Institutional Review Board Policies and Procedures

Mission Statement

The mission of the Adventist University of Health Sciences (ADU) Institutional Review Board (IRB) is to provide ethical and legal guidance, support, and approval for researchers involving human subjects at the University as they engage in the pursuit of knowledge that honors God and the community.

Goals

- To ensure that research involving human subjects follow federal and state guidelines for research.
- To ensure that research involving human subjects conducted at ADU meet the moral and ethical standards established by the University and federal and state rules, thus minimizing or avoiding ethical issues.
- To assure that the rights and welfare of human subjects are protected in a research study.
- To guarantee that voluntary participation and informed consent is provided by all subjects.
- To assure the primary ethical principles (respect for persons, beneficence, and justice) are provided to human subjects, as outlined in the Belmont Report.
- To review research protocols and related materials to ensure that all human subjects are protected from physical or psychological harm.
- To approve research for which the risks to human subjects are balanced by the potential benefits to society.
- To provide an unbiased approval process for all research conducted at the University by the faculty and their research teams.

Projects Requiring Review and Approval by Institutional Review Board

All ADU investigator-initiated research involving human subjects must be submitted for review and approval by both the Scientific Review Committee (SRC) and the Institutional Review Board (IRB). No human subject research must be conducted without prior IRB approval.
Human subjects are defined as “living individual(s) about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information” [Federal Policy 45 CFR §46.102(f)]. In other words, all systematic investigation with data collection and data analyses from human subject requires prior IRB approval before the beginning of data collection. Examples of the collection of human subject data include: face-to-face surveys, email surveys, or by any other type of data collection interaction with the subject; focus groups with qualitative data analyses; treatment studies. Also, projects including the use of drugs or devices (either approved or unapproved by the FDA) must be submitted to the IRB.

**Administration**

Any institution engaging in human subject research supported by a department or agency to which Federal policy applies must establish an IRB to review and approve the research. If the research is supported by the United States Department of Health and Human Services (DHHS), such designations must have prior approval of its Office for Protection from Research Risks (OPRR). The Office for Human Research Protections (OHRP), within the Department of Health and Human Services (DHHS) and the Food and Drug Administration (FDA) regulates IRBs. Additional requirements by the United States Department of Defense are necessary for studies using military personnel, or when the human research involves populations in conflict zones or among foreign prisoners.

**Jurisdiction**

- The IRB has the authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction as specified by both federal and local institutional policy [Federal Policy 45 CFR §46.112].
- Research that has been reviewed and approved by the IRB may be subject to review and disapproval by officials of ADU [Federal Policy 45 CFR §46.112].
- Officials of ADU may not approve of research that has been disapproved by the IRB [Federal Policy 45 CFR §46.112].
- The IRB functions independently of, but in coordination with, other committees.
- The IRB retains jurisdiction over all research involving human subjects conducted, supported, or otherwise subject to by any federal agency that has adopted the human subjects’ regulations [Federal Policy 45 CFR §46.101(a)].
- Exempt research includes educational testing or surveys with no identifying information. [Federal Policy 45 CFR §46.101(b)].
- The IRB must protect the welfare of human subjects involved in research, whether or not the research is supported by a federal department or agency [Federal Policy 45 CFR §46.103 (b)(1)].
Approved research is subject to reevaluation annually or more regularly as specified by the IRB [Federal Policy 45 CFR §46.109(e)].

**Recommended Reading**

The ADU IRB recommend the reading of the following documents:

**Belmont Report:** It describes the ethical principles that should be followed by investigators involved in research with human subjects.

**Code of Federal Regulations:** The 45 CFR §46 is the Federal Regulation that describes the authority and responsibility of IRBs in protecting human subjects.

**Membership**

Members of the IRB will be appointed by the President of the University on a yearly basis. Before participating in any IRB meetings, all members must complete the IRB member module in the Collaborative Institutional Training Initiative (CITI) online training program (if not currently certified by ADU) and become familiar with the code of Federal Regulations governing the protection of human research subjects per CFR Title 45 Part 46, the Belmont Report, and the Common Rule. IRB members are expected to attend meetings and conduct reviews for assigned studies. Members are expected to review all applications on the agenda and prior meeting minutes.

