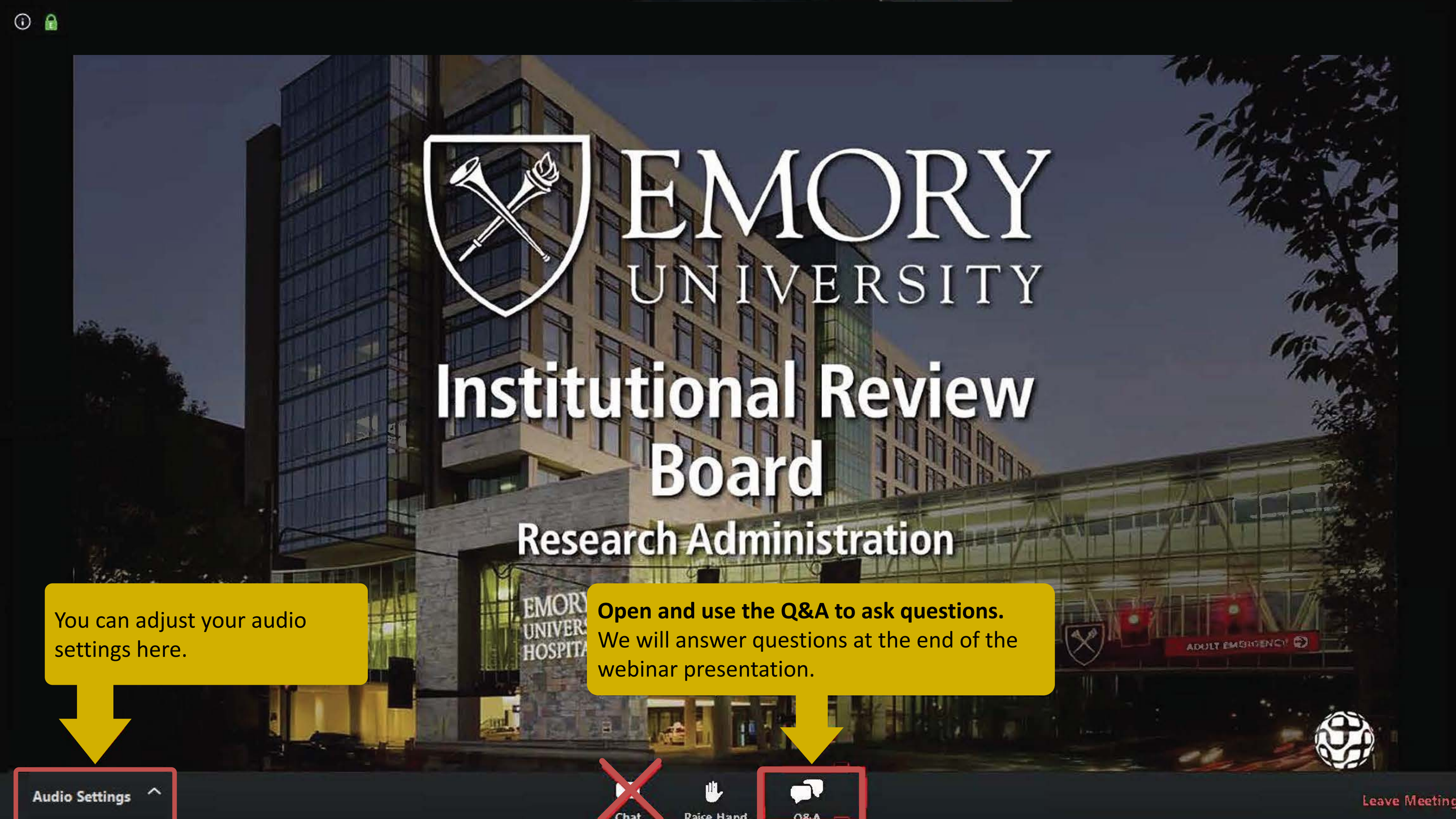
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Open and use the Q&A to ask questions.
We will answer questions at the end of the webinar presentation.
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Q&A
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VA Research Studies: How are they different from Emory studies

By: Brianna Wong

Overview

Brianna Wong, CCRC

Atlanta VA/Emory IRB Liaison

13+ years of research experience in phase I through phase IV studies including industry and CSP studies. Experience ranging from recruitment and study visits to regulatory and team management, including extensive knowledge of GCP guidelines and regulations, design and implementation of policies, and oversight of clinical trials. She is skilled in research regulatory knowledge and implementation, collaboration between teams and other stakeholders as well as creating and developing effective tools and documents, including electronic data capture systems, to assist in the successful conduct of clinical trials. Since her start at the Atlanta VA in 2015, she has held several roles in the research department including Research Coordinator, Interim Associate Director of NODES, NODES Enrollment Manager and currently, the VA/Emory IRB Liaison.

