A Randomized Controlled Open-label Study Comparing the Use of Real-time Continuous Glucose Monitoring (Rt-CGM) to Point of Care Testing (POCT) for Glycemic Monitoring in Patients Post-hospitalization for Diabetic Foot Ulcers.

NCT06054659

Date: August 23, 2025

You Are Being Asked to Be in a Research Study

Randomized controlled open label study comparing the use of real-time continuous glucose monitoring (rt-CGM) to fingerstick blood glucose (FBG) for glycemic monitoring in patients post hospitalization for diabetic foot ulcers.

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study, you will be one of up to 140 people who are being studied at Emory and Grady Health System.

Why is this study being done?

This study is being done to help answer the question: The use of continuous glucose monitoring (CGM) in comparison of the fingerstick blood glucose (FBG) will improve the healing of diabetic foot ulcers (DFU) at 16 weeks (about 4 months) post-hospital discharge.

You are being asked to be in this research study because the current system of glucose control may not be optimal for better wound healing in patients with diabetic foot ulcers. The CGM system allows medical staff and diabetic patients to monitor and make treatment decisions to improve glucose control, without the need for performing finger sticks. Hence, the use of CGM will decrease the painful and burdensome task of performing finger sticks several times per day and may prevent low blood glucose in patients with diabetes.

Do you have to be in the study?

It is your choice to join this research study. You do not have to be in it. Your choice will not affect your access to medical care for your condition. Before you choose, take time to learn about the study.

What do you have to do if you choose to join this study?

If you qualify and choose to join the study, you will participate for 16 weeks (about 4 months) post-hospitalization. The researchers will ask you to do one of the following: 1) Have a CGM placed before you leave the hospital and change it every 14 days to monitor your glucose for 16 weeks after hospitalization or 2) Continue monitoring your blood glucose with fingerstick testing and directed by your diabetes or primary care doctor. In this case, you will also be asked to wear a CGM device that will be applied by a member of the research team 4 times during the study for a total of 70 days. You will not be able to use this CGM to monitor your glucose and will be asked to save it after each 14-day period and return it at your next research visit or mail it with a prepaid shipping container provided by the study team. All CGM devices will be paid for by the study. Performing finger sticks glucose testing is considered standard or usual care and this will not be paid for by the study. After the first visit which will occur in the hospital, you will be scheduled for research visits at 4, 8, 12, and 16 weeks after

your hospitalization. Whenever possible, these visits will be scheduled on the same day as one of your clinic appointments.

How is this study going to help you?
If you are in the study, you will be helping the researchers answer the study question. Participation in the study may increase your awareness of low blood glucose levels and improve the management of diabetes. The study may help in the management of patients with diabetes and healing of diabetic foot ulcer.

What are the risks or discomforts you should know about before deciding?
The study will take time. The device that is being tested may not work any better than regular care and may even cause harm by not providing accurate glucose values. All studies have some risks. Some risks are relatively small, like being bored or wasting time. Some are more serious. Risks for this study include:

- Freestyle Libre (**already FDA-approved for patients with Diabetes)** insertion, some of which include pain or bleeding with insertion (<10%)
- loss of privacy
- loss of confidentiality

You can find a full list of expected risks, their frequency and severity in the section titled "What are the possible risks and discomforts?" section of this document.

Alternatives to Joining This Study
The alternative to this study is not to participate and continue care with your diabetes or primary care doctor.

Costs
You WILL NOT have to pay for any of the study procedures, in particular to those that are not covered by your medical insurance. Since performing fingerstick is considered standard or usual care, this will generally not be paid for by the study. If you do not have insurance or access to the Grady discount program, the study team may be able to provide supplies in certain cases. While you will not be charged for research visits, you or your insurance will pay usual fees for any clinical visits that occur on the same day, even if they are held in the same location as your research visits. These may include routine visits with your diabetes or infectious diseases doctors, or podiatrist.

The study team can help you work out how much you might have to pay. There is more

information in the cost section below.

What Should You Do Next?

Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions such as how much time you will have to spend on the study, any words you do not understand and more details about study procedures. Make sure you understand which parts of the study are research and which are standard care that you would have even if you did not join the study. Take time to think about this and talk about it with your family and friends.

Emory University and Grady Health System
Consent to be a Research Subject

Title: Randomized controlled open label study comparing the use of real-time continuous glucose monitoring (rt-CGM) to point of care testing (POCT) for glycemic monitoring in patients post hospitalization for diabetic foot ulcers.

IRB #: STUDY00006202

Principal Investigator: [redacted]

Sponsor: NIH/ NNDIK

Introduction
You are being asked to be in a medical research study. This form tells you what you need to think about before you choose if you want to join the study. **It is your choice. If you choose to join, you can change your mind later and leave the study.** Your choice will not cause you to lose any medical benefits. If you choose not to join this study, your doctor will still treat you.

Before you decide:
- Read this form or have it read to you
- Listen to the study doctor or study staff explain the study to you
- Ask questions about anything that is not clear

You will get a copy of this form. Take your time to think about joining the study. You may wish to discuss it with family or friends. Do not sign this form if you still have questions or something does not make sense to you. By signing this form, you will not give up any legal rights.

This trial will be registered and may report results on www.ClinicalTrials.gov, a publicly available registry of clinical trials. This website will not include information that can identify you. At most the Web site will include a summary of the results. You can search this website at any time.

What is the purpose of this study?
The purpose of this study is to look at the benefits of using a Continuous Glucose Monitoring (CGM) system compared with standard of care testing for patients with diabetes type 2 and diabetic foot ulcer and how this will be improved wound healing.

You are asked to join this study because you have diabetes and a diabetic foot ulcer and would benefit from improving your blood sugar levels. The Freestyle Libre system allows you to monitor your blood glucose lowering the need for performing finger sticks and is a medical device approved by the U.S Food and Drug Administration (FDA). A total of 102 subjects will participate in this study. The duration of this study is 16 weeks after your discharge from Grady Hospital.

What will you be asked to do?
We are asking you to participate for 16 weeks (about 4 months) in a research study after your hospital discharge using a medical device approved by the U.S. Food and Drug Administration (FDA) for glycemic control.
During your hospitalization, we will randomly (like a flip of coin) assign you to one of the intervention groups:

Group 1 (Real time – Continuous glucose monitoring): You will wear a Freestyle Libre sensor in the arm placed by a study team prior to hospital discharge. You will be provided information on CGM use and may receive additional educational guidelines for diabetes management by a certified diabetes educator. You will be asked to use your own glucometer and doing finger sticks as needed including for CGM calibration.

Or

Group 2 (Standard of Care): You will continue to check your blood sugars as usual by fingerstick with your regular glucose meter as recommended by your diabetes doctor, primary care provider, or any other provider who helps you manage your diabetes. If you do not have a glucometer, this will be can by your care team and insurance regardless of participation in this research study. After leaving the hospital you may also receive standard of care diabetes education with a certified diabetes educator and a CGM will be placed on your abdomen or arm that will be monitoring your blood sugars. You will not be given a device that allows you to see your blood sugars and will only wear it for 14 days following hospitalization, and your study visits at week 4, week 8, week 12, and week 16 (total of 70 days). You will be asked to remove the device after 14 days and to bring it in for your next study visit.

How the Freestyle Libre CGM System Works:

The CGM System includes a combined transmitter and sensor as well as a receiver. The transmitter/sensor is about 1 inch. The sensor probe is flexible, thicker than a strand of a human hair and is about a ½ inch long. The needle is slightly thicker and the same length as most insulin syringe needles. The sensor probe is inside the needle. Once the sensor probe is inserted, the needle is pulled out and the sensor probe stays under your skin for up to 14 days. The sensor continuously measures your blood sugar levels. The transmitter snaps onto the sensor pod and collects and stores blood sugar information for up to 14 days.

We will continue to follow your diabetes foot care with either Infectious Diseases Clinic or the Podiatry Clinic located within the diabetes center.

