Technology-Based Intervention for Reducing Sexually Transmitted Infections and Substance Use During Pregnancy

NCT03826342

Date of IRB Approval: March 5, 2023

UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Health Check-up for Expectant Moms (HCEM)
a.k.a. **"**Technology-Based Intervention for Reducing Sexually Transmitted Infections and Substance Use During Pregnancy"

Company or agency sponsoring the study: This study is being paid for by a grant from the Eunice Kennedy Shriver National Institute of Child Health and Human Development of the National Institutes of Health.

Principal Investigator: Golfo Tzilos Wernette, Ph.D., Principal Investigator, Department of Family Medicine, University of Michigan

Study Coordinator: Kristina Countryman, MPH, Research Coordinator, Department of Family Medicine, University of Michigan

1.1 Key Study Information: Based on your responses in the short survey, you are eligible to take part in our research study. This form contains important information that will help you decide whether to join the study. Take the time to carefully review this information. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your family, friends, or other doctors about joining this study. If you decide to join the study, you will be asked to sign this form before you can start study-related activities. Before you do, be sure you understand what the research study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about diseases and how to treat them. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time.

Research studies do not always offer the possibility of treating your disease or condition. Research studies also have different kinds of risks and risk levels, depending on the type of the study. You may also need to think about other requirements for being in the study. For example, some studies require you to travel to scheduled visits at the study site in Ann Arbor or elsewhere. This may require you to arrange travel, change work schedules, find child care, or make other plans. In your decision to participate in this study, consider all of these matters carefully.

This research is studying whether changing an individual's behaviors may have an impact as a prevention from acquiring sexually transmitted infections (STIs) and using alcohol/drugs during pregnancy. This research will screen and assess for STI risk as well as alcohol/drug use risk during pregnancy and will offer an intervention to reduce these risks during pregnancy. Your health-related information as well as urine or vaginal swab samples will be collected for this research study. Due to the COVID-19 pandemic, these visits may be conducted remotely, both over the telephone and through a secure link to our study website. Remote visits will include urine or vaginal swab samples (for STI testing), however they may or may not be collected the same day as the study visit. We will contact you

to arrange the collection of a specimen for STI testing as close as possible to the remote study visit. Vaginal swab samples for STI testing are self-collected with an at-home testing kit.

This study involves a process called randomization. This means that the computer program that you will receive in the study is not chosen by you or the researcher. The study design divides study participants into separate groups, based on chance (like the flip of a coin), to compare different treatments or procedures. If you decide to be in the study, you need to be comfortable not knowing which study group you will be in.

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study, some of these risks may include discomfort when answering sensitive questions about your medical history and history of alcohol/drug use, and when learning more about these topics. More detailed information will be provided later in this document.

This study may offer some benefit to you now or others in the future through the knowledge gained by conducting this study. More information will be provided later in this document.

We expect the amount of time that you will participate in the study will be nine months or less, depending on when you join.

You can decide not to be in this study. Alternatives to joining this study include not participating and receiving your prenatal care as usual.

Even if you decide to join the study now, you are free to leave at any time if you change your mind.

More information about this study continues in Section 2 of this document.

2. PURPOSE OF THIS STUDY

2.1 Study purpose: Sexually transmitted infections (STIs) are at a record high in the United States, and STI risk is an increasingly costly public health concern for American childbearing women. STIs and alcohol/drug use are interrelated and common and have significant direct and indirect relationships with health and functioning over the longer term for mother and fetus. Undetected and untreated STIs can lead to serious long-term consequences for childbearing women including infertility. Because of this intersection between substance use and STIs and because both are clearly associated with poor health outcomes, it is strongly recommend targeting both risks during pregnancy. This project will screen and assess for STI risk as well as alcohol/drug use risk during pregnancy and will offer an intervention to reduce these risks during pregnancy. The intervention could be readily integrated into prenatal health care settings and thus reduce the risk for adverse outcomes for very large numbers of vulnerable women and infants.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?
Pregnant women who are between the ages of 18-45 years old, are currently residing in the state of Michigan and who take part in behavioral risk factors related to alcohol/drug use risk and sexual health risk during pregnancy, are eligible to participate in the study. Women who cannot provide informed consent or unable to understand English are not eligible to participate in the study.

3.2 How many people are expected to take part in this study?
A total of 250 pregnant women are expected to participate in the study from Michigan Medicine OB Clinics, University of Michigan Family Medicine clinics, and other OB clinics in the state of Michigan including Luke Clinic in Detroit and Flint. The intervention group and the control group will both be comprised of 125 pregnant women.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?
This study includes four separate visits. If you decide to participate in this study, you will be randomly (by chance) assigned to one of two groups, intervention or control; both include using a computer to complete assessment questions. The assessment (which will take about 45 minutes) will include questions about general health, alcohol and drug use, and sexual behavior, as well as your beliefs about these behaviors. After completing the questions, and if you are assigned to the intervention, the computer will present you with information about the effects of alcohol and drug use during pregnancy, as well as education about reducing your risk for sexually transmitted infections during pregnancy. If you are not randomly assigned to the intervention, the computer will present you with information about television programs and will ask you questions about your favorite television shows. The entire visit will take approximately 90 minutes to finish and can be completed while you are waiting for or after your medical appointment, or can be completed remotely, by phone and through a secure link to our study website. If a medical staff needs to enter the room to initiate patient care with you, we will

immediately stop and will set up a time to meet after your appointment. When the study visit is completed remotely, you will access the study program and survey questions online using your own smartphone, computer, or tablet.

For everyone in this study, there will be four separate visits. Due to the COVID-19 pandemic, these visits may be conducted remotely, both over the telephone and through a secure link to our study website. After this initial session that you will complete today, we will coordinate a time with you to complete the second and third assessment sessions using the computer and/or telephone. We will also send you an email/text link to our confidential study site where you will complete two "booster" sessions at 2 weeks from today and at 4 weeks from today. If you are in the intervention these booster sessions will provide a brief review of the information that was presented on the computer and shared with you during your first visit. If you are in the control group, these booster sessions will continue to ask you about your favorite television show programs. The second visit (whether in-person or remote) will occur 2 months after the first, the third visit (whether in-person or remote) will occur 6 months after the first. The fourth and final visit (the postpartum assessment) will be completed either in the clinic, remotely, in your home, or at another location of your preference. In this session, the computer will ask you similar questions that it asked you during the first visit.

We will also collect biological samples (specific infections assessed will include three STIs most common among sexually active childbearing women: 1) Trichomoniasis; 2) Chlamydia trachomatis; 3) Neisseria gonorrhea). If the assessment visits are completed remotely and you are a Michigan Medicine patient, the study will collect biological samples for the above listed STIs at specific prenatal visits with your provider. In this case, you will be directed to a Michigan Medicine Lab after your prenatal visit to provide a urine sample for STI testing. STI results will be shared with your Michigan Medicine provider and will be available in your personal medical chart in order to make such treatment available as necessary. For non-Michigan Medicine participants, including Luke Clinic patients, an at-home STI testing kit (using a self-collect vaginal swab) will be mailed to you, which you will mail back with our pre-paid postage. The specimens are sent to The Center for Innovative Diagnostics for Infectious Diseases at the John Hopkins University School of Medicine for analysis. Specimens cannot be de-identified as your name and address will be included in the specimen kit. However, all results from the at-home STI tests are kept completely confidential. The results of the at-home STI testing kit will not be included in your electronic health record but will be shared with your health providers upon request. Michigan Medicine participants may also choose the at-home STI testing kit if they prefer. If any STI test results come back positive, you will receive medical treatment to ensure a cure, which will be available for pick up at a U of M Pharmacy or in person if an injection is required for treatment. This treatment will be covered by the research study at no expense to you. If the STI is reportable, it will be reported to the Health Department as required by law. If the assessment visits are completed remotely, the study will also view your medical record to collect the results of any STI tests that your provider orders during your pregnancy up to your final postpartum visit.

Research staff will work with you to make sure you receive the treatment and follow-up testing you need. Should you prefer to receive further services elsewhere, research staff will assist you in accessing the medical care you desire to the best of their ability. Our study team will also access your medical records in order to collect information pertaining to any drug or STI testing results collected during the duration of your study participation. The results of these tests will be kept confidential and will not be provided to anyone outside of the research staff.

