Office of Intramural Research
Office of Human Subjects Research Protections

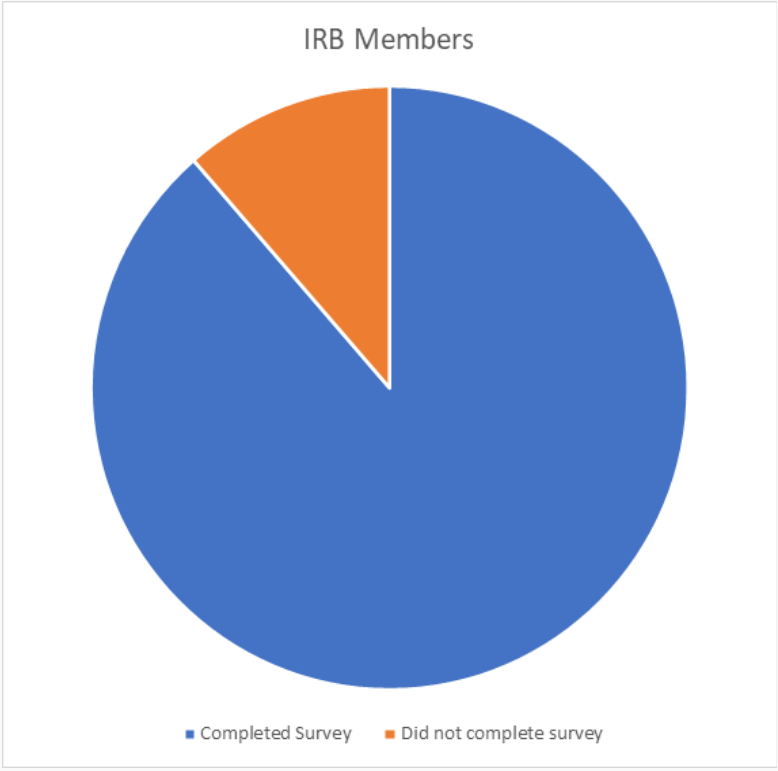
IRB MEMBER UPDATE

Summer Edition JUNE 2023

IN THIS ISSUE

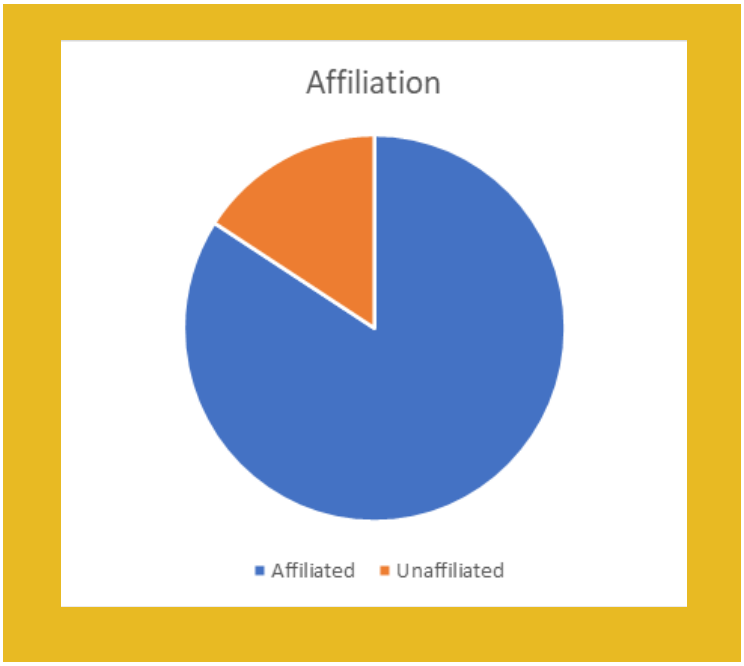
2022 IRB MEMBER SURVEY RESULTS

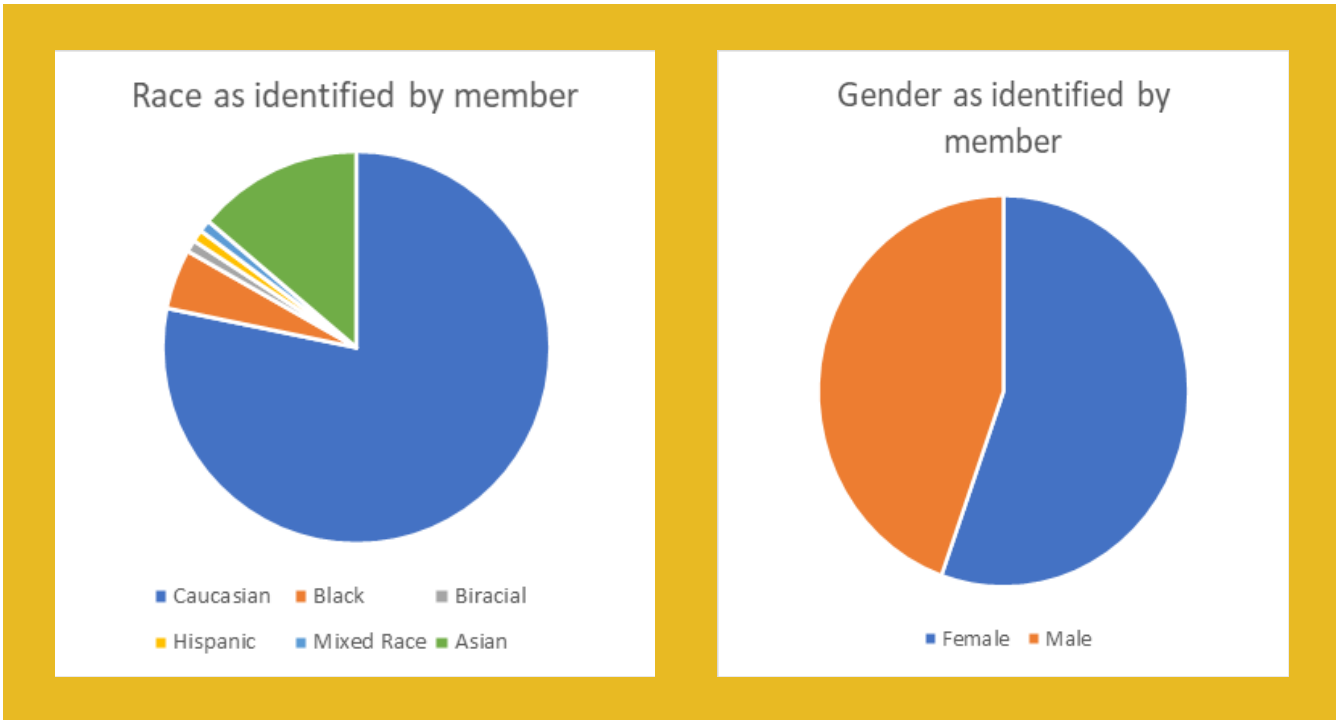
Most of our members completed the survey. Thank you so much as your input MATTERS!



2022 IRB MEMBER SURVEY RESULTS, CONTINUED

Who are we? Member statistics of those who responded:





HOW WE FUNCTION:

In terms of how our meetings function, all but two members agreed:

- That our current IRB review process allows for adequate protection of human subjects research.
- The number of actions reviewed at each meeting seemed reasonable to review in the time frame allotted for the IRB meetings
- That in the past year they have been able to adequately prepare for review of the agenda items for each meeting
- That they have a good working relationship with OHSRP staff and other IRB Members
- And ALL members felt they are an active contributor during the meetings.

Not all the members were able to meet the minimal attendance expectation of IRB members by attending at least one meeting per month. About 20% said they were unable to do this. Please remember—your monthly attendance at IRB meetings is critical to the ongoing success of the NIH IRB.