Procedures at each study:

1. Baseline (hospital) study visit: This visit will occur while you are still in the hospital. You will be asked to complete the informed consent process as well as a series of surveys about your experience in managing your diabetes. It may take up to 20 minutes to answer all the survey questions. You will wear a blinded CGM during your hospital stay and prior discharge this device will be removed and replaced with another device depending on what group you will be randomized (Group 1 or Group 2). You will also have pictures taken of your foot wound that will be used for study purposes. Finally, you will have the CGM device applied. **If you are enrolled in Group 1 only,** you will also be given additional CGM supplies to be used in between study visits and instructed on how to reapply it every 14 days. **If you are enrolled in Group 2 only**, you will be asked to wear a blinded CGM for up to 14 days after discharge. You will not be able to see any glucose readings from this device.
2. Weeks 4, 8, and 12, and 16: These visits will occur 4, 8, 12, and 16 weeks after your hospitalization, respectively. During this time, the study team will review your glucose control either by CGM (Group 1) or fingerstick (Group 2). You will also have pictures of your foot with the wound taken at each study visit. **If you are enrolled in Group 1 only**, you will also be given CGM supplies to change every 14 days between research study visits. **If you are enrolled in Group 2 only**, you will be asked to wear a blinded CGM for 14 days during the periods between each study visit. You will not be able to see any glucose readings from this device.

Final study visits (week 12 and 16): during these study visits, the study team will review your study team will review your glucose control either by CGM (Group 1) or fingerstick (Group 2). You will also be asked to complete the surveys at week 12 only that were done when you first enrolled in the study in addition to one more survey about your experience with CGM (Group 1 only). You will also have pictures taken of your foot wound that will be used for study purposes (both at weeks 12 and 16). If you are unable to attend this study visits for any reason, the study team may

reach out to you and ask that you send a text message with a photo of your foot showing the area where the foot wound was originally located.

Who owns your study data and samples?

If you join this study, you will be donating your samples and data. You will not be paid if your samples or data are used to make a new product. If you leave the study, the data and samples that were already collected may still be used for this study.

What are the possible risks and discomforts?

If you choose to take part in this study, keep in mind there may be risks. You should discuss these with your Study Clinician and/or regular doctor. The most common risks and discomforts expected in this study are:

Risks of Wearing the CGM System

When the sensor is inserted, you should expect a feeling like an insulin injection, or less painful. After insertion, you may feel some tenderness, but you should not feel any large amount pain.

Pain, redness, swelling, and minor bleeding at the sensor insertion site (<10% and minor 1%) are possible risks with use of the device. Significant or serious health risks with the study device is not expected. The device is FDA-approved for use in patients with diabetes.

Redness may occur where the adhesive pads are placed. This will occur in most research participants and will clear up no more than a week after removal. You may develop an allergic reaction to one or more parts of the sensor and transmitter (<10%). This is like allergies that occur due to hospital tape or jewelry. Allergic reactions will usually be mild and require only a skin cream to make them better. Major allergic reactions are rare. If you have an allergic reaction you should notify the study researcher or study staff.

On rare occasions, the sensor may cause skin to blister or peel. If this happens you should notify the study staff as soon as possible. There is a chance that the sensor or needle may break. This is not expected to occur; but, if it does, you should talk with your Study Clinician about what to do.

Risks of Fingerstick Testing

When taking a fingerstick, your fingers may feel sore and tender. Rotate which finger you take your finger sticks to make It is more comfortable for you. This part of your standard or usual care for diabetes.

Patients being treated for diabetes are at risk for both low and high blood sugars. Both fingerstick and CGM devices are approved for monitoring of blood sugars and can help detect both hyper and hypoglycemia. If you have high or low blood sugars during the study, please discuss treatment with your diabetes doctor.

Rare but possible risks include:

- Loss of privacy
- Breach of confidentiality
- Discomfort or embarrassment when answering some of the questions on the surveys.

This study may include risks or side effects that are unknown at this moment.

Researchers may learn something new during the study that may affect your choice to be in the study. If this happens, they will tell you about it. Then you can choose if you want to stay in this study. You may be asked to sign a new form if you choose to stay in the study.

Will you benefit from the study?

