



Scholarly Study Submission Guideline

Ahu.Research.Office@ahu.edu

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1. AHU Web-based Scholarly Study Proposal

Process and Timeline

The AdventHealth University (AHU) Web-based Scholarly Study Review involves several approving committees and offices, including:

1. **Research Office (RO):** to manage scholarly studies and website information applications and serve as a resource to investigators.
2. **Center for Academic Research Excellence (CARE):** to support project development, Institutional Review Board (IRB) submission, and other academic support to investigators.
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 and determination of Quality Improvement-Quality Assessment.
6. **External Funding Steering Committee (EFSC):** to grant approvals for requested funds deemed necessary for study completion.
7. **Research Institutional Clearance Committee (RICC):** to grant clearance to scholarly studies to ensure that the study 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.

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2. Terminologies

PI = Principal Investigator

SubI = Sub Investigators, the other investigators besides the Principal Investigator

HSR = Human Subject Research

NHSR = Non-Human Subject Research

QI/QA = Quality Improvement/Quality Assessment

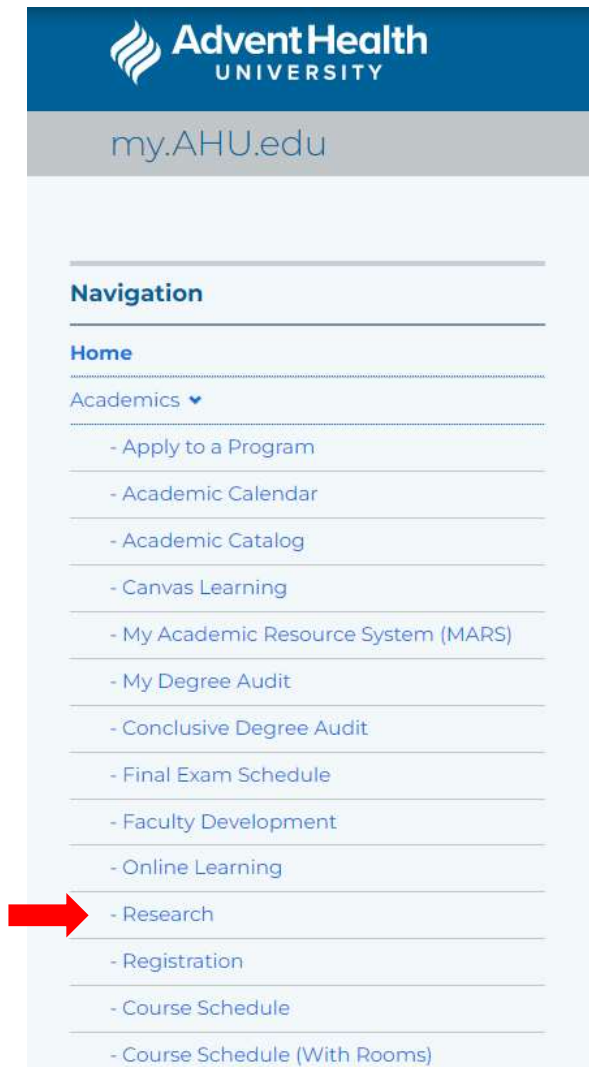
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3. Common Questions

3.1 Is there an AHU Research Website?

Yes. Login to **my.ahu**. On the left side of the screen, click on "**Academics**." Scroll down the page and click on the "**Research**" webpage.

Or use the link <https://my.ahu.edu/academics/research>.

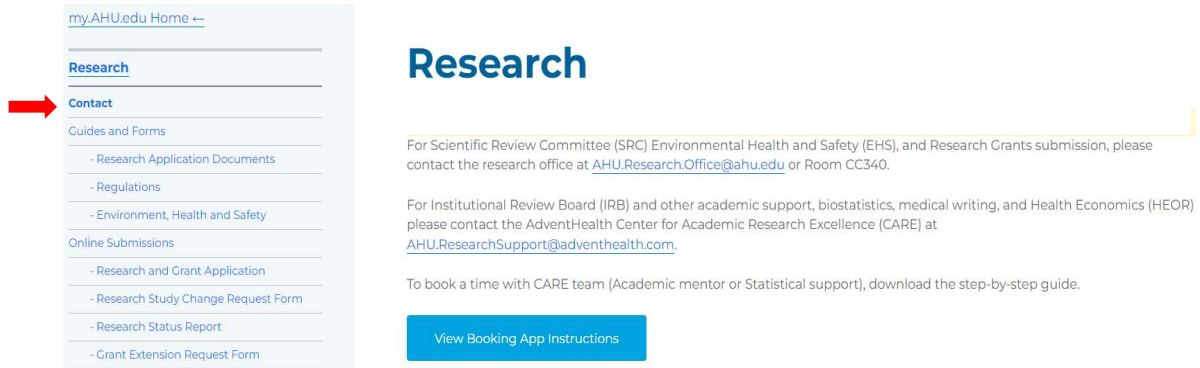


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3.2 Where do I find the Research Office and CARE team contacts?

If you are already on the "Research page" described above, the **"Contact page" is the first.**

Or use the link <https://my.ahu.edu/academics/research>.



my.AHU.edu Home ←

Research

Contact

Guides and Forms

- Research Application Documents
- Regulations
- Environment, Health and Safety

Online Submissions

- Research and Grant Application
- Research Study Change Request Form
- Research Status Report
- Grant Extension Request Form

Research

For Scientific Review Committee (SRC) Environmental Health and Safety (EHS), and Research Grants submission, please contact the research office at AHU.Research.Office@ahu.edu or Room CC340.

For Institutional Review Board (IRB) and other academic support, biostatistics, medical writing, and Health Economics (HEOR) please contact the AdventHealth Center for Academic Research Excellence (CARE) at AHU.ResearchSupport@adventhealth.com.

To book a time with CARE team (Academic mentor or Statistical support), download the step-by-step guide.