- The IRB must consist of at least five members with varying backgrounds experience and expertise to promote complete and adequate review of research activities conducted by the institution [Federal Policy 45 CFR §46.107].
- Members must be qualified through experience and expertise and diversity of backgrounds, as well as knowledge of community attitudes and training in protecting the rights and welfare of human subjects, including considerations of race, ethnicity and cultural heritage, but must not consist entirely of members of one profession. This variety enables the IRB to provide an evaluation of research activities from the standpoint of someone inside and outside the scientific and scholarly discipline.
- For FDA-regulated research, a member is present who is a licensed physician.
- For research involving a vulnerable category of participants, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, a member is representing the vulnerable population’s interests.
- A list of current IRB members must be submitted to OPRR and kept in IRB records [Federal Policy 45 CFR §46.103(b)(3) and 45 CFR §46.115(a)(5)]. The list must identify members by name, earned degrees, representative capacity, indications of experience (such as board certifications or licensures) and any employment or other relationship to the institution.
- The IRB may invite one or more individuals with competence in special areas to assist in the review of protocols that require expertise beyond or in addition to that available on the IRB.

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Examples of such research studies are the ones involving a vulnerable category of participants, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons,

- IRB will include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.
- IRB will include at least one member who is not otherwise affiliated with ADU and who is not part of the immediate family of a person affiliated with ADU.
- Any changes in IRB membership must be reported to any department or agency supporting or conducting the research, unless the department or agency has accepted the existence of a DHHS-approved Assurance\(^2\) [Federal 45 CFR §46.103(a)], in which case the changes must be reported to the OPRR within 90 days [Federal Policy 45 CFR §§46.103(b)(3) and 46.115(a)(5)].
- The renewal of IRB registration must be done every three (3) years.

### IRB Members

<table>
<thead>
<tr>
<th>Name</th>
<th>Degree</th>
<th>Academic Area</th>
<th>Affiliation</th>
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</thead>
<tbody>
<tr>
<td>Archer, Len M.</td>
<td>Ph.D.</td>
<td>Science</td>
<td>Adventist University of Health Sciences</td>
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<tr>
<td>Chair</td>
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<tr>
<td>Bennie, Scott</td>
<td>PT., D.Sc</td>
<td>Physical Therapy</td>
<td>Adventist University of Health Sciences</td>
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<td>Dobias, Stan</td>
<td>D.Min.</td>
<td>Religion/Ethics</td>
<td>Adventist University of Health Sciences</td>
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<td>Fore, Carolyn</td>
<td>Ph.D.</td>
<td>Nursing</td>
<td>Adventist University of Health Sciences</td>
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<td>Florida Hospital</td>
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<td></td>
<td>Community Member</td>
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<tr>
<td>Harrington, Lillian</td>
<td>A.S.</td>
<td>Recording Secretary</td>
<td>Adventist University of Health Sciences</td>
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<tr>
<td>(Non-voting)</td>
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<td>Adventist University of Health Sciences Student Representative</td>
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### Record Keeping

The Institution and IRB must prepare and maintain:

- Adequate documentation of IRB activities [Federal Policy 45 CFR §46.115].
- Written IRB procedures and membership lists [Federal Policy 45 CFR §46.103].

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\(^2\) A written document satisfactory to the federal department or agency head that the institution will comply with the requirements set forth in this policy
• Copies of all research proposals reviewed, minutes of all IRB meetings, records of all continuing review activities, copies of all correspondence between IRB and investigators, and statements of significant findings provided to subjects [Federal Policy 45 CFR §46.116(b)(5)].
• Records of voting actions must be detailed to include: attendance at each meeting; actions taken by the IRB; the vote on actions (including number 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 [Federal Policy 45 CFR §46.115(a)(2)].
• Records of all research project applications submitted to, and reviewed by the IRB, as well as IRB decisions must be maintained for at least three years or three years after completion of research that is conducted, and be available for inspection and copying by authorized representatives of the department or agency conducting the research at a reasonable time and manner [Federal Policy 45 CFR §46.115(b)].