1. **Experience counts:** In our experience, it takes the average reviewer about a year to become a good IRB reviewer. The IRB review process is not intuitive, even (and perhaps particularly so) for people that are experienced grant and/or manuscript reviewers. It takes practice and that can only happen by regular attendance at meetings.
2. **Distribution of expertise:** It is critical that we have wide expertise and that it is distributed across all the meetings. When a study has completed the IRBO pre-review process and is ready for committee review, we look at the upcoming meetings to find the relevant expertise. If no one has signed up, we cannot match the protocol to the expertise. Ideally, expertise is distributed somewhat evenly across the month. If we have 10 oncologists, but only one comes each month…then we cannot review those studies in a timely manner.
3. **Quorum, quorum, quorum:** We cannot meet if we don't have quorum. If we can't meet, we can't review, and researchers can't do their work. We currently are holding 4 meetings per week, which means we need at a minimum 16 people each week (not counting Chairs) to sign up. Given that we currently have around 115 members on the roster, this should not be a problem. However, as many people are not signing up, we are struggling to meet quorum for many meetings.
4. **All are needed:** To hold a meeting, we must have at least one non-scientist. To review FDA-regulated research we must have at least one physician scientist. Once we send out the agenda (a week prior to the meeting) we are counting on you to be there! If you withdraw from the meeting after the agenda has been sent out, we risk losing expertise and/or quorum and may have to cancel the meeting. Please don't do that unless it is absolutely critical.

OUR CONTINUED LEARNING:

The survey showed that our members feel confident and comfortable in their roles. All but two agreed that they had adequate knowledge of ethical principles, human subjects protection regulations, NIH policy and procedures to fulfill their role on the IRB.

As you know, we have been presenting a new "TIP sheet" each month at the beginning of the meetings. Most members agreed that they felt the monthly TIP sheets have provided valuable educational information. Some did say the information was redundant:

- With other information they receive/ learn about as a researcher
- They hear the information more than once if they attend more than one meeting per month.

In terms of how we can improve, there were several helpful comments that we have taken to

heart.

- Slides are being read sometimes and this makes it less interesting.
  - We will work to make the presentations more engaging.
- Question of whether the presenter has command of the material.
  - We agree that some of the topics are challenging and that the presenters may not always be able to answer questions. When that happens, the presenters will solicit the input from the Chair. It would be great to have a subject matter expert (SME) present on topic within their area of expertise, but we'd need to do a recording in advance. However, this doesn't get around the fact that the SME wouldn't be there for any questions after members watch the recording. If we did this, maybe we could offer to send any questions we cannot answer to the SME and get back to the person who asked the question. We have done that on a few occasions already when we did not have a definitive answer for a challenging question. We will explore this possibility further.
- Whenever possible, consider adding the slides or the specific topic to the agenda ahead of the meeting.
  - The TIP sheets are included on the agenda ahead of the meeting under the supporting documents tab.
  - The presentations are only recorded when we know ahead of time that we will be on leave for an IRB meeting unless the presentation is very process oriented such as the presentation about how to review a CR which was posted on the IRB member resource section of the website.
- Suggestion to add case presentations/a case-oriented approach to the presentation.
  - Great idea which we can try to incorporate!

WHAT MEMBERS WANT TO LEARN MORE ABOUT:

- *"An even deeper dive on ways to assess vulnerability for those groups not explicitly named in the Common Rule would be helpful."*
  - In December 2022, we had a TIP sheet which covered review of research with subjects who are potentially vulnerable from a medical, economic, or social standpoint.
  - In February 2023, we had a TIP sheet about research with adults lacking capacity to consent.
  - We will explore doing a TIP sheet to cover research with employees.
- "Logistics of working with outside IRBs"
  - We have a planned TIP sheet covering multisite research later this year.
- "Minor Assent; Waiving Assent, Parental Permissions, Waivers of IC and Waivers of Documentation"
  - We have planned a TIP sheet to cover waiver of consent and waiver of documentation of

consent later this year.

° We had a TIP sheet in July 2022 which covered assent and parental permission.

- *"I think devices are confusing to even the OHSRP staff (and certainly to most reviewers) and we could improve how we make determinations in a more consistent manner."*
  ° We agree that devices can be confusing! We had a TIP sheet which covered devices in March 2022. This topic has also been covered more than once in our OHSRP Education Series sessions, but not specifically from an IRB member's perspective. We will work on creating another session on this topic as it remains a challenge for us all!

