Wittenberg University

Research Ethics and Compliance

Policy on Institutional Review Board and Procedures

PURPOSE

The purpose of this policy is to define Wittenberg University's Institutional Review Board (IRB) and the procedures the IRB will use to review human subjects research proposals. Government regulations require Wittenberg to maintain an Institutional Review Board (IRB) to review research at the University that involves human subjects. Wittenberg's IRB is responsible for evaluating the risks of participating in research projects, requesting modification of projects when risks can be reduced, and assuring that subjects give their informed consent to participate. Research projects cannot begin without the IRB's approval.

DEFINITIONS

Data: facts, figures, and information. For the purpose of this policy, the term "data" is considered to be material from primary sources analyzed as part of scholarly efforts.
Harm: any physical, psychological, social, or financial damage or injury, which might have been avoided without sacrificing the goals of the activity, as well as any damage or injury whatsoever whose extent cannot be justified by the contribution of the research to the expansion of human understanding.
Human subject: any specific living person, or information about a living person, who is the subject (participant) or object of study for the purpose of expanding our knowledge or understanding.
IRB: Institutional Review Board
Minimal risk: Federal guidelines state, "minimal risk means that 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."
Principal investigator: the primary person conducting the research. The principal investigator (P.I.) can be a professional or a student.
Review: a process of oversight resulting in an acknowledgment of the status ("approved," "pending required amendments," or "not approved") of a project under the guidelines of this policy.
Research: a systematic investigation designed to develop or contribute to generalizable knowledge. In other words, any activity conducted for the purpose of expanding knowledge or understanding, including the collection and analysis of data from questionnaires, observation, manipulation, sampling, experimentation, interview procedures, etc.
Risk: potential for physical, psychological, social, or financial harm.

INTRODUCTION TO INSTITUTIONAL REVIEW BOARD

Federal regulations require institutions conducting human subjects' research to have an Institutional Review Board review and approve the research. Specifically, IRB procedures and processes are guided by the Code of Federal Regulations, 45 CFR 46. Part A is referred to as the "Common Rule." Parts B, C, and D, govern research that uses vulnerable populations as subjects; Pregnant women, human fetuses, and neonates; Prisoners; and Children, respectively.

The IRB must review research that meets any of the following conditions:

- The proposal meets both the definitions of "research" and research with "human subjects"

- Wittenberg sponsors the research
- Wittenberg University property or University faculty or students are the subjects of the research
- A Wittenberg employee or student conducts or directs the research (whether or not it is in connection with the employee's University responsibilities).

The IRB's purview includes biomedical, behavioral, and survey research, and student research directed by a faculty member. The IRB must conduct its review even when the potential risk of harm to subjects is "minimal." The Code of Federal Regulations (45 CFR 46) explicitly gives the IRB alone the authority to determine if only "minimal risk" exists.

The IRB's approval is not permanent and can be revoked. Continuing projects must be reviewed and approved at least annually. In addition, the IRB has the authority to suspend or terminate its approval when the research is not being conducted in accordance with its requirements or has been associated with unexpected harm to subjects.

TYPES OF REVIEW

The IRB is responsible for determining the type of review that it will use for a research proposal. Three primary types of review are: 1) exempt, 2) expedited, and 3) full board.

EXEMPT

A research proposal may be eligible for exemption from the Common Rule if all the activities associated with the research fall into one or more of several categories under 45 CFR 46.104. Social, behavioral, and educational research typically falls into one of these categories:

1) Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior
3) (i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:
    a. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
    b. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
    c. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

    (ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact

on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

4) Secondary research for which consent is not required
5) Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or
possible changes in methods or levels of payment for benefits or services under those programs.
6) Taste and food quality evaluation and consumer acceptance studies
7) Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §46.111(a)(8).
8) Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use

(Note: If Subpart C applies, research with prisoners cannot be exempt, and if Subpart D applies, research with children may or may not be exempt, depending on the research methods.)

EXPEDITED

An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110. Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure. A list of the research categories allowed for expedited review are delineated here**.**

If the primary risk to subjects is a breach of confidentiality and the risk can be managed to no more than minimal, then the research may be reviewed through an expedited process. If research involves more than minimal risk and/or does not fall into one of the categories of research eligible for expedited review, it must be reviewed by a convened IRB. An expedited review is conducted by one or more IRB members.

FULL IRB REVIEW

If the research does not meet the criteria for expedited review it must be reviewed by the full IRB. A review of the full IRB must have the following characteristics:

1) Review at a convened meeting where a quorum (majority) is present; non-scientific member MUST be present
2) In order to approve the research, the IRB must determine that all of the requirements specified in 45 CFR 46.111 are met
3) A majority of those present must approve the research
4) Members with a conflict of interest may provide information but may not participate in the review OR be present for a vote and he/she does not count toward the quorum
5) For any research involving prisoners, the full IRB must participate in the review and a prisoner advocate must be present as a voting member of the IRB

ADDITIONAL TYPES OF REVIEW

For research that has been approved, there are additional types of review carried out by the IRB.