Institutional Responsibilities

The Institution must:
• Designate or establish an IRB to review and approve research involving human subjects performed at its facility and by its employees and students.
• Provide a written Federalwide Assurance (FWA) that it will comply with the requirements of the Policy and receive approval of the Assurance. For more detail, please refer to the link: http://www.hhs.gov/ohrp/irbs-and-assurances.html
• Certify that the Assurance has been reviewed and approved by the IRB. (The FDA does not require the submission and approval of an Assurance) [Federal Policy 45 CFR §46.103].
• Provide adequate space and staff to support the activities of the IRB [Federal Policy 45 CFR §46.103(b)(2)].
• Prepare written procedures and guidelines to be followed by the IRB in conducting its responsibilities.
• Appoint an official with legal authority to act and speak for the institution. The appointment must be made by the President or CEO of the institution.
• Provide training for all personnel conducting research in order to make them aware of all policies and procedures.
• Conduct regular audits to ensure that all policies and procedures are being adhered to.

CITI Certification

• ADU participates in the Collaborative Institutional Training Initiative (CITI).
• In order to conduct any human subject research, you need to be CITI Certified.
• All researchers (faculty, students, staff or external investigator) who submit research proposals involving human subjects will need to be CITI-certified prior to IRB approval.
• CITI certification must be renewed every five years and must be maintained throughout any human subjects research.
CITI Training Instructions

- To conduct research with human participants at Adventist University of Health Sciences, the Institutional Review Board (IRB) requires that all researchers be certified via the CITI Program\(^3\). The CITI Program provides research ethics education to all members of the research community.

- To be certified at ADU, a set of modules must be completed via the CITI website with an overall score of 80%. The modules “required” and “optional” for ADU researchers will appear automatically once you have registered.

- The “optional” modules required for CITI approval will be indicated during the ADU Web-based Scholarly Project Submission Form completion process.

- Once completed, CITI will issue you a “completion certificate” and notify the Adventist University IRB. Unless renewed, your certification will expire in 5 years.

Returning Users

Returning users may simply log in to the CITI web page and complete their training or refresher courses. If prior login information has been forgotten, click on the “forgot login” link to recover login information.

New Users

If you are a new user, you will be asked to register. Here are the steps to follow in creating a CITI log in and to complete the course requirements in the Human Research Curriculum.

To begin the CITI registration process, the user must open the CITI website by using the following link:

https://www.citiprogram.org/default.asp:

1. Click on the ‘Register’ link
2. Under ‘Select Your Organization Affiliation,’ type and select “Adventist University of Health Sciences.” Go to the next step
3. Type in your Personal Information. Go to the next step
4. Create your Username and Password. Go to the next step
5. Complete the sections on Gender, Ethnicity, and Race. Go to the next step
6. Complete the CEU page. Go to the next step
7. Complete the Information requested by ADU. Go to the next step
8. In the “My Learner Tools for Adventist University of Health Sciences” box, please click on “Add a Course or Update Learner Groups. Choose the course option and continue. Click ‘Next’
9. Question 1 – Human Subjects Research. Click on one:
   - Biomedical Research Investigators
   - Social & Behavioral Research Investigators
   - IRB Members
10. Question 2 – Health Information Privacy and Security (HIPS). Click on:
     - Health Information Privacy and Security (HIPS) Course – information for Investigators

\(^3\) https://www.citiprogram.org/default.asp
11. Question 3 – Responsible Conduct of Research. Click on one:
   Faculty
   Staff
   Students
   IRB members

Question 4 – Good Clinical Practice. Click on:
   Not at this time

12. Click the [Submit] button.
13. You will receive a confirmation email from citiprogram-noreply@med.miami.edu which will include the next step in finalizing your registration. Please check your spam folder for this email and if you have any questions or need assistance, contact adu.research.office@adu.edu or directly CITI Support at citisupport@med.miami.edu

Compliance/Non-compliance

The FDA and OPRR may conduct investigations whenever there are reports of non-compliance. Such investigations may include a site visit. The following consequences can result from non-compliance:

- Non-compliance may result in termination or suspension of support.
- Institutional officials will be informed whenever a compliance review is proposed.
- Breach of compliance by an Institution, IRB, or the Research Investigator may result in monitoring, suspension, or withdrawal of approval of the Institution’s Assurance.

