IRB Members

IRB members are selected to ensure a diverse set of perspectives and expertise appropriate to the many kinds of research under review. Our IRB members are physicians, researchers, clinicians, nurses, pharmacists, physical therapists (among other members of the medical community), engineers, lawyers, non-scientists and community members all contributing their knowledge, viewpoints, and hard work.

As an IRB member you are required to read the DUHS IRB Member Manual. A few key sections of the manual have been reproduced below. Please refer to your Member Manual for instruction on how to prepare and present a protocol review at an IRB meeting. The Member Manual also contains general information on the organization, purpose and function of the IRB.

Please Click Here for the PDF Version of the DUHS IRB Member Manual

Required Training for IRB Members

All DUHS IRB members are required to complete the following training:

- Complete the required ethics credentialing (CITI modules)
- Observe two IRB meetings
- Meet in person for an hour’s orientation session
- Read the DUHS IRB Member Manual

Ethics Credentialing (CITI Modules) For IRB Members

All IRB Members must complete the same ethics training required of Duke researchers, which
is a set of online CITI modules.

Please Click Here for Information and Instructions about this Requirement.

Additionally, IRB Members and staff are required to complete the 3 CITI modules as named below on the **CITI website**:

- Vulnerable Subjects - Research Involving Prisoners
- Vulnerable Subjects - Research Involving Children
- Vulnerable Subjects - Research Involving Pregnant Women, Human Fetuses, and Neonates

These must be completed before you can be granted access to the eIRB as an IRB member.

**IRB Primary Reviewer Checklists**

For your convenience, we have attached the IRB Primary Reviewer Checklists here:

- **IRB Primary Reviewer Checklist-Amendment**
- **IRB Primary Reviewer Checklist-Continuing Review**
- **IRB Primary Reviewer Checklist-New Protocol**
- **IRB Primary Reviewer Checklist-UPIRTSO**

Click Here for More IRB Reviewer Checklists

**Tools Available to IRB Members**

This website contains:

- **Duke HRPP Policies**
- **Links to the Federal Regulations and Guidance**
- **Standard Language for Consent Forms**
- **Checklists for IRB Reviewers**
- **Navigating the eIRB**

**Housekeeping Notes for IRB Members**
1. Communicate with your IRB Chair prior to the IRB meeting if you find that a protocol has significant problems that could cause the protocol to be deferred at the IRB meeting.
2. Communicate with the PI and study team prior to the IRB meeting to answer questions you have about the study, clarify issues, ask about study enrollment and progress, or ask for documentation you may be missing.
3. Upload into the eIRB by 1:00 PM on the day of the IRB meeting:
   - your completed Primary Reviewer Checklist,
   - any tracked consent forms, research summaries, or other documents,
   - any additional Checklists,
   - and all your email correspondence with the study team.
4. If you find you cannot attend a meeting, please find a replacement from your Department (another IRB Member) to attend the meeting in your place. Notify the IRB Board Specialist for your meeting immediately, so protocol assignments can be sent to another reviewer. NOTE: If no one from your department attends the IRB meeting, then all protocols from your department may have to be pulled from the agenda. Federal Regulations require the appropriate expertise present at the meeting in order to review the items on the agenda.
5. Lunch: Please tell your Board Specialist if you have special dietary needs.
6. The Board Specialist maintains quorum in the room and records the vote count for each vote. If you have to leave an IRB meeting temporarily to respond to a page, make a phone call, or visit the restroom, please catch the eye of the Board Specialist so she/he knows you are leaving.
7. Tell your Board Specialist if you have to leave an IRB meeting early, or if you have to arrive late.
8. Visitors: Visitors are welcome at our IRB meetings. If you would like to bring a visitor with you to observe the meeting, please tell the Board Specialist as soon as possible, so that she/he can make appropriate arrangements for a visitor. All visitors must sign a confidentiality agreement prior to the start of the IRB meeting.
9. If you are having trouble uploading your Primary Reviewer documents into eIRB, can’t find something in eIRB, or need help navigating through eIRB, call your Board Specialist.
10. Parking: The IRB will supply you with a Hock Plaza parking permit only if you are unable to attend the IRB meeting any other way. There are only a few parking places designated for the IRB in Hock Plaza. The board specialist will ask when sending you the meeting agenda if you need a parking permit. If you do, a parking pass will be emailed to you to print and use. These passes are only good for one meeting and for the day stipulated. Wave the barcode that is in the upper right corner near the red light to ENTER and EXIT the gates. Please place the pass on the dashboard of your vehicle while parked.

Useful Definitions

IRB Member Responsibilities

Conflict of Interest for an IRB Member