Research Submission Guideline

Ahu.Research.Office@ahu.edu
Room CC340

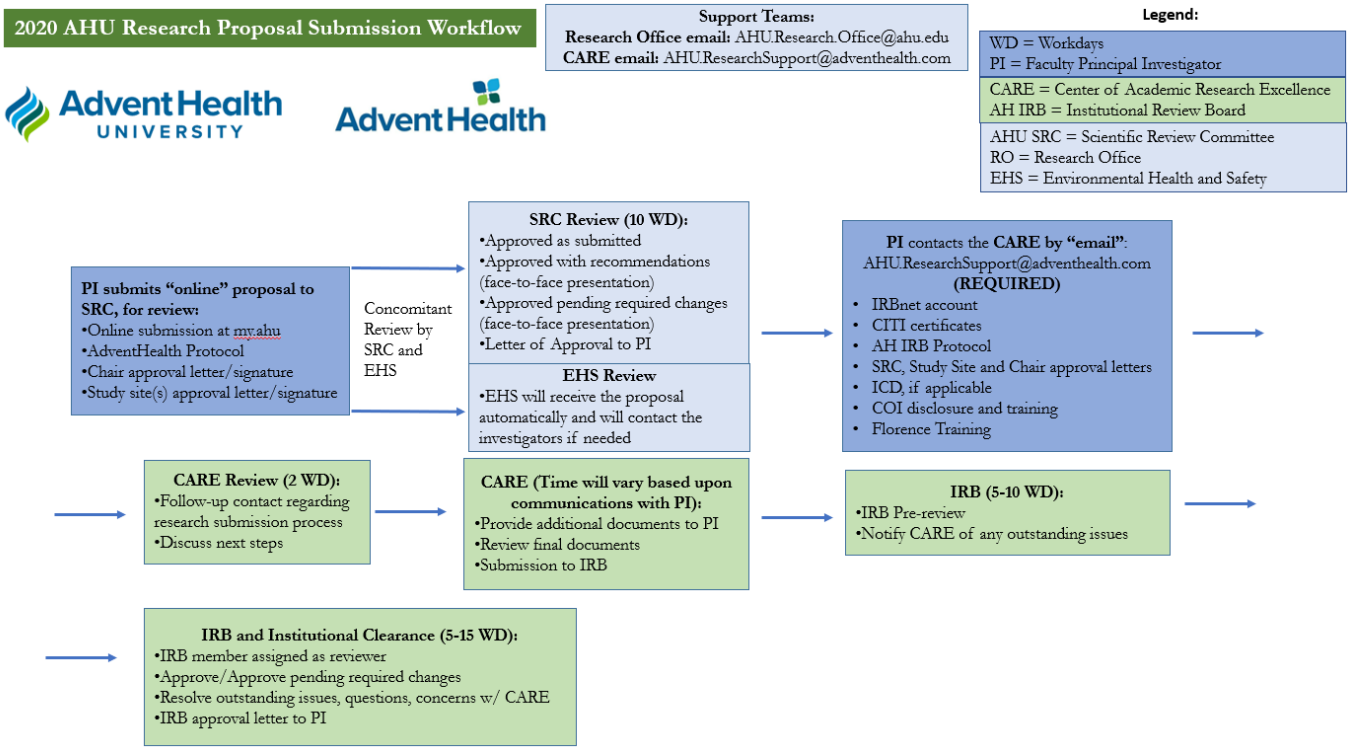
AHU Web-based Research Proposal Process and Timeline

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. **Center for Academic Research Excellence (CARE):** 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.

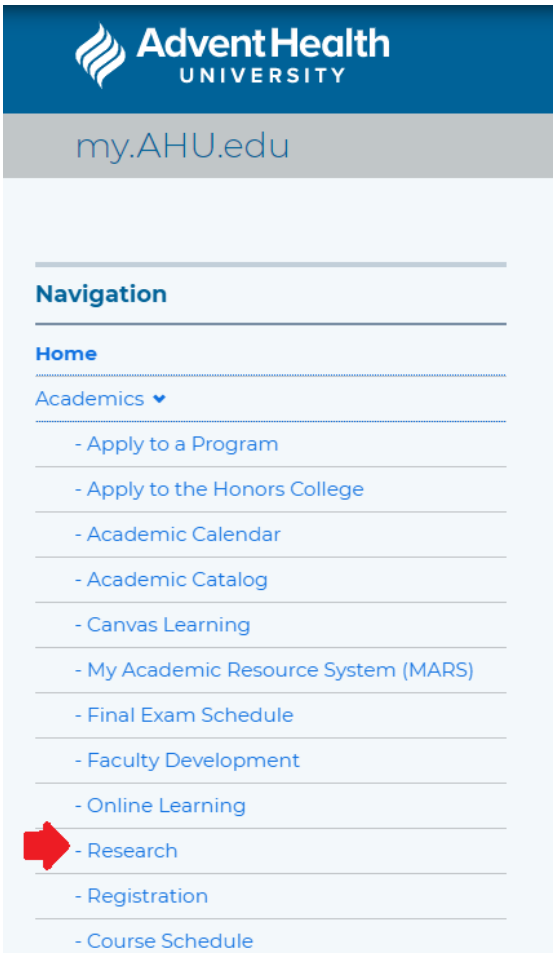
RESEARCH SUBMISSION AND REVIEW WORKFLOW



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

I- PI submits proposal to the SRC (and EHS, if applicable) for review:

- The minimal documents required by SRC (and EHS, if applicable) 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".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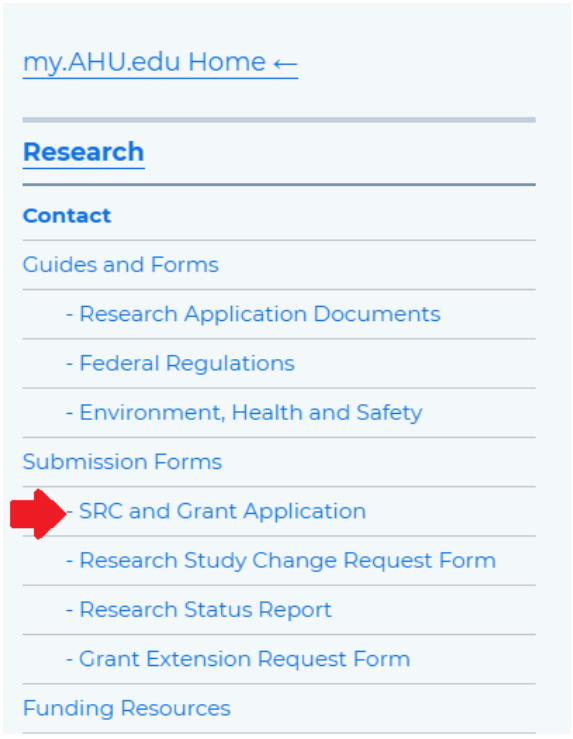
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Research
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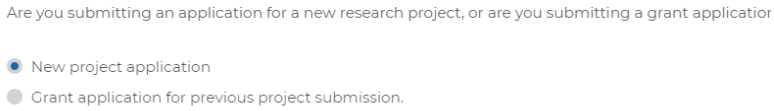
Funding Resources

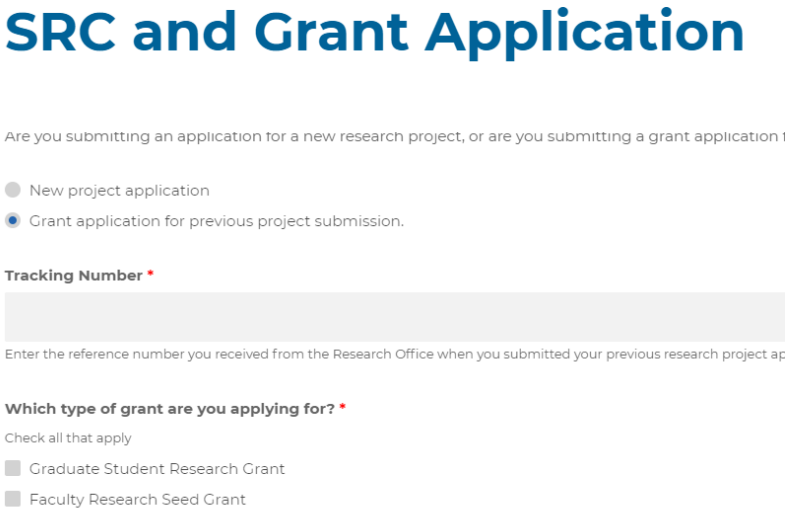
SRC and Grant Application



- 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 approval from Environmental Health Safety Office (EHS).
- 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.
- SRC and EHS (if applicable) decisions are announced within 10 working days. 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.
- For 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/research-application-documents.
- 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.

II- Internal Grant application (optional):

- After completion of the application to the SRC, an **automatic option** to select internal grant will appear. If the proposal was already approved by SRC and IRB, a grant application can be done separately through the AHU Research Website at https://my.ahu.edu/academics/research/submission-forms, clicking on the link "Grant Application Previous Project Submission".



- If Graduate Student Research Grant or Faculty Research Seed Grant application had been 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.
- RO will notify the investigators about the EFSC decision on the internal grant application. The review timeline is dependent on the type of grant.

III- PI submits proposal to CARE for review and submission to the IRB:

- After receiving the SRC approval letter, the PI will be responsible for revising the proposal based on the items requested or suggested by SRC before submission to CARE.
- The PI **must contact CARE by email** at AHU.ResearchSupport@adventhealth.com **for review and IRB submission.**

- CARE will review the protocol and follow-up with the PI about the IRB submission process and discuss the next steps.
- PI will submit to CARE:
  - 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)
- **CARE will be responsible to upload the documents to IRBNet and notify the investigator about study status**.
- The IRB oversees Human Subjects Research Human Subjects Research studies require IRB review and approval.
- 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)

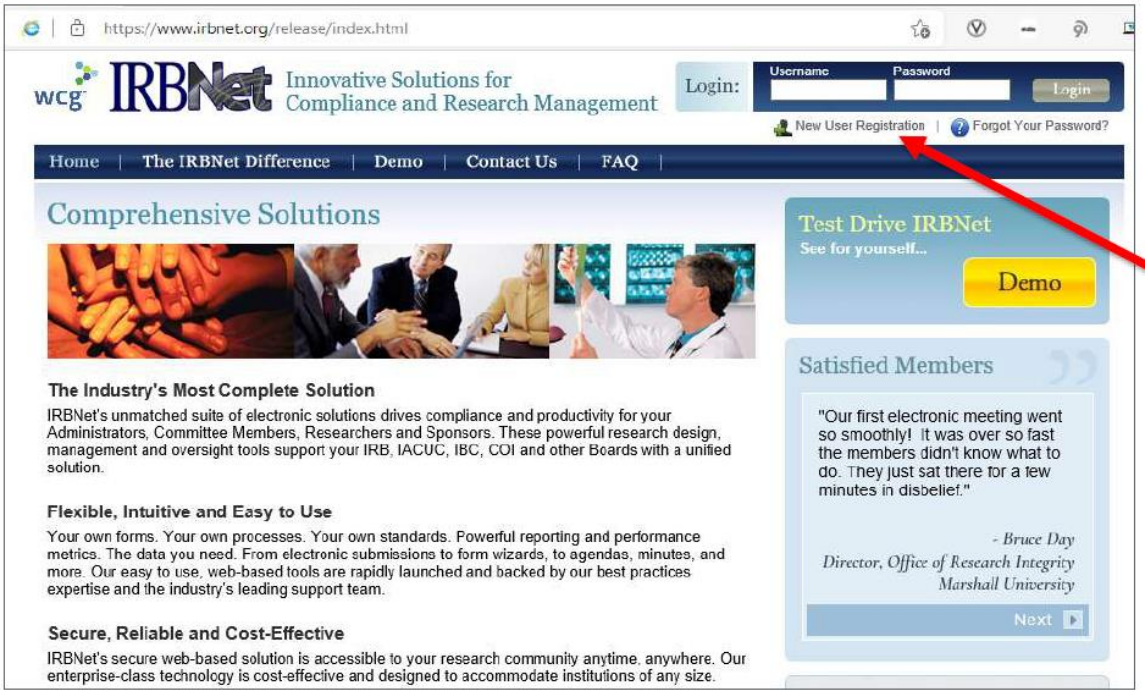
IV- Basic requirements for the submission of human research studies to the AdventHealth IRB:

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 are **only required for faculty and staff. Students are not required to complete the COI.** There are some special situations (federal grants) that 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.**

1. 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**.

