Institutional Review Board (IRB) Policy Manual

Table of Contents

Institutional Review Board Policy Manual

Alvernia University (AU) encourages and supports the scholarly endeavors of its faculty, staff, and students. This pursuit of scholarship will often include human participants for data collection and analysis. The AU Institutional Review Board (IRB) reviews human participant research applications to ensure that the rights and welfare of those participants are protected; that risks have been considered and minimized; that the potential for benefit has been identified and maximized; that all human participants only volunteer after being provided with legally effective informed consent; and that any research is conducted in an ethical manner and in compliance with established standards.

These policies apply to all human participant research conducted at AU. Individuals seeking to conduct human participant research may not recruit participants or begin data collection until they have obtained approval by the AU IRB. All human participant research must go through a review process using the Research Determination Tool, to assess whether it meets criteria for Exemption or requires further review by the AU IRB. Typically, usual educational work that is done as part of a course, course evaluation procedures for program improvement, and surveys or interviews that do not identify the participants generally qualify as Exempt.

Several documents were very helpful in the development of this manual and include:

- American Psychological Association's Institutional Review Board: The College Planning Guide
- Maricopa County Community College District IRB Handbook: Standard Operating Procedures (December 2017)
- Stockton University IRB Guidelines & Regulations
- US Department of Health and Human Services Office of Human Research Protections and Food and Drug Administration's IRB Written Procedures: Guidelines for Institutions and IRBs (May 2018

Importance and Institutional Authority of the IRB

The AU IRB has the responsibility to oversee procedures for human participant research to ensure compliance with the guidelines established by the U.S. Department of Health & Human Services (DHHS) Office of Human Research Protections (OHRP) and the Food & Drug Administration (FDA). The AU IRB does not evaluate the soundness of the proposed research study, the merits of the research design, or the potential contribution to the body of scholarly literature. Instead, the AU IRB is charged with and committed to evaluating each project's compliance with ethical standards protecting and ensuring the rights, privacy and confidentiality, and welfare of those individuals participating in research projects at our institution.

The AU IRB is registered with the federal OHRP (FWA# 00034676), within the U.S. DHHS as IRB#IORG0008623. IRB's must comply with DHHS and FDA regulations in Code of Federal Regulations 45 part 46 (45 CFR 46) and 46 and 21 CFR parts 50 and 56, respectively, when reviewing human participant research. This Policy Manual empowers AU IRB to enact these regulations.

IRB Purpose and Principles

The IRB exists for one reason – to ensure that human research participants are treated with respect, protected from undo risk, and informed of their rights which includes the right to withdraw without any penalties (refer to Appendix A for the definitions of terms). This purpose, as well as the guiding principles for ensuring human participant protection, is found within the 1979 Ethical Principles and Guidelines for the Protection of Human Subjects of Research (i.e., The Belmont Report, found in

Appendix B). The Belmont Report summarized the findings from the National Commission for the Protection of Human Participants of Biomedical and Behavioral Research; a group tasked with establishing national standards designed to protect research participants.

As a result of the Commission's work, three basic ethical principles emerged. These include:

1. Respect for Persons – The report calls for investigators to respect individuals and to treat them as *autonomous agents* and for those unable to act with full autonomy (vulnerable participants), it requires that special review be put in place to ensure that they are not subjected to situations which they cannot fully comprehend.
2. Beneficence – Rather than focusing on kindness the report requires investigators to treat individuals with dignity, respect, and in a manner that protects participants from harm while also seeking to *secure their well-being*. Even when benefits may not be readily or ever apparent to participants, studies should seek to *maximize possible benefits and minimize possible harms*.
3. Justice – For the purposes of behavioral research, the commission implores investigators to ensure a *fairness of distribution* regarding the selection of participants, especially where benefits are direct and readily apparent.

The Belmont Report also explores the boundaries between practice, research, and applications. This series of principles summarizes that information:

1. Participants' legal rights will be respected; their rights to privacy, dignity, and comfort will also be considered in approving proposed research.