New Study Submissions

Project Submission Process

1. Create IRBNet Project
2. Download the Checklist in IRBNet for the IRB of Record
3. Create IRB Application in the IRB's system –DO NOT SUBMIT
4. Add VA required forms to IRBNet package
5. Add IRB forms to IRBNet package
6. Submit to IRBNet
7. HS/PO/ISSO Pre Review
8. Pre-Review Sign-Off and Authorization to Submit to IRB
9. Submit to IRB (This may be in IRBNet or in another portal depending on which IRB is being used)
10. IRB Review and Approval
11. Project in IRBNet is unlocked after Pre-Review Sign-Off
12. **IRBNet Project is updated with final documents from IRB**
13. **Submit IRBNet Project**
14. PO/ISSO Post-Review
15. R&D Committee Review and Approval
16. ACOS/R Letter

BOLDED items are performed by the submitters. Non bolded items are performed by reviewers.

Emory IRB

Create eIRB and IRBNet (VAIRRS) submission at the same time **2 duplicate Submissions**

Follow eIRB checklist under the Atlanta VA Healthcare System Research Administration Library on IRBNet (VAIRRS) for documents needed.
Be sure to submit complete package to the Atlanta VA Research Administration Board

VA Pre-Review and PO/ISSO Review

When complete, you will receive a General Determination letter in IRBNet (VAIRRS)

Address changes based on General Determination letter and changes requested in eIRB

Changes required by PO/ISSO will be listed in the General Determination letter. Other changes required by the IRB Liaison will be listed in a comment in your eIRB submission.

IRB approval obtained

Save your approval letter and documents to upload into IRBNet (VAIRRS) for the post-review and R&D review.

VA Post-Review/R&D review and Final Approval

PO/ISSO will review again for any changes that needed to be made. R&D meets once monthly. You may not begin work on project until you have your R&D approval letter.

What is the difference between IRB of record and IRBNet (VAIRRS)?

- For VA research studies, your IRB of record is one of the following: Emory IRB, NCI CIRB, the VA Central IRB, Advarra, or WCG.
- This is the committee who reviews and approves your project, however, they do not provide final permission for you to conduct your study at the VA (VA R&D approval).
- You must have both IRB and VA R&D approval to conduct your study at the VA.
- For submissions made to the Emory IRB, you will submit to BOTH IRBNet (VAIRRS) AND eIRB.

- IRBNet (VAIRRS) is NOT the IRB
- IRBNet (VAIRRS) is the VA system used to track pre-reviews, post-reviews, and R&D reviews

Common Problems with New submissions

New study submissions can be daunting if you don't know where to find the resources to help you. Luckily, there are a ton of resources available to you to use.

Check out the Emory IRB website and the VA research SharePoint Website for helpful resources.

Problem 01

Staff listed on study who are not VA research credentialed/ credentialing needs updating

Problem 02

Not using the Emory protocol templates (*New Biomedical Protocol) and VA ICF/HIPAA templates

Problem 03

Not submitting the VA Pre-Review before submitting to the eIRB

Problem 04

Not completing HIPAA Waiver Request forms correctly. For exempt VA only studies, there is a different HIPAA Waiver Request form

IRB Meetings

IRB Meetings must be able meet quorum in order to meet

All study submissions must be ready for submission 2 weeks prior to the meeting to allow the reviewers ample time to review

VA Studies may only be reviewed on the following committees (Biomedical) *No studies may be reviewed on the socio-behavioral committee.

Meetings Schedule

B1	B2	A2	B3
1st Wednesday	2nd Thursday	3rd Wednesday	4th Tuesday

How long will it take for my VA study to be approved?

Remember that you may NOT start working on your project until the project has gone through ALL of the reviews (VA pre-review in IRBNet/VAIRRS, eIRB review and approval, VA post-review in IRBNet/VAIRRS, R&D review and approval in IRBNet/VAIRRS). You must have your R&D approval letter in order to start work!

"Exempt" does NOT mean exempt from initial IRB and R&D review!!

While there may be multiple options for IRB review, there is only 1 R&D review (no exempt or expedited R&D review). R&D meetings only occur ONCE PER MONTH.

IRB Exempt

2-3 months

- Must be reviewed initially by a designated reviewer.
- Must still obtain R&D approval before start
- Do not generally need further IRB review after initial approval, but some modifications may still require review.

IRB Expedited

2-3 months

Most minimal risk studies that fall within one of the allowable expeditable categories

IRB Full Board

3-6 months

Greater than minimal risk studies or anything that does not fall clearly within one of the expeditable categories

Staff Changes at the VA

Study Staff Adds/Removals

1. When do I need to submit staff changes?
2. How do I submit staff changes?
3. What systems do I enter staff changes in?
4. Who needs to be added as staff on the study?
5. When does staff not need to be added under study staff?
6. DUAs and HIPAA Authorizations- how they relate to staff changes

Check out the Emory IRB website and the VA research SharePoint Website for helpful resources.

Problem 01

Staff listed on study who are not VA research credentialed/ credentialing needs updating

Problem 02

Not entering staff changes in eRRRP

Problem 03

Not checking protocol for staff changes that need to be made

Problem 04

Not understanding what your HIPAA Authorization covers

Staff Changes

Adding Staff

- Separate modification or at the time of continuing review
- Staff members may not work on the research project until they are approved by IRB.
- PI changes must go through additional designated review and take longer for approval (these modifications should be set up as modifications to “other parts of the study” in the current system.
- You may have a staff ONLY modification open at the same time as any other modification/CR (max of 2 open submissions).
- eRRRP approval must be provided before IRB add approval
- If adding/changing a VA PI/Co-I, you must submit a FCOI to IRBNet

Removing Staff

- Removal of staff in eIRB comes first
- eRRRP submission to remove staff after eIRB approval
- What if study is in paper writing stages?
  - Is the study staff and/or PI still accessing PHI?
    - No- you can close the study with eIRB, but keep open with VA R&D
    - Yes- Keep open and keep only staff accessing PHI on staff list. Anyone no longer accessing PHI may be removed from staff.

DAC Members

- All DAC members who will be helping with the study must be listed as study staff. They will access PHI
- Remember, if you plan to use DAC, you must have a way to fund the use of the DAC. Unfunded studies need to have a justification for how they will be paying for the DAC.

Adding Staff at the VA

These are several items that need to be checked before submitting a modification to add a staff member to your study in eIRB. If these are not complete, the addition will not be processed.

01

Does the staff member have an Emory sponsored account and have they logged into eIRB using their account in the last 30 days? (If they haven't logged into the eIRB using their Emory account, their name will not show up as an option to add)

02

HAS THE STAFF MEMBER COMPLETED ALL VA RESEARCH CREDENTIALING AND REQUIRED CITI TRAINING? THESE ARE SEPARATE ITEMS. CONFIRM WITH TEDRA RICKS (TEDRA.RICKS@VA.GOV) IF YOU ARE NOT SURE IF THE STAFF MEMBER HAS COMPLETED ALL VA RESEARCH CREDENTIALING. THE STAFF MEMBER MUST HAVE A CURRENT SCOPE OF PRACTICE UNDER THE VA INVESTIGATOR'S NAME (OR A LISTED CO-I ON THE STUDY). THE CITI EMORY TRAINING AND VA TRAINING ARE NOT INTERCHANGEABLE.

03

Has a staff add been submitted to eRRRP for the staff addition and been approved by the CO? This approval will need to be submitted in your submission or emailed to me (Brianna.Wong@va.gov) as confirmation.

04

Has the IRB Staff Matrix been updated and uploaded to your submission? This is required for projects that list more than just the VA as a research location.

Atlanta VAMC IRB Staff Assignment Matrix

Emory IRB Study #

- Please check the box below for each site where a staff member is engaged in Human Subject research (has access to Protected Health Information (PHI) or access to patients). Persons not engaged in Human Subjects research (no PHI/Participant access) should not be listed in eIRB. Principal investigators are responsible for
- ensuring that their study staff are current with ALL training requirements. Log a comment on the study's main eIRB history page and attach the completed matrix to that comment. This form must be updated and
- re-posted in a new comment each year at continuing review.

Staff Member's Full Legal Name	Atlanta VAMC Assignment PHI/Participant access	Emory/other assignment PHI/ Participant Access

DUAs/HIPAAs/Staff not accessing PHI

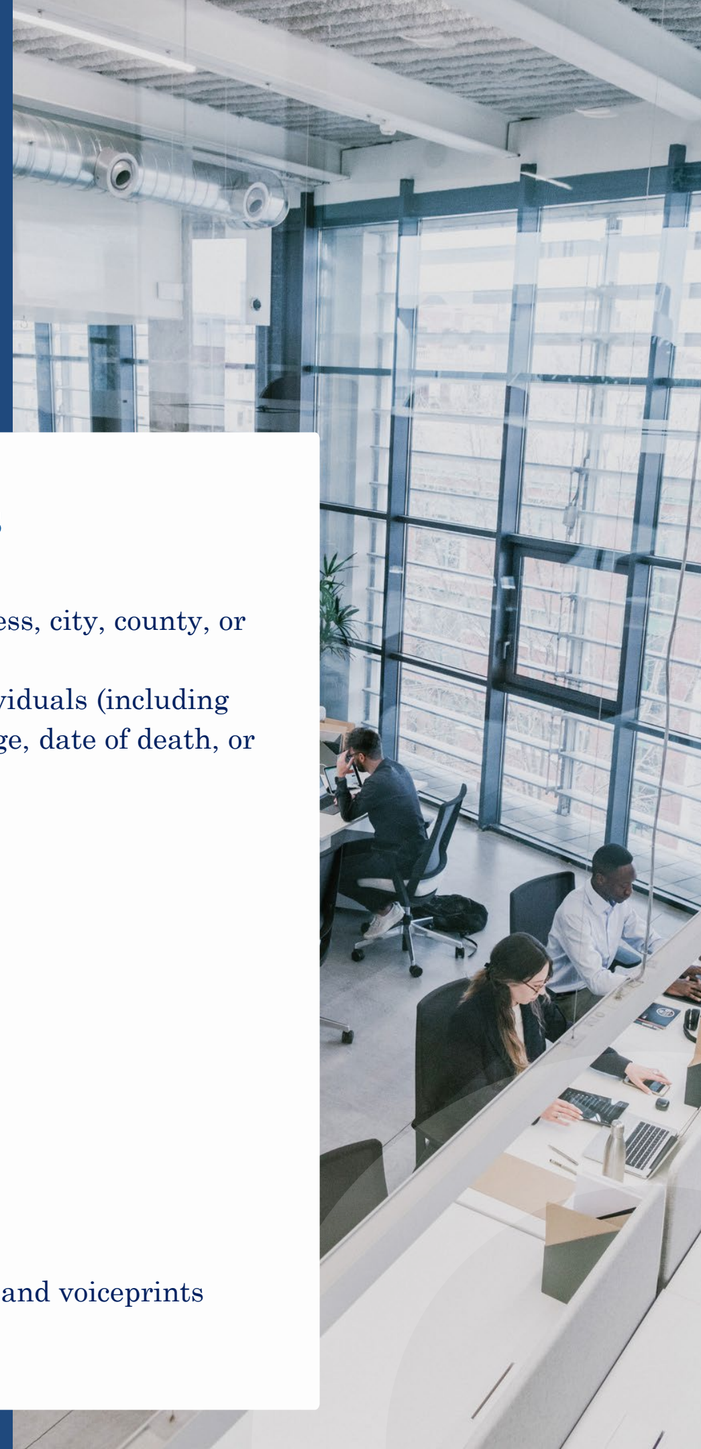
"Accessing PHI" is the key term

What if I have a DUA/HIPAA Authorization?

- Staff/groups listed on a DUA do not need to be listed as staff on your submission if they will not be accessing PHI.
  - If they are accessing PHI, list them under "External Staff members"
    - "External staff members" should ONLY be used for DUAs and Staff under a Reliance Agreement. All other study staff must be listed under the main study staff section (must have a sponsored Emory account)
- Staff/groups listed on a HIPAA Authorization do not need to be listed as study staff
- For questions on DUAs, contact Ashley Scales at Ashley.Scales@va.gov
- VHA handbook 1200.12 on DUAs
- VHA data portal for DUAs

PHI Categories

Patient names
Geographical elements (such as a street address, city, county, or zip code)
Dates related to the health or identity of individuals (including birthdates, date of admission, date of discharge, date of death, or exact age of a patient older than 89)
Telephone numbers
Fax numbers
Email addresses
Social security numbers
Medical record numbers
Health insurance beneficiary numbers
Account numbers
Certificate/license numbers
Vehicle identifiers
Device attributes or serial numbers
Digital identifiers, such as website URLs
IP addresses
Biometric elements, including finger, retinal, and voiceprints
Full face photographic images
Other identifying numbers or codes



Amendments that require additional reviews by VA PO or ISSO

The following situations require an amendment submission in IRBNet/VAIRRS for VA Pre-review and Post-review, in addition to the eIRB submission:

- Any change in HIPAA Authorization
- Any change in location from where data is collected (ex. You will now be using VINCI instead of just clinic lists in CPRS)
- Change in method of data collection/storage (change in software or storage location)
- Addition of or changes in app or software used to conduct the study
- Any change that would change any information on your VA PO 10-250 form or your ERDSP wizard

- You must submit to IRBNet/VAIRRS and obtain approval prior to the IRB submission being processed.

- If your submission will need VA PO review, be sure to submit a new VA form 10-250 with the submission as well as any documents that reflect the changes (protocol, consent form, HIPAA Authorization, etc.)

- Once you receive your General Determination letter with pre-review approval, you should submit in eIRB and include your approval documents.

- After IRB approval, you must submit back to IRBNet/VAIRRS for the post-review and obtain approval (either the VA form 10-250 will be signed and published or the ERDSP wizard will be approved- another letter is not published for these amendment changes), prior to implementing the changes.

CONTINUING REVIEWS

Common problems with Continuing Reviews

Continuing Reviews should be submitted 30 days in advance of the study expiration date, at a minimum, but preferably 45 days in advance.

You will begin to receive communication from me 60 days in advance of your study's expiration.

If your study lapses in approval, you must stop all research activities on the project immediately and submit an RNI for the lapse.

Problem 01

Staff Credentialing is not up to date.

Please keep track of your staff credentialing using the VA Research Staff Training Log in your Regulatory Documents

Problem 02

Proper Study Status Choices not selected

Problem 03

Numbers don't match from last continuing review

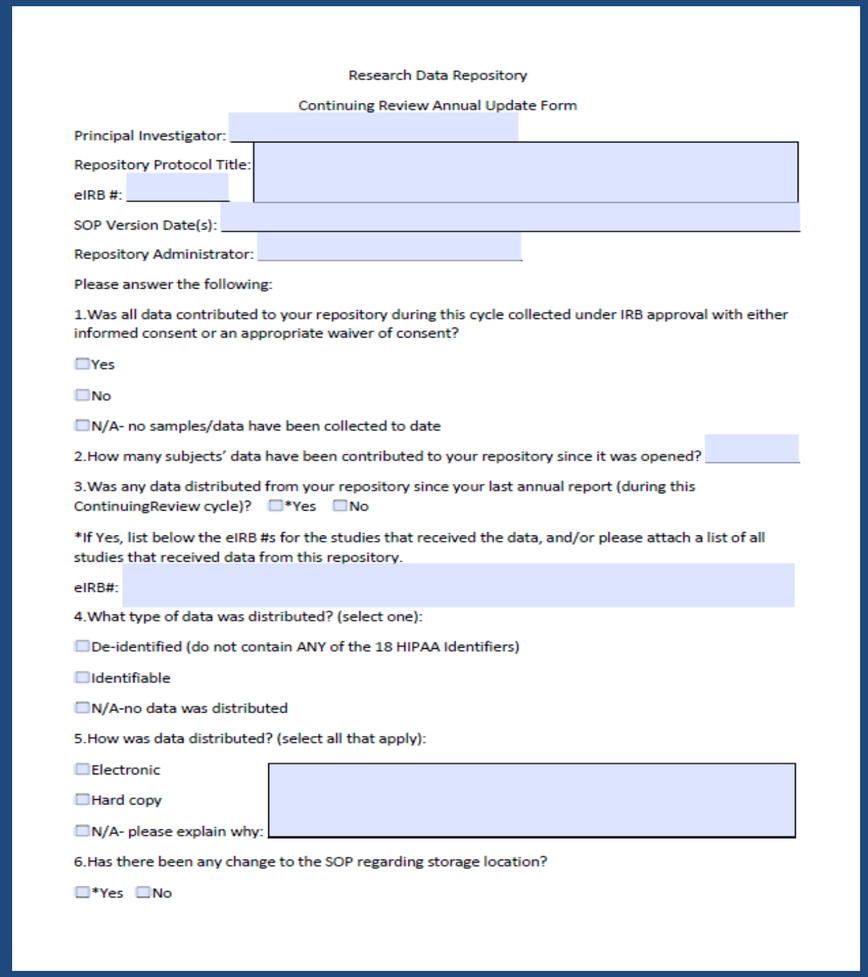
RESEARCH STAFF TRAINING LOG
Atlanta VA Medical Center

Staff Name	
Protocol Title	
Principal Investigator	
Research Coordinator	
IRB Number	

Staff Name	List VA Required Training and Study Relevant Training	Date

My VA study is/involves a data repository. Is there anything extra that I need to do at the VA?

Yes! For data repositories, you must submit the VA data repository worksheet at continuing review. Additionally, you must submit the data repository worksheet on a yearly basis to IRBNet/VAIRRS.



Research Data Repository

Continuing Review Annual Update Form

Principal Investigator:

Repository Protocol Title:

eIRB #:

SOP Version Date(s):

Repository Administrator:

Please answer the following:

1.Was all data contributed to your repository during this cycle collected under IRB approval with either informed consent or an appropriate waiver of consent?

☐Yes

☐No

☐N/A- no samples/data have been collected to date

2.How many subjects' data have been contributed to your repository since it was opened?

3.Was any data distributed from your repository since your last annual report (during this ContinuingReview cycle)? ☐*Yes ☐No

*If Yes, list below the eIRB #s for the studies that received the data, and/or please attach a list of all studies that received data from this repository.

eIRB#:

4.What type of data was distributed? (select one):

☐De-identified (do not contain ANY of the 18 HIPAA Identifiers)

☐Identifiable

☐N/A-no data was distributed

5.How was data distributed? (select all that apply):

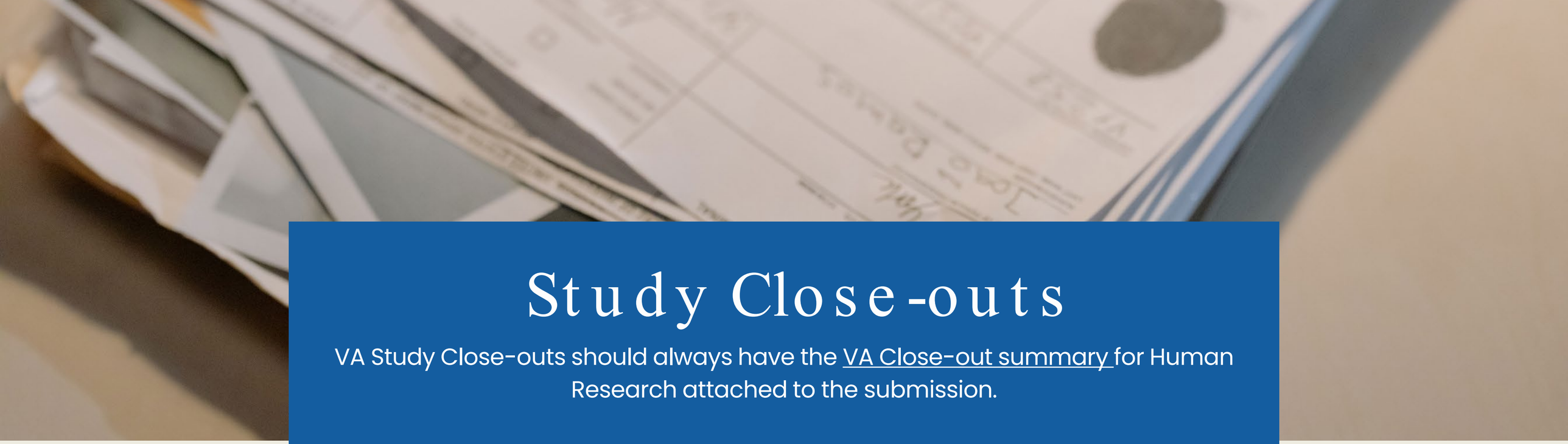
☐Electronic

☐Hard copy

☐N/A- please explain why:

6.Has there been any change to the SOP regarding storage location?

☐*Yes ☐No



Study Close-outs

VA Study Close-outs should always have the VA Close-out summary for Human Research attached to the submission.

Please be sure to double check all enrollment numbers for close-outs.

If a PI is leaving the Atlanta VA and will not be transferring the study to their new VA location or transferring the study to a new local PI, the study must be closed out

VA close-outs are not finalized until they have gone through the VA R&D closure.

Atlanta VA Health Care System
Decatur, Georgia

Close Out Summary for Human Subjects Research

Dear Principal Investigator, The following information is required as part of your study close-out process. Please submit the completed form and any other relevant documents in eIRB with your eIRB study close-out request.

IRB Number:
PI:

Title of study:

Is the study closing because the PI is leaving the AVAHCS? .....☐Yes ☐ No 1. Study Enrollment and Participation

How many persons were enrolled (consented) in this study: .....

If your study included **both** Emory and VA participants, how many subjects signed a VA consent form? .....

If a records/chart review, how many records were reviewed in this study: .....

2. VA Tissue Banking

a. Did this study collect tissue samples? .....☐Yes ☐No

b. If yes, will future research be conducted on those samples .....☐Yes ☐No

Please contact the Human Studies Analyst in the VA Research Office concerning closing your study if you answered yes to either question.

3. Research Data Repository

Does this VA study establish a data repository? .....☐Yes ☐No

If yes, please contact the HRPP Compliance Manager in the VA Research Office concerning closing your study.

4. Documents

Please contact the VA Clinical Studies Center for storing your study documents as required.

"Procedures for Closing Human Research Studies" is located on the AVAHCS Research website under the subheading Close Out and Storage of Research Records: The webpage URL is:
www.atlanta.va.gov/services/research/investigators.asp

(Please continue on the next page.)

GENERAL IRB TURNAROUND TARGETS

Note: All times are in business days

TYPE OF SUBMISSION	TURNAROUND FOR PRE-REVIEW SCREENING BY IRB STAFF	IRB REVIEW TYPE [1]	TURNAROUND FOR INITIAL IRB REVIEW AFTER IRB REVIEW IS ASSIGNED [2]	TURNAROUND FOR DETERMINATION LETTER AFTER INITIAL IRB REVIEW
New Study	**Initial screening:** within two weeks of IRB Staff assignment **Screening of requested changes:** up to two weeks, depending on complexity of changes	**Full Board**	1-3 weeks (i.e., next available meeting)	2 days after convened IRB meeting
		Expedited or Exempt	5 days	2 days after review is submitted
Modification	**Initial screening:** within two weeks **Screening of requested changes:** around one week, depending on complexity of changes	**Full Board**	1-3 weeks (i.e., next available meeting)	2 days after convened IRB meeting
		Expedited or Exempt	5 days	2 days after review is submitted
Continuing Review	**Recommendation: Submit Continuing Reviews 45 days before study expiration.** *Avoid time delays by ensuring the submission form is complete, all study members have up-to-date CITI training, and all required material is uploaded to the submission, including Monitoring Board (DSMB) reports.*			
	Initial screening: about three to four weeks; sooner if Grady ROC review is required	**Full Board**	1-3 weeks before expiration (based on agenda availability)	2 days after convened IRB meeting
		Expedited	2 weeks	2 days after review is submitted

I want to add the VA as a site to my Emory project. What do I do?

Consider these points:

- Are you only adding the VA for recruitment?
  - If so, this is not allowable. You must follow the guidance for posting non-VA research advertisements at the VA.
- Who will be the VA PI? Emory PI cannot be the VA PI also. May not wear 2 hats at the same time. VA PI must be VA research credentialed. If you want to become a VA PI, reach out to Tedra Ricks (Tedra.Ricks@va.gov) to begin credentialing. Also, send your CV to the VA Research COS, Dr. Mike Hart (Charles.Hart3@va.gov).
- You will need VA research credentialed staff to conduct the study at the VA (all research procedures that are able to be conducted on VA campus must be conducted on VA campus).
- How does the study benefit the VA research program? Will funding be provided to the VA (FAVER)? If not, will the study be used by a VA investigator to help them on the path to submitting a CDA in the future? Discuss with and obtain approval from Atlanta VA Research Department AO, Dr. Ashley Scales (Ashley.Scales@va.gov) if you are not sure how the study benefits to the VA research program.