- Fill and confirm your contact information and click "Register"

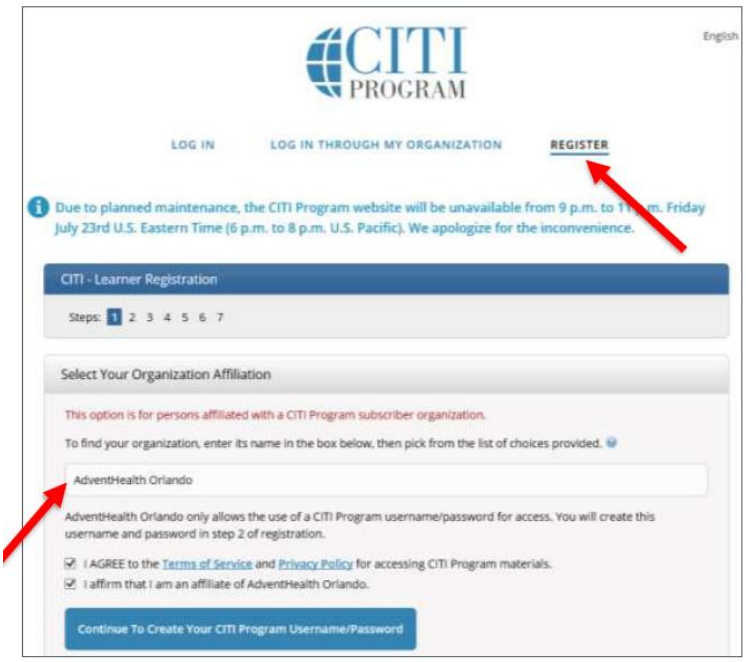
○ Upon registration, you will receive an activation e-mail. Complete activation of your account by using the link received in this email.

○ Should you have questions, please contact the AdventHealth IRB Orlando at 407-200-2677 or AH.IRB.general@adventhealth.com.

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.

○ 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)

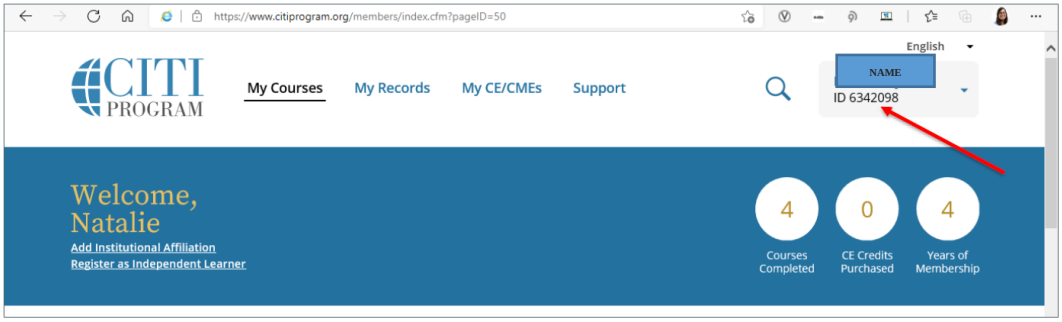


- **Take the** REQUIRED courses (to be completed every **3 years**)
  - "Basic Biomedical" or "Basic Social/Behavioral" depending on the type of research that you will be conducting.
    - ✓ Biomedical Research: for research that involves any drugs/devices, medical record data, physical activity, venipuncture, 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.

