

Clinical Studies Center

April 2023

Presenters: Clayton Carruth, Daniel Roysden

VA



U.S. Department of Veterans Affairs

Atlanta VA Health Care System

Agenda

- Project Submission Process
- Emory Staff Change Process and CITI Updates
- Research Policy and SOP Updates

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.

Add or Remove Staff Members to an Emory IRB Study

Presenter: Daniel Roysden, PhD

Contact: Daniel.Roysden@va.gov

VA phone extension: 202512

VA



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How to add or remove staff members. This is NOT the process for adding a new PI to a study (Exempt/ Expedited/ Full Board) or for removing a co-I for a greater than minimal risk study (Full Board).

1. Go to the study home page. Click “Create Modification/CR”.

The screenshot displays the study home page interface. On the left, under the heading "Next Steps", there are four dark blue buttons: "View Study", "Printer Version", "Create Modification/CR", and "Report New Information". Below these are two links: "Prepare Letter" (with a pencil icon) and "Assign Coordinator" (with a person icon). On the right, a process flow diagram shows a sequence of steps in rounded rectangles: "Pre-Submission" leads to "Pre-Review", which leads to "IRB Review", which leads to "Post-Submission". Below "Pre-Review" and "IRB Review" are "Clarification Requested" boxes, with arrows indicating a feedback loop from the review stages back to their respective clarification boxes. Below the diagram is a navigation bar with tabs: "History", "Funding", "Contacts", "Documents", and "Follow-on Submissions". Below the tabs is a "Filter by" section with a dropdown menu set to "Activity" and a search input field with a magnifying glass icon.

2. Choose “Modification/Update” and then select “Study team member information”. DO NOT submit combined staff changes with changes to other parts of the study. It delays the staff change approval.

You Are Here: Mycotics Surveillance (AVAMC--... > _IRBSubmission

Creating New: IRB Submission

Modification / Continuing Review / Study Closure

*** What is the purpose of this submission? ?**

Continuing Review

Modification / Update

Modification and Continuing Review

[Clear](#)

i To change the PI, choose 'Other parts of the study/site' scope

Modification scope:

Study team member information

3. Summarize the MOD **exactly as shown**. DO NOT use excessive wording or titles. Each add must have a designated role from the acceptable roles in eIRB.

3. * Summarize the modifications: ?

Add Emily Nelson, Paola Santos, and Dong Li as "Other Collaborator".

Acceptable roles are:

2. * Role in research: (check all that apply)

- Co-Investigator
- Study Coordinator
- Study Nurse
- Lab Tech
- Admin Assistant
- Research Fellow
- Data Entry
- Other Collaborator
- PHI Requestor or Collector Only

4. Add the study team member. Select the role. Answer #3 and #4 as appropriate.

Add Study Team Member

1. * Study team member: ?

Emily Nelson

2. * Role in research: (check all that apply)

- Co-Investigator
- Study Coordinator
- Study Nurse
- Lab Tech
- Admin Assistant
- Research Fellow
- Data Entry
- Other Collaborator
- PHI Requestor or Collector Only

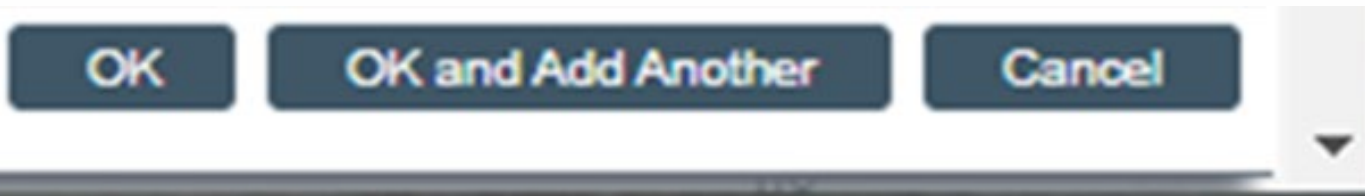
3. * Is the team member involved in the consent process?

Yes No [Clear](#)

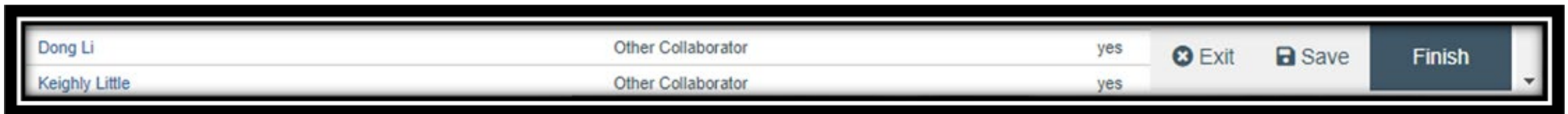
4. * Does the team member have a financial interest related to this research? ?

Yes No [Clear](#)

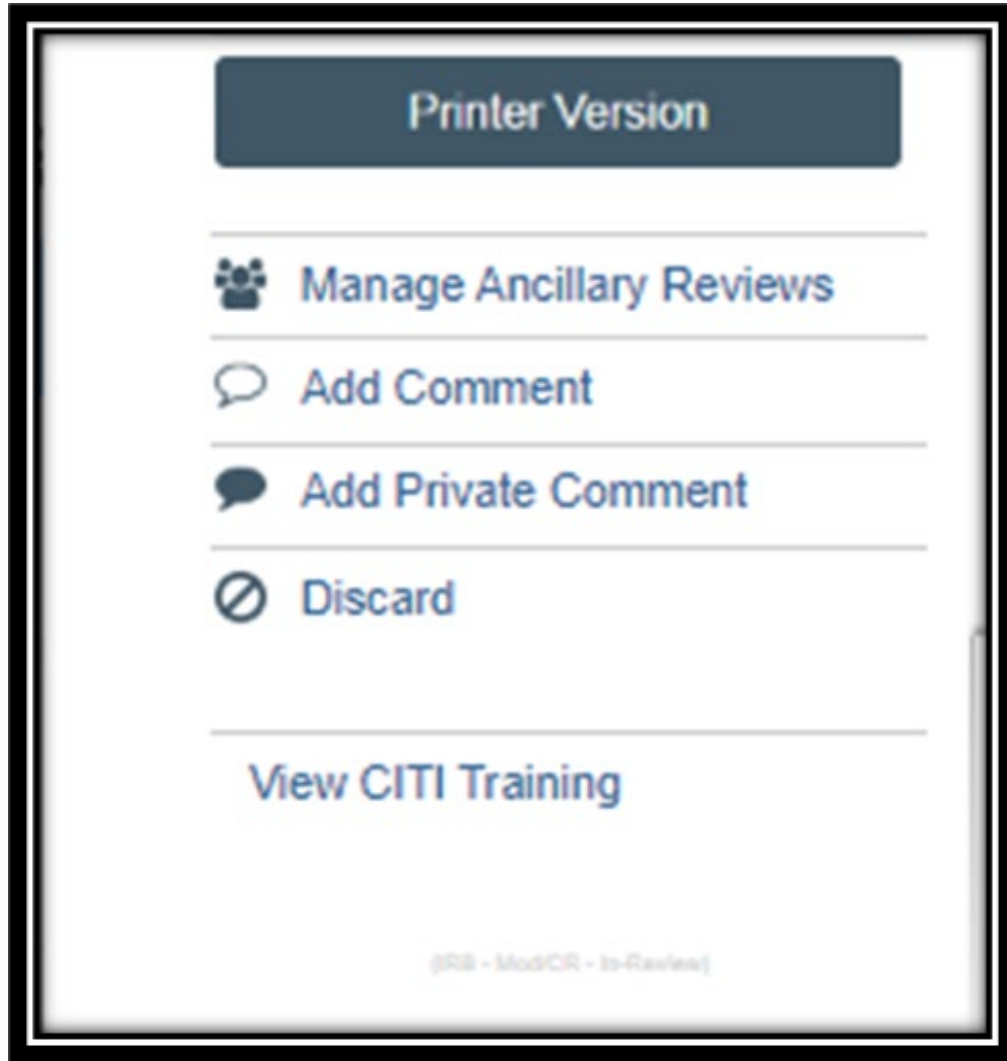
Additional names can be added as necessary using “OK and Add Another” located at the bottom righthand side of the “Add” page.



Be sure all names have been added to the study staff list. Then click “Finish”



5. Add a comment to the Modification.



The screenshot displays a user interface with a dark blue button labeled "Printer Version" at the top. Below it, a list of actions is presented, each with a horizontal line separator: "Manage Ancillary Reviews" (with a group of people icon), "Add Comment" (with a speech bubble icon), "Add Private Comment" (with a speech bubble icon), and "Discard" (with a circle and slash icon). At the bottom of the list is a link labeled "View CITI Training". The status "(CR - ModCR - In-Review)" is visible at the very bottom of the interface.

The comment is necessary for quickly running the required research credentialing check. No supporting documents required for VA/GA EIP staff. No need for an email notification, leave it blank.

Your comment is visible to anyone with access to this submission.

1. Comment:

Add Emily Nelson, Paola Santos, and Dong Li as "Other".

