Research Proposal Guideline

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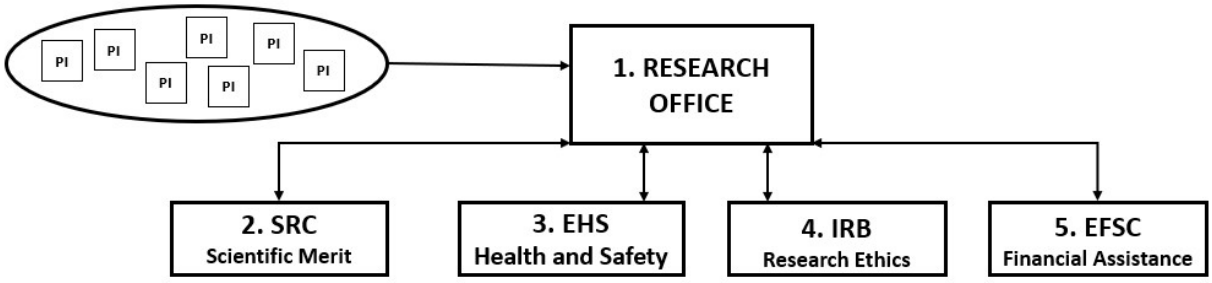
1. AHU Web-based Research Proposal Process and Timeline

The Adventist University of Health Sciences (AHU) Web-based Research Proposal Process involves several approving committees and offices including:

1. Research Office (RO): to manage applications for registration of research studies, submit application forms for approvals from appropriate committees, and serve as a resource to investigators and other interested individuals.
2. Scientific Review Committee (SRC): to grant approvals on the scientific merits of proposed studies.
3. Environmental Health and Safety Office (EHS): to assure environmental protection, fire and life safety, emergency management, laboratory, chemical, biological and radiation health and safety.
4. Institutional Review Board (IRB): to grant approvals on the ethical merits of studies involving human subjects.
5. External Funding Steering Committee (EFSC): to grant approvals for requested funds deemed necessary for study completion.

The AHU Research Office (RO) manages the AHU Web-based Research Proposal Applications process linking Scientific Review Committee (SRC), Institutional Review Board (IRB), External Funding Steering Committee (EFSC), and Environmental Health and Safety Office (EHS) committee's reviews and approvals, with notifications to investigators.

There is an open submission system which means that any investigator may submit an application at any time.



- Applications for SRC, IRB, and EFSC review must be submitted to RO through the AHU Web-based Research Proposal Process posted at https://my.ahu.edu/academics/research/submission-forms
- The RO will notify all investigators involved in the study about the requirements, including the confirmation of the need of approval from all the appropriate resources as SRC, IRB, EHS, EFSC, and CITI Certification.
- RO will be responsible to submit the study proposal to SRC and EHS office if necessary, within five working days after submission.
- RO will notify the investigators about the summary of the SRC and EHS reviews within 13 working days.
- Following the SRC approval, RO will be responsible to submit the study proposal to IRB and will notify the investigators about the summary of the IRB review within 18 working days.
- Following the IRB, if Graduate Student Research Grant or Faculty Research Seed Grant application had been selected during the completion of the application, the RO will be responsible to submit the study proposal to EFSC and will notify all investigators about the summary of the EFSC review within 18 working days.

The total time to complete the "AHU Web-based Research Proposal Process" with SRC and IRB approvals is 36 working days.

If the application includes grant requests, the total time to receive the approvals from the three committees is 54 working days.

Research will not commence until the IRB approval letter is provided as well as all other required approvals, such as EHS approval, CITI documents, and approvals of departments or divisions that require approval of the use of their resources.

2. Requirements for application to AHU Web-Based Research Proposal Process

- Research studies conducted by AHU student;
- Research studies conducted by AHU faculty bearing the University name / logo;
- Research studies conducted at AHU facilities;
- Research studies conducted involving AHU personnel;
- Research studies being conducted at another entity. The submission to AHU process must be prior to submission to any external entities.

