NIH Office of Intramural Research
Office of Human Subjects Research Protections

IRB MEMBER UPDATE

Late Summer Edition **SEPTEMBER 2024**

IN THIS ISSUE

UPCOMING IRB MEMBER RETREAT

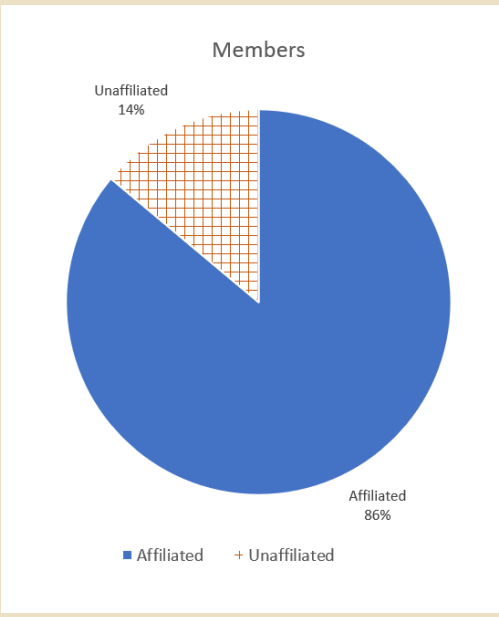
Save the date! The annual IRB member retreat will be held on Monday, October 7, 2024, from 1:00-5:00 PM in Building 31 on the NIH campus in 6C rooms F and G. Here is a link to the campus map: https://ors.od.nih.gov/maps/pages/nih-visitor-map.aspx. Some parts of the retreat will be via Zoom for members who are not able to come to the NIH campus. If at all possible, please plan to attend the retreat in person.

IRB MEMBER SURVEY

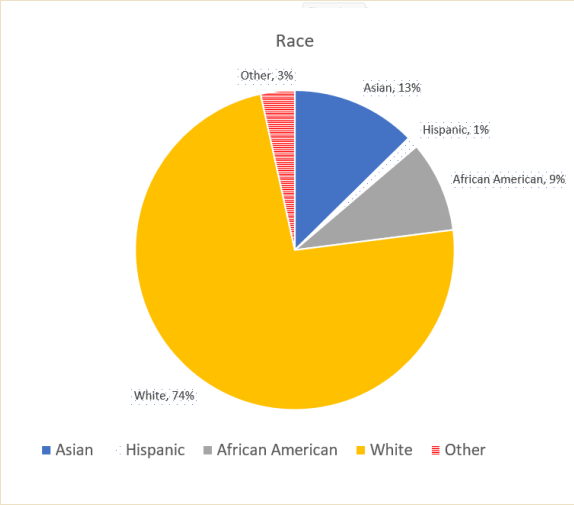
Members will recall that an IRB member survey was conducted in December 2023. Eighty-seven people responded to our survey sent out at the end of 2023. As of that time, we had 115 members on our roster. This means that we had a 76% response rate to our survey. Below are the results of the survey.

IRB MEMBER SURVEY

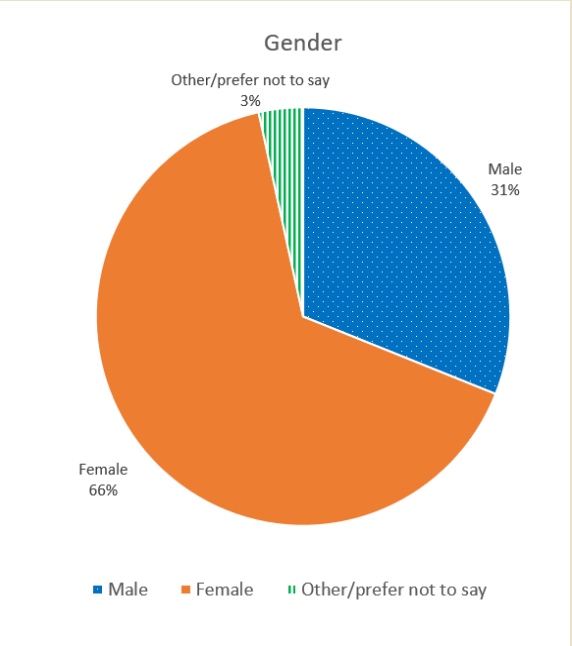
WHO ARE WE?



