Full Board Study Reviews and Board Meeting Discussions

AAHRPP – TRAINING PROGRAM

Review Process

- Primary Reviewer System
  - 1 Primary Reviewer and approximately 2-4 Secondary Reviewers assigned to each new study
    - **Designated Reviewers**
    - Primary Reviewer writes Summary
  - New studies sent to Designated Reviewers electronically via eIRB
    - Will receive email notification
  - Approximately 10 days to review studies and provide comments and questions
  - Will be asked to provide an initial determination of Approval, Conditional Approval, Disapproval, Tabled, or Deferred
  - All other Board Members that are not assigned a review have access to the study to review all elements of the study prior to the meeting
    - **Non-Designated Reviewer**

Documents to Review

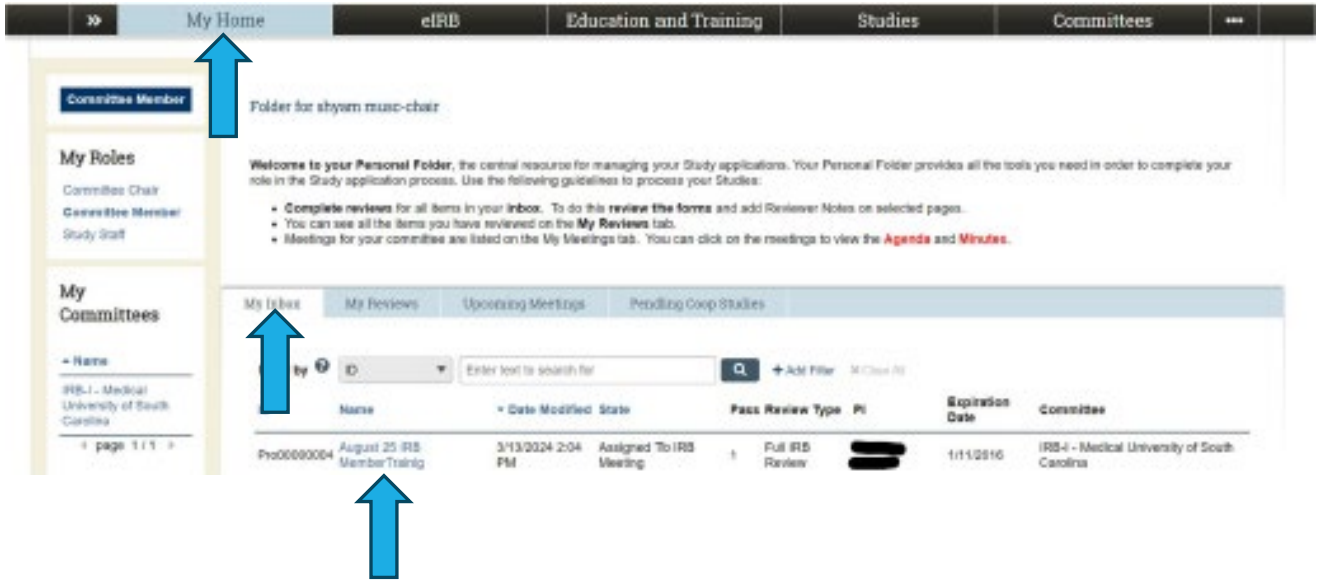
- Protocol
- Informed Consent Document(s)
- Application
  - Smartforms
  - Attachments
    - Advertisements, Surveys, etc.

Reviewer Checklist(s)

- Checklist(s) submitted to the Primary Reviewer(s) at time of assignment
- Checklist(s) to ensure compliance with all of the requirements are available in eIRB and the IRB Committee Member page on the IRB website (https://research.musc.edu/resources/ori/irb/irb-committee-member)
- Use Checklist(s) as tool to assist in review
- If you are not able to answer a checklist question, then a comment or question to the PI is needed.

