



IRB Policy and Procedures Manual

This manual is designed to assist research investigators in the process of applying for and receiving approval from the IRB for research proposals. The manual also provides the policies and procedures for the functioning of the IRB. For convenience to the users the manual is divided into two sections: GUIDE FOR RESEARCHERS and GUIDE FOR IRB OPERATIONS.

GUIDE FOR RESEARCHERS

Amridge University Policies Regarding the Institutional Review Board

Faculty members, students or others, other than the Amridge University Center for Institutional Research, conducting research on human subjects in association with the University must have prior approval of the Institutional Review Board (IRB). Students must receive approval from the IRB prior to data collection.

Although research investigators are ultimately responsible for the ethical treatment of their human subjects, it is the policy of the University that all faculty members conducting research associated with the University involving human subjects must receive approval from the IRB before commencing their projects or beginning data collection. This requirement also applies to student research investigators who are collecting data under the supervision of a faculty member. Students engaged in projects for theses, dissertations, independent research courses, or faculty-student collaborations must seek IRB approval in cooperation with their committee Chairperson or faculty advisor. The IRB may require a background check of the investigator before approving a research plan involving research subjects who are minors.

Entities external to the University conducting research involving University students, employees, facilities or data must secure approval of the Executive Leadership Team which may require review and approval by the IRB.

Amridge University's Policy Establishing the IRB

The IRB is established and is charged to review research associated with the University to ensure that the use and treatment of human subjects is ethical and in compliance with established standards. It is the intent that the IRB meets the requirements of the Code of Federal Regulations, Title 45 CFR Part 46, in structure and function.

Procedures for Requesting and Securing IRB Approval

The researcher (Principal Investigator) must complete and submit the Amridge University IRB Application to the IRB (via email to irb@amridgeuniveristy.edu) and obtain IRB approval prior to collecting data.

The IRB will respond via email and inform the principal investigator that:

- a) The research plan is approved by the IRB, or
- b) Additional information must be provided before the IRB can make a determination, or
- c) The research plan is not approved by the IRB.

Procedures for Requesting IRB Approval for a Research Plan that Does Not Involve Human Subjects

If the research investigator and the committee Chairperson or faculty advisor determine that the research plan does not involve human subjects as defined below, the research investigator must still complete the Amridge University IRB Application. The IRB shall make the final determination as to whether or not a research plan does not involve human subjects.

Definition of “Human Subject”

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains (a) data through intervention or interaction with the individual or (b) identifiable private information.

Training

All faculty who serve on a dissertation committee must document having received training in protecting human subjects through a course approved by the Vice President of Academic Affairs. The Vice President of Academic Affairs is responsible for receiving this documentation from the faculty member and for maintaining it during the member’s term on the IRB. Faculty members will submit their course completion documents to the Vice President of Academic Affairs or his or her designee.

Faculty who are not serving on a dissertation committee but who are undertaking research, even research not directly connected with the University, must still document having received the appropriate training to the Vice President of Academic Affairs.

All students undertaking a thesis or dissertation at the University must document having received training in protecting human subjects through the course specified by the Vice President of Academic Affairs. One such course is provided by the National Institutes of Health at: <https://phrptraining.com/>. Students are responsible for providing their documentation to the IRB at the time the Amridge University IRB Application is submitted.

Types of IRB Review

While the IRB has the sole authority to determine the type of review to conduct of the proposed research, the following categories give researchers a guide for requesting a particular type of review and for ensuring the proper documents accompany the request.

Exempt Research

Exempt Research is defined as research that is exempted from the IRB approval process by Federal Regulation Title 45 CFR 46.104. Note, however, that by University policy, all research must be approved by the IRB unless exempted approval is obtained from the IRB. Examples of exempted research include:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless (a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects and (b) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
3. Research involving the use of educational tests, survey procedures, interview procedures, or observation of public behavior that is not exempt under category 2 if (a) the human subjects are elected or appointed public officials or candidates for public office or (b) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. Research involving the collection or study of existing data documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

Applying for Exempted Approval

The principal investigator must apply to the Chair of the IRB via email and submit the Amridge University IRB Application, along with other necessary evidence, to document that the proposed research does fit one of the exempted categories. The Chair of the IRB may either approve the request for exemption or refer the matter to the full IRB for a decision. The Chair of the IRB will notify the principal investigator of his/her decision via email.

Expedited Review

Expedited review is appropriate when the proposed research involves "no more than minimal risk" to human subjects (45 CFR 46.110). By the University policy, research involving minors is not eligible for expedited review and must be reviewed by the full IRB.

Applying for Expedited Review

The principal investigator must apply to the Chair of the Amridge University by submitting the IRB Application along with all recruitment materials and documentation of ethics training. The Chair will decide if the proposal qualifies for expedited review. If so, the Chair will appoint one other member of the IRB to review the proposal. The two members will make their decision jointly, and the Chair will notify the principal researcher of the decision.