You may not benefit from joining the study. If you are a Standard care group, you will continue to treat your diabetes based on the fingerstick blood sugar results. This study is designed to learn more about wound healing and CGM. The study results may be used to help others in the future. Your sugar control and low sugar events may improve while you are in this study; but it may not, and it may even get worse.

Will you be paid for your time and effort?

We are planning to provide compensation to you by a personal payment card. We issue this to you free. The payment card is a prepaid debit card. It can be used exactly like a MasterCard. We load money onto your card electronically every time you need to be paid. You will be paid $50 following each completed study visit (baseline/hospitalization, week 4, 8 12 and 16). Payment for the baseline hospital visit (first visit) will be split into two payments of $25 after completing the informed consent and $25 after being assigned to the study group. If you are not able to continue with the study before being assigned to a study group, either because you withdraw or do not meet all study criteria, you will only receive $25. If you do not finish the study, we will compensate you for the visits you have made. You will get $250 total, if you complete all study visits. You may be offered additional compensation to help cover the cost of transportation for study visits.

The card scheme is run by Greenphire, an independent company specializing in payments for research studies and clinical trials. To issue your card, we need to give Greenphire some of your personal information. Banks and other financial institutions can access this information if they need to verify your identity when you use your card. Emory University is required by law to report any payments we make to the IRS. To do this, Emory University Department of Finance needs to keep your Social Security Number on file. We are asking you to allow us to communicate your name, address, date of birth, research study name and Social Security Number to Greenphire and Emory University Department of Finance. If you want to receive e-mail or text alerts when payments are made to you, we will ask you to provide your e-mail or phone number as well. All this information will be stored on computers owned by Greenphire. Greenphire will not have access to any other information collected during this study. Full instructions about using your card are included when we issue it. Please ask if you have any questions or concerns about the card.

We would also like the option of compensating you in the form of cash, check or gift card if ClinCard accessibility is not available. You will be asked to fill out a tax form, including your Social Security or Taxpayer Identification Number, in order to be reimbursed, depending on the amount and method of payment. Some payment methods involve mail coming to your house, which may be seen by others in your household. You can decline payment if you are concerned about confidentiality, or you can talk to the study team to see if there are other payment options. You will need to fill out a W-9 form.

What are your other options?

If you choose not to join this study, you can get care outside of this study. The study doctor will discuss these with you. You do not have to be in this study to be treated for diabetes and wound care.

Taking part in this study, however, may make you unable to participate in some other research studies, if they exclude people who have taken certain treatments. You should discuss this with the researchers if you have concerns. You may wish to research other study options at websites like clinicaltrials.gov and ResearchMatch.org.

How will your private information be protected?

Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Certificate of Confidentiality

There is a Certificate of Confidentiality from the National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory and Grady Health System will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory and Grady Health System received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory and Grady Health System from making the following disclosures about you:

- Giving state public health officials information about certain infectious diseases,
- Giving law officials information about abuse of a child, elderly person or disabled person.
- Giving out information to prevent harm to you or others.

Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

Storing and Sharing your Information

De-identified data from this study (data that has been stripped of all information that can identify you), may be placed into public databases where, in addition to having no direct identifiers, researchers will need to sign data use agreements before accessing the data. We will remove or code any personal information that could identify you before your information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Your data from this study may be useful for other research being done by investigators at Emory or elsewhere. To help further science, we may provide your deidentified data to other researchers. If we do, we will not include any information that could identify you. If your data or specimens are labeled with your study ID, we will not allow the other investigators to link that ID to your identifiable information.

In general, we will not give you any individual results from the study of the samples you give us. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

Medical Record

Copies of the consent form that you sign will be put in any Emory and Grady Health System medical record you have now or any time during the study.

Emory and Grady Health System may create study information about you that can help with your care. For example, the results of study tests or procedures. These study results will be put in your Emory and Grady Health System medical record. Anyone who has access to your medical records will be able to have access to all the study information placed there. The confidentiality of the study information in your medical record will be protected by laws like the HIPAA privacy rule. State and federal laws may not protect the research information from disclosure.

