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

This template [HRP-502p] should be used when obtaining assent from minors--children under the age of 18—or adults represented by a surrogate (due to lack of decisional capacity) to take part in non-interventional research—research involving various types of interactional or observational methodologies, such as observation, interview, focus group, survey, qualify of life or interactional research. [Use with Protocol Template HRP-503b].

***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 th*ose* 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 Non-Interventional Research [HRP-502d] or to the Surrogate Consent for Non-Interventional Research [HRP-502f] 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., Mr./Ms., 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, or teacher, as applicable] to explain any words you don’t understand about the study.

**What is the study about?**

Briefly describe what you are doing in this study and what you hope to learn.

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

Describe in simple language step-by-step the study procedures the subject—child or adult represented by a surrogate—will undergo.

**[For example:** First you will take two tests. The tests will last about 30 minutes. For these tests you will need to select pictures and answer questions based on pictures. After the tests, you will listen to some short stories and answer questions about what you would say or do in the story. This part will take about one hour. Some questions may be more difficult than others but there are no right or wrong answers. We just want to know what you would do or say in the story. You may skip any question that you do not want to answer, and you may take a break if you need one. [**NOTE**: If the research plans to audio- or visually-record or photograph subjects and such recordings/images are required to take part in the research, disclose here your plans to record/photograph subjects. If recording or photographing is not required to take part in the main study, instead disclose the optional recording/photos in an addendum following the assent signature block. Find the “Addendum Consent to Record or Photograph Subjects in Research” template at HSPP Toolkit Forms & Templates Addenda.].

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

Describe any risks of harm or discomforts that may occur for each procedure or interaction. Include physical, psychological, social risks of harm, if applicable. [**For example**: You might feel upset by some of the questions or get mad if you cannot figure out how to answer a question. If this happens, tell us. We can help. Also, your answers could be seen by other people not on the study by mistake. We will be extra careful to lock up your answers so that this does not happen.] If you do not anticipate any harms or burdens will occur, say instead: We do not think anything bad can happen to you by taking part in the study.

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

If the subject will derive direct benefit from participation, explain that here. If there are no direct benefits state: There are no direct benefits to you for taking part in this research. If applicable, consider also stating some other non-tangible benefits. **For example**: You may enjoy listening to the stories and answering the questions.

**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 answer sheets locked up. Your name will not appear on the answer sheets; we will use a code number instead. If we tell others about the study, we will not mention your name.

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

You do not have to take part in this study if you do not want to. Just tell the researcher no. No one will get angry or upset if you do not take part. If you do want to take part now, you can always change your mind later and decide to stop taking part in the study.

**What if I have questions?**

If you have any questions, concerns, or want more information about the study, you can contact the Principal Investigator: [Provide investigator’s name, Department and Rutgers contact number or email address.] [For students only: You can also contact my faculty advisor [provide name and Rutgers contact info.]

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](mailto: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 of you*r* questions and you agree to take part in the study.

[If the IRB requires the parent(s) or guardian to give permission for the child’s enrollment 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.

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