2. Risks to participants must be reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result.

3. Adequate provision(s) must be made for all facilities, procedures, and professional attention necessary for the protection of the individual as a research participant.

4. Adequate provisions should be made for recruiting a participant population that is representative of the population base in terms of gender and minority representation, unless the nature of the study justifies a specific participant population.

5. Research involving human participants must be supervised by qualified persons.

6. Participation of a human participant in research must be voluntary, and the right to withdraw at any time must be provided. Information provided to gain participant consent must be adequate, appropriate, and presented in lay language appropriate to the participant population.

Role of the IRB

The AU IRB functions through the Division of Academic Affairs/Provost Office in coordination with the Office of Institutional Research. This structure allows for alignment of the various academic and administrative units at AU. The IRB advises and makes recommendations to the Senior Vice-President for Academic Affairs/Provost, to policy and administrative units, and to members of the AU community on all matters related to human participant research.

Membership

The AU IRB is an Institutional Committee as per the Faculty Handbook and must have at least five voting members. As such, members are appointed by the provost for 2-year terms, which can be extended indefinitely. Appointees must be sufficiently qualified to review research applications in terms of regulations, applicable law, and standards of professional conduct. The members must be chosen with

nondiscriminatory consideration of race, gender, cultural backgrounds, clinical experience, and sensitivity to such issues as community attitudes to ensure diversity of membership. To ensure diversity of experience and expertise, membership is informed by requirements of the Office of Human Research Protections within the federal Department of Health and Human Services. Membership consists of six faculty representatives, at least two from each College and no more than two from any one College. At least two members must teach regularly in the Graduate Program; one must teach three credits annually in a graduate program and one of the two must teach in a doctoral program, and all should hold a terminal degree. Additional members include a representative of the Office of Institutional Research and two Community members, one representing the Bernardine Franciscan Sisters and one from the Greater Reading area. One of the faculty representatives will be appointed Chair by the Provost and serves an ongoing term with a 3-credit per semester reassigned time workload. The immediate past-Chair serves a 1-year term as a non-voting member.

IRB Member Training- AU IRB uses Collaborative Institutional Training Initiative (CITI) resources for detailed education of its members on the regulations, guidelines, ethics, and policies applicable to human participant research. Specifically, IRB members are required to complete initial and renewal certification in the following CITI modules:

1. Social Behavioral OR Biomedical Research Basic/Refresher
2. Social Behavioral OR Biomedical Research Responsible Conduct of Research
3. Information, Privacy, Security
4. Conflicts of Interest
5. IRB Members
6. IRB Chair (IRB Chair only)

Proof of continuing certification is provided when members upload the completion certificates in IRB Net under Training & Credentials tab.

Meetings

The full AU IRB convenes monthly as needed for application review. Meeting space is provided through the Office of Institutional Research, which is staffed by the Institutional Research Data and Research Specialist. All official IRB applications and business records are kept electronically on secure, password protected sites, either IRB Net or SharePoint. Only the IRB Chair has full access to all IRB Net and SharePoint files, while designated IRB members and administrators (i.e., the Director of the Office of Institutional Research and the GA) have limited access based on review responsibilities.

Voting

Approval of research is by a majority vote of a quorum of the voting members. Should the quorum fail during a meeting (e.g., loss of a majority through recusal of members with conflicting interests or early departures, or absence of a nonscientist member), the IRB may not take further actions or votes unless the quorum can be restored.

Conflicts of Interest

A Conflict of Interest is a benefit, economic or otherwise, that could affect or appear to affect the design, conduct, or reporting of research. HHS regulations contained in article 45 CFR 46.107(e) and AU IRB stipulate that no IRB member may participate in the IRB's initial or continuing review of a project in which the member has a conflicting interest, except to provide information requested by the IRB. OHRP

recommends that except when requested by the IRB to be present to provide information, IRB members absent themselves from the meeting room when the IRB reviews research in which they have a conflicting interest, and such removal should be noted in the IRB meeting minutes.