IRB Review Procedures

- Applications for IRB review are submitted to the Research Office (RO) through the ADU Web-based Scholarly Project Submission process.
- RO will notify all investigators on receipt of application, submission to IRB, and notification of IRB’s decision.
- RO will be responsible to submit the study proposal to IRB chair after SRC approval.
- The IRB chair will submit to the IRB members.
- These reviewers will complete a written review that includes formative feedback.
- In the event that a project requires immediate approval due to unexpected circumstances beyond the principal investigator’s control, the Chair reserves the right to provide a decision without the Committee’s input. The Committee will be informed by the Chair on such decisions ex post facto.
- When an investigator requires an expedited approval, it may be granted by the Chair (for example, if approval needs to be granted prior to submission of a grant). Should an expedited approval be granted, the investigator will be notified so that grant submission
may proceed. In such instances, the IRB will review and formally approve the study at a later date with appropriate formative feedback.

- An IRB decision will be provided to the Research Office (RO) within 20 working days from the day of submission and the RO will notify the investigators of the decision in 3 working days after receipt of the IRB decision.

Decisions by the IRB will assigned as follows:

- Approved
- Disapproved
- Exempt approval
- Expedited approval

In the event of a significant disagreement in levels of approval, the Chair will mediate a decision with the Committee.

Exemptions

The federal government has identified certain categories of research involving human subjects that qualify for exemption from federal regulations. Adventist University of Health Sciences is authorized by the federal law to determine whether research studies, which are proposed by the Principal Investigator (PI) to be exempt from federal regulations, actually qualify for exemption. Such determination is made on behalf of the University by the IRB. Only the IRB has authority to make a determination that a study is exempt from federal regulations and from IRB review and approval. When the IRB notifies a PI that a research project is EXEMPT, it also notifies the PI that the research is approved for initiation or continuation.

In order to qualify for exemption, a research study must fall entirely within one or more of the six categories for exemption and it cannot place subjects at greater than minimal risk. If the research involves prisoners, then it does not qualify for exemption from federal regulations and IRB review.

"Exemption" as used in this document means exemption from the requirements set forth in Regulations for the Protection of Human Subjects (Title 45 Part 46 of the Code of Federal Regulations), such as the requirement for a written informed consent document. Determinations of exemption are made by the IRB.

Exemption does not mean that the research activity is exempt from the laws of the State of Florida, nor does it mean that the research need not conform to the principles of ethics. While IRBs can be more inclusive or restrictive, under the statute, exemptions to IRB approval include research activities in which the only involvement of human subjects will be in one or more of the following categories:

A. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:

1. Research on regular and special education instructional strategies.

4 7 C.F.R. § 1c.101
2. Research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods.

B. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
   1. Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects.
   2. 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.

C. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (B)(2) of this section, if:
   1. The human subjects are elected or appointed public officials or candidates for public office
   2. Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

D. 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.

E. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:
   1. Public benefit or service programs
   2. Procedures for obtaining benefits or services under those programs
   3. Possible changes in or alternatives to those programs or procedures
   4. Possible changes in methods or levels of payment for benefits or services under those programs.

F. 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.

**Expedited Review**

Expedited review is a procedure through which certain kinds of research may be reviewed and approved without convening a meeting of the IRB. A list of categories of research has been established in the Federal Register that may be reviewed by the IRB through an expedited review process. An IRB may use the expedited review procedure to review either or both of the following:

1. Some or all of the research appearing on the list of categories of research (established in the Federal Register) and found by the reviewer(s) to involve no more than minimal risk.

