Official Study Title:
Effect of Oral Cimetidine in the Protoporphyrias

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Mass General Brigham

Research Consent Form
Certificate of Confidentiality Template
Version Date: February 2021

Subject Identification

Protocol Title: Effect of Oral Cimetidine in the Protoporphyrias

Principal Investigator: Amy Dickey, MD

Site Principal Investigator: Karl E. Anderson, M.D.

Description of Subject Population: Patients with protoporphyria 15 years old or older

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

Some of the people who are eligible to take part in this study may not be able to give consent because they are less than 18 years of age (a minor). Instead we will ask their parent(s) to give permission for them to take part in the study and will ask them to agree (give their assent) to take part. Throughout the consent form, "you" always refers to the person who takes part in the study.

IRB Protocol No: 2021P002095
IRB Expiration Date: 3/26/2026
Consent Form Valid Date: 3/27/2025
IRB Submission: CR5/AME28

Key Information

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. Your decision won't change the medical care you get within the University of Texas Medical Branch at Galveston (UTMB) now or in the future.

The following key information is to help you decide whether or not to take part in this research study. We have included more details about the research in the Detailed Information section that follows the key information.

Why is this research study being done?

In this research study we want to learn more about whether taking oral cimetidine pills (a medication normally used to treat gastrointestinal issues such as acid reflux) regularly can reduce the level of protoporphyrin in your blood, and if it can affect your Protoporphyria symptoms.

How long will you take part in this research study?

If you decide to join this research study, it will take you about 9 months to complete the study, which includes 4 study visits (either at home or in person at UTMB) and 6 phone calls in between visits.

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

If you decide to join this research study, the following things will happen:
About 4 study visits (either at home or in person) over the course of 9 months, with 6 phone calls in between. These study visits will include:

- Review of your medical history
- Study questionnaires (daily via a text message)
- Collection of blood samples for lab testing

Why might you choose to take part in this study?

We cannot promise any benefits to you from taking part in this research study. You may benefit from participation in this research if cimetidine lowers protoporphyrin levels; however, the investigators do not know if this will happen. Others with Protoporphyria may benefit in the future from what we learn in this study.

Why might you choose NOT to take part in this study?

Taking part in this research study has some risks and requirements that you should consider carefully.

Important risks and possible discomforts to know about include:

- Most common side effects of oral cimetidine: headache, diarrhea, dizziness, drowsiness
- Risks associated with a blood draw
- The possibility of having Erythropoietic protoporphyria (EPP) pain

A detailed description of side effects, risks, and possible discomforts can be found later in this consent form in the section called "What are the risks and possible discomforts from being in this research study?"

Other things to consider are the time commitments for study visits and phone calls.

What other treatments or procedures are available for your condition?

Other treatments or procedures that are available include Scenesse, an approved treatment for Protoporphyria.

If you have questions or concerns about this research study, whom can you call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Amy Dickey, MD is the person in charge of this research study. You can call her at 206-681-0218 anytime. You can also call Paul Jiang at 781-354-9735 with questions about this research study.

If you have questions about the scheduling of appointments or study visits, call Paul Jiang at 781-354-9735.

UTMB's Contact Information:

Site Principal Investigator:	Karl E. Anderson, M.D.	Phone#: 409-772-4661
Site Research Coordinator:	Csilla K Hallberg	Phone#: 409-747-4832

If you want to speak with someone **not** directly involved in this research study, please contact the Mass General Brigham IRB. You can call them at 857-282-1900.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research
- Any pressure to take part in, or to continue in the research study

Detailed Information

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.

Why is this research study being done?

The purpose of this research study is to look at whether taking oral cimetidine regularly can reduce the level of protoporphyrin in your blood, and if it can affect your Protoporphyria symptoms. Protoporphyrin is the compound that builds up in the body of people who have Protoporphyria.