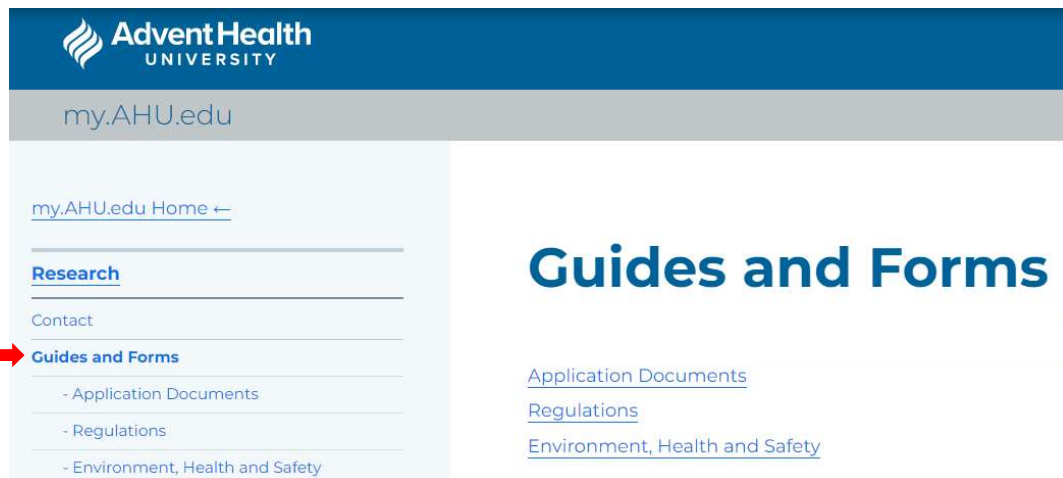
[View Booking App Instructions](#)

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3.3 Where do I find the application documents?

The second page is the **"Guides and Forms"** if you are already on the "Research page" described above, <https://my.ahu.edu/academics/research/guides-and-forms>.

There you will find all the scholarly study application documents that you need to submit a scholarly study (HSR, NHR, QI/QA, and case-scenario). Just click on **"Application Documents."** You will also find regulations and Environmental, Health, and Safety information.



The screenshot shows the my.AHU.edu website. The header features the Advent Health UNIVERSITY logo and the my.AHU.edu URL. The left sidebar contains a navigation menu with the following items: my.AHU.edu Home (with a back arrow), Research, Contact, Guides and Forms (highlighted with a red arrow), Application Documents, Regulations, and Environment, Health and Safety. The main content area is titled 'Guides and Forms' and lists the same three items: Application Documents, Regulations, and Environment, Health and Safety.


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3.4 I have consulted the CARE team, and my documents are ready to be submitted to the SRC, IRB, and/or internal grant review. Where do I submit my proposal?

The third subpage in the Research Website contains the **"Online Submissions."** Click on **"Scholarly Studies and Internal Grant Application."**

Or use the link

<https://my.ahu.edu/academics/research/online-submissions>



my.AHU.edu

[my.AHU.edu Home ←](#)

Research

Contact

Guides and Forms

- Application Documents
- Regulations
- Environment, Health and Safety

Online Submissions

- Scholarly Studies and Internal Grant Application
- Study Change Request Form
- Study Status Report
- Grant Extension Request Form

Funding Resources

- Grant Guidelines and Deadlines
- Research Expense Terminologies and Human Resources Approved Rates
- Faculty Research Seed (FRS) Grant Award Purchasing Procedures

Online Submissions

[Scholarly Studies and Internal Grant Application](#)
[Study Change Request Form](#)
[Study Status Report](#)
[Grant Extension Request Form](#)

Click on "New Study Application" to start the submission of your scholarly project.

Scholarly Studies and Internal Grant Application

Are you submitting an application for a new study, or are you submitting a grant application for a previous study submission?

- ☒ New study application
 ☐ Grant application for previous study submission.

The first page of the form asks for the type of study you are submitting. It will allow the System to guide you to the specific form and ask questions related to the requirements for each type of study.

Scholarly Studies and Internal Grant Application

Select the type of study *

Definitions and additional information will be displayed below when you select a study type.

- ☐ Not sure
- ☐ Human Subject Research (HSR)
- ☐ Non-Human Subject Research (NHSR)
- ☐ Quality Improvement/Quality Assessment (QI/QA), Evidence-Based Practice
- ☒ Case Study/Case Report
- ☐ Literature review and others

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3.5 I already have SRC and IRB approvals. Where do I submit an internal grant application?

The grant application portal is located on the same web page as the SRC and IRB submission, the third subpage in the Research Website called **"Online Submissions."** Click on **"Scholarly Studies and Internal Grant Application."**

Then, select the option **"Grant application for previous study submission."**

The screenshot shows the Advent Health University my.AHU.edu portal. The left sidebar contains a navigation menu with sections: Contact, Guides and Forms, Online Submissions, and Funding Resources. Under Online Submissions, the link 'Scholarly Studies and Internal Grant Application' is highlighted with a red arrow. The main content area is titled 'Scholarly Studies and Internal Grant Application'. It features two radio button options: 'New study application' and 'Grant application for previous study submission', with the latter selected. Below this is a 'Tracking Number' field with a placeholder text: 'Enter the reference number you received from the Research Office when you submitted your previous research project application.' At the bottom, there is a section 'Which type of grant are you applying for?' with checkboxes for 'Graduate Student Research Grant' and 'Faculty Research Seed Grant'.

Or use the link

<https://my.ahu.edu/academics/research/online-submissions/scholarly-studies-and-internal-grant-application>.

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3.6 Where do I find information on internal grants?

The "**Funding Resources**" is the fourth subpage on the Research Website. It contains grant guidelines and deadlines, research expense terminologies, and purchasing procedures.

