NIH Office of Intramural Research
Office of Human Subjects Research Protections

IRB MEMBER UPDATE

IN THIS ISSUE

IRB MEMBER ANNUAL SURVEY

Your voice is important! We sent out the IRB Member Annual Survey to you all via email on December 6, 2023. Please take 5 minutes to respond to this survey if you have not already done so. The RCRC members have a separate survey to complete. These surveys are important in helping us figure out what processes are working well and where there is room for improvement.

- **IRB Member Survey link**
- **RCRC Member Survey link**
- **Both surveys should be completed by December 31, 2023**

Member Attendance

A reminder that IRB meetings are scheduled for 1 hour and 30 mins.

While sometimes meetings end earlier, please only sign up for a meeting if you can attend for the entire planned timeframe.

Every member is important for the meeting and maintaining quorum. Trying to predict the length of a meeting from the posted agenda is also not reliable, so the IRB Chair and IRB Analyst should be notified as soon as any unforeseen circumstances occur that may alter your attendance.

Arrive on time and plan to attend the entire 90-minute session.

IRB Member Retreat

Thank you everyone for your attendance at the 2023 IRB Member Retreat!

This year we explored how the IRB applies regulations and protects vulnerable subjects through several games and quizzes. We then had a presentation by one of our own investigators, Dr. John Tisdale, Senior Investigator in NHLBI, on advancements in treating Sickle Cell Disease. This was followed-up by a participant panel where members had the opportunity to explore the participant experience, and IRB members who do not regularly interact with subjects were able to directly ask questions to expand their viewpoint.

The format this year was different than the previous year, and we welcome your feedback in the IRB Annual Survey. We want to know what you enjoyed and was helpful, and where we can further grow.

We also announced at the retreat that we were unable to obtain approval for issuing CMEs for attending IRB meetings. This is unfortunate since each meeting is different and presents its own educational opportunities.

OHSRP Education Series

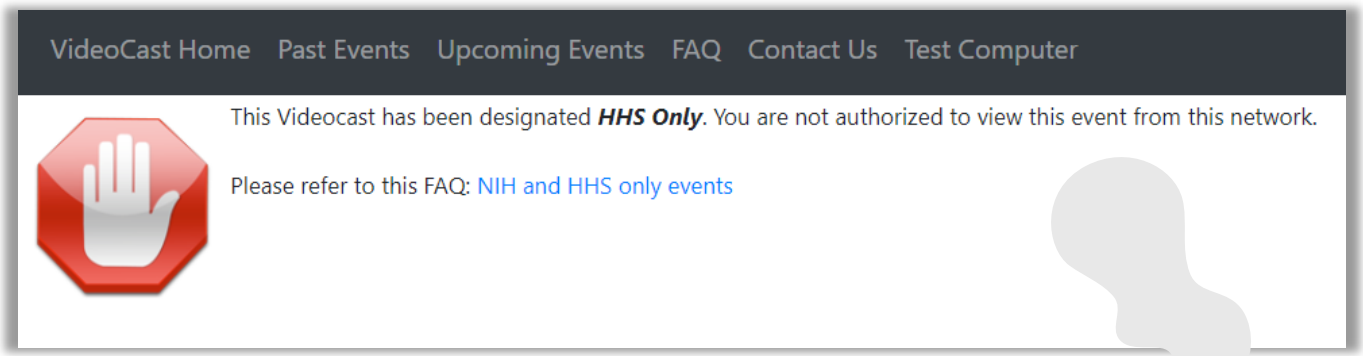
OHSRP Education Series sessions are intended to present topics of interest to those individuals in the NIH IRP involved in human subjects research. These sessions usually occur on the first Thursday of the month from 3-4 PM.

The OHSRP Education Series sessions are streamed live through the NIH videocast. The presentations are then archived in the Past Events section of the NIH videocast site. A link to the videocasts as well as the slides from the sessions are posted on the OHSRP website approximately two weeks after each session in the Presentation Archive section of the OHSRP website. The OHSRP website is the more user-friendly option and contains direct links to the recorded presentations and slides.

Please note that IRB members with NED accounts are now included on the emails announcing future sessions. Unaffiliated members are only included on the announcements for OHSRP Education sessions that are broadcast worldwide.

Certain education sessions are only accessible to the HHS community; these sessions are labeled as such on the NIH videocast website. (Some sessions prior to June 2023 are limited to NIH staff only.)

Unaffiliated members will be able to find these sessions on the website, but will not be able to view the session and will see the below error message if they try to view the presentation:



New Final Guidance Issued from the U.S. Food and Drug Administration

In August, the U.S. Food and Drug Administration (FDA) issued the final version of "Informed Consent: Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors," which supersedes the 1998 guidance. The guidance is intended to assist IRBs, clinical investigators, and sponsors involved in clinical investigations of FDA-regulated products in carrying out their responsibilities related to informed consent. The guidance provides the Agency's recommendations regarding informed consent and describes FDA regulatory requirements to help ensure the protection of the rights and welfare of human subjects in clinical investigations.

