NIH Office of Intramural Research
Office of Human Subjects Research Protections

IRB MEMBER UPDATE

Summer 2026

IN THIS ISSUE

IRB Member Tip Sheet Archive

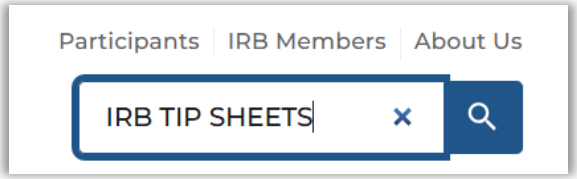
Each IRB meeting begins with a short practical overview of a topic helpful for reviews.

You can find all Tip Sheets under the Active IRB Members page of the OHSRP website:

- Under IRB Member Resources - TIP Sheets

-OR-

- Search for IRB Tip Sheets in the search bar at the top of the page.



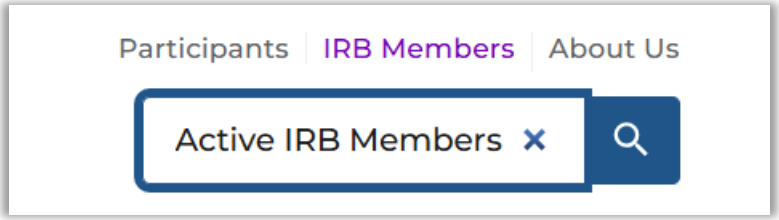
IRB Member Tip Sheets cont.

As we repeat topics, the updated tipsheet will replace the old tip sheet. Below is a list of topics that we have reviewed so far in 2026:

- **IRB Review of Multi-site Research**
- **IRB review of New Information Being Communicated to Participants**
- Research Involving Medical Devices
- **Reviewing Community-Based Participatory Research (CBPR)**
- **Component Analysis and IRB Review of Research Involving Children**
- **Preparing for the 2026 AAHRPP Accreditation Site Visit**
- IRB Review of Reportable Events

How to find IRB Member Education!

Links to educational resources can be found in the Active IRB Members section of the IRB Member Hub below the IRB Meeting Scheduler. The quickest way to find this is by searching for Active IRB Members in the search bar.



Below the IRB Scheduler are links to IRB Member education including:

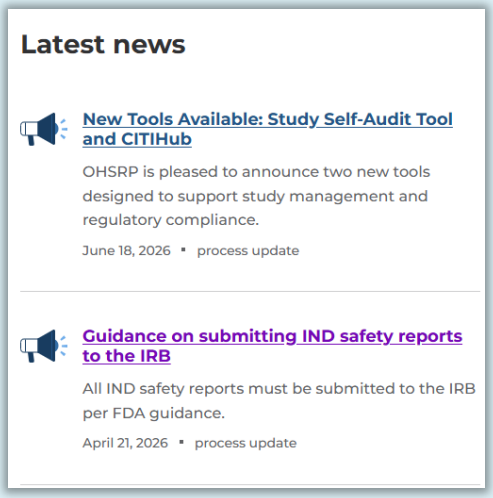
- IRB Member Resources - TIP Sheets
- IRB Member Resources - Presentations
- IRB Member Newsletters
- OHRP Educational Resources for IRB Members and Administrators
- TIPS for Preparing an IRB member review

Navigating the IRBO Website -

Finding information on any website can be challenging.

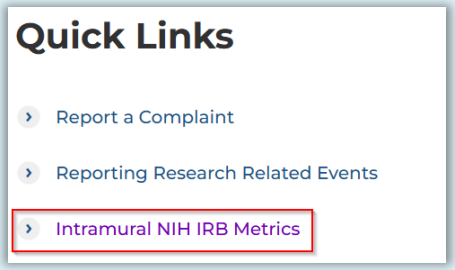
KNOW THE LATEST NEWS UPDATES!

Scroll to the bottom of the OHSRP website landing page to view the section titled Latest news.



VIEW INTRAMURAL NIH IRB METRICS!

There are four dashboards which provide information about NIH IRB submission volumes and approval timelines. Scroll to the bottom of the front page and find Intramural NIH IRB Metrics under the Quick Links.



IRB Member Retreat

SAVE THE DATE! Monday, September 28, 2026

Come to the IRB Member Retreat and meet your fellow IRB members in person. The retreat will be held in Building 31 on the main NIH campus in Bethesda. It will include educational opportunities and presentations. There will be a remote option for participation. However, in-person attendance is encouraged.

AAHRPP Accreditation

Calling On IRB Members - For the Reaccreditation Site Visit!

This year, our Human Research Protection Program (HRPP) will participate in our 4th reaccreditation with the Association for Accreditation of Human Research Protection Programs (AAHRPP). This is an important opportunity to demonstrate our continued commitment to ethically sound, scientifically valuable research and the protection of research participants. AAHRPP is an independent, nonprofit accrediting body. AAHRPP uses a voluntary, peer-driven, educational model to evaluate whether human research protection programs meet rigorous standards for quality, accountability, and continuous improvement.

