Screening and Intervention for Glaucoma and eye Health through Telemedicine- SIGHT

NCT04274764

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UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Screening and Intervention for Glaucoma and eye Health through Telemedicine- SIGHT

Company or agency sponsoring the study: Centers for Disease Control and Prevention

Principal Investigator: Paula Anne Newman-Casey, M.D, Ophthalmology and Visual Sciences
Study Coordinators: Suzanne Winter

1.1 Key Study Information

You may be eligible to take part in a 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.

This study involves screening for glaucoma in community clinics to decrease barriers to care and provide a chance for early diagnosis, treatment and education to reduce vision loss from glaucoma. Glaucoma is an increased pressure in the eyeball that causes gradual vision loss. We can test for glaucoma with specialized cameras that take pictures of the eye. This study will provide glaucoma screening, a free eye exam to see if you need glasses, help ordering free or low-cost glasses, help getting your glasses fit, and help scheduling follow-up care if it is needed. For those who have or are suspected to have glaucoma, you will receive standard of care education. If you speak English, you will be randomized to either standard of care education or to “ehealth ” education. eHealth education is viewing the education materials from a video on the computer. The study team will let you know if you will receive health coaching at your second visit.

Your vision screening related information will be collected for this research study by a University of Michigan ophthalmic technician here in the clinic. The ophthalmic technician is like an eye nurse and is certified to conduct vision screening testing. Your information will be transmitted through the secure University of Michigan health record to be read by a University of Michigan Ophthalmologist for evaluation and management. You will be scheduled for a follow up visit with the ophthalmic technician about a month after your first visit to receive your diagnosis, education (if applicable) and pick up the eyeglasses you ordered and have the eyeglasses fit for you.

1.2 Risks of Being in the Study

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:

Disclosure of personal identifying information. (Likelihood: Rare)
The researchers will try to minimize these risks by using a study ID rather than your name on surveys and study data to reduce this risk. Eye exam and tests results that are done as part of your clinical eye care will be stored securely on the University of Michigan Medical Record System, to which, under Health Insurance Portability and Accountability Act (HIPAA) regulations, you will have access.
Reaction to having your eyes dilated prior to photography. (Likelihood: Rare)
All participants will be instructed to return to the clinic if they should experience any headache, eye pain, or nausea after their examination for further assessment.

1.3 Benefits of Being in the Study

This study will offer some benefit to you now and others in the future by:

- Receiving a free eye exam and free or low cost glasses if needed
- Free glaucoma screening, diagnosis and education
- Assistance in scheduling an appointment with an ophthalmologist should it be needed

This study may benefit others in the future by allowing us to understand how to best screen for glaucoma and other eye diseases.

You can decide not to be in this study. If you need eye care and you are a patient at The Hope Clinic, the alternative to joining this study is to request a referral to Ophthalmology for eye care from your primary care physician. If you need eye care and you are a patient at Hamilton Clinic, the alternative to joining this study is to request a referral to the eye clinic for eye care from your primary care physician or make an appointment at the eye clinic yourself.

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

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

Millions of Americans are at risk for diseases that can affect their eyes and are either unable to access eye care services or do not know that eye screening could reduce their risk of vision loss. There are several factors that account for insufficient eye care including financial, educational, cultural, and demographic factors. In addition, there is a shortage of eye care doctors in the country and primary care providers do not have all the necessary tools to check for diseases than can lead to loss of eyesight.

The purpose of this research is to set-up a tele-medicine based glaucoma screening program to screen people who visit the community clinics for glasses, glaucoma, and other eye diseases. Telemedicine is the use of technology that enables remote healthcare. Basically it makes it possible for physicians to treat patients whenever needed and wherever the patient is, by using a computer or smartphone.

Through the SIGHT program, people will take part in free glaucoma screening and eyeglasses exams to increase eye care access and reduce vision loss from glaucoma by early detection and treatment.

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?

Anyone who is 18 years of age or older, not pregnant and who can come to the Hope Clinic in Ypsilanti, MI or the Hamilton Clinic in Flint, MI, will be eligible to participate. We will not screen children in this program. We will also exclude anyone unable to give an ocular and social history such as those with cognitive impairment like dementia. If you have had sudden changes in your vision or sudden eye pain you will not be able to participate at this time and will be directed to see the physician in the clinic.

If you are unable to read English, we will give you a brief consent summary or full consent in the language you can read and ask you to sign it. We will also give you a written summary in English. A friend or family member(witness) that is fluent in both English and your language will be included to translate for you. The witness will sign both the English and non- English forms and you will receive a copy of these signed forms. Study personnel will ask your friend or family member to repeat in your language the written summary that is in English.

3.2 How many people are expected to take part in this study?

We expect approximately 5800 people to participate in this study.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

Baseline screening examination: You will have a screening examination in a private room at the clinic; which is expected to take approximately one hour.

