day 1.
2. Approximately one half of the patients (20-25) will receive placebo (no active ingredient): Once daily by mouth, following a 3-tablet loading dose on Day 1.

You have an equal chance of being in either of the study groups.

Neither you nor the study doctor or the study staff will be able to pick which study group you are in. You will not know and the study doctor or study staff will not know which group you are in. The study doctor and study staff can find out if it is necessary to know for your health. If this happens, the study doctor or study staff may not be able to tell you which study group you were in until everyone finishes the study (which may be years in some cases).

At the Baseline day, the following procedures are to be performed:

- You will take a loading does of 3 tablets. Thereafter, you will take 1 tablet every day at bedtime for 8 weeks.
- You will continue to fill out an itch diary where you will record your itch severity nightly and the time that you take your study medication.
- Mail in Itch Diary.
- If Screening and Baseline visits are combined, you will be given an itch diary to record your nightly itch score for 1 week (7 days) before starting Study Drug.

Phone Call at Month 1

- You will be asked about any side effects you may have had and any medications you may have taken.
- The study doctor or study staff will administer the questionnaires verbally and record your responses. Alternatively, questionnaires may be completed online.
- You will receive a new itch diary.
- If you are a female of childbearing potential, a urine sample will be collected for a pregnancy test.
- Blood and urine samples will be collected for safety laboratory tests. Testing will be completed at a lab close to your home.
- Additional medication will be dispensed after laboratory test results have been reviewed.

End of Treatment Visit (Month 2, at Stanford)

- You will be asked about any side effects, you may have had and any medications you may have taken.
- Vital signs (blood pressure, pulse, temperature) will be assessed
- An abbreviated physical examination, including assessments of weight, height, skin and lymph nodes will be performed.
- Photographs will be taken (if you consented to photography).
- You will be asked to complete your questionnaires. Questionnaires may be completed on paper or online.
- Your itch diary will be reviewed and collected.
- You will receive a new Itch Diary and a return envelope to send the itch diary back to us after the follow-up phone call at the end of Month 3.
- Your study medication bottle will be collected.
- If you are a female of childbearing potential, a urine sample will be collected for a pregnancy test.
- Blood and urine samples will be collected for safety tests.

Follow-up Period Phone visit at Month 3

- You will be asked about any side effects, you may have had and any medications you may have taken.
- The study doctor or study staff will administer the questionnaires verbally and record your responses. Alternatively, questionnaires may be completed online.
- You will mail in your Itch Diary for the previous month in an envelope provided to you by the study staff.

You will find out if you were on active drug or on placebo after the last study patient completes study treatment. At that time**,** you will be given the option to continue your study participation by taking active drug for 12 months.

If you would like to continue with the treatment,

- you will be provided with the research medication and
- research daily itch diary.
- you will be followed up by phone at baseline, 1 month, 2 months, 6 months and 12 months.
- you will have no on-site visits.
- you are required to perform lab tests at baseline, 1 month, 2 months, 6 months and 12 months while on the extension at a lab convenient to you.

If you decide not to continue on active drug, the study doctor or study staff will call you for your follow up phone call and you will have completed 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.

To confirm to the extent medically possible that you are not pregnant, you agree 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 investigator and which will not interfere with the proposed investigation.

Effective contraception is defined as follows: oral/implant/injectable/transdermal contraceptives, intrauterine device, condom with spermicide, or diaphragm with spermicide. Abstinence or partner's vasectomy is acceptable if the female agrees to use effective contraception if she decides to discontinue abstinence or to have sexual intercourse with a non-vasectomized partner.

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 investigator 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.

PHOTOGRAPHY

If the skin on the area of your body that itches has redness, scratches, nodules, or lesions, you will be asked to allow photographs to be taken of the affected area(s). If you agree, photographs will be taken. This photography is optional. You can still be in

the study even if you do not want the study doctor or study staff to take photographs of your affected areas of itch. Be aware that photographs taken during this study will be used for information purposes only. Your name will not be used if the photographs are shared at meetings or in publications.