Continuing review must be conducted at intervals appropriate to the degree of risk, but not less than once per year. Expedited review procedures may be used for continuing review if the initial review was expedited and no new risks were identified. Expedited review procedures may be used if the first review was through a full board if, (1) when during the initial review the IRB determined that the research involves no more than minimal risk and no additional risks have been identified, or (2) the remaining activities are limited to data analysis.

Changes or modifications to approved research plans must be reviewed and approved before implementation. Expedited review procedures may be used to approve "minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

Reports of *unanticipated problems* involving risk to the research subjects also must be reviewed through the procedures outlined in Wittenberg policy on *Reporting on Unanticipated Problems in Research*.

MEMBERSHIP

Membership on the Institutional Review Board is dictated by 45 CFR 46.107.

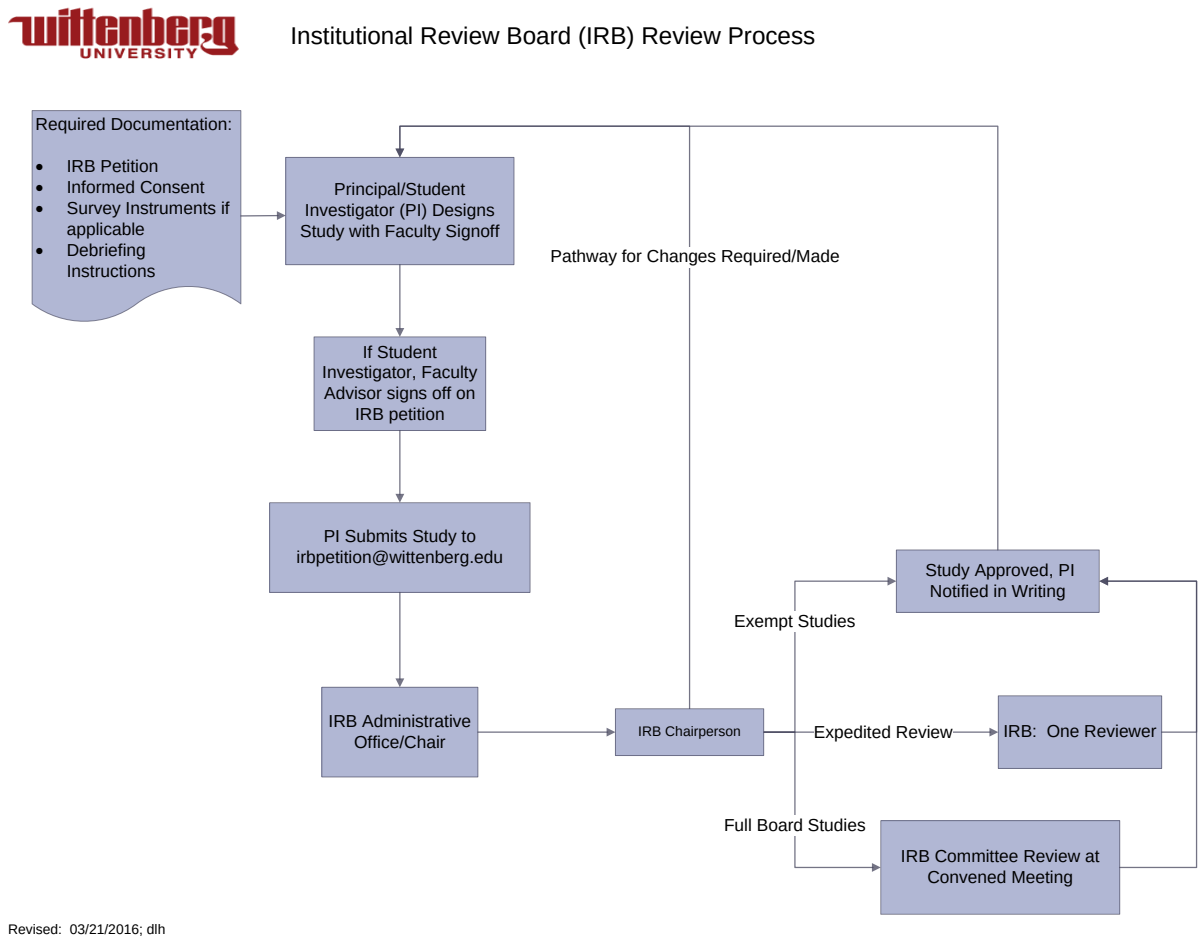
The Institutional Review Board (IRB) shall have at least five members, with varying backgrounds to promote complete and adequate review of the research activities typically undertaken at Wittenberg University. The IRB shall be sufficiently qualified through the experience, expertise and diversity of its members, including consideration of race, gender, cultural backgrounds and sensitivity to issues such as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. Among the membership, there must be at least (1) one member whose primary concerns are in scientific areas, (2) one whose primary concerns are in nonscientific areas, (3) one who has a medical background, (4) one who represents the perspective of research participants, and (5) one who is not otherwise affiliated with and who is not part of the immediate family of a person affiliated with Wittenberg University. The IRB members may not all be from a single profession. When reviewing research proposals involving prisoners as subjects, a prisoner or prisoner representative will also serve as a voting committee members.

