

Research Proposal Application Guideline

<u>Ahu.Research.Office@ahu.edu</u> Room CC340



1. AHU Web-based Research Proposal Process and

Timeline

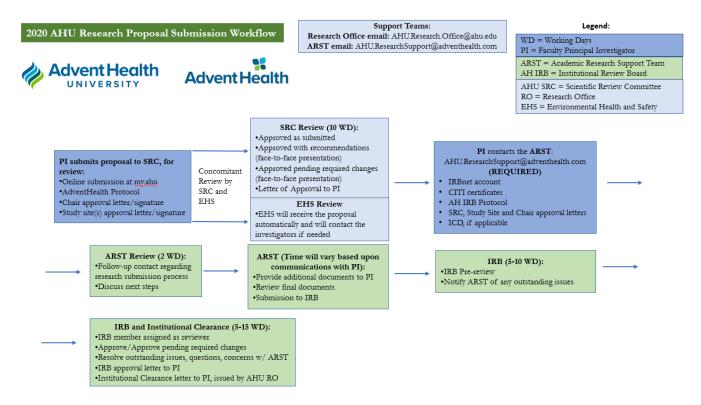
The AdventHealth University (AHU) Web-based Research Proposal Process involves several approving committees and offices including:

- 1. **Research Office (RO):** to manage applications of research studies and website information and serve as a resource to investigators and other interested individuals.
- 2. Academic Research Support Team (ARST): to support Institutional Review Board (IRB) submission, and other academic support to investigators and other interested individuals.
- 3. Scientific Review Committee (SRC): to grant approvals on the scientific merits of proposed studies.
- 4. Environmental Health and Safety Office (EHS): to ensure environmental protection, fire and life safety, emergency management, laboratory, chemical, biological and radiation health and safety.
- 5. **Institutional Review Board (IRB):** to grant approvals on the ethical merits of studies involving human subjects as well as projects not involving human subjects.
- 6. External Funding Steering Committee (EFSC): to grant approvals for requested funds deemed necessary for study completion.
- 7. **Institutional Clearance:** to grant approval for research clearance to make sure that the research will be conducted in compliance with ethical and professional standards.

There is an **open submission system** which means that any investigator may submit an application at any time. The committees will conduct reviews during working days (WD). Holidays and school breaks are not considered working days.



Research Submission and Review Workflow



Documents required for research applications to the SRC, IRB, and internal grants, can be accessed through the link <u>https://my.ahu.edu/academics/research/guides-and-forms</u>, in the list of "Research Application Documents."

I- PI submits proposal to the SRC for review:

- The minimal documents required by SRC are:
 - AH protocol
 - Chair Approval Letter
 - Study Site(s) Approval Letter(s)
- Applications for SRC review must be submitted through the AHU Research Website at https://my.ahu.edu/academics/research/submission-forms, clicking on the link "SRC and Grant Application".
- After completion of the application to the SRC, an option to select internal grant will appear. If Graduate Student Research Grant or Faculty Research Seed Grant application had been



Research Proposal Guideline

selected, the RO will be responsible to submit the study proposal to EFSC and will notify all investigators about the summary of the EFSC review.

- Upon completion of submission to the SRC and the internal grant, the Principal Investigator (PI) will receive an automatic confirmation email.
- SRC and EHS (if applicable) decisions are announced within 10 working days.
- The EHS has two types of approval:
 - o Approval
 - Disapproval
- The SRC has
 - Approved as submitted (score 30-40)
 - Approved with recommendation(s) (score 20-29). Presentation is required.
 - Approved pending required change(s) (10-19). Presentation is required.
 - Change(s) required for resubmission (0-9). Presentation is required.
- Investigators will receive an Outlook invitation for a 5-10-minute presentation to the SRC at the next scheduled meeting, if proposal score is less than 30 based on SRC Evaluation Rubric. More details on the rubric may be found at <u>https://my.ahu.edu/academics/research/submission-forms</u>, clicking on the link "SRC and Grant Application".
- RO will notify the investigators about the EFSC decision on the internal grant application. The review timeline is dependent on the type of grant.

II- PI submits proposal to ARST for review and submission to the IRB:

- After SRC approval, the PI will be responsible for revising the proposal based on the items requested by SRC before submission to ARST.
- The PI must contact the ARST at <u>AHU.ResearchSupport@adventhealth.com</u> for review and IRB submission.
- ARST will review protocol and follow-up with PI about the IRB submission process and discuss the next steps. PI will submit to ARST:
 - SRC approval letter, Study Site(s) Approval Letter(s) and Chair Approval Letter
 - AH Protocol (DO send in Word version. DO NOT send in pdf version)
 - Informed Consent Document (ICD), if applicable (DO send in Word version. DO NOT send in pdf)



Research Proposal Guideline

• ARST will be responsible to submit the study proposal to the IRB and notify the investigator about study status.

The steps required by IRB for study personnel and final project approval are:

- Creation of IRBNet account by Principal Investigator, Sub-Investigator(s) and study personnel.
- Completion of CITI requirements, affiliated with AdventHealth Orlando by Principal Investigator, Sub-Investigators, study personnel and Synchronization of CITI account.
- Completion of Conflict of Interest (COI) Disclosure and Training. Conflict of Interest forms are only required for faculty and staff. There are some special situations (federal grants) that would have students completing those forms.

Creation of IRBNet account:

- Go to www.IRBNet.org.
- Click "New User Registration".
- Affiliate with AdventHealth Orlando.
- Complete activation of your account via a link received in an email upon registration.
- Should you have questions, please contact the AdventHealth IRB Orlando at 407-200-2677 or <u>AH.IRB.general@adventhealth.com.</u>

Completion of CITI requirement:

- Register on www.citiprogram.org make sure your "institutional email" is the one you will check regularly.
- Select AdventHealth Orlando as your affiliated institution. (NOTE: We cannot accept Certificates of Completion under another institution's affiliation. Modules completed under another institution's affiliation will be credited to the required modules for AdventHealth once you affiliate under AdventHealth)
- AHU CITI certificates will be accepted until December 31, 2020.
- **Take the** REQUIRED courses:



Research Proposal Guideline

- "Basic Biomedical" or "Basic Social/Behavioral" depending on the type of research that you will be conducting.
- Health Information Privacy and Security (HIPS). CITI trainings expire every 3 years. You must renew them to maintain your education credentials with the AdventHealth IRB. Link IRBNet with AdventHealth Orlando CITI account.
- DO NOT upload CITI certificates to IRBnet. Follow the next item on how to link accounts.

Link the AdventHealth Orlando CITI account with the IRBnet account:

- Log into IRBNet, <u>https://www.irbnet.org/release/index.html</u>, and navigate to your User Profile.
- Click the link to "add an external account" you'll need your CITI Member ID number.
- A verification email will be sent to the institutional email address you entered in CITI.
- Once you have verified this email, your account will be linked, and your CITI certificates will automatically import into IRBNet within 24 hours of completion of the course.

Conflict of Interest (COI) Disclosure and Training

- Contact ARST for access to the Conflict of Interest Disclosure Form (COI)
- Once completed, submit your COI documentation to the Office of Research Integrity (ORI) at <u>AH.ORI@adventhealth.com</u>
- The CFD Research Conflict of Interest Training will be assigned to your ALN account. This training will be provided to you by AH ORI (AdventHealth Office of Research Integrity).

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