We will use these photographs to record changes in the affected area if the itching lessens or stops. All reasonable efforts will be made to protect your identity, including blocking your eyes with a black bar, or using only partial face photographs if the affected area is the face.

CONSENT FOR PHOTOGRAPHY

I agree to have photographs taken for the study. I further agree that any pictures taken of me during this study may be used for information purposes only, if considered appropriate, unless I notify the study doctor in writing that she is not to use these photographs prior to publication. All reasonable efforts will be made to protect my identity, including blocking of my eyes, or using only partial face photographs. Please check **one box** below:

- ❑ Yes, I agree to allow the study doctor or study staff to photograph the area(s) of my skin affected by itching as described in this form. I also agree to the release and uses of the photographs as described above.

- ❑ No, I do not agree to allow the study doctor or study staff to photograph the areas of my skin affected by itching during the study. I can still be in the rest of the study.

PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

- Follow the instructions of the Protocol Director and study staff.
- **Take the study drug as instructed – at bedtime without food, at least 2 hours after your evening meal.**
- Complete your questionnaires as instructed.
- You should **avoid eating grapefruit** while participating in this study.
- Complete your itch diaries as instructed.
- **Have your blood drawn and urine collected for safety testing.** Additional research drug cannot be dispensed until laboratory results are reviewed by the study doctor.
- Keep your study appointments. If it is necessary to miss an appointment, please contact the Protocol Director or research study staff to reschedule as soon as you know you will miss the appointment.

- Tell the Protocol Director or research study staff about any side effects, doctor visits, or hospitalizations that you may have.
- Tell the Protocol Director or research staff if you believe you might be pregnant or gotten your partner pregnant.
- Keep the study drug in a safe place, away from children and for your use only.
- Ask questions as you think of them.
- Tell the Protocol Director or research staff if you change your mind about staying in the study.

WITHDRAWAL FROM 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. Chiou at (650) 721-8418.

We will perform the following procedures if you decide to withdraw from this study:

- You will be asked about any side effects, you may have had and any medications you may have taken
- Vital signs (blood pressure, pulse, temperature) will be assessed
- Photographs will be taken (if you consented to photography)
- You will be asked to complete your questionnaires
- Your itch diary will be reviewed and collected
- If you are a female of childbearing potential, a urine sample will be collected for a pregnancy test (if leaving study prior to Month 1 visit)
- Blood and urine samples will be collected for safety laboratory tests.
- Blood samples will also be taken to assess the amount of research medication you have in your blood (if leaving study prior to Month 1 visit).
- Your study medication bottle will be collected

The Protocol Director 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:

- Failure to follow the instructions of the Protocol Director and study staff.
- The Protocol Director 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.

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 Protocol Director if you have any questions.

You may have side effects from the drugs or procedures used in this study, and they will vary from person to person. Everyone taking part in the study will be watched carefully for any side effects. However, doctors do not know all the side effects that may happen, and there may be unknown side effects that occur.

During this study, your blood will be drawn to perform a variety of tests. The risks of drawing blood include temporary discomfort from the needle in your arm, bruising, swelling at the needle site and, in rare instances, infection.

To date, over 1000 subjects have been studied on Serlopitant in previous studies. Most of the side effects were mild or moderate.

The most commonly reported side effect was headache.

Other most commonly reported (>2% of patients) side effects include:

diarrhea	dizziness	urinary tract infection
nausea	drowsiness	cough, upper respiratory tract infection
dry mouth	tiredness	back pain
irritation of the nose and mouth	high blood pressure	irritation of the sinuses

Less commonly reported (<2% of patients) side effects include:

vomiting	disturbance in attention	pain in the nose and mouth
abdominal pain	irritation of the eye	joint pain
heart burn	itch	bone pain

The following rare but serious side effects were reported;

- spontaneous abortion or miscarriage occurred in one patient taking a low dose of Serlopitant (5 times lower dose than in this study). This event was considered not related to study treatment.