One IRB

The AU IRB follows the OHRP Single IRB Policy by honoring the decision of the IRB of record on a research project initiated outside of AU. All that AU requires is a copy of the decision letter from the approving institution to keep for our records. The AU IRB does not provide an approval letter but will send a letter of acknowledgement of the decision letter. The research may move forward once this acknowledgement letter has been sent.

Procedures for New Projects

Applications must be submitted by the Primary Investigator, defined as a person who holds a full-time, part-time, or temporary appointment at AU. Students must identify a co-principal investigator or faculty advisor for all research projects. Completion of the Research Determination Tool is the first step in determining whether the project meets the definitions of human participant research.

Applications determined to meet Exempt Review designation as per the Research Determination Tool do not receive IRB review. Expedited Reviews are conducted on an ongoing basis by the Chair and assigned reviewers as needed. Limited IRB review may be required to determine exemption and will be conducted via expedited review as needed. The entire IRB is convened monthly as needed for applications that require full review.

Applications are submitted via IRB Net and acknowledged by the AU IRB Chair as complete or requiring additional information. The IRB Chair reviews all project submissions to determine the level of review required and to assign reviewers via electronic notice. For Expedited Reviews, the Chair and another IRB member reach a consensus decision. IRB members are assigned on a rotating basis for consideration of Expedited Reviews.

In conducting the initial review of the application/project materials, the IRB evaluates each project on an individual basis to assess whether the investigator is providing adequate resources to protect the participants (i.e., research staff, social support services, equipment, and/or training). Therefore, the IRB must obtain information in sufficient detail to determine if protection for human participants has been provided as required under HHS regulations contained in article 45 CFR 46.111 (i.e., risks to participants are minimized, selection of participants is equitable, additional safeguards have been included for vulnerable populations, and consent/assent has been obtained in accordance with applicable laws). Project materials must include:

- completed application form,
- the full research proposal,
- a full participant packet including
    - explanation of procedures/participation requirements,
    - an informed consent document,
    - questionnaires and assessment instruments, and
    - recruitment materials/advertisements
- sample site permission letter(s),
- current CITI Certificates for all research personnel (including student researchers),
    - Biomedical and/or Social and Behavioral Research Basic/Refresher
    - Biomedical and/or Social and Behavioral Responsible Conduct of Research

    - Conflict of Interest, and
    - Information, Privacy, Security
- Agency-approved protocol with informed consent for any federal grant-sponsored research

The Research Determination Tool, the IRB application form, templates for Informed Consent and Site Permission documents, as well as links to the CITI Training Modules can be found via the My Alvernia IRB portal and on the IRB webpage.

Levels of Review

There are three determinations related to the level of review required, which are explained in detail here.

Exempt applications involve the research of subjects that do not meet the definition of human participants and/or do not involve any risk or harm to human participants. Investigators should use the Research Determination Tool (Appendix C) to decide if criteria for exemption are met. If there is any doubt, a project application should be submitted via IRBNet.

Limited IRB Review may be conducted via the Expedited Review process to determine qualification for exemption. Research that falls into one the following two categories for exemption would require this type of review

Category 1 (iii): 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) where 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. There must be adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

Category 3 (i)(C): 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 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. There must be adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

*benign behavioral interventions are brief, 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 intervention offensive or embarrassing. Examples include having subjects play an online game or having them solve puzzles under various noise conditions.

Expedited applications involve little to no risk or harm to human participants and do not need to be reviewed by the full IRB. Project applications will be acknowledged by the IRB GA within one week and investigators will be notified via email that either:

1. Information is required with details on what is needed, or
2. The application is complete.

Once the project application is complete, the IRB Chair will review all documents, make requests for modifications to the content as needed, and assign a member reviewer. The review process will be completed within two weeks and investigators will receive automatic email notification of the decision via IRB Net and an email from the AU IRB email account with the official decision letter attached.

