Issued: 18Apr11

Document Submission to the IRB: What Documents Associated with a Research Application Require IRB Review?

Every research application submitted to the IRB should include a Research Plan describing the study, and all associated consent and recruitment materials. Other documents are handled as follows:

1. **Questionnaires, interview and focus group guides**:

    a. The IRB will need to see the questions of all instruments that are not used in standard practice. The IRB will make a determination about the sensitivity of the questions and the risk to participants.

    b. If a standard questionnaire (e.g., commercially available, commonly accepted as standard of care, or well-known published instruments) is used, the PI may simply identify the title of the document and state that it is a standard tool; submission is not required.

2. **Investigator Brochures (IB), IB Updates, Updated Sponsor's Protocol, Clarification Memo(s), Letters of Amendment**:

    a. All of the above documents must be submitted to the IRB, and they will be reviewed by an IRB member/P&T liaison.

3. **Case Report Forms (CRFs) for Clinical Trials**:

    a. The IRB does not require submission of CRFs.

    b. If a PI submits CRFs, the IRB will acknowledge receipt, but will not review them.

    c. Since some of these documents are large, the IRB will accept receipt of the documents on disk, with a hard copy of the cover page. The disk and page will be kept in the study file in the IRB office. The IRB will acknowledge receipt.

4. **MedWatch Reports and IND Safety Reports**:

    a. The IRB will not review MedWatch Reports or IND Safety Reports. The study sponsor often requires that these documents be submitted to the IRB, but there is no obligation for the IRB to review these documents.

    b. Since some of these documents are large, the IRB will accept receipt of the documents on disk, with a hard copy of the cover page. The disk and page will be kept in the study file in the IRB office. The IRB will acknowledge receipt.