# Assent of Children to Participate in Research

**Study # \_\_\_\_\_\_\_\_\_\_\_\_\_**

## **Title of study*:*** *[As title appears in the IRB application and grant/contract, sponsored protocol. Best to bold the title.]*

# Why am I being asked to take part in this research?

You are being asked to take part in a research study about *[Include the subject of study in plain language]*. You are being asked to take part in this research study because you have *[Explain, in plain language, the condition or situation that makes this individual eligible for the research]*. If you take part in this study, you will be one of about *[Number]* people at this site.

# Who is doing this study?

The person in charge of this study is *[Name of investigator]*. *[If the PI is a student, add the following statement]* [He/She] is being guided in this research by *[Name of Faculty Advisor]*. However, other research staff may be involved and can act on behalf of the person in charge.

# What is the purpose of this study?

By doing this study, we hope to learn *[Explain purpose in plain language]*.

# Where is the study going to take place and how long will it last?

The study will be take place at *[Insert facility name]*. You will be asked to participate in *[Number]* visits which will take about *[State in minutes or hours]*. The total amount of time you will be asked to volunteer for this study is *[Total amount of time]* over the next *[State in days, months or years]*.

# What will you be asked to do?

* *Describe all procedures in lay language, using simple terms and short sentences. “You will be asked to…”*
* *Explain exactly what the individual taking part will need to do as part of this research.*
* *List and briefly explain all tests and/or procedures that will need to be done, including the purpose of each (for example, depression scales, word association test, blood tests, ECG, blood pressure, x-ray, and so on).*
* *Explain the questions that will be asked, interviews/surveys and/or medical procedures that may be conducted.*
* *Answer the following questions for the subject: What is being performed as part of the research? If applicable, what is being performed as part of the care the subject would normally receive?*
* *Prepare a time line chart or schema to accompany descriptions of procedures and tests for studies that require more than 1 or 2 steps/visits.*
* *Provide a lay description of the randomization procedures, if applicable, and describe the chances of being assigned to any one group.*

# What things might happen if you participate?

*[If the research involves minimal risk to the subject, include the following statement:]*

To the best of our knowledge, your participation in this study will not harm you.

*[If the research involves any procedures which could cause possible physical harm, describe the risks in lay terms and any ramifications that could result should an adverse event occur, e.g., because of this medicine, procedure.]*

You may experience discomfort while participating in this research study. This may include…

*[If the research involves any procedures which could cause possible emotional or mental harm, include the following statement:]*

Although we have made every effort to try and make sure this doesn’t happen, you may find some questions we ask may upset you. If so, we will tell you and your parents or guardian about other people who may be able to help you with these feelings.

In addition to the things that we have already talked about, listed above, you may experience something *[Unpleasant, uncomfortable, hurtful, bad]* that we do not know about at this time.

# Is there benefit to me for participating?

We cannot promise that you will receive benefit from taking part in this research study. However, some people have experienced *[Describe what might happen]* when *[Procedure being done]*.

# What other choices do I have if I do not participate?

*[This statement is sufficient if there are no alternatives for the participant:]* You do not have to participate in this research study.

Alternatives to participating include: *[If there are alternatives to participating in the study, describe those here:*

* *Describe the procedures/treatments/interventions*
* *A statement that they may discuss alternatives with their personal physician.]*

# Do I have to take part in this study?

You should talk with your parents or guardian and others about taking part in this research study. If you do not want to take part in the study, that is your decision. You should only take part in this study if you want to volunteer.

# Will I receive any compensation for taking part in this study?

You will receive *[Describe compensation]* for taking part in this study. If you stop participating before the study is over, the payment you receive will be based on the amount of time you were in the study.

*[Or]*

You will not receive any compensation for taking part in this study.

# Who will see the information about me?

Your information will be added to the information from other people taking part in the study so no one will know who you are.

*[Or]*

We will share your information with *[Your parents, guardian, teachers, other doctors, etc.]* so that they can better help you.

### [Or if the study is anonymous:]

No one, not even the people who are doing this study, will know that the information you provide comes from you.

*[If applicable (i.e., for studies involving focus groups), include the following language]*

The researchers will do everything we can to make sure what you say in the focus group is kept confidential. However, we cannot promise that other participants in the focus groups will keep what you say to themselves. The researchers would like to remind participants to respect the privacy of your fellow participants and not repeat what is said in the focus group to others.

# Can I change my mind and quit?

If you decide to take part in the study you still have the right to change your mind later. No one will think badly of you if you decide to stop participating. Also, the people who are running this study may need for you to stop. If this happens, they will tell you when to stop and why.

# What if I have questions?

You can ask questions about this study at any time. You can talk with your parents, guardian or other adults about this study. You can talk with the person who is asking you to volunteer by calling *[Name of principal investigator at telephone #]*. If you think of other questions later, you can ask them. If you have questions about your rights as a research participant, you can also call the MGS IRB at (813) 974-5638 or contact the IRB by email at [IRB@mgsns.org](mailto:IRB@mgsns.org)

# Assent to Participate

I understand what the person conducting this study is asking me to do. I have thought about this and agree to take part in this study. I have been given a copy of this form.

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Name of person agreeing to take part in the study Date

*[If obtaining the signature of the child add this line* - *otherwise remove]*:

**Signature of child agreeing to take part in the study: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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Printed name & Signature of person providing Date

Information (assent) to subject