2. Supporting documents:

+ Add

Name

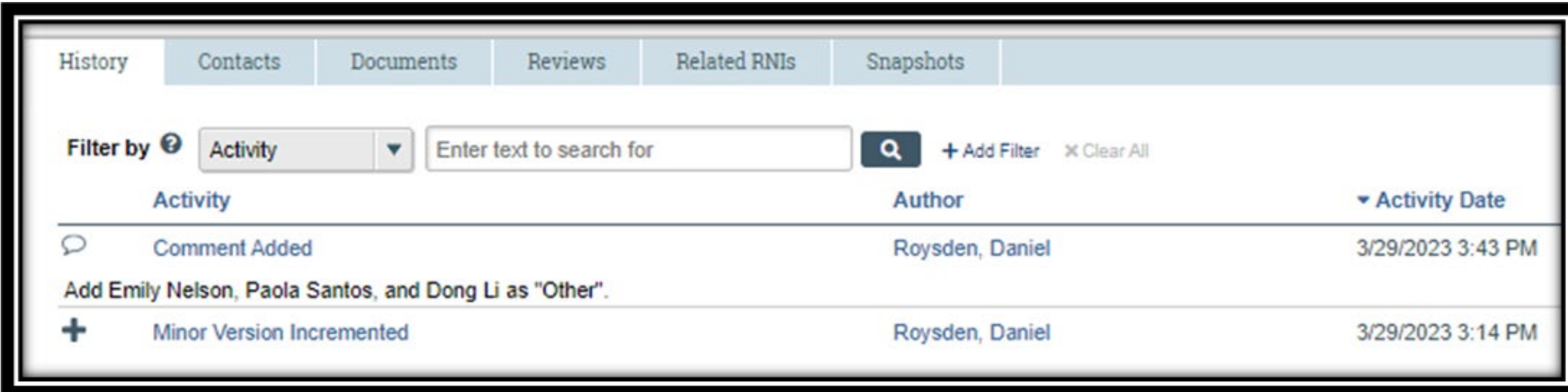
Description

There are no items to display



3. Who should receive an e-mail notification? ?

- PI/PI Proxy/Primary Contact
- Study Team
- IRB Coordinator

6. The comment will appear in the MOD history.



The screenshot shows a web interface with a navigation bar containing tabs for History, Contacts, Documents, Reviews, Related RNIs, and Snapshots. Below the navigation bar is a filter section with a dropdown menu set to 'Activity', a search input field with the placeholder 'Enter text to search for', and buttons for '+ Add Filter' and 'x Clear All'. The main content area displays a table with the following data:

	Activity	Author	Activity Date
	Comment Added Add Emily Nelson, Paola Santos, and Dong Li as "Other".	Roysden, Daniel	3/29/2023 3:43 PM
	Minor Version Incremented	Roysden, Daniel	3/29/2023 3:14 PM

7. Don't forget to submit the MOD. Separately request the staff change via email to the IRB liaison until eRRRP is back online, then request via eRRRP.

8. Removing names is just as easy, simply follow the above. Include "Remove *Staff Name*" in the MOD Summary and the logged comment.



Documentation SOP

Major Updates

- Consolidation
- Guidance on Patient Binders
- Creation of Supplemental Documents

Reminders

- Notes in CPRS must be completed within 72 hours of the visit
- Non-Veteran patient records should be created before the scheduled visit
- Accounting of Disclosures Form

CPRS Notes

Location for Current Activities

Select the appointment or visit that should be associated with the note or orders .

Encounter Location
ATL RESEARCH-STUDY Apr 07,17 13:01

Clinic Appointments Hospital Admissions **New Visit**

Visit Location
ATL RESEARCH-STUDY
ATL RESIDENTIAL CARE
ATL RHEUM TELE MED MONITORIN
ATL RHEUM-E-CONSULT-PHARM-X
ATL RHEUMATOLOGY CLINIC A
ATL RHEUMATOLOGY CLINIC B
ATL RHEUMATOLOGY-CONTINUITY

Date/Time of Visit
NOW

Historical Visit: a visit that occurred at some time in the past or at some other location (possibly non-VA) but is not used for workload credit.

Visit Location

- **ALWAYS** select “ATL Research-Study or other ATL Research-Clinic

Historical Visit

- **ALWAYS** select Historical Visit

Doing both of these will minimize the risk of a participant being billed for a research encounter!



External Monitoring

Major Updates

- Updates to Standard SOP Template
- Removed Language for Read-Only Accounts in CPRS
- Added Allowance for Remote Monitoring
- Updated Entrance and Exit Forms – included at the end of the SOP document

Reminders

- Notify the CSC of any External Monitoring Visits Prior to the Visit
- Complete the Entrance and Exit Forms for All Visit of an External Entity
- Monitors are to Immediately Report any Instances of Potential Serious Non-Compliance to the CSC



Research Recruitment

Major Updates

- Update to Standard SOP Template
- Consolidation
- Encryption of Recruitment Emails

Reminders

- No Cold Calling
- All Recruitment Material Must be Approved by IRB
- Encrypted Email Recruiting is Allowed if IRB Approved