Reviewer guide: Waiver or Alteration of Informed Consent

This reviewer guide should be completed and retained in the study file.

|  |  |
| --- | --- |
| **PI Name:** | Click or tap here to enter text. |
| **Protocol Title:** | Click or tap here to enter text. |
| **IRB #:** | Click or tap here to enter text. |
| **IRB Reviewer(s):** | Click or tap here to enter text. |
| **Date Completed:** | Click or tap here to enter text. |

# General waiver or alteration of consent:

The requirement to obtain informed consent can either be **waived entirely** or **altered[[1]](#footnote-2)** (omitting or altering some of the elements of consent) if **ALL** of the following are true:

|  |
| --- |
|[ ]  The research involves no more than **minimal risk** to the subjects |
|[ ]  The research **could not practicably be carried out** without the waiver or alteration |
|[ ]  If the research involving using **identifiable** private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format |
|[ ]  The waiver or alteration will not **adversely affect the rights and welfare** of the subjects |
|[ ]  Whenever appropriate, the subjects will be provided with **additional pertinent information** after participation. |

**COMMENTS:** Click or tap here to enter text.

# 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 informed consent if **EITHER** of the following conditions are 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** |

*This section cannot be used for* ***FDA****-regulated research, or* ***NIJ****-regulated**or other research under* ***pre-2018*** *requirements.*

**COMMENTS:** Click or tap here to enter text.

# Waiver of documentation of informed consent

The requirement for **written** **documentation** of consent can be waived if **ONE** of the following is true:

|  |  |
| --- | --- |
| [ ]  | The **only** record linking the subject and the research would be the informed consent form, and the principal risk would be potential harm resulting from a breach of **confidentiality**. * Each subject (or legally authorized representative) will be **asked whether the subject wants documentation** linking the subject with the research, and the subject’s wishes will govern.

*Cannot be used for* ***FDA****-regulated research.* |
| [ ]  | The research presents no more than **minimal risk** of harm to subjects AND involves no procedures for which **written consent is normally required** outside the research context. |
| [ ]  | The subjects or legally authorized representatives are members of a **distinct cultural group** or community in which signing forms is not the norm, AND * the research presents no more than **minimal risk** of harm to subjects, AND
* there is an appropriate **alternative mechanism** for documenting that informed consent was obtained.

*Cannot be used for* ***FDA****-regulated research, or* ***NIJ****-regulated or other research under* ***pre-2018*** *requirements.* |

**COMMENTS:** Click or tap here to enter text.

1. An alteration may only omit or alter the elements of consent *content* listed under 46.116(b) and (c), not the general requirements for consent *process* at 46.116(a). An alteration of consent is most commonly granted for studies using deception or incomplete disclosure. [↑](#footnote-ref-2)