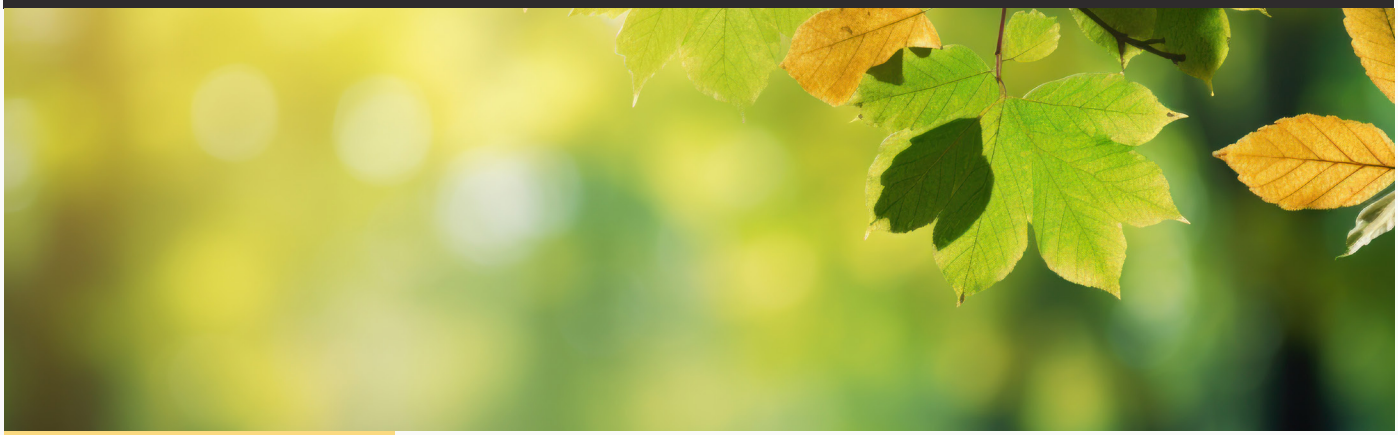
NIH Office of Intramural Research
*Office of Human Subjects Research Protections*

# OHSRP NEWSLETTER

Quarterly Edition June 2024



## IN THIS ISSUE



## LETTER FROM THE OHSRP DIRECTOR

Several months ago, I met with someone that I consider a mentor and we talked about leadership philosophies. This person shared with me their own philosophy, which was summed up in 2 succinct statements. After that discussion, I spent a lot of time trying to distill what I feel is my own philosophy into a similarly succinct statement. I am not sure it really qualifies as a philosophy; it is more like a guiding principle I try to remember to use when making decisions that may impact other people, which is pretty much almost every decision. It also happens to be one of the principles "Green's 5 principles of research ethics".

Principle 1: It's not about me.

As clinicians providing care for patients, we have a strong obligation to act in the patients best interest. In making treatment decisions, we must use our knowledge of medicine and clinical judgment along with our understanding of the patients goals and values, to come up with a treatment plan that is best for that one patient, and not allow our own personal interests to interfere or influence that decision. Similarly, as investigators, while our obligation to the participant differs in some ways from our obligation to patients, we cannot let our own personal agenda interfere with doing what is right for the participant and the integrity of the research.

Many times, our own interests are in alignment with the needs of the participant and the goals of the research. But sometimes they are not. For example, a participant's personal interest might be better

served by not enrolling in a study even though they are eligible, but our interest as a researcher is to reach our enrollment goal, as ultimately that is what leads to completing the study and publishing papers, which is the currency that furthers our own career goals.

Think about how we talk about obtaining the informed consent from participants for research participation. How many times have you heard or said something like "Dr Jones is consenting the patient" or "I am going to consent the patient for this study", or maybe when in the room with the person, "I'd like to get your consent to participate in this study". When we frame things that way, it implies that the only right answer is for the person to agree to participate. That's an "about me" approach.

The actual goal of the consent conversation is to use our knowledge and expertise to facilitate the person's decision making, so they can determine for themselves whether or not participation is the right thing for them, at this point in time in their life. Rather than saying "I'd like to get your consent for this study", we could say something like "I'd like to tell you about this research study and help you decide whether or not participating is right for you. Either decision is totally fine." That's a "not about me" statement.