After you deliver, we will collect hospital medical records to identify birth (health) outcomes of your infant (e.g., head circumference, weight) and yourself. If you deliver outside of Michigan Medicine, we will ask you to sign a request for outside records authorization form which will allow us to request that these birth/health outcomes be sent to us from that birth center. Participants from the Luke Clinic locations will have their birth outcomes collected directly from their chart by a member of our research team.

To keep in necessary contact with you while you are part of the study, the study team may contact you by any of the following methods: phone calls, text messages, and email. As a general disclaimer, text messaging is not a secure transmission medium. No private medical information will ever be sent via text message, but your phone number and the content of the message may be seen by parties outside of the university/study team without either our knowledge or your knowledge. You can opt out of receiving text messages, but in order to fully participate in the study, you do have to allow us to call and email you.

As someone participating in this research study, you have certain responsibilities that may apply to this study, such as ensuring that you arrive at all of your scheduled appointments, and report any adverse reactions you may have during the study.

4.2 How much of my time will be needed to take part in this study?
For everyone in the study, there will be four separate visits (initial assessment, and three follow-up assessments at 2-months/8-weeks, 6-months/24-weeks, and 6-weeks postpartum) whether they are in-person or remote. The initial visit will take about 90 minutes and each follow-up session will take approximately 30-40 minutes. Additionally, you will complete two booster sessions (approximately 10-15 minutes) on a mobile site at 2-weeks and at 4-weeks after the initial assessment.

4.3 When will my participation in the study be over?
Your participation in the study will be over after the 6-week postpartum assessment, which at the longest, will be 9 months after you first joined the study.

4.4 What will happen with my information and/or biospecimens used in this study?
Your biospecimens (STI testing results) and collected information may be shared with the sponsor, the Eunice Kennedy Shriver National Institute of Child Health and Human Development of the National Institutes of Health.

Your biospecimens (STI testing results) and collected information will be shared with health care providers at Michigan Medicine as well as pediatrician to coordinate any ongoing medical care. For non-Michigan Medicine patients, including Luke Clinic patients, results will be shared with outside providers as requested by the participant.

Your identifiable private information and identifiable biospecimens may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

With your approval, we would like to keep your contact information for the purpose of contacting you about future studies that may interest you. All contact information would be kept confidential and only

used by the study team for future studies. This is not a requirement to be a part of the study however, and you can choose to opt in or out at the end of this consent form.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

There is some potential for you to experience low-to-moderate risks by participating in this study. The known or expected risks are:

- Potential discomfort around assessment questions, as these could reveal sensitive information about your medical history and history of alcohol/drug use. The intervention condition could also reveal sensitive information about these topics and cause discomfort.
- Potential discomfort/feeling upset after viewing images of sexually transmitted infections (STI's) in women.
- Distress if the STI testing reveals a diagnosis of trichomoniasis, chlamydia or gonorrhea; these results would be shared with your health team to coordinate your medical care, and also with your pediatrician to monitor any necessary ongoing care for your infant.
- There is also the risk of withdrawal/withdrawal symptoms from substances.

The researchers will try to minimize these risks by:

- You have the ability to skip any question that makes you uncomfortable.
- You have the ability to skip the images of STI's if you do not want to view them.
- You can quit the study at any time for any reason.

Additionally, there may be a risk of loss to confidentiality or privacy. See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 If I take part in this study, can I also participate in other studies?

Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.3 How could I benefit if I take part in this study? How could others benefit?

You may not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study. The potential benefits to you in participating in this study include the opportunity to reflect on your health behaviors and to increase the likelihood of having a healthy pregnancy. You may also benefit by learning if you have an STI and being assisted in accessing treatment if necessary. Additionally, if you completed the intervention condition, we hope the information learned from this research study will help to develop an effective program to reduce sexually transmitted disease risk among pregnant women. Regardless of which condition you completed, you will receive resources for safer sex and a brochure specifically designed to facilitate reductions in alcohol/drug use during pregnancy.

5.4 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?
Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?
Participation in this study is solely voluntary. You may end your participation at any time.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?
You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 “Contact Information”.

7.2 Could there be any harm to me if I decide to leave the study before it is finished?
You are free to leave the study before it finishes. There could be some potential health consequences in not following through with recommended STI treatment should your diagnosis be positive.

7.3 Could the researchers take me out of the study even if I want to continue to participate?
Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?
The study will pay for research-related items or health care services (e.g. STI treatment) that are provided only because you are in the study. If you are not sure what these are, see Section 4.1 above or ask the researchers for a list. If you get a bill you think is wrong, call the researcher's telephone number listed in Section 10.1.