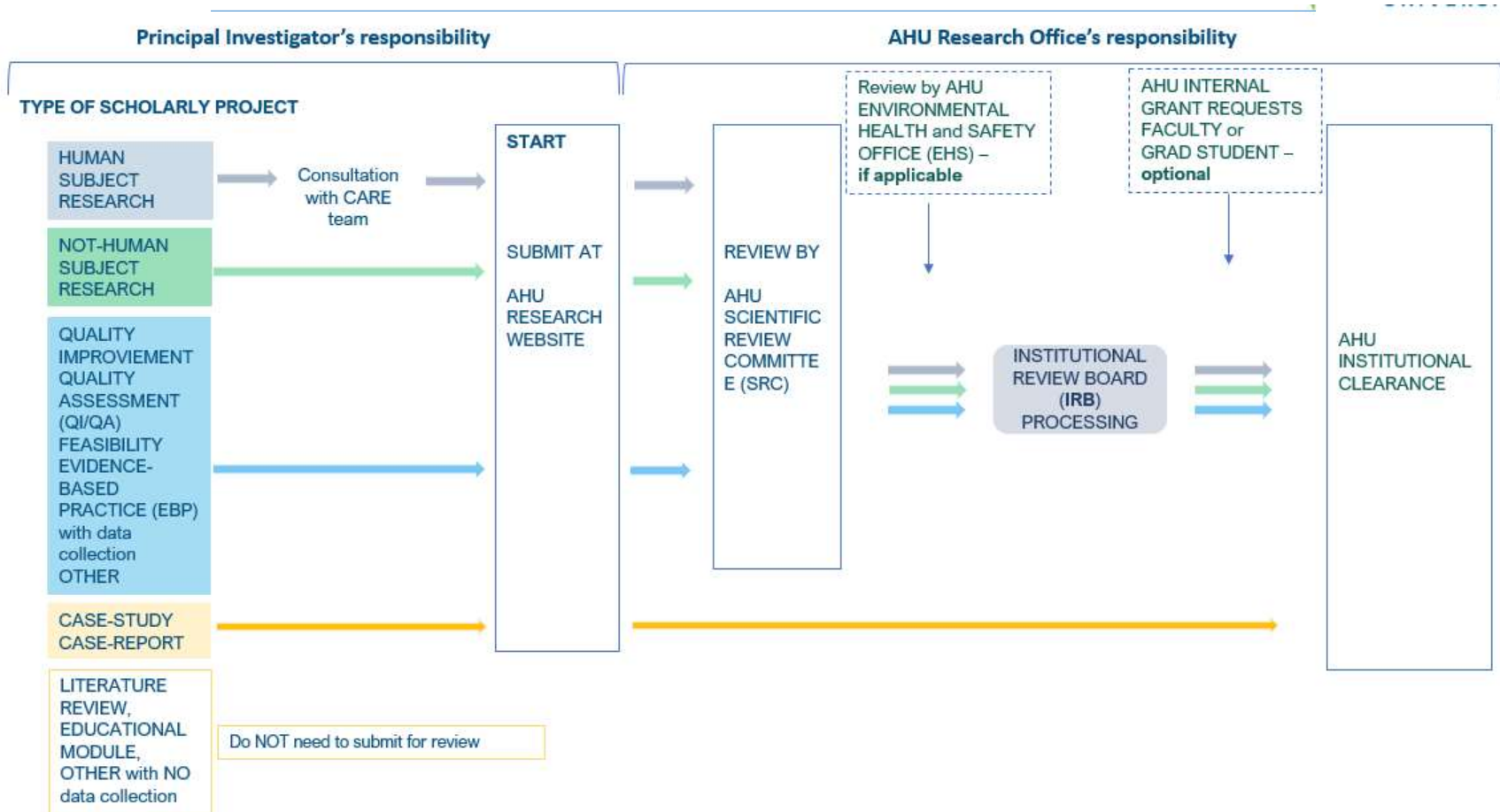
You can access the page also using the link

<https://my.ahu.edu/academics/research/funding-resources>.



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4. Submission and Review Workflow of Scholarly Studies and Internal Grant Application



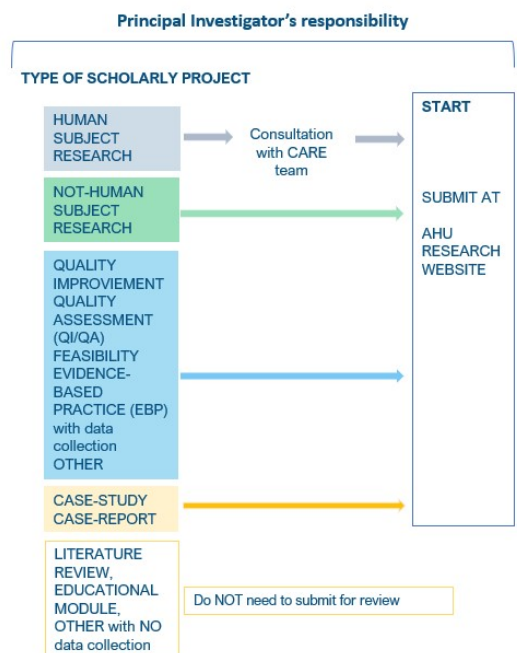
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4.1 Step-by-step of how to submit a scholarly study application to the SRC, IRB, and internal grants:

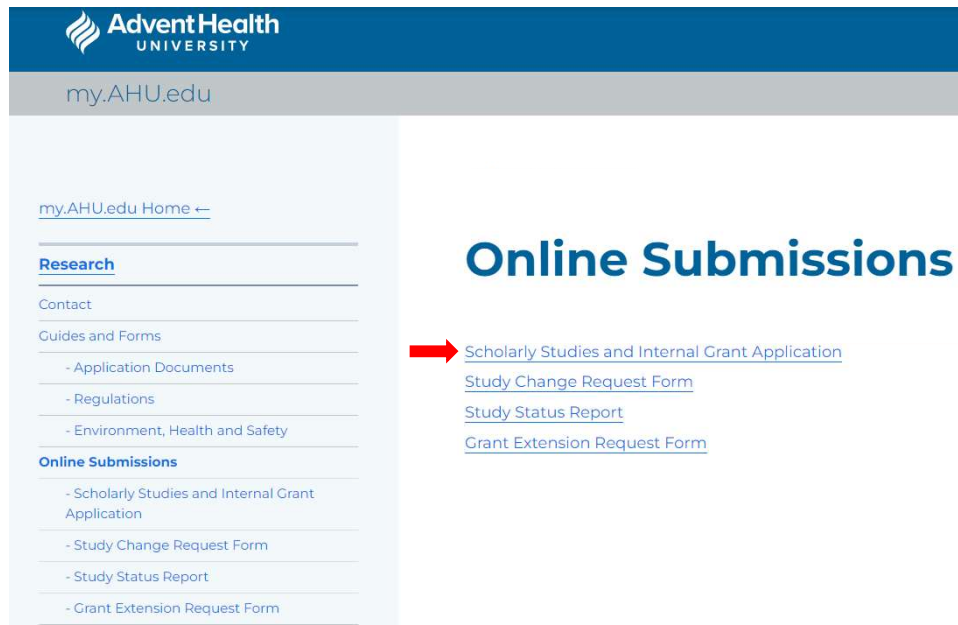
I- If Human Subject Research, the Principal Investigator (PI) consults the CARE team by email:

- Prior to the online submission, the Principal Investigator (PI) communicates with the CARE team by email at AHU.ResearchSupport@adventhealth.com. Find this email also on the Research webpage, under Contact. The team will set up an appointment to meet and help you develop your proposal or help to finalize it. They are experts on scientific merit and regulatory processes. Their consultation will minimize the timeline and back and forth from SRC, IRB, and investigators.
- The CARE team will review and suggest improvements on the proposal, determination forms, consent form/participant agreement, and any other document that may be important for the SRC and IRB review.
- The CARE team will send you a "Clearance letter" when it is a HSR to be submitted online to the Research Office along with the other documents.