The U.S. Food and Drug Administration (FDA) has approved cimetidine to treat gastrointestinal issues such as acid reflux, but the FDA has not approved cimetidine to treat Protoporphyria.

Who will take part in this research?

We are asking you to take part in this research study because you have been diagnosed with a Protoporphyria - either Erythropoietic Protoporphyria (EPP) or X-Linked Protoporphyria (XLP

The total number of people expected to take part in this research study across all sites is up to 40.

Funds for conducting this research are provided by the National Institutes of Health and a grant from the Food and Drug Administration.

What will happen in this research study?

Before any study research procedures or tests are done, you will be asked to sign this consent form. Before the study starts, you must tell the study doctor about any other research studies that you are taking part in and any medications that you are taking, including non-prescription medications, vitamins or herbal remedies. The study team will review your medications before you enter the study and you should inform the study team of any new medications before starting them and of any changes to existing medications before changing them.

This research study will compare cimetidine to placebo. The placebo looks exactly like cimetidine, but contains no cimetidine. Placebos are used in research studies to see if the results are due to the study drug or due to other reasons.

At some time during the study, we will give you cimetidine. At another time, we will give you placebo.

Screening Visit
During the first study visit (Screening Visit), the study doctor will assess whether you are eligible to participate in the study. Genetic and/or biochemical tests will be reviewed to confirm your diagnosis of Protoporphyria. It is possible that the tests performed during the Screening Visit may show that you are not eligible to participate. If this is the case the study doctor will tell you why.

During the screening visit we will:

- Review your medical history
- Draw blood for lab tests
- Complete questionnaires
- Perform a pregnancy test if you are a woman who is able to become pregnant
- Give you a light dosimeter. This is a small device that you will wear throughout the study which will capture the amount of UV exposure you get each day. You will not be able to see how much UV exposure the device measures.

You do not need to take any contraception to be part of this study, however if you are a female of child-bearing potential we will be testing to see if you are pregnant in the beginning and during the study. If you are pregnant or become pregnant you will not be able to participate as pregnancy is known to affect Protoporphyria symptoms. There is no evidence that short-term use of cimetidine affects an unborn child negatively.

When blood samples are collected the amount of blood taken will be approximately 25 milliliters/5 teaspoons. A total of 125 milliliters/ 25 teaspoons of blood will be drawn throughout the study.

Treatment Periods and Washout
The study has three parts after screening: Treatment Period 1 (three months), Washout Period (three months), and Treatment Period 2 (three months).

There will be 1 study visit, and monthly phone calls, during each Treatment Period 1 and 2. Visits will last about 60 to 90 minutes. You will be asked to attend study visits at the University of Texas medical Branch or these visits will be arranged remotely and you will have to visit a local lab to have blood samples taken.

Treatment Period 1
For the first three months of the study (Treatment Period 1) the treatment you get will be chosen by chance, like flipping a coin. You will have an equal chance of being given either cimetidine or placebo. Neither you nor the study doctor will know which study treatment you are getting; however, this information could be obtained in an emergency. The treatment will be mailed to you at home.

Washout Period
There is a three month washout period between Treatment Periods 1 and 2. During this time you will not take any study medication. You will have one study visit or phone call during this time. After the washout period is over you will start Treatment Period 2.

Treatment Period 2
For the last three months of the study (Treatment Period 2) you will receive the treatment that was not given in Treatment Period 1. If you received cimetidine in Treatment Period 1 you will receive placebo in Treatment Period 2. If you received placebo during Treatment Period 1, you will receive cimetidine in Treatment Period 2.

End of Study
There will be one final study visit once you have finished Treatment Period 2.