Race as identified by survey respondents



Gender as identified by survey respondents



HOW WE FUNCTION?

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

- That our current IRB review process allows for adequate protection of human subjects research and that they were an active contributor at meetings.
- 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

Regarding attendance: We ask that members attend one meeting each month. This is for many reasons, but one of the important reasons is that by attending the 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. Of the survey respondents, only 10% said they were not able to meet the once/month attendance expectation. In reality, in 2023, 70% of members did not attend an IRB meeting once/month (less than 12 meetings in the year). With our flexible meeting schedule, we hope that you will make an effort to sign up for one meeting/month moving forward. If your other job duties are such that you do not have time to attend one IRB meeting each month, and you need to step down from the IRB, please contact Tiffany or Nicole.

OUR CONTINUED LEARNING

Our survey showed that our members feel confident and comfortable in their roles. All but three people felt that they have adequate knowledge of ethical principles, human subjects protection regulations, and NIH policy and procedures to fulfill their role as a member.

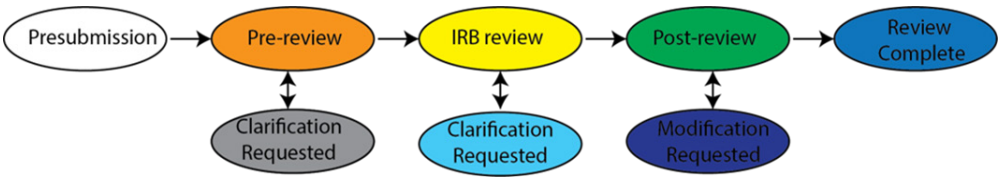
Most members feel that the monthly Tip sheets have provided valuable information and would like for those to continue. We will keep those coming! You provided very helpful suggestions for what you would like to learn more about. Many of you told us that you like the live versions of the presentation better than the taped version, and we will return to those as we can.

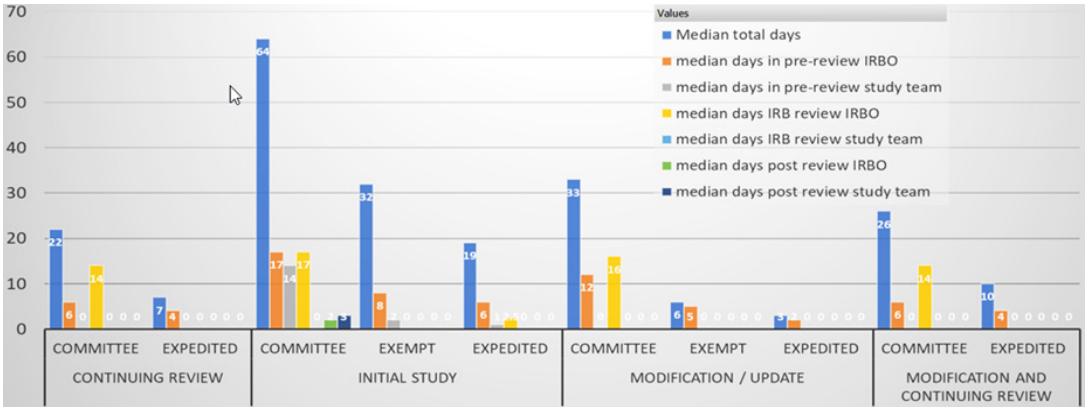
Thanks to those members who provided suggestions for educational topics on the survey as well as ideas for the retreat. These ideas are also helpful in OHSRP's planning for our broader OHSRP Education Series as well as for IRB member tip sheet presentations. A summary of the most frequently mentioned ideas can be found in the last section of the newsletter.

