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106: Review of Nonexempt Research

The intent of this Standard Operating Procedure (SOP) is to describe the review process for human subjects research studies that require Expedited or Full Board Review at Illinois State University (ISU). This SOP is for use by anyone who conducts human subjects research at ISU and is approved by the Institutional Review Board.

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1. Protocol Submission and Pre-Screening

Nonexempt research is submitted by the Principal Investigator (PI) in the electronic IRB submission system.. For Full Board Review level studies, protocols must be submitted and complete two weeks prior to the convened meeting to be eligible for review. Meeting dates and submission deadlines are published on the website. Expedited Review level protocols are reviewed continuously and can be submitted at any time.

All research team members who will be consenting participants, interacting or intervening with participants to collect data, or having access to identifiable data must be named in the protocol and must have current CITI training.

The Human Subjects Research Specialist (HSRS) or other REC staff pre-screens the submission to assign an initial level of review and screen to ensure the following.

- Submission form fully completed with clear responses to the questions asked, and routed to the correct review level or exempt category(/ies)
- All required documents are attached:
    - CITI training for study personnel not linked through the system
    - Consent documents, including recruitment flyers and debriefing statements, if applicable
    - Site permissions, if applicable
    - Surveys, interview questions, instruments

Incomplete submissions are returned to the PI by the HSRS to correct the deficiencies. If the PI does not respond to the HSRS within 30 days, the submission will be administratively withdrawn. Once the initial submission pre-screen is complete, the HSRS then makes the preliminary determination as to the level of review. If the submission is routed for Expedited Review, the Chair has the authority to move it to Full Board Review.

Regardless of review level, the IRB can only approve research that meets the criteria articulated in the federal regulations:

§46.111 Criteria for IRB approval of research.

(a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

(1) Risks to subjects are minimized: (i) By using procedures which are consistent with

sound research design and which do not unnecessarily expose subjects to risk, and (ii)

whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects 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 effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. 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, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116.

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117.

(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(b) When some or all of the subjects 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 subjects.

2. Expedited Review

The IRB may use the expedited review procedure only for studies eligible for such review under the federal regulations. These activities must present no more than minimal risk and must fall within the specific categories listed in the regulations.

The IRB Chair (or Vice Chair when the Chair has a conflict) serves as the Expedited Reviewer. The Chair has the option of consulting with other IRB members or with outside experts regarding the submission. The Chair enters into the submission and makes an approval decision:

- Approve as submitted,
- Require revisions to secure approval, or

- Refer the study to Full Board Review.

The IRB Chair does not have the authority to deny a study. For submissions returned to the PI pending revisions, the submission will be administratively withdrawn if the PI does not respond within 30 calendar days. Submissions returned to the PI for revisions more than twice may be referred for Full Board Review.

3. Full Board Review

The IRB Executive Committee (EC) is responsible for reviewing all protocols designated as Full Board Review at a regular or special convened meeting. The HSRS, after completing pre-screening, will designate two reviewers from the EC to prepare reviews for presentation at the full committee meeting. The study is then assigned to the appropriate agenda, giving all members of the EC access to the study prior to the IRB meeting.

The primary reviewers will be asked to briefly summarize the study and state their recommendations (approve, require revisions, or deny). The full committee will then discuss the study, and, as necessary, experts in the area may be consulted for their opinions. The PI is asked to be present to answer questions and provide feedback, but only joins the meeting after the EC has completed initial discussion and is excused from the meeting prior to further discussion and decision by the EC. PI attendance is not mandatory. After discussion is concluded, a vote is taken after a motion and a second are made. As in all business before the IRB, a majority vote of the quorum is required before any action may be taken.

All research protocols brought to the EC must either be:

- Approved as submitted,
- Returned to PI for minor revisions,
- Denied with recommendations for major revisions, or
- Tabled for further information.

A motion to return to PI for minor revisions must include whether the IRB Chair is authorized to review the changes and approve the study or whether the changes must be reviewed by the entire EC or a subcommittee thereof. The IRB Chair may always bring the changes back to the committee if deemed necessary. PIs are free to offer further information as to why they may be unable or unwilling to make the revisions required. In such cases, the study is returned to the EC for consideration at its next meeting. For submissions returned to the PI pending minor revisions, the submission will be administratively withdrawn if the PI does not respond within 30 calendar days.

4. Approval Period

With the exception of federally funded studies submitted prior to the Revised Common Rule (2018), Expedited Review protocols do not expire under federal regulations although the IRB can require continuing review at their discretion.

Research studies approved under Full Board Review are approved for a period not to exceed one year. In certain cases, the IRB may require a shorter approval period and/or interim reporting on the progress of the research and the status of the human subjects as a condition of approval. The exact period of approval and any conditions will be stated on the approval letter.

Full Board Review studies that will extend beyond the one year must obtain approval annually prior to the expiration date of the protocol by completing a renewal submission in the electronic submission system.

PIs are responsible for ensuring that approval of their protocol does not lapse. PIs are notified automatically via email from the system at several points prior to the expiration date. The PI must complete a renewal submission in the electronic system when additional time is needed beyond the approval period stated in the approval letter. For full board review protocols, the PI must attach a copy of a consent form that was used to enroll participants that matches the most recent form bearing the approval stamp. The renewal submission must be submitted at least two weeks prior to expiration in order to give the IRB adequate time for review. For Full Board continuations, it must be submitted prior the deadline for the next meeting.

In the event that re-approval does not occur prior to the expiration date, federal regulations make no provision for any grace period extending the conduct of research beyond the expiration date of IRB approval. A lapse in IRB approval of research occurs whenever an investigator has failed to provide continuing review information to the IRB or the IRB has not conducted continuing review and re-approved the research by the expiration date of IRB approval. In such circumstances, all research activities involving human subjects must stop after IRB approval expired, unless it is determined to be in the best interests of already enrolled subjects to continue participating in the research. Enrollment of new subjects cannot occur after the expiration of IRB approval. Review of whether continuing participation of already enrolled subjects in a research project during the period when IRB approval has lapsed is appropriate will be made by the IRB Chair or the convened IRB depending on the circumstances.

When IRB approval of ongoing research project lapses and the investigator wants to continue the project, the IRB should complete continuing review for the project as soon as possible. Investigators may resume the human subjects research activity once continuing review and approval by the IRB has occurred. The IRB must document why the lapse in IRB approval occurred, and, if appropriate, any corrective actions that the investigator, institution, or IRB is taking to prevent any such lapse of approval of the project from occurring again in the future.

Approval of an ongoing research project that has lapsed can subsequently be re-approved for one year, with the new expiration date being one year so as to retain the original anniversary date on which prior approval periods expired.

If the IRB notes a pattern of non-compliance with the requirements for continuing review (e.g., an investigator repeatedly or deliberately neglects to submit materials for continuing review in a

timely fashion or the IRB itself is frequently not meeting the continuing revie dates), the IRB should determine whether such a pattern represents serious or continuing non-compliance that needs to be reported to appropriate institutional offices, the HHS agency that supported the research, and OHRP (45 CFR 46.103(b)(5)).