



Waiver or Alteration of Informed Consent Guidance

Scope: This document provides guidance for instances where a waiver of documentation of informed consent or a waiver or alteration of the informed consent process is permissible per federal regulations.

- **Instructions:** If you wish to request a waiver or alteration to your consent process/documentation, include justification in your Research Plan based on the criteria below.

A. Waiver of documentation of informed consent

In certain circumstances, the IRB may waive the requirement to obtain a signed consent form. This commonly occurs in research involving telephone interviews, online surveys, and in situations where the protection of participants would be enhanced by not collecting a signed form (e.g., if the research involves sensitive topics such as domestic violence). Examples of common substitutions include an oral consent process, where the investigator reads a consent document and the participant responds verbally, or an online process, where the participant reads the consent form on a computer and responds by clicking a button.

The IRB must approve a waiver of documentation of informed consent (to not obtain a signature) based on the criteria below:

- If requesting a waiver to obtain a signed consent form, provide justification in the Research Plan for one of the following categories:
 - Describe how the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Note- Each subject must be asked whether he/she wants documentation linking the subject with the research, and his/her wishes will govern.

OR

- Describe how the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

Note: The IRB may require the investigator to provide subjects with a written statement regarding the research.

B. Waiver or alteration of the consent procedure

In certain circumstances, the IRB may approve a consent process which does not include, or which alters, some or all of the elements of informed consent or waive the requirements to obtain informed consent. This commonly occurs in research involving deception in which the full purpose of the research is not disclosed to participants (since doing so might affect the results) and in research involving records review.

The IRB must approve an alteration of consent elements or a waiver of informed consent based on the criteria below:



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- If requesting an alteration to informed consent elements or an informed consent waiver, provide justification in the Research Plan for ALL of the following:
 - Describe how the research involves no more than minimal risk to the subjects.
 - Describe how the waiver or alteration will not adversely affect the rights and welfare of the subjects.
 - Describe how the research could not practicably be carried out without the waiver or alteration.
 - Describe how, whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Note: The IRB may require that the investigator conduct a debriefing process or provide participants with a written statement regarding the research.