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Subject: Functions and Operations
Division: IRB
Date: March 1, 2012

IRB Policy 104.1: RESEARCH SUBMISSION REQUIREMENTS

Policy

IRB members must often rely solely on the materials submitted by Investigators to conduct initial and continuing review of research projects. Therefore, this material must provide IRB members with enough information about a study to assess if it adequately meets criteria for approval. A submitted protocol will be scheduled for IRB review when staff has determined that the information and materials submitted present an adequate description of the proposed research.

Submission Requirements for Initial Review

1. Required: Investigators applying for initial approval of proposed research must submit:

    a) An Application for Behavioral Study Review or an Application for Bio-Medical Study Review
    b) A detailed research protocol,
    c) Informed consent form(s),
    d) CV/Biographical Sketch, and
    e) Certification of education in the protection of human subjects (if the IRB does not have this on file).
    f) Financial Disclosure Form

2. If applicable: Investigators must submit:

    a) Supplemental Application for Research Involving Prisoners
    b) Supplemental Application for Research Involving Children
    c) Supplemental Application for Research Involving Pregnant Women, Human Fetuses, and Neonates
    d) Supplemental Application for Research Involving DNA, Tissue, Sample Banks
    e) Supplemental Application – Investigational Drug Information Record
    f) Supplemental Application – Indications for IND and IDE
    g) Assent/parental permission form
    h) All surveys, questionnaires, etc. that are indicated in the protocol
    i) Recruitment materials (e.g. flyers, advertisements, copy of radio advertisements)
    j) Statement of Investigator Form (FDA 1572)
    k) Investigator's Brochure/Package Insert
    l) If outside facilities or agencies are used as research sites, letters of agreement. If these facilities have an IRB, include a copy of the letter of approval for this study.
    m) Application for Expedited Review
    n) Data and Safety Monitoring Plan, or information regarding the Data and Safety Monitoring Board

(if one has been established)

Submission Requirements Throughout the Study's IRB Approval Period

1. During the approval period, Investigators must submit documentation to inform the IRB about changes in the status of the study including, but not necessarily limited to:

    a) Amendments/Addenda to approved protocols/consent forms
    b) Reports of serious adverse events or unanticipated problems
    c) Deviations from the protocol

2. Amendments/Addenda to Approved Protocols/Consent Forms: The following should be submitted to the IRB office:

    a) An Application for an Amendment (Change)/Addendum (New),
    b) Revised Document(s) (Protocol, Consent Form, Recruitment Material, etc.) with track changes indicating where the document(s) has been changed

3. Serious Adverse Events (SAE)/Unanticipated Problems: The following should be submitted to the IRB office (within 48 hours of discovery of the event/risk, and 24 hours of discovery of a deaths):

    a) Serious Adverse Event (SAE)/Unanticipated Problem Report Form,
    b) Any records (physicians' notes, hospital discharge summaries, biopsy, x-ray or other laboratory results, autopsy findings, etc.) which may help clarify the nature of the SAE/unanticipated risk.

4. Protocol Deviations: It is the responsibility of the investigator to submit reports of all protocol deviations to the IRB after their occurrence. The following should be submitted to the IRB office:

    a) Deviation Form
    b) Revised protocol and/or consent form, if necessary, with track changes indicating where the document(s) has been changed
    c) SAE/Unanticipated Problem Report Form, if necessary.

5. Investigators are responsible for reporting the following to the IRB in a timely fashion: new information that may impact the risk/benefit ratio of the study; irregularities in conducting the study, Data and Safety Monitoring Board reports, and copies of all external SAE reports.

Submission Requirements for Continuing Review

Investigators applying for continuing approval of research must submit the following (at least two weeks in advance of the IRB meeting held prior to the study's expiration, and two weeks in advance of the study's expiration for an expedited review):

1. Application for Continuing Review (with progress report)
2. Approved protocol
3. Approved consent form
4. Approved recruitment materials

Special Reporting Requirements

In special circumstances, determined at the time of review, the IRB may stipulate that some type of review should take place more frequently than once a year. When special reporting requirements are set as a condition of approval, the investigator must submit either the required information or a progress

report, as indicated in the approval letter. For example, if the IRB is concerned with the recruitment rate of a study at the time of its continuing review, the IRB may stipulate in its approval that enrollment should be reviewed again in six months. Therefore, in six months the investigator must submit a letter to the IRB informing it of the study's current enrollment.

Submission Requirements for Final Review

When a project has been completed or when the investigator's participation in a project has ended, the investigator must submit a final report summarizing all activity carried out through the protocol. For a Final Review, an investigator must submit the following to the IRB:

1. Application for Final Review,
2. Summary of Research Results, and
3. Any publications resulting from the study.

Submission Requirements for Study Close-Outs

If for any reason an investigator decides to close-out a study before its completion as per protocol, the investigator must submit a final report summarizing all activity carried out through the protocol, and the reasons for the study's closure. To Close-Out a study, an investigator must submit the following to the IRB:

1. Application for Final Review,
2. Summary of all activity carried out through the protocol,
3. Reasons for the study's closure, and
4. A draft of a letter informing subjects' of the study's closure, and how they will be affected by it, if necessary.

Submission Requirements for Exemptions from IRB Review

For studies, which are deemed to be exempt from IRB review by 45 CFR 46.101(b), an investigator must submit the following to the IRB Department:

1. Application for Exemption from IRB Review,
2. Protocol (can follow the 'Exempt Protocol Template')
3. Informed Consent, if necessary
4. Information Sheet, if necessary
5. All questionnaires/measures to be used, if applicable

Action Taken if Documentation is Not Adequate or Additional Information is Required

If the IRB or IRB staff determines that the submitted documents are not adequate, Investigators may be required to submit additional information, or their presence may be required to answer questions or explain the details of the study. Incomplete submissions will not be reviewed by the IRB.

Responsibility

The IRB Administrator is responsible for maintaining current research submission requirements for interested investigators and for preliminary triage of non-routine submissions. IRB Administrator is responsible for preparing member review materials and reviewing submission elements.

Applicable Regulations and Guidelines

45 CFR 46.115
21 CFR 56.115