On March 1 of this year we put in place a new policy requirement for translation of research informed consent documents for participants who are non-English speaking (see **Policy 301-Informed Consent**). The goal of this new policy is to facilitate the prospective participant's decision making and enhance safety during the study, should the person choose to enroll. While this will add some additional cost and burden, this is "not about me".

*—Jonathan M. Green, MD, MBA*

DIRECTOR

# GOLD STAR AWARD

We are pleased to announce that two different research teams will be receiving the Gold Star award for this issue. The first award is given to Senior Investigator, Dr. Luigi Ferrucci; Research Nurse, Linda Zukley; Clinical Protocol Coordinator, Christal Evans; and any others in NIA, who may have worked on the development of the protocol, "Measuring Protein Turnover in Humans Across the Lifespan by Metabolic Labeling with Deuterium Oxide (IRB001944)". This study's primary aim is to evaluate the half-life of a range of proteins in muscle, peripheral blood mononucleated cells (PBMCs), and skin and test the hypothesis that for specific proteins, older persons have different protein turnover than younger persons. The IRB Analyst who conducted the pre-review reported that the protocol was very well-written and that it was returned to the team for a few formatting changes. The IRB Reviewer for the full board meeting had only a couple of concerns. The reviewer was able to ask the PI about these issues before the meeting and get a quick response. The reviewer's concerns were thoroughly addressed by the PI. The reviewer was very appreciative, as this helped make for a smooth and short discussion at the meeting. Ultimately, the study was approved at the meeting and the protocol and consent form went back to the team for only some minor revisions to secure approval. **Congratulations to Dr. Ferruci, Ms. Zuckley, Ms. Evans, and the other members of Dr. Ferruci's research team!**

The second Gold Star Award is being bestowed upon PI, Dr. Elizabeth Kang; Research Nurse, Pamela Graham; and the other members of Dr. Kang's team in NIAID for an outstanding consent form. The consent form was submitted as part of the initial review for "A Phase I/II, Non-Randomized, Open-Label Study of Pcclchim-P47 (Lentiviral Vector Transduced CD34+ Cells) in Patients with P47 Autosomal Recessive Chronic Granulomatous Disease (AR-CGD) (IRB001562)" that went to full board in January. The OHSRP analyst who conducted the Partnership for Informed Consent Optimization (PICO) review stated that she was "super impressed" with the consent form. While it included some complicated terminology, it was extremely well-written. The finished product demonstrated that someone had put a great deal of thought into the language choices. The analyst also really appreciated the use of the images in the consent form to help with comprehension. The PICO analyst and the full board committee each returned the consent form with a few minor edits. **Congratulations to Dr. Kang, Ms. Graham, and the other members of Dr. Kang's research team!**

## EXPECTATIONS FOR IRB-APPROVED STUDIES INVOLVING GENOMIC RESEARCH

In the fall of 2022, OHSRP issued IRB Guidance on the Return of Secondary Genomic Findings. This guidance covers the requirements for all new studies and modifications to existing studies, approved on or after October 1, 2022, when they involve genomic research. At that time, we also updated the NIH Protocol Templates and the Consent Library to include guidance and template language on this topic.

Nevertheless, we have discovered that there are existing IRB-approved studies (i.e., those approved prior to October 1, 2022) which discuss returning genetic/genomic results, while omitting critical content in the protocol and informed consent documents. Accordingly, in this issue, we will cover what we generally consider to be the minimum expectations for IRB-approved studies involving

genetic testing or whole exome or genome sequencing (WES or WGS), regardless of when the research was first IRB-approved. This information applies to studies which are enrolling or have active subjects and include genetic testing, genomic sequencing, or interrogation of genetic/genomic data. These requirements do not apply to existing studies in which all the genetic/genomic data analysis and return of results are complete. Finally, we will go over the basic requirements for protocols and consent forms for those studies which must comply with the Genomic Data Sharing Policy or when the PI wishes to share genomic data in a repository, even when not required.

## PRIMARY FINDINGS VS. SECONDARY FINDINGS

**Primary findings** refer to those genetic findings related to the aims of the research as described in the IRB approved protocol. **Secondary findings** refer to those findings that were detected in the genomic research and are unrelated to the aims of the research. Secondary findings have previously been called incidental findings. However, this terminology is misleading and is no longer considered appropriate and should not be used in the protocol or consent form.

## IMPORTANT REMINDERS ABOUT RETURN OF RESULTS

No