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IRB Review

- ICH requires Sponsors to obtain a statement from Investigators that their local IRB is organized and operates according to ICH-GCP and applicable laws and regulations.
- ICH requires Sponsors to obtain documentation of IRB approval prior to shipping investigational product to an Investigator.

Informed Consent

- A process by which a subject voluntarily confirms his/her willingness to participate in a trial having been informed of all aspects of the trial
- Informed consent is documented by means of a written, signed and dated informed consent form

IRB Review

If the University of Louisville Human Subjects Protection Program were to become ICH-GCP compliant, the UofL IRB would provide the following statement to investigators who conduct Clinical Trials for sponsors intending to submit study results to European Union, Japanese or United States pharmaceutical manufacturers for drug approval.



Section 4.9 :Records and reports

- Should ensure accuracy, completeness, legibility and timeliness of data to sponsor in CRF
- Correction in CRF should be signed, dated
- Maintain trial related documents
- Financial agreements in place
- Access to records by monitor, regulatory agency or auditors
- Progress reports to IRB

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