Decatur Memorial Hospital

INSTITUTIONAL REVIEW BOARD
SOP 404: Continuing Review

POLICY

Continuing review of approved research must be substantive and meaningful. HHS regulations at 45 CFR 46.111 set forth the criteria that must be satisfied in order for the IRB to approve research. These criteria include, among other things, determinations by the IRB regarding risks, potential benefits, informed consent, and safeguards for human research participants.

PROCEDURES

1. Interval for Continuing Review

1.1 The DMH IRB will conduct continuing reviews of all non-exempt research at intervals appropriate to the degree of risk, but not less frequently than once per year.

1.1.1 The IRB may approve a continuing review for a month or two, based on their need for additional information leading to a second subsequent review within a short amount of time.

2. Lapse in IRB Approval

2.1 The regulations make no provision for any grace period extending the conduct of research beyond the expiration date of IRB approval. Therefore, continuing review and re-approval of research must occur on or before the date when IRB approval expires.

2.2 If the IRB has not reviewed and approved a research project by the study's current expiration date, i.e. IRB approval has expired, all research activity must stop. No new patients may be enrolled in the study. However, if the investigator is actively pursuing renewal with the IRB and the IRB believes that an overriding safety concern or ethical concern exists, then the IRB may permit the study to continue for the brief time required to complete the review process.

3. Criteria for Renewal

3.1 Since the purpose of the continuing review is to review the progress of the entire study and not just changes in it, the DMH IRB will revisit the same criteria used to grant the initial approval. The IRB shall determine with each continuing review that the following requirements are satisfied:

3.1.1 Risks to participants are minimized

3.1.1.1 By using procedures that are consistent with sound research design and which do not unnecessarily expose participants to risk, and

3.1.1.2 Whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes

3.1.2 Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may be expected to result.

3.1.2.1 In evaluating risks and benefits, the IRB will consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies that participants would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effect on the research on public policy) as among those research risks that fall within the purview of its responsibility.

3.1.3 Selection of participants is equitable

3.1.3.1 In making this assessment, the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, and pregnant women.

3.1.4 Informed consent will be sought from each prospective participant or the participant's legally authorized representative, in accordance with and to the extent required by appropriate local, state and federal regulations.

3.1.5 Informed consent will be appropriately documented as required by local, state and federal regulations.

3.1.6 When appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of participants.

3.1.7 When appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.

3.2 The IRB must also ensure that:

3.2.1 When some or all of the participants are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these participants.

4. Continuing Review

4.1 The following information should be summarized in the annual progress report:

4.1.1 Study status

4.1.2 Number of participants accrued to date and since the last review

4.1.3 Research results obtained thus far

4.1.4 Any complaints about the study

4.1.5 If participants have withdrawn from the study, and why

4.1.6 DSMB/DMC findings

4.1.7 Changes in the protocol that have a real possibility of affecting the risk-benefit ratio

4.1.8 Unanticipated problems involving risks to subjects or others

4.2 The annual progress report may consist of a Word document for those NCORP protocols where patients are still being followed for survival only, are deceased or completed, or the investigator wants to permanently close the study, but has to wait on the research base.

4.2.1 The Word document must include:

4.2.1.1 The name of the NCORP site

4.2.1.2 The status of the patients

4.3 For research that is not federally funded, a brief annual status report can be submitted in place of the annual progress report under the following conditions:

4.3.1 The study has not yet been activated due to the budget, contract, or technology required; thus, no participants have been enrolled.

4.3.2 The study is closed to accrual and all participants are deceased or completed, but data analysis is still ongoing.

4.3.3 The study is closed to accrual with no active patients. Waiting for site close out visit.

5. Review Process

5.1 A progress report may not be conducted through an expedited review procedure, unless (1) the study was eligible for, and initially reviewed by, an expedited review procedure, or (2) the study has changed such that the only activities remaining are eligible for expedited review.

5.2 The annual status report will be conducted through an expedited review procedure.

6. Possible Outcomes

6.1 Approve

6.2 Approve as amended, where the IRB administrator makes the changes in real-time and forwards the modified documents to the regulatory compliance coordinator.

6.3 Disapprove

6.4 Tabled, usually due to a lack of quorum

6.5 Withdrawn. This may happen when a change in research activity to permanently close the study has already been approved by the IRB co-chair, and the two submissions cross.

SCOPE

This SOP applies to all IRB members, the IRB administrator, and members of the research community.