

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 six categories under 45 CFR 46.101. Of the six categories, social, behavioral, and educational research typically falls into one of three categories:

- 1) Research conducted in commonly accepted educational settings involving normal educational practices
- 2) Educational tests, survey (of adults), interviews (of adults), or observation of public behavior unless subjects can be identified and disclosure of data could place subject at risk
- 3) Educational tests, surveys, interviews, or observation of public behavior that involve elected/appointed public officials/candidates for public office or search conducted under federal statute
- 4) Collection/study of existing data, documents, records, specimens, if publicly available or if the researcher does not retain identifiable information
- 5) Research and demonstration projects conducted approved by federal Department/Agency heads designed to study/evaluate public benefit or service programs
- 6) Taste and food quality evaluation and consumer acceptance studies

(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

A research proposal review that is not exempt, may be expedited if the proposal meets two criteria:

- 1) The research poses no more than minimal risk to subjects. "No more than 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" (Protection of Human Subjects 2009).
- 2) The research consists of only one or more research activities specified in the federal regulations as eligible for expedited review below:

- a. Clinical studies on drugs or medical devices for which an investigational new drug (IND) or an investigational device exemption (IDE) application is NOT required. Similarly, a study with a cleared/approved medical device that is being used in accordance with its cleared/approved labeling.
- b. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture
- c. Prospective collection of biological specimens for research purposes by noninvasive means
- d. Collection of data through noninvasive procedures (physical sensors; weighing; MRI; etc.) routinely employed in clinical practice provided that:
 - i. The noninvasive procedure must not involve general anesthesia or sedation routinely employed in clinical practice or procedures involving x-rays or microwaves.
 - ii. Where medical devices are employed, they must be cleared/approved for marketing.
- e. Research involving data, documents, records, or specimens that have already been collected OR will be collected for solely non research purposes
- f. Collection of data from voice, video, digital, or image recordings made for research purposes
- g. Research on individual or group characteristics or behavior: Including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies
- h. Continuing review: no new subjects, all interventions completed; and, still active for follow up with subjects; or no additional risks; or research limited to data analysis
- i. Continuing review of research not conducted under an investigational new drug (IND) application or investigational device exemption (IDE) and where categories two (2) through eight (8) do not apply

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 the Code of Federal Regulations, Title 45 Public Welfare, Department of Health and Human Service, Part 46, Protection of Human Subjects (45 CFR 46), and Title 21 Food and Drug Administration, Department of Health and Human Services, Part 56 (21 CFR 56).

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.

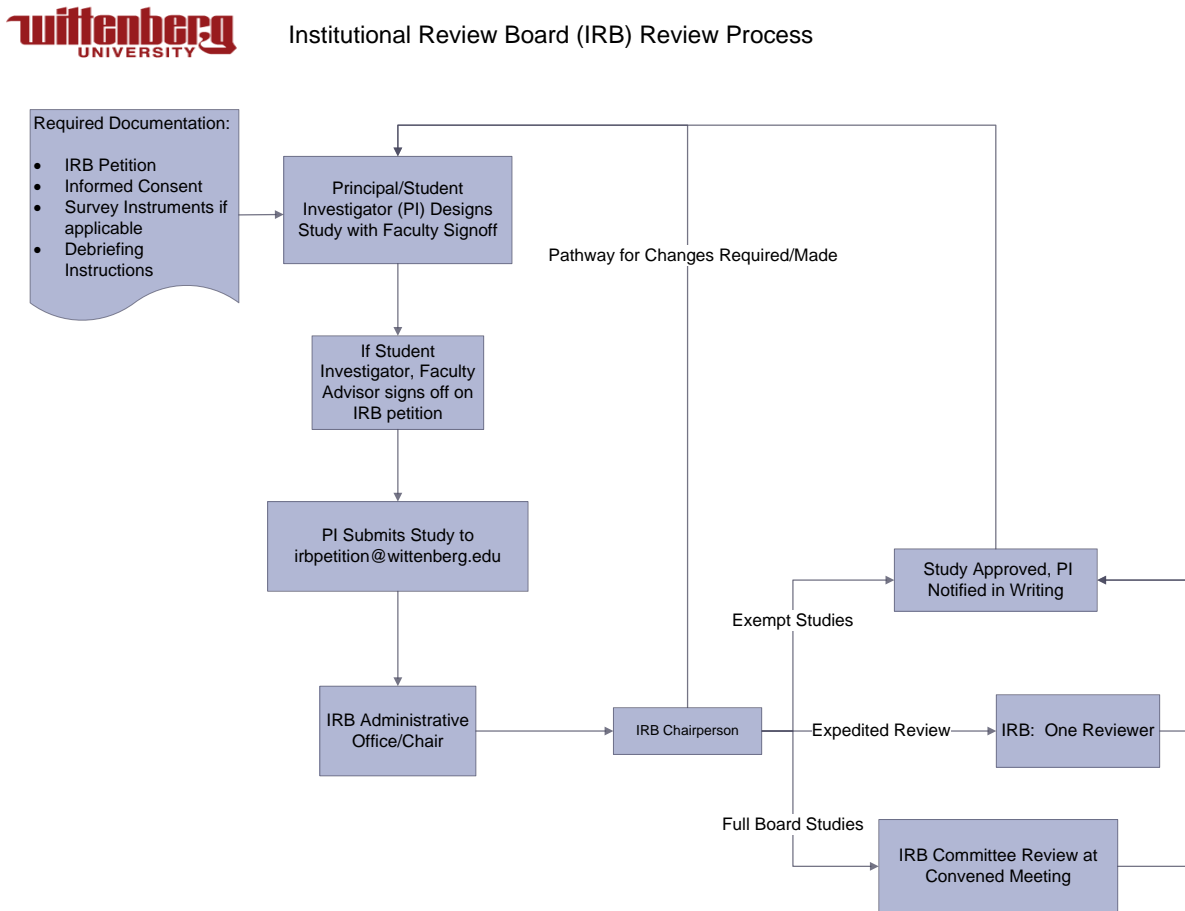
THE REVIEW PROCESS

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, strategies for minimizing risk to subjects. The final determination of the review category for the research is made by the IRB.

Investigators must fulfill the Human Subjects-Responsible Conduct of Research training requirement as specified by Wittenberg’s Policy on the *Protection of Human Subjects in Research* before the IRB will give final approval. Department and Faculty Advisor signoff is mandatory for the IRB petition. Where appropriate the Department Chair must sign the IRB petition before submission. When the primary investigator is a student researcher, the Faculty Advisor must be listed on the IRB petition, and must be copied on the email to irbpetition@wittenberg.edu when the student investigator submits the documentation. The signoff represents consideration of scientific merit, availability of resources, or other issues at the department level. All students conducting research must have a Faculty Advisor. 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.

Figure 1.



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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 four 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. Investigators need to be advised that 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 (45 CFR 46.115(b)). The research proposals, associated documentation, and the written IRB decision are maintained in the MyWitt portal, under Campus, Projects, and then Institutional Review Board Repository.

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