Clinical Studies Center

April 2023

Presenters: Clayton Carruth, Daniel Roysden

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

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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".

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.

3. Summarize the MOD <mark>exactly as shown</mark>. 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

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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
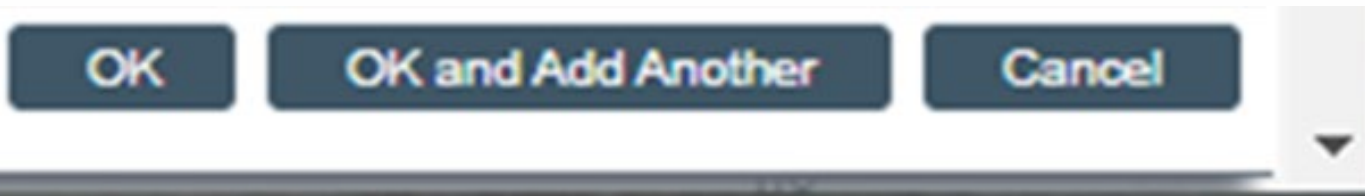- ☑ Other Collaborator
- ☐ PHI Requestor or Collector Only

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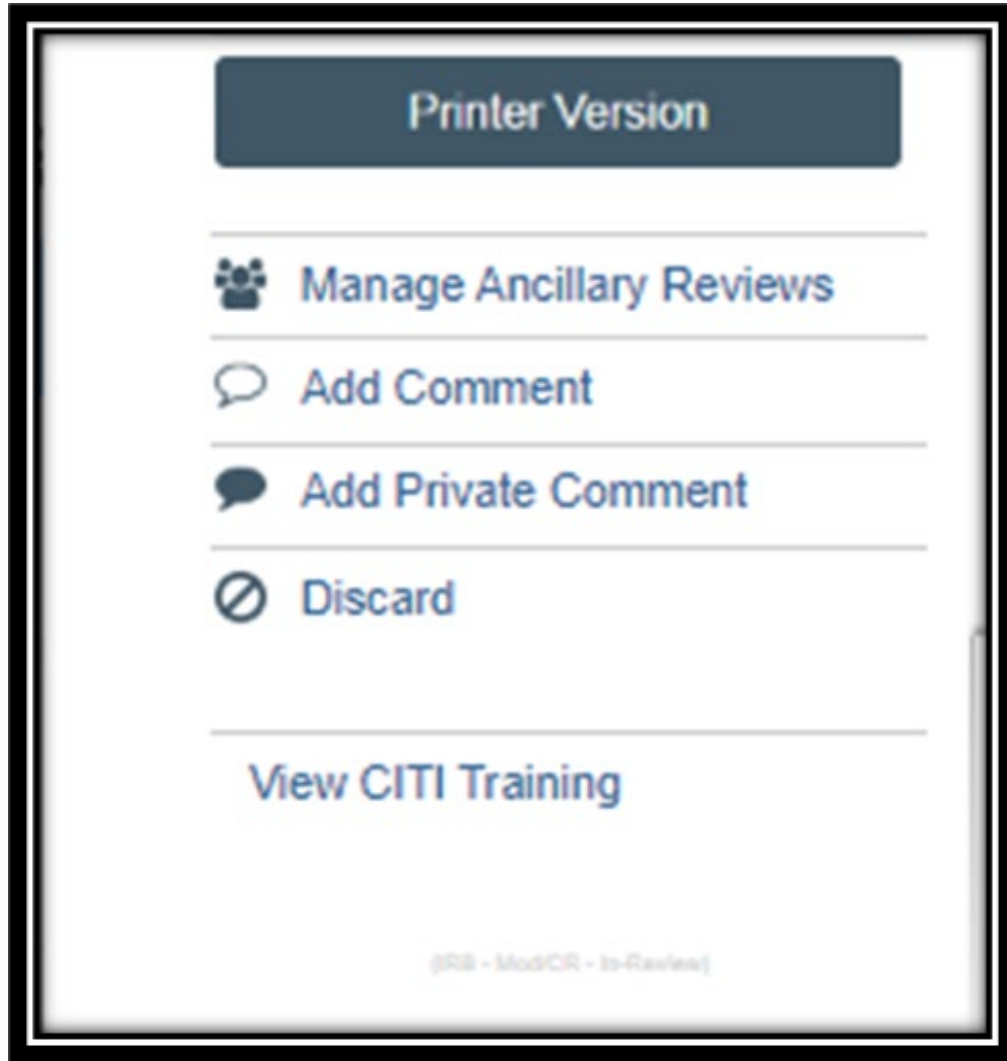
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Additional names can be added as necessary using "OK and Add Another" located at the bottom righthand side of the "Add" page.

Be sure all names have been added to the study staff list. Then click "Finish"
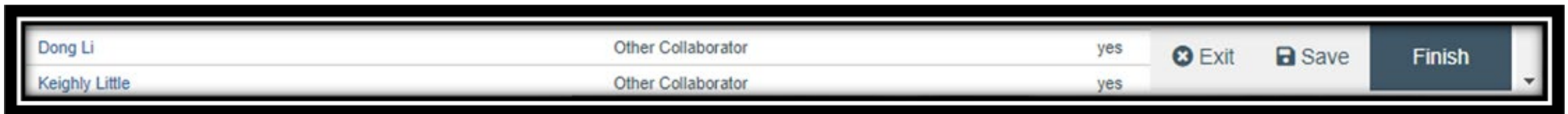
5. Add a comment to the Modification.

The 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".
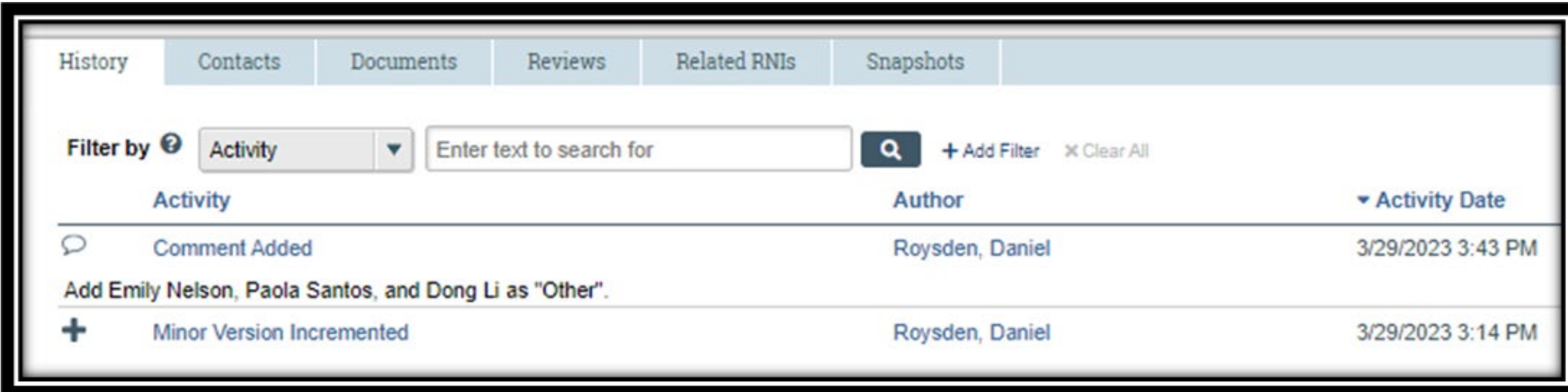
2. Supporting documents:

+ 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.

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

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