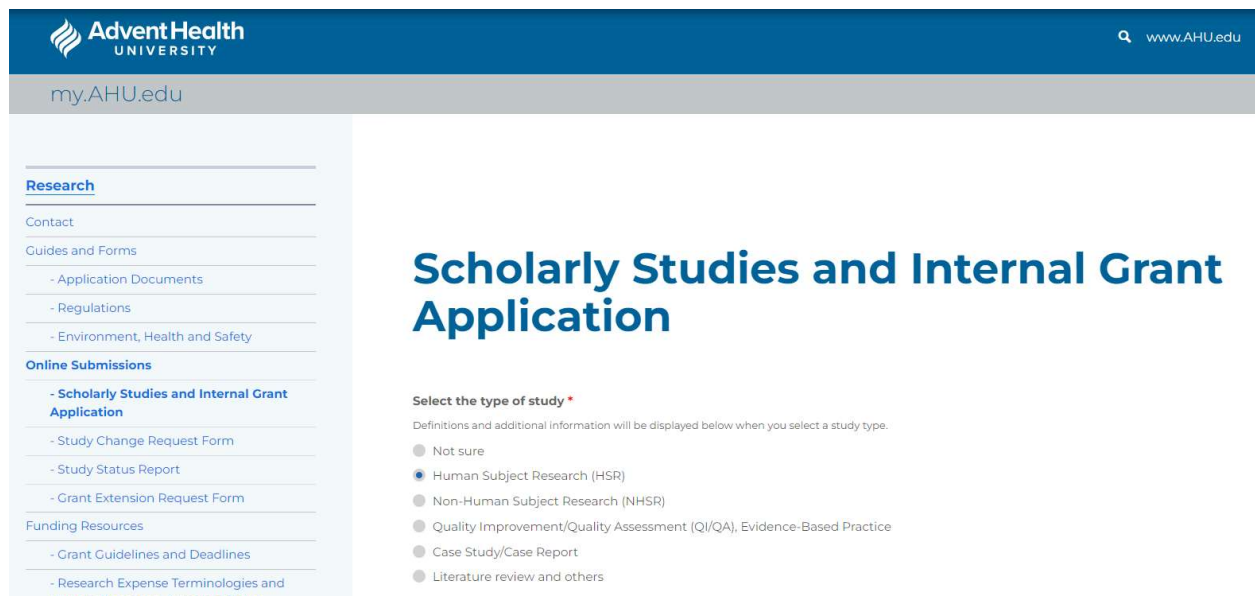
II- Principal Investigator submits the study online:



- Applications for SRC, IRB, and internal grant review must be submitted through the AHU Research Website at <https://my.ahu.edu/academics/research/online-submissions>, clicking on the link **"Scholarly Studies and Internal Grant Application."**

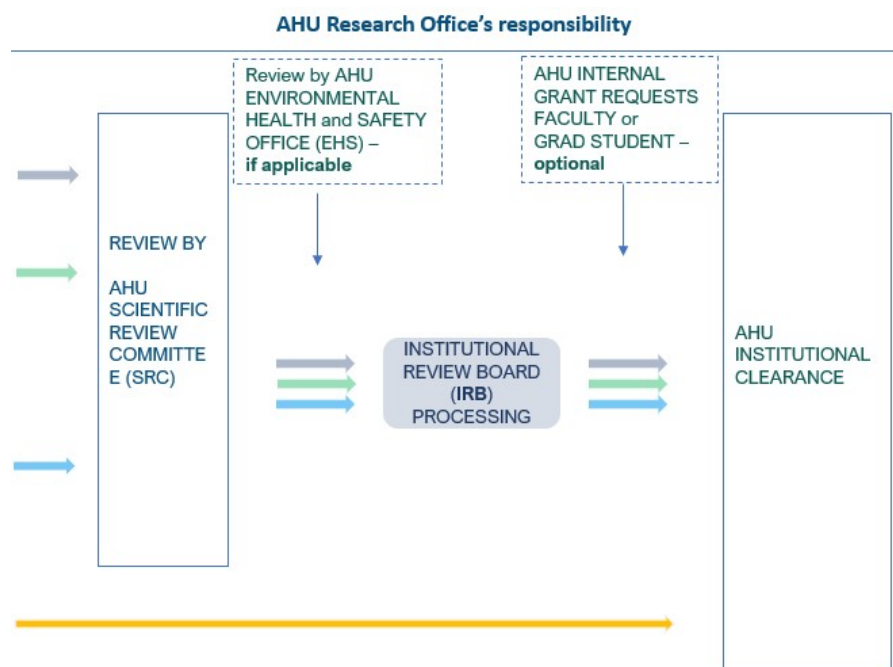


- The application process is auto-explanatory. The first question will be for you to select the type of study. Have all the documents ready to be uploaded.



- When filling in the online application form, a specific question regarding the need for an EHS review will appear as follows:
 - Does your study involve any 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? If yes, your study needs the Environmental Health Safety Office (EHS) approval.
- You will receive an automatic email confirming the submission.
- **The Research Office will receive your online submission and will utilize an initial pre-screening review process, in which it reviews the completeness, compliance, and documents required for research committees to oversee the project.**

III- Research Office submits to the SRC and EHS for review:



The Research Office is responsible for submitting your documents to the reviewing committees.

- The EHS has two types of approvals:
 - Approval

- Disapproval
- The SRC has four types of approvals:
 - 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 may receive an Outlook invitation for a 5-10-minute presentation to the SRC at the next meeting if the proposal score is less than 30 based on the SRC Evaluation Rubric.
- Detailed information on the SRC review criteria may be found in the document "AHU SRC Evaluation Rubric" at <https://my.ahu.edu/academics/research/guides-and-forms/application-documents>.
- The Research Office will inform the investigators of SRC and EHS (if applicable) decisions within 10 working days if there is no need for extra information or actions to complete the review.
- After receiving the SRC approval letter, the PI is responsible for revising the proposal based on the items requested or suggested by SRC and resubmitting the changes by email to the Research Office.

IV- Research Office submits the application to the CARE team for IRB submission:

- The Research Office will submit the application documents to the CARE team.
- The CARE team will review the protocol and other documents, follow up with the PI about the IRB submission process, and discuss the next steps.
- **CARE will be responsible for uploading the documents to IRBNet and notifying the Investigator about the study status.**
- The IRB oversees Human Subject Research.
- IRB has three types of review:
 - Full Board:
 - ✓ applied for more than "minimal risk" to subjects
 - ✓ not covered under other review categories
 - Expedited:
 - ✓ Not greater than minimal risk

- ✓ Fits one of the 9 Expedited Review Categories (defined by federal regulations 45 CFR 46)
- Exempt:
 - ✓ Less than "minimal risk"
 - ✓ Fits one of the 6 Exempt Categories (defined by federal regulations 45 CFR 46)
- The IRB makes the determination if a study is Exempt, Expedited, Greater Than Minimal Risk/Full Board, or Not Human Subject Research.
- The determination of Not Human Subject Research will be conducted for NHSR and QI/QA.
- The Research Office will notify the investigators of the IRB decision.

