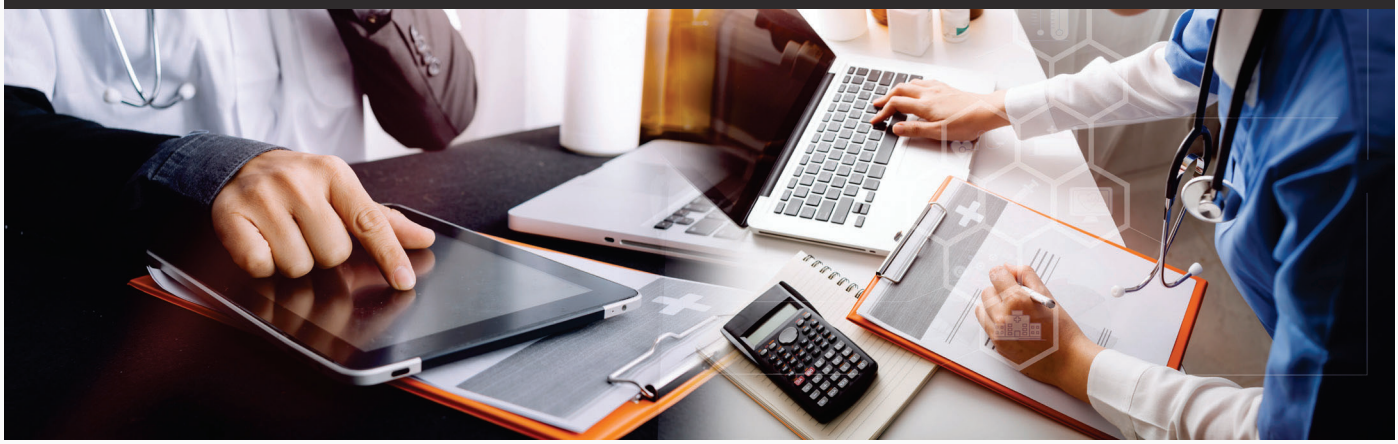
NIH Office of Intramural Research
Office of Human Subjects Research Protections

OHSRP NEWSLETTER

FALL Edition OCTOBER 2024



IN THIS ISSUE

LETTER FROM THE OHSRP DIRECTOR

In my last letter, I referred to "Green's 5 principles of research ethics" and discussed one of them, the principle of "It's not about me". I am sure that since reading that you have been wondering about the other 4 principles. I am equally certain that those wonderings have not been keeping you up at night! Nonetheless, I thought I would share another one of those principles with you today.

#2: Remember, it's about ethics, not just compliance.

We hear a lot about compliance. Investigators are told they must comply with this regulation or that policy. Inevitably this comes with filling out forms and some sort of review and/or monitoring process. This all piles up and at the end of the day it seems like doing the actual research is an afterthought. Certainly not what anyone envisioned when embarking on a clinical research career. There is so much compliance, it is easy to lose track of the why.

So, when I say "Remember its about ethics, not just compliance", what am I talking about. Compliance is about following the rules. In a given situation, an individual must know what the rule is and follow it. Similarly, the compliance office must determine what the applicable rule was and if it was followed. In contrast, ethical decision making is about asking the question "what ought I do in this situation". Among all the available options, which choice is the "most right" choice. A way more nuanced, and often more difficult, question than just asking if the rules were followed.

Although IRBs and IRB offices are considered part of institutional compliance programs, the rules the IRB applies and monitors flow directly from and are easily connected back to fundamental ethical principles. Respect for persons (informed consent, protections for vulnerable persons, protection of privacy and confidentiality), beneficence (risk minimization, favorable risk: benefit assessment, data and safety monitoring) and justice (equitable subject selection). Although the human subjects protections regulations are rules that we must follow, in doing so we are making sure that fundamental ethical principles are adhered to.

In human subjects research, if we ask "what is the right thing to do in this situation", we will virtually always be compliant. However, if we only ask, "what is the compliant thing to do", we may not always be making the ethical choice.

