Institutional Review Board Procedures at Southwestern University

Guiding principles:

The mission of the Southwestern University (SU) Institutional Review Board (IRB) is to evaluate SU faculty and staff research proposals to ensure that human participants are treated with respect and safety and that their rights are protected. The SU IRB follows standards and procedures modeled after the "Code of Federal Regulations Title 45 Part 46: Protection of Human Subjects" and "Introduction to the Responsible Conduct of Research" published by the Office of Research Integrity. These and other documents are posted on the IRB website. Historically, the vast majority of research conducted at SU has involved minimal risk; hence, standard procedures at SU are in keeping with this fact but also include provisions for research involving more than minimal risk.

IRB Membership:

Federal regulations require an IRB to have at least 5 members with varying experiences and areas of expertise appropriate to the kinds of research being conducted at the institution so as to bring informed and diverse perspectives to the review process. One IRB member must be from outside the SU community and not a close relative of a SU community member. Prior to service, IRB members should familiarize themselves with the information posted on the SU IRB website. In addition, the Senior Executive Secretary for Strategic Planning and Assessment (or designate) will keep a permanent record of all IRB communications; hence, Nancy Schutz should be copied on ALL formal communications related to the operations of the IRB.

Submission and review procedure:

1) Proposals for new or continued research projects are submitted by the Principal Investigator (PI), who must be a SU faculty or staff member, to irb@southwestern.edu using the forms posted on the IRB website. Nancy Schutz (or designate) will monitor this email address and upon receipt will number and label the proposals with the semester, a number indicating submission order, and the surname of the Principal Investigator using the following format: F13_01(name of PI). Labeled proposals will be forwarded to the IRB Chair for possible pre-review. The Chair may invite the PI to make revisions prior to distribution to the committee in order to facilitate a timely review process.
2) IRB members will review proposals and formulate their opinions in writing with respect to the following question: In your best judgment, is the proposed research ethical and does it protect the rights of participants, and if not, what, if any, revisions could the PI make to the proposal so that the research is acceptable to you. Reviewers comments should clearly indicate the nature of the concern(s), and where possible, suggested revisions that would resolve these concerns to the satisfaction of the reviewer. In keeping with the mission of the IRB, comments should focus on issues related to the protection of human subjects. It is not within the mission of the IRB to consider grammar, spelling, researcher safety, or methodological issues unless they compromise the viability of the research (that is, it *is* an ethical issue when the costs do not justify the benefits).
3) Reviewers should also indicate if they believe the research involves more than *minimal risk*. According to the Code of Federal Regulations Title 45 Part 46.102 (definition), "*minimal risk* means the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the

performance of routine physical or psychological examinations or tests." In cases where the majority of reviewers believe that the research involves more than minimal risk a convened meeting of the IRB will be scheduled to discuss the proposal, including whether the project requires more than annual review and whether the project will require verification from sources other than the PI that no material changes have occurred since previous IRB review. Minutes will be taken at convened meetings of the IRB.

4) Reviews should be emailed to the entire IRB (cc Nancy). When a proposal has been submitted by an IRB member, that individual should be omitted from the discussion. All communication should use the proposal label in the subject line as an identifier ([e.g., F13_01(name of PI)]. Reviewers should make every effort to complete reviews in a timely fashion, normally within 2 weeks and sooner if possible.
5) The Chair will consider all reviewer comments and concerns, resolve differences in opinion among reviewers through discussion if necessary and possible, distribute a draft decision letter to the IRB for comment and approval *if* there are significant differences of opinion, and email a comprehensive decision letter to the PI that reflects the majority opinion of the IRB. Decisions may be to approve as written, approve pending receipt of a revised proposal (in the case of minor revisions), or deny pending submission of an adequately revised proposal (in the case of major revisions). The decision letter will include a statement that no substantive changes to the proposal may be made without prior IRB approval except when necessary to eliminate apparent immediate hazards to the participants. The decision letter will also contain a statement directing the PI to report any unanticipated problems involving risk or compliance with procedures to the Chair of the IRB and, if applicable, to the sponsoring government agency.
6) Proposals that are denied and subsequently revised and resubmitted should be labeled as "REV" [e,g., F13_01REV(name of PI)]. Depending on whether the reasons for denial and/or the revisions are complex and/or controversial, the Chair may choose to approve the proposal as revised or to distribute it to the IRB for re-review.
7) Reviews may be completed by the Chair and one additional IRB member in cases where a submission involves only minor changes to recently approved proposals or the continuation of previously approved proposals. IRB members will be copied on these decisions for their information only.
8) When SU is not in session (e.g. during winter and summer breaks), reviews may be completed by the Chair and one additional IRB member unless at least one of these persons believes that the research involves more than minimal risk. In this latter case a convened meeting of the IRB will be called or the proposal will be deferred until SU is in session. IRB members will be copied on these decisions for their information only.
9) PIs may appeal IRB decisions in writing. According to federal regulations, only the IRB can reconsider an IRB decision; no other individual or office can alter an IRB decision concerning a research protocol involving human subjects.
10) At any time each member of the IRB is entitled to ask the Chair to call a convened meeting of the IRB to discuss procedures, specific proposals, or any other matter pertaining to the work of the IRB. Each member of the IRB is also entitled to review any documents pertaining to the work of the IRB (e.g., draft or final decision letters etc.).

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