V- Research Institutional Clearance:

- **The research will not commence until the IRB approval letter is provided and all other required approvals, such as EHS and departments or divisions that require documentation to use their resources.**
- **The Research Office will inform the investigators when the study has received approvals from all the parties.**

VI- Internal Grant application (optional):

- After the application to the SRC is completed, an **automatic option** to select an internal grant will appear. If SRC and IRB already approved the proposal, a grant application can be made separately through the AHU Research Website at <https://my.ahu.edu/academics/research/online-submissions>, clicking on the link **"Grant Application Previous Project Submission."**

SRC and Grant Application

Are you submitting an application for a new research project, or are you submitting a grant application?

- ☐ New project application
- ☒ Grant application for previous project submission.

Tracking Number *

Enter the reference number you received from the Research Office when you submitted your previous research project application.

Which type of grant are you applying for? *

Check all that apply

- ☐ Graduate Student Research Grant
- ☐ Faculty Research Seed Grant

- Suppose Graduate Student Research Grant or Faculty Research Seed Grant application has been selected. In that case, the RO will be responsible for submitting the study proposal to EFSC and will notify all investigators about the summary of the EFSC review.
- The Principal Investigator (PI) will receive an automatic confirmation email upon online submission.
- Research Office will notify the investigators about the EFSC decision on the internal grant

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5. Documents and Requirements for Submission of Scholarly Studies and Internal Grant Application

Templates can be downloaded at <https://my.ahu.edu/academics/research/guides-and-forms/application-documents>.



5.1 Documents

Documents required for Human Subject Research:

- ✓ HRP-200 FORM: Initial Review Application
- ✓ HRP-201 FORM: Research Personnel
- ✓ Appropriate AH Consent Form Template:
 - HRP-500 – Template Consent
 - Or HRP-501 - Template Consent for Minimal Risk Research
 - Or HRP-508 – Template Consent for Exempt Research

- ✓ Appropriate AH Proposal template:
 - HRP-504 - Prospective Research Study Protocol Template
 - Or HRP-504 - Qualitative Research Study Protocol Template
 - Or HRP-504 - Retrospective Research Study Protocol Template
- ✓ Study Site(s) approval letter(s)
- ✓ Chair Certification Letter
- ✓ CARE team Clearance Letter

Documents required for Non-Human Subject Research:

- ✓ AHU Non-Human Subject Research proposal/protocol template
- ✓ IACUC approval from partnering institution if an animal study
- ✓ AH Form: Determination of Human Subject Research
- ✓ Study Site(s) approval letter(s)
- ✓ Chair Certification Letter

Documents required for QI/QA:

- ✓ AHU QI/QA proposal/protocol template
- ✓ Participant Agreement Template, if human participants
- ✓ AH Form: Determination of QI/QA vs. Research
- ✓ Study Site(s) approval letter(s)
- ✓ Chair Certification Letter

5.2 Requirements

Requirements for the submission of HSR to the AdventHealth IRB:

1. Creation of an IRBNet account by all researchers (Principal Investigator, Sub-Investigator(s), and study personnel).
2. Completion of the Collaborative Institutional Training Initiative (CITI) research training requirements, **affiliated with AdventHealth Orlando**, by all researchers (Principal Investigator, Sub-Investigators, and study personnel)
3. Linking of CITI account with IRBNet account

4. Completion of Conflict of Interest (COI) Disclosure and Training. Conflict of Interest forms is **only required for faculty and staff. Students are not required to complete the COI.** Some special situations (federal grants) would have students completing those forms.
5. Completion of Florence Training for the e-Regulatory System. **Florence Training is required for all individuals conducting human subjects research, including students.**

Requirements for the submission of NHSR:

1. Creation of an IRBNet account by Principal Investigator.
2. Completion of the Collaborative Institutional Training Initiative (CITI) research training requirements, **affiliated with AdventHealth University**, by all researchers (Principal Investigator, Sub-Investigators, and study personnel).
3. Completion of Conflict of Interest (COI) Disclosure and Training. Conflict of Interest forms is **only required for faculty and staff. Students are not required to complete the COI.** Some special situations (federal grants) would have students completing those forms.

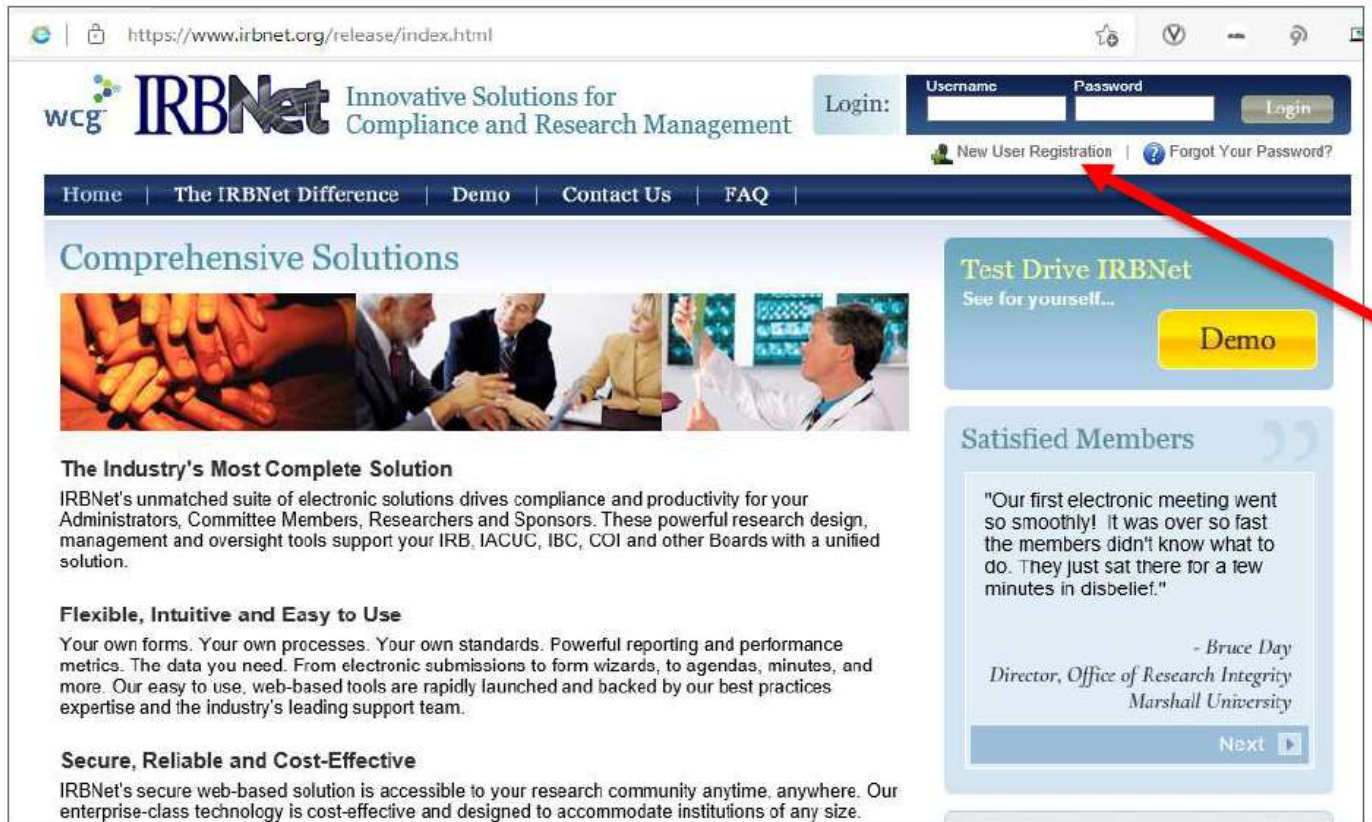
Requirements for the submission of QI/QA:

1. Creation of an IRBNet account by Principal Investigator.

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6. Creation of an IRBNet account:

- Go to www.IRBNet.org
- Click "New User Registration"



- Follow the instructions:
 - Accept the terms of use
 - Add affiliation → Choose **AdventHealth Orlando**.

Welcome to IRBNet

Register Now

Don't have an existing account? Registering is a simple two step process:

1. Complete the registration information below. Once you register you will automatically be sent an activation email to verify that your email address is valid.
2. Click on the link contained within your activation email to verify that your email address is valid and to activate your account.


First Name:

Last Name:

Email Address:

Verify Email Address:

Phone Number:

Your Research Institution or Organization: 

If you do not see your organization listed you may [add a new organization](#).

Choose a Username and Password for your new account. You can use this Username and Password to access all IRBNet services.

Username:

Password:

Verify Password:

- Fill in and confirm your contact information and click "Register."
- Upon registration, you will receive an activation email. Complete activation of your account by using the link received in this email.
- Should you have questions, please contact the AdventHealth IRB Orlando at 407-200-2677 or AH.IRB.general@adventhealth.com.

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7. Completion of the Collaborative Institutional Training Initiative (CITI) research training requirement:

2. Completion of the Collaborative Institutional Training Initiative (CITI) research training requirement:

- Register on www.citiprogram.org – make sure your "institutional email" is the one you check regularly.

English

LOG IN LOG IN THROUGH MY ORGANIZATION **REGISTER**

i Due to planned maintenance, the CITI Program website will be unavailable from 9 p.m. to 1 p.m. Friday July 23rd U.S. Eastern Time (6 p.m. to 8 p.m. U.S. Pacific). We apologize for the inconvenience.

CITI - Learner Registration

Steps: **1** 2 3 4 5 6 7

Select Your Organization Affiliation

This option is for persons affiliated with a CITI Program subscriber organization.

To find your organization, enter its name in the box below, then pick from the list of choices provided.

AdventHealth Orlando

AdventHealth Orlando only allows the use of a CITI Program username/password for access. You will create this username and password in step 2 of registration.

☒ I AGREE to the [Terms of Service](#) and [Privacy Policy](#) for accessing CITI Program materials.

☒ I affirm that I am an affiliate of AdventHealth Orlando.

Continue To Create Your CITI Program Username/Password

- **If Non-Human Subject Research, contact the Research Office for instructions.**

- **If Human Subject Research**, type and 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)
- **If HSR, take the REQUIRED courses (to be completed every 3 years)**
 - "Basic Biomedical" or "Basic Social/Behavioral" depending on the type of research you will be conducting.
 - ✓ Biomedical Research: for research that involves any drugs/devices, medical record data, physical activity, venipuncture, radiation, or the collection of biological samples or physiological statistics.
 - ✓ Social & Behavioral Research: for research involving surveys, interviews, observation, focus groups, etc.
 - ✓ If the study involves both biomedical and social & behavioral research, take the biomedical course.
 - Health Information Privacy and Security (HIPS).
 - ✓ For ALL types of human subject research.
 - Good Clinical Practice (GCP):
 - ✓ **ONLY for** research personnel conducting research subject to FDA oversight or otherwise subject to ICH-GCP research, such as clinical trials of drugs, biologics, and devices, as well as those involved in behavioral intervention and social science research studies.
- CITI training expires every 3 years. You must renew them to maintain your education credentials with the AdventHealth IRB.
- **DO NOT upload CITI certificates to IRBNet. Follow the next item on how to link both accounts.**

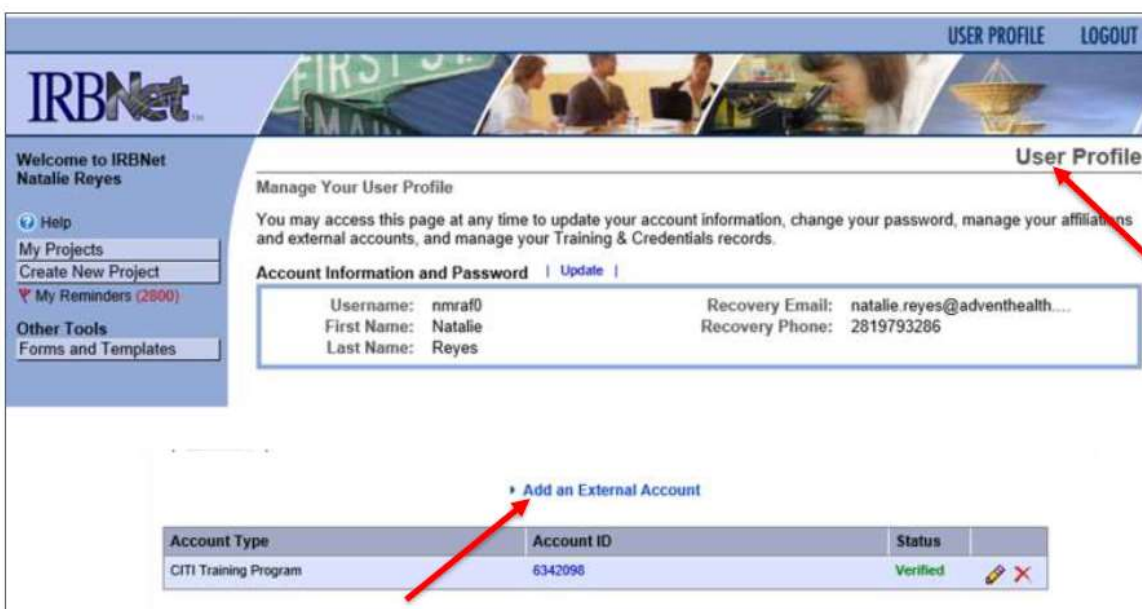
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8. Linking the AdventHealth Orlando CITI account with the IRBNet account

- Log in to your CITI account and get your ID number



- Log into IRBNet (www.IRBNet.org) and navigate to your "User Profile" (on the top right side of your screen).
- Go to the third section down ("External Accounts") and click the link to "add an external account" – you'll need your CITI Member ID number.



