**Emory University**

**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.

]

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 “individual identifiable health information” (IIHI).

The IIHI for this study includes [Insert list of IIHI that will be used]. To protect your IIHI, 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 IIHI for this study:

* The Principal Investigator and the research staff.
* [fill in], who funds this Research,, and people or companies they use to carry out the study
* Emory offices who are part of the Human Research Participant Protection Program, and those who are involved in research-related administration and billing
* Other researchers and centers that are a part of this study.
* Any government agencies who regulate the research including the Office of Human Subjects Research Protections (OHRP) and the US Food and Drug Administration (FDA)
* [any other parties that apply including possible future researchers who want to contact subjects for studies – if none, remove this bullet]

We will disclose your IIHI when required to do so by law in the case of reporting child abuse or elder abuse, in addition to subpoenas or court orders.

The investigators have obtained a Certificate of Confidentiality for this study. If Emory received a subpoena for study records that identify you, we would say no, and the Certificate gives us this authority. The Certificate does not prevent you or someone other than you from making disclosing your information. The Certificate also does not prevent Emory from releasing information about you:

* + Information to state public health offices about certain infectious diseases
  + Information to law officials if child abuse has taken place
  + Information Emory gives to prevent immediate harm to you or others
  + Information Emory gives to the study sponsor as part of the research

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 facilities.

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

**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, or with researchers at other institutions that maintain at least the same level of data security that we maintain at Emory. 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.

**Returning Results to Participants/Incidental Findings**

**[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](mailto: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)**.**

## 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