**NCI CIRB Site Information and Authorization Form for Research Participants**

**What Is This Document?**

This study is being done at multiple sites. This part of the consent form includes information about your site and is specific to participation at your site only. Before you make your decision about joining the study, the study team will review this form and the main consent form with you. You will have a chance to ask questions about anything that is not clear.

**Title**:

**Principal Investigator:**

**Sponsor:**

**Investigator-Sponsor:**

**Study-Supporter:**

*If you are the legal guardian of a child who is being asked to participate, the term “you” used in this authorization refers to your child.*

**Costs of Participation**

***OPTION 1:*** *There are no costs, research or standard of care related, associated with the study*.

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 in the main consent form, the cost of treatment for those complications may be charged to you or your insurance.

***OPTION 2:*** *The sponsor will pay for certain items or services associated with the study.*

The study sponsor will pay for certain items and services that you may receive if you take part in this study.

You will have to pay for the items or services for which the study sponsor does not pay. The sponsor will not pay for your regular medical care. If you have insurance, Emory will submit claims to your insurance for items and services that the sponsor does not cover. Emory will send in only those claims for items and services that it reasonably believes your insurance will pay and that the sponsor has not paid.

The actual amount that you have to pay depends on whether or not you have health insurance and whether or not that insurance will pay for any research study costs. Generally, insurance companies will not pay for items and services that are required just for a research study. Some insurance companies will not pay for regular medical treatment or treatment for complications if you are in a study. How much you will have to pay for any co-payments, deductibles or co-insurance depends on your plan. Emory and the sponsor will not pay for these costs.

It is a good idea to contact your insurance provider and tell them you want to be in this research study. Ask them what they will pay for and what they will not pay for. You can also ask the study team for help in figuring out what you will have to pay.

If you do not have insurance, Emory will review your case as part of its program for low-income patient care. The standard policies of that program will apply. The program will figure out if you have to pay any costs for taking part in the study and what those costs will be.

***OPTION 3:*** *The sponsor will not pay for any items or services associated with the study.*

The study sponsor does not plan to pay for any items or services that you may receive if you take part in this study.

You will have to pay for the items or services that are part of this study. The sponsor will not pay for your regular medical care. If you have insurance, Emory will submit claims to your insurance for items and services that are part of this study. Emory will send in only those claims for items and services that it reasonably believes your insurance will pay and that the sponsor has not paid.

The actual amount that you have to pay depends on whether or not you have health insurance and whether or not that insurance will pay for any research study costs. Generally, insurance companies will not pay for items and services that are required just for a research study. Some insurance companies will not pay for regular medical treatment or treatment for complications if you are in a study. How much you will have to pay for any co-payments, deductibles or co-insurance depends on your plan. Emory and the sponsor will not pay for these costs.

It is a good idea to contact your insurance provider and tell them you want to be in this research study. Ask them what they will pay for and what they will not pay for. You can also ask the study team for help in figuring out what you will have to pay.

If you do not have insurance, Emory will review your case as part of its program for low-income patient care. The standard policies of that program will apply. The program will figure out if you have to pay any costs for taking part in the study and what those costs will be.

**How will my study drug be provided?**

The research team for this study includes non-licensed team members who may obtain your consent or help guide you through the study. There are some kinds of questions only licensed clinicians can answer. For example, detailed questions about drug interactions. If you have questions like these, the non-licensed coordinator will ask a licensed study team member to answer your questions. You may also call the pharmacy at pharmacy at (404) 712-4718 if you have questions about the study drug.

**Research and Your Medical Record**

If you have been an Emory Healthcare patient before, then you already have an Emory Healthcare medical record. If you have never been an Emory Healthcare patient, you do not have one. An Emory Healthcare medical record will be made for you if an Emory provider or facility gives you any services or procedures for this study.

Copies of the consent form/HIPAA authorization that you sign will be put in any Emory Healthcare medical record you have now or any time during the study.

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: [ ]

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

**How is my Genetic Information Protected? What are the Risks?**

A Federal law called the Genetic Information Nondiscrimination Act (GINA) provides some protection for your genetic information. This law generally will protect you in the following ways:

* + Health insurance companies and group health plans may not request your genetic information that we get from this research.
  + Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
  + Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

However, this Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

In addition to GINA, the State of Georgia has laws that prohibit insurers from using genetic testing information for any non-treatment purpose. However, like GINA, this state law protection has exclusions for life insurance and other types of insurance policies.

**Radiation Risks**

**Authorization to Use and Disclose Protected Health Information**

**Option 1: (treatment and billing)**

The privacy of your health information is important to us. We call your health information that can be used to identify you and relates to your treatment or payment, your “protected health information” or “PHI.” To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the “Privacy Rules.” Here we let you know how we will use and disclose your PHI for this study.

