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 (PI) can be a professional or a student.
Co-Principal investigator (Co-PI): if the principal investigator is a student, the Co-PI is the faculty advisor
Co-investigators: other students or faculty involved in the project
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 eight categories under 45 CFR 46.101. Of the eight categories, social, behavioral, and educational research typically falls into one of three 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 (including visual or auditory recording) if at least one of the following criteria is met:

   i. 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;

   ii. 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

iii. 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).

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: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

i. The identifiable private information or identifiable biospecimens are publicly available;

ii. Information, which may include information about biospecimens, 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, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

iii. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or

for “public health activities and purposes” as described under 45 CFR 164.512(b); or

iv. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*

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. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

i. Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

6) Taste and food quality evaluation and consumer acceptance studies:

i. If wholesome foods without additives are consumed, or

ii. If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

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, if the following criteria are met:

i. Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with § 46.116(a)(1) through (4), (a)(6), and (d);

ii. Documentation of informed consent or waiver of documentation of consent was obtained in accordance with § 46.117;

iii. An IRB conducts a limited IRB review and makes the determination required by § 46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and

iv. The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

(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 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).

A proposal may be expedited if the research consists of only one or more research activities specified in the federal regulations as eligible for expedited review below:

9) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

i. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

ii. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

10) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

i. (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

ii. from other adults and children [2], considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

11) Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine

prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

12) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)
Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject=s privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

13) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

14) Collection of data from voice, video, digital, or image recordings made for research purposes.

15) 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. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

16) Continuing review of research previously approved by the convened IRB as follows:

i. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

ii. where no subjects have been enrolled and no additional risks have been identified; or

iii. where the remaining research activities are limited to data analysis.

Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

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.

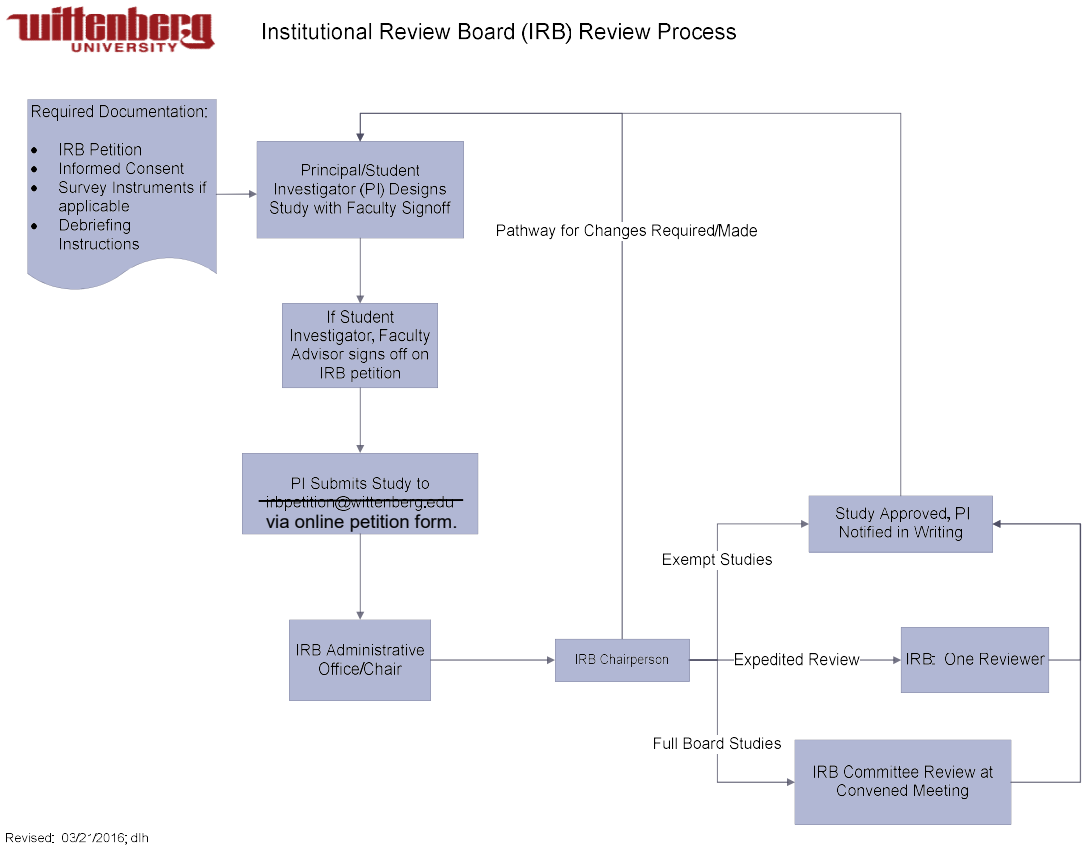
THE REVIEW PROCESS

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. 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, 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. Revised October 2025 – Implementation of automated online petition form and workflow through Etrieve SoftDocs



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 IRB Team Site, under Files.

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