- *"2023 DMS Policy"*
  ° We covered the DMS policy in an OHSRP Ed session in February 2023, but that was more oriented towards PIs. We will consider how this information relates to our IRB review and create a TIP sheet on this topic.

- *"Recruitment, social media use for outreach/recruitment"*
  ° We have a **Guideline for Recruitment and Screening on our website with the relevant policy (302**). Brenda Curtis and Tiffany Gommel covered the social media aspect of this at the April 2023 OHSRP Ed session, **A How to Guide: The Use of Social Media in Research**, but we've not covered it in a tip sheet.

- *"Ethical principal covering Racial and Gender issues in clinical research"*
  ° We are not sure exactly what is meant here- possibly principle of justice when it comes to equitable subject selection? We had a TIP sheet on equitable subject selection in February 2022, but it was a general discussion and not focused specifically on race and gender issues.

eIRB System Implementation Updates

PROTECT POST GO-LIVE EDUCATION

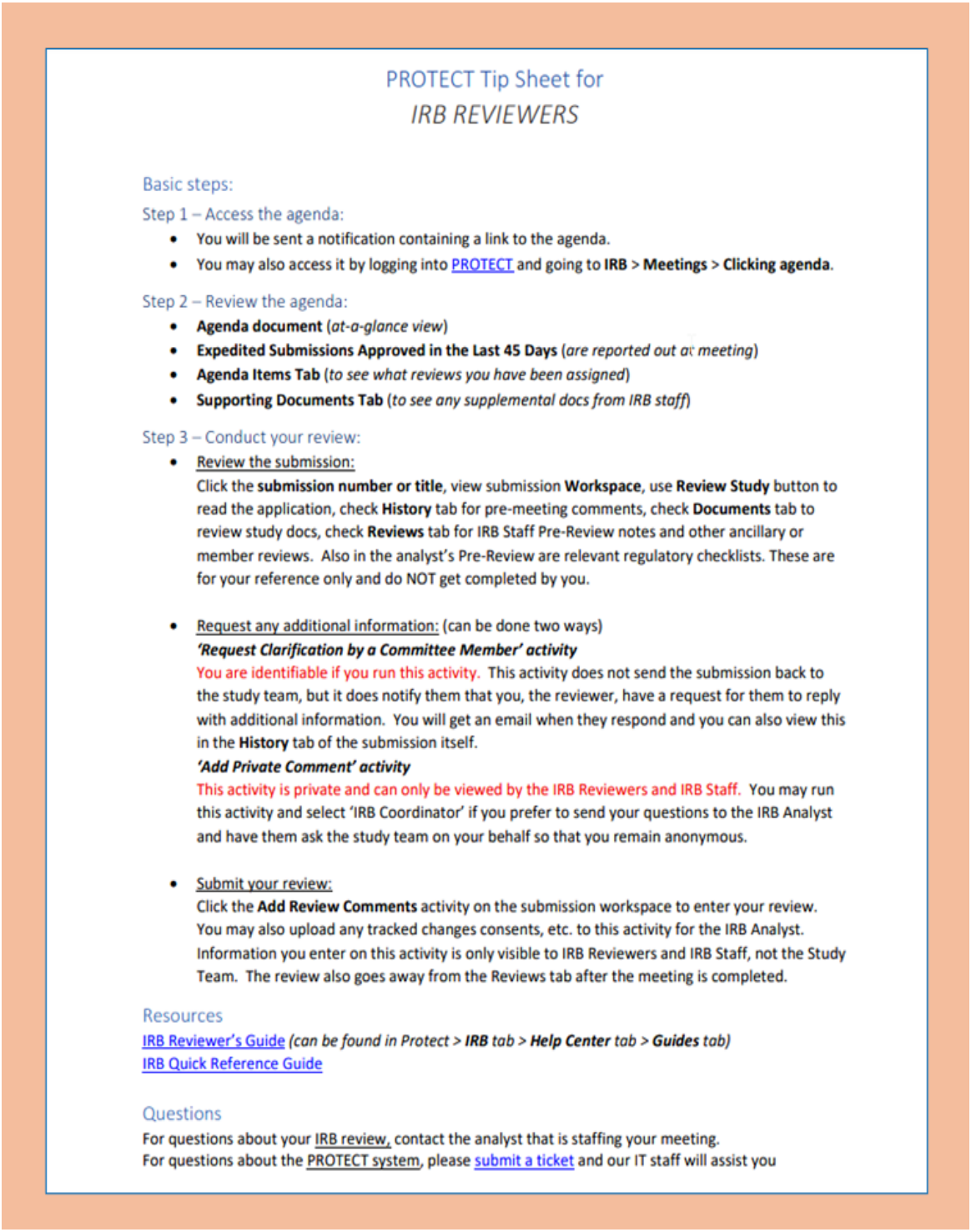
During the month of April, our PROTECT trainers attended each IRB meeting to deliver a refresher course for IRB members on:

» how to know when they have reviews assigned,
» how to locate and find all of the contents of a submission for their review, and
» how to complete the review.

The education was brief but packed with information and very well received. We hope that you were able to observe a session. If not, the PowerPoint for this session is available here.

IRB REVIEWER'S TIP SHEET (NEW)

One of the tools we introduced in the April IRB Member education sessions was the *IRB Reviewer's Tip Sheet*. This is a one-page, high-level process tip sheet to help you complete your PROTECT review. You can view the tip sheet here. A screenshot is also below:



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

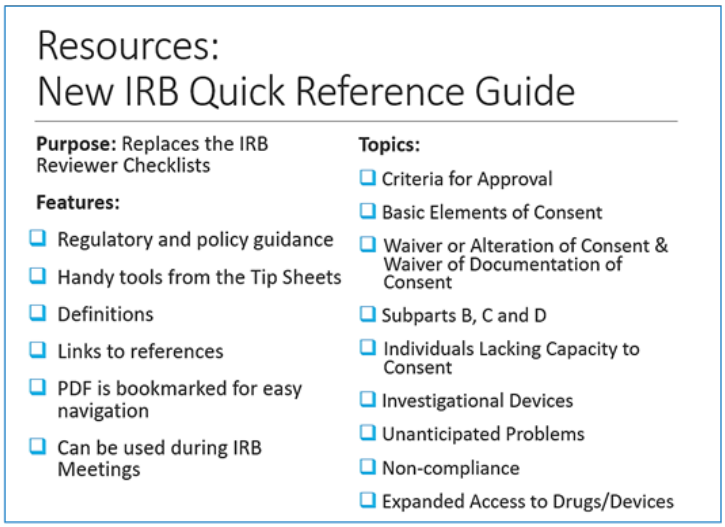
IRB Reviewer's Guide *(can be found in Protect > **IRB** tab > **Help Center** tab > **Guides** tab)*
IRB Quick Reference Guide

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

IRB QUICK REFERENCE GUIDE (NEW)

One of the tools we introduced in the April IRB Member education sessions was the IRB Quick Reference Guide. This is a detailed index of regulatory tools and checklists. This replaces the IRB Reviewer Checklists. You can view the Reference Guide here. A screenshot recapping this tool's contents is also below:



NEED PROTECT HELP?

How to submit a support ticket OR Join us at our daily Virtual Help Desk Hours

The PROTECT Trainers are online during business hours (8:00 a.m. - 4:30 p.m. EST) to assist you with anything you need pertaining to your reviews. You may submit a ticket to get 1:1 help **here**.

We also have 2 hours of live Help Desk Support every day. The link and hours are below:

Members of our PROTECT Core team will be available via Zoom for help. Join the Zoom meeting to have your questions answered.

Monday, Wednesday, & Friday from 10:00 – 12:00

Tuesday & Thursday from 1:00 – 3:00

Link to Zoom Meeting: Click here to join the meeting

IRB MEMBER REVIEW RESOURCES PAGE

The IRB Member Review Resources page on the OHSRP website has a great deal of information to assist IRB members. At the top of the page, there are links to training sessions and videos from the Office for Human Research Protections (OHRP). Some of these videos (e.g., Quorum and Voting in IRB Meetings and sessions (e.g., What is Human Subjects Research?) may be particularly helpful for new IRB members.