Full Board Review

The full IRB will review all research proposals that do not qualify for either exempted or expedited review. The full IRB will review all proposals which involve minors as research participants. Additionally, the principal researcher may, at any time, request a review by the full IRB.

GUIDE FOR IRB OPERATIONS

Purpose of the IRB

The primary purpose of the University's Institutional Review Board (hereafter "IRB") is to ensure the protection of the rights and welfare of all individuals used as subjects for research projects in accordance with the University's stated policies as well as with federal, state, and local regulations including "Code of Federal Regulations, Title 45 Public Welfare, Department of Health and Human Services, Part 46 Protection of Human Subjects, Effective January 21, 2019."

Scope of the IRB

The scope of the IRB encompasses all research conducted by anyone associated with the University.

Definition of "Research"

Research is defined as "work which contributes to the generalized knowledge about a subject." Work undertaken as part of a course for the purpose of illustrating a particular technique or methodology is not considered research and therefore does not require approval by the IRB. Similarly, research activities using online databases or other forms of archival research (i.e., research pursuits that do not require eliciting responses from, taking measurements of, or otherwise studying human participants) are not reviewed by the IRB. An exception to this general principal regarding archival investigation would be when such investigation would allow individual persons to be potentially identified and thus risk violating the subject's confidentiality and/or right to provide informed consent.

Researchers should note that while Federal policy allows for certain types of research, as defined here, to be exempt from IRB review, the University policy is that all research, as defined here, must be approved by the IRB whether it meets the Federal standards for "exempt" or not unless exempted approval is obtained from the IRB.

Responsibility for Ethical Treatment

Although research investigators are ultimately responsible for the ethical treatment of their human subjects, the University policy is that all full-time, visiting, and part-time faculty conducting research at the University involving humans must present their research plans by completing the necessary forms provided by the IRB and to obtain approval from the IRB before commencing their projects or beginning data collection.

This policy also applies to student research investigators who are collecting data under the supervision of a faculty member. Students engaged in projects for theses, dissertations, independent research courses, or faculty-student collaborations which utilize participation by human subjects should seek approval in coordination with their committee Chairperson.

Principal investigators or co-principal investigators who are formally affiliated with the University and who conduct research associated with other institutions are also required to seek approval from the IRB, unless they have received approval from an approved institutional review board at their host institution. In this case, a copy of the approval form must be sent to the IRB at the University.

Goal of the IRB

The goal of the IRB is to assure that the use and treatment of human subjects participating in research at the University is ethical and in compliance with established standards. The task of the IRB is not to evaluate the soundness of the research, the merits of the research design, nor the contributions of the research to the larger scientific literature. Rather, the IRB is charged with evaluating a project's compliance with ethical standards in regard to issues such as informed consent, confidentiality, use of deception, and potential risk to participants. These standards conform to AAMFT, AAPC, and/or ACA Codes of Ethics, as appropriate.

Responsibilities of the University and of Research Investigators

Responsibilities of the University

Amridge University bears full responsibility for the performance of all research involving human subjects, including compliance with federal, state, and local laws as they relate to such research. In meeting its obligations in this area, the University is guided by the ethical principles set forth in the report of the Ethical Principles and Guidelines for the Protection of Human Subjects of Research, and adheres to the regulations of Title 45, Part 46, of the Code of Federal Regulations for the Protection of Human Research Subjects.

The University requires that all projects involving human subjects be reviewed and approved by the IRB to assure the following:

- a) The benefit to the subject and the importance of the knowledge to be gained outweigh the risks to the subject to the extent that a decision to allow the subject to accept these risks is warranted;
- b) The rights and welfare of subjects will be adequately protected;
- c) The researcher provides each participant with an informed consent document as required by law and by the appropriate professional codes of ethics; and
- d) The activity will be reviewed at regular intervals.

Any research involving human subjects that is undertaken without the prior approval of the IRB may be terminated, suspended, or postponed by the University at its sole discretion.

Responsibilities of the Research Investigator(s)

The principal research investigator and each person assisting the principal investigator bears the responsibility for protecting the rights and welfare of human research subjects and for complying with all applicable laws, regulations, and professional codes of ethics. Before beginning any project, research investigators must provide their research proposal to the IRB via the required IRB forms in sufficient time to allow the IRB to take action. While the principal investigator will, as part of this process, request a type of IRB action, the IRB alone decides to which category the proposal belongs. Research investigators are responsible for providing a copy of the approved and signed informed consent document to each subject at the time of consent, unless the IRB has specifically waived this requirement. All signed consent documents are to be retained in a manner approved by the Vice President of Academic Affairs.