FULL BOARD TURNAROUND TIMES

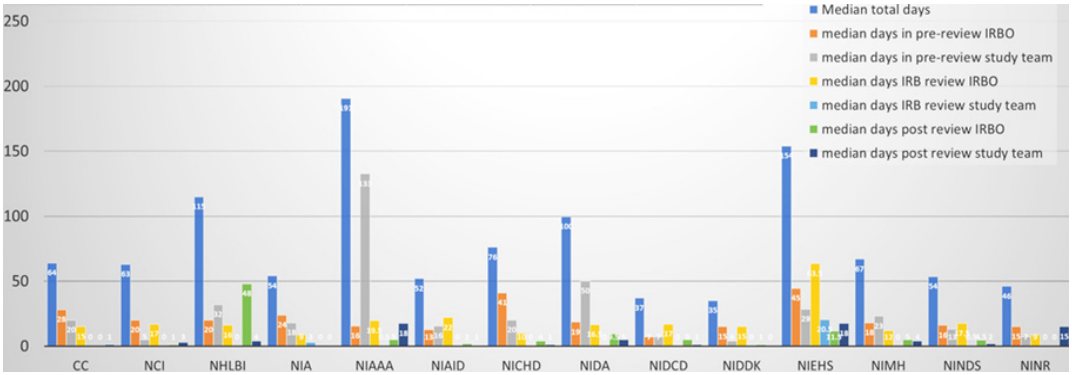
Have you wondered about turnaround times for protocols undergoing IRB review? The following information was presented at a recent OHSRP Town Hall and includes information about median times for approval of various types of review and information about turnaround time for Full Board Reviews of Initial Reviews.

Median days to approval All NIH Jan 1- July 31, 2024





Review intervals-Full Board Initial review Jan 1-July 31, 2024



IRB MEMBER GOLD STAR

We are excited to announce a new IRB Member Gold Star Award! This award will go to an IRB member who has contributed to the IRB in an above and beyond manner. Our inaugural recipient is Mary Frances Wedekind Malone who is one of our IRB Chairs. Not only is she a knowledgeable pediatric oncologist, but she has embraced the role of IRB member and Chair. Mary Frances is a relatively new Chair, but you would not be able to tell. Her presence, demeanor, and ability to preside over challenging IRB meeting issues is beyond impressive. In addition to her giving her time as a Chair in the NIH IRB, she is a member of the RCRC and was recently appointed as Vice-Chair of this Committee. As part of that role, she participates in a weekly meeting to review RNI forms that are submitted to the IRB. She is a pleasure to work with from a fellow Chair, analyst, and OHSRP leadership perspective. We are lucky to have her on our team and are proud to give her this first Gold Star Award for her meaningful contributions to the IRB.

REMINDERS: IRB APPOINTMENTS AND PROCESSES

As per ***NIH Policy 201, IRB Membership and Composition***, the IRBO Director identifies and recommends new members to the Executive Chair. The Director may consult with the potential member's IC Scientific Director and/or their Clinical Director. A new member is appointed for a one-year term and, if continued service is deemed mutually agreeable, the member may be reappointed to serve a renewable 3-year term.

At each IRB meeting, members vote (if not recused) on whether the IRB criteria are met (or continue to be met for actions other than IRs) for each item on the agenda. Please remember that this means all members attending a meeting need to have reviewed all items on the agenda in order to be prepared to vote. Members should be sure to complete their reviews enough in advance of the meeting so that any questions that the reviewer has for the study team can be addressed prior to the meeting.

If a reviewer has a question for the study team, please address the question within PROTECT and not via email. Use the "Request Clarification by Committee Member" activity to communicate back and forth with the team. Note that study team members can see the name of the IRB member who sent the requested clarification. If you prefer to stay anonymous, use the Private Comment activity to ask the IRB Coordinator to send questions or comments to the study team on your behalf.

