

INFORMED CONSENT FORM

Official Title

Renewal of the Multi-center Randomized Controlled Trial of Refeeding in Anorexia Nervosa

Study

Individualized Study of Refeeding to Optimize iNpatient Gains (iStRONG)

ClinicalTrials.gov Identifier

NCT04966858

Document Date

August 16, 2024

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: Individualized Study of Refeeding for Optimal iNpatient Gains (iSTRONG)

For PARENTS OF MINOR PARTICIPANTS and ADULT PARTICIPANTS

Research Project Director:	Andrea Garber, PhD, RD, Professor of Pediatrics, UCSF 3333 California St, Suite 245, Box 0503, San Francisco, CA. Phone: 415-514-2180; e-mail: andrea.garber@ucsf.edu	
Study Coordinators:	Siena Vendlinski strongstudy@ucsf.edu	415-476-6779 (work) or siena.vendlinski@ucsf.edu

**** PLEASE NOTE:** Throughout this document, "you", may be referring to "your child", if this form is being reviewed by a parent of a minor **

This is a clinical research study. Your study researcher, Andrea Garber, PhD, RD, from the UCSF Division of Adolescent Medicine, or her research staff will explain this study to you.

STUDY SUMMARY

Introduction: We are asking you to consider taking part in a research study being done by Andrea Garber at UCSF.

The first part of this consent form gives you a summary of this study. We will give you more details about the study later in this form. The study team will also explain the study to you and answer any questions you have.

Research studies include only people who choose to take part. It is your choice whether or not you want to take part in this study. Please take your time to make a decision about participating. You can discuss your decision with your family, friends and health care team.

Purpose of the study: Atypical anorexia nervosa (AAN) is a new diagnosis describing patients who meet all criteria for anorexia nervosa (AN) except body mass index. These patients responded poorly to the superior nutritional rehabilitation (or "refeeding") treatment that we studied in a previous clinical trial, so we still need to find the best refeeding treatment for this group.

This study will examine the safety and efficacy of a **new individualized treatment that has the potential to improve treatment outcomes** for people with AAN, a diverse and growing patient population. If you choose to take part in this study, you will receive one of two treatments during your hospitalization. You will either receive the hospital's standard-of-care treatment, which uses set meal sizes for all patients, or Individualized Caloric Refeeding (ICR), which personalizes the meal sizes for each patient's measurements. At the start, the ICR approach may provide the same amount of food as the standard approach or a little bit more, and both approaches will aim to end up at the same amount by the time you leave the hospital.

Study Procedures: If you choose to be in this study, you will be randomly assigned to receive either the standard hospital treatment or the ICR treatment during this hospitalization. All other clinical care by your doctors in the hospital will remain the same. There are a few extra things that you would do in the hospital if you are in the study, including a survey online, some interview questions, giving extra blood that would be collected around the time when you are already getting your regular hospital blood draws, and a metabolic test that involves breathing into a machine called an indirect calorimeter. Also, if you decide to participate, we would collect small sample of stool from the commode collection container for future research.

After getting out of the hospital, there are no specific instructions from the study about treatment or what to eat – you should talk to your doctor about what they recommend. We'll ask you to come back to our study site four times over the next year to do the tests again (the surveys, blood draw, and indirect calorimeter breathing machine), in addition to measuring your vital signs (including heart rate and blood pressure). You would be in this study about one year and visit the research site approximately four times.