The available OHRP videos and sessions are listed in the screenshot below and on the IRB Member Review Resources page, and brief summaries of these trainings are described below.

OHRP Simplifying Informed Consent

This video is about creating a meaningful informed consent document. There are examples illustrating how to discern which information is meaningful for potential participants, and how to best convey this information in consent documents. Simplifying the informed consent document is intended to help optimize the consent process and to facilitate the goal of enabling potential participants to make informed decisions about whether or not to participate in the research based on their own values and goals.

IRB MEMBER REVIEW RESOURCES PAGE, CONTINUED

OHRP Quorum and Voting in IRB Meetings

Quorum:

- To establish quorum, a majority of the IRB members must be present including, at least one member whose primary area is in non-scientific areas.
- Without quorum, the IRB cannot review or act on any research protocols.
- When alternates for primary members are present *(Note that alternates cannot count toward quorum unless they are replacing a primary member who is not present.)*

Voting:

- After reviewing a protocol, a convened IRB can vote to approve the research, require modifications to secure approval, defer the research for later review by the convened board at a later meeting, or disapprove the research.
- The regulations state that in order for the research to be approved, it must receive the votes of the majority of members.

Abstaining:

- There are instances when members may choose to not vote and abstain. This occurs because members may not feel they are adequately informed to decide on approval of the study or are genuinely undecided.
- Members who participate for a protocol review, but abstain from voting, are still considered to be members present at the meeting. Note that abstaining members still count towards quorum and for calculating what constitutes a majority vote for approval of a research study.

OFFICE OF COMPLIANCE AND TRAINING IRB TIP SHEET

When an IRB Member Abstains vs. Recuses (Due to Conflict of Interest (COI))

Abstaining Member	Member who Recuses Due to COI
Attends a meeting and participates in review of protocols	Must be recused and may not participate in the review of the relevant protocol except to provide information
Counts toward a quorum	Cannot count towards a quorum
Counts toward voting	Cannot vote

OHRP: What are IRBs?

This three-part lesson discusses the purpose and membership requirements of IRBs and the functionality of a Human Research Protection Program (HRPP) office.

What is Human Subjects Research?

This four-part lesson explains how the Common Rule regulations define "research" and "human subjects" and explains what it means to be exempt from the regulations. The lesson focuses on the Revised Common Rule (2018 Requirements).

Independent Review of Research

This five-part lesson describes the regulatory requirements for IRB Review and the criteria for IRB review and approval under the Common Rule. This lesson focuses on the Revised Common Rule (2018 Requirements).

Office of Compliance and Training Tip Sheet Presentations

The IRB member tip sheets are located on the IRB Member Review Resources page of our website and presentations on the tip sheet topics are provided at the beginning of that month's IRB sessions. More tip sheets will be coming your way, so stay tuned. Please contact the office of Compliance & Training email for questions or suggestions about topics you are interested in and would like to see covered in upcoming tip sheets. Questions can be submitted to our Compliance and Training mailbox at OHSRPCompliance@od.nih.gov.

IRB Member Tip Sheets

- Payment of Research Subjects June-2023.pdf
- Secondary Genomic Findings and RoR-May 2023.pdf
- PROTECT Tip Sheet for IRB Reviewers-April 2023.pdf
- IRB Review of International Research-March 2023.pdf
- Research Involving Individuals Without Consent Capacity-Feb 2023.pdf
- IRB review of CRs in PROTECT -Jan 2023-VIDEO.mp4
- IRB review of CRs in PROTECT -Jan 2023.pdf
- Research w Economically or Socially Vulnerable Subjects-Dec_2022.pdf
- Research Involving Pregnant Subjects-November 2022.pdf
- IRB Member Review of Consent Forms-October 2022.pdf
- COI-What IRB Members Need to Know September 2022.pdf
- IRB Review of Possible UPs August 2022.pdf
- Research Involving Children July 2022.pdf
- Reportable Event Review Process-IRB vs. RCRC June 2022.pdf
- Consent form considerations for Early Phase research May 2022.pdf
- Data and Safety Monitoring Plans April 2022.pdf
- Equitable Selection February 2022.pdf
- Device Determinations March 2022.pdf

COLLABORATIVE IRB TRAINING INITIATIVE (CITI) COURSES THAT MAY BE OF INTEREST TO IRB MEMBERS

IRB members are only required to take the CITI course, Biomedical 101. However, there are other CITI courses available that might be of interest to you especially as you review protocols enrolling vulnerable populations or that involve types of research with which you may be less familiar (e.g., sociobehavioral research.) To access additional CITI courses, log into our NIH CITI account on the NIH CITI Training page and click on the green box that says CITI training.