ASSENT

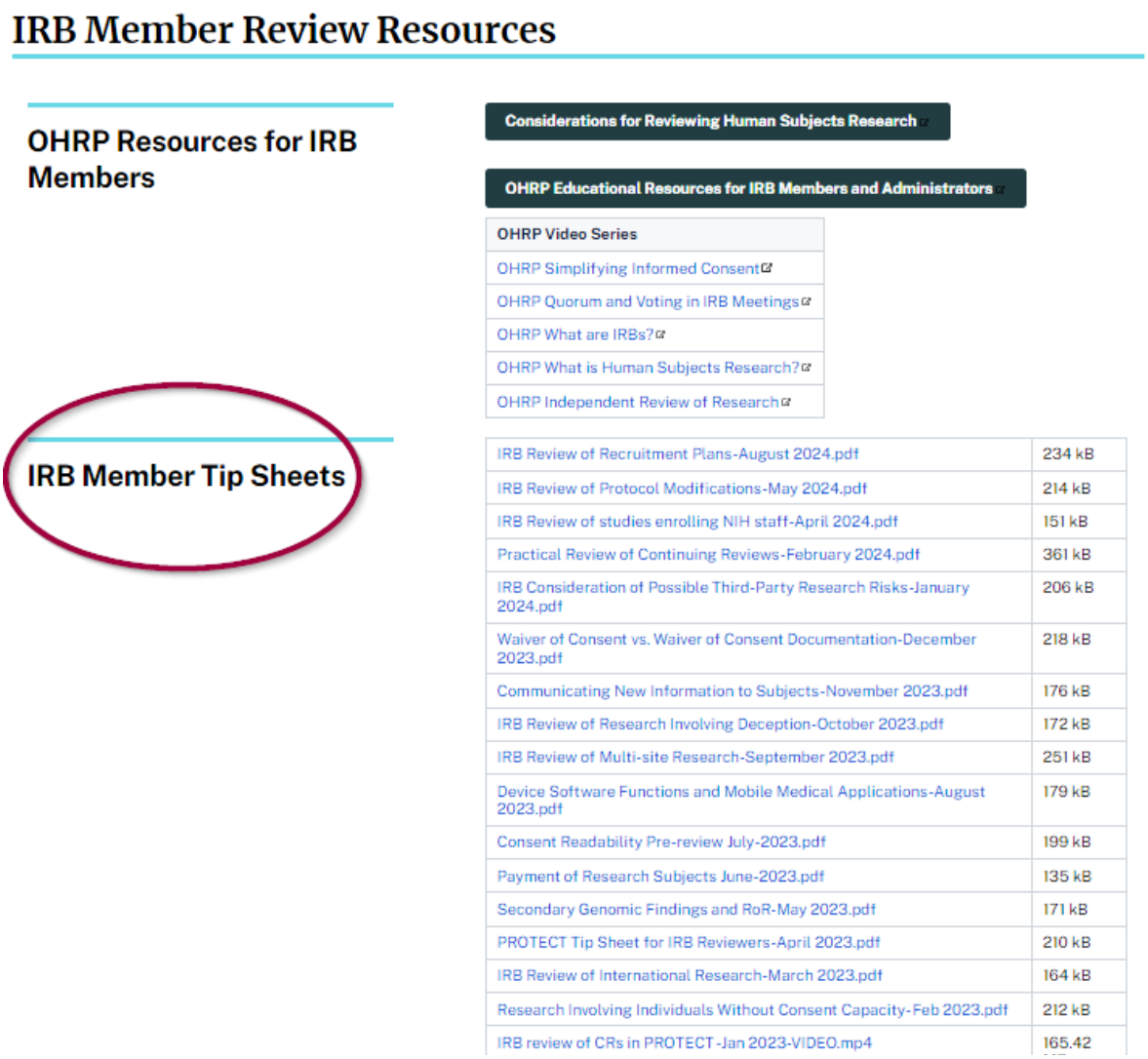
In their response to the IRB member survey, a few members requested information on the process of obtaining assent from minor subjects. Unless waived by the IRB, when minors participate in human subjects research, parental (or guardian) permission must be obtained along with the assent of the minor. Federal regulations (45 CFR 46.402(b)) state "Assent means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent." When reviewing research involving enrollment of minors, the IRB considers the age, maturity and psychological state of the children who will be involved when deciding if the children are capable of providing assent. In some cases, the IRB may decide that the capability of some children is so limited that they will not be able to provide their assent, and the Board waives this requirement. Additionally, if the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the requirement for assent of the children may be waived by the IRB.

If assent will be required, the IRB determines if the assent will be written or verbal. At the time the protocol is submitted for initial review or if children are being added as potential participants, the PI is expected to propose a plan indicating which children being enrolled will be able to provide assent and whether the assent will be written or verbal. The NIH IRB prefers that the PI submit an age appropriate written assent form for IRB review. The OHSRP website provides an assent template for use with children roughly 7-13 years of age. If older minors will be enrolled, the IRB may approve a process in which older minors sign the long form consent (which should have been written at a 6th- 8th grade level.) In this case, there will be a section of the signature block that includes a place for the minor to sign the assent line. For younger children who are capable of providing assent but who cannot yet read, the PI may propose, and the IRB may approve, a verbal assent process instead. Children too young to assent should still have the research explained to them in terms appropriate to their level of understanding and maturity.

