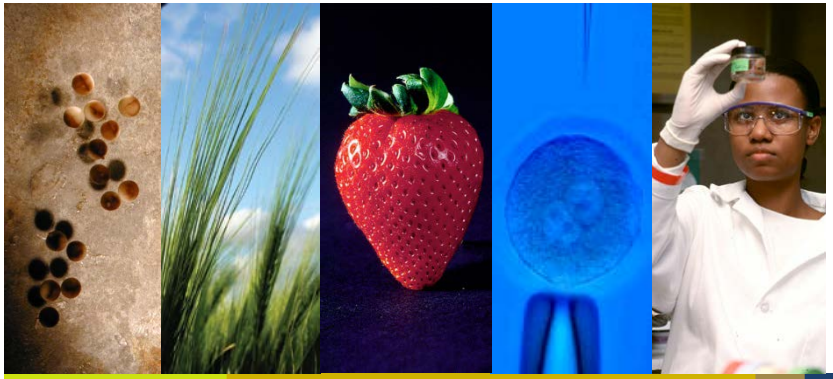

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FDA Draft Guidance: IRB Responsibilities for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the Determination of Whether an IND/IDE is Needed

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Reviewing the Qualifications of Investigators

- Affiliated institutions; the FDA recommends that the IRB obtain a statement from institutional officials (i.e. department chairs) regarding the investigator qualifications to conduct the proposed research.

- Non-affiliated intuitions; the FDA recommends that the IRB obtain the curriculum vitae, verify professional associations, and medical licensure of the investigator, subinvestigator, and other necessary study staff to verify the qualifications.

Reviewing the Qualifications of Investigators

FDA provides publicly available information about a clinical investigators inspectional history

- **Clinical Investigator Inspection List**

www.fda.gov/Drugs/InformationOnDrugs/ucm135198.htm

- **Clinical Investigators – Disqualification Proceedings**

www.fda.gov/ICECI/EnforcementActions/ucm321308.htm#database

Determining the adequacy of the research site

- Affiliated institutions; obtain a statement form an appropriate person (i.e. department chair) at the research site/institution stating the facilities are adequate

- Non-affiliated institutions: ask the investigator to provide a description of the facility where the research will take place, including its staffing and resources relevant to the research under review

Determination the use of an IND

- The IRB may request the investigator to provide documentation about the need for an IND
- Unable to resolve the issues, the IRB should follow its procedures for resolving controverted issues
- FDA Resource; *Draft Guidance for Industry: Investigational New Drug Applications (INDs) — Determining Whether Human Research Studies Can Be Conducted Without an IND.*

Determination the use of an IDE

- The IRB is to review the sponsor's determination
- If the IRB determines the device is SR, the IRB will inform the investigator and, when appropriate, the sponsor.
- FDA Resources:
  - *Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors - Significant Risk and Nonsignificant Risk Medical Device Studies.*
  - *Procedures for Handling Inquiries Regarding the Need for an Investigational Device Exemptions Application for Research Involving Medical Devices*

Sources

- www.fda.gov

- http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ProposedRegulationsandDraftGuidances/default.htm