CONSENT SELF-AUDIT CHECKLISTS

Writing a consent document can be a challenging process, involving an understanding of the research project to be undertaken and familiarity with the various federal, state, and local requirements for the content of consent. In addition, this information must be presented in a way that will facilitate understanding of the research project for the people who are being asked to participate.

This series of checklists covers the regulatory requirements for consent documents, the requirements for documenting consent, and situations when a waiver or alteration of consent may be applied. In addition, guidance is provided for writing consent documents for a variety of situations.

This series includes checklists and guidance for:

- Consent Checklists – Regulatory Criteria (expedited and convened review only):
  - Common Rule:
    - General Requirements for Informed Consent
    - Basic Elements of Consent
    - Additional Elements of Consent
  - Food and Drug Administration (FDA) requirements
  - Local and other requirements:
    - UIC-Specific Consent Requirements
    - Other requirements
- Documentation of Consent
- Waivers of consent
  - Waiver of documentation of consent
  - Waiver of consent / Alteration of consent
  - Guidance on waiver requirements for specific situations
- Guidance: General writing tips
  - Consent
  - Assent, Parental Permission, Proxy (LAR) Consent
  - Claim of Exemption (Exempt) Consent Document Guidance

These checklists and guidance can be used to verify the following:

- Consent documents follow regulatory criteria and UIC policies.
- Criteria are met for waiver / alteration of consent and waiver of documentation of consent
- Consent documents follow recommendations on writing consent, assent, parental permissions
- As applicable, consents follow requirements for obtaining consent/ assent/permission in vulnerable populations and special situations.

NOTE:

- Consent documents for projects requiring convened or expedited review should follow the UIC consent template language found on OPRS website at:

https://research.uic.edu/human-subjects-irbs/getting-started-preparation-for-submission/forms/. Deviations from the text (formatting, language) may be approved at the discretion of the IRB.
    - The UIC consent template incorporates language consistent with the DHHS and FDA regulatory criteria and UIC requirements.
- Consent documents for projects undergoing review as a Claim of Exemption should follow the UIC guidance found on the OPRS website at: https://research.uic.edu/general-faqs/ under the section Informed Consent.
- If a non-UIC site is relying on UIC IRB review for this study, the federal criteria (DHHS, FDA) still apply, but local context language may be required in place of UIC-specific consent language.
- UIC OPRS policies regarding the consent document and process can be found at: https://research.uic.edu/human-subjects-irbs/policies/
- There may be additional consent requirements specific to vulnerable populations and special circumstances, such as research involving children, decisionally impaired individuals, prisoners, members of the military, pregnant women, non-English speakers, UIC students / employees, and individuals unable to see, read, or write.

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