—Jonathan M. Green, MD, MBA
DIRECTOR

GOLD STAR AWARD

We want to recognize two different groups as part of our Gold Star award for this issue.

The first Gold Star award goes to Dr. Marcelo Amar, a PI in the Lipoprotein Metabolism Laboratory in the Cardiovascular and Pulmonary Branch in **NHLBI**; Alifiya Bikineyeva, MD, MPH, a Protocol Navigator in **NHLBI**; and the rest of the research team. The research team submitted an initial review at the end of May 2024 for a Pilot Study designed to investigate the safety and potential effectiveness of a human milk oligosaccharide (HMO)-based synbiotic supplement. The protocol hypothesizes that a synbiotic supplement, containing a pro-biotic containing beneficial bacterial species along with a pre-biotic that will support the growth of beneficial gut bacteria, will be more effective in treating intestinal microbiota dysbiosis than supplementing with either just a pro-biotic or pre-biotic. The protocol was well-written and required few edits. The submission was returned with a request for a couple of clarifications to the protocol and consent. The Board approved the initial review with two stipulations. The PI responded with changes on the same day and final approval of the protocol was executed the next day. **Congratulations to Dr. Amar, Dr. Bikineyeva and all the other members of the research team!**

The second Gold Star award goes to Emmes who supports all IRB submissions, among other responsibilities, for NEI. Specifically, the following Emmes staff members are being recognized: Audrey Hoppenjans, Jenny Pilallis, Erika Dallmann, Samuel Chow, Grace Johns, Alexandra Chang, and Supriya Menezes. These staff persons are being recognized because they have been proactively working to ensure that all NEI protocols are compliant with current regulations and policies over the last year. They have taken the initiative to review all of their existing protocols to assess for compliance and address any outstanding issues. The Emmes team have been great partners with IRBO staff in ensuring human subjects research protections are met within NEI. **Congratulations to NEI and the Emmes clinical study managers!**

MANAGING CONSENT/RE-CONSENT OF NON-ENGLISH SPEAKING PARTICIPANTS AFTER CONSENT CHANGES

On March of 2024, OHSRP implemented a revision to HRPP Policy 301 Informed Consent involving the requirement to translate consent forms into anticipated languages when enrollment of non-English speaking individuals is anticipated. A guidance document was also issued with a full explanation of the process and expectations with regard to obtaining consent from non-English speaking participants.

As expected, this policy change has led to research teams having to obtain and maintain many more versions of translated consent forms than before. Specifically in cases in which the English version of the consent form is revised, the research team must put in a request with a translation service to revise the existing translated consent form(s) with the corresponding changes.

Accordingly, there is often a time gap before the new revised translated consent form is available. Situations may arise in which a non-English speaking person presents for initial enrollment into the study or a currently enrolled participant must be reconsented, but the revised version of the translated consent in that person's language is not yet available. Given that, OHSRP has further revised the guidance document to provide specific guidelines as to how these situations should be managed.

ACCESS TO THE TRANSLATED CONSENT DOCUMENT

Prior to the revisions to Policy 301, once the revised English version of the consent form was approved, the previous practice was as follows:

1. PSS de-activated the current translated consent document on the CC website.
2. HMID (Medical Records) de-activated the translated consent document in the iMed system.
3. The navigator or study team might de-activate the translated consent document in PROTECT.

Now under the revised guidance, the teams should follow this process:

1. The translated consent documents should not be de-activated on the CC website, in iMed, or in PROTECT until the revised translated consent form is available.
2. When the revised translated consent document becomes available, the team should upload it into PROTECT, for IRB review and approval.
3. Once it is approved, the previous translated consent document will be replaced on the CC website and updated in iMed with the new translated consent document.

CONSENTING/RE-CONSENTING NON-ENGLISH PARTICIPANTS

Prior to the revision of the policy, when the revised translated consent document was not yet approved and available, research teams generally consented or re-consented non-English speakers with the translated short form consent and the English long form consent.

CONSENTING NEW NON-ENGLISH PARTICIPANTS

Per the revised guidance, when new subjects are being enrolled, the following process should be followed:

1. The Short Form Consent should NOT be used.
2. The study team should wait until the translated consent document is available, before enrolling a new participant.

