



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.

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. (This waiver not permissible for FDA regulated research).

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.

OR

- If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, describe how the research presents no more than minimal risk of harm to subjects and an appropriate alternative mechanism for documenting that informed consent was obtained. (This waiver not permissible for FDA regulated research).

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

B. General 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.

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 research could not practicably be carried out without the waiver or alteration.



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- If the research involves using identifiable private information or identifiable biospecimens, describe how the research could not practicably be carried out without using such information or biospecimens in an identifiable format
- Describe how the waiver or alteration will not adversely affect the rights and welfare of the subjects.
- 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.

C. Screening, Recruiting, or Determining Eligibility

An IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting or determining the eligibility of prospective subjects without first obtaining informed consent. This is a common practice in research requiring screening for robust inclusion/exclusion criteria in advance of an initial study visit when consent would normally occur.

If requesting approval to screen, recruit, or determine eligibility before informed consent is obtained, explain in the *Research Plan* which of the following conditions is met:

- The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative
- The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

D. Waiver or Alteration of Consent in Research Involving Public Benefit and Service Programs

For research projects involving public benefit and service programs conducted by or subject to the approval of state or local officials, the IRB may waive the requirement to obtain informed consent or may approve a consent procedure that omits some or all of the elements of informed consent.

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 or demonstration project is to be conducted by or is subject to the approval of state or local officials and is designed to study, evaluate or otherwise examine:
 - A. Public benefit or service programs;
 - B. Procedures for obtaining benefits or services under those programs;
 - C. Possible changes in or alternatives to those programs or procedures; OR
 - D. Possible changes in methods or levels of payment for benefits or services under those programs

AND

- Describe how the research could not practicably be carried out without the waiver or alteration.

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