We have submitted our written application for reaccreditation, and AAHRPP has already concurred that our policies and materials meet the accreditation standards. The site visit is a comprehensive evaluation of how our policies and procedures are put into practice across our HRPP. AAHRPP describes the site visit as an "Evaluation of Practice." The AAHRPP peer reviewers will assess how our organization's HRPP operates through a documents review and interviews with key personnel, including Institutional Review Board (IRB) members and Chairs. These conversations help the Site Visitors understand how the IRB carries out its responsibilities and supports the conduct of ethical research.

As IRB members, you play an essential role in this process. During the site visit, AAHRPP peer reviewers are expected to interview IRB members in groups of like members, such as Chairs, scientific members, and non-scientific members. We have already invited some members to be interviewed when we submitted our Step 2 application to AAHRPP. If for any reason these members will not be available during the site visit, we may call on other members to be their alternates.

If you are selected to be interviewed, we will hold preparation sessions this Summer, so you will know what to expect and feel comfortable sharing your experience. Your participation will help demonstrate the strength, professionalism, and shared commitment that make our HRPP successful. Thank you to all of our members for the care, insight, and dedication you bring to this important work.

IRB Gold Star Members

Congratulations to Stacey Doran and Cole Allick for receiving the Summer IRB Member Gold Star Award!

Stacey Doran has served as an IRB member since November 2024 and has consistently demonstrated exceptional thoroughness and dedication in her reviews. During a particularly complex initial review on April 2, she took the time to carefully evaluate both the consent materials and protocol, applying her subject matter expertise to provide thoughtful, detailed feedback to the study team.

Stacey's ability to clearly explain complex scientific concepts to fellow board members greatly enhanced the quality of the discussion. She also identified important concerns within the submission, ensuring that key issues were addressed and that the protection of human subjects remained at the forefront.

Her attention to detail, intellectual rigor, and willingness to ask challenging but necessary questions make her an invaluable member of the IRB. Stacey's contributions consistently elevate the review process, and she is highly deserving of recognition as a Gold Star IRB Member.

Cole Allick joined the IRB in February of this year and, despite being a new member, has already made a meaningful impact. With a background in Tribal Health and Community-Based Participatory Research, he brings a valuable and distinct perspective to board discussions.

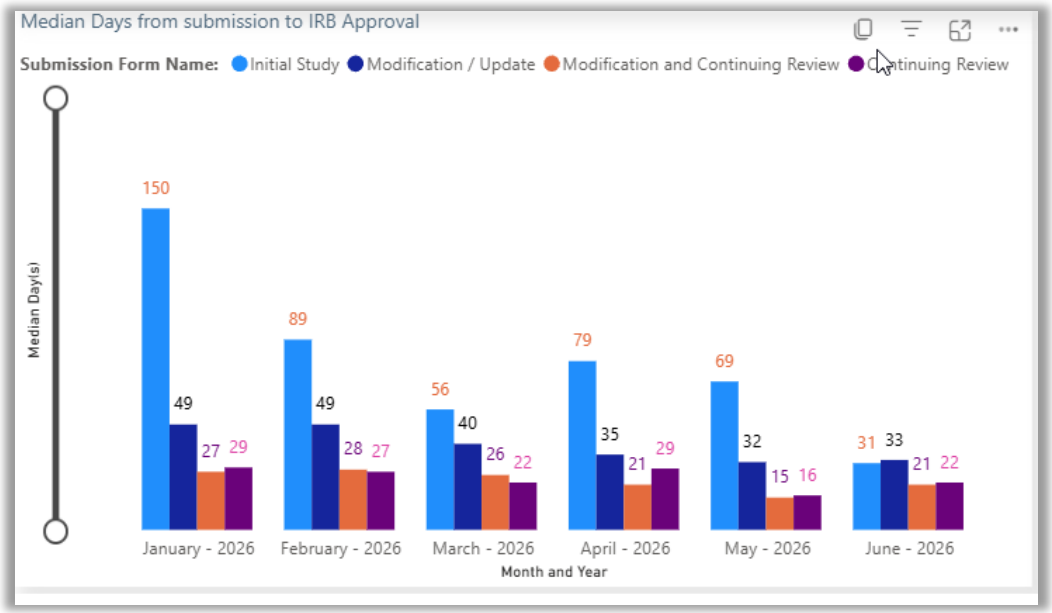
Cole has quickly adapted to the review process, demonstrating a strong ability to provide clear, concise, and thoughtful continuing review (CR) evaluations. He consistently contributes insightful comments and is confident in sharing his expertise, particularly in areas where his background enhances the board's understanding.

We are excited to have Cole as part of the IRB and greatly value the perspective and expertise he brings. His contributions strengthen the review process, and he is a promising and highly appreciated member of the board.

