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# Waiver of Informed Consent and Waiver of Informed Consent Documentation

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The purpose of this presentation is to explain the situations where federal regulations permit the IRB to grant a waiver and/or alter a change in the informed consent process for research studies.

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# Waiver of Informed Consent and Waiver of Informed Consent Documentation

## Regulatory Differences

- DHHS requires consent documents to be signed by the subject only
  - FDA requires consent documents to be signed and dated by the subject only
  - DHHS and FDA require participants be provided copies of consent documents, which do not have to be signed or dated
  - *NHRMC policy requires consent documents to be signed and dated by the subject and by the investigator obtaining consent.*
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# Waiver of Informed Consent and Waiver of Informed Consent Documentation

Options for consent include:

- Obtain written documentation of consent using the long form
  - Obtain written documentation of consent using the short form
  - **Waive the requirement for obtaining consent**
  - **Waive the requirement for written documentation of consent**
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# Waiver of Informed Consent

**Requirements for an IRB to waive the requirement for informed consent (45 CFR 46.116 D):** *These requirements are documented in the research application.*

- The research is not FDA regulated
- The research involves no more than minimal risk to the subjects
- The waiver or alteration will not adversely affect the rights and welfare of the subjects
- The research could not practicably be carried out without the waiver or alteration
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation

**A retrospective chart review study is the most common circumstance for granting a waiver of informed consent.**

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# Waiver of Informed Consent Documentation

## **Requirements for an IRB to waive the requirement for documentation of informed consent (45 CFR 46.117 C):**

*These requirements are documented in the research application.*

- 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.
  - 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.
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# Waiver of Informed Consent Documentation

Circumstances where waiver of consent documentation might be used:

- Phone consent
- Verbal consent
- Survey consent
- Almost all minimal risk research

**It is the responsibility of the IRB to make sure there's an adequate consent process in place.**

It is the responsibility of the PI to carry it out.

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# Waiver of Informed Consent & Waiver of Informed Consent Documentation

Under certain circumstances an information sheet will be provided to the subjects, or implied consent language will be used with surveys/questionnaires.

- The information sheet contains all of the required elements of consent and provides the subjects with additional information about the study, including contact info for the researcher. This allows the subject to notify the researcher if the subject does not want their data to be used for the research study.
  - Implied consent language contains all of the required elements of consent and is used as the cover page for surveys/questionnaires. It states that the subjects' completion of the survey/questionnaire implies their consent to participate in the research study.
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