

## Frequently Asked Questions about IRBs

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### **Must an institution establish its own IRB?**

No.

Although institutions engaged in research involving human subjects will usually have their own IRBs to oversee research conducted within the institution or by the staff of the institution, FDA regulations permit an institution without an IRB to arrange for an "outside" IRB to be responsible for initial and continuing review of studies conducted at the non-IRB institution. Such arrangements should be documented in writing. Individuals conducting research in a non-institutional setting often use established IRBs (independent or institutional) rather than form their own IRBs. Also see the information sheets entitled "Non-local IRB Review" and "Cooperative Research."

*For the study on Antibiotic Use in Third Molar Extraction, the University of Cincinnati's Institutional Review Board (IRB) has agreed to serve as the study's IRB. The IRB approves the clinical sites and monitor the project's patient/surgeon activities. The University of Cincinnati's IRB will accept proof of application to your institution IRB.*

### **May a hospital IRB review a study that will be conducted outside of the hospital?**

Yes.

IRBs may agree to review research from affiliated or unaffiliated investigators, however, FDA does not require IRBs to assume this responsibility. If the IRB routinely conducts these reviews, the IRB policies should authorize such reviews and the process should be described in the IRB's written procedures. A hospital IRB may review outside studies on an individual basis when the minutes clearly show the members are aware of where the study is to be conducted and when the IRB possesses appropriate knowledge about the study site(s).

### **May an independent IRB review a study to be conducted in an institution with an IRB?**

Generally, no. Most institutional IRB have jurisdiction over all studies conducted within that institution. An independent IRB may become the IRB of record for such studies only upon written agreement with the administration of the institution or the in-house IRB.

### **Does a doctor, in private practice, conducting research with an FDA regulated product, need to obtain IRB approval?**

Yes.

The FDA regulations require IRB review and approval of regulated clinical investigations, whether or not the study involves institutionalized subjects. FDA has included non-institutionalized subjects because it is inappropriate to apply a double standard for the protection of research subjects based on whether or not they are institutionalized.

An investigator should be able to obtain IRB review by submitting the research proposal to a community hospital, a university/medical school, an independent IRB, a local or state government health agency or other organizations.

## **Role of the Private Practice Investigator** (Individual Site Study)

The role of the Site Primary Investigator is responsible for the direction and oversight of compliance, financial, personnel, and other related aspects of the research project and for coordination within their practice. Duties include:

- Site Selection / Enrollment in PBRN
- Human Subjects Research
- Good Clinical Practice Training
- Submit Application to IRB
  - Submit materials approved by national IRB approval. May need to tailor to sites IRBs requirements.
    - Study Protocol
    - Informed Consent Document (sometimes IRBs require their own template language)
    - Financial information
    - Data Collection Forms
    - Address Confidentiality
    - Requirements will be different based on the IRB
  - Note if changes occur to the approved documents, this must be reported to the National PI for approval prior to submission to local IRB
- Training of site personnel if having office staff assist (even if its data entry)
- Maintenance of communication records (emails, letters, phone calls, etc.)
- Recruitment of patients
- Reports to the IRB
  - Protocol Deviations
  - Unanticipated Events (reports these events to IRB and to Lead Investigator)
  - Status reports on the study
- Enter Data Collection (RedCap)
- Prepare for Audit of Data (compare data in database to data in medical record)

**Estimated Time Commitments Primary Investigator  
(Individual Site Study)**

1 hour	Site Selection / Enrollment in PBRN
2-4 hours	Human Subjects Research/Good Clinical Practice Training
1 day	Submit Application to IRB Submit materials approved by national IRB approval. May need to tailor to sites IRBs requirements. <ul style="list-style-type: none"><li>• Study Protocol</li><li>• Informed Consent Document (sometimes IRBs require their own template language)</li><li>• Financial information</li><li>• Data Collection Forms</li><li>• Address Confidentiality</li><li>• Requirements will be different based on the IRB</li></ul> <i>Note if changes occur to the approved documents, this must be reported to the National PI for approval prior to submission to local IRB</i>
1 day	Training of site personnel if having office staff assist (even if its data entry)
1 hour weekly	Maintenance of communication records (emails, letters, phone calls, etc.)
1-2 hours daily	Recruitment of patients (consent process depends on study design; may be 20 minutes– 1 hour of discussing with patient)
1-2 hours weekly	Reports to the IRB Protocol Deviations Unanticipated Events Status reports on the study
30min-1hour <i>per participant</i>	Enter Data Collection
2-3 days	Prepare/Participate in Audit of Data (compare data in database to data in medical record)