NIH CITI Training

CITI Training | Training Records | Training FAQs | Expired CITI Training

- Navigate to the CITI Training Portal via the CITI Training link above.
  - **When you open the NIH CITI Portal, do NOT click on Add Institutional Affiliation.**
  - **Click on "View Courses" to the right of National Institutes of Health**
- Use your NIH AD email address for CITI Registration. To find your AD Email address navigate to the NIH NED website. Allow 1 day for completed training to appear in PROTECT.
- If there are any training discrepancies (such as if an individual believes they have completed the training but it is not accurately reflected in PROTECT), please submit an PROTECT Help Desk Ticket and **attach the completed training certificates.** This will allow the NIH PROTECT Support Team to confirm the accuracy of the required training.

You will be taken to your account page. Scroll to the bottom of the page and click on "Add a Course."

After clicking on "Add a Course," a list of course options appear, and you can click the box for any specific course and then click "next." The course you chose will be added to the list of your "Courses Ready to Begin." We hope you will find them informational and helpful in your role as an IRB member.

PLANNING FOR EMERGENCIES

Have you ever wondered what would happen to IRB review if we had an emergency? Well, you already know what happens when we have a pandemic, and most folks are told to go home and to stop working in-person for the foreseeable future. Amazingly, although none of us could have anticipated COVID-19 and its impact on the research enterprise, we managed to adapt and learn pretty quickly. In fact, it taught us all sorts of lessons, such as:

- The IRB doesn't have to meet in-person and can function efficiently in the virtual environment
- Some folks may have needed more equipment than before, while others needed training and technical support
- The NIH could rise to the occasion and prioritize important research to help find solutions to the COVID pandemic, and for Intramural Research Program investigators this required the IRB's assistance
- The IRB is critical to help investigators navigate tricky waters when their participants could not come to the Clinical Center or research had to stop temporarily or unexpectedly, and to provide guidance on what investigators needed to do to obtain research consent via telehealth platforms,

  and

- We learned that the IRB prefers to meet virtually rather than in person even once the pandemic "officially" ended

That said, the pandemic is only one type of emergency that a healthcare or research organization can experience. Any type of emergency that can affect a community can affect a healthcare or research organization. When Katrina hit, this was a difficult lesson learned by affected healthcare organizations, some of whom never recovered.

Our accrediting body has established a new standard requiring Human Research Protection Programs (HRPP) to have an emergency plan to continue IRB oversight during and immediately following an emergency. This is certainly a best practice. After all, it is better to be prepared and have a plan in place in advance of an emergency rather than be caught unprepared. OHSRP is in the process of preparing our emergency response plan also referred to as a Continuity of Operations Plan (COOP). This involves assessing the types of emergencies that our organization might experience and planning for our response to the best of our ability. The focus of the HRPP COOP is to ensure that regulatory oversight and especially the IRB oversight, can continue to function during and immediately following an emergency. As a federal agency we must follow the Federal Emergency Management Agency (FEMA) requirements and we must integrate our HRPP COOP into the larger NIH COOP. As with any plan, it must be distributed and practiced so that folks know what to do during an emergency. Once the HRPP COOP is finalized, we will conduct desk top exercises, also referred to Testing, Training and Education (TT&E), that will inform how our plans need to be adjusted. We will also conduct education so that you will know how we plan to respond and what types of communications to expect from us during and immediately following an emergency, so that the IRB can continue to function. Stay tuned for more information and education coming this Fall.

