Informed Consent Process

Informed consent is a not just a document but a conversation or process that informs the research participants about the purpose of the study, the risks, potential benefits, and alternatives. It allows the potential participant to make an informed decision about whether or not to participate based on their goals or ideas. Additional information about the informed consent process can be found at: http://answers.hhs.gov/ohrp/categories/1566

Review the different consent processes to determine which on applies to your research.

Waiver or Alteration of Consent

The IRB may approve a consent procedure that does not include or alters some or all of the elements of informed consent or the IRB may waive the requirement to obtain consent provided that the following criteria are met. This method could be appropriate for studies using archival data collection or studies that may involve deception.

To request approval for a waiver or alteration of consent indicate in the Q&A form how your study fulfills each criteria.

- The research involves no more than minimal risk to the participants.
- The waiver or alteration will not adversely affect the rights and welfare of the participants.
- The research could not practicably be carried out without the waiver or alteration.
- Whenever appropriate, the participants will be provided with additional pertinent information after participation.

Waiver of Consent Documentation

When consent for research is obtained through means other than in writing, such as verbally, online or through audio or video recording, a *waiver of consent documentation* may be requested. The IRB may grant a waiver of consent documentation if criterion 1 or 2 is met.

To request approval for a waiver of consent documentation describe in the Q&A form the consent process and indicate the criterion that applies to your study and how your study fulfills the criterion.

Criterion 1 – The principal risks are those associated with a breach of confidentiality concerning the participant's participation in the research, and the consent document is the only record linking the participant with the research.

Criterion 2 - Study participation presents minimal risk of harm to the participant and the research involves no procedures requiring consent outside the context of participation in a research study.

Written Consent

Written consent refers to obtaining the participant’s or the participant’s legal representative’s signature on a consent form. The consent form should be used as a tool to discuss the research study with the participant. The subject should be given adequate time to read the consent form

and to have his/her questions about research answered by the researcher before signing the consent form. The signed consent form provides a record that the consent process took place.

Describe in the Q&A form the consent process for the research. Indicate when and where the consent process will take place and who will conduct the consent process.

Use the consent form template, containing the required elements of consent, on the IRB website to develop the consent form that will be used to obtain written consent. Consent forms should be written at a 10th grade reading level using simple sentences and written as if speaking with the participant. Upload a copy of the consent form. If applicable, upload foreign language versions of the consent form