3. Research Study and Professional Study Definitions

3.1 Research Study Criteria

For a study to be considered as research, the following criteria must be met:

1. There is a problem statement providing the background conditions that propel and justify the study.
2. Literature review is conducted by summarizing a review of scientific articles, books and other sources (dissertations, conferences, etc.) to provide evidence-based context for the study.
3. There is a hypothesis or study question expressing the anticipated outcome or problem to be addressed by the study.
4. A description of the methodology or study design describing how the study will be conducted.
5. The critical integration and analyses of compiled information or data gathered by using appropriate methodology.
6. Results and findings are reported, including their significance, if appropriate, to support study conclusions.

7. Implications of findings are disseminated so that others may provide feedback, benefit from the results, as well as stimulate further ideas for future studies. The findings are disseminated upon each program's discretion and approval. (Adapted from: AHU Faculty Handbook, Appendix F)

3.2 Professional Study Criteria

For any study that does not meet all the research study criteria listed above, it should be considered a Professional Study. However, the criteria for a Professional Study are determined at the discretion of each academic program. It may adopt some of the criteria for a research study or it could require other criteria more pertinent to the educational goals of the program.

A Professional Study includes Quality Improvement studies (QI) and Quality Assessment (QA) studies. QI/QA is often described as "systematic, data-guided activities designed to bring about immediate (or nearly immediate) improvements in health care delivery" (Lynn et al., 2007) and the combined efforts of everyone to make changes that will potentially lead to better patient outcomes, better system performance, and better professional development, classroom learning improvements. In medical institutions, QI/QA is a necessary, integral part of hospital operations and is not subject to review as research, as defined under federal regulation. Rather, it is governed by accreditation and hospital standards.

Reference: Lynn J, et al. The ethics of using quality improvement methods in health care. Ann Intern Med 2007:146:666-674

3.3 Requirements for Research Study and Professional Study

The table below seeks to differentiate the requirements for both types of studies.

Research Study	Professional Study
The criteria of what constitute a Research Study are listed above. Students and faculty will incorporate the seven criteria into their study.	The criteria of what constitute a Professional Study will be determined by the graduate program.
Must be submitted through the AHU Web-based Research Proposal Process to RO.	Each department will track their Professional Studies in electronic format and make this information available to RO as needed.
A faculty will guide and mentor students throughout the study. A faculty supervisor is required when the PI is a student.	A faculty will guide and mentor students throughout the study.
SRC approval is required.	SRC approval is not required.
IRB approval and CITI Certification are required when the study involves human subjects, drugs, biological products, medical devices, food supply, cosmetics, or radiation.	IRB approval and CITI Certification are not required.
Studies that involve blood, tissues, bodily fluids, chemical, biological products or other potentially infectious materials or risk assessment must receive approval from the Environmental Health and Safety Office.	The Program Department determines the need for review from Environmental Health and Safety Office.
It is eligible for Graduate Student Grants or Faculty Research Seed Grants.	It is eligible for Graduate Student Grants as a second priority to Research Studies. It is not eligible for Faculty Research Seed Grants. They may be eligible for other types of available grants.

4. Required Application Documents

4.1 Instrumentation:

Any survey, questionnaire, or other instrumentation to gather data. It is expected that instrumentation is properly validated as much as possible.

4.2 Consent Form:

All prospective research involving human subjects must provide a document to elicit agreement from participants with full knowledge of their voluntary participation, study purpose, study procedures, any potential discomfort, risk, and benefits, confidentiality, costs and compensation for participation, and contact information.

4.3 Study Site Director Approval Letter:

This letter acknowledges that the investigators have received approval to conduct the research at the identified study site. This letter needs to have the Principal Investigator's name, study title, facility's name, facility director's name, contact information, and signature. The Study Site Director Approval Letter is necessary:

- When the study is collecting data outside of AHU, for example Cardiology Center of FH.
- When the study collection of or analyses data takes place in an AHU Center, Laboratory, or PI's external department.