- hypothyroidism (under active thyroid gland) in one patient taking Serlopitant at a very low dose (20 times lower than in this study) and
- peripheral neuropathy (weakness, numbness and pain from nerve damage) in one patient taking Serlopitant at the same dose as in this study. Both of these events were considered not related to study treatment.
- recurrent depression with suicidal thoughts, was reported in July 2015, that was not related to the drug and caused the patient to be hospitalized for a long period of time.

In a recent study conducted at Stanford the following mild or moderate side effects were reported in patients treated with Serlopitant at 5 mg per day; headache, nausea, dizziness, skin infection, chest infection, diarrhea, cold, cough, pain, toothache and flu-like symptoms.

An unexpected serious side effect of pulmonary embolism (blood clot in the lung) was reported in May 2018, which was determined not to be related to the drug, and resulted in death.

Data collected to date in young adult animals and in adult clinical trial patients taking Serlopitant support clinical trials in adolescent patients.

If you decide to enroll in this study, you may need to stop taking certain medications prior to starting the study. Additionally, once you start taking the study medication, you should not change which medications you are taking, or how much of your medications you are taking. If you feel that you must change your medications while enrolled in the study, we may need to end your participation.

Please tell the study doctor or study staff right away if you have any side effects. Please tell them if you have any other problems with your health or the way you feel during the study, whether or not you think these problems are related to the study drug.

Sometimes people have allergic reactions to drugs or product ingredients. 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 a symptom of a life-threatening allergic reaction (anaphylaxis) are:

- A rash
- Having a hard time breathing
- Wheezing
- A sudden drop in blood pressure (making you feel dizzy or lightheaded)
- Swelling around the mouth, throat, or eyes
- A fast pulse
- Sweating

You should get medical help and contact the study doctor or study staff if you have any of these or any other side effects during the study.

If you decide to be in this study, you might have to continue to take your current medications and you may not be able to add any additional medications. Make sure to tell the study staff about all the medicines you take so you will know if any must continue throughout the study. If you stop your regular medication to be in the study, your symptoms might come back or your health might get worse.

Some people in the study will get placebo instead of Serlopitant. Taking placebo is the same as not taking anything for your chronic itch. If you take placebo during this study, it is possible that your chronic itch may get worse.

Completing questionnaires could lead you to feel uncomfortable or upset. Please tell the study doctor or study staff if you feel uncomfortable or upset while completing the questionnaires. You have the right to refuse to answer any question.

You should talk to the study doctor or research staff if you have any questions.

POTENTIAL BENEFITS

Taking part in this study may or may not cause your health to improve. Information from this study may help doctors learn more about Serlopitant and the treatment of chronic itch in patients with EB. This information may benefit other patients with chronic itch related to EB.

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 get help for your chronic itch. Although most common treatments for itch have not worked for you, some other things you may be able to consider are:

- Anticonvulsants and gabapentin
- Opioid receptor agonists and antagonists
- Antidepressants such as SSRIs
- Alternative wound care dressings

You should discuss your alternatives to participating in research with the study doctor or study staff. In addition, you may discuss your options with your regular health care provider.

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 Protocol Director.

You will be told of any important 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.

ClinicalTrials.gov

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.

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 Food and Drug Administration (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 Serlopitant; the results will be provided to the sponsor, the Food and Drug Administration and other federal and regulatory agencies as required.

We may schedule blood tests for you at a local lab to run safety lab tests. We will need to provide information on your identity (name, date of birth, address, etc.) to order these tests.

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 purpose of this study is to learn if a research medication known as Serlopitant is effective and safe to use in patients with EB and chronic itch.

The study doctor and study staff may carry out certain statistical tests on your information, along with the information collected from the other patients who entered the study. The study doctor may report results at medical meetings and in medical magazines, so that other doctors can find out about the results of the study. The results of this study may be used for future medical research.