Add External Account

Please provide your external account information.

Account Type: CITI Training Program

CITI Member ID:

* Your CITI Member ID is the 5 to 8-digit number shown at the top of the page when you log in to your CITI account.

Continue Cancel

Account Type	Account ID	Status
CITI Training Program	6342098	Verified

- A verification email will be sent to the "institutional email" you entered to open your CITI account. **It may take up to 24 hours for you to receive this email. Make sure you click on the second link in the verification email.**
- Once you have verified this email, your account will be linked, and the status of your IRBNet external account will change to "Verified."

► [Add an External Account](#)

Account Type	Account ID	Status	
CITI Training Program	6342098	Verified	 

- Your CITI certificates will automatically import into IRBNet **within 24 hours.**

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9. Completion of Conflict of Interest (COI)

Disclosure and Training

- All individuals conducting research, EXCEPT STUDENTS, must complete the COI.
- **Contact the Research Office to access the Conflict of Interest Disclosure Form (COI) and training.**
- You will receive an email providing:
 - a) A link to the **CFD Research Conflict of Interest Training** on the Adventist Learning Network (ALN)
 - Once completed, the AdventHealth Office of Research Integrity and AHU Research Office will be automatically notified. No need for any other action.
 - COI training needs to be completed **every 4 years**
 - b) The **COI disclosure form** as a PDF attachment
 - Once completed, submit your COI documentation to the Research Office.
 - **COI disclosure** needs to be completed **annually**.

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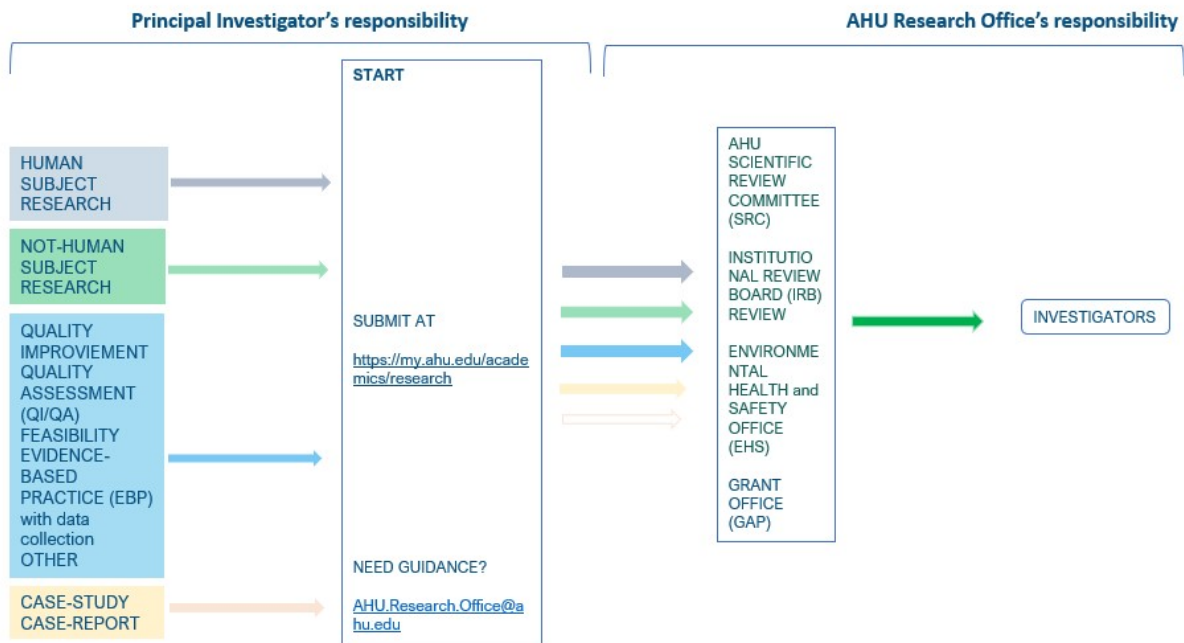
10. Completion of the Florence Training

- All individuals conducting human subjects research must complete Florence Training for the e-Regulatory System, including students.
- Florence is the e-Regulatory tool that AdventHealth uses to store all regulatory documentation.
- **Contact CARE for access to the Florence Training.**
- You will receive an email from the AdventHealth Office of Research Integrity containing the training material as a PDF attachment (this is the training). **There will be Florence training specific for the PI, and all other study personnel will receive Florence training specific for Coordinators (i.e., students and other staff). There is a 2- hour video included in the coordinator training (this is a guide and not mandatory).**
- Once completed, follow the instructions provided in the email:
 - Access the Florence "training" environment login page (<https://uatv2.researchbinders.com/>) by using the link provided
 - Log in (using your AH email and single sign-on), go to My Profile and select SET SIGNING PIN. Florence will send you an email with instructions.
 - Clicking on the email link will direct you to create a 4 DIGIT PIN
 - In Reports, select Signature My Queue and choose the **AHU Binder**
 - Sign the attestation page – the SIGN button will be gray; look for the yellow box, click on it, then click SAVE and enter your PIN in the pop-up window
 - Once you sign, the AdventHealth Office of Research Integrity will be automatically notified. You will be added to the Florence "live" environment, where your study's regulatory documentation will be stored.
 - Since the live environment is a different link than the training environment you previously used, **you will need to reset your signing pin before you can sign documents:**
 - Access the Florence "live" environment (<https://v2.researchbinders.com/#/sign-in>) using the link.

- Go to My Profile and select SET SIGNING PIN. Florence will send you an email with instructions.
- Clicking on the email link will direct you to create a 4 DIGIT PIN
- Florence is a one-time training.

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11. Approved Scholarly Study and Internal Grant Submission of Reports Workflow