4.4 Quotes for Grant purposes:

All itemized grant application must be accompanied by rationale and documented quotes of costs.

4.5 Collaborative Institutional Training Initiative (CITI) Certification:

AHU participates in the Collaborative Institutional Training Initiative (CITI). The four main courses are described as "questions". Question 1, 2, and 3 are required courses for every AHU personal submitting a study involving human subject. External Co-investigators may submit their affiliated institution CITI Certificates.

Below is some general information in reference to CITI:

- To conduct research with human participants at AdventHealth University, the Institutional Review Board (IRB) requires that all investigators (Principal Investigator and Co-

investigators - faculty, students, staff or external investigator) to be certified via the CITI Program prior to IRB approval. The CITI Program provides research ethics education to all members of the research community.

- Animal and biohazard studies are not within the University capacity currently.
- CITI certification must be renewed every five years and must be maintained throughout any human subject's research.
- To be certified at AHU, a set of modules must be completed via the CITI website with an overall score of 80%. The modules "required" and "Supplemental" for AHU researchers will appear automatically once you have registered. A running tally is compiled in the Grade Book. If you want to improve a score on a quiz, you may repeat any quiz in which you didn't score 100% correct. Scores obtained after a completion report has been issued will not be reflected on the completion report.
- The "Supplemental" modules required for CITI approval will be indicated during the AHU Web-based Research Proposal Form completion process.
- Once completed, CITI will issue you a "completion certificate" that you will upload during the online application process.

4.6 How to Complete the CITI Certification

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

1. Click on the 'Register' link
2. Under 'Select Your Organization Affiliation," type and select "AdventHealth University" as your participating institution. 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 AHU. Go to the next step
    a. If you already have an account created with another institution, log in to your account and go to the Main menu.
    b. In the bottom of the page, click on [Click here to affiliate with another institution].
    c. You will then identify AdventHealth University as your participating institution.
8. To enroll in a course:
    a. You will be presented with a series of questions or options to enable you to enroll in the Learner Group. Your role in research does not affect your curriculum choices. The course(s) you are enrolled in depends only on your answers to the "Select Curriculum" questions.
        - **Question 1, 2, and 3 are required courses for every type of research proposal involving human subject.**
        - Question 1 – Human Subjects Research. You are required **to complete only one** of the following modules:
            - Biomedical Research Investigators
            - Social & Behavioral Research Investigators
            - IRB Members
        - Question 2 – Health Information Privacy and Security (HIPS). Click on: Health Information Privacy and Security (HIPS) Course – information for Investigators
        - Question 3 – Responsible Conduct of Research. **You are required to complete only one** of the following modules:
            - Faculty
            - Staff
            - Students
            - IRB members
        -

- Question 4 – Good Clinical Practice: is required only if your study is related to drugs, biological products, medical devices, food supply, cosmetics, and/or products that emit radiation.
- Question 5 - Biosafety/Biosecurity: is required only if your study involves one of the following: human-derived blood, body fluids, tissues, cell-lines, recombinant-DNA, microorganisms (bacteria, archaea, fungi, protozoa, algae, viruses), chemical, potentially infectious materials, radioactive materials, risk assessment, toxins, animal, plant, or biological products from human, animal, and microorganism. Your study will be submitted for the Environmental Health Safety Office review and decision of the necessity of Question 5 Certificate from the investigators.

b. The next page is the Main Menu. This page lists the courses you have chosen. The Main Menu also provides several "Learner Tools" designed to help you.

