**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.

]

Study records can be opened by court order. They also may be provided in response to a subpoena or a request for the production of documents.

# Certificate of Confidentiality

There is a Certificate of Confidentiality from the National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory from making the following disclosures about you:

* Giving state public health officials information about certain infectious diseases,
* Giving law officials information about abuse of a child, elderly person or disabled person.
* Giving out information to prevent harm to you or others.

Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

**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]**

**Confidentiality**

Certain offices and people other than the researchers may look at study records. Government agencies and Emory 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 Office of Compliance]. Study funders may also look at your study records. Emory 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 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 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.

**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)**.**

## 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