IRB Metrics from January 2026 – June 2026

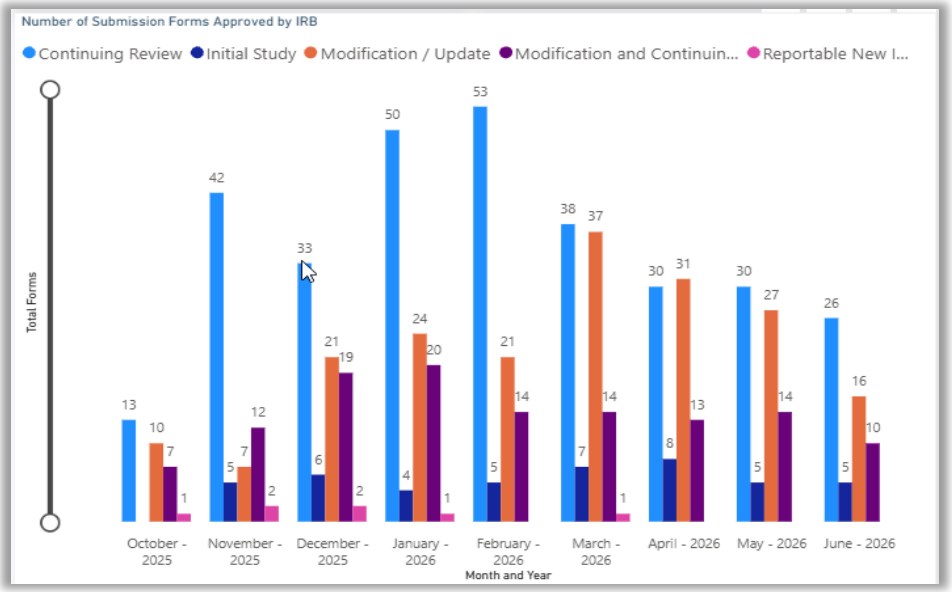
The IRBO is constantly tracking metrics to see what types of submissions are coming in and how we can improve turnaround times. Below you will find relevant metrics for the first six months of CY2026 with a summary provided below each graph.

Median days to approval – Full Board: January – June 2026



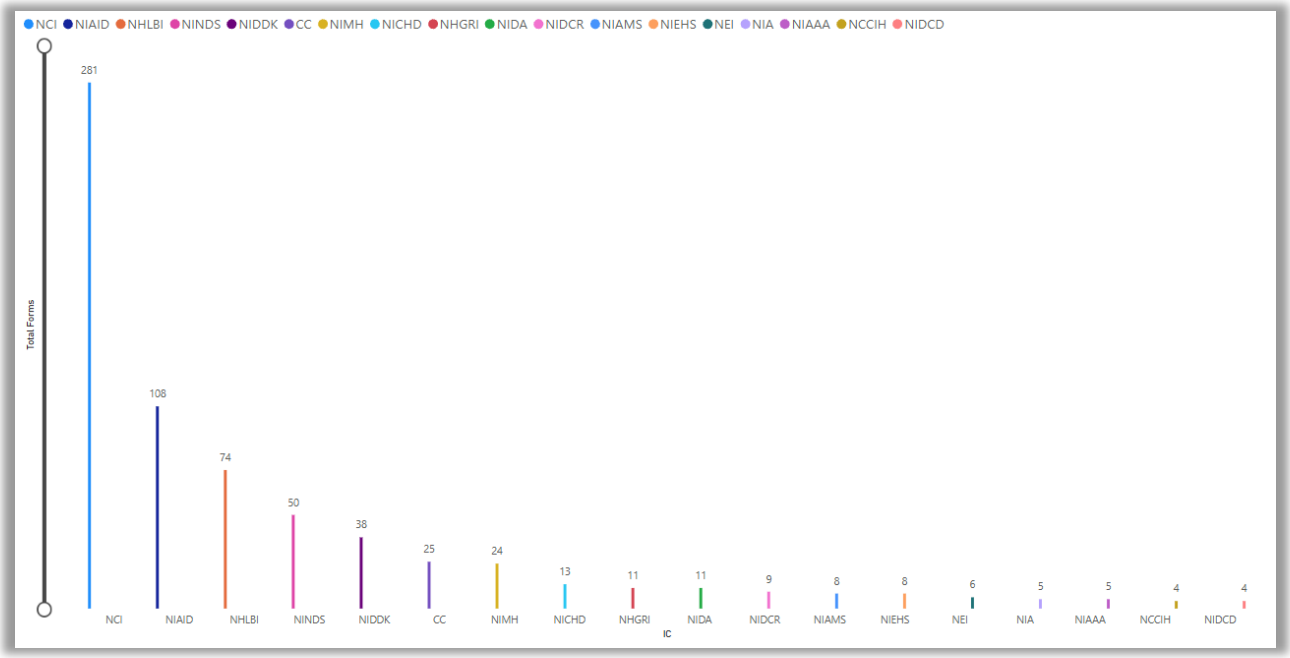
From the chart above, we can see that the median number of days from submission to approval have decreased overall for both initial reviews and modifications. This is particularly noticeable for the initial reviews that in January had a 150 day median turn-around time that dropped to a 31 day median turn-around in June.