- The Add a Course or Update Learner Groups link allows you to go to the enrollment questions and change your "Learner Group" by providing new responses to the enrollment questions.
- The View Previously Completed Coursework link allows you to see your past scores, view expirations, and print completion reports.
- The Update Institution Profile link allows you to update your institution-specific details, such as your institutional ID or employee number, email, department, role in research, etc.
- The View Instructions page link brings you back to this page.
- The Remove Affiliation link allows you to unaffiliate with an institution if you are no longer required to be certified under them and wish to no longer receive email notifications regarding courses under the institution. Please be aware that you will not have access to previous scores or completion reports obtained under the institution unless you remain affiliated.
- You may affiliate with another institution. The software will sum the requirements of both institutions so that you need not retake modules common to the requirements of both institutions.

9. Click the Title of the Course to begin or continue the course.
10. Please Complete the Integrity Assurance Statement presented at the top after clicking a course title. The system will allow you to start taking the course modules after completing it.
11. Complete the Required modules and associated quizzes. The Supplemental and Elective modules are required only for certain research studies. Research Office will contact you if any additional modules are needed. Please be aware that Supplemental and Elective Modules do not count towards nor appear on a completion report.
12. When you complete all Required Modules in your curriculum and any necessary Elective Modules, you will be shown a list of Optional Modules. You may return to the course site at a future time to review these modules.
13. When you complete all required modules successfully, you may print your completion report through the link: Print Report from your Main Menu or your Previously Completed Coursework page.
14. You are encouraged to use multiple log on sessions to compete all the courses.
15. Print or download a Completion Report as evidence that you have met your institutional requirements. You may return to the course site in the future to obtain a copy of the completion report. The My Reports page will allow you to access any completion reports you have earned.
16. If you have any questions or need assistance, contact ahu.research.office@ahu.edu or directly CITI Support at support@citiprogram.org or to 888-529-5929.

4.7 Investigators Eligibility and Obligations in Research

Principal Investigator (PI) is the primary individual responsible for the preparation, conduct, and administration of a research study, grant, cooperative agreement, training or public service study, contract, or other sponsored study in compliance with applicable federal and state laws and regulations and institutional policy governing the conduct of the approved research. Students at AHU are not eligible for designation as principal investigator. Faculty and staff at AHU are eligible for designation as principal investigator, as well as, external faculty or researcher.

Co-Investigator(s) (Co-Is) are key personnel who have responsibilities similar to that of a PI on research studies. While the PI has ultimate responsibility for the conduct of a research study, the Co-I is also obligated to ensure the study is conducted in compliance with applicable laws and regulations and institutional policy governing the conduct of sponsored research. Faculty, staff, and staff at AHU are eligible for designation as principal investigator, as well as, external faculty or researcher.

Each PI and Co-PI certifies with every proposal submission that all information provided is true and complete and that the proposal conforms to the University policies and procedures applicable to sponsored activities.

The obligations of all Investigators conducting research at AHU are:

A. Research will not commence until the IRB approval letter is provided as well as all other required approvals, such as SRC and EHS approval, and approvals of departments or divisions that require approval of the use of their resources.
B. Comply with all requirements and determinations of the IRB.
C. Ensure that there are adequate resources to carry out the research safely. This includes, but is not limited to, enough investigator time, appropriately qualified research team members, equipment, and space.
D. Ensure that research staff are qualified (e.g., including but not limited to appropriate training, education, expertise, credentials, protocol requirements and, when relevant, privileges) to perform procedures and duties assigned to them during the study.
    1. Investigators and research staff are required to complete CITI training and continuing training at least every five years.
E. Conduct or supervise the research.
F. Conduct the research in accordance with the relevant current protocol approved by the IRB.
G. Protect the rights, safety, and welfare of subjects involved in the research.
H. Submit proposed modifications to the RO prior to their implementation.
    1. Do not make modifications to the research without prior IRB review and approval unless necessary to eliminate apparent immediate hazards to subjects.
I. Submit progress report or final report as requested by RO.

J. Do not accept or provide payments to professionals in exchange for referrals of potential subjects ("finder's fees.")

K. Do not accept payments designed to accelerate recruitment that were tied to the rate or timing of enrollment ("bonus payments") without prior IRB approval.

