NIH Office of Intramural Research
Office of Human Subjects Research Protections

IRB MEMBER UPDATE

SPRING, APRIL 2025

IN THIS ISSUE

BYE, ZOOM, HELLO, TEAMS!

Zoom is out. Teams is in. NIH has mandated that all virtual meetings take place by Microsoft Teams instead of Zoom.

- Like with Zoom, you will be provided a Teams link that will allow you to log directly into the IRB meeting.
- After selecting the meeting link, you will be prompted to download the Microsoft Teams app if you do not already have it installed on your device.
- You will then be prompted to create an account with the email address that you provided to the IRB for use. You will need access to your email to verify your account.
- If you are on a computer and not a mobile device, you also have the option to set up an account for Teams meetings via the web-based version at https://teams.microsoft.com/. However, it does not appear that they will allow you to use this pathway on a mobile device.

More Teams Meeting Tips

You can bookmark the meeting link on your web browser for easy access into the meeting. To do this, you can copy the hyperlink location, edit an existing bookmark, and copy the new hyperlink into the bookmark. Make sure the bookmark has a name you can find easily.

External Users Verification: Per NIH IT, some users may need to verify their identity via a captcha code before they are allowed into the meeting. This extra step ensures the security of the meeting and prevents unauthorized access.

Biomedical 101: Updated your CITI training? Let us know.

As a member of the IRB, you are required to take the **CITI Biomedical 101 Basic course**. This course provides an expansive review of human subjects research topics for biomedical research. Every three years after the Basic course has been completed, you are required to complete the Biomedical Refresher course which is shorter. Do not attempt to take the Biomedical Refresher course until you are reminded by CITI that your refresher training is due, because CITI will not make the refresher course available to you until 90 days prior to the expiration of your prior Biomedical course.

We need to maintain a copy of every member's completion certificates. This is important since this is a requirement for maintaining our AAHRPP Accreditation. As represented by the "gold seal," AAHRPP accreditation offers assurances to research participants, researchers, sponsors, government regulators, and the general public that an Institution's human research protection program is focused, first and foremost, on excellence.

We ask that you send us a copy of your completion certificate each time you complete the CITI Biomedical course.

If you forget, no problem, and we will remind you at re-appointment time.

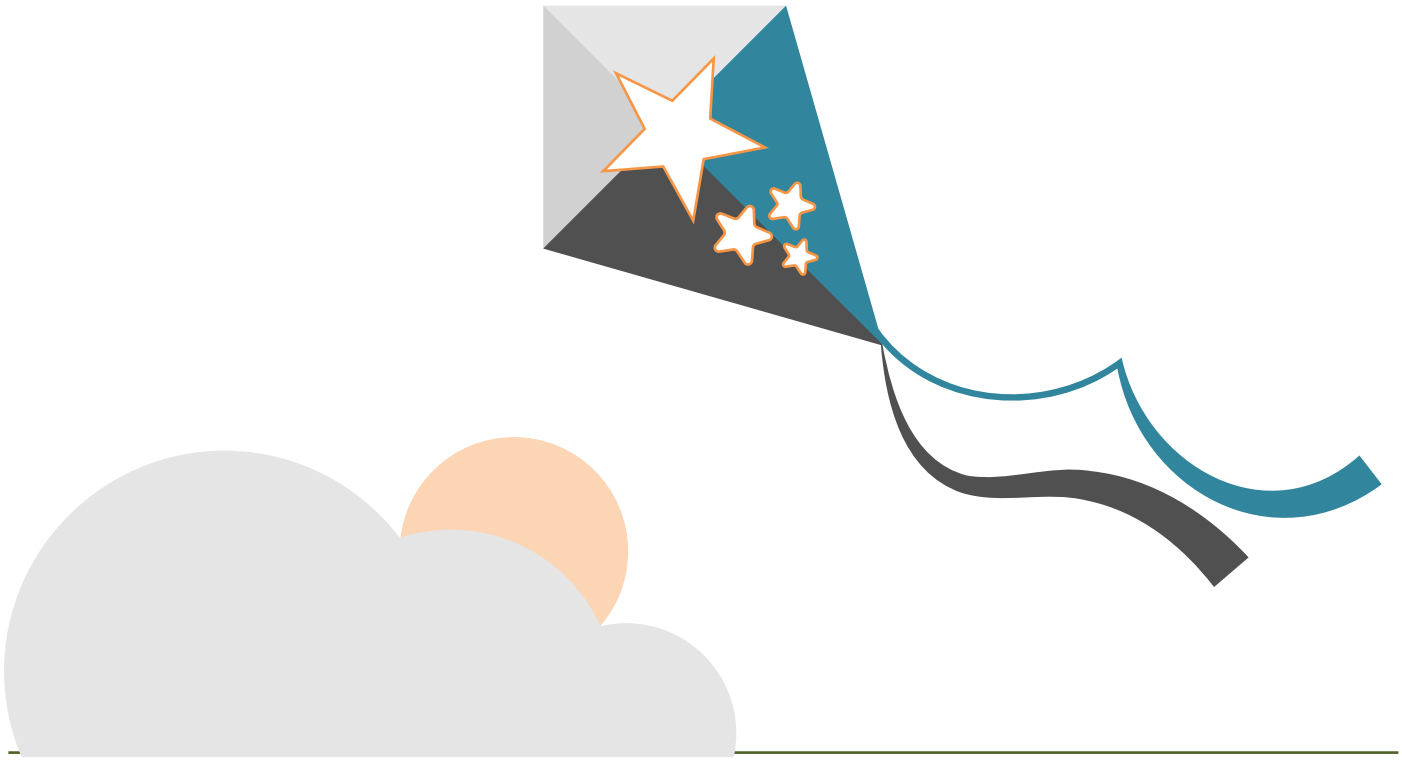
You can email your certificate to mollie.fraser@nih.gov

IRB Member Gold Star ☆ ★ ☆ Stephanie Weiss

Congratulations to Dr. Stephanie Weiss for receiving the Spring IRB Member Gold Star Award! As a dedicated staff clinician with the National Institute on Drug Abuse (NIDA) and a committed board member since 2021, Dr. Weiss has consistently demonstrated exceptional preparation and thorough discussion of each agenda item. Her proactive approach in communicating and addressing concerns with the Principal Investigator, Chair, and the IRB analyst prior to meetings has significantly contributed to the efficiency and effectiveness of the board's work. Well done, Dr. Weiss, for your outstanding contributions and exemplary service!

Dr. Stephanie Weiss has truly exemplified dedication and excellence in her role as an IRB member. In addition to her consistently outstanding reviews, she demonstrated exceptional commitment this past January. When faced with two complex submissions from NIDA that required her expertise, Dr. Weiss immediately recognized the challenge of addressing both in a single meeting. Despite her demanding schedule, she proactively communicated with the IRB staff and proposed a solution. By attending two IRB meetings a week apart, she ensured that she could thoroughly review both submissions without causing significant delays for the study team. This level of dedication and proactive problem-solving highlights Dr. Weiss's invaluable contribution to the board and the advancement of research.

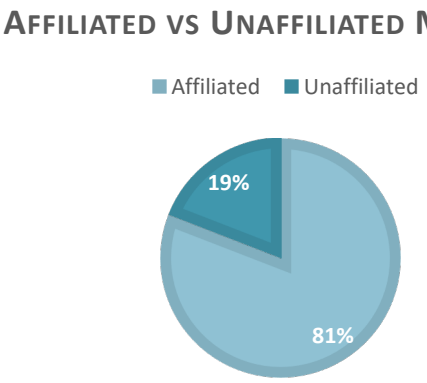
Congratulations again to Dr. Stephanie Weiss for her well-deserved IRB Member Gold Star Award! Her exemplary service and unwavering commitment are truly deserving of this recognition.



2024 IRB Member Survey Results

Every year, a survey is sent out to IRB members asking for feedback. Eighty-nine people responded to the survey sent out at the end of 2024. At that time, we had 143 members on the roster. This means we had a 62% response rate to the survey.

The following is an overview of the results from the respondents of the survey:



Question from Survey	% Answered Yes
Do you feel you have adequate knowledge of ethical principles, human subjects protection regulations, NIH policy and procedures to fulfill your role on the IRB?	96%
Does the IRB review process allow for adequate protection of human subjects research?	97%
Does the number of actions reviewed at each meeting seem reasonable to review in the time frame allotted for the IRB meetings?	99%
Are you able to meet the minimal attendance requirement of IRB members by attending at least one meeting per month?	88%
In the past year have you been able to adequately prepare for review of the agenda items for each meeting?	99%
Are you able to access the materials in PROTECT you need to conduct your review prior to the IRB meeting?	94%
Do you feel you are an active contributor during the meeting?	100%
Do you feel you have a good working relationship with OHSRP staff and other IRB Members (i.e., communicate with Analysts, active discussion at meetings)?	97%
Do the monthly TIP sheets provide relevant information?	98%
Did you attend the IRB member retreat this past year?	65%
Are you comfortable completing reviews in PROTECT?	91%

2024 IRB Member Survey Results continued

Summary of Suggested Points of Growth:

- Having more consistency with encouraging discussion and listening to dissenting views.
- Making sure that concerns are addressed, and the meeting does not feel rushed.
- Encouraging unaffiliated members to express their views.
- If members do not ask PIs questions soon enough in advance, other members can have difficulty in addressing and resolving issues during the actual IRB meeting.
- PROTECT can be challenging when trying to find needed items, especially when navigating the history of the study.

Additional training suggestions from the survey:

- How to evaluate the protocol and consent document
- Tips on how to navigate PROTECT
- How to format and present your review and best practices for conducting your review
- Topics on radiation safety including how radioactive drugs are regulated
- Intramural-extramural collaborative protocols
- How to review a protocol for local context
- How to evaluate for adequacy of recruitment over time
- Editing consent documents and what types of submissions allow edits to be approved
- Use of AI in IRB review
- Return of secondary genomic findings
- Considerations when enrolling infants
- Enrolling family members of NIH staff and study team members
- What is the role of the IRB unaffiliated community member

If you have any additional concerns or feedback at this time, please feel free to send it to us at OHSRPCompliance@od.nih.gov.

Recruitment Slow? When the IRB should be concerned

At the time of continuing review (CR), the study team reports the study's current total enrollment numbers and the number of subjects recruited in the last year.

There are times where the number of subjects recruited looks small when compared with the planned enrollment. However, sometimes there are valid reasons that number is low, or the study was designed knowing that recruitment would be low. So when should the IRB be concerned?

The first thing to do is to assess the protocol. Look at the study design, the recruitment plan, and the statistical section. The protocol may mention that investigators expect slow recruitment and directly address the issue. For example, if the researcher is studying a rare disease, recruitment is more likely to be low and sporadic, and this should have been accounted for in the study design. A Phase 1 study may be purposely designed to recruit slowly for safety reasons. As long as the study can eventually meet its study goals, there is no need to discuss this during the CR.

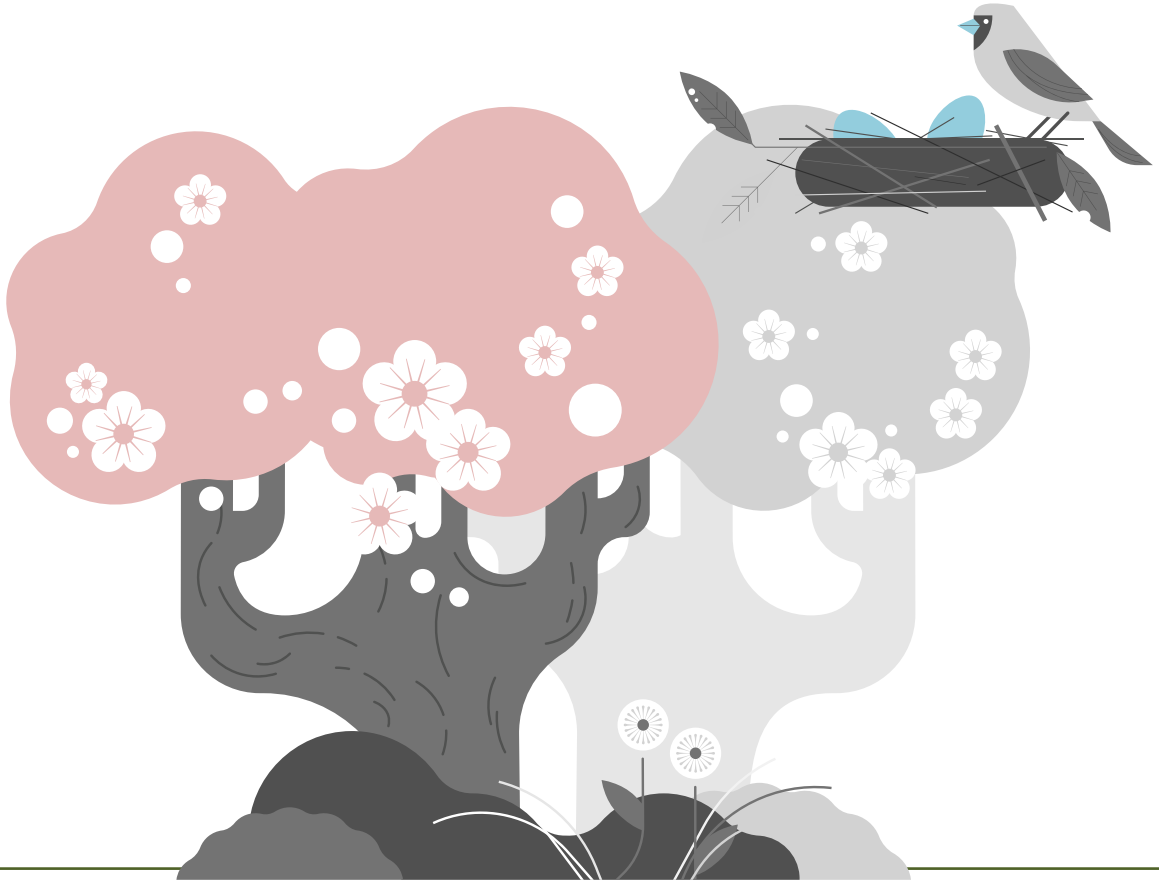
The IRB should be concerned that enrollment is slow/low if there is an ongoing problem with recruitment and the research may not be able to be completed as planned.

If protocol recruitment is slower than planned, the PI should be aware and concerned before the IRB is concerned. The PI will know that their research goals are at risk and should be taking steps to improve recruitment, or they should provide a reason for slow recruitment. If IRB reviewers are concerned about the rate of recruitment, they can ask the PI for an explanation and what activities are being taken to address the issue. This question for the PI should not be asked during the IRB meeting or last-minute. The IRB member(s) need to complete their review and ask any questions early enough to give the PI a few days to respond.

For example, the reviewer might find out that no subjects were recruited in the last year because research has been paused due to funding cuts or maybe there was a drug manufacturing issue. Another reason could be that the PI usually gets referrals from a local source that is no longer available. These are examples that the PI should be trying to actively address.

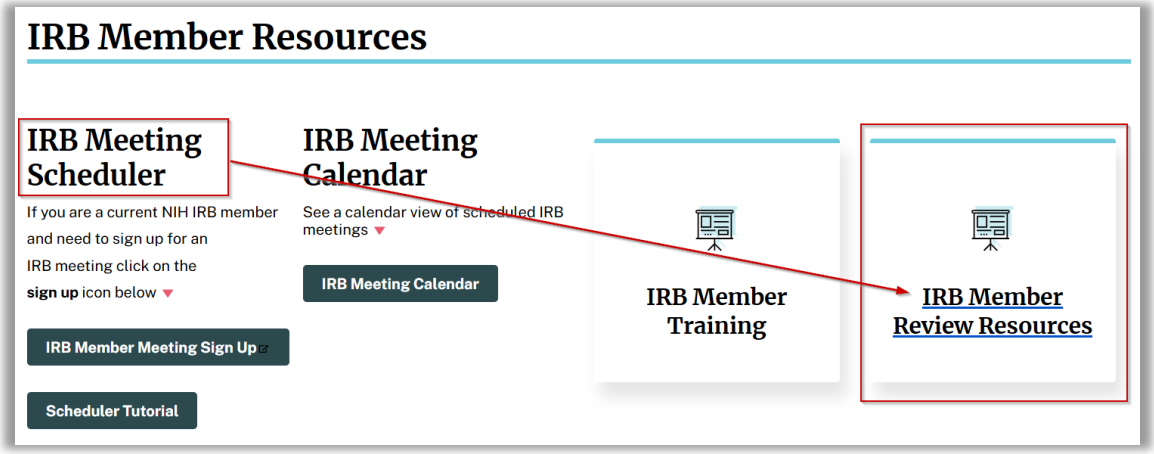
If the study objectives can never be met, should any subjects continue to be exposed to the risks of the research? At CR, the IRB determines if a study still meets the criteria for approval. Remember that the criteria for IRB approval of research indicates that "risks to subjects are minimized" and that "risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may be expected to result." Can the IRB continue to approve a protocol that requires resources, an individual's time, effort and that puts participants at potential risk when there is a real possibility that the study will be terminated before ever reaching its objectives?

Hopefully, most delays in recruitment can be addressed or are due to self-limiting problems.

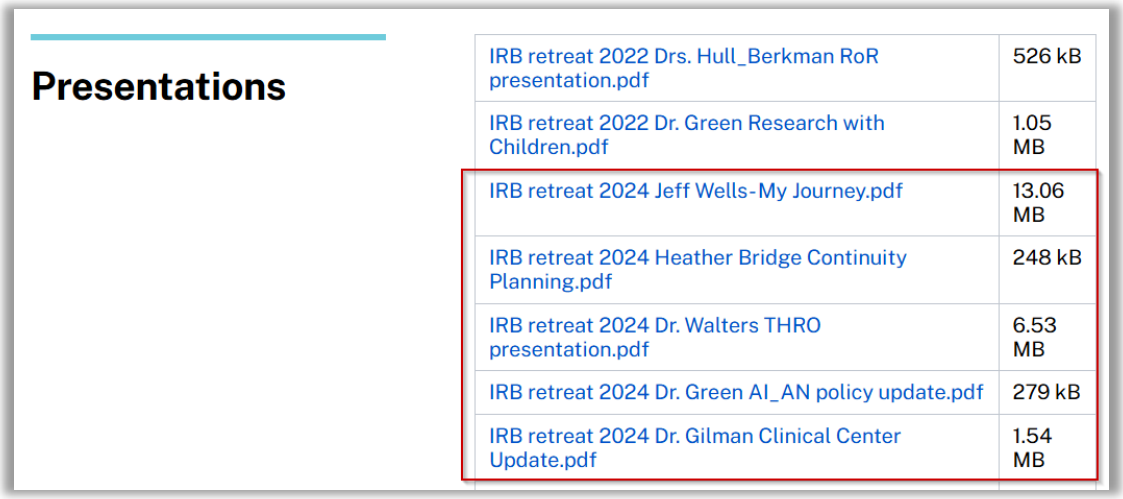


Presentations and Tip Sheets for IRB Members

Want help for your reviews? Look for the IRB Member Review resources! They are located right next to the IRB Meeting Scheduler that you use each month to sign up for your meetings.



Ghosts of IRB Retreat Pasts - The IRB holds a retreat every year where all members have the chance to meet in person and learn about emerging topics and stories that highlight the importance of our work. The slides from these presentation are archived in the IRB Member Review Resources.



The 2024 retreat included the following presentations:

- Dr. James Gilman (Former CEO of the NIH Clinical Center), NIH Clinical Center [CC]: *Where Have We Been & Where Are We Headed.* Dr Gilman presented the changes and progress of the NIH CC since the events of 2015-2016 (FDA inspection of the Pharmacy and the subsequent Red Team Report). He identified what he sees as guiding principles and strategic aims for the CC as well as his thoughts and hopes for its future.
- Dr. Jonathan Green (Director of OHSRP): *American Indian and Alaska Native [AI/AN] Populations in Clinical Research.* Dr. Green discussed the pending policy that will describe the additional protections and considerations that apply when conducting or reviewing NIH IRP research that enrolls AI/AN persons or uses samples/data collected from AI/AN persons.

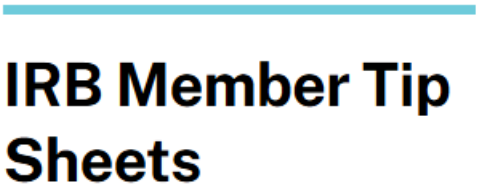
- Dr. Karina Walters (Director of the Tribal Health Research Office (THRO)): *American Indian and Alaska Native Populations in Clinical Research.* Dr. Walters discussed the vision and values that guide the mission of the THRO and the history that led to its establishment. She also presented important information that IRBs should consider when reviewing such research.
- Heather Bridge (Director, HRPP Policy & Accreditation): *Continuity Planning for IRB Members.* Heather reviewed OHSRP's plan to protect the safety of research participants during an emergency.
- Jeffery Wells, *My Journey*. Mr. Wells is a trauma survivor who shared his life journey that led him to be a part of PREP-IT's study's Patient-Centered Outcomes Core. This unique advisory body includes patient advisors, experts in patient engagement, and a communications/media expert. PREP-IT engaged several patients as coinvestigators to shape these trials from the ground up through their lived experiences, affecting the approach to patient recruitment and care. Mr. Wells also described his experience working with the Maryland Division of Corrections for over two decades as he also serves as a prisoner representative for the NIH IRB.

IRB Member Tip Sheets and Education Sessions

Month-long Groundhog Day - At the beginning of every IRB meeting, there is a presentation of information related to the IRB Tip Sheet. The Tip Sheet is a concise overview of a topic that comes up during IRB reviews which can be found under the Supporting Documents tab on the IRB meeting page. The topic rotates monthly, and the Tip Sheets are archived in the IRB Member Review Resources section of the OHSRP website. Since there have been quite a few new members over the past two years, you may notice that some topics are intentionally being repeated this year.

Here is a list of topics from the past year:

- IRB Consideration of Possible Third-Party Research Risks
- Practical Review of Continuing Reviews
- Enrollment of NIH Staff
- Practical Review of Modifications
- Review of Recruitment Plans and Materials
- In Vitro Diagnostics (IVD) Devices
- Appropriateness and Processes for Obtaining
- Assent from Individuals Who Lack Consent Capacity
- Considerations for Including Healthy Volunteers in
- Clinical Research
- Protocols Involving Investigational Devices
- Vulnerability of Subjects Participating in Human Subjects Research
- Inclusion of Children in Clinical Research Pediatric Component Analysis
- Review of Informed Consent Documents in PROTECT
- Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research



If there are any new topics that you would like covered or prior topics that you would like covered again, please feel free to contact us at OHSRPCompliance@od.nih.gov.