Possible Risks: There are risks to taking part in any research study. Some of the most likely risks of participation in this study include:

- **Blood Draw (venipuncture):** Blood draws during the inpatient admission and study follow-up visits (after the hospitalization) may cause temporary discomfort from the needle stick, and risk for bruising, infection, and fainting. While you are in the hospital, the team will attempt to draw study blood samples at the same time as the standard of care lab draw to avoid extra needle sticks.
- **Indirect calorimetry:** Breathing into the indirect calorimeter to measure metabolic rate can be uncomfortable for some people - our small hand-held indirect calorimeter features a mouthpiece and nose clip instead of an enclosed breathing canopy, which improves comfort, and you only need to breathe into it for 10-15 minutes.
- **Randomization risks:** As in any randomized controlled trial, you will be assigned to a treatment by chance, and the treatment you receive may prove to be less effective or to have more side effects than the other study treatment(s) or other available treatments.
- **Nutrition assessments, interviews, and questionnaires:** Talking about diet and filling out questionnaires about health and feelings can be upsetting or bring up difficult issues.

We'll tell you about the other risks later in this consent form.

Possible Benefits: You may benefit directly from participating in the study, but this cannot be guaranteed. It is possible that one of the two study treatments may shorten your hospital stay, but there is no way to know if that will be true ahead of time.

Your Other Options:

You do not have to agree to participate in this study. Your other choices include:

- Getting treatment or care for your condition without being in a study.

Please talk to your doctor about your choices before agreeing to participate in this study.

Below is a more complete description of this study. Please read this description carefully. You can ask any questions you want to help you decide whether to join the study. If you join this study, we will give you a signed copy of this form to keep for future reference.

DETAILED STUDY INFORMATION

This part of the consent form gives you more detailed information about what the study involves.

Research studies include only people who choose to take part. Please take your time to make your decision about participating. You may discuss your decision with your family and friends and with your health care team. If you have any questions, you may ask your study doctor.

You are being asked to take part in this study because you are being hospitalized for medical instability due to malnutrition, and you may have atypical anorexia nervosa.

Why is this study being done?

The purpose of this study is to examine the safety and efficacy of a new individualized treatment that has the potential to improve treatment outcomes for patients with atypical anorexia nervosa, a diverse and growing patient population. In this study, you will get either the standard of care diet, or the new treatment, ICR, as your meal plan during this hospitalization. You will not get both and you will not get to choose which treatment you get.

The National Institutes of Health (NIH) National Institute of Child Health and Human Development (NICHD) pays for the conduct of this study.

How many people will take part in this study?

About 74 people between the ages of 12-24 yrs will take part in this study, with 37 enrolled at UCSF and 37 at Stanford University. Half the participants at each hospital will receive the ICR diet, and half will receive the standard diet.

What will happen if I take part in this research study?

Whether or not you choose to participate, you will have daily measurements of your weight, vital signs (like blood pressure) and laboratory testing because that is the standard care for patients with malnutrition during this type of hospitalization. However, if you do agree to participate in the study, there are a few extra things that we would ask you to do.

During your hospitalization...

If you choose to take part in this study, you will be "randomized" into one of the study groups described below. Randomization means that you are put into a group by chance. A computer program will place you in one of the groups. Neither you nor your doctor can choose the group you will be in. You will have an equal chance of being placed in either group.

- **If you are in group A**, you will receive the **Individualized Caloric Refeeding (ICR) treatment**, which personalizes the size of the meals for you as an individual. In general, the ICR diet will start with either about the same amount of food as the standard diet or a little bit more, and both diets will end up providing the same amount.
- **If you are in group B**, you will receive **standard-of-care treatment** throughout your hospitalization, which uses set meal sizes for all patients.

The following tests and procedures are part of regular care during your hospitalization and will also be used for the study:

- Weight will be measured every morning.
- Vital signs will be measured multiple times a day.
- Blood will be drawn every morning for the first 7 days, and every other day after that, to measure electrolyte levels in the blood.