3. However, if the study team determines it is in the best interest of the new participant to be enrolled prior to that time, they should take the following steps:
    - Conduct informed consent with the participant using the existing translated consent document with an interpreter and obtain a signature;
    - Verbally inform the participant of the changes in the new English version of the consent; and
    - Document the consent process and what new information was relayed in the Consent Note in the medical or research record.
4. Then, when the revised version of the translated consent document is available and IRB-approved, the study team should:
    - Provide the new translated version of the consent document to the participant;
    - Re-consent the participant using an interpreter; and
    - Obtain the participant's signature on the revised translated consent document.

The IRB's rationale for this change in practice is that in the absence of the revised translated long form, it is better to use the old translated long form because the short form contains no study specific information. The most recent translated long form contains most of the important information about the study in the participant's language. Furthermore, some information about the study that is written in the first language of the participant is better than none.

RE-CONSENTING NON-ENGLISH PARTICIPANTS

Per the Guidance, when existing subjects need to be re-consented, the study team should wait to re-consent participants with the revised translated consent document, unless they determine it is in the best interest of the participant to be informed of the changes before the new translation is available. Specifically, if the information in the revised consent document needs to be provided to participants emergently, the team should:

1. Verbally inform the participant of the changes with the assistance of an interpreter;
2. Document this process in the research and/or medical record; and
3. When the revised translated consent is approved and available, re-consent the participant and obtain a signature.

EXAMPLES OF "IN THE BEST INTEREST" OF THE PARTICIPANT

Any decisions to consent or re-consent a participant, prior to the revised translated consent document being available, should be related to the safety or welfare of the participant. Some examples include:

1. The participant needs to undergo a research procedure or wants access to a research treatment urgently;
2. The participant is about to undergo a new procedure for which they have not yet provided consent; or
3. The participant needs to be provided information about a new risk associated with the research.

PI AND OTHER STUDY STAFF CHANGES IN CONSENTS

The study teams may revise the PI and other study staff information (names and contact information) in the translated consent form without formally seeking a new translation or obtaining a new translation certification, **when that is the ONLY change being made to the English version of the consent form**. Please note that this is only permissible when the names on the translated consent are written in the Latin alphabet, i.e. in the same alphabet as on the English version of the consent. The revised translated consent form may be submitted to the IRB at the same time as the MOD which addresses the changes to the English version of

the consent form.

For additional questions or concerns about this topic, please email IRB@od.nih.gov.

OTHER UPDATES

DOCUMENTS REQUIRING IRB REVIEW

We have updated the OHSRP website to provide some guidance about what types of documents and materials must be submitted for IRB review versus which do not. In some cases, the need for IRB approval really depends on the content of the document versus the type of document, e.g., see the information about course curriculums, data collection forms, instructional materials, newsletters, press releases, and Internet postings of study descriptions limited to CT.gov-style content. Please visit the new Documents Requiring IRB Review web page to review this important information.

IRB MEETINGS IN DECEMBER

Please note that no IRB meetings will occur during the last two weeks in December of this year (i.e. the weeks of Dec. 23rd and Dec. 30th). If your study's expiration date will occur during that period, we ask that you please make sure to submit your continuing review well in advance to avoid lapses in approval.

POLICY UPDATE REMINDER

Top Ten Tips for Improving Consent Documents

1. Use short sentences.
2. Use the simplest words possible.
3. Only one idea per paragraph.
4. Use conversational language ("we" rather than "the technician").
5. Break up dense blocks of text with bullets or spaces.
6. Do not describe investigational products or research interventions as treatment.
7. Acronyms – minimize them. But if you use them, explain them the first time.
8. Use the most direct form of a verb ("We will take your blood pressure," rather than "Your blood pressure will be taken.")
9. Describe procedures in the "What Will Happen During The Study" section, and risks in the section titled, "What Are the Risks and Discomforts of Being in the Study?" (Do not put procedures and risks together.)
10. Spell out abbreviations:
    - e.g. = for example
    - i.e. = in other words

COMING SOON: PROTECT System Upgrade (software version 10.5.7)

On a regular basis, the Huron Consulting Group makes available to their Human Subjects Research software clients mini upgrades to their existing software version. The institutions can apply these patches to their local systems on their own time frame. These upgrades typically contain bug fixes as well as some improvements that clients requested and voted on in a monthly user group meeting with the vendor.