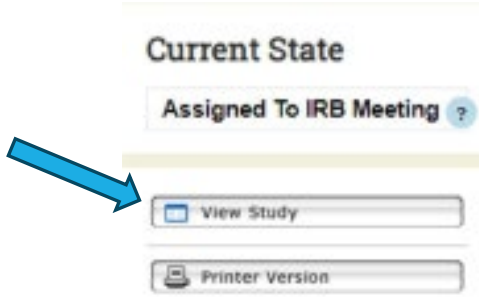
Designated Reviewer

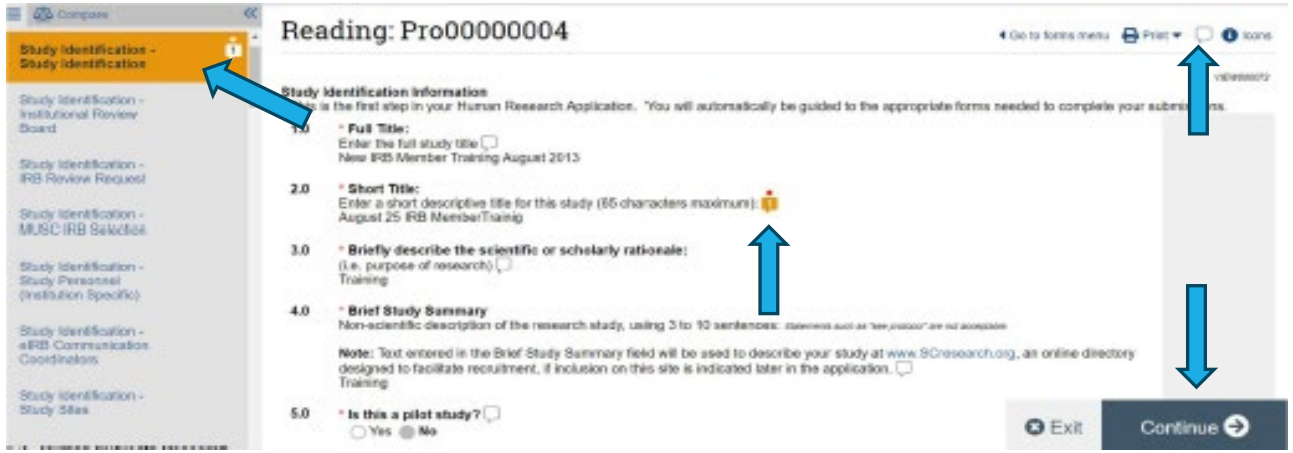
- Receive notification via email that you have been assigned as a designated reviewer
- Click on Protocol ID (in email) **OR**
- Log-on to the eIRB system using NetID and Password
  - Click “My Home” tab → “My Inbox” → Select Study name



Designated Reviewer

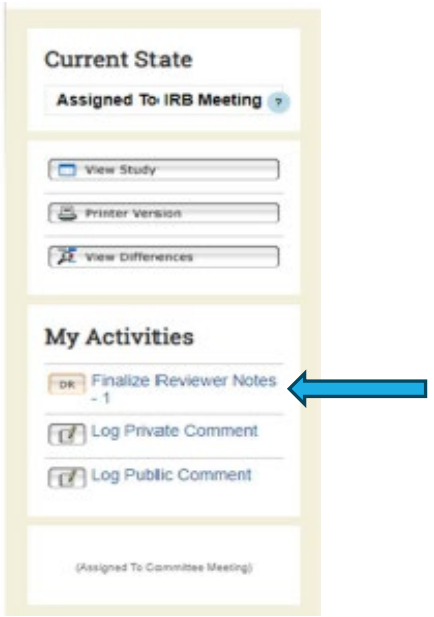
- Use View Study button to start your review
  - Allows you to leave reviewer comments as you proceed
  - Navigate through each Smartform
    - Page by page by clicking “Continue” **OR**
    - Navigate to a specific smartform by clicking on the left-hand side of the screen
  - Leave reviewer comments at the page **OR** field level using bubbles
    - Use “Private Comment” option