If choose to take part in the study, then you will need the following extra tests and procedures that are outside of regular care:

- **Blood Samples:** Extra tubes of blood (a total of 3-4 teaspoons) will be drawn for the study tomorrow and once again near the end of the hospitalization (with less blood, about 2 ½ teaspoons), when you are getting ready to be discharged. A small portion of the blood will be kept anonymously in long-term storage for future research.
- **Indirect Calorimetry:** We will ask you to breathe into a small hand-held device called an indirect calorimeter, to measure metabolic rate. First we'll have you lay down and rest comfortably for 15-20 minutes, followed by breathing into the device for 10-15 minutes while you continue to lie down.. During the pandemic, the study may ask you to take a COVID-19 test prior to participating in indirect calorimetry. If this is required, we will ask you to sign another consent form for the COVID-19 test.
- **Stool Sample Collection (UCSF participants only):** As part of standard care during your hospitalization, you may use a bedside commode instead of the regular toilet. Hospital staff will collect a small sample from the commode collection container and it will be kept anonymously in long-term storage for future microbiome research. You do not have to do anything extra for this sample collection.

We will also ask you to complete surveys and interviews for the study:

- **Online Survey** (33 min today, 10 min on discharge): We will send a survey link via email or text message, which will ask questions about your thoughts and feelings for you to fill out on your own. Once today, and again before leaving the hospital.
- **Nutrition Assessment** (up to 20 min – today only): Our trained research staff will ask you to recall everything you ate in the last 24 hours before being admitted to the hospital.
- **Health Care Interview** (10 min – today only): Research staff will ask you about your health care in the last 6 months, such as how many doctor's visits you have been to, how much of it was covered by insurance, and what kind of medications you have taken.
- **Daily quick text surveys** (<1 min, each day): During the hospitalization at UCSF, we will text you a quick check-in every evening to ask how you are feeling on a scale of 0-100 in terms of stress.

- **Parent surveys:** If it is okay with you, we would like to ask your parents to answer some questions in a parent survey, too. The parent surveys will ask about how your parent thinks you are doing, their perception of your thoughts and feelings, and some questions about their own feelings about helping you manage an eating disorder.

The parent surveys are completely optional. If you would rather *not* have your parents answer questions, or if you are an adult and you are choosing not to tell them you are in the hospital at all, that is okay. Just check the “no” box below, and you can still fully participate in the study. If you do say yes, we would only contact your parent *after* they already know you are in the hospital. If yes, we will ask your parent(s) if they want to participate. If they do not want to fill out the parent surveys, you may still participate in the full study.

***** Adult participants: Do you give our study team permission to contact your parent(s) for the following:**

- ☐ **NO**, the study team may not contact my parent(s).
- ☐ **YES**, the study team may contact my parent(s) to ask if they are interested in filling out surveys about my health.
- ☐ **YES**, the study team may contact my parent(s) if I harm myself or report intent to harm myself.

***** Parents of minor participants: Do you give the study permission to contact you about filling out parent surveys about your child’s health?**

- ☐ **NO**, the study team may not contact me.
- ☐ **YES**, the study team may contact me to ask if I’m interested in filling out surveys about my child’s health.

Parent Name

Phone number

Relationship (e.g. Mother, Father, Grandma, etc.)

Email address

After you leave the hospital...

We will schedule four follow-up study visits: 3 months, 6 months, 9 months, and 1 year after leaving the hospital. There are no special instructions from the study about what to eat after you leave the hospital – you should talk to your doctor about what they recommend.

These study visits are not part of your regular doctor’s care. If you choose to receive care with the UCSF Adolescent Medicine outpatient clinic, then we can coordinate your study visits when you have regular doctor’s visits to minimize extra procedures and extra travel.

Follow-up study visits will be scheduled in the morning, because we need you to be fasting (without eating breakfast yet) for the blood test.

Follow-up visit location: All follow-up study visits will take place at the UCSF Pediatric Clinical Research Center at 1825 4th Street, 6th floor, Area C.