- If you do not already have one, you will receive a University of Michigan Medical Record Number (MRN). This will link your medical information from this screening exam.
- You will be asked to confirm your address and contact information.
- You will be asked to take a baseline survey about your overall health, your eye health and your finances.
- We will help you pick out free or low cost glasses, if needed, using an on-line website.

Medical evaluation: You will receive vision exam, which includes fundus photography and Optical coherence tomography (OCT), eyeglasses, eye pressure and glaucoma tests. The fundus photograph uses a specialized camera with a microscope that takes a picture of the back of your eye. The OCT is a light sensor camera that takes pictures of your retina. To measure eye pressure, a very light probe is used to make momentary and gentle contact on the eye. Your eyes will need to be dilated for these tests.

An ophthalmologist from the University of Michigan will interpret your tests and send a report to your address on file and send follow-up recommendations to the ophthalmic technician. You will then be scheduled for a follow-up visit with the ophthalmic technician to receive education about your diagnosis and free or low cost glasses if you need them.

Follow-up visit for glasses, diagnosis and education: You will follow up with the ophthalmic technician about a month after your first screening visit. We need at least 4 weeks between your screening appointment and your follow-up appointment if glasses are ordered. Glasses take 21 business days to arrive.

If you ordered glasses, the ophthalmic technician will help fit them to your face.

We will go over the ophthalmologist's recommendations who interpreted your screening tests and give you a copy of the ophthalmologist's letter that was also mailed to you. If your results indicate glaucoma, we will also provide education about your diagnoses. The education session may be audio recorded will take up to an hour.

If you are English speaking and your results indicate glaucoma, you will be randomized to either standard of care education or to eHealth education. This means that the education type you 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 the two types of education. If you decide to be in the study, you need to be comfortable not knowing which education group you will be in. The education session may be audio- recorded and will take up to hour.

If the ophthalmologist finds that your eyes are completely healthy, meaning no signs of glaucoma, we will call you to cancel the follow-up appointment. However, if you have ordered eyeglasses, you will need to return to the clinic to get the eyeglasses.

At the end of this visit, you will be asked to complete a survey. If you do not come back to the clinic for a second visit, you we will be asked to complete the follow-up survey over the phone with the ophthalmic technician.

The ophthalmic technician will help you arrange any follow-up eye care you need with providers that you can afford.

Additionally, we would like to contact to you to possibly participate in other research studies in the future. We would contact you by phone or postal mail. If this is OK, we will ask you to sign an additional section at the end of this form.

Access to medical records: By participating in this research project, you authorize the access of your clinic medical records to be shared with the researchers.

4.2 How much of my time will be needed to take part in this study?

- **SIGHT Program Initial Visit:** All participants will spend approximately one hour with the ophthalmic technician, which will include questions about your overall and eye health and your demographics, doing tests for glasses and for glaucoma screening, helping you pick out free or low cost glasses, if you need them, and scheduling you for a follow-up visit.
- **SIGHT Program Follow-up**: About one month after your first visit, you will come back to pick up your glasses (if ordered), and have the ophthalmic technician go through the ophthalmologists'

diagnoses and recommendations, including education about your diagnosis. This visit will take up to 60 minutes, depending on your diagnosis and the education you receive.

- **Phone call:** If you were given assistance by an ophthalmic technician for a follow-up appointment regarding your glaucoma diagnosis with an ophthalmologist, the ophthalmic technician may call you to talk for 5-10 minutes about any issues getting to the follow-up appointment with the ophthalmologist.
- **Follow up with an Ophthalmologist in 3-6 months**: If you need to be further evaluated for eye disease by an ophthalmologist, we will help you set up an appointment with an ophthalmologist that you can afford.

To assess your vision and vision-related quality of life, and if you take part in this study prior to 2022, you may be invited to participate in the SIGHT program again in 2 years.

4.3 When will my participation in the study be over?

- , Your participation will end after your follow-up visit with the ophthalmic technician (approximately 4-8 weeks).

4.4 What will happen with my information used in this study?

The ophthalmic technician will enter all data into both the UM electronic health record and a secure research database. Data will be entered into the medical record as a 'no charge' research visit.

With appropriate permissions, your collected information will be stripped of all identifiers and then may also be shared with other researchers, here, around the world, and with companies. Your de-identified information may be used for future research studies without additional informed consent.

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?

During an eye exam, there is a small chance of getting a scratch on the cornea. If this occurs, first aid will be administered.

Dilating drops are used routinely in clinical eye examinations, however there is a small chance that the drops can cause an allergic reaction. If this occurs, the eye will be flushed with saline solution and the reaction will be managed with routine topical treatment as necessary.

Dilated participants may rarely experience headache, eye pain or nausea after their examination. The ophthalmic technician will instruct participants to return to the clinic if they experience any of these complaints. If a participant should return to the clinic with any of these complaints the technician will perform a recheck. The technician will contact the ophthalmologist on call if further care is needed.

