**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 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. We will also comply with legal requests, including subpoenas or court orders, that require us to disclose your IIHI.

**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)
    - [ADD ANY OTHERS WHO WILL USE/DISCLOSE IIHI]

In certain cases where a researcher moves to a different institution, your IIHI may be disclosed to that new institution and their oversight offices. The IIHI will be disclosed in a secure manner and under a legal agreement signed by both institutions to ensure it continues to be used under the terms of this consent and authorization.

**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.