This guidance is currently being reviewed by OHSRP and the NIH Clinical Center since some of the new recommendations may require changes in our Policies that first require a reevaluation of resources and coordination between departments. You may see some changes in 2024 related to use of the short form consent process in the NIH Intramural Research Program that come directly from this guidance.

FDA is currently engaged in providing notices of proposed rulemaking and announcing comment periods on various topics to harmonize FDA clinical research regulations with the 2018 Common Rule to the extent practicable and consistent with other statutory provisions. This guidance about informed consent does not address possible future changes to FDA's informed consent regulations that may be developed as part of these harmonization efforts. FDA may amend this guidance to reflect such changes or to address new questions related to informed consent.

For members who are interested, there was also draft guidance issued on September 26, 2022 titled, "Draft Guidance for Industry, Sponsors, and IRBs: Ethical Considerations for Clinical Investigations of Medical Products Involving Children."

Presentations hosted by OHRP on Current Hot Topics

Did you know that OHRP hosts free online educational mini tutorials, videos, webinars, and presentations of current Hot Topics in human subjects research protection?

Some of these sessions are linked on the IRB Member Review Resources page on the OHSRP website, but there are many more that are available on OHRP's Online Education Page.

Following are some recent highlights directly from the OHRP website:

Hot Topics

- Intersection of Emerging Technologies & Research Ethics - Challenges & Opportunities (9/27/2023): "Speaker Michael Zimmer, Ph.D., Director of Center for Data Ethics and Society, Marquette University, and Co-founder of the Pervasive Data Ethics for Computational Research (PERVADE) project, discussed emerging artificial intelligence (AI) technologies, the ways that these technologies may be implemented in the context of human subjects research, and how the IRB can evaluate the ethics of research using AI technologies."
- Diversity, Equity and Inclusion in IRB Review and Oversight (9/27/2023): "Speaker Barbara Bierer, M.D., Professor of Medicine, Harvard and Director of the Multi-Regional Clinical Trials Center (MRCT) examined the role of the human research protection programs (HRPPs) in creating expectations for equity and justice within research and discussed some innovative approaches and practical measures that HRPPs can adopt to promote diversity, equity, and inclusion within their programs."
- Exploring the Ethical and Practical Considerations of Psychedelics Research (9/14/2023): This exploratory workshop examined the "ethical and practical considerations for psychedelics research with the goal of promoting an open and grounded discourse on how to conduct research that is inclusive and protective of participants."

General IRB Education

- The Who, What, Why, and Where of IRB Meetings and Membership (8/17/2023): This presentation provides "an overview of the requirements for IRB meetings and membership, including quorum, minutes, records, and more."
- Unlocking the Mysteries of the §46.111 Criteria for IRB Approval of Research (8/14/2023): This presentation explains "the criteria for IRB approval of research and include case studies and interactive quizzes to demonstrate the way the criteria can be applied."

IRB Member Tip Sheets and Education Sessions

This is our second year of IRB Member Tip Sheets and education sessions. Every month a tip sheet is sent out with the IRB meeting agendas that gives a brief overview of a topic commonly discussed by members at IRB meetings. This is followed by a brief presentation of the information during the IRB meetings for that month. The hope is that these tip sheets will provide a snapshot of the topic and include links to more detailed information.

The IRB Member Tips sheets are available on the IRB Member Review Resources page on the OHSRP website. We encourage you to refer to these Tip sheets when you are reviewing an action that involves one (or more) of the topics below.

Here are the topics that were covered this year:

- Continuing Reviews / Completing Continuing Reviews in PROTECT
- IRB Review of Research Involving Potential Subjects Lacking Consent Capacity
- IRB Member Review of International Research
- PROTECT Tip Sheet for IRB Reviewers
- Secondary Genomic Findings
- Payment for Research Participation
- Informed Consent Readability Pre-Review
- Digital Heath Tools - Device Software Functions and Mobile Medical Applications
- IRB Review when NIH is the Reviewing IRB for Multi-site Research
- IRB Review of Non-exempt Human Subjects Research Involving Deception
- Communicating New Information to Currently Enrolled Research Subject
- IRB Waiver of Informed Consent vs Waiver of Documentation of Informed Consent

Here are the topics that were covered in CY2022:

- Research with Economically or Socially Vulnerable Subjects
- Research Involving Pregnant Subjects
- IRB Member Review of Consent Forms
- COI-What IRB Members Need to Know
- IRB Review of Possible UPs
- Research Involving Children
- Reportable Event Review Process-IRB vs. RCRC
- Consent form considerations for Early Phase research
- Data and Safety Monitoring Plans
- Device Determinations
- Equitable Selection

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.