Follow-up study visit tests and measurements:

- **Blood drawing (venipuncture):** At each study visit, a blood sample will be drawn by inserting a needle into a vein in your arm. Each sample will be approximately 3-4 teaspoons. Over the course of a year, a total of about 6 ½ to 7 ½ tablespoons will be drawn for the whole study. A small portion of the blood will be kept anonymously in long-term storage, for future study by our group.
- **Height, weight, and vital signs:** For each study visit we will measure your height, weight, and orthostatic vital signs (5 minutes resting, 2 minutes standing). These measurements are also part of routine clinical care in the outpatient Adolescent Medicine Clinic – if you are in care in our clinic and you have an appointment near the time of the study visit, we will not need to repeat these measures at the study visit.
- **Indirect Calorimetry:** Just like in the hospital, we will ask you to breathe into small device for 10-15 minutes, after lying down resting for 15-20 minutes. If the hospital still requires COVID-19 tests for breathing-related research at the time of your study visit, we will ask you to complete a COVID-19 test prior to arriving, after signing another consent form for the test.

Follow-up questionnaires and interviews:

- **Online Survey (26 min):** At the time of each study visit, we will send a survey link via email or text message, which will ask questions about your thoughts and feelings. Ideally, you should fill it out on the same day as the study visit.
- **Nutrition Assessment (20 min):** Our trained research staff will ask you to recall everything you ate in the last 24 hours.
- **Health Care Interview (10 min):** Research staff will ask you about health care you have received between study visits, such as how many doctor's visits you have been to, and what kind of medications you have taken.
- **Parent surveys:** If you selected "yes" above, we will ask your parents to fill out a survey at the time of your follow-up visits.

In addition to the procedures described above, we will also collect two pieces of information from your medical record. First, we would collect information about the medical care you received in the hospital (like blood pressure and laboratory tests). Second, we would want to look at your hospital bills to find out if the study treatment could change the cost of treating atypical anorexia nervosa. You would not have to do anything extra for this except say that it is OK (by signing this form) to get this information from our billing department. As with all your information, this will be kept completely confidential.

Optional Home Visits: If you live far away and it is difficult for you to travel to our research center for follow-up study visits, then we will offer the option of a home visit. A member of the study team will bring equipment to your home to measure your height, weight, and indirect calorimetry. We would not do a blood draw or vital signs. If any health or safety concerns are identified at the home visit, our study staff will contact your primary care doctor.

Contacting your non-UCSF doctor: If it is okay with you, we would like to ask your primary care doctor to provide a few pieces of medical information. We would only ask for information that the doctor routinely measures at your visits, including height, weight, blood pressure, temperature, and heart rate. This way, we will have access to “back up” measurements in case you ever miss a follow-up study visit or home visit.

If you sign this form, indicating it is okay for us to ask your doctor for this information, then we will also ask you to sign a medical information release form to give your doctor permission to release the information to us.

Staying in touch: If you choose to participate, we will also ask for your contact information so that we can stay in touch with you about the study via phone, text, or email to schedule your follow-up visits. If we are in touch by text message, these would be from a regular phone and therefore unsecured – if someone has access to your phone, they may find out that you are participating in a research study. We will use a more secure platform to send you survey links via text message and email. We may also send you a birthday card in the mail, or very occasional updates or newsletters about our research to your email through the year that you participate. If you give extra permission at the very bottom of this form, by initialing next to the optional “consent for future contact,” then we may let you know if/when we are doing other studies that you might be interested in. Research is voluntary and you may opt out of the study at any time – if so, we would stop contacting you immediately.

How long will I be in the study?

You will be assigned to one of the two refeeding treatments for the duration of your hospitalization. After you are discharged from the hospital, we will no longer ask you to eat a specific diet. We will ask you to visit the research center for follow-up exams and surveys four times: 3 months, 6 months, 9 months, and 1 year after discharge.

Can I stop being in the study?

Yes. You can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop your participation safely. It is important to tell the study doctor if you are thinking about stopping so any risks from the study diet can be evaluated by your doctor. Another reason to tell your doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you.