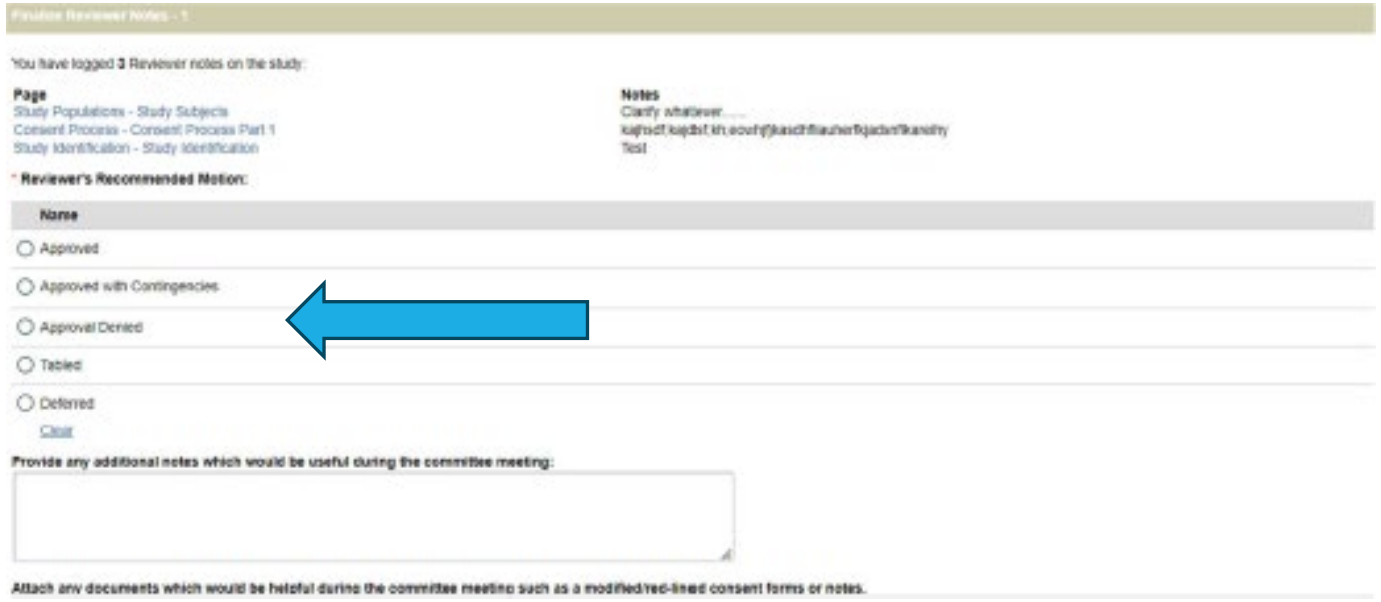




Designated Reviewer

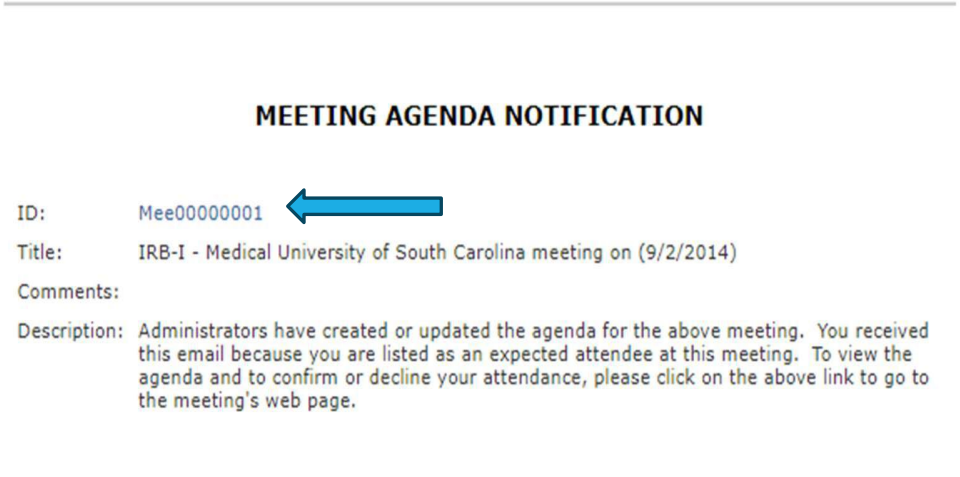
- Select “Exit” **or** “Finish” when your review is complete
- Select “Finalize Primary Reviewer Notes”
- Add Reviewer’s Recommended Motion
- Select “OK” to finalize your review





Non-Designated Reviewer

- Receive notification via email that the meeting agenda is ready for review
- Log in to eIRB system using your NetID and Password
  - Make sure you are in your “Committees Tab”
- Confirm your attendance
- Click on link listed under “Work Space” to access the study



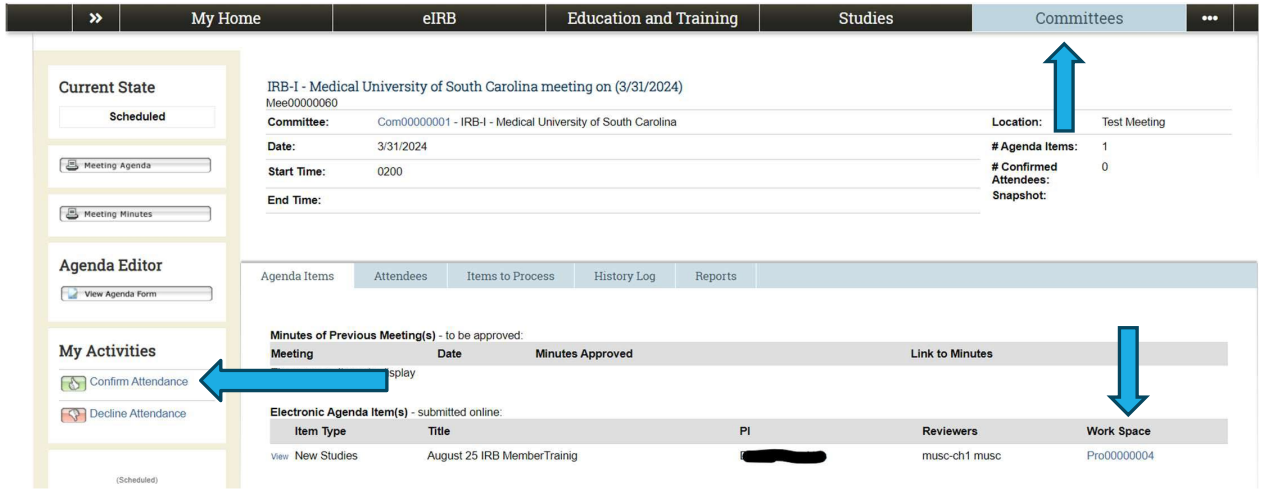
MEETING AGENDA NOTIFICATION

ID: Mee00000001

Title: IRB-I - Medical University of South Carolina meeting on (9/2/2014)