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5 [45 CFR 46.110](#)
2. Minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

In order to be considered for Expedited review the research MUST meet the following criteria:
1. The research activities must present no more than minimal risk to human subjects. 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.
2. All of the research activities involve only procedures listed in one or more of the research categories established in the Federal Register. The categories in this list apply regardless of the age of subjects, except as noted.

**Full Review**

Any study that does not meet the criteria for Exempt or Expedited review must be submitted for a full review.

**Conflict of Interest**

To avoid a conflict of interest, any principal investigator or co-investigator who is responsible for the design, conduct, or reporting of a sponsored research project which is conducted under the auspices of the University must disclose financial or other interests that are, or may be perceived to be, related to the project. However, the IRB is required to consider all real or potential conflicts of interest, regardless of funding, type of conflict, or level of financial conflict. A *Conflict of Interest Form* must be signed and submitted along with any application requiring IRB review.

**Informed Consent**

Informed consent is a process by which permission is obtained from a subject before conducting a healthcare intervention on a person, providing therapy or enrolling an individual in a clinical trial, or conducting a research study. Informed consent is obtained according to guidelines from the fields of medical ethics and research ethics and is required for IRB projects involving human subjects research. Informed consent can be only be provided by a subject who has a clear understanding of, and an appreciation for, the implications and consequences of their role or action. To provide informed consent, a subject must have adequate reasoning faculties and be in possession of all the relevant facts regarding their participation. A mental, physical, chemical or psychological impairment to reasoning and judgment may prevent informed consent and include such conditions as: basic intellectual or emotional immaturity, high levels of stress such as PTSD, a severe intellectual disability, severe mental illness, intoxication, severe sleep deprivation, Alzheimer's disease, or being in a coma. An *Informed Consent Form* must be submitted along with any application requiring IRB review.
Waiver of Informed Consent

The IRB may waive the informed consent requirement if the project involves only minimal risk, anonymous data collection, and falls into one of these categories:

1. Research involving normal educational practices.
2. Research on individual or group behavior or characteristics of individuals where the researcher does not manipulate the subjects' behavior and the study does not involve more than minimal risk.
3. Surveys and questionnaires that are determined by the IRB to involve perception, cognition, or game theory and do NOT involve gathering personal information, invasion of privacy or potential for emotional distress. (If there is any uncertainty regarding the appropriateness of waiving informed consent, it is strongly recommended that informed consent be obtained.)
4. Studies involving physical activity where the IRB determines that no more than minimal risk exists and where 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 performance of routine physical activities.

What to Do About Informed Consent When Using Data from Previous Studies

For some studies involving human subjects, a researcher may work with data from human subjects that was collected previously. These projects do not involve any interaction with human subjects by the researcher or data collection from the subjects. These types of studies fall into three categories:

1. If collected data are not de-identified/anonymous (e.g., a data set that includes patient name, birth date, phone number, or other identifying variables), the project is considered a human subject project. The project requires IRB review and approval. The investigators, as well as all assistants involved in data collection, must comply with all relevant privacy laws.
2. If the data are in a de-identified/anonymous format, the project does not require IRB approval, but the project must comply with the following conditions:
   a. The professional providing the data must certify in writing that the data have been appropriately de-identified and are in compliance with all privacy laws, including HIPAA.
   b. During the final Scientific Review Committee (SRC) review and approval process, the SRC must ensure that the data were appropriately de-identified by reviewing written documentation provided by the PI.
3. If the data are publicly available (e.g. in print, or electronic format) the project does not require IRB review or approval. Examples of such projects include examination of statistics from hospital records or crime statistics.
Applicable Laws and Regulations

Federal Policy for the Protection of Human Subjects
7 CFR §1c.101
21 CFR §56.108(b) [FDA: IRB functions and operations]
21 CFR §56.120-124 [FDA: Administrative actions for non-compliance]

Federal Register 56 (June 18, 1991): 28026 [FDA]
45 CFR §46.103 [DHHS: Assuring Compliance with this policy]
45 CFR §46.123 [DHHS: Early termination of research support]

Sources Cited