The study doctor may stop you from receiving the study treatment at any time if he/she believes it is in your best interest, or if the study is stopped. This would mean they would change your diet during this hospitalization to a different one that the study did not assign. If you stop receiving the study diet part way through the hospitalization, you can still remain in the study and fill out surveys and do follow-up visits if you choose to.

iSTRONG Study Chart

You will receive the ICR study diet or standard diet every day while you are in the hospital. The chart below shows what will happen to you during your hospitalization as part of the study. The left-hand column shows the day, and the right-hand column tells you what to do on that day.

DURING THE HOSPITALIZATION

Day	What you do
<i>First full day in the hospital</i>	- Research tubes of blood will be drawn - Breathing machine while you rest (30 min) - Fill out survey online (~32 min) - Interviews with research staff members: - Nutrition Assessment (~20 min) - Health Care Questions (~10 min) - Receive \$100 gift card
<i>Every day in the hospital</i>	Quick check-in survey (less than 1 minute) – texted to your phone
<i>The day before discharging from the hospital</i>	- Research tubes of blood will be drawn - Breathing machine while you rest (30 min) - Fill out survey online (~10 min)

FOLLOW-UP STUDY VISITS: After leaving the hospital

Day	What you do at each visit
<u>Four visits:</u> 3 months 6 months 9 months 1 year	- Visit the Pediatric Clinical Research Center (PCRC) at: 1825 4th Street, 6th floor, Area C. <i>Please do not eat in the morning before arriving to the visit</i> - Blood test - Breathing machine while you rest (30 min) - Height, weight, and vital signs - Fill out survey online (~26 min) - Interviews with research staff members: - Nutrition Assessment (~20 min) - Health Care Questions (~10 min) - Receive \$100 gift card

What side effects or risks can I expect from being in the study?

You may have side effects while on the study, listed below. 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 happen. Side effects may be mild, or in some cases, side effects can be serious.

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

Risks and side effects related to the study include those which are:

Likely

- **Blood drawing (venipuncture) risks:** Drawing blood may cause temporary discomfort from the needle stick, bruising, infection, and fainting.
- **Indirect calorimeter risks:** Breathing into the indirect calorimeter can be uncomfortable for some people - our hand-held indirect calorimeter features a mouthpiece and nose clip instead of an enclosed breathing canopy, which improves comfort, and requires only a fraction of the breathing time.
- **Nutrition assessments, interviews, and questionnaires:** Talking about diet and filling out questionnaires about one's health, thoughts, feelings, and behaviors can be upsetting or bring up difficult issues.

Less Likely

- **Randomization risks:** You will be assigned to a treatment program by chance, and the treatment you receive may prove to be less effective or to have more side effects than the other study treatment(s) or other available treatments.
- **Blood draw risks:** While discomfort is common and likely (above), bruising, infection, or fainting from the blood draw are less common side effects.
- **Unknown Risks:** The experimental treatments may have side effects that no one knows about yet. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

Rare but serious

- **Risks to confidentiality:** Certain aspects of your protected health information (such as name and diagnosis), medical history, hospital billing data, and demographics will be collected for this study. A data breach would lead to loss of privacy. We have tight security measures in place to prevent such a breach from happening.
- **Refeeding syndrome:** Any patient with malnutrition admitted to the hospital for refeeding is at risk for the refeeding syndrome, **whether you participate in the study or not.** Early signs of the refeeding syndrome include changes in the electrolyte levels in your blood. If it gets more severe, the refeeding syndrome can rarely include cardiac arrest, coma and death. Therefore, doctors monitor all patients with malnutrition closely for any signs of side effects during the refeeding process. Doctors keep you safe by proactively prescribing oral mineral/electrolyte supplements to prevent these rarer risks. We have never seen these serious side effects within our

program at this hospital. While there is no evidence to suggest that one refeeding treatment would put you at higher risk than the other, it is still unknown if the new treatment, ICR, may be more likely to cause the refeeding syndrome, and so study patients are monitored closely by the doctors to prevent any serious side effects. Changes in blood levels of electrolytes may happen earlier on the ICR treatment, so the doctors will monitor blood levels closely, even early on in the hospitalization.