During all study visits and scheduled phone calls we will:
- Ask about any side effects you might be experiencing
- Review your medications
- Perform a pregnancy test if you are a woman who is able to become pregnant

During most study visits and scheduled phone calls we will we will:
- Complete questionnaires
- Check the light dosimeter

During some study visits and scheduled phone calls we will:
- Review your medical history
- Draw blood for lab tests

During every day of the last two months of taking either study drug or placebo, you will receive a daily text questionnaire through an app on your phone which will ask if you have had any Protoporphyria symptoms that day, and if so how severe they were and whether you experienced any pain. During those same days, you will be asked to continuously wear a small light dosimeter that connects with your personal cell phone. This light dosimeter will measure the

amount of light that you are exposed to each day. You may be asked to complete additional days/weeks of light dosimetry and text questionnaires in order to ensure proper device connection and functioning.

Your Responsibilities If You Take Part in This Research

If you decide to take part in this research study, you will be responsible for the following things:

- Reliably taking the study medications on a daily basis and reporting if and when medication has not been taken. If you realize you missed a dose of the study medication, please contact the study team immediately.
- Coming to your scheduled study visits on time
- Providing us with blood samples at each visit
- Providing accurate details about your medical history as well as medications you are taking.
- Reporting any illnesses or medical problems that occur during the time you are taking the study medication
- Completing quality of life questionnaires at each study visit
- Completing a daily text questionnaire about your symptoms
- Wearing your light dosimeter device. Further instructions on how to wear the device will be provided.
- Answering phone calls from the study team every month and accurately reporting any medical problems on these calls

How may we use and share your samples and health information for other research?

The samples and information we collect in this study may help advance other research. If you join this study, we may remove all information that identifies you (for example your name, medical record number, and date of birth) and use these de-identified samples and data in other research. It won't be possible to link the information or samples back to you. Information and/or samples may be shared with investigators at our hospitals, at other academic institutions or at for-profit, commercial entities. You will not be asked to provide additional informed consent for these uses.

The clinical information collected for this study will be stored at the Data Management and Coordinating Center and also sent to a Federal data repository. The data management center uses several layers of protection for the clinical data stored there. It meets all of the local and federal security requirements for research datacenters.

Because this project involves the use of medications or a medical device, it is necessary that we make a note of your participation in the electronic medical record. That way anyone treating you will be aware of your participation and may be able to avoid any unfortunate outcomes that could arise if your research participation were unknown.

Will you get the results of this research study?

At some point after the study, we will return a summary of participants' individual level light dosimetry data if this summary is requested by the participant. This summary will not include personal health or light exposure recommendations. The quality of this summary of the data will depend on how complete your survey responses are and how complete the light sensor data is. Forgetting to wear the device or to answer surveys will decrease the quality of this information. The information provided will include no recommendations or suggestions about your own health. The research we are doing is only a steppingstone in understanding EPP. Most of the findings that come from studying your information will not be relevant to your personal health. However, in the future, this may change.
You can choose to receive newsletters from porphyria patient advocacy organizations that may provide updates about the research studies we are doing. This newsletter will not announce your results or anyone else's, but it may tell you some information about what we are learning about EPP. We will also publish what we learn in medical journals, and information about these articles may be shared in communication from porphyria patient advocacy organizations.

What are the risks and possible discomforts from being in this research study?

Risks associated with participation in this study include the following:

- **Taking cimetidine may cause you to have one or more of the follow side effects: headache, diarrhea, dizziness, drowsiness and breast enlargement, and some less common but serious side effects like confusion, excitement, depression, nervousness and visual or auditory hallucinations. In addition, cimetidine could have side effects in Protoporphyria patients that may not be present in the general population. Cimetidine is also known to affect the immune response. Although in general it improves immune responses, it is theoretically possible that it could impair the immune response in some situations.**
- The risks of a blood draw include pain, bruising, and the slight possibility of infection at the place where the needle goes in. Some people feel dizzy or may faint during or after a blood draw.
- As with any drug, an allergic reaction can occur. Allergic reactions can be mild or more serious and can even result in death. Common symptoms of an allergic reaction are rash,

itching, skin problems, swelling of the face and throat, or trouble breathing. If you are having trouble breathing, call 911 immediately.