Number of Forms Approved by NIH IRB – Full Board: January – June 2026 = 684



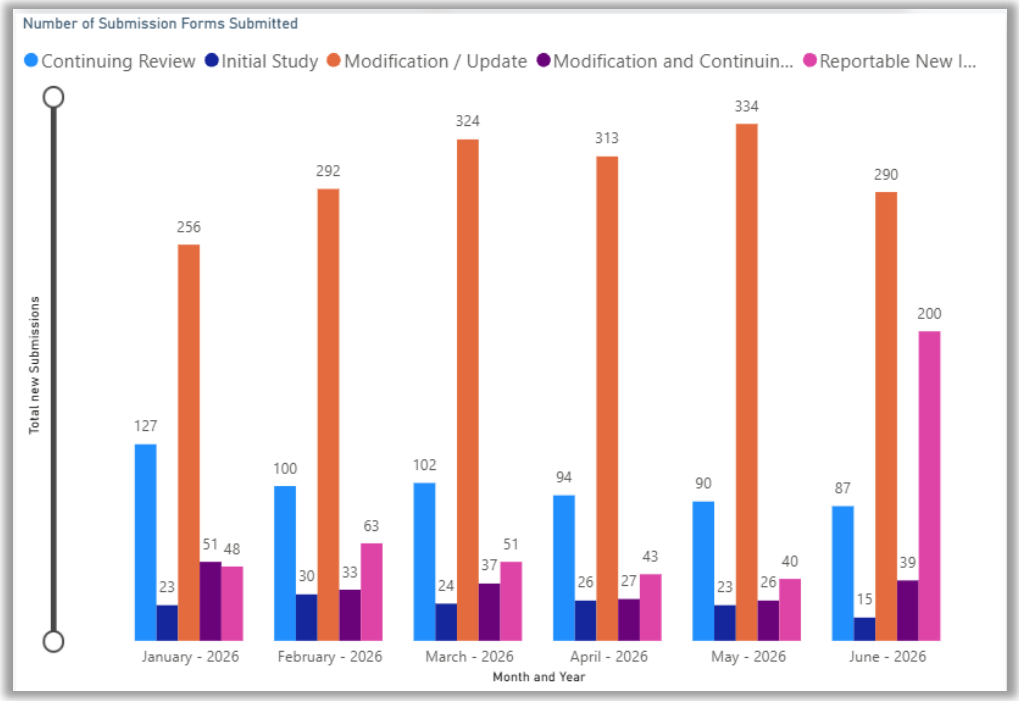
In the previous graph, we see that for CY2026 thus far, 684 submissions have been approved by the full board NIH IRB. Of those submissions, 34 were initial reviews and 156 were modifications (that were not part of a continuing review). There were two reportable events that were reviewed by the full board NIH IRB since January.

Number of Forms Approved per IC by NIH IRB – Full Board: January – June 2026



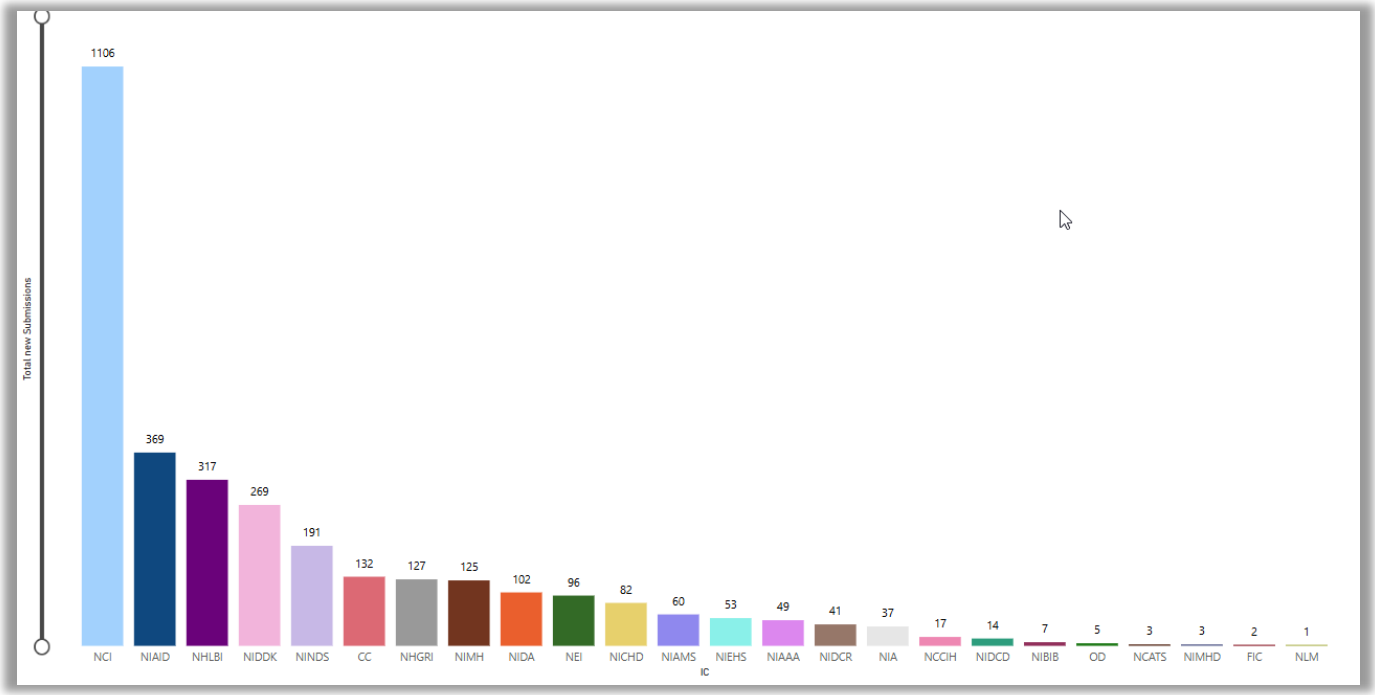
Above is a breakdown of submissions approved by the full board NIH IRB since January 2026 by IC. NCI, NIAID, and NHLBI submit the majority of the actions ("forms") that require full board approval. This does not include submissions that can be reviewed via the expedited or exempt pathways.