Applications requiring full review of the convened IRB expose human participants to some risk. The full IRB convenes the fourth Tuesday of the month and will review project applications that have been submitted at least two weeks prior to the meeting date. Meeting dates and application deadlines are posted on the IRB page of the AU website (IRB Proposal Procedures & Forms | Alvernia University).

Categories of Action

The IRB may make one of the following decisions based on its review of the project application and accompanying documents:

1. Approval - The IRB approves the protocol and accompanying documents submitted. Final approval is effective on the day the study is approved by an action of the convened IRB, IRB Chair, or designee and expires within one (1) year of the date the project was approved.
2. Conditional Approval – The IRB requires specific modification(s) of information and/or documents within a project application. Specific changes are clearly outlined by the IRB and the investigators are informed via email of the required changes or additional information, including a deadline for submitting the changes. The IRB Chair or designee has the authority to complete an administrative review of the changes submitted unless the IRB requires, or the IRB Chair decides, that the material or information must be reviewed by the convened IRB or another IRB delegate. Upon satisfactory review, the IRB issues approval as of the date that the requested information or materials are approved. However, the expiration date of the IRB approval is determined by the date of the initial IRB review. Participants must not be recruited into the study until final approval has been issued. If the conditions of the approval are not met, the IRB may withdraw the approval.
3. Incomplete: The IRB raises significant questions regarding the project application or determines the information provided is inadequate to assess risk/benefit ratio. The IRB informs the investigator via email of the specific information requested and reconsiders the project application after additional information is received from the investigator.
4. Disapproval: The IRB determines the project application fails to meet one or more criteria for approval of research. Disapproval cannot be granted through the expedited review mechanism and shall be given only by majority vote at a convened meeting of the IRB. The IRB informs the Investigator in writing of the IRB's concerns. The Investigator can respond to the IRB for clarification. College administration cannot overturn the IRB's decisions without evidence of policy violations (see Policy Violations section below).

Procedures for Existing Projects

Within 60 days of the expiration date of the research project, the investigator will receive email notification from IRB Net reminding them of this deadline. If the research has been completed, a Study Completion letter should be uploaded under the project number in IRB Net (See Instructions for submitting a subsequent package within a project in the IRB Net User Guide). If the research has not been completed, a Study Continuation request letter should be uploaded under the project number in IRB Net. If no renewal is requested by the expiration date, no further data collection is permitted. The AU IRB Chair completes an administrative review of all documents for existing projects and notifies the investigator of the decision within two weeks of receiving them.

If there are changes to a research project after it has been approved, a Study Modification form must be submitted via IRB Net. Such changes include but are not limited to amendments to inclusion/exclusion criteria, population expansion, changes in procedures or the consent form. The research project may not continue until the changes have been approved by the IRB. Substantive changes may result in the application being treated as a new project, which may require that the full IRB convene to review it.

Otherwise, an expedited or administrative review by the AU IRB Chair will be completed within two weeks.

Unanticipated Problems

Any occurrence that was unforeseen at the time it happened, that increased the risk of harm to participants, and which is probably or definitely related to or caused by the research is considered an unanticipated problem. These events or issues include breaches of confidentiality, availability of new information about risk, and/or risks or side effects that were identified in the informed consent but that occur with greater frequency or severity than expected.

If these criteria are met, the IRB requires that the investigator promptly reports the event or issue using the Unanticipated Problems form submitted via IRB Net. Specific information about the corrective action to be taken must be included. Once this form is received, the AU IRB may approve the change in research, request further modifications to further protect the participants, or terminate the project.

The IRB can also suspend or terminate research based on information received during its continuing review or from participant complaints made to the IRB. Suspension is a temporary halt to all research activities, while termination is the permanent halt to all research activities. These determinations are made when research is not being conducted in accordance with IRB requirements and/or is associated with unexpected serious harm to participants.