During the course of the project, research investigators must report to the Chairperson of the IRB any changes in the approved protocol or any emerging problems of investigation that may significantly alter

the original concept of the project. Similarly, the primary research investigator must report to the Chairperson of the IRB any instances of injuries or unexpected problems involving risks to subjects or others which may occur during the course of the project.

Composition and Appointment of the IRB

Membership Categories

Since the IRB is responsible for the final review and approval of projects involving human subjects, the selection of the IRB members is a matter of utmost concern for the University. The Vice President of Academic Affairs shall be responsible for recommending members for the IRB. IRB members shall be appointed by the President of the University. The IRB shall consist of at least five voting members and must include the following:

- a) male and female members;
- b) representatives from a variety of professions, including scientific (e.g., therapy) and philosophical (e.g., theology);
- c) at least one public member who is not otherwise affiliated with the University and who is not part of the immediate family of someone affiliated with the University.

No one may be excluded from membership on the IRB on the basis of sex, race, color, or national origin.

The IRB shall not have a member participate in the IRB's initial or continuing review of any project in which said member has a conflicting interest, except to provide information requested by the IRB. The IRB may, at its discretion, invite individuals with competence in special areas (independent consultants) to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

Term of Membership Appointment

Initial appointment: Members shall be appointed for a three-year term except for memberships beginning Summer Semester 2012 which shall be appointed to staggering terms of 1, 2 or 3 years.

Reappointment: Three months before the end of their term, members should submit a letter to the Chairperson expressing their desire either to remain on the IRB or to be replaced. However, members may resign from the IRB at any time by submitting a letter of resignation to the President of the University. If a member resigns prior to the expiration of his or her term of membership, the Chairperson of the IRB shall inform the Vice President of Academic Affairs, who shall facilitate the appointment, by the President, of a new member to complete the term of membership.

Replacement: If a member finds that he or she is unable to attend meetings for an extended period, the Chairperson of the IRB must be informed so that a replacement may be appointed. Additionally, members may be removed from the IRB before their term is completed by the President in his sole discretion or for reasons of poor attendance for which there is no reasonable justification.

Review of Membership Composition

The Chairperson of the IRB, with the assistance of the other IRB members, periodically reviews the composition of the IRB to ensure the membership continues to conform to the categories specified in this policy. In the event that any necessary changes to the IRB membership are identified during this review, the Chairperson shall notify the Vice President of Academic Affairs, along with recommendations for modifications to the membership to accomplish such changes.

Any changes in membership are to be reported immediately to the Vice President of Academic Affairs by the Chairperson of the IRB.

Alternate Members

Alternate members may be appointed to the IRB by the President. These alternate members are listed on the membership roster of the IRB along with the name(s) of IRB members for whom the alternate may serve. Alternate members will serve any time a primary member must recuse himself or herself because his or her research protocol is being reviewed by the full IRB. The alternate member will receive and review the same material that the primary member has received. When an alternate member substitutes for the regular member at a meeting, the alternate is counted in the quorum and has voting privileges.

Roles within the IRB

IRB Chairperson: The Chairperson of the IRB is appointed to a three-year term by the President. Any individual appointed as the Chairperson of the IRB must have served as an IRB member prior to the appointment as Chairperson and shall be knowledgeable of the protection of human subjects. The Chairperson of the IRB is a voting member of the IRB and presides over all IRB meetings. The Chairperson has authority to sign all IRB documents. The Chairperson of the IRB will be evaluated every three years by the Vice President of Academic Affairs. The Vice President of Academic Affairs may seek input from the IRB members serving under the Chairperson during this evaluation. The Chairperson of the IRB may serve multiple terms. Three months before the end of his or her term, the Chairperson should submit a letter to the Vice President of Academic Affairs expressing the desire either to remain on the IRB as the Chairperson or to be replaced.

IRB Vice-Chairperson: A Vice-Chairperson of the IRB may be appointed to a three-year term by the President. The Vice-Chairperson of the IRB may assist the Chairperson in determining which proposed research plans qualify for exemption from review or for expedited review. The Vice-Chairperson of the IRB may chair an IRB meeting when the Chairperson is unavailable.

Recording Secretary: The Chairperson of the IRB shall appoint, from the IRB members, a Recording Secretary. The Recording Secretary shall record the actions of the IRB and shall file the records of actions as prescribed by the Vice President of Academic Affairs.

IRB Meetings

The IRB may meet on a regular schedule or may meet on an as-needed basis. A quorum at all IRB meetings consists of a majority of its voting members. The IRB must have a quorum to conduct any business.

IRB Records

The IRB shall prepare and maintain adequate documentation of IRB activities which must be retained for at least three (3) years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the University at reasonable times and in a reasonable manner. Such records shall include:

- a. Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators and reports of injuries to subjects.
- b. Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.
- c. Records of continuing review activities.
- d. Copies of all correspondence between the IRB and the investigators.
- e. A list of IRB members identified by name; earned degrees; experience such as board certifications and licenses sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship with the University.
- f. Written procedures for the IRB for conducting research reviews and for ensuring prompt reporting to the IRB of proposed changes in a research activity.