Dilating drops are not recommended in pregnancy unless clearly needed. There are unlikely but possible risks to the fetus from using dilating drops during pregnancy. That is why you should not participate in this study if you are pregnant or you might be pregnant.

The researchers will try to minimize these risks by using only one type of mild dilating drop. You will receive sunglasses if you need them to reduce the light sensitivity you will experience for up to 24 hours after receiving dilating eye drops.

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 What happens if I get hurt, become sick, or have other problems as a result of this research?
The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors**.**

Dilated participants will be instructed to return to the clinic if they should experience any headache, eye pain, or nausea after their examination. A side effect can occur 5 minutes to 8 hours following the eye exam. If a participant should return with any of these complaints, the technician will perform a recheck of the participant and contact the ophthalmologist on call if needed according to study protocols.

5.3 If I take part in this study, can I also participate in other studies?
Yes, you may participate in other studies.

5.4 How could I benefit if I take part in this study? How could others benefit?
This study will offer some benefit to you now by: (1) Receiving a free eyeglasses exam and free or low cost glasses if you need them. (2) Free glaucoma screening, diagnosis and education. (3) Assistance in scheduling an appointment with an affordable ophthalmologist should it be needed.

This study may benefit society in the future by allowing us to understand how to best structure eye care to people who live in communities with limited access to glaucoma care resources.

5.5 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?
You can decide not to be in this study. Alternatives to receiving eye care without joining this study at the Hope Clinic is to request a referral from your clinic primary care physician to Ophthalmology for eye care through the volunteer staffed Kellogg Eye Clinic that takes place 6 times a year. An alternative to receiving eye care without joining the study at the Hamilton Clinic is to go to the eye clinic at Hamilton Clinic and ask to be scheduled for Ophthalmology at Hamilton Clinic

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

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?

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?

If you leave the study before it is finished there will be no harm to you. You will no longer be entitled to the benefits of next level of services in the study as you would if you remained in the study. However, your stopping the study will not affect your normal standard of care offered by the Hope Clinic or the Hamilton Clinic.

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 the SIGHT Program vision and glaucoma screening. You will be responsible for paying for any glasses that you choose that are not free. You and/or your insurance company will be responsible for any costs associated with follow-up care with the ophthalmologist, this is not part of the study. If you cannot afford follow up care at either the Hamilton Clinic or the Hope Clinic, study team members will put you in touch with financial counselors at either clinic to help you find affordable follow-up eye care. 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
- 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.

The study team has given you instructions about this research study. It is important that you follow these instructions carefully. If you get sick, have a medical complication, or are injured as a result of your being in the study such as getting a scratched cornea, or having eye pain/nausea/headache after your eyes are dilated call the study team at **734-436-1186**.The study team will communicate with the doctor, and will set up treatment for you. You will get free medical care for any complication, injury, or illness caused by a study procedure. The UMHS and the study doctor are responsible for determining whether your condition was the result of your participation in the study. The UMHS will pay for your treatment only if the need for treatment has been caused by the study procedures. This means that you or your health plan must pay for any treatment that is part of your usual medical care or that is related to a medical condition you had before participating in the study. It is not the general policy of the federal funding agencies to compensate or provide medical treatment for human subjects in federally funded studies.

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?
No. You will not be paid for taking part in this research study.

8.3 Who could profit or financially benefit from the study results?
The researchers conducting the study: No
The University of Michigan: No

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?
All information collected about you during the study will be placed into a research record. This research record will not show your name, but will have codes entered in it that will allow the information to be linked to you. We will keep your research record confidential and limit access to only members of the study team. You will not be identified in any reports on this study. When information is presented publicly or published, no information will identify individual patients.

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 for harm to self or others. Additionally, 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 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.

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.

- If you tell us or we learn something that makes us believe that you or others have been or may be harmed, we may be required to report that information to the appropriate agencies.

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.)
- All records relating to your condition, the treatment you have received, and your response to the treatment
- Demographic information
- Personal identifiers

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
- Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study.
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- Information about your study participation may be included in your regular UMHS medical record.
- 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.

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: Paula Anne Newman-Casey, MD- **Study Coordinator:** Suzanne Winter, MS
Mailing Address: Kellogg Eye Center, 1000 Wall St, Ann Arbor, MI 48105
Telephone: 734-436-1186

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?

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.)*
  Other (specify):_____

12. SIGNATURES

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 or assent 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): _____

Consent to audio recording/eye photographs for purposes of this research

I agree to be audio recorded as a subject in this research study. I also agree that the recording may be used for the purpose of this research. I understand that I can stop the recording at any time and remain a participant in the study

Print Legal Name: _____

Signature: _____

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

Consent to be Contacted for Unspecified Future Research
This project involves the option to allow the study team to contact you for future research studies. I understand that it is my choice whether or not to allow the study team to contact me in the future. 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.

_____ Yes, I agree to let the study team contact me for future research.

_____ No, I do not agree to let the study team contact me for future research.

Print Legal Name: _____

Signature: _____

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

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: _____