**PHI that Will be Used/Disclosed:**

The PHI that we will use or disclose for this 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 PHI Will be Used/Disclosed:**

* To conduct this research study
* To evaluate the safety and effectiveness of the drug, device and/or other intervention being studied and ensure integrity of the data
* To provide study-related treatment and for payment for such treatment
* To conduct healthcare operations
* To ensure compliance with state and federal regulations and provide oversight of the study
* To determine your health, vital status or contact information should you be unreachable during the study
* For the administration and payment of any costs relating to subject injury from the study
* [ADD ANY OTHER PURPOSES FOR WHICH PHI WILL BE USED/DISCLOSED]

**Use and Disclosure of Your Information That is Required by Law**:

We will use and disclose your PHI 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.

**Authorization to Use PHI is Required to Participate**:

By signing this form, you give us permission to use and disclose your PHI for this research study. You do not have to sign this form. If you do not sign this form, you may not join this study, but you can still receive non-research related treatment.

**People Who will Use/Disclose Your PHI:**

* The Principal Investigator and the research staff
* The sponsor of the research, its agents, study monitors and contractors including laboratories if applicable
* Institutional Review Boards (people who provide ethical review of research)
* Other Emory offices and persons who watch over the safety, effectiveness and conduct of the research
  + Government agencies that regulate the research as applicable to this study (e.g. regulatory agencies within and outside the United States such as the Office for Human Research Protections, Food and Drug Administration)

**Expiration of Your Authorization**

Your HIPAA authorization will expire when this research study ends.

**Revoking Your Authorization**

If you sign this form, at any time later you may revoke (take back) your permission for the use of your information. If you want to do this, you must contact the study team in writing at:

At that point, we will stop collecting your PHI. We may use or disclose the PHI already collected so we can follow the law, protect your safety, make sure that the study was done properly and the data is correct. 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. If we disclose your PHI to people who are not covered by the Privacy Rules, then your PHI won’t be protected by the Privacy Rules. People who do not have to follow the Privacy Rules can use or disclose your PHI to others without your permission if they are not required by law to protect the privacy of your PHI. For example, the Sponsor and companies working with the Sponsor on this study are not covered by the Privacy Rules.

To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your PHI 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. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove specific identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without those specific identifiers may be used or disclosed to other people or organizations for purposes besides this study without your further consent.

**Option 2: (obtaining PHI, but no treatment and no billing)**

The privacy of your health information is important to us. As part of this study, we will get your protected health information (PHI) from health care entities who are covered by the Health Insurance Portability and Accountability Act and regulations (HIPAA). Because the health care entities are covered by HIPAA, we must have your authorization to get your PHI from them. However, once we get your PHI from the health care entities, it changes from PHI to individually identifiable information (IIHI) and is no longer covered by HIPAA. We will put your IIHI in a separate research record that is not a part of your medical record. IIHI placed in the separate research record is not covered by HIPAA.

**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.

OR

**Research-Related Treatment**

This study involved research-related treatment that will not be electronically billed to any insurance company or government benefits program (e.g., Medicare, Medicaid). You may not receive the research-related treatment unless you sign this authorization. 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 disclosed for this 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:**

* To conduct this research study
* To evaluate the safety and effectiveness of the drug, device and/or other intervention being studied and ensure integrity of the data
* To provide study-related treatment
* To conduct healthcare operations
* To ensure compliance with state and federal regulations and provide oversight of the study
* To determine your health, vital status or contact information should you be unreachable during the study
* For the administration and payment of any costs relating to subject injury from the study
* [ADD ANY OTHER PURPOSES FOR WHICH IIHI WILL BE USED/DISCLOSED]

**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

**Authorization to Use IIHI is Required to Participate:**

By signing this form, you give us permission to use and disclose your IIHI for this research study.

**People Who will Use/Disclose Your IIHI:**

* The Principal Investigator and the research staff
* The sponsor of the research, its agents, study monitors and contractors including laboratories if applicable
* Institutional Review Boards (people who provide ethical review of research)
* Other Emory offices and persons who watch over the safety, effectiveness and conduct of the research
* Other researchers and centers that are a part of this study
  + Government agencies that regulate the research as applicable to this study (e.g. regulatory agencies within and outside the United States such as the Office for Human Research Protections, Food and Drug Administration and Veterans Administration)

**Expiration of Your Authorization**

Your HIPAA authorization will expire once no more PHI is needed from your medical records for this study.

**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 the study team at:

At that point, we will stop collecting your IIHI. We may use or disclose the IIHI already collected so we can follow the law, protect your safety, make sure that the study was done properly and the data is correct. 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 the research records for this study because the study does not include treatment that is billed to insurers or government benefit programs. Your information collected for this study may be disclosed to others without your permission. The researchers, Sponsor, and people and companies working on this study 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 purposed. 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.

***TO BE FILLED OUT BY SUBJECT ONLY***

Please **print** your name, **sign**, and **date** below if you:

1. agree to authorize the use and disclosure of your protected health information as described above for this study and any optional studies you agreed to participate in via the consent form.
2. accept the additional Emory and Georgia-specific terms 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 Research Participant**

**Signature of Research Participant (18 or older and able to consent) Date Time**

**Signature of Legally Authorized Representative**

**Authority of Legally Authorized Representative or Relationship to Participant**