THE REVIEW PROCESS

At Wittenberg the IRB review process follows the process map in Figure 1. First, the Principal Researcher (Faculty/Staff/Student) designs and submits study via email to irbpetition@wittenberg.edu. Researchers must include a completed petition form, documentation for informed consent, survey instruments, if applicable, and debriefing instructions. When submitting a research proposal for IRB review, the Principal

Investigator must include a separate form that is the Informed Consent document. Materials approved by the IRB must be unaltered when used by the Investigators (see the *Policy on the Protection of Human Subjects in Research* for additional information on Informed Consent). The petition template requires the Investigator to explain the project, the sampling and selection method, and strategies for minimizing risk to subjects. The final determination of the review category for the research is made by the IRB.

Figure 1.



Investigators must fulfill the CITI Social and Behavioral Responsible Conduct of Research training as specified by Wittenberg's Policy on the *Protection of Human Subjects in Research* before the IRB will give final approval. Faculty Advisor signoff is mandatory for the IRB petition. The Faculty Advisor is listed as the primary investigator. Student researchers may be listed as co-investigators. Faculty Advisor are the ones who submit the petition and research materials to irbpetition@wittenberg.edu. Faculty are responsible for screening their students' research projects.

Once submitted to irbpetition@wittenberg.edu an IRB tracking number will be assigned to the proposal. The IRB Administrator will acknowledge receipt of the submission to the Investigator, ensure the proposal documentation is complete, and distribute the materials to a member of the IRB for review type determination.

An initial review of the application is conducted by an IRB member. If a study is approved as exempt or determined to be not human subjects' research, no further IRB action is required. The IRB Administrator will communicate the decision to the primary Investigator(s). Any significant changes to the approved study must be submitted and reviewed by the IRB prior to initiation. Once the proposal has been reviewed by the IRB reviewer or the full IRB depending on type of review, the investigator will be notified in writing when the study has been approved, that includes the duration of the IRB approval.

The timeframe for the IRB review will depend on the type of review that must carry out. For studies that may be considered exempt, the IRB will communicate to the investigator within five working days. In expedited reviews, in which there is minimal risk of harm, the investigator can expect to hear from the IRB within ten working days. For studies that require a full board review, the IRB will need twenty working days in order to complete the review. To avoid delays in implementing a study, Investigators need to seek IRB approval as soon as possible once it is determined IRB approval is necessary. The IRB does not ordinarily meet during academic year breaks unless special arrangements have been made. The criteria for the IRB review is annotated on the IRB Petition form and the Informed Consent template.

IRB REVIEW RESULTS

There are three possible outcomes for an IRB Review:

1) Approved – the Investigator will be notified in writing, no further action is required from the investigator prior to initiating the study
2) Revise and Resubmit - The IRB may ask for additional information or may request alterations in the research protocol. If the IRB has strong objections to a proposed project or needs substantial additional information, it will likely request a meeting with the principal investigator. Research protocols can be revised and resubmitted as many times as necessary to receive the IRB's approval.
3) Disapproval or Denied – The full IRB determines that the proposed research, because of the level of risk involved to the human subjects, cannot be initiated

IRB approval of a research proposal expires in one year from the date of approval. If the project will continue beyond the approval period, the Investigator must resubmit the documents for renewal of the approval. At any time during the research study, Investigators must report any unanticipated problems (see Wittenberg's policy on *Reporting Unanticipated Problems in Research*) to the IRB which will then make a determination on whether the study may continue. Any modifications to the research protocol must be submitted to the IRB prior to the start of the modified research.

IRB RECORDS

Wittenberg University will track and retain the documents reviewed as part of research proposals regardless of the type of review, for a minimum of three years. The Department of Health and Human Services protection of human subjects regulations require institutions to retain records of IRB activities and certain other records frequently held by investigators for at least three years after completion of the research. The research proposals, associated documentation, and the written IRB decision are maintained in the Institutional Review Board Proposal Repository.

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