L. Unless the IRB affirmatively approved a protocol to include the following populations, such subjects may not be enrolled:

    1. Adults unable to consent
    2. Children
    3. Neonates of uncertain viability
    4. Nonviable neonates
    5. Pregnant women
    6. Prisoners
    7. Individuals unable to speak English

M. When consent, permission, or assent are required by the IRB ensure that they are obtained and documented in accordance with the relevant current protocol as approved by the IRB.

N. Retain research records (including signed consent documents) for the greater of:

    1. Seven years after completion of the research;
    2. The retention period required by the sponsor;
    3. The retention period required by local, state, or international law; or
    4. HIPAA requires signed authorizations to be retained for six years from the date signed or the date when it last was in effect, whichever is later.

O. Employ sound study design in accordance with the standards of a discipline and design studies in a manner that minimizes risks to subjects.

P. Update the IRB with any changes to study personnel.

Q. Lead investigators of a multi-site study to ensure there is a plan to manage information that is relevant to the protection of subjects and submit that plan to the IRB.

5. Withdraw of a Research Proposal

Research Office (RO) has the authority to withdraw a research proposal application after 30 days of not receiving information or document required directly by the RO or any other committee involved in the approval process (SRC, IRB, EHS, and EFSC). The investigators have up to 14 days to claim for reconsideration. The RO has 10 working days to review the request and issue a response.

6. Web-Based Research Proposal Application Steps

Before starting to fill out the form, Research Office advices you to read this "Web-Based Research Proposal Guideline".

You may download the **"Working Document for Web-Based Research Proposal Form"** to build a draft for your online proposal. You may use it to communicate with your supervisor and co-investigators.

You can find guides and form at https://my.ahu.edu/academics/research/guides-and-forms

To complete the online Research Proposal Form, please go to the webpage https://my.ahu.edu/academics/research/submission-forms

Click in "Research Proposal Forms".

Are you applying a new research proposal, or are you submitting a grant application for a previous research study submission?

If you are submitting a new research study for AHU research team review, please select: "New proposal application".

If your study has AHU SRC and/or IRB approval and you are submitting only a grant application (Faculty Research Seed Grant or Graduate Research Student Grant), please select: "Grant application for previous proposal application"

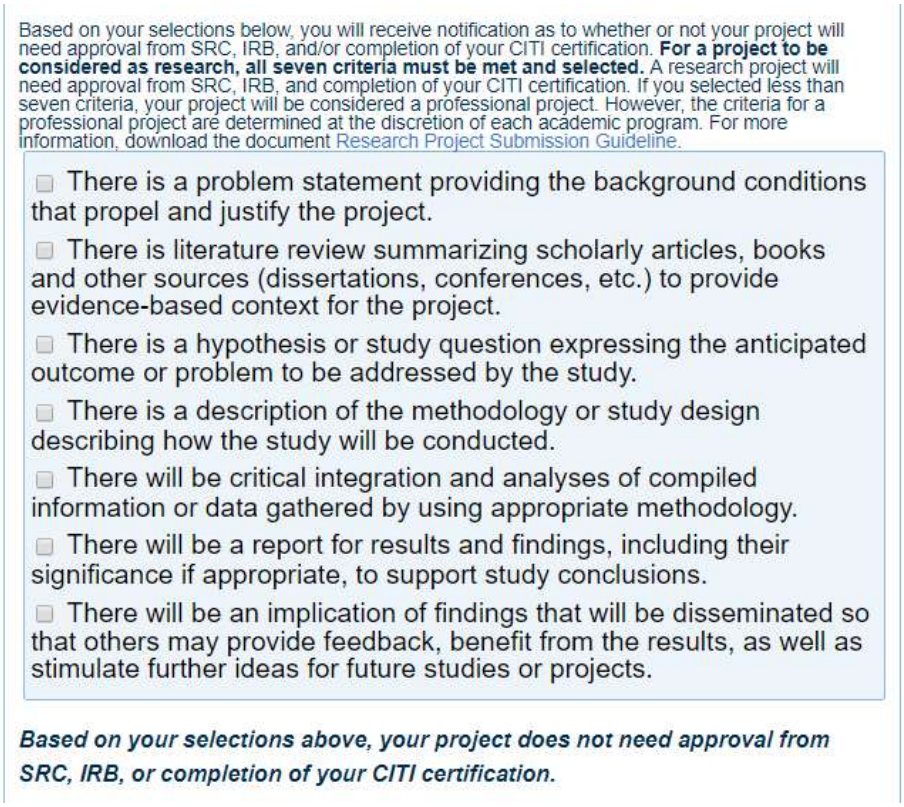
You will be directed to the appropriate application form.