IRB MEMBER EDUCATION OPPORTUNITIES

IRB Member Tip Sheets:

The IRB Member Tip sheets are available along with other educational information on the IRB Member Review Resources page on the OHSRP website. See the screenshot below.



IRB Member Review Resources

OHRP Resources for IRB Members

Considerations for Reviewing Human Subjects Research

OHRP Educational Resources for IRB Members and Administrators

OHRP Video Series
OHRP Simplifying Informed Consent
OHRP Quorum and Voting in IRB Meetings
OHRP What are IRBs?
OHRP What is Human Subjects Research?
OHRP Independent Review of Research

IRB Member Tip Sheets

IRB Review of Recruitment Plans-August 2024.pdf	234 kB
IRB Review of Protocol Modifications-May 2024.pdf	214 kB
IRB Review of studies enrolling NIH staff-April 2024.pdf	151 kB
Practical Review of Continuing Reviews-February 2024.pdf	361 kB
IRB Consideration of Possible Third-Party Research Risks-January 2024.pdf	206 kB
Waiver of Consent vs. Waiver of Consent Documentation-December 2023.pdf	218 kB
Communicating New Information to Subjects-November 2023.pdf	176 kB
IRB Review of Research Involving Deception-October 2023.pdf	172 kB
IRB Review of Multi-site Research-September 2023.pdf	251 kB
Device Software Functions and Mobile Medical Applications-August 2023.pdf	179 kB
Consent Readability Pre-review July-2023.pdf	199 kB
Payment of Research Subjects June-2023.pdf	135 kB
Secondary Genomic Findings and RoR-May 2023.pdf	171 kB
PROTECT Tip Sheet for IRB Reviewers-April 2023.pdf	210 kB
IRB Review of International Research-March 2023.pdf	164 kB
Research Involving Individuals Without Consent Capacity-Feb 2023.pdf	212 kB
IRB review of CRs in PROTECT-Jan 2023-VIDEO.mp4	165.42

So far in 2024, the following topics were addressed during Tip sheet presentations at IRB meetings:

- IRB Consideration of Possible Third-Party Research Risks
- Practical Review of Continuing Reviews
- Enrollment of NIH Staff
- IRB Review of Protocol Modifications
- IRB Review of Recruitment Plans
- In Vitro Diagnostic Devices

OHSRP EDUCATION SERIES

Unless otherwise noted below, the videos for these sessions are available to all NIH IRB members. Topics covered so far this year include the following:

- ***To Pay or Not to Pay: Is That the Question?*** In this presentation, Dr. Christine Grady, Chief of the Department of Bioethics at the NIH Clinical Center, discussed the common ethical concerns raised about payment of participant as well as the reasons to pay participants. She also presented empirical data about payment to participants as it relates to recruitment, understanding, and willingness to participate. Downloadable slides: Participant compensation; NIH Videocast: To Pay or Not to Pay: Is That the Question?
- ***An Overview of IRB Expectations When Non-English-Speaking Persons Enroll in Research: The Importance of Ensuring Comprehension***. (The video recording of this session is not available to non-NIH/non-HHS staff because the content was specific to a new processes and policy changes becoming effective at NIH.) This session described the ethical basis for presenting consent documents in the participant's preferred language and the updated NIH IRP requirements for translating informed consents.
- ***IVDs, LDTs, FDA and CLIA: Understanding the Alphabet Soup of Laboratory Assay***. (The video recording of this session is not available to non-NIH/non-HHS staff because the content was specific to NIH researchers' use of IVDs and LDTs.) This session was intended to make NIH research teams aware of when FDA or CLIA regulations apply to the use and reporting of results from in vitro testing of biospecimens. Downloadable slides: OHSRP_CLIA_seminar; NIH Videocast: IVDs, LDTs, FDA and CLIA: Understanding the Alphabet Soup of Laboratory Assay
- ***IRB Review of Research Involving AI [Artificial Intelligence]*** was presented by Dr. Benjamin Silverman Senior IRB Chair at Mass General Brigham, Human Research Affairs. Dr. Silverman addressed issues that are very relevant to IRB members such as ethical considerations raised by AI as well as IRB considerations for the review of research involving AI. Downloadable slides: Silverman-AI_Talk; NIH Videocast: IRB Review of Research Involving AI Additional information can be found later in this newsletter where additional resources regarding use of AI in human subjects research are provided.
- The session titled, ***Key Ethical Issues in Pediatric Research*** covered topics including need for pediatric research, the assent process, assessing risk level in such research, and justification for non-beneficial research. The speaker for this session was Dr. David Wendler, senior investigator, and head of the section on research ethics in the NIH Clinical Center Department of Bioethics. Downloadable slides: Peds_Research_ethics; NIH Videocast: Key Ethical Issues in Pediatric Research
- ***CARE: A Model for the Integration of Cultural Humility into Human Subjects Research*** was presented by Dr. Sana Loue, professor in the Department of Bioethics at Case Western Reserve University School of Medicine in Cleveland, Ohio. She holds secondary appointments in the departments of Psychiatry, Global Health, and Population and Quantitative Health Sciences, as well as in social work at the University's School of Social Work. In this session, Dr. Loue clarified the differences between cultural competence and cultural humility. She also explained how cultural humility can be integrated into human

