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Remote Informed Consent Procedures

Determining the Best Consent Process

- Determine the Informed Consent process you will use, which provides a mechanism for participants to consent remotely. This process may not utilize the standard signed (hardcopy) consent form; however, the IRB may approve waivers of documentation of consent in certain situations, and an alternative method is used to obtain consent in lieu of a signature (e.g., verbal consent).

Waiver of Documentation of Informed Consent [45 CFR 46.117(c)]

The IRB may waive the requirement for the PI to obtain a signed consent form for some or all subjects if it finds either that the:

A. Only record linking the participant and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality (Note: Subjects must be asked whether they want documentation linking them with the research, and their wishes must govern. (Example: domestic violence research where the primary risk is discovery by the abuser that the participant is talking to researchers),

B. 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. Procedures such as non-sensitive surveys, questionnaires, and interviews generally do not require written consent when conducted by non-researchers, OR

C. The subjects or LARs are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

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Methods that do not require a “Waiver of Signed Consent”

- **Wet signature** – The traditional pen and paper signature. Researchers should consider the possible barriers in getting the form to the participants (e.g., via regular mail or email) and how the hardcopy will be returned to the researchers.
- Researchers should consider the technological capacity of their participant population, if they will be asked to print, scan and email a signed form back to the researchers.

Methods that do not require a “Waiver of Signed Consent”

- **Electronic signature** - An “electronic signature” is an electronic sound, symbol, or process, attached to or logically associated with an electronic record or adopted by a person with the intent to sign a record.
- For use of electronic signatures, the IRB will consider such issues as how the electronic signature is created, if the signature can be shown to be legitimate, and if the consent document can be produced in hard copy for review by the potential subject.
- If properly obtained, an electronic signature can be considered ‘original’ for the purposes of recordkeeping. For FDA regulated research, “electronic” documents would be subject to a specialized set of requirements found at 21 CFR Part 11.
- May require a waiver of signed consent, if the signature cannot be shown to be legitimate (e.g., typing name in Qualtrics).

Methods that require a “Waiver of Signed Consent”

- **Verbal consent** – Consent is provided by the participant’s oral acknowledgement to participate in the study. This process would likely be the most feasible when conducting interviews or focus groups.
- Researchers should consider distributing the consent form to all potential participants beforehand (e.g., via email), allowing them time to review the document on their own.
- Use of this process in research requires a waiver of documented consent approved by the IRB.

Methods that require a “Waiver of Signed Consent”

- **Online Consent/Implied Consent** - For web-based surveys or questionnaires, the consent form may be presented online, and require participants to perform some action, such as clicking “I agree,” before proceeding with any research activities (e.g., answering survey questions on a website).
- This is an acceptable approach for low-risk research conducted online.
- However, be aware that this method does not document informed consent, and therefore, use of this process requires a waiver of documented consent by the IRB.

Additional Resources

ORI website: https://research.ucr.edu/ORC

- Forms
- FAQs
- IRB Office Hours: https://research.ucr.edu/orc/irb-office-hours
- Resources: https://research.ucr.edu/orc/resources
  - *How to IRB* Tutorial
  - Informed Consent Guide and Templates
  - Best Practices for Doing Research with Participants Remotely
  - Top Reasons for Delays in Application Reviews

Who to Contact: irbsupport@ucr.edu

- Office is primarily working remotely. Email is best method of contact.

Additional Resources

For additional information regarding the transition to Kuali protocols system and available training opportunities, please see below the Kuali IRB Resources:

- Please visit: https://research.ucr.edu/kuali-research. This site is being continually updated with IRB information and resources as they become available.
- Kuali IRB FAQs
- Kuali IRB Training Videos and Guides