The results of some study tests and procedures will be used only for research purposes and will not be placed in your medical record. For this study, those items include: CGM and DFU reports.

Tests and procedures done at non-Emory and Grady Health System places may not become part of your Emory and Grady Health System medical record. Also, if you decide to be in this study, it is up to you to let your other health providers know.

In Case of Injury

If you get ill or injured from this research, [redacted] at telephone number [redacted]. Emory and Grady Health System will help you get immediate medical care. However, Emory, Grady Health System, the Federal Government (including but not limited to the National Institutes of Health as applicable) do not have programs to pay for this medical care or compensate you if you are hurt from being in this study.

The costs for any treatment or hospital care you receive as the result of a study-related injury that are not covered by a health insurer will be billed to you.

You do not give up any legal rights you may have by being in this study, including any right to pursue a claim through the legal system.

Costs

There will be no costs to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities. If the study procedures result in any medical complications that would not fall under "injury" as discussed above, the cost of treatment for those complications may be charged to you or your insurance.

Withdrawal from the Study

You have the right to leave a study at any time without penalty.

For your safety, however, you should consider the study doctor's advice about how to go off the study treatment. If you leave the study before the last planned study visit, the researchers may ask you to complete some of the final steps such as lab work or imaging as applicable.

The researchers also have the right to take you out of the study without your consent for any reason. They may do this if they believe it is in your best interest or if you do not agree to changes that may be made in the study.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. As part of this study, we will be requesting health care entities who are covered by the Health Insurance Portability and Accountability Act and regulations (HIPAA) to provide us with health information that identifies you ("individually identifiable health information" or "IIHI"). Because the health care entities are covered by HIPAA, we must have your authorization to obtain your IIHI from them. However, the researchers who get your IIHI from the health care entities are not covered by HIPAA. Once they receive your IIHI from the health care entities, they will put it in a separate research record that is not a part of your medical record. IIHI placed in the separate research record is not be covered by HIPAA.

Purpose of this Authorization:

By signing this form, you give us permission to get your IIHI from health care entities and to use and share your IIHI as described in this document. You do not have to sign this form. If you do not sign this form, then you may not participate in the research study.

No Provision of Treatment
There is no research-related treatment involved in this study. You may receive any non-research related treatment whether or not you sign this form.

IIHI that Will be Used/Disclosed:

The IIHI that we will use or share for the research study includes:

- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study.
- Laboratory test results.

Purposes for Which Your IIHI Will be Used/Disclosed:
We will use and share your IIHI for the conduct and oversight of the research study. Once we have your IIHI we will keep it in a separate research record that will be used for the conduct of the study. If you leave the study, we may use your IIHI to determine your vital status or contact information.

Use and Disclosure of Your IIHI That is Required by Law:
We will use and disclose your IIHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults. We will also comply with legal requests or orders that require us to disclose your IIHI. These include subpoenas or court orders.
People Who will Use/Disclose Your IIHI:
The following people and groups will use and disclose your IIHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your IIHI to conduct the Study.
- Emory and Grady Health System may use and disclose your IIHI to get payment for conducting the study and to run normal business operations.
- The Principal Investigator and research staff will share your IIHI with other people and groups to help conduct the study or to provide oversight for the study. This includes sharing your IIHI with people and groups at other sites who are helping conduct the study.
- The following people and groups will use your IIHI to make sure the research is done correctly and safely:
    - Emory, Grady Health System, and Georgia Tech offices that are part of the Human Research Participant Protection Program and those that are involved in study administration. These include the Emory IRB, the Emory University and Grady ROC and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - Public health agencies.
    - Research monitors and reviewer.
    - Accreditation agencies.
- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your IIHI may be shared with that new institution and their oversight offices.

Expiration of Your Authorization

Your IIHI will be used until this research study ends.

Revoking Your Authorization

If you sign this form, at any time later you may revoke (take back) your permission to use your IIHI. If you want to do this, you must contact [redacted] at ([redacted], 69[redacted]
[redacted]

At that point, the researchers would not collect any more of your IIHI. But they may use or disclose the information you already gave them as described in this Authorization. If you revoke your authorization you will not be able to stay in the study.