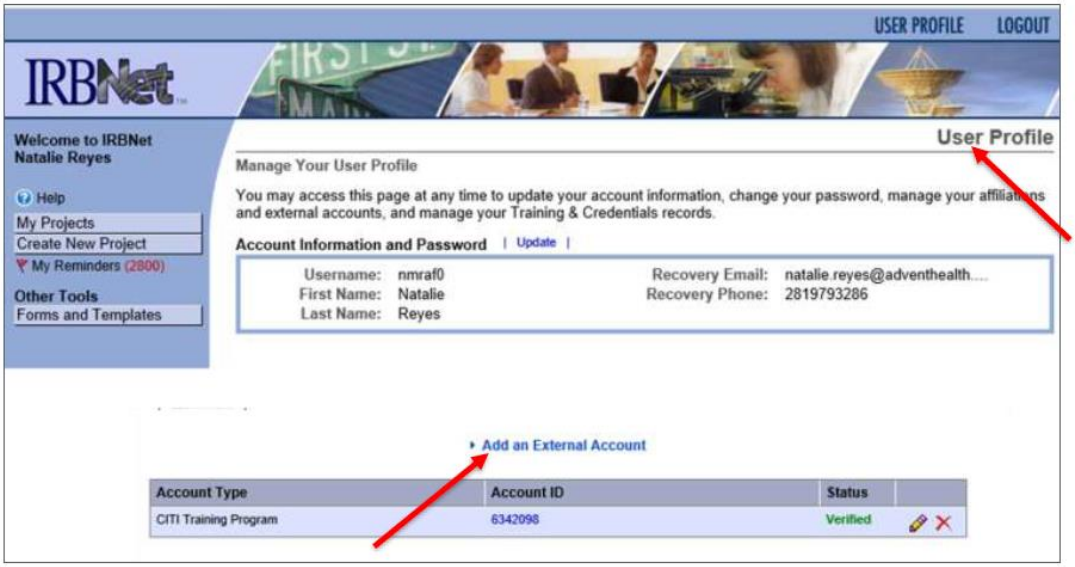
- CITI trainings expire every 3 years. You must renew them to maintain your education credentials with the AdventHealth IRB.
- **DO NOT upload CITI certificates to IRBNet. Follow the next item on how to link both accounts.**

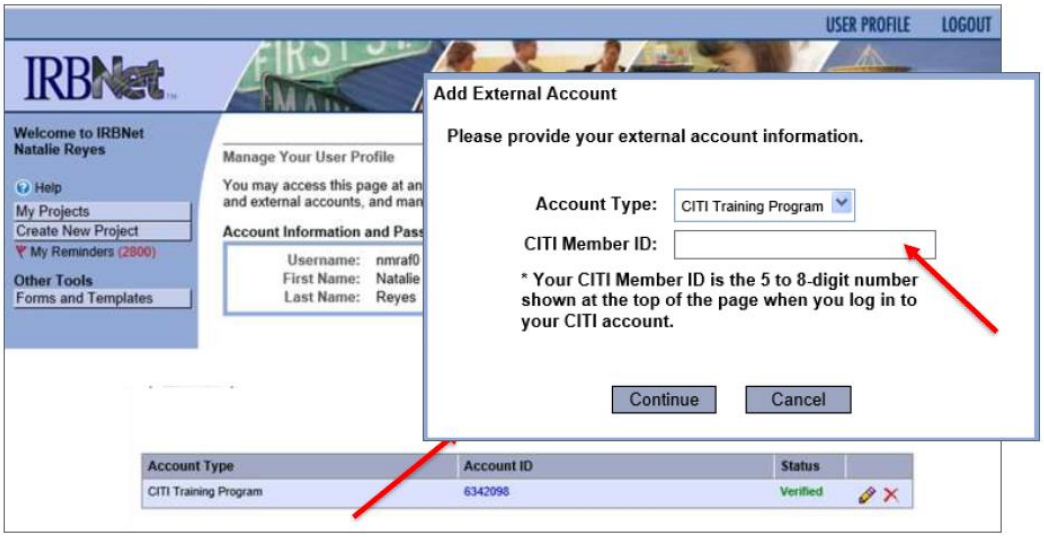
3. Linking the AdventHealth Orlando CITI account with the IRBNet account:

- Log in your CITI account and get you 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.





- A verification email will be sent to the "institutional email" you entered to open your CITI account. **It may take up you 24 hours for you to receive this e-mail. 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".

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

4. Completion of Conflict of Interest (COI) Disclosure and Training

- All individuals conducting research, EXCEPT STUDENTS are required to complete the COI.
- **Contact CARE for access to the Conflict of Interest** Disclosure Form (COI) and training.
- You will receive an email from the AdventHealth Office of Research Integrity 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 will be automatically notified. No need of 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 Office of Research Integrity (ORI) at AH.ORI@adventhealth.com **with copy to the CARE team** at AHU.Researchsupport@adventhealth.com
- COI disclosure needs to be completed **annually.**

5. 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 that is 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 and 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 re-set your signing pin before you can sign documents:**
  - Access the Florence "live" environment (https://v2.researchbinders.com/#/sign-in) by using the link provided.
  - 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.

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.