PROTECT Tip Sheet for
IRB REVIEWERS

Basic steps:

Step 1 – Access the agenda:
- You will be sent a notification containing a link to the agenda.
- You may also access it by logging into PROTECT and going to **IRB** > **Meetings** > **Clicking agenda**.

Step 2 – Review the agenda:
- **Agenda document** (*at-a-glance view*)
- **Expedited Submissions Approved in the Last 45 Days** (*are reported out at meeting*)
- **Agenda Items Tab** (*to see what reviews you have been assigned*)
- **Supporting Documents Tab** (*to see any supplemental docs from IRB staff*)

Step 3 – Conduct your review:
- Review the submission:
  Click the **submission number or title**, view submission **Workspace**, use **Review Study** button to read the application, check **History** tab for pre-meeting comments, check **Documents** tab to review study docs, check **Reviews** tab for IRB Staff Pre-Review notes and other ancillary or member reviews. Also in the analyst's Pre-Review are relevant regulatory checklists. These are for your reference only and do NOT get completed by you.

- Request any additional information: (can be done two ways)
  'Request Clarification by a Committee Member' activity
  You are identifiable if you run this activity. This activity does not send the submission back to the study team, but it does notify them that you, the reviewer, have a request for them to reply with additional information. You will get an email when they respond and you can also view this in the **History** tab of the submission itself.
  'Add Private Comment' activity
  This activity is private and can only be viewed by the IRB Reviewers and IRB Staff. You may run this activity and select 'IRB Coordinator' if you prefer to send your questions to the IRB Analyst and have them ask the study team on your behalf so that you remain anonymous.

- Submit your review:
  Click the **Add Review Comments** activity on the submission workspace to enter your review. You may also upload any tracked changes consents, etc. to this activity for the IRB Analyst. Information you enter on this activity is only visible to IRB Reviewers and IRB Staff, not the Study Team. The review also goes away from the Reviews tab after the meeting is completed.

Resources
IRB Reviewer's Guide *(can be found in Protect > **IRB** tab > **Help Center** tab > **Guides** tab)*
IRB Quick Reference Guide

Questions
For questions about your IRB review, contact the analyst that is staffing your meeting.
For questions about the PROTECT system, please submit a ticket and our IT staff will assist you