**Emory University**

**Oral Consent and HIPAA Authorization Script and Information Sheet**

**For Research Study Screening**

**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 [name of study] study. To see whether you may be a candidate for this study, we need to ask you for some information about yourself. But first, let me tell you about this screening interview and what we will do with your information.

1. This screening interview will take about XX minutes.
2. You can also stop the screening interview at any time. This is completely voluntary.
3. We can send you an information sheet about this screening, along with the screening questions, if you would like. We will also give you a form you can send in later if you change your mind and want us to remove your information from our records.
4. We will ask you about your [fill in condition or health history topic] and will record this information in a [logbook/excel spreadsheet/database] containing information from others who have also shown interest in the study.
5. This information will only be used for the research study you are interested in [or if not, specify how it will be used].
6. The only risk to you in this phone screening is a potential loss of privacy. However your privacy is very important to us and we will be very careful with your information.
7. Your health information that identifies you is your “protected health information” or “PHI.” We will use your PHI to screen you for our research study
8. The PHI we will use includes INSERT PHI THAT WILL BE USED.
9. To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act (called HIPAA or “the Privacy Rule” for short).
10. The following persons or groups may use and/or disclose your PHI 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
* Any government agencies who regulate the research including the Office of Human Subjects Research Protections and the FDA
* [any other parties that apply including possible future researchers who want to contact them for studies – if none, remove this bullet]
1. We will disclose your PHI when required to do so by law in the case of reporting child abuse or elder abuse, in addition to subpoenas or court orders.
2. You may revoke your authorization at any time by calling the principal investigator,[name], or by using the form that we will send to you.
3. 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.
4. 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.
5. Your authorization will not expire because your PHI will need to be kept indefinitely for research purposes.
6. We can send you a copy of this information, if you would like.

## Contact Information

## If you have questions about this study, your part in it, or if you have questions, or concerns about the research you may contact the following:

## [Name], [Role]: [telephone number]

##

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.

You can also stop the screening interview at any time. This is completely voluntary.

## Consent

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

Do you agree to participate in the screening process, and authorize the use and disclosure of your protected health information as I described?

Participant agrees to participate: Yes No

If Yes:

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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)

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Relationship of Legally-Authorized Representative to Participant

Signature of Person Conducting Informed Consent Discussion Date Time

Name of Person Conducting Informed Consent Discussion