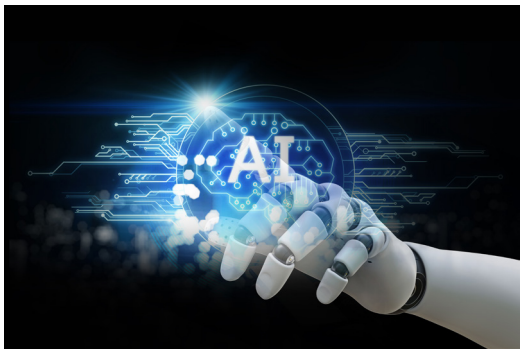
subjects research. Downloadable slides: CARE Model; NIH Videocast: CARE: A Model for the Integration of Cultural Humility into Human Subjects Research

Upcoming OHSRP Education Series sessions are included on the OHSRP Event Calendar and streamed live via 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.

PRESENTATIONS HOSTED BY THE HHS OFFICE FOR HUMAN RESEARCH PROTECTIONS (OHRP)

- Are you a new IRB member? As part of your new IRB member training, you attended an orientation and completed the CITI training course, Biomedical 101. While certainly not required, you may want to also look at the checklist created by OHRP titled, ***Training Checklist for Someone Working with IRBs***, which includes multiple resource links in each of the following main areas:
  - » Basic Information about Human Research
  - » Brief History of the Formation of Ethical and Regulatory Frameworks for Protecting Humans in Research
  - » Understanding the Framework of the Federal Regulations for Human Research Protections and IRB Review of Research
  - » Institutional Review Boards (IRBs) Basics, What Are They and What Do They Do?
  - » Communicating with Participants through Informed Consent
- An OHRP webinar celebrating the ***National Research Act 50th Anniversary*** was held on July 12, 2024, and included a series of very interesting topics. The presentation covered not only review of critical historical events such as the work done by the National Commission and subsequent evolution of the Regulations for Human Research Protection, but it also addressed topics such as listening to the voice of the participant, participatory action research and community-led studies, research with indigenous populations, and community ethics review boards. The final session was a panel discussion in which participants explored the potential impact of scientific advances in the coming decades. Information about the event can be found on the OHRP website and the event link can be found on the NIH videocast.
- In February 2024, Dr. Ivor Pritchard, OHRP Senior Advisor to the Director, presented ***The Principles of the Belmont Report and the Ethics of Human Research***. During the presentation, he discussed not only how the Belmont principles apply to human subjects research but also how they have evolved in response to changes in society and the research landscape. The video recording can be found on YouTube and the slides can be downloaded from the OHRP website.

