**[USE YOUR DEPARTMENT LETTERHEAD]**

**ASSENT TO TAKE PART IN RESEARCH**

This template [16.307 (HRP-502n)] should be used when obtaining either.

* assent from minors [children under the age of 18 (or age of majority of the region where the research will occur)], or
* assent from adults represented by a surrogate.

**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.

This template [16.307 (HRP-502n)] should be used for interventional research—research in which participants are assigned to receive one or more interventions and manipulations of the participant or the participant’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).

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 [[16.301 (HRP-502a)](https://research.rutgers.edu/researcher-support/research-compliance/human-research-protection-program/toolkit#tab=panel-2)] to obtain assent from those children.

For children, the IRB may permit an assent signature line to be added to the Parental Permission for Interventional Research [[16.303 (HRP-502c)](https://research.rutgers.edu/researcher-support/research-compliance/human-research-protection-program/toolkit#tab=panel-2)] to obtain participant assent at the same time as obtaining parental permission or surrogate consent.

For adults represented by a surrogate, the IRB may permit an assent signature line to be added to the Surrogate Consent for Interventional Research [[16.305 (HRP-502e)](https://research.rutgers.edu/researcher-support/research-compliance/human-research-protection-program/toolkit#tab=panel-2)] to obtain participant assent at the same time as obtaining surrogate consent.

**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 eIRB+.
* The assent document should be written at the 6th-8th grade reading level of the participants 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 HRPP Toolkit 1.003 (HRP-103a) Standard Operating Procedures to learn more](https://research.rutgers.edu/researcher-support/research-compliance/human-research-protection-program/toolkit#tab=panel-4).]
* Visit the [Human Research Protection Program Toolkit | Rutgers Research](https://research.rutgers.edu/researcher-support/research-compliance/human-research-protection-program/toolkit) to obtain referenced Toolkit Forms & Templates
* Visit the [HRPP Guidance Topics | Rutgers Research](https://research.rutgers.edu/researcher-support/research-compliance/human-research-protection-program/hrpp-guidance-topics) to obtain referenced Guidance documents.
* Contact the IRB Office at irboffice@research.rutgers.edu if you need further assistance.

**TITLE OF RESEARCH:** [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 research that involves people like yourself and see if you would like to take part in it. Please ask me, other research staff, [your parent, your surrogate decision-maker, your teacher, etc., as applicable] to explain any words you don’t understand about the research.

**What is this research about?**

Describe briefly in simple language why you are doing the research 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 research?**

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

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

Describe the inclusion and exclusion criteria in plain language. Describe only those conditions that the participants 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 research?**

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

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

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 research 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 Research** (delete this section if it is not applicable to the research)

If the research 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 a member of the research team may take blood from your arm with a needle placed in a vein. There may be a black or blue spot on your 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 researcher if you start having sex while you are in this research. 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 researcher 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 researcher to explain.

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

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

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

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

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

Briefly and simply describe the measures you will take to protect participants’ 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 research, we will not mention your name.

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

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

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

You don’t have to take part in this research if you don’t want to. No one will get angry or upset if you do not want to be in the research. Just tell us. And remember, you can change your mind later if you decide you don’t want to be in the research 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 the researcher, or you can talk to someone else at any time during the research. Here are the telephone numbers to reach us:

If you have questions, concerns, or want more information about the research you can call the researcher 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 participant, you can contact the Rutgers IRB/Human Research Protection Program via phone at (973) 972-3608 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?**

You may ask questions about any part of the research 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 research.

[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 research, 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 research. You will be given a copy of this form to keep.

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| **ASSENT TO TAKE PART IN THIS RESEARCH****Participant’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 research have been answered. I agree to take part in this research.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 research 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 PARTICIPANTS:**

Translation of the consent form (verbal or written) must have prior approval by the IRB. For more information, go to [HRPP GUIDANCE Non-English-Speaking Participants](https://research.rutgers.edu/researcher-support/research-compliance/human-research-protection-program/hrpp-guidance-topics). See also [HRPP Toolkit Non-English Considerations](https://research.rutgers.edu/researcher-support/research-compliance/human-research-protection-program/toolkit#tab=panel-2&chapter=pnon-english-short-forms-p-17290).

**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/research documents (Braille). For more information, go to [HRPP Toolkit Forms & Templates Special Consent Considerations](https://research.rutgers.edu/researcher-support/research-compliance/human-research-protection-program/toolkit#tab=panel-2&chapter=pspecial-consent-passages-p-17286).

**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 research will find consent addenda language at [HRPP Toolkit Forms & Templates Consent Addenda](https://research.rutgers.edu/researcher-support/research-compliance/human-research-protection-program/toolkit#tab=panel-2&chapter=pconsent-addenda-p-17288).