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 (e.g., 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: Dr. Albert Chiou, Stanford University, Dermatology Dept., 450 Broadway St. Pavilion C MS:5334, 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, your name, address, phone number, or social security number. Your records include:

- Medical records
- Medical history
- Physical exams
- Laboratory results
- Photographs (if you agreed to participate in the study photography)
- Interviews and/or questionnaires
- Information from other procedures you have as part of the study

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 Protocol Director, Dr. Albert Chiou
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Research Staff

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:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services
- The funding agency, Epidermolysis Bullosa Research Partnership, and anyone acting on its behalf

- Menlo Therapeutics Inc., the company providing the study medication
- The Food and Drug Administration
- Quest Diagnostics

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 December 31, 2045 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 (e.g., if included in your official medical record).

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

_____ _____
Signature of Legally Authorized Representative (LAR) Date
(e.g., parent, guardian or conservator)

_____ _____
Print Name of LAR LAR's Authority to Act for Participant

FINANCIAL CONSIDERATIONS

Payment/Reimbursement
The study will cover reasonable costs for transportation and housing. If you stay overnight for a research visit, the study will also reimburse you per diem for food (about $50 per day per person).

You will be paid $75 per visit to help support your participation in this trial. The maximum you may receive is $225.

Payments may only be made to U.S. citizens, legal resident aliens, and those who have a work eligible visa. You may need to provide your social security number to receive payment.

Costs
If you participate in this study, the study will pay for those services, supplies, procedures, and care associated with the 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.

Sponsor
EB Research Partnership is providing financial support and Menlo Therapeutics Inc. is providing study drug for this study.

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 Protocol Director and the research study staff 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. **You will be responsible for any associated co-payments or deductibles as required by your insurance.**

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 Protocol Director will assist you in applying for supplemental benefits and explain how to apply for patient financial assistance from the hospital.

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

CONTACT INFORMATION

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 (650)-723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 3000 El Camino Real, Five Palo Alto Square, 4th Floor, Palo Alto, CA 94306.

Appointment Contact: If you need to change your appointment, please contact Melissa Barriga at 650-736-8033.

Alternate Contact: If you cannot reach the Protocol Director, please contact Irene Bailey at 650-721-7149.

Questions, Concerns, or Complaints: 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 Protocol Director, Dr. Albert Chiou at (650) 721-8418. You should also contact him at any time if you feel you have been hurt by being a part of this study.

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 to be 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.

May we contact you about future studies that may be of interest to you? ☐ Yes ☐ No

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

_____
Print Name of Adult Participant

_____ _____
Signature of Legally Authorized Representative (LAR) Date
(e.g., parent, guardian or conservator)

_____ _____
Print Name of LAR LAR's Authority to Act for Participant
(e.g., parent, guardian or conservator)

The IRB determined that the permission of two parents is recommended in accordance with 21 CFR 50.55 unless one parent is deceased, unknown, incompetent, not reasonably available, or only one parent has legal responsibility for the care and custody of the child. *Not reasonably available* means that the other parent is not present during the consenting process, or will not be available prior to the start of research procedures.

_____ _____
(If available) Signature of Other Parent or Guardian Date

_____ _____
Print Name of Other Parent or Guardian Authority to Act for Participant

STANFORD PERSONNEL ONLY

_____ _____
Signature of Person Obtaining Consent Date

_____
Print Name of Person Obtaining Consent

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 consent.

_____ _____
Signature of Witness Date

_____
Print Name of Witness

(e.g., staff, translator/interpreter, family member)

- *Translated short form must be signed and dated by both the participant (or their LAR) AND the witness.*
- *The English consent form (referred to as the "Summary Form" in the regulations):*
  - *Must be signed by the witness AND the Person Obtaining Consent (POC).*
  - *The non-English speaking participant/LAR does not sign the English consent.*
  - *The non-English speaking participant/LAR should not sign the HIPAA participant line*
  - *If the participant or the LAR is non-English speaking, the Person Obtaining Consent (POC) must ensure that 1) the LAR's Description of Authority is completed and 2) 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.*