ARTIFICIAL INTELLIGENCE (AI)



- In response to the December 2023 IRB member survey, some respondents identified review of research using AI as a topic they would like to know more about. Below are some currently available resources as well as an excellent upcoming opportunity in September.
- OHSRP Education Series session (as noted above) IRB Review of Research Involving AI was presented by Dr. Benjamin Silverman. NIH videocast: **IRB Review of Research Involving AI**; Downloadable slides: **Silverman-AI_Talk**
- All IRB members have access to various CITI training resources via the NIH CITI account. If you are interested in learning more about AI, CITI provides content on this topic. To access this webinar, first access your NIH CITI account, scroll to the bottom of the page where your active courses are listed, and click on "Add a course." Towards the bottom of the list of available courses that is displayed, check the box for the webinar titled ***Artificial Intelligence (AI) and Human Subject Protections***. The webinar then will show up on your list of "courses ready to begin." The presentation looks at the current regulatory framework, existing protections, ethical tools and principles that can be considered when reviewing human subjects research that involves AI.
- See the NIH Office of Science Policy webpage titled ***Artificial Intelligence in Research: Policy Considerations and Guidance***.
- The NIH Library has numerous resources and classes about using AI in the research of various disorders. These are listed here, though you will be asked to provide your NIH credentials to access this information. For anyone who wants a deeper dive into this topic, the Library offers access to **free eBooks and audiobooks on the topic of AI** though this also requires logging on with NIH credentials.
- OHRP upcoming workshop, ***The Evolving Landscape of Human Research With AI – Putting Ethics to Practice*** (see **Upcoming Educational Opportunities** below)

UPCOMING EDUCATIONAL OPPORTUNITIES

- OHRP 2024 Exploratory Workshop, September 19, 2024, 9:45 AM – 4:15 PM EDT: ***The Evolving Landscape of Human Research With AI – Putting Ethics to Practice***. This workshop will explore the ethical and practical considerations for the use of AI in research involving humans. No registration is required.
- OHRP Webinar, October 17, 2024. ***Differing Approaches to Measuring and Ensuring IRB Effectiveness***. This webinar will include discussion from experts about four key approaches for attempting to measure IRB effectiveness: (1) post-approval monitoring to verify compliance with IRB requirements, relevant regulations, and institutional policies, (2) accreditation and peer review; (3) study participant considerations, and (4) the quality of IRB deliberations. Registration is required.

- OHSRP Educational Series session, September 12, 2024, 3-4 PM, ***Community-Engaged Research to Address Cardiometabolic Health Disparities*** via NIH Videocast. The speaker for this presentation is Dr. Tiffany Powell-Wiley, Earl Stadtman Investigator and Chief of the Social Determinants of Obesity and Cardiovascular Risk Laboratory at the NIH who also has a joint appointment in the Cardiovascular Branch at NHLBI and in the National Institute on Minority Health and Health Disparities (NIMHD). Dr. Powell-Wiley's interdisciplinary team uses community-engaged research, epidemiologic methods, and translational approaches to better understand social factors that promote obesity and limit cardiovascular health. During this session, Dr. Powell-Wiley will (1) Define community engagement and community-based participatory research (CBPR), (2) Describe the role of community engagement in addressing cardiometabolic disease impacted by social determinants of health, and (3) Illustrate the role of community-engaged research and CBPR in addressing clinical trial diversity.

IRB MEMBER SUGGESTIONS FOR EDUCATIONAL TOPICS

Thanks to IRB members who provided suggestions for educational topics that we will incorporate into the Tip sheets or OHSRP education series as we can. The following were the most common topics requested by IRB members for future educational efforts:

- Issues related to research with "vulnerable" populations/situational vulnerabilities such as:
  - » Assent for cognitively impaired subjects
  - » Issues to consider when reviewing research involving participants with mental illness
- Expedited vs. full board review of submissions (Which actions can undergo expedited review?)
- Multi-site studies and considerations when the NIH IRB is the Reviewing IRB for other sites
- Cycle and process of protocol review once submitted to IRB including RNI reviews
- Expectations for how to do specific types of reviews as an IRB member
- Use of human specimens such as:
  - » Genetic testing and return of results
  - » Sharing of data and specimens
- Research involving use of investigational devices (for example, what information is needed for the IRB to determine a study is NSR?)
- Acceptable justifications for enrolling pregnant women in studies
- How to consider compensation for research participation (Dr. Christine Grady gave an excellent presentation on this topic for the January 2024 at the OHSRP Education Series. For more information and links for the slides and the videocast, see the first bullet in the section of this newsletter titled **OHSRP Education Series**.)

Many thanks for all of your ideas!