For more information about risks and side effects, ask your study doctor.

Are there benefits to taking part in the study?

We do not know if participating in this study will make you better. There is a chance that if you are in the group that receives ICR, your hospitalization may be shortened – but we cannot guarantee that this will be true.

Even if there is no direct benefit to you immediately, this study will help doctors learn more about refeeding, and it is hoped that this information will help in the treatment of future patients with atypical anorexia nervosa.

What other choices do I have if I do not take part in this study?

Your other choices may include:

- Getting treatment or care for your condition without being in a study.

Please talk to your doctor about your choices before deciding if you will take part in this study.

What will happen if I agree to donate my specimens?

If you agree to let researchers collect and store your specimens for future research, by signing this consent form, the following will happen:

- A small portion of the study-specific blood samples and the stool samples, described above, will be saved in what is called a “tissue bank” or “biobank” for possible future research. We also will collect and save information from your medical record, including things like vital signs, results of physical examinations, diagnoses, medications, other treatments, and survey responses. We do not know for sure if your banked specimens or medical record will be used in the future, but they might be used in research about the microbiome in eating disorders, hormonal changes in refeeding, metabolic changes in refeeding, or other research.
- As described above, we will draw extra blood two times while you’re in the hospital (2 ½ - 4 teaspoons each time) You will also have blood drawn at each of your four study follow-up visits. Some of this blood will be tested right away for the current study, and a portion of it will go to the tissue bank for future research. The stool samples that we will collect while you are in the hospital, as described above, will be sent directly to the tissue bank for future research.

- The tissue bank will not have identifiable information about you or who you are, although they may be able to see the dates of your hospitalization.
- When we are ready to take the samples out of the tissue bank for future research, our study team may also gather additional information from your medical record at that time. The researchers who run this study are the only ones who will have access to your identifiable information.
- If other scientists not a part of this study would like to analyze your specimens, we will provide de-identified specimens and other de-identified medical information (for example, diagnosis, blood pressure, age), but we will not give them your name, address, phone number, or any other information that would identify you. Your anonymous information may also be included in a health research database (controlled access, not public). Reports about any research will not be given to you or your doctor.
- The research will not change the care you receive. Your specimen and any information about you will be kept until it is used up or destroyed. Your personal health information cannot be used for additional research without additional approval from either you or a review committee.
- Your specimens will be kept for about five years. If you decide later that you do not want your specimens and information to be used for future research, you can notify the investigator in writing at andrea.garber@ucsf.edu, and we will destroy any remaining identifiable specimens and information if they are no longer needed for your care. However, if any research has already been done using portions of your specimens, the data will be kept and analyzed as part of those research studies.

What risks are involved with donating specimens for research?

Collecting specimens: The risks of your blood draws for tissue banking are described in the risks section above.

Confidentiality: Donating specimens to a tissue bank may involve a loss of privacy, but information about you will be handled as confidentially as possible. Study data will be physically and electronically secured. As with any use of electronic means to store data, there is a risk of breach of data security. Your name will not be used in any published reports from research performed using your specimen. The manager of the UCSF BIOS Repository tissue bank and select tissue bank staff members will not have access to any identifying information about you and they will not release any identifying information about you to researchers using your specimen outside of our study team. The UCSF Institutional Review Board and other University of California personnel also may see deidentified information about you to check on the tissue bank.

How will my specimens and information be used?

Researchers will use your specimens (blood and stool samples) and information to conduct this study. Once the study is finished using your specimens and information, we may share them in a de-identified way with other researchers so they can use them for other studies in the future. We will not share your name or any other personal information that would let the researchers know who you are. We will not ask you for additional permission to share this de-identified information.

Research results: There may be times when researchers using your information and/or specimens may learn new information. The researchers may or may not share these results with you, depending on a number of factors.

How will information about me be kept confidential?

