**Verbal** – HIPAA – IIHI – Confidentiality Language Selection – Emory and/or CHOA and/or CHOA Hughes Spaulding

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**Directions**: Select HIPAA, IIHI, or Confidentiality Language below from consent toolkit page based on what applies. Reference the HIPAA Applicability Worksheet which will let you know which section (HIPAA, IIHI, Confidentiality) to choose.

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# Accessing PHI, treating and billing to third party payor, research at a covered entity

If, HIPAA worksheet indicates HIPAA applies to research (Accessing PHI, treating and billing to third party payor, research at a covered entity). Insert this HIPAA language: **HIPAA Applies to Research Records** pasted below:

**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**:

Your privacy is very important to us. There is a law that protects your health information kept by your medical provider; this law is called HIPAA. Your health information that identifies you is your “protected health information” (PHI).

The PHI for this study includes [Insert list of PHI that will be used]. To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act (HIPAA). If you join the study, the following persons or groups may use and /or disclose your PHI for this study:

**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 and Children’s Healthcare of Atlanta and Children’s Healthcare of Atlanta at Hughes Spalding Hospital 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)

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.

You may revoke your authorization at any time by calling the Principal Investigator, [name], or by writing to the address listed on the information sheet that we will send to you. If identifiers (like your name, address, and telephone number) are removed from your PHI, then the remaining information will not be subject to the Privacy Rules. This means that the information may be used or disclosed with other people or organizations, and/or for other purposes.

If we share your PHI with other groups who do not have to follow the Privacy Rule, then they could use or disclose your PHI to others without your authorization. Let me know if you have questions about this. If you do not give your authorization, you may still receive non-research related treatment. We will put a copy of this informed consent form for the research study into any medical record that you may have with Emory Healthcare and Children’s Healthcare of Atlanta and Children’s Healthcare of Atlanta at Hughes Spalding Hospital facilities.

Your authorization will not expire because your PHI will need to be kept indefinitely for research purposes.

# Obtaining PHI but no treatment and billing to third party payor for research

If HIPAA worksheet indicates **HIPAA doesn't apply to data once it's in my research records (obtaining PHI but no treatment and billing to third party payor for research).** Insert this HIPAA language, then use IIHI language pasted below:

**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 and Children’s Healthcare of Atlanta and Children’s Healthcare of Atlanta at Hughes Spalding Hospital 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]

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.

You may revoke your authorization at any time by calling the Principal Investigator, [name], or by writing to the address listed on the information sheet that we will send to you. If identifiers (like your name, address, and telephone number) are removed from your IIHI, then the remaining information will not be subject to the Privacy Rules. This means that the information may be used or disclosed with other people or organizations, and/or for other purposes.

If we share your IIHI with other groups who do not have to follow the Privacy Rule, then they could use or disclose your IIHI to others without your authorization. Let me know if you have questions about this. If you do not give your authorization, you may still receive non-research related treatment. We will put a copy of this informed consent form for the research study into any medical record that you may have with Emory Healthcare and Children’s Healthcare of Atlanta and Children’s Healthcare of Atlanta at Hughes Spalding Hospital facilities.

Your authorization will not expire because your IIHI will need to be kept indefinitely for research purposes

# The research is not accessing, using, or storing any PHI from a covered entity

If the research is **not accessing, using, or storing any PHI from a covered entity**, then include confidentiality language pasted below.

Confidentiality

Certain offices and people other than the researchers may look at study records. Government agencies and Emory and Children’s Healthcare of Atlanta and Children’s Healthcare of Atlanta at Hughes Spalding Hospital employees overseeing proper study conduct may look at your study records. These offices include [the Office for Human Research Protections, the funder(s), the Emory Institutional Review Board, the Emory and Children’s Healthcare of Atlanta and Children’s Healthcare of Atlanta at Hughes Spalding Hospital Office of Compliance. Study funders may also look at your study records. Emory and Children’s Healthcare of Atlanta and Children’s Healthcare of Atlanta at Hughes Spalding Hospital will keep any research records we create private to the extent we are required to do so by law. A study number rather than your name will be used on study records wherever possible. Your name and other facts that might point to you will not appear when we present this study or publish its results.

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

The following people and groups will use and disclose your information in connection with the research study:

* The Principal Investigator and the research staff will use and disclose your information to conduct the study and give you study related treatment.
* Emory and Children’s Healthcare of Atlanta and Children’s Healthcare of Atlanta at Hughes Spalding Hospital may use and disclose your information to get payment for study related activities and to run normal business operations.
* The Principal Investigator and research staff will share your information with other people and groups to help conduct the study or to provide oversight for the study.
* \_\_\_\_\_\_\_\_\_\_ is the Sponsor of the study. The Sponsor may use and disclose your information to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your information to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
* The research team and the Sponsor may use and disclose your information, including disclosure to insurance carriers to administer payment for subject injury.
* [ADD ANY OTHERS].
* The following people and groups will use your information to make sure the research is done correctly and safely:
	+ Emory and Children’s Healthcare of Atlanta and Children’s Healthcare of Atlanta at Hughes Spalding Hospital offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRB, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
	+ Other researchers and centers that are a part of this study.
	+ Government agencies that regulate the research including: Office for Human Research Protections; Food and Drug Administration; Veterans Administration.
	+ Public health agencies.
	+ Research monitors and reviewer.
	+ Accreditation agencies.
	+ ADD ANY OTHERS.
* Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your information may be shared with that new institution and their oversight offices. Information will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent.