NIH Office of Intramural Research
Office of Human Subjects Research Protections

IRB MEMBER UPDATE

December 2025

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IRB Member Annual Survey

Your voice is important! The annual IRB member survey was sent out in early December.

We ask that all members to complete it, as your feedback helps us improve our processes, strengthen communications, and ensure the IRB is meeting member needs.

Coming Soon…

IRB Member Certification Form

The Certification Form for IRB Members Who are Non-NIH Federal Employees and Non-Federal Members will be available in December.

Please complete this and return to Mollie Fraser.

New Website Launched

In July, we announced the launch of our new Office of Human Subjects Research Protections (OHSRP) website:

https://irbo.nih.gov/

Please bookmark this updated URL.

The former website is no longer available.

Our new site is designed to be easier to use and includes the following improvements:

1. Easy Navigation: A simple layout, displaying most common content up front
2. Simple language: Straight-forward instructions for your most common tasks
3. Robust search capability: Improved searchability of content, instructions, policies, trainings, and templates
4. Organized regulatory/training/policy/process info: A more intuitive layout of the resources you need to plan, submit, and conduct your human subjects research.
5. Latest News and Updates: A "News" area to keep you apprised of recent HRPP announcements and news.
6. New and improved IRB member page: Additional resources for you as an IRB member have been added to our website.

IRB Meeting Presentation Tips

NIH IRP tips to presenting a review at IRB meetings!

OHSRP has developed a guide to support IRB members as you prepare for each meeting.

This resource was created in response to feedback from our last IRB member survey, as several members requested guidance on how to conduct and present reviews at Board meetings.

This document, TIPS for Preparing an IRB Member Review downloads as a pdf from the OHSRP Active IRB Members webpage.

The main webpage for IRB members, the IRB Member Hub, can be accessed from the top right-hand corner of any page on the website.

From there, members can click on the link to the OHSRP Active IRB Members webpage where, in addition to the newly added tips for IRB members when preparing reviews as mentioned above, members also have access to the IRB scheduler for signing up for meetings, guidance on conducting reviews, and a variety of additional resources available to members.

Previous monthly IRB member tip sheets can be found on the IRB Member Resources - Tip Sheets page towards the bottom of the Active IRB members page.

New NIH HRPP Policy involving American Indian/Alaska Native Persons

The American Indian/Alaska Native Persons (AI/AN) policy is now in effect.

The NIH Institutional Review Board (IRB), IRB Operations Office (IRBO) and the **NIH Tribal Health Research Office (THRO)** work together to ensure compliance with Tribal research oversight requirements.

The IRBO determines whether research falls under this policy and requires investigators consults with the THRO when needed. The NIH IRB reviews THRO recommendations to confirm that required Tribal approvals have been obtained before granting research approval. The IRBO and the IRB will seek additional guidance from THRO if approvals are unclear.

Final approval of research cannot be issued until all required Tribal Authority or Tribal IRB approvals are secured, including for initial reviews and modifications.

When Tribal IRBs or Research Review Boards (RRBs) provide input, the NIH IRB considers this as part of the local context review. For research reviewed by an external IRB, the IRBO ensures NIH Investigators cannot be approved by the Reviewing IRB as a site until all Tribal approvals are complete.

Additionally, when the NIH IRB is the Reviewing IRB, the IRBO ensures that substantive reviews are conducted by an IRB that, when feasible, is composed of a majority of American Indian/Alaska Native (AI/AN) members, in line with Policy 405 - Research Involving American Indian/Alaska Native Persons, Their Data and Biological Material and Policy 3014-201-IRB Membership and Composition.

For a better understanding of Tribal sovereignty, check out the ***Cultural Humility Toolkit for Indigenous People of the United States*** **(Mayo Clinic)**. One of our IRB members, Guthrie Capossela, MNM, (Hunkpapa Lakota from the Standing Rock Sioux Tribe) led a team comprised of Native and allied staff to create this toolkit to assist Mayo Clinic in its health equity journey regarding Native people. **We have attached the toolkit to the same email that provides this newsletter.**

IRB Gold Star Member

Congratulations to Dr. Sadia Sarzynski for receiving the Winter IRB Member Gold Star Award!

Dr. Sarzynski frequently utilizes her expertise as a Staff Clinician in the Critical Care Medicine Department of the Clinical Center to provide thorough knowledgeable reviews. She employs her first-hand clinical experience to raise practical concerns that impact participant safety. When providing the board with her assessments, she not only offers detailed descriptions of her assigned action but presents it in a way that is understandable to both clinicians and non-scientists. This at times has included providing visuals of human anatomy or procedures to augment her summaries. Dr. Sarzynski is always proactive, making sure her reviews are in well before the meeting and contacting teams when clarifications are necessary. She is an indispensable resource for the board especially for protocols focusing on cardiac interventions and frequently makes herself available when the board needs her expertise.

New CITI Training Course Available

A new CITI course, **Essentials of Software as a Medical Device [SaMD] & Clinical Decision Support Systems [CDSS]**, has been added to the list of courses available to any IRB member who has access to the NIH CITI account.

Course Description from CITI: "This course helps navigate the regulatory aspects related to SaMD and CDSS when conducting clinical evaluations or investigations. It also addresses special considerations for SaMD and CDSS, such as [Artificial Intelligence/Machine Learning] AI/ML-enabled medical devices, combination medical devices, and the regulatory obligations investigators have when developing their own CDSS and SaMD. In addition, the course discusses considerations for the design, development, and deployment of SaMD and CDSS, so developers, clinician-researchers, and sponsor-investigators can prevent wasted time, money, and resources and ensure safe and effective SaMD and CDSS."

How to Access the Course? Log into your NIH CITI account and scroll to the bottom of the page where your courses are listed. Click on "Add a Course" at the bottom of that page, and you will be taken to the list of all courses available to those who access the NIH CITI account portal. This new course is near the bottom of the page. Click the box for this course and then hit "Next." The course will be added to you list of "Courses Ready to Begin."

Link to IRB member training resources from the OHRP newsletter

Training from OHRP! Although it may seem surprising to many, human subjects protections training for IRBs is not actually a requirement of 45 CFR part 46.

However, the regulations at 45 CFR 46.107(a) do call for IRB members to have "professional competence" and "knowledge of institutional commitments (including policies and resources) and regulations, applicable law, and standards of professional conduct and practice."

OHRP offers a very helpful "Training Checklist for Someone Working with IRBs."

This checklist provides a basic list of resources for the following individuals:

1) New IRB members (including community members)
2) Investigators wanting to know what to expect when submitting a protocol for review
3) IRB administrators
4) Existing IRB members who want to brush up on the basics

OHRP and FDA also have recently updated their 2018 joint guidance titled Institutional Review Board Written Procedures: Guidance for Institutions and IRBs (2025).

The guidance document includes training and education for HRPPs, IRB members and support staff, regarding what they may want to address in their written procedures.

Additionally, OHRP offers a variety of free training resources available for institutions and IRBs to use on their Human Research Protection Training webpage.

IRB Member Educational Moment

Understanding MRI Device Classification and Approval in Research

A Framework for Device Classification for Clinical Research Protocols using MRI in the In Vivo NMR Center (Revised March 23. 2023) provides helpful information regarding use of MRIs at NIH. (The document downloads as a pdf.)

MRI research at the NIH In Vivo NMR Center often involves not just the MRI scanner but also coils, monitoring equipment, software, and novel research pulse sequences. Because these are considered FDA-regulated devices, the IRB plays an essential role in ensuring they are safe and used in compliance with federal regulations.

Here's what IRB members should know:

- **Device Classification & Safety Review:** All devices used in MRI research must be reviewed by the NMR Center Safety Committee before IRB submission to ensure they are safe for use in the MRI environment.
- **IRB's Role:** The IRB must confirm whether each device is FDA-cleared and being used as intended. If not, it is considered an investigational device and subject to additional review.
- **Risk Determination:** For studies involving investigational devices, the IRB decides whether the study is exempt from the requirement for an Investigational Device Exemption (IDE), Non-Significant Risk (NSR), or Significant Risk (SR).
    - **NSR Studies:** The IRB can approve under abbreviated IDE requirements, and no FDA review needed.
    - **SR Studies:** Require both IRB approval and FDA-approved IDE before the study can begin.
- **Documentation:** Protocols must list all devices and include regulatory status, safety data, and NMR Safety Committee approval as an appendix.

These determinations are **study-specific** and must be made in the context of the **full protocol**, not just the device alone. Your role as an IRB member is critical to ensuring MRI research is both safe and compliant with FDA and human subjects protections.

Additional information is available from FDA at Device Advice: Comprehensive Regulatory Assistance. The definition of "devices" and information on classification of devices can be found in the FDA guidance document How to Determine if Your Product is a Medical Device (2022). In very rare cases, studies that are potentially subject to the IDE regulations may be exempt. This is addressed in the FDA regulations at 21 CFR 812.2(c). If the PI thinks there are grounds for exempting a study or a device, they should need to indicate this in their protocol or speak to the IRB before submission of the IR.

For MRI systems, there is specific guidance available on the SR determination: See Criteria for Significant Risk Investigations of Magnetic Resonance Diagnostic Devices: Guidance for Industry and FDA Staff (2014). This guidance provides the FDA's thinking on this topic. Generally, the FDA deems magnetic resonance diagnostic device studies significant risk when the MRI is used under any of the operating conditions specifically listed in the document. They are not affirming, conversely, that studies where the MRI systems are operating below those conditions are automatically non-significant risk. *The SR/NSR determination is based on the entirety of the study.*

IRB Member Tip Sheets and Education Sessions

Each IRB meeting kicks off with a short presentation based on the monthly IRB Tip Sheet, a quick, practical overview of a topic that often comes up during reviews.

You can find all Tip Sheet under the Active IRB Members page of the OHSRP website at the bottom in the section labeled IRB Member Resources - TIP Sheets.

Below is a list of topics that we reviewed in 2025. The links open download as a pdf.:

- IRB Review of studies with Investigational Devices - Jan 2025
- Research Involving Children: Component Analysis – Feb 2025
- IRB Member Review of Informed Consent Documents in PROTECT – March 2025
- Review of Research Including Pregnant Women – April 2025
- Research with Adults Who Lack Consent Capacity – May 2025
- IRB & RCRC Review of Reportable Events - June 2025
- Enrollment of NIH Staff or Family members in NIH Research – July 2025
- Updated PROTECT Tips for IRB members – August 2025
- IRB Waiver of Informed Consent & Waiver of Documentation of Consent– Sept 2025

Do you have a Tip Sheet topic to suggest or feel that any of these topics require a longer session?

Feel free to email suggestions to the Compliance and Training Inbox at ohsrpcompliance@od.nih.gov or contact any of the members of Compliance and Training directly.