**Emory University** **and Children’s Healthcare of Atlanta and**

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

**Oral Consent Script**

**For a Research Study**

**Title**:

**IRB #:**

**Principal Investigator:**

**Faculty Advisor:**

**Sponsor:**

**Investigator-Sponsor:**

**Study-Supporter:**

If you are the legal guardian of a child who is being asked to participate, the term “you” refers to the child.

## Introduction and Study Overview

Thank you for your interest in our [type of research] research study. We would like to tell you what you need to think about before you choose whether or not to join the study. It is your choice. If you choose to join, you can change your mind later on and leave the study.

The purpose of this study is [fill in]. The study is funded by [fill in]. This study will take about [amount of time] to complete.

If you join, you will be asked to [describe all procedures involved in the study]

[List possible risks and/or discomforts, indicating their likelihood of occurrence if available]

[

You may not benefit from joining the study. Your condition may improve while you are in this study or it may get worse. This study is designed to learn more about… The study results may be used to help others in the future.

]

[Select HIPAA, IIHI, or Confidentiality Language from [consent toolkit page](https://www.irb.emory.edu/forms/consent/index.html) based on what applies. Reference the HIPAA Applicability Worksheet which will let you know which section (HIPAA, IIHI, Confidentiality) to choose.]

**Storing and Sharing your Information**

We will store all the data [and specimens] that you provide using a code. We need this code so that we can keep track of your data over time. This code will not include information that can identify you (identifiers). Specifically, it will not include your name, initials, date of birth, or medical record number. We will keep a file that links this code to your identifiers in a secure location separate from the data.

We will not allow your name and any other fact that might point to you to appear when we present or publish the results of this study.

Your data [and specimens] may be useful for other research being done by investigators at Emory or elsewhere. We may share the data [or specimens], linked by the study code, with other researchers at Emory and Children’s Healthcare of Atlanta and Children’s Healthcare of Atlanta at Hughes Spalding Hospital, or with researchers at other institutions that maintain at least the same level of data security that we maintain at Emory and Children’s Healthcare of Atlanta and Children’s Healthcare of Atlanta at Hughes Spalding Hospital . We will not share the link between the study code and your identity.

OR

Your data [and specimens] from this study will not be shared with anyone outside this study, even if we take out all the information that can identify you.

We may also place data in public databases accessible to researchers who agree to maintain data confidentiality, if we remove the study code and make sure the data are anonymized to a level that we believe that it is highly unlikely that anyone could identify you. Despite these measures, we cannot guarantee anonymity of your personal data.

We will use your [specimens and] data only for research. We will not sell them. However, the results of this research might someday lead to the development of products (such as a commercial cell line, a medical or genetic test, a drug, or other commercial product) that could be sold by a company. You will not receive money from the sale of any such product.

**Certificate of Confidentiality**

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

**Compensation**

***If there is no compensation:*** You will not be compensated for being in this study.

***If there is compensation:***You will get $insert ***compensation amount*** for each completed study visit for your time and effort. If you do not finish the study, we will compensate you for the visits you have completed. You will get $insert compensation amount total if you complete all study visits.

***If there is reimbursement for certain expenses like travel or parking:*** The study will provide reimbursement for certain expenses related to your participation, specifically ***insert expense types.***

Emory may be required to report your payment(s) to the IRS depending on how much you receive in a year. You must give the researchers a valid Social Security number or Taxpayer Identification Number for IRS reporting purposes. If you do not, your amount may be reduced because taxes are taken out. Please talk to your study team for more details.

***Include the following statement if you are using a third-party compensation method, like Greenphire. Modify as necessary to reflect the system being used:***

A company called ***insert company name*** is working on behalf of the study to compensate participants. ***Insert company name*** will need to collect certain personal information about you to set up your account. The company will see this study title, but will not see any research-related information about you.

**Returning Results to Participants/Incidental Findings**

**In Case of Injury**

We will give you emergency care if you are injured by this research. However, Grady Health System has not set aside funds to pay for this care or to compensate you if a mishap occurs.  If you believe you have been injured by this research, you should contact Dr. [physician name] at [phone number].

**[INSERT OTHER SECTIONS FROM MODULAR CONSENT FORM HERE]**

**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 [study contact person(s)] at [telephone number(s)]:

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 404-712-0720 or 877-503-9797 or irb@emory.edu.

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

If you are a patient receiving care at Children’s Healthcare of Atlanta or Children’s Healthcare of Atlanta at Hughes Spalding Hospital and have a question about your rights, please contact the Children’s Institutional Review Board at 404-785-7477.

## Consent

Do you have any questions about anything I just said? Were there any parts that seemed unclear?

Do you agree to take part in the study?

Participant agrees to participate: Yes No

If Yes:

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Participant

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Legally-Authorized Representative (if non-treatment study, must be parent/legal guardian of minor, or have Power of Attorney for Research)

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Relationship of Legally-Authorized Representative to Participant

Signature of Person Conducting Informed Consent Discussion Date Time

Name of Person Conducting Informed Consent Discussion