Number of Forms Submitted to IRB (Full board, Expedited, Exempt): January – June 2026 = 3208

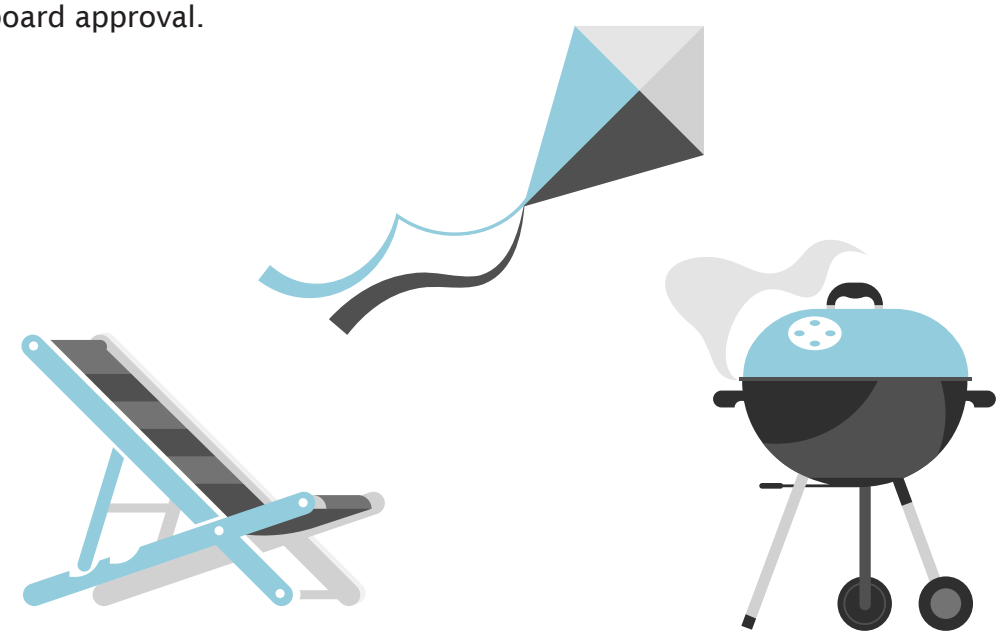


This previous graph is the number of all submission received by the NIH IRB overall broken down by month. This includes submissions that require full board approval and events that can be approved via the expedited and exempt pathways. RNI submissions have more than quadrupled after the new requirement by the FDA to submit IND Safety Reports to the IRB.

Number of Forms Submitted to NIH IRB per IC (Full board, Expedited & Exempt): January – June 2026



This is the number of all submission received by the NIH IRB overall broken down by IC. This includes submissions that require full board approval and events that can be approved via the expedited and exempt pathways. NCI, NIAID, and NHLBI still lead in the number of submission, but you can see here an increase in submissions for the ICs that perform research that does not require full board approval.