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

- Health care given during the study as part of your regular care
- Items or services needed to give you study drugs or devices
- Monitoring for side effects or other problems
- Deductibles or co-pays for these items or services.

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to the researchers listed in Section 10 below or call your health plan's medical reviewer.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?
For your participation in this study, you will receive either cash (in-person visits only) or check, and gift cards (total equivalent to $225) for your participation ($5 for taking the eligibility screener, $60 for initial session, $20 gift cards for each booster session, $30 for completing the first follow-up assessment, $30 for completing the second follow-up assessment, and $60 for completing the final follow-up assessment during postpartum).

8.3 Who could profit or financially benefit from the study results?
Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how the confidentiality of your research records will be protected in this study, and any sub-studies described in this document.

9.1 How will the researchers protect my information?
If you choose to participate in this study, we are committed to protecting your privacy. The Principal Investigator of the study will protect your confidentiality to the extent of the law. No identifying information (including your name) will be entered into the computer or onto the paper assessment, which will insure your protection.

You should know, however, that someone from the research team must provide information to the state authorities if there is discovery of child or elder abuse. If you tell us or we learn something that makes us believe that your child or others have been or may be physically harmed, we may be required to report that information to the appropriate agencies. Additionally, information will be provided to the authorities if you disclose that you are at harm to yourself or to others. Subject to these restrictions, authorization to use data collected from you in the course of this study, including your protected health information, will have no expiration date. While this study is in progress, you will not be allowed access to protected health information about you maintained by the researchers, but you may request access to such information when the study is over.

A study team may consist entirely of mandated reporters, a combination of mandated and non-mandated reporters, or entirely of non-mandated reporters. The above language accommodates each of these scenarios.

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

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the SPONSOR which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law surrounding child abuse and neglect, elder abuse and neglect, or harm to self or others. The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

A description of this trial will be registered and may report results on www.ClinicalTrials.gov, a publicly available registry of clinical trials, 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.

9.2 What protected health information (PHI) about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

Medical information and billing records are protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). This type of information is called protected health information (PHI). PHI about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)
- Sexually transmitted disease and/or other communicable disease status
- All records relating to your condition, the treatment you have received, and your response to the treatment
- Demographic information
- Personal identifiers
- Other Information (birth outcomes and drug testing results)

Luke Clinic patients will have their medical information obtained directly from their medical chart by a member of the UM research team.

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study
- Information about your study participation may be included in your regular UMHS medical record.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, Social Security number, payment amount, and related information for tax reporting purposes.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

In this study, your responses on the short screening survey will be connected to your study responses, and will be kept confidential. The results of your STI screening will be uploaded onto your personal medical record in Michigan Medicine (Michigan Medicine patients only) and read by your doctor in order to provide STI treatment should you screen positive at any point in the study.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

9.3 What happens to information about me after the study is over or if I cancel my permission to use my PHI?
As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission to use my PHI expire?
Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below). If you withdraw your permission, you may no longer be eligible to participate in this study.

10. CONTACT INFORMATION

10.1 Who can I contact about this study?
Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Golfo Tzilos Wernette, Ph.D.
Mailing Address: Department of Family Medicine, 1018 Fuller Street, Ann Arbor, 48104
Telephone: (734) 936-5508

Study Coordinator: Kristina Countryman, MPH
Mailing Address: Department of Family Medicine, 1018 Fuller Street, Ann Arbor, 48104
Telephone: (734) 998-7134

You may also express a question or concern about a study by contacting the Institutional Review Board listed below:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768 (For International Studies, include the appropriate calling codes.)
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.
When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?
You will receive a copy of the signed and dated informed consent.

Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)*

12. SIGNATURES

Sig-A

Consent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with [NAME OF STUDY TEAM MEMBER OBTAINING CONSENT] _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Would you be interested in being contacted by our team for a future study? If yes, we would store your contact information and keep it confidential and only used by our study team for the purpose of contacting you about future studies that may interest you. *(Please circle one):*

Yes

No

If the informed consent process is being conducting remotely, the research team will read Section 12, "Signatures", to the patient over the telephone and obtain verbal consent rather than a signature.

Sig-G

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Printed Legal Name:
_____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____