**ASSENT TO TAKE PART IN A RESEARCH STUDY**

This template [HRP-502n] should be used when obtaining assent from minors—children under the age of 18—or assent from adults represented by a surrogate to take part in interventional research—research in which subjects are assigned to receive one or more interventions and manipulations of the subject or the subject’s environment that are performed for research purposes so that the investigators can evaluate their effects (e.g., clinical trials, CBT, Behavioral Modification studies, or randomized outcome studies). [Use with Protocol Template 503a]

**Assent** is an affirmative agreement by an individual not capable of giving legally valid consent, such as a child or an adult represented by a surrogate for decision-making purposes.

If children to be recruited are older, e.g., ages >14, and the investigators assess the children will likely comprehend adult language, consider instead modifying the Adult Consent for Interventional Research [HRP-502a] to obtain assent from those children

For children or adults represented by a surrogate, the IRB may permit an assent signature line to be added to the Parental Permission for Interventional Research [HRP-502c] or to the Surrogate Consent for Interventional Research [HRP-502e] to obtain subject assent at the same time as obtaining parental permission or surrogate consent, as applicable.

**INSTRUCTIONS:**

* **[BLUE]** highlighted text provides instructions and sample language to guide you in constructing the assent document.
* **Delete all instructional text** prior to uploading the document to e-IRB.
* The assent document should be written at grade reading level of the subjects to be recruited.
* **NOTE:** If the research is conducted, supported, or otherwise subject to regulation by any Federal Department or agency, such as Dept of Defense, Dept of Energy, Dept of Justice, Dept of Education or Environmental Protection Agency, additional protocol plans may be required. [Go to HSPP Toolkit HRP-103a Appendices to learn more.]

Visit the Human Subjects Protection Program (HSPP) website <https://go.rutgers.edu/HSPP-Toolkit> to obtain referenced Toolkit Forms & Templates and <https://go.rutgers.edu/HSPP-Guidance> to obtain referenced Guidance documents. Contact your IRB Office at <https://go.rutgers.edu/ContactUs> if you need further assistance.

**TITLE OF STUDY:** [Add the Title of the study here.]

**Principal Investigator:** [Add the PI’s name and credentials here (i.e. M.D., Ph.D., etc.).]

**Who are you and why are you meeting with me?**

I am [name] and I work at Rutgers, The State University of New Jersey, School of [specify] in the Department of [specify]. I would like to tell you about a research study that involves people like yourself and see if you would like to take part in it. Please ask me, other study staff, [your parent, your surrogate decision-maker, your teacher, etc., as applicable] to explain any words you don’t understand about the study.

**What is this research study about?**

Describe briefly in simple language why you are doing the study and what you hope to learn. LIMIT SENTENCES TO TWELVE WORDS (OR FEWER) WHERE POSSIBLE.

**Why have I been asked to take part in this study?**

Explain in plain and simple language why the potential subject—child or adult represented by a surrogate—is being invited to take part in the study. LIMIT SENTENCES TO TWELVE WORDS (OR FEWER) WHERE POSSIBLE.

**Who can be in this study? And who may not? How long will the study take?**

Describe the inclusion and exclusion criteria in plain language. Describe only those conditions that the subjects would be expected to understand. State how long their participation will take in hours, days or months.

**What will happen to me if I take part in this study?**

Describe in simple language the procedures step by step, that subjects will undergo.

**Can something bad happen to me or will I feel uncomfortable if I take part in this study?**

Sometimes things happen to people in research studies that may hurt them or make them feel bad. These are called risks. The risks of this study are…

Describe in plain language what the risks and discomforts may be for each procedure/intervention, include physical, psychological, and social. If the incidence of these risks or discomforts is known, it should be stated (at least in terms of rare, occasional, or common).

**For Adolescents who can Become Pregnant in this Study** (delete this section if it is not applicable to the research)

If the study medicine is taken by a person who is pregnant (having a baby) it may hurt the baby. If you have had your first menstrual period and have begun to have sex, it is possible for you to become pregnant. If you have had your first menstrual period, a urine pregnancy test will be done at your first visit to make sure that you are not pregnant. This will not hurt. You will be asked to “pee” in a cup, put it in a tube and the pregnancy test will be done or the study doctor may take blood from my arm with a needle placed in a vein. There may be a black or blue spot on my arm called a bruise, or bleeding, or infection, at the place where my blood is drawn. But the chances of getting an infection are rare.

