

Informed Consent Process Types

Normal Consent Process: Select this option as the default consent process, unless a waiver or alteration is more appropriate for the study. This process includes consenting adults, assenting children, and seeking parental permission. Both the consent form(s) and the consent process must include all of the essential elements required by federal regulations.

Waiver of Documentation of Consent: Select this option for studies seeking to waive or alter the requirement that participants must sign the consent form. This waiver is most appropriate for online questionnaires/surveys, or where the researcher data involves the collection of sensitive information.

- The IRB must determine either: (1) the principal risk to participants is a potential loss of confidentiality and a signed consent form is the only record linking participants to the study, or (2) the study does not involve procedures that would require written consent outside of a research context (i.e. observation of public behavior).

Waiver of Informed Consent: Select this option for studies seeking to waive the entire consent process, including the consent form. A Waiver of Informed Consent is most appropriate when there is no interaction with participants (i.e. retrospective chart review).

- The IRB must determine that: (1) the study involves little to no risk to participants, (2) participants will not be adversely affected by the waiver, (3) study would be unfeasible without the waiver, and (4) if applicable, additional information will be provided to participants.

Alteration of Consent: Select this option for studies involving a deviation to the normal consent form and/or process that does not involve either a Waiver of Documentation (signature) or a Waiver of Informed Consent (entire consent process).

- Studies seeking to remove or change the basic elements of the informed consent document must seek approval through this process and provide justification for the alteration of the document and/or consent process (i.e., studies involving deception).