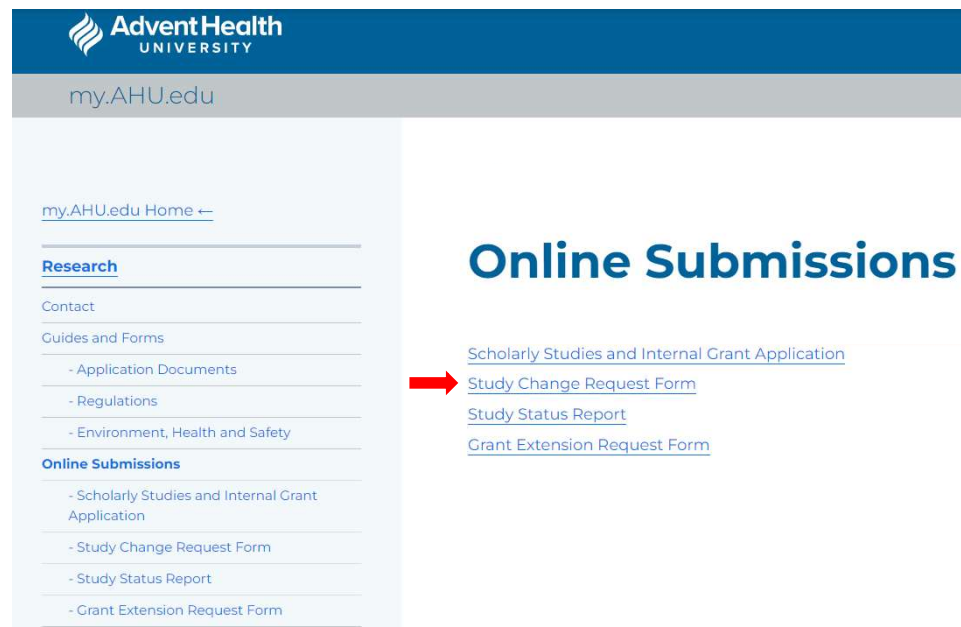


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11.1 Step-by-step of how to submit a scholarly study change request:

Principal Investigator submits the change request online:

- Change request applications must be submitted through the AHU Research Website at <https://my.ahu.edu/academics/research/online-submissions/study-change-request-form>.



- The application process is auto-explanatory. You may download the "Change Request Form Checklist" at <https://my.ahu.edu/academics/research/guides-and-forms/application-documents> to learn about the items in the online form.
- For Human Subject Research, you will also need to upload the HRP203 - Modification Application.

11.2 Step-by-step of how to submit a scholarly study status report:

Principal Investigator submits the status report online:

- Applications of progress report, final Report, or promptly reportable Report must be submitted through the AHU Research Website at <https://my.ahu.edu/academics/research/online->

[submissions/study-status-report.](#)

The screenshot shows the my.AHU.edu website. At the top is the Advent Health UNIVERSITY logo and the URL my.AHU.edu. On the left is a navigation menu with links to my.AHU.edu Home, Research, Contact, Guides and Forms, and Online Submissions. The Online Submissions section lists links to Scholarly Studies and Internal Grant Application, Study Change Request Form, Study Status Report, and Grant Extension Request Form. The main content area is titled 'Online Submissions' and contains the same list of links.

- Then, select the type of Report that you wish to submit.

Report type *

- ☐ Study Progress Report
- ☐ Study Final Report
- ☐ Promptly Reportable Report

- The application process is auto-explanatory. You may download the "Study Progress Report Checklist and Study Final Report Checklist" at <https://my.ahu.edu/academics/research/guides-and-forms/application-documents> to learn about the items in the online form.

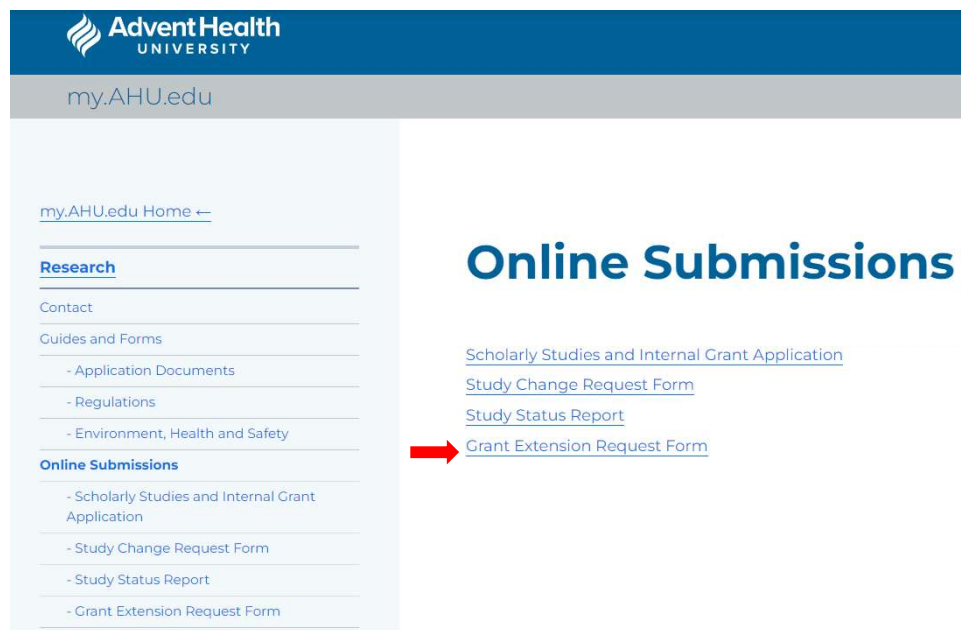
- The Principal Investigator (PI) is responsible for submitting reports for every scholarly study approved by the SRC and/or IRB. Write a comprehensive report communicating information on the findings, dissemination, changes, and issues. Progress Reports must be submitted annually. Final Reports must be submitted according to the schedule outlined in the IRB or grant award letter.

- If the type of scholarly study is Human Subject Research, you will be asked at the end of the progress and final reports to upload the HRP 202 Form – Continuing Review Application.
- Progress Reports must be submitted annually according to the schedule outlined in the IRB approval letter, grant award letter, or the Research Office's request.
- Final Reports must be submitted when a study is complete or discontinued.
- Submit HRP 204 Promptly Reportable Form when needed. Applicable only for Investigators conducting Human Subject Research approved by the IRB.

11.3 Step-by-step of how to submit a grant extension request:

Principal Investigator submits the grant extension request form online:

- Applications for the grant extension request must be submitted through the AHU Research Website at <https://my.ahu.edu/academics/research/online-submissions/grant-extension-request-form>.



12. Documents and Requirements After Approvals

Scholarly Activity Review Process Workflow – Requirements AFTER Approvals



Templates can be downloaded at <https://my.ahu.edu/academics/research/guides-and-forms/application-documents>.

5.1 Documents

5.1.1 Documents required for Human Subject Research:

Note: Retain research records for the greater of 7 years after completion of the research or others as described.

Based on the HRP-070 Investigator Obligations in Research and AHU P&P:

Modifications/changes:

- ✓ HRP-203 - Modification Application

Changes to study personnel:

- ✓ HRP-203 - Modification Application
- ✓ Modify the approved HRP-201- FORM: Research Personnel

Annual Progress or Final Report:

- ✓ AHU Progress Report or Final Report
- ✓ HRP-202 FORM: Continuing Review Application

Based on the HRP-069 Prompt Reporting Requirements in Research):

Prompt Report, within 10 days

- ✓ HRP-204 Promptly Reportable Information

5.1.2 Documents required for Non-Human Subject Research, Quality Improvement/Quality Assessment, Case Report/Case Study:

Annual Progress or Final Report:

- ✓ AHU Progress Report or Final Report

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