It is important that you tell [choose: your parents or surrogate representing you] or the study doctor if you start having sex while you are in this study. You must use a reliable way to stop you from becoming pregnant; this is called “birth control”. You can use a condom (also called a rubber) along with a sperm-killing jelly and birth control pills. The study doctor will answer all of you and your [choose: parent’s or surrogate] questions about birth control. If you are having sex but are not sure if the type of sex you are having can cause you to have a baby, please ask the study doctor to explain.

If you don’t take reliable birth control measures, you are asked not to sign up for this study and asked not to sign this assent form.

You should also tell the study doctor about all medicines that other doctors may have given you to take.

**Can something good happen to me if I take part in the study?**

Be very clear about what and whether the subject can expect direct benefit for participation in the study.

**Will others know what I say and do in the study?**

Briefly and simply describe the measures you will take to protect subjects’ privacy and confidentiality. For example: We will keep any item with your name on it locked up or we will use a code number instead of your name. If we tell others about the study, we will not mention your name.

**Will I be given anything to take part in this study?**

If subjects will receive compensation: You will receive [specify] for being in the study. Payment should be age appropriate gift certificates or tokens and not cash. If subjects will not receive compensation, say instead: No. You will not be paid to take part in the study.

**What if I do not want to take part in this study?**

You don’t have to take part in this study if you don’t want to. No one will get angry or upset if you do not want to be in the study. Just tell us. And remember, you can change your mind later if you decide you don’t want to be in the study anymore.

**What if I have questions?**

You can ask questions at any time. You can ask now. You can ask later. You can talk to me or you can talk to someone else at any time during the study. Here are the telephone numbers to reach us:

If you have questions, concerns, or want more information about the study you can call the study doctor at: (add PI contact information).

If you have questions, concerns, problems, information or input about the research or would like to know your rights as a research subject, you can contact the Rutgers IRB or the Rutgers Human Subjects Protection Program via phone at (973) 972-3608 or (732) 235-2866 or (732) 235-9806 OR via email irboffice@research.rutgers.edu, or you can write us at 335 George Street, Liberty Plaza Suite 3200, New Brunswick, NJ 08901.

**What are my rights if I decide to take part in this research study?**

You may ask questions about any part of the study at any time. Do not sign this form unless you have had a chance to ask questions and have been given answers to all your questions and agree to take part in the study.

[For research with children: If the IRB requires the parent(s) or legal guardian to give permission for the child to take part in the study, add the following sentence:] If you say yes, your parent(s) or guardian will also be asked if it is ok for you to take part in this study. You will be given a copy of this form to keep.

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| **ASSENT TO TAKE PART IN THIS STUDY****Subject’s Signature:**I have read this entire form, or it has been read to me, and I believe that I understand what has been talked about. All my questions about this form and this study have been answered. I agree to take part in this study.Name (Print): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature: Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Signature of Investigator or Responsible Individual:**To the best of my ability, I have explained and discussed the important details about the study including all information contained in this assent document. All questions have been accurately answered.Investigator/Person Obtaining Consent Name (Print): Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**FOR NON-ENGLISH-SPEAKING SUBJECTS:**

Translation of the consent form (verbal or written) must have prior approval by the IRB. For more information, go to HSPP GUIDANCE Non-English-Speaking Subjects. See also HSPP Toolkit Forms & Templates Special Consent Considerations.

**SURROGATE OR LEGALLY AUTHORIZED REPRESENTATIVE CONSENT:**

Use of a surrogate or legally authorized representative to consent for an adult research subject must have prior approval by the IRB. For more information, go to HSPP GUIDANCE Surrogate Consent Process.

**SPECIAL CONSENT CONSIDERATIONS**

When research plans to enroll individuals’, who cannot read or write (illiterate or low literacy), who cannot see (blindness or vision-impairment), or who cannot hear (deafness or hearing-impaired), special protections apply, such as the need for an impartial witness to observe the consent conversation, interpretation of the consent conversation (American Sign Language) or translation of the consent/study documents (Braille). For more information, go to HSPP Toolkit Forms & Templates Special Consent Considerations.

**CONSENT ADDENDA:**

Investigators seeking consent to audio or visually record aspects of the research, take photographs, or store information or biospecimens for future research secondary to a main study will find consent addenda language at HSPP Toolkit Forms & Templates Consent Addenda.