Results of the IRB Member Evaluation Survey

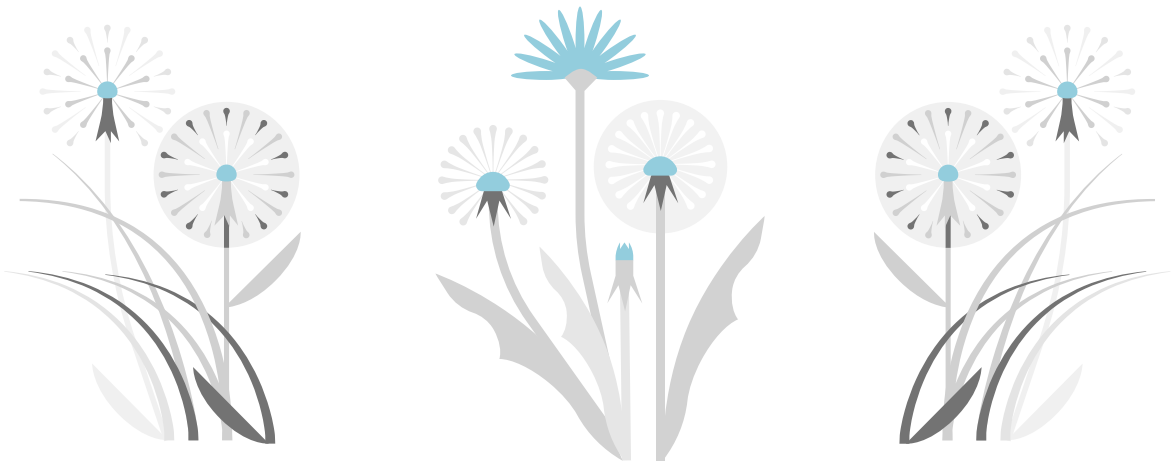
2025 IRB Member Survey Results! At the end of each calendar year, the IRB members are asked to complete their annual evaluation survey. Here are the results of the 2025 evaluation survey.

Of the 123 IRB members, 83 IRB members responded (67%).

Here are the summary results from that survey from members overall (All but one member agreed for each category):

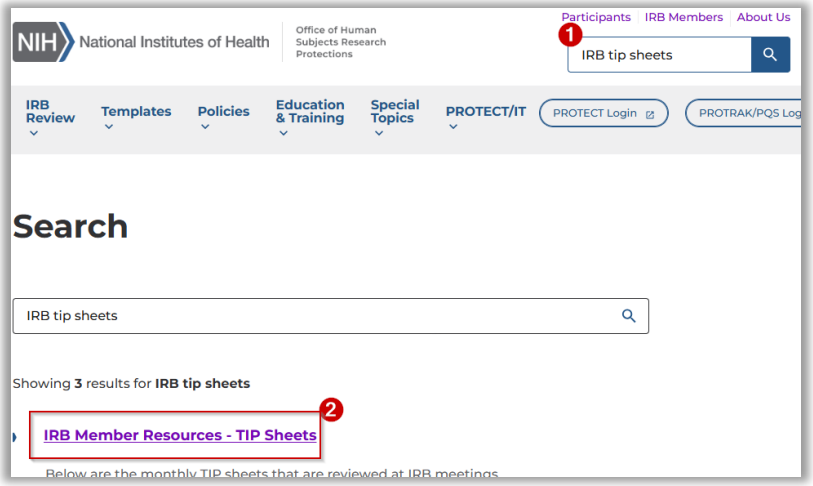
- Overall members felt that they had adequate knowledge of ethical principles, human subjects protection regulations, NIH policy and procedures to fulfill their role on the IRB. Continuing training was requested on NIH policies and various risk regulatory categories.
- The current review process of the NIH IRB is felt to allow for adequate protection of human subjects research.
- The number of actions reviewed at each meeting seem reasonable, and members reported they have adequate time to prepare before the meeting and discuss the submissions during the meeting. It was expressed that fewer submissions at some meetings would allow more time to review and discuss initial reviews and allow for more discussion on complicated issues that arise during the meeting.
- Members are able to access the materials in PROTECT to complete their reviews in the system and reported they have a good working relationship with OHSRP staff and other IRB members.

We ask that members attend one meeting each month. This is for many reasons, but one of the important reasons is that by attending meetings regularly, you gain experience as an IRB reviewer and become more comfortable in your role and with the process. If you rarely attend meetings, it is like a brand-new experience each time. While most members expressed that they were able to fulfill the one-meeting-a-month requirement, some expressed that their primary job or transient life circumstances sometimes make the requirement difficult to meet. If there are changes in your life that make the requirement impossible to meet, please contact Nicole or Tiffany to let them know.



Results related to the IRB TIP SHEETS! Members overall expressed that the monthly tip sheets provide information relevant to members' reviews. They were asked to provide feedback on the format of the tips sheets and the accompanying presentation that takes place at the beginning of each meeting.

- **Survey Feedback:** Tip Sheets should be displayed more prominently on the website.
  Response: IRB members who are looking for the tip sheets can type "IRB tip sheets" into the search bar on our website, and a result labeled **IRB Member Resources - TIP Sheets** is returned. Click on the link to find the relevant tip sheets. See screenshot.



- **Survey Feedback:** Tip Sheets are typically limited to about 10 minutes. There was feedback that this was too long and suggested 5 minutes.
  Response: Our Compliance and Training group will try to further abbreviate material presented at IRB meetings, though it is often challenging to provide the necessary content in less than 10 minutes.