Our NIH PROTECT IT Team has been working to prepare for applying some of these recent upgrades to the system and get it as current as possible - up to version 10.5.7, which is advised by the vendor to keep the system in good health.

This series of upgrades should be applied to the PROTECT system in October.

NIH PROTECT system users can look forward to the following improvements:

- PI Proxies will be able to run the *Report Continuing Review Data* activity on multisite studies.
- An *Expiration Date* column will be added to the *IRB Project* > *In Review* tab.
- PIs and Proxies will be able to edit/submit an RNI for their related submissions. Previously, only the person who created the RNI could edit or submit it.
- Those who create RNIs will be able to run an activity called *Manage Editors* to add anyone in the system to the RNI so they can also edit the RNI.
- RNI submission forms will be editable when sent back to the user in an *Action Required* state.

Full release notes explaining all of these changes will be made available upon the release – users can find these descriptions on the IRBO Website under NIH PROTECT Release Notes once the release goes live in October.

COMING SOON: IMPROVED HELP TEXT AND APPLICATION QUESTIONS

The leaders in our IRB and Compliance offices have coordinated an effort to review and improve some of the IRB SmartForm Application questions and the system's "help text" (the question mark icon bubble text) to be easier for users to understand and to gain more complete responses on the forms.

This upgrade should be applied to the PROTECT system in October.

NIH PROTECT system users can look forward these improvements in the following IRB Submission Type forms:

- Initial Study Application
- Modification/Update Application
- Continuing Review/Study Closure Application
- Reportable New Information Application

A more detailed description of how the questions and help text were revised will be sent out in a system email blast once the release goes live in October.

NOTE: We made sure in our optimizations to be sure not to change the meaning of any questions, nor did we add any new questions.

RESULTS & RESPONSE: PROTECT CUSTOMER SATISFACTION SURVEY

In June 2024, we issued a customer satisfaction survey to all PROTECT system users. The purpose of the survey was to understand user experience with the PROTECT system, and the training and support that are provided by our PROTECT Training team. It is our intention to issue the survey annually and use the results to respond to your feedback and improve your user experience.

At the August 2024 *OHSRP Education Series*, our directors gave updates on the HRPP, to include an overview of the survey results and how we plan to respond to help you feel more satisfied with the system.

RESULTS:

Please be sure to view these results in the NIH Videocast for the **OHSRP Town Hall**. We plan to roll out upcoming classes in response to your feedback.

CLASSES:

Users can look forward to courses on the following topics:

- Reports
- Optimizing Your Dashboard
- Tips & Tricks for Navigation/Workspaces
- Tips & Tricks for a clean document "cabinet"

Be sure to check back on our **PROTECT Training page** to see dates of these classes once posted.

OUTREACH

Our PROTECT support team and leadership will be reaching out to SRCs, RSC, and Ancillary Review community to offer in-person face time (gather questions, feedback, and ensure optimization of workflow).

POLICY UPDATES

Some of the content in this article was covered at the August OHSRP Townhall. However, that was a high-level overview of what has been happening with the human research protections (HRP) policy series, Manual Chapter 3014. This article provides more details about the specific policies that have been revised this Summer, and what to expect for the remainder of this year.

ACCREDITATION UPDATES

OHSRP is required by NIH policy to conduct a regular review of our policy series at least every 5 years. This is necessary to ensure that policies remain current and relevant. OHSRP reviews its policy series starting at year 3 of that 5-year cycle, because we have a large number of policies to review. Our reaccreditation cycle with the Association for Accreditation of Human Research Protection Programs (AAHRPP) also falls on a 5-year cycle. By starting our review cycle early, we ensure that any needed policy revisions can be made, cleared, and implemented prior to our re-accreditation site visit. We started our review of Manual Chapter 3014 this Summer and will continue our review through the end of the year.

WHAT TO EXPECT

We will look at every HRP policy to see if it is current. Most policies will not need policy changes.

When they do need changes, the changes will fall into two (2) buckets:

1. **Technical revisions** – Policies with technical revisions *do not* have any policy changes. These involve grammar, spelling or link fixes, formatting updates, etc. Therefore, usually, you will not see any change to the Transmittal Notice telling you that these have occurred.
2. **Partial revisions** – These are usually minor policy changes or updates needed to keep the policy current. You will see a notification in the Transmittal Notice of the policy, outlining the nature of the changes. These are the types of revisions that we typically discuss in this Newsletter to inform you of what has changed. (See below for a list of partial revisions made so far during this review cycle.)

In terms of technical revisions, with this review cycle, we are going through the policies and removing inline external links. We found that external links break fairly frequently. It can be a challenge to update them across all policies. Therefore, going forward, you will only see external links in the Transmittal Notice, in Section D – Definitions and in References. MC 3014-103 Education Program is a great example of a policy that had technical revisions but no policy changes. This was one of our oldest policies, so we updated the formatting to match the rest of the series. Other policies with **technical revisions** so far:

- 3014-104 Subject Complaints (09/03/2024)
- 3014-107 Privacy and Confidentiality (06/20/2024)
- 3014-108 OHSRP Quality Assurance and Quality Improvement Program (09/03/2024)
- 3014-302 Subject Recruitment and Compensation (09/03/2024)

POLICY UPDATES, CONTINUED

Below is a list of policies with **partial revisions**. Note that some of the revised policies are still being processed by OMA but will be published very soon.

- 3014-100 - NIH Intramural Research Program's Human Research Protection Program (effective 9/10/2024): The partial revision adds the Tribal Health Research Office as a component of the NIH IRP HRPP and the newly established Human Fetal Tissue Review Committee as an ancillary review committee for IRP research.
- 3014-101 - Organizational Structure of the OHSRP (coming soon): This revision specifies responsibilities of the NIH Intramural Research Program (IRP) Institutional Officials (IOs) consistent with the updated Delegation of Authority, General No. 44.
- 3014-102 – Investigator Conflict of Interest and Government Royalties (effective 09/09/2024): This policy is revised to remind investigators to disclose to the IRB when they are listed as an inventor for any intellectual property that is being evaluated in the research study under review. Investigators are reminded to consult OHSRP for questions about whether the protocol is a Covered Research Protocol.
- 3014-106 - Ancillary Reviews (coming soon): To clarify that ancillary reviews are required for intermediate-size patient population and treatment IND expanded access protocols. To add the requirement for Intramural researchers to obtain prospective approval from the Human Fetal Tissue (HFT) Review Committee, and human subjects review, before use or acquisition of HFT. This includes research involving HFT that may be considered to be not human subjects research (NHSR). To add information about review by the NIH Protocol Royalty Analysis Committee (PRAC) when the NIH IRB is informed that an investigator is listed as an inventor for any intellectual property that is being evaluated in the research under review.
- 3014-301 Informed Consent (coming soon): This revision includes requirements for the consent of persons who are blind/illiterate at E.2.I. These revisions are consistent with the existing consent FAQs on this topic.
- 3014-502 - Expanded Access, Including Emergency Use of Investigational Drugs, Biologics, and Medical Devices (Test Articles) (effective 09/10/2024): To clarify ancillary reviews are required by policy for intermediate-size patient population and treatment IND expanded access protocols.
- 3014-801 - Reporting Research Events (effective 07/21/2024): This revision clarifies the authorities of the OHSRP Director, IRBO Director and/or IRB Chair to immediately suspend, or have the PI take additional actions necessary to protect the health, safety, or welfare of subjects in response to a Reportable event or refer it for review by the RCRC or IRB.
- 3014-802 - Non-Compliance in Human Subjects Research (effective 07/05/2024) This revision clarifies the authorities of the OHSRP Director, IRBO Director and/or IRB Chair to immediately suspend, or have the PI take additional actions necessary to protect the health, safety, or welfare of subjects in response to an allegation of non-compliance or refer it for review by the RCRC.