Other Items You Should Know about Your Privacy
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. HIPAA does not apply to research that does not include treatment that is billed to insurers or government benefit programs. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them. The researchers and people working with them are not covered by the Privacy Rules. They will only use and disclose your information as described in this Consent and Authorization.

To maintain the integrity of this research study, you generally will not have access to your IIHI related to this research until the study is complete. When the study ends, and at your request, you generally will only have access to your IIHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. You will not have a right of access to IIHI kept in a separate research record used only for research purposes. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your IIHI. Information without identifiers is not subject to HIPAA and may be used or disclosed with other people or organizations for purposes besides this study.

Contact Information

If you have questions about the study procedures, appointments, research-related injuries or bad reactions, or other questions or concerns about the research or your part in it, contact [redacted] at [redacted].

This study has been reviewed by an ethics committee to ensure the protection of research participants. If you have questions about your **rights as a research participant**, or if you have **complaints** about the research or an issue you would rather discuss with someone outside the research team, contact the Emory Institutional Review Board at [redacted] or [redacted] or [redacted]

To tell the IRB about your experience as a research participant, fill out the Research Participant Survey at https://tinyurl.com/ycewgkke.

If you are a patient receiving care from the Grady Health System and have a question about your rights, you may contact the Office of Research Administration at [redacted]

Consent

TO BE FILLED OUT BY SUBJECT ONLY

Print your name, **sign**, and **date** below if you choose to be in this research study. You will not give up any of your legal rights by signing this form. We will give you a copy of the signed form to keep.

_____

Name of Subject

_____ _____

Signature of Subject (18 or older and able to consent) **Date**

TO BE FILLED OUT BY STUDY TEAM ONLY

_____

Name of Person Conducting Informed Consent Discussion

_____ _____

Signature of Person Conducting Informed Consent Discussion **Date**

Optional Study Information

Biological specimen banking:

If you join the study, we may store blood, urine, or foot tissue specimens that were collected as part of your routine, standard medical care, and store them for future research to develop tests to better predict if a foot ulcer will heal. We will remove all identifiable information from the specimens, and they could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative.

What is the purpose of this study?
Specimens collected for this study will be used in future research to better understand diabetic foot wound healing.

What will I be asked to do?
Any specimens collected would have otherwise been discarded. We will not ask you to anything different in order to obtain these samples.

Will I benefit directly from the study?
This substudy is not designed to benefit you directly. This study is designed to learn more about the process of wound healing . The study results may be used to help others in the future.

Will I be compensated for my time and effort?
You will not be offered compensation for being in this substudy.

What are my other options?
You can participate in the main study and not take part in this substudy.

Withdrawal from the Substudy
You have the right to leave this substudy at any time without penalty. You may stay in the main study even if you leave this substudy.

The researchers also have the right to stop your participation in this substudy without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

These are the expected reasons why the researchers may stop your participation:
• Discarded tissue cannot be used for any reason (eg. contamination, poor sample)

Contact Information
See contact information for the main study, above.

HIPAA Authorization for Optional Substudy

You do not have to authorize the use and disclosure of your PHI for the optional study(ies). If you do not, you can still be in the main research study.

Your PHI will be used in the Optional Substudy the same way it will be used and disclosed for the main study, with the following differences:

- The following types of PHI may be used or disclosed for the optional substudy: date of birth, medical history
- The purpose of the use and disclosure is for the optional substudy described above
- The following *additional* people may use or disclose your PHI: principal investigator, co-investigators, sponsor

Consent and Authorization

TO BE FILLED OUT BY SUBJECT ONLY

Please **print** your name, **sign**, and **date** below if you agree to be in the optional study(ies) described above. By signing this form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep.

_____

Name of Subject

_____ _____

Signature of Subject (18 or older and able to consent) **Date**

TO BE FILLED OUT BY STUDY TEAM ONLY

_____

Name of Person Conducting Informed Consent Discussion

_____ _____

Signature of Person Conducting Informed Consent Discussion **Date**