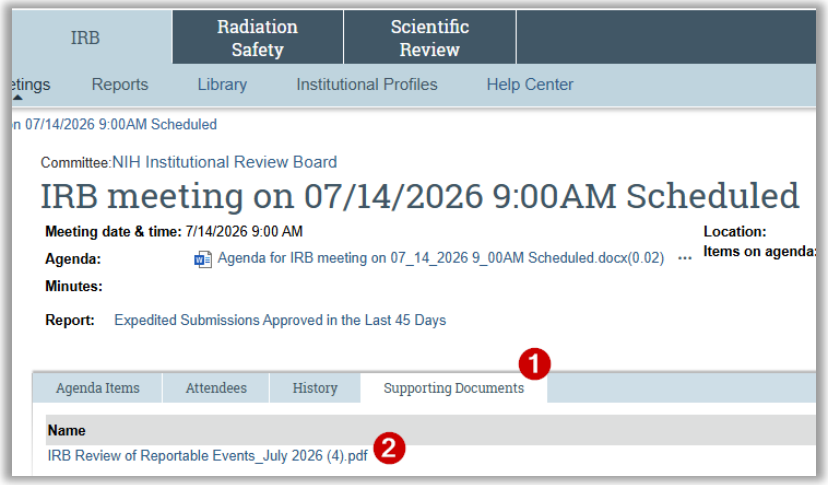
- **Survey Feedback:** There was a request for more examples or for the presentations to be more interactive, but it was acknowledged that doing that would add more time.
  Response: Though it would take more time, we can certainly try to add more case examples in the presentations. We strongly encourage members to ask any questions they have about the content after the tip sheet information is presented at the beginning of IRB meetings.

- **Survey Feedback:** Some preferred the live presentations since they felt more welcoming to questions. Others expressed that both live presentations and recorded ones worked fine.
  Response: We can try to do more of these sessions live at the beginning of the meetings. However, if the staff member presenting the content at every IRB meeting that occurs in a given month is out sick or on leave, we need to have a recorded session available.

- **Survey Feedback:** Someone requested that the tip sheet educational content be provided outside of the meetings.
  Response: The goal of in-person trainings is to allow members to ask questions, as the tips sheets relate directly to their role as an IRB member.

- **Survey Feedback:** Some requested including the tip sheet as a link in the agenda along with a copy of the slides and recording of the presentation so they could re-review the material after the meeting.

  Response: The tip sheets are available on the meeting page under supporting documents.



Here are some of the topics suggested for future Tip Sheets:

- **Suggested Topic:** Once a year refresher on common topics (i.e. vulnerable populations, devices, consent process, etc.)

  Response: Since we regularly have new members joining the IRB, we try to cover specific topics yearly, and these include research with special populations that we more typically see in NIH research studies (e.g., separate sessions for research with children, pregnant women, NIH employees, and those who lack capacity to consent to research). We also have tried to have at least one session each year on research that involves devices and another on the consent process. We also cover IRB review of potential unanticipated problems yearly. Additionally, since the IRB often deals with requests for waiver of consent and/or waiver of documentation of consent, we cover that annually too. We welcome suggestions of what other topics the members believe should be covered each year.

- **Suggested Topic:** Artificial intelligence (AI) and use of AI as an NSR device

  Response: This would be a great topic for a tip sheet presentation. OHSRP leadership is in the process of creating an addendum that investigators will complete when their research involves use of AI.

- **Suggested Topic:** SAE meetings/discussions

  Response: SAEs only require expedited reporting via RNI if they meet the reporting criteria in Policy 801, Reporting Research Events. (e.g., The SAE is also an unanticipated problem (UP).) We try to cover this information when we do the annual tip sheet session on reporting UPs to the IRB. SAEs only require reporting at the time of Continuing Review if they occur at a greater severity or frequency than expected. As a result, a study may have a number of SAEs that are not related to the research and that do not require reporting to the IRB.

- **Suggested Topic:** Waivers

  Response: We usually cover this topic annually.

- **Suggested Topic:** Use of Plain Language for Informed Consents

  Response: When we do the annual tip sheet on informed consent, we provide information on Plain Language and demonstrate where relevant resources can be found.

- **Suggested Topic:** Collecting data from subjects about family members and what is acceptable

  Response: We have recently added a web-page titled Collecting Information About Participants' Family Members which has information on this topic.

- **Suggested Topic:** Repository Protocols
  Response: Typically, these do not undergo review at convened IRB meetings, but related information can be found on our web page on Secondary Research as well as on the Repository Protocol Template (which can be downloaded from the Protocol Templates page of the OHSRP website).

- **Suggested Topic:** How to start up a new study
  Response: We typically consider this topic to be more relevant to investigators and study teams rather than IRB members. However, our website has information on this topic on the Protocol Development webpage. Additionally, slides and a video are available for a session titled *Planning Your Protocol* that can be found on the NIH Investigator Seminar Series webpage.

IRB Member Educational Moment

Ethical Considerations when Including Children in Clinical Research

The regulations for the protection of children in research under the Department of Health and Human Services (HHS) are found in 45 CFR 46 Subpart D, and the United States Food and Drug Administration (FDA) regulations for including children are found in 21 CFR 50 Subpart D. They are nearly identical except for some minor differences.