WHAT IS NEXT

We will continue to review the remainder of the policy series to look for any needed updates. If you have a policy suggestion, please write to heather.bridge@nih.gov. We will keep you apprised of future policy revisions here in this newsletter. However, if any time sensitive or important policy changes are made, we will certainly inform you via announcements such as email blasts, and/or education sessions.

WHAT'S NEW

If you attended the OHSRP Townhall, Jonathan gave a brief preview of a new policy that is coming soon, *"Research Involving American Indian/Alaska Native Persons, Their Data and Biological Materials."* This policy was developed in concert with the Tribal Health Research Office (THRO), Office of Science Policy and with Institute/Center input. We encourage you to view the OHSRP Townhall slides posted on the OHSRP Presentation Archive. We will conduct an OHSRP Education Session about this important new policy after it is published. We hope to publish this new policy this Fall.

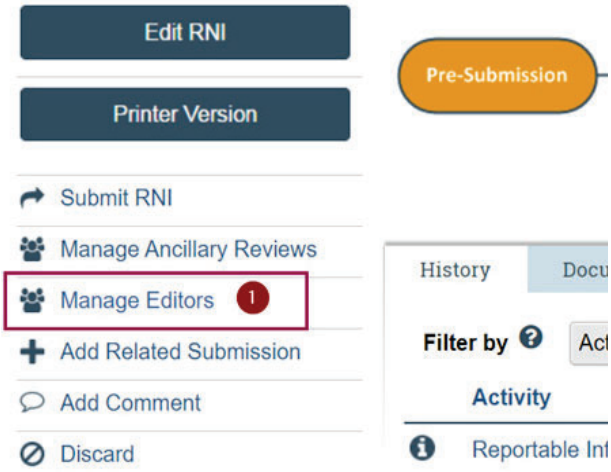
UPDATES COMING TO THE REPORTABLE NEW INFORMATION (RNI) FORM

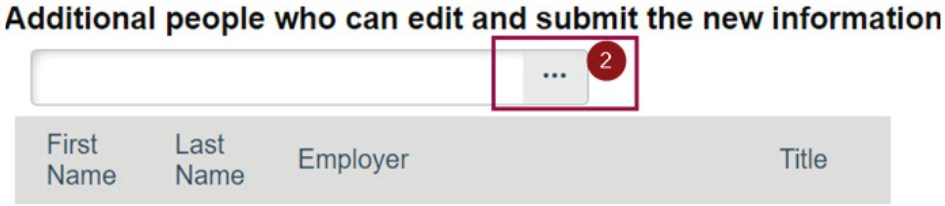
UPDATED HELP TEXT

You will soon note additional help text on the RNI form that provides details regarding what information should be included in specific sections of the form. We hope this will result in more complete initial RNI submissions and reduce requests for clarification.

NEW "MANAGE EDITORS" FEATURE

Good news! Previously, situations could occur when the person who submitted the RNI was not available to respond to a request for clarification from the IRB. As a result, the RNI would be "stuck" on the study side until the RNI creator became available. With the latest PROTECT upgrades, a new activity (Manage Editors) has been added. PIs and Proxies will be able to not only submit RNIs but will also be able to edit an RNI created by someone else for their study. Additionally, the RNI creator and IRB staff can add other editors. To add editors, first click on the tab labeled "Manage Editors." (See step 1 below.) Then click on the ellipsis which will allow you to select others who will be able to edit the RNI. (See step 2 below.)