Suspension or Termination of Approval

The IRB may suspend or terminate approval of research that is not being conducted in accordance with its requirements which shall include a statement of the reasons for the IRB's action and which shall be reported promptly to the principal investigator and to the Vice President for Academic Affairs.

IRB Communications

Official communications between research investigators and the IRB will be via email. The IRB maintains an email address of irb@amridgeuniversity.edu. The Chairperson of the IRB is responsible for receiving emails and distributing them to other IRB members, as necessary. In communications with a student, the IRB Chairperson will copy the message to the student's thesis or dissertation chair.

Protocol Review

Every proposal involving human subjects must be reviewed and approved or exempted by the IRB before the start of the project or submission of the proposal to an outside sponsor. To initiate review, the principal investigator must submit the proposal via email to IRB@amridgeuniversity.edu.

Ongoing projects will be reviewed by the IRB annually unless the IRB specifies a more frequent review. The principal researcher and (where applicable) committee chair have the primary responsibility to submit the documents for the required review.



IRB Application

The goal of the Amridge University IRB is to assure that the use and treatment of human subjects participating in research at the University is ethical and in compliance with established standards. The task of the IRB is not to evaluate the soundness of the research, the merits of the research design, nor the contributions of the research to the larger scientific literature. Rather, the IRB is charged with evaluating a project's compliance with ethical standards in regard to issues such as informed consent, confidentiality, use of deception, and potential risk to participants. Official communications between research investigators and the IRB will be via email (irb@amridgeuniversity.edu). The Principal Investigator, even if a student, should communicate directly with the IRB.

Your proposed research may not proceed unless approved by the IRB. Your ethics training certificate and all recruitment materials (e.g. informed consent form, interview guide, permission letters, etc.) must be included with this application.

Principal Investigator:	Phone #:	Email address:
Dissertation Chairperson (if applicable):	Phone #:	Email address:
College/School: <input type="checkbox"/> College of Business and Leadership <input type="checkbox"/> College of General Studies <input type="checkbox"/> School of Education and Human Services <input type="checkbox"/> Turner School of Theology	Principal Investigator is: <input type="checkbox"/> Student <input type="checkbox"/> Faculty Member <input type="checkbox"/> Staff	
Project Title:		
Type of Research (Please note that the IRB has the final determination of the review type): <input type="checkbox"/> Exempt <input type="checkbox"/> Expedited Review <input type="checkbox"/> Full Review		
Participant Population & Recruitment: <i>Include the approximate number of participants, gender, and age(s). Describe exactly how potential participants will be identified and recruited, and be sure to include all recruitment materials (i.e. recruitment letter, flyers, social media posts, etc.) in the appendix.</i>		
Site/Organization Permission: <i>If the site of a private organization is used for recruiting or data collection or participants will be recruited using proprietary organizational information (private member lists, clients, etc.), explain this</i>		

process here. If so, explicit permission from an authority figure of the organization on organizational letterhead should be included in the appendix.

Informed Consent:

Explain (a) who will obtain informed consent and (b) when participants will be asked to provide informed consent form. Also, you must include a copy of the Informed Consent Form in the appendix.

Research Procedure:

*Describe the research design and procedure. Describe exactly what is to be done to/with participants and what they will be expected to do. Specify the total time it will take for any participant to participate, the number and duration of sessions for each participant, and the time period over which a participant will participate. **VERY IMPORTANT:** The focus of this section should be on the procedures regarding the participants themselves. There is no need to provide an in-depth discussion on why the specific methodology was chosen. All instruments/protocols (including interview questions, surveys, etc.) must be included in the appendix.*

Benefit & Risk:

If this study has no more risks than everyday life, you must state that explicitly. Have the risks involved been minimized and are they outweighed by the benefits? If more than minimal risk is involved, you must explain what additional measures will be taken to ensure participant safety.

Anonymity or Confidentiality:

Describe how either anonymity or confidentiality of participants will be maintained. Please note that anonymity cannot be promised if a participant signs an informed consent form.

Audio and/or Video Recordings (if applicable):

Explain the disposition of any applicable recordings. Clearly and explicitly state how long these will be kept, where they will be stored, and when they will be destroyed.

Data Storage:

Explain where and how all data will be stored (all data must be kept for a minimum of 5 years).

Compensation:

If participants will be compensated in any way, you must explain the method and amount of payment. If no compensation will be provided, please state so.

By typing my name below, I certify that I am knowledgeable and agree to comply with all regulations and policies governing research with human participants.

Principal Investigator:	Date:
Dissertation Chairperson:	Date:
Your ethics training certificate, instruments/protocols, and recruitment materials must be included in the Appendix.	

Appendix