

READ THIS PAGE FULLY BEFORE STARTING YOUR FORM

INFORMED CONSENT IS A PROCESS, NOT JUST A FORM

Information must be presented to enable persons to voluntarily decide whether or not to participate as a research participant. It is a fundamental mechanism to ensure respect for persons through provision of thoughtful consent for a voluntary act. The procedures used in obtaining informed consent should be designed to educate the participant population in terms that they can understand. Therefore, informed consent language and its documentation (especially explanation of the study's purpose, duration, experimental procedures, alternatives, risks, and benefits) must be written in "lay language", (i.e. understandable to the people being asked to participate). The written presentation of information is used to document the basis for consent and for the participants' future reference. The consent document should be revised when deficiencies are noted or when additional information will improve the consent process.

DIRECTIONS FOR THE USE OF THESE TEMPLATES

ALL TEMPLATES

- **Do not adjust the margins or use the footer.** The IRB will place an approval stamp in the footer once your research has been approved. Un-stamped consent forms are not valid for research.
- **Replace bracketed items in the header**, such as “[Title of Study]” with the requested information. Make sure to delete the brackets after imputing your information.
- Read guidelines for each section, complete as applicable for your project and then delete the template guidelines. Example text may be used if needed but should not be italicized. **Instructions in red font should be replaced or deleted.**
- Phrases such as “I understand...” or “You understand...” are not appropriate and should not be included in the document.
- ***If your study is determined by the IRB to be more than minimal risk:*** there are additional elements of informed consent which will be required. If you believe your study is more than minimal risk, you may contact the Office of Research Integrity for guidance for a description of all the elements of informed consent.

EXEMPT RESEARCH CONSENT TEMPLATE

- ***If using this template for online surveys:*** cut and paste the consent language onto the first page of your survey when you have completed your consent form. However, for IRB review please upload the consent document as a separate document on IRBNet.
- ***If using this template for an anonymous survey (personal identifiers such as name will not be collected):*** submit the completed Appendix M2 – Waiver of Signed Consent to the IRB for review.

CHILD ASSENT TEMPLATE

- It is particularly important that the assent is written in language understandable to the participant population. The document should be written at an appropriate grade level for the group of participants. Most word processors include the ability to assess reading level.
- If your research involves children of multiple age groups, it may be necessary to create more than one assent to ensure appropriate reading levels for each group.

Note to the Investigator: Under the usual conditions of research, informed consent is obtained from the prospective participant. In the case of an adult with diminished decision-making capacity or a non-autonomous child, obtaining informed consent may not be possible and permission from a legally authorized representative must be obtained. However, individuals capable of some degree of understanding (generally, a child of seven or older or individuals with diminished decision-making capacity) should participate in research only if they assent (agree). Assent means a participant's affirmative agreement to participate in research.