Can I combine my Emory and VA submissions?

- In general, NO.
- Very rare exceptions (applies to studies already approved in this manner)- study must be conducting exact same procedures at both sites in the exact same way using the exact same resources
- New studies do not qualify to be combined
- Contact Brianna Wong to discuss if your study qualifies

If I can’t add the VA as a site, what can I do?

1) Add the VA as a separate site with a VA PI
2) Recruit VA patients under the Non-VA research advertisement posting policies.
    1) Just because you enroll veterans, does not mean the study is a VA study.
    2) VA study means the study must be occurring under a VA investigator and on their VA time, and/or on the VA campus
3) VA regulations do not prevent a VA provider discussing treatment options with VA patients, including options that may be only available in the research environment
    1) There is a clear line between a VA provider giving VA patients information about options that may include research and the VA provider acting as an agent of individual non-VA studies, thus engaging the VA and the referring clinician in human subjects research.
    2) VA cannot refer VA patients for affiliate studies in which the VA physicians are conducting those same studies during their affiliate duties, yet the VA is not engaged in the research. A federal employee cannot use his or her federal employment to benefit his or her non-Federal position.
    3) A VA provider cannot review the medical records of VA patients to screen these VA patients for non-VA studies because the authority to access a VA patient’s PHI for treatment, payment, and health care operations does not cover research purposes without research authority.
    4) The VA provider cannot act as an agent of the non-VA investigator.
    5) VA providers cannot determine if the veteran patients are eligible for the study.
    6) A VA provider in the course of his or her clinical duties talking with a VA patient about options for treatment and/or giving the VA patient basic information about the study and contact information (similar to the basic level found in an advertisement), is allowable.
    7) If a VA patient chooses to allow a VA provider to give his or her contact information to a non-VA provider, there has to be permission to do so. In addition, PHI cannot leave VA for research purposes without a written authorization; the information that can be given by a VA provider to a non-VA research study team is limited to contact information (name and telephone number).

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Additional Changes and updates

- Atlanta VA RCO (Rodney Thompson) new phone number: 404-315-4100 ext. 373190. Update consents (Modifications and new studies)

- No more training reminder emails from the Research Office. Use VA staff tracking log! Expired trainings=non-compliance (RNI)

- HIPAA Authorizations are not owned by the IRB, so they will no longer be stamped at CR

INSIGHT is a comprehensive application to manage the grant and research funding process.

INSIGHT centralizes IRB approval, contract management, regulatory compliance, study budgeting, and financial management into a single application.

Insight Phase 1 Go Live - August 29, 2025

Insight Phase 1 Training - August 1, 2025

Insight Phase 2 - August 2026

Click Here for more information

VA New Study Submission Cut-off: *VA Pre-review must have been submitted by June 29, 2025*
(some rare exceptions-Check with VA Research Office).

"Want to learn the system now to save you time later post go-live and provide your useful feedback at the same time? Join the UAT team today. Contact Karen Cotter. Information here."

INSIGHT will only be used for the Emory IRB submission portion of study approvals/modifications/continuing reviews. It does not change the other VA processing or routing of other VA Research paperwork (ie. VA pre-reviews, post-reviews, R&D review and approval, fCOIs, etc) which will still occur in their current systems (ie. IRBNet).

THANK YOU!

Brianna Wong, CCRC

Atlanta VA/Emory IRB Liaison

Find me on Teams

Brianna.Wong@va.gov

Resource Page

- IRB Staff Matrix
- eRRRP Website
- Guide on adding staff change in eRRRP
- Regulatory Binder Checklist and logs
- HIPAA Waiver Request Form (Exempt Studies- Data collection only)
- Close-out Summary for Human Studies
- VA Reportable Event Policy
- Emory IRB Website (Go here for protocol templates)
- Atlanta VA Research Website
- IRBNet/VAIRRS
- Submission Checklist for Emory studies
- CITI Training Website
- Annual Data Repository Form
- VHA Handbooks/Directives
- VA ORD Tool