Be aware that you can go back and forth during the process of completing the form using the arrows. Don't forget to click on "Save Draft" every time that you decide to logoff.

You will be asked to select all the options below that apply to your study:

Based on your selections, your study will be indicated whether it will need approval from SRC, IRB, and/or completion of your CITI certification. ***For a study to be considered as research, all seven criteria must be met and selected. A research study will need approval from SRC, IRB, and completion of your CITI certification.***

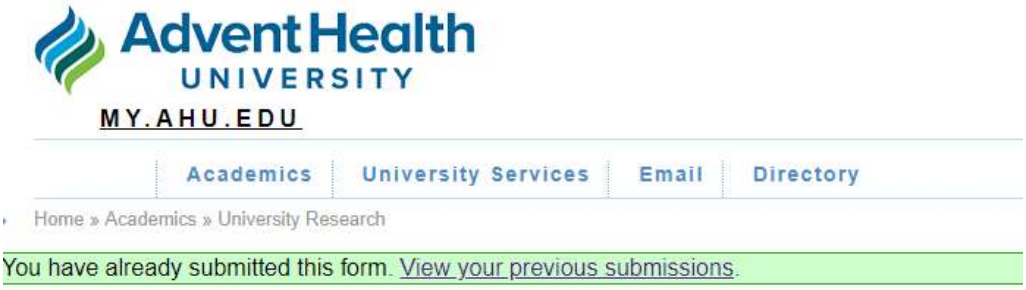
If you selected less than seven criteria, your study will be considered a Professional Study. However, the criteria for a Professional Study are determined at the discretion of each academic program.


Based on your selections below, you will receive notification as to whether or not your project will need approval from SRC, IRB, and/or completion of your CITI certification. **For a project to be considered as research, all seven criteria must be met and selected.** A research project will need approval from SRC, IRB, and completion of your CITI certification. If you selected less than seven criteria, your project will be considered a professional project. However, the criteria for a professional project are determined at the discretion of each academic program. For more information, download the document Research Project Submission Guideline.

- ☐ There is a problem statement providing the background conditions that propel and justify the project.
- ☐ There is literature review summarizing scholarly articles, books and other sources (dissertations, conferences, etc.) to provide evidence-based context for the project.
- ☐ There is a hypothesis or study question expressing the anticipated outcome or problem to be addressed by the study.
- ☐ There is a description of the methodology or study design describing how the study will be conducted.
- ☐ There will be critical integration and analyses of compiled information or data gathered by using appropriate methodology.
- ☐ There will be a report for results and findings, including their significance if appropriate, to support study conclusions.
- ☐ There will be an implication of findings that will be disseminated so that others may provide feedback, benefit from the results, as well as stimulate further ideas for future studies or projects.

Based on your selections above, your project does not need approval from SRC, IRB, or completion of your CITI certification.

You can view and download your previous submission. Click on the green box at "View your previous submissions".



7. Research Office Contact

For SRC, IRB, Grant submissions, CITI Certification, or any other research questions, please contact the Research Office:

Leana Araujo, Ph.D., Research Officer

Phone: 407-609-1388

Email: *AHU.Research.Office@ahu.edu*