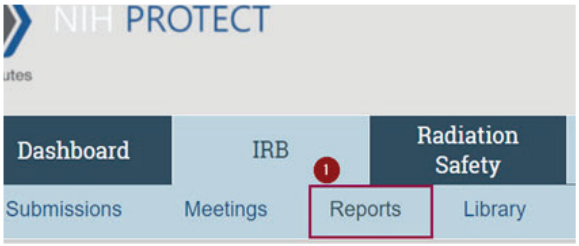


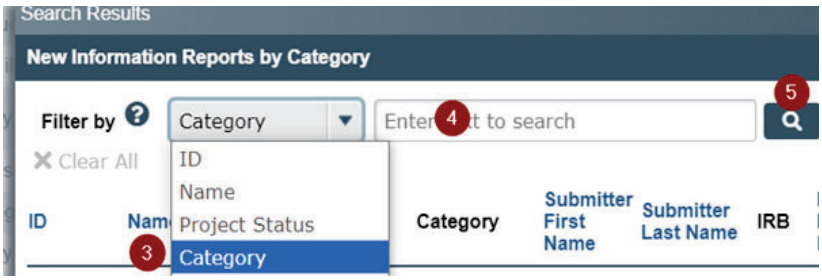
ABILITY TO EDIT IN THE ACTION REQUIRED STATE

Another change expands the ability to edit RNIs in the Action Required state to the RNI creator, responsible parties and additional editors. Previously, these users were not able to edit RNIs in this state.

NEW REPORT

Another report has been added: "New Information Reports by Category" which allows the user to sort by category of event as listed in line #4 of the RNI (e.g., non-compliance, major protocol deviation, UP, short form use, etc.) To access this report, click on the IRB tab and then on Reports (step 1 below). Once the page of reports opens, go to the last item in the section with the various New Information Reports which is labeled "New Information Reports by Category" as noted in step 2 below. Select "Category" from the dropdown (step 3 below). Then enter the category of event that is to be displayed (use the terms as listed in item #4 of the RNI) and hit the search button (steps 4-5 below).





NIH INVESTIGATOR SEMINAR SERIES

Since the last NIH newsletter, the Investigator Seminar Series has covered a wide variety of topics that we hope were helpful to those involved in conducting human subjects research. Slides and links to the video recordings for past sessions can be found on the **OHSRP Investigator Seminar Series Information** webpage.

In February, Jeff Rollins and Shirley Rojas from OHSRP presented *NIH Investigators and Multi-Site Research* and addressed the topic of single IRB review of multi-site studies as well as NIH PI responsibilities when the NIH IRB serves as the Reviewing IRB. They identified key considerations for planning a multi-site study that will be reviewed by the NIH IRB and provided an overview and tips for submitting a multi-site study for NIH IRB review in PROTECT.

The March session featured speaker Dr. Rita Misra who is the Supervisory Regulatory Affairs Specialist/FDA Strategy and Communication Lead in the Office of Sponsor and Regulatory Oversight in NCI's CCR. Dr. Misra provided information about which studies are FDA regulated and how these studies are regulated by FDA. Also addressed was the topic of responsibilities of both sponsors and investigators as well as special considerations related to expanded access protocols, cancer studies and research involving companion/*in vitro* diagnostic devices.

The Essential Role of Statistics and Collaborative Partnership in empowering clinical research was the topic for the April session of the OHSRP Investigator Seminar Series. Dr. Nusrat Rabbee, Chief of the Biostatistics and Clinical Epidemiology Service, Office of the NIH Clinical Center Chief Medical Officer covered the following topics: statistical integration in study design, data analysis proficiency, and ethical and transparent reporting.

Our speaker for the May session was Susan Vogel, Clinical Regulatory and Operations Specialist in the NIAID Office of Clinical Research Policy and Regulatory Operations. Her presentation was titled *Know Before You Go-International Research* which addressed the importance of regulations when conducting NIH supported international research including concerns related to risk mitigation. She also discussed assessing both the adequacy and needs of international sites and determining when such sites are ready to initiate research activities. Finally, the session covered approaches to ensure appropriate implementation and oversight of studies conducted in international settings.

June's session, *Research Enrolling "Vulnerable" Individuals-What Investigators Need to Know* was presented by Peg Sanders of OHSRP and addressed what is meant by the term "vulnerability" in the context of individuals enrolling in human subjects research. Vulnerability can be categorical versus contextual, and the session addressed which potentially vulnerable groups are specifically identified in the HHS Protection of Human Subjects regulations as well as other potentially vulnerable groups not addressed in regulation. The session identified research related concerns based on type of vulnerability and presented various regulatory and ethical issues to be considered by investigators.

