Official Study Title:
Effect of Oral Cimetidine in the Protoporphyrias

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Research Consent Form
Certificate of Confidentiality Template
Version Date: August 2022

Subject Identification

Protocol Title: Effect of Oral Cimetidine in the Protoporphyrias

Principal Investigator: Amy Dickey, MD

Site Principal Investigator:

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.

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 Mass General Brigham 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 MGH) 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.

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. If you are not from the United States, note that the status of cimetidine in your country may differ.

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 number of people expected to take part in this research study at Massachusetts General Hospital is up to 40 participants. 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.

In some cases, the entire study can be completed remotely through virtual visits and through mailing devices and medications.

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 Massachusetts General Hospital or these visits will be arranged remotely and you will have to visit a local lab to have blood samples taken. If labs outside the U.S. collect blood samples, your samples and personal data will be shipped to the U.S. for processing as part of this study.

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.

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:
- 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. Investigators in this study will maintain a code-link that will allow linking the biological specimens to you, but this code-link will not be shared with outside investigators. 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. We will only share identifiable samples for other research if you separately consent for those studies.

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 U.S. local and federal security requirements for research data centers. If you are not a U.S. resident, you should be aware that the personal health information collected as part of the study will be protected in accordance with U.S. federal and state privacy laws, which may not be as strict as the laws in your country of residence.

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 and phone number 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 Mass General Brigham 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 Mass General Brigham 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 or virtual study visit and $25 dollars for each scheduled study phone call, for a total of up to $550 for the completion of the entire study.

Reasonable travel expenses may be reimbursed by check. Proper receipts will need to be provided to the study team. Checks require some time to be prepared and will be given to you once processed and available.

Tax law may require Massachusetts General Hospital to report the amount of payment you receive from Massachusetts General Hospital 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 Massachusetts General Hospital in a calendar year. You would be responsible for the payment of any tax that may be due. You may therefore need to file a U.S. tax return.

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. If you are a Canadian resident, your provincial health insurance plan will cover medically required services provided in Canada, but there may be exclusions or limitations applicable to health services and hospitalization in the United States. You should consult with your health benefit plan or provincial health insurance plan to determine whether the costs of care incurred as a result of participating in this study are covered.

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

We will offer you the care needed to treat any injury that directly results from taking part in this research study. If you are a Canadian resident and suffer such an injury while you are in Canada, however, you should contact your local care provider or emergency facility to seek care for the injury as needed. You should also let the study doctor know at the telephone number provided earlier in this form.

If you receive care with us, we reserve the right to bill your insurance company, provincial health insurance plan (Canadian residents), or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer. If your provincial health insurance plan (Canadian residents) does not cover care provided in the U.S., you may be billed personally for the cost of such care.

If you are a Canadian resident and receive care for the injury in Canada, your provincial health

insurance should cover the cost of all medically required services. You may be billed for any additional costs.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the beginning of this consent form.

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

Federal law requires Mass General Brigham to protect the privacy of health information and related information that identifies you. We refer to this information as "identifiable information." If you are not a U.S. resident, you should be aware that the personal health information collected as part of the study will be protected in accordance with U.S. federal and state privacy laws, which may not be as strict as the laws in your country of residence.

In this study, we may collect identifiable information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable information and why:

- Mass General Brigham researchers and staff involved in this study
- The sponsor(s) of the study, and people or groups it hires to help perform this research or to audit the research
- Other researchers and medical centers that are part of this study
- The Mass General Brigham ethics board or an ethics board outside Mass General Brigham that oversees the research
- A group that oversees the data (study information) and safety of this study
- Non-research staff within Mass General Brigham who need identifiable information to do their jobs, such as for treatment, payment (billing), or hospital operations (such as assessing the quality of care or research)
- People or groups that we hire to do certain work for us, such as data storage companies, accreditors, insurers, and lawyers
- Federal agencies (such as the U.S. Department of Health and Human Services (DHHS) and agencies within DHHS like the Food and Drug Administration, the National Institutes of Health, and the Office for Human Research Protections), state agencies, and foreign government bodies that oversee, evaluate, and audit research, which may include inspection of your records
- Public health and safety authorities, if we learn information that could mean harm to you or others (such as to make required reports about communicable diseases or about child or elder abuse)
- Other researchers within or outside Mass General Brigham, for use in other research as allowed by law.

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 Mass General Brigham, 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. Under Canadian privacy law, (but subject to some limitations due to Study requirements and other laws), you may have certain additional rights with regard to your identifiable information, including the right to access your identifiable information and the right to correct incomplete or inaccurate identifiable information. However, these rights are also subject to the legal obligations of the study team and sponsor to maintain the integrity of the study data. Therefore, it may not be possible to exercise some of these rights until the end of the

Study. 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 study team involved in this research study and the individuals managing the dataset. 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:

☐ YES NO

_____ _____
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)

Consent Form Version Date: Version 12 05March2024