Instructions for creating your assent form

The UTRGV IRB’s general policy is to obtain the assent of all children (ages 7-17 years). Recognizing that, depending on the age of the children, there are likely to be differences in language comprehension, *multiple assent forms may be required to cover different age groups*. For example, it may well be appropriate to simplify the language and use a larger font for younger children.

Under special circumstances, the requirement to obtain the assent of a child can be waived by the IRB. Usually this involves an experimental treatment that is likely to be beneficial and there are no other acceptable and available alternative treatments. You must request and justify that the IRB consider such a waiver. The IRB will determine if a waiver is appropriate and notify you of its determination. You may not enroll a non-assenting child subject in research without written approval of the IRB. In these and other cases, the IRB may determine that a child advocate be present during the assent and permission process.

* *Use the following template as a basis for your informed consent form.*
* *Text in italics should be deleted.*
* *Non-italic text should be retained.*
* *Text in [brackets] should be retained and edited appropriately.*
* *Do not use the terms “treatment”, “therapy”, or “device”. Instead use terms such as “study treatment/therapy/device” or “research treatment/therapy/device.” This avoids therapeutic misconception.*
* *Do not use the term “patient” instead use the term “you”.*

NOTE: Do not, under any circumstances, submit a consent form with instructional text still included. This will delay approval of your application.

# Purpose

We are doing a study about [*Very simply describe why the research is being done. Gear the description to the anticipated age group. Avoid jargon*.] It is up to you if you are in this study. I will be discussing this with your parents too. Your parents are not allowed to have you participate unless you agree.

# Description of the Study

*[Describe what procedures will be done. For treatment studies also describe which procedures would be done even if the subject was not a participant in the study and, in the language appropriate for the age group of the child, describe the differences between receiving medical care and participating in research.]*

# Risks

*[Describe the risks in a way that is understood by children.]*

# Benefits

*[In terms that the child can understand, describe what primary and direct benefits the child might experience. Also, add whether or not benefits to others might be possible.]*

# Other Choices

Delete this section if not relevant. For treatment studies describe alternative treatments in words such as “If you decide not to be in this study, you will get [describe alternative treatments or state that there are not alternative treatments and that they do not have to participate]. “If you do not want to participate, your doctor will still take care of you.”

# Who to talk to about questions

If you have questions about the study you can ask us now or later. Your parents have been given our contact information.

If you have questions about your rights in the study, contact The University of Texas Rio Grande Valley Institutional Review Board at (956) 665-3598 or irb@utrgv.edu.

I agree to take part in the study.

 Child’s Name Signature Date