INSTITUTIONAL REVIEW BOARD
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Request to Alter or Waive Informed Consent

Informed consent is a process. Federal regulations (45 CFR 46.116 and 21 CFR 50.20) require that no investigator may involve a human being as a subject in research unless legally effective informed consent has been obtained. Researchers are required to inform participants in written or verbal form of the primary purpose of the research project and of any procedures which they will undergo. Additionally, participants are to be informed of their rights regarding the study (i.e., voluntary participation, protecting anonymity or confidentiality, privacy, etc.) and any risks or benefits associated with the project.

Occasionally there are reasons to request IRB approval to waive obtaining written consent or to alter the requirements of consent. The IRB will determine and approve which type of consent applies to your research.

1. Study Title

Enter information here.

2. Type of Waiver Request

___ I am requesting to waive the required documentation of signed informed consent.
Complete Section A.

___ I am requesting to waive or alter the required elements of the informed consent process.
Complete Section B.

Section A: Request for Waiver of Documentation of Signed Informed Consent

If you are requesting IRB approval to waive the required documentation of signed informed consent (e.g., for telephone or mailed surveys, internet research, etc.), indicate the condition that best fits your research study. Explain how your research study meets this condition and answer the question that follows. **Note: For research involving a clinical investigation governed by 21 CFR 50 and 21 CFR 56, only Condition 2 applies.**

___ **Condition 1**
The informed consent document would be the only record linking the subject and the research. The principal risk in collecting informed consent would be the potential harm resulting from a breach of confidentiality. Each subject will be asked whether s/he wants documentation linking her/him with the research, and the subject's wishes will govern.

Justify why your study meets this condition.

___ **Condition 2**
The research presents no more than minimal risk to the subject and does not involve procedures for which written consent is normally required outside of the research context (i.e., questions are not being asked that could result in potential embarrassment, personally

___ or professionally).

Justify why your study meets this condition.

___ **Condition 3**
The requirements in 21 CFR 50.24 are met. These pertain to exceptions in gathering informed consent due to emergency research situations.

Justify why your study meets this condition.

If you are requesting to waive signed informed consent, you must submit a verbal script or cover letter to the IRB that addresses the required elements of consent as stated in 21 CFR 50.25 and 45 CFR 46.116.

How will you explain and review the informed consent process with the participants?

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research (21 CFR 56.109, 45 CFR 46.117 (c)).

Section B: Request for Alteration or Waiver of the Informed Consent Process

___ I am requesting to alter the required elements of the informed consent process.

___ I am requesting to waive the required elements of the informed consent process.

If you marked the first option, describe which elements of consent will be altered and/or omitted and justify the alteration.

Non-Clinical Studies
You must justify your request to waive or alter the informed consent process in accordance with each of the following four criteria established under 45 CFR 46.116(d)(1-4). **Note: In the case of a clinical investigation governed by the FDA, these criteria do <u>not</u> apply and waiver or alteration of the informed consent is allowed only in accordance with 21 CFR 50.23 and 21 CFR 50.24.**

Provide supporting information for all four criteria.

___ 1. The research involves no more than minimal risk to the subjects.

Justify why your study meets this condition.

___ 2. The waiver or alteration will not adversely affect the rights and welfare of the subjects.

Justify why your study meets this condition.

___ 3. The research could not practicably be carried out without the waiver or alteration.

Justify why your study meets this condition.

___ 4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

If a debriefing statement is used, submit a copy with this application. Justify why your study meets this condition.

Clinical (Medical Device and/or Drug) Studies

You must justify your request for an exception from the general requirements for obtaining informed consent in accordance with 21 CFR 50.23 (i.e., circumstances are life-threatening; informed consent cannot be obtained from the subject; time is not sufficient to obtain consent from the subject's legal representative; no alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the life of the subject) or 21 CFR 50.24 (i.e., emergency research).

Justify your exception request.