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total privacy. Some information from your medical records will be collected and used for this study. The signed consent form and some of the research tests will be added to your medical record. Therefore, people involved with your future care and insurance may become aware of your participation and of any information added to your medical record as a result of participation. Study tests that are performed by research labs, and information gathered directly from you by the researchers will be part of your research records but will not be added to your medical record. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. Your blood samples and stool samples may be de-identified and sent to an outside laboratory for testing. To protect your confidentiality, the outside laboratory will not have access to your name, or any personal information. Instead, we will give you an anonymous study ID number such as 3001 and an anonymous fake name such as AB123 that will be sent to the lab with your tube of blood or your stool samples. Therefore, they will have access to the results of the tests, but they won't know who the results belong to.

Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

- Representatives of the National Institutes of Health
- Representatives of the University of California
- Representatives of Stanford University

Are there any costs to me for taking part in this study?

No. The study will pay for all items associated with this research study; you or your insurer will not be billed for any study-specific activities.

Two types of procedures will be done during this study. Some are part of your standard medical care and others are only for research. You or your insurer will be billed for the standard medical care that is not part of the study, such as the cost of hospitalization. You will be responsible for your co-pays, deductibles, and any other charges that your insurer will not pay. There is a possibility that your insurer may not cover all standard medical care costs if you are receiving medical services out of network. Any procedures done only for research, such as the research blood samples and the follow-up study visits, will not be charged to you or your insurer.

Will I be paid for taking part in this study?

In return for your time you will be paid a total of \$500 for taking part in this study. This includes \$100 on enrollment and \$100 at each follow-up visit that is completed.

During follow-up visits, the cost of gas will be reimbursed if you travel more than 50 miles roundtrip to the site from your house. Parking validation will also be provided during follow-up visits.

What happens if I am injured because I took part in this study?

It is important that you tell your study doctor, Dr. Andrea Garber, if you feel that you have been injured because of taking part in this study. You can tell Dr. Garber in person, call her at 415-514-2180, or email her at andrea.garber@ucsf.edu.

Treatment and Compensation for Injury: If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of California or the study sponsor NICHD, depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Institutional Review Board at 415- 476-1814.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you, and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Who can answer my questions about the study?

You can talk to your study doctor about any questions, concerns, or complaints you have about this study. Contact your study doctor Andrea Garber at 415-514-2180.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the office of the Institutional Review Board at 415-476-1814.

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

CONSENT

You have been given copies of this consent form and the Experimental Subject's Bill of Rights to keep.

You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to participate or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign below.

Participant's Name	Age	Participant ID#

Participant's Signature	Date

Person Obtaining Consent's Signature	Date

If participant is under 18 years old:

If you wish to allow your child to participate in this study, you should sign below.

The person being considered for this study is unable to consent for himself/herself because he/she is a minor. By signing below, you are giving your permission for your child to be included in this study.

Parent or Legal Guardian's Name

Parent or Legal Guardian's Signature

Date

If the parent is a non-English speaker and interpreter services were used:

Witness Signature

Date

Interpreter number

Contact info for sending surveys and study materials:

Phone: _____

Mailing Address: _____

Email address: _____

Consent for using your data for other research studies (optional)

If you give permission, we may share your research data with other UCSF studies you consent to. Please indicate below whether you give permission to share your research data with other UCSF studies you are enrolled in.

_____(Initial) I give consent to have my research data from this study shared with another UCSF study that I am enrolled in.

Consent for Future Contact (optional)

If you give permission, we may want to re-contact you after you have completed the study. Please indicate below whether you give permission for the study to contact you in the future for the following three reasons (you may choose between 0 and 3 options).

_____(Initial) I give consent to be contacted about future research by this study team.

_____(Initial) I give consent to be contacted in the future if the study team would like to request missing data or ask me to sign a release form from another doctor.

_____(Initial) I give consent to be contacted in the future about the published results of this study.