**TEMPLATE INSTRUCTIONS**

This template serves as a starting point for researchers when developing their participant assent materials. Researchers will be responsible for customizing this template to fit the specific needs and requirements of their study to ensure all regulatory and agency specific requirements that may apply are included.

While exempt studies are not held to the full assent requirements set forth in [45 CFR 46 Subpart D](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-d/index.html#46.401) and [45 CFR 46.116](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.116), there must be an assent process that includes the same the basic elements of informed consent to ensure participants have sufficient information to make an informed decision about participation. Projects funded or regulated by certain agencies, may require additional elements to be included. Agency specific requirements include, but are not limited to:

* [DOJ requirements](https://www.ecfr.gov/current/title-28/chapter-V/subchapter-A/part-512/subpart-B/section-512.16)
* [FDA requirements](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/informed-consent)
* [NIH requirements](https://policymanual.nih.gov/3014-301)
* [NIJ requirements](https://nij.ojp.gov/funding/informed-consent-requirements)

When developing your assent materials, the information presented must align across all submission materials (exempt application, recruitment materials, data collection materials, etc.).

To facilitate participant understanding, the language utilized in the assent materials should be:

* Developmentally appropriate for the study population and aimed at no higher than an 8th grade reading comprehension level for adult participants when possible.
* Free of technical jargon and legalese
* If abbreviations and acronyms are used, spell out the full term and indicate its abbreviation in parenthesis at its first mention.

Additional helpful guidance for developing assent materials can be found under the guidance section of the [WSU IRB Forms webpage](https://irb.wsu.edu/forms/).

When customizing this template:

* Bracketed text in red font indicates instructions and prompts for the researchers.
* Unbracketed text in black font indicates sample starter text based on the basic required elements of participant assent for most studies but will not be comprehensive for all.
* Please ensure that finalized forms are revised so that all brackets are deleted, and that all text font is black.
* Submit only the finalized form, do not include this instruction page in your submission file.

**ASSENT SCRIPT/FORM**

**[Template For Exempt Research]**

**Research Study Title:** [Study Title as listed on the submitted application]

**WSU IRB #:** [##### to be assigned by the WSU HRPP/IRB after processing of submission]

**Principal Investigator Information:**

[First Last name]

[WSU college/department affiliation]

[WSU Phone number]

[WSU email address]

**Introduction**

We want to tell you about a research study being done by [Principal Investigator First and Last name] at [our/my] school, Washington State University (WSU). A research study means that [I/ myself and a group of people like me] are asking a question and are looking for people to help us answer it. We would be excited to have your help with this study. We asked permission from other adults, like your parents/guardians, and our school if we can do this study, but you have the final say on if you want to help us. Before letting us know if you want to help, we want to share with you all the things you would need to know to make a choice.

**What You Should Know**

We're doing this study to learn about [insert a brief and clear explanation of the research objectives]. Your part in the study would help us [insert potential impact or significance of the study and any benefits].

We are looking for children who are:

* [List eligibility criteria].

If you decide to help us, you would:

* [List and describe each participant-based study procedure such as interviews, surveys, experiments, observations, or interventions. Your descriptions should be concise and presented in terminology that your participants will easily understand].

These activities should take about [estimated total duration, e.g., minutes, hours, days, weeks, etc.].

As a thank you for your help, you could get [Include disclosure of any compensation/incentives for participation including amount awarded, how and when payment will be issued, and any stipulations that may apply].

[Customize for level of confidentiality of collected/recorded data and how you will protect participant’s privacy. Include how data will be stored, who it will be shared with and for what reasons] If you decide to help, anything you share with us will be kept between us unless we need to share something with another adult to keep you safe.

It is important to know that by helping us with this study, you could:

* [List all risks associated with participating in the study].

To help lessen these risks, [Include any risk mitigation/management strategies and available resources/referrals that may be offered if applicable].

If you choose to help, and then change your mind, that is okay. You can change your mind at any time. You can say “no” or skip questions you don’t want to answer. You will not get in trouble, and no one will be mad at you.

**Questions**

If you have any questions before you decide if you want to help us, you can ask:

[Researcher’s First Last name]

[Researcher’s role such as Principal investigator, Co-Investigator, research assistant, Research coordinator]

[Researcher’s contact information]

**Participant’s Indication of Assent**

[ ]  I asked any questions I wanted to ask, and I understand everything that was shared with me. I want to help with this study.

☐ I do not want to help with this study.

[When developing procedures for obtaining the participant’s indication of assent it is important that the researchers understand that **signed written assent is not a requirement for studies certified as exempt**. Researchers should customize how they are recording indication of assent to best support their study design and are urged to not include fields where identifiers are collected unless necessary. For studies that will utilize a signed written assent procedure, include the optional recommended elements bellow as needed.]

Participant's Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Participant's Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Researcher's Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Researcher's Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Witness’s Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Witness’s Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_