Emory University
Consent to be a Research Subject

Title:

Principal Investigator:

Funding Source:

If you are the legal guardian of a child who is being asked to participate, the term "you" used in this consent refers to your child

Introduction
You are being asked to be in a research study. This form is designed to tell you everything you need to think about before you decide to consent (agree) to be in the study or not to be in the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study. You can skip any questions that you do not wish to answer.**

Before making your decision:
- Please carefully read this form or have it read to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. By signing this form you will not give up any legal rights.

Study Overview
The purpose of this study is to…

Procedures

Risks and Discomforts

New Information
It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Benefits
This study is not designed to benefit you directly. Y This study is designed to learn more about…. The study results may be used to help others in the future.

Compensation
You will not be offered payment for being in this study.

OR SOMETHING LIKE

You will get $____ for each completed study visit. If you do not finish the study, you will be paid for the visits you have completed. You will receive $____ total, if you complete all study visits.

Other Options Outside this Study

If you decide not to enter this study, there is care available to you outside of this research. [List the major standard care options and/or possibility of other studies] We will discuss these with you. You do not have to be in this study to be treated for [condition] OR to get [list services].

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 Research Compliance and the Office for Clinical Research.]. 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.

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

There is a Certificate of Confidentiality for this Study:

What the Certificate of Confidentiality protects:
The National Institutes of Health has given this study a Certificate of Confidentiality. Emory would use it to block a legal request to give out study information. For example, if Emory received a subpoena for study records, we would say no. The Certificate gives Emory legal backup to say no. It covers information about you that could harm your image or finances. It also covers information about you that could harm your chances at a job or getting insurance.

What the Certificate of Confidentiality does not protect:
The Certificate would not protect some information about you, including any information:

- you give out yourself
- someone other than you or Emory gives out
- that Emory must give to state public health offices about certain infectious diseases
- that Emory must give to law officials if child abuse has taken place
- that Emory must give to prevent immediate harm to you or others
- that Emory needs to give to the study funder

Voluntary Participation and Withdrawal from the Study

You have the right to leave a study at any time without penalty. You may refuse to do any procedures you do not feel comfortable with, or answer any questions that you do not wish to answer.

The researchers and funder also have the right to stop your participation in this study without your consent if:

- They believe it is in your best interest;
- You were to object to any future changes that may be made in the study plan;
- [reasons specific to this study – delete if none]
- or for any other reason.

Contact Information

Contact [researcher contact person] at [tel numbers]:

- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury, or
- if you have questions, concerns or complaints about the research

Contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu:

- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research.
- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.

Consent

Please, print your name and sign below if you agree to be in this study. By signing this consent form, you will not give up any of your legal rights. We will give you a copy of the signed consent, to keep.

_____
Name of Subject

_____ _____
Signature of Subject Date Time

_____ _____
Signature of Person Conducting Informed Consent Discussion Date Time

_____ _____
Signature of Legally Authorized Representative Date Time

_____
Authority of Legally Authorized Representative or Relationship to Subject

_____ _____
Signature of Assent for 17 year old Subject Date Time