Policy Violations

As the institutional body charged with assurance of human participant safety, the IRB is also tasked with ensuring that research conducted at the University is conducted ethically in accordance with the principles outlined in the Belmont Report. Accordingly, the IRB is responsible for ensuring adherence to that report and to the processes outlined in the IRB Policy Manual. All projects authorized by the IRB must meet strict ethical standards in line with accepted best practices, and violations of this policy, regardless of the reason, are taken seriously and will be dealt with by the IRB.

Should any violations of this policy occur, the IRB will require that the activity in question be halted until corrective action is taken. In situations where participant safety is compromised, and/or the violations are apparent, the Chair of the IRB may require immediate suspension of any research activity prior to review by the full Board. The IRB will review the reported violation and determine if additional information or further investigation is required and copy the Office of the Provost on all correspondence between the review board and the involved parties. Note that any research misconduct may impact employment at the institution.

While the IRB can and will assist in any investigation, the IRB will adhere to the decisions made by the Senior Leadership Team regarding continued institutional approval of the project. It is expected that the Senior Leadership Team will determine the applicable course of action in accordance with established University assurances, policies, and procedures.

Appendix A: Belmont Report

The Belmont Report (hhs.gov)

Appendix B: Code of Federal Regulations 45 Part 46

eCFR :: 45 CFR Part 46 (July 19, 2018) -- Protection of Human Subjects

Appendix C: Research Determination Tool

Alvernia IRB Research Determination Tool As mandated by Federal Regulation 45 CFR 46, the Alvernia Institutional Review Board (IRB) is required to review and approve ALL research involving human subjects. This form is intended to assist researchers in determining what level of IRB review is required. Novice researchers are encouraged to fill out the form with one or more seasoned research investigators as part of a peer review prior to		YES	NO	NOT SURE
Section A: Does your activity/project involve human subjects?	Is the data for the activity/project being collected about living individuals?	☐	☐	☐
	Is the data collected via intervention or interaction with individuals?	☐	☐	☐
	Does the data contain identifiable private information?	☐	☐	☐
If any question in Section A is "YES," go to Section B. If any question in Section A is "NOT SURE," go to Section B & C. If all questions in Section A are "NO," IRB review is not required.				
Section B: Is the activity/project research?	Is the activity/project a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge?	☐	☐	☐
If any question in Section A is "YES" and Section B is "YES," submit an IRB Application form. If Section B is "NO," go to Section D If Section B is "NOT SURE," go to Section C.				
	Does the activity/project involve secondary data sets with identifiable private information?	☐	☐	☐

Section C: Is IRB review required for approval?	Does the activity/project use identifiable specimens or cell lines from other institutions or are they commercially available?	☐	☐	☐
	Is the data collected for administrative purposes with the intention of publication?	☐	☐	☐
	Does the activity/project involve the use of publicly available data that contains sensitive, personal, or identifiable data?	☐	☐	☐
	Does the interview or survey focus on experiences, opinions, and/or sensitive information about people?	☐	☐	☐
	Is the activity/project a biography that is generalizable?	☐	☐	☐
	Is the activity/project an oral history that is generalizable?	☐	☐	☐
	Does the activity/project involve case histories of multiple individuals?	☐	☐	☐
	Is the activity/project a genetic study providing private information about live relatives?	☐	☐	☐
	Is the activity/project a class-related assignment that may lead to publication/conference presentation?	☐	☐	☐
If any question in Section C is "YES," submit an IRB Application form. Review the categories of expedited review to determine if a study requires full or expedited review & submit an IRB Application Form. If all questions in Section C are "NO," go to Section D. If any question in Section C is "NOT SURE," please contact the IRB.				
Section D: Is the focus of the activity/project on a specific population?	Does the activity/project intentionally focus on one or more specific populations listed below? If you check "YES" to any of the box(es), complete the IRB application form.	☐	☐	☐
	☐ Children (age < 18 years) ☐ Neonates/Fetuses/In vitro Fertilization Persons ☐ Mentally disabled or cognitively impaired persons ☐ Adults with legal guardians	☐ Prisoners ☐ Pregnant or lactating women group(s)— describe: ☐ Alvernia Students—name subject pool, if applicable:		