The FDA also developed a Draft Guidance in 2022 called, "Ethical Considerations for Clinical Investigations of Medical Products Involving Children." To accompany that guidance, they released an easy to follow "Snapshot" document that highlights the important points and which is easier to follow. They also released a 14-minute Podcast discussing and recapping the draft guidance. If interested, you can also view the public docket for this draft guidance.

Why is it important that children be included in clinical research?

Unfortunately, children can become sick or require medical help just like adults. However, children are not small adults. Their developing bodies, organs, immune system, and metabolisms process medications differently than adults do. Including children in research is vital to ensure treatments are safe, effective, and correctly dosed for the exact stage of a child's growth. There are also many conditions that are only found in children. Without pediatric studies, doctors are often forced to prescribe medications that have only been tested on adults, leaving their safety and efficacy for children unknown

When should children not be included in clinical research?

Children should not be enrolled into a clinical investigation unless their participation is necessary to answer an important scientific and/or public health question directly relevant to the health and welfare of children. Adults should generally be enrolled prior to children, and any research procedures that do not contribute to a scientific objective should be eliminated. However, there are some conditions that only affect children, and testing on adults first may not be possible.

How do you justify the risk of including children in research?

Research involving children must be rigorously justified using a framework of risk-benefit analysis and vulnerable population protections. In assessing the risks and potential benefits, the IRB should consider the circumstances of the children to be enrolled in the study-for example their health status, age, and ability to understand what is involved in the research-as well as potential benefits to subjects and other children with the same disease or condition. HHS regulations in 45 CFR part 46, subpart D provide four different approval categories of risk versus benefit that would allow children to be included in research. The IRB is responsible for documenting the approval category and providing a rationale for their choice.

Why do we perform pediatric component analysis?

Component analysis is an ethical framework used to separately evaluate the risks and potential benefits of individual procedures within a study, rather than assessing the trial as a whole. It ensures vulnerable pediatric patients are not exposed to unacceptable risks without direct benefit.

Each intervention that is conducted solely for research purposes, and not needed for clinical management or routine clinical care, must be evaluated separately to determine whether it offers the prospect of direct benefit to the enrolled child. For interventions that offer no direct benefit, component analysis mandates that the risks be restricted to a "minor increase over minimal risk." This prevents children from being subjected to unsafe procedures just to advance science.

How do we include children in placebo-controlled trials?

If children are included in the treatment arm of the protocol, the risk of the treatment can usually be justified by the potential benefit of the potential treatment of the disorder. However, how do you include a placebo control group when there would be no benefit to the child to receive placebo? This is done by controlling the risk to these subjects. The risk to the children in the placebo control arm (randomized or not) needs to be either minimal or no more than a minor increase over minimal risk.

When minimizing the risk of receiving placebo to these children, the IRB needs to consider multiple factors including the placebo drug itself, how the placebo is being administered, any procedures being used for the administration, and the frequency and duration of the placebo administration. The IRB must also consider the risk to these children in withholding known effective therapy and the possible use of rescue therapy.

For example, during a placebo controlled, multi-site trial of an investigational product (IP) in affected children, IP or placebo was administered by IV infusion. FDA discovered that some study sites were inserting PICC lines into the children for the infusion. This is a type of central line catheter placed in a big vein leading to the heart. The FDA determined that while PICC use was justified in children receiving active IP due to the prospect of direct benefit, it was not justified in children receiving placebo as it represented a greater than minimal risk procedure being performed without prospect of direct benefit. The FDA determined that this was violation of FDA regulations.

What should the IRB consider when reviewing the justification for including healthy children in research?

When enrolling healthy children in a protocol, the PI should be providing a justification for their inclusion in clinical research. Healthy children can only undergo minimal risk procedures.

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. However, the justification for the inclusion should be beyond the fact that they are only undergoing minimal risk procedures. Healthy children generally do not receive medical benefit from research. The IRB should consider if scientific goals can be achieved using only adults or children with the targeted disease. Healthy children should only be enrolled if scientifically necessary to establish baseline or control data or if there is generalizable knowledge to be gained that is specific to children.

Available Optional CITI Courses

NIH has more options for training through CITI than those required by our education policy. These training modules include more in-depth discussions of research related topics beyond what we can cover in our tip sheets.

Here are some of the available topics that may be of interest:

- Vulnerable Subjects - Research Involving Children
- Vulnerable Subjects - Research Involving Pregnant Women, Fetuses, and Neonates
- Vulnerable Subjects - Research Involving Prisoners
- Vulnerable Subjects - Research Workers/Employees
- Genetic Research in Human Populations
- Phase I Research
- Unanticipated Problems and Reporting Requirements in Social and Behavioral Research
- Unanticipated Problems and Reporting Requirements in Biomedical Research
- Artificial Intelligence (AI) and Human Subject Protections
- Essentials of Software as a Medical Device & Clinical Decision Support Systems
- Social Media and Research Recruiting
- Understanding Consent Requirements and "Key Information" Under the Revised Rule Webinar

To access the courses, 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. Click the box for this course and then hit “Next.” The course will be added to you list of “Courses Ready to Begin.”