Our final session in July titled *Protocol Registration and Results Reporting on Clinical Trials for the Intramural Research Program* was presented by Kim Mitchell, RHIA, who is Chief of Protocol Services for the NIH Clinical Center. During this session the following topics were addressed: registering protocols, updating protocol information, results reporting, and compliance.

OHSRP EDUCATION SERIES SESSIONS

Links to the recorded videocast and slides are posted in the *Presentation Archive section of the Education and Training page of the OHSRP website.*

Since the last newsletter, the March session titled *IVDs, LDTs, FDA and CLIA: Understanding the Alphabet Soup of Laboratory Assay* made NIH research teams aware of when FDA or CLIA regulations apply to the use and reporting of results from *in vitro* testing of biospecimens. Speakers for this session included the following: Dr. Jonathan Green, OHSRP Director; Dr. Joseph Chinquee, Clinical and Scientific Manager for the NCI Laboratory of Pathology; and Dr. Keith T. Schmidt, Pharmacist in the NCI Clinical Pharmacology Program.

Given the widespread interest in use of Artificial Intelligence (AI) in general, and more specifically as it relates to its use in human subjects research, our timely April session covered *IRB Review of Research Involving AI*. It was presented by Dr. Benjamin Silverman, Senior IRB Chair at Mass General Brigham, Human Research Affairs. Dr. Silverman addressed the ethical considerations raised by AI, as well as IRB considerations for the review of research involving AI.

The May 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.

Our July presentation, *CARE: A Model for the Integration of Cultural Humility into Human Subjects Research*, featured guest speaker Dr. Sana Loue, Professor in the Department of Bioethics at Case Western Reserve University School of Medicine in Cleveland, Ohio. 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 and identified strategies for the development and application of cultural humility in research.

August included an *OHRP Town Hall* with members of OHSRP leadership. Jonathan Green, OHSRP Director, reviewed the updates related to translation of consent forms for non-English speaking participants and previewed a pending new policy regarding enrollment of American Indian/Alaska Native persons in NIH intramural research. Heather Bridge, OHSRP Director of Policy and Accreditation, presented information on policy updates as OHSRP approaches its Triennial review of policies. Tiffany Gommel, IRBO Director, provided IRBO metrics for 2024 as well as OHSRP staff updates. Nicole Grant, OHSRP Associate Director and IRB Executive Chair, reviewed results from the PROTECT Satisfaction Survey and demonstrated updates to the OHSRP website.

The September session, *Community-Engaged Research to Address Cardiometabolic Health Disparities*, was presented by Dr. Tiffany Powell-Wiley, Earl Stadtman Investigator and Chief of the NIH Social Determinants of Obesity and Cardiovascular Risk Laboratory. During the session, Dr. Powell-Wiley defined community engagement and community based participatory research. She described how this approach is being used to address cardiometabolic disease impacted by social determinants of health and how it can help address clinical trial diversity.

Upcoming sessions in the OHSRP Education Series include the following interesting topics: issues related to obtaining assent from individuals who lack capacity to consent to research; research regarding detecting and managing suicide risk; and considerations for planning, recruitment and conduct of inclusive research involving Sexual and Gender Minority (SGM) populations. This latter presentation will be conducted by staff from the Sexual & Gender Minority Research Office (SGMRO). In advance of

that session, the SGMRO asked that we make the IRP community aware of some of the resources that already exist on their website including their SGM-Related Resources webpage, Culturally Competent Gender-Related Communications (C3) Training Resource, Sexual & Gender Minority Measurement & Data as well as a helpful resource titled Gender Pronouns & Their Use in Workplace Communications.

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 via live NIH videocast though they may occur on other Thursdays in the month based on the federal holiday schedule or speaker availability.

CONTACT OHSRP COMPLIANCE & TRAINING

For compliance or training related questions, requests for in-person training, or to submit ideas for the OHSRP Education Series, please email us at OHSRPCompliance@od.nih.gov.