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

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

**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
  + 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 PHI]

In certain cases where a researcher moves to a different institution, your PHI may be disclosed to that new institution and their oversight offices. The PHI 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 HIPAA authorization.

**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.