GOVERNMENT ACCOUNTABILITY OFFICE (GAO) REPORT: INSTITUTIONAL REVIEW BOARDS - ACTIONS NEEDED TO IMPROVE FEDERAL OVERSIGHT AND EXAMINE EFFECTIVENESS

The GAO provided the following report to Congressional Requesters: US Government Accountability Office report Institutional Review Boards: Actions Needed to Improve Federal Oversight and Examine Effectiveness. Highlights of the Report can be downloaded from this link. The March 22, 2023 meeting of the Secretary's Advisory Committee on Human Research Protections (SACHRP) featured discussion on this topic by members of the GAO (minutes 7:00-21:00 of the video.) Additional discussion at this meeting is referenced below.

Why Was the GAO Study Done?

- "IRBs review research studies involving human subjects to ensure that risks to subjects are minimized, and participants have sufficient information to consent to participate. In the past, IRBs were based at research institutions, such as academic centers. Over time, independent IRBs have played a more prominent role in reviewing research on human subjects. Some policymakers and others have raised questions about the increased use of independent IRBs and the effects on protecting human subjects.
- GAO was asked to examine independent IRBs, processes used to protect human subjects, and standards of IRB quality, among other things. The report describes the composition of the IRB market and examines OHRP and FDA oversight of IRBs, among other objectives.
- GAO reviewed federal laws, regulations and articles published between 2010 and June 2021; analyzed IRB registration, drug application, and inspection data; and interviewed FDA and OHRP officials, experts, and stakeholders, and 11 IRBs selected for variation in type, size, and other factors."

The **objectives** of the GAO Report were as follows:

- To describe the composition of the IRB market
- To describe the practices selected IRBs have implemented to help strengthen the quality of their reviews
- To examine OHRP and FDA oversight of IRBs

GAO findings:

- Most IRBs are based at universities (HHS data) and were also responsible for reviewing most research involving certain investigational drugs from 2012 through 2020 (FDA data). Some IRBs are independent, and per FDA, these independent IRBs have reviewed an increasing share of investigational drug research: 25 percent of this research in 2012, and 48 percent in 2021.
- FDA and OHRP oversee about 2,300 U.S.-based IRBs through routine or for-cause

inspections that assess whether IRBs follow federal regulations when reviewing research. However, GAO found the agencies inspect relatively few IRBs. OHRP officials said they aim to conduct three to four routine inspections annually, while FDA conducted an average of 133 inspections annually between fiscal years 2010 and 2021. Neither agency has conducted a risk-based assessment of their IRB inspection program to help ensure they inspect enough IRBs annually and to optimize their responsibilities in protecting human subjects.

- OHRP and FDA have not assessed to what extent IRB reviews are effective in protecting human subjects because the agencies have not determined the best approaches to do this. Evaluating effectiveness is challenging in part due to an absence of validated measures and because IRBs are only one part of the framework of stakeholders responsible for protecting human subjects.

What are the **Recommendations** From the GAO Report?

The following is a summary of the four recommendations: HHS and FDA should conduct annual risk assessments to determine if the agencies are routinely inspecting an adequate number of IRBs and to optimize the use of inspections in the oversight of IRBs and protection of research participants. The Secretary of Health and Human Services should ensure that OHRP and FDA convene stakeholders to examine approaches and subsequent implementation of measures to assess IRB effectiveness in protecting human subjects. HHS concurred with the recommendations.

The March 22, 2023 meeting of the Secretary's Advisory Committee on Human Research Protections (SACHRP) also featured discussion of the charge to SACHRP regarding the final recommendation that "The Secretary of Health and Human Services should ensure that OHRP and FDA convene stakeholders to examine approaches for measuri ng IRB effectiveness in protecting human subjects, and implement the approaches as appropriate. These could include effectiveness measures; peer audits of IRB meetings and decisions; mock protocols; surveys of IRB members, investigators, and human research participants; or other approaches." This SACHRP meeting featured three speakers who discussed the following as related to the Committee's charge: Who are the stakeholders? What constitutes effectiveness in protecting research participants? What potential effectiveness measures can be identified? The discussion by the speakers and subsequent discussion by SACHRP can be found on the **video of the March 22, 2023, SACHRP meeting** from minutes 23:00-2:17:00.