Comments:

Description: Administrators have created or updated the agenda for the above meeting. You received this email because you are listed as an expected attendee at this meeting. To view the agenda and to confirm or decline your attendance, please click on the above link to go to the meeting's web page.



Non-Designated Reviewer

- Use View Study **OR** Printer Version to start your review
- Open attachments by clicking on the blue text hyperlinks
- As a Non-Designated Reviewer, you do not need to leave comments on the study, but can take notes to contribute to the discussion at the Board Meeting

Application: Smartforms

- Study Sites
  - Is the study being done at the VA?
    - If so, are the proper VA forms submitted?
- Subject Populations
  - Will children be enrolled?
  - Will subjects include those that are cognitively impaired with fluctuating decision capacity?
  - Pregnant women, neonates and fetuses, prisoners?
- Remuneration
  - Review the amount of payment and the proposed method of disbursement
  - Assure that neither entails problems of coercion or undue influence
- Protections Against Risk(s)
  - Ensure Privacy and Confidentiality are being protected
    - Ex. Substituting codes for identifiers, limiting access to identified data, storage of research records
- Special Concern Areas
  - Does the study involve an investigational new drug, medical device, Gene Therapy?
  - Is there an IND or IDE#?

Attachments: Advertisements, Surveys, etc.

- Advertisements
  - Review information contained in the advertisement(s)
  - Mode of communication
  - Does the procedure for recruiting subjects afford adequate protections?
  - Ensure the information is not misleading or coercive
    - Ex. Emphasis does not need to be on payment or say things like “free treatment”
- Surveys
- Scripts
- Investigator Brochure

Attachments: Protocol

- Specific Aims
- Inclusion/Exclusion Criteria
- Identification of Subjects
- Sample Size
- Statistical Analysis
- Data Safety Monitoring
- Use Checklist as a tool

Attachments: Informed Consent

- Who will obtain consent?
  - Child assent
- Who will be giving consent?
  - LAR?
- Informed Consent process
- Are all required elements included?
- Was the MUSC consent template used?
- Is the ICF written in lay terms?
- Risks and Discomforts should be listed clearly and in order of seriousness
- Is there any benefit to the subject?
  - If there is no benefit to the subject, a statement indicating this should be included
- Procedures listed must incorporate all aspects of what subjects will encounter
  - Ex. # of visits, how much blood to be drawn, randomization, etc.
  - Must be in chronological order
- Use Checklist as a tool

Review Process

- Reviewer submits comments/questions/concerns and study is returned to the PI
- PI responds to and addresses reviewer comments/questions/concerns
  - Deadline for response is the Friday prior to the scheduled Tuesday Board meeting
- Prior to the scheduled Tuesday Board Meeting the Primary Reviewer will write a study summary
  - Use scientific rationale and brief summary from page 1 of the eIRB application and combine them to provide concise overview of the study
  - Include brief information regarding: the study population, payment information, study procedures, risks, etc.

Review & Approval Process

- Full Board discussion at IRB meeting
- Primary reviewer will start discussing their review of the study providing any information on questions they asked and whether their questions were answered
- The Chair will guide the discussion and request a motion
  - Approval
  - Conditional Approval
  - Tabled
    - The Board has substantial questions about the study and needs clarification before providing a determination
  - Disapproval
    - The study is not approved to be conducted at MUSC

Final Thoughts!

- A thorough review by IRB board members is necessary to be able to assure that the rights and welfare of human subjects participating in research are adequately protected
- All members of the committee receive an email notification that the agenda is ready on the Friday prior to the Tuesday meeting. All members of the committee have access to the full materials on the agenda through the eIRB system
- Every board member has expertise and can provide an individualized perspective to the convened meeting which should allow for a more robust discussion amongst board members and a more thorough review
- Please review IRB agenda items to prepare for the meeting
  - Designated Reviewer: Return study with comments to Administrator prior to set deadline
  - Non-Designated Reviewer: Make notes for discussion at convened meeting
- Recuse yourself if you have a conflict on a specific protocol
- If you are not able to attend a meeting, please notify the IRB Administrator in advance to give time to secure an alternate member
- Please be prompt
- All discussions and materials are to be kept confidential.

What questions do you have about the process?