- There may be additional unforeseeable risks. If the investigators learn of any significant new findings which may change the risks involved in this study, they will be communicated to you as soon as possible.
- Although we will not give other researchers your name, we will give them basic information such as your race, ethnic group, and sex. This information helps researchers learn whether the factors that lead to health problems are the same in different groups of people. It is possible that such findings could one day help people of the same race, ethnic group, or sex as you. However, they could also be used to support harmful stereotypes or even promote discrimination.
- Your name and other information that could directly identify you (such as address, or social security number) will never be placed into a scientific database. Your date of birth will be placed into the database. However, because your genetic information is unique to you, there is a small chance that someone could trace it back to you. The risk of this happening is very small, but may grow in the future. Since the database includes genetic information, a break in security may also pose a potential risk to blood relatives as well as yourself. For example, it could be used to make it harder for you (or a relative) to get or keep a job or insurance. If your private information was misused it is possible you would also experience other harms, such as stress, anxiety, stigmatization, or embarrassment from revealing information about your family relationships, ethnic heritage, or health conditions.
- Wearifi, the company producing the light sensing device, will be receiving location information about you for the purpose of being able to determine the known light intensity in your region. Your location is potentially identifiable. A smartphone application will be downloaded on your phone, and your phone is a direct identifier. Alternatively, this application can be downloaded on a smartphone that we provide. Wearifi has agreed not store your phone number and will not keep this direct identifier in their system. Wearifi will not continue to store your data after completion of data analysis. All of the data transmitted to Wearifi will be transmitted in a coded form without identifiers. However, there is a small risk that someone at Wearifi may be able to identify you and your location.

What are the possible benefits from being in this research study?

It is important to know that you may not get any benefit from taking part in this research. Others may not benefit either. However, possible benefits may be:

- Lowering the levels of erythrocyte protoporphyrins. Lower protoporphyrin levels may result in some improvement of sun sensitivity symptoms

- Contribution to scientific knowledge and therefore possibly help for other individuals with this condition by what is learned from the study results

What other treatments or procedures are available for your condition?

You may decide not to take part in this research study without any penalty. The choice is totally up to you.

Instead of being in this research study, your choices may include:

- Taking Scenesse, an approved treatment for Protoporphyria

Can you still get medical care within the University of Texas Medical Branch (UTMB) if you don't take part in this research study, or if you stop taking part?

Yes. Your decision won't change the medical care you get within UTMB now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

We will tell you if we learn new information that could make you change your mind about taking part in this research study.

What should you do if you want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

Will you be paid to take part in this research study?

You will be reimbursed $100 dollars for each in-person study visit and $25 dollars for each study phone call, for a total of up to $550 for the completion of the entire study. You will be reimbursed for each visit that you complete, even if you do not complete the overall study. You will be issued a UTMB Clincard, which is a debit card that your funds are loaded onto. When a study visit is completed, funds will be approved and loaded onto your card. The funds are generally available within 48 hours and can be used at your discretion. You will be issued one card for the duration of your participation. If your card is lost or stolen, you can contact customer service at 1-866-952-3795. We will collect some information about you, including name, address, telephone number, date of birth, email address, if applicable, and your social security number (if a US citizen) in order to issue the debit card. All information is stored in a secure

fashion and will be deleted from system once the study has been completed and the funds on the card have been all used.

Travel expenses will be reimbursed via Clincard use. Proper receipts will need to be provided to the study team.

Tax law may require The University of Texas Medical Branch (UTMB) to report the amount of payment you receive from UTMB to the Internal Revenue Service (IRS) or other agencies, as applicable. Generally, this reporting would take place if you receive payments that equal $600 or more from UTMB in a calendar year. You would be responsible for the payment of any tax that may be due.

We may use your samples and information to develop a new product or medical test to be sold. The Sponsor, hospital, and researchers may benefit if this happens. There are no plans to pay you if your samples or information are used for this purpose.

What will you have to pay for if you take part in this research study?

Study funds will pay for study visits, tests, and procedures done only for this research. Although study funds will pay for certain study-related items and services, we may bill your health insurer for, among other things, routine items and services you would have received even if you did not take part in the research. You will be responsible for payment of any deductibles and co-payments required by your insurer for this routine care or other billed care. If you have any questions about costs to you that may result from taking part in the research, please speak with the study doctors and study staff. If necessary, we will arrange for you to speak with someone in Patient Financial Services about these costs.

What happens if you are injured as a result of taking part in this research study?

It is important that you report any illness or injury to the research team listed page 3 of this form immediately. Compensation for an injury resulting from your participation in this research is not available from the University of Texas Medical Branch at Galveston.
You or your insurance company or health care plan, will be billed and you will be responsible for any charges.
You will be responsible for paying any costs related to illnesses and medical events not associated with being in the study. There are no plans to provide other forms of compensation. However you are not waiving any of your legal rights by participating in this study.

If you take part in this research study, how will we protect your privacy?

All results obtained in this study will be kept confidential and only available to the research study team. Your individual information will not be reported, only the results of all participants as a group.
Data or specimens collected in this research might be deidentified and used for future research or distributed to another investigator for future research without your consent.

How will my privacy be protected?
We have rules to protect information about you. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form you provide your permission, called your "authorization," for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records. This could include information about HIV and genetic testing, or treatment for drug or alcohol abuse or mental health problems.

The research team will know your identity and that you are in the research study. Other people at UTMB, particularly your doctors, may also see or give out your information. We make this information available to your doctors for your safety. If you think this study might affect your clinical care, please inform your doctor.

People outside of UTMB may need to see or receive your information for this study. Examples include government agencies (such as the Food and Drug Administration), safety monitors, other sites in the study and companies that sponsor the study.

We cannot do this study without your authorization to use and give out your information. You do not have to give us this authorization. If you do not, then you may not join this study.

We will use and disclose your information only as described in this form; however, people outside UTMB who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

The use and disclosure of your information has no time limit. You may revoke (cancel) your permission to use and disclose your information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your

contact information. The Principal Investigator's name, address, phone and information are on page one of this consent form.

If you do cancel your authorization to use and disclose your information, your part in this study will end and no further information about you will be collected. Your revocation (cancellation) would not affect information already collected in the study, or information we disclosed before you wrote to the Principal Investigator to cancel your authorization.

Finally, please specifically authorize the use of your private health information relating substance abuse, psychiatric information, or HIV/AIDS, if applicable, for the above-described purposes.

Initial: _____

Who can I contact with questions about this Research study?
If you have any questions, concerns or complaints before, during or after the research study, or if you need to report a research related injury or bad side effect, you should immediately contact Karl Anderson, M.D. at 409/772-4661 or, if after normal office hours, at 409/789-3231.

Certificate of Confidentiality
A federal Certificate of Confidentiality (Certificate) has been issued for this research to add special protection for information and specimens that may identify you. With a Certificate, unless you give permission (such as in this form) and except as described above, the researchers are not allowed to share your identifiable information or identifiable specimens, including for a court order or subpoena.

Certain information from the research will be put into your medical record and will not be covered by the Certificate. This includes records of medical tests or procedures done at the hospitals and clinics, and information that treating health care providers may need to care for you. Please ask your study doctor if you have any questions about what information will be included in your medical record. Other researchers receiving your identifiable information or specimens are expected to comply with the privacy protections of the Certificate. The Certificate does not stop you from voluntarily releasing information about yourself or your participation in this study.

Even with these measures to protect your privacy, once your identifiable information is shared outside of the University of Texas Medical Branch, we cannot control all the ways that others use or share it and cannot promise that it will remain completely private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your identifiable information. Your permission to use and share your identifiable information does not expire.

The results of this research may be published in a medical book or journal, or used to teach others. However, your name or other identifiable information **will not** be used for these purposes without your specific permission.

Your Privacy Rights
You have the right **not** to sign this form that allows us to use and share your identifiable information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your identifiable information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others, and such information may continue to be used for certain purposes, such as to comply with the law or maintain the reliability of the study.

You have the right to see and get a copy of your identifiable information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Research Consent to Receive Unencrypted Text Message Communications

Text messages by mobile/cell phones are a common form of communication. The "Effect of Oral Cimetidine in the Protoporphyrias" research study involves sending you text messages that are relevant to the research study. Texting over mobile/cell phones carries security risks because text messages to mobile/cell phones are not encrypted. This means that information you send or receive by text message could be intercepted or viewed by an unintended recipient, or by your mobile/cell phone provider or carrier.

Below are some important points about texting in this research study.

- Text messages are not encrypted, and therefore carry security risks. This research study and Partners Healthcare are not responsible for any interception of messages sent through unencrypted text message communications.

- You will be responsible for all fees charged by your carrier's service plan for text messaging. This research study and Partners Healthcare are not responsible for any increased charges, data usage against plan limits or changes to data fees from the research texts.

- Your text message answers to survey questions will only be read the University of Texas Medical Branch staff involved in this research study. Your text responses will be stored and will not be read immediately. Please call the study staff if you have questions or concerns requiring immediate attention.

- Text messaging should not be used in case of an emergency. If you experience a medical emergency, call 911 or go to the nearest hospital emergency department.

- You may decide to not send or receive text messages with staff associated with this research study at any time. You can do this in person or by sending the research number a text message that says, "Stop Research Text."

- Your agreement applies to this research study only. Agreeing to other texts from Partners Healthcare, for example appointment reminders, is a separate process. Opting out of other texts from Partners Healthcare is a separate process as well.

- It is your responsibility to update your mobile/cell phone number with this research study in the event of a change.

I have had the chance to ask questions about texting with staff associated with this research study. I have been informed of the risks and other information covered above and consent to the use of unencrypted text communications associated with this research study.

I consent to receive unencrypted text communication:

_____ _____

Subject signature Date

Research Consent to Receive Unencrypted Email Communication

This study requires email communication, both in the form of survey links sent by email and, if necessary, email reminders to wear the light dosimetry device or to complete surveys. The surveys themselves are secure once the link in the email is opened.

The Partners standard is to send email securely. This requires you to initially set up and activate an account with a password. You can then use the password to access secure emails sent to you from Partners HealthCare. Some study-related communication from porphyria patient advocacy organizations will not be encrypted. Unencrypted email is not secure and could result in the unauthorized use or disclosure of your information. If you consent to receive communications by unencrypted email despite these risks, Partners HealthCare will not be held responsible. Agreeing to receive unencrypted email communication may increase the ease of the study for you, as you will not need to use a password to access these emails. Your preference to receive unencrypted email will apply to emails sent from this research group/study only.

I consent to receive unencrypted email communication:

_____ _____

Subject signature Date

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

Signature of Subject:

I give my consent to take part in this research study and agree to allow my identifiable information to be used and shared as described above.

_____	_____	_____
Subject	Date	Time (optional)

Signature of Parent(s)/Guardian for Child:

I give my consent for my child to take part in this research study and agree to allow his/her identifiable information to be used and shared as described above.

_____	_____	_____
Parent(s)/Guardian for Child	Date	Time (optional)

Assent

Statement of Person Giving Assent

- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions, and my questions have been answered.

Signature of Child:

I agree to take part in this research study and agree to allow my identifiable information to be used and shared as described above.

Child, Ages 15-17	Date	Time (optional)

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.
- I have answered all questions about this research study to the best of my ability.

Study Doctor or Person Obtaining Consent	Date	Time (optional)

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