Consent Forms

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Requirements

Current version of Institutional Review Board IRB approved consent form and the dated and stamped IRB approval letter.

Tips / Additional Information

If consent forms are maintained electronically or filed in the IRB section of the Binder, include a signed and dated note-to-file indicating the location.

Once the IRB approves a new version of the consent form, the previous version expires. Previously approved versions can be kept in the IRB section of the Regulatory Binder.

The IRB website provides guidance on the following:

- Staff Requirements for Obtaining Informed Consent
- Obtaining Consent from Non-English Speaking Subjects
- Obtaining Surrogate Consent
- The Clinical Trial Consent Development section of ResearchGo assists sites with properly documenting informed consent according to federal regulations, institutional policies and good clinical practices.

Applicable GCP sections:

- 8.2.7
- 8.2.3
- 8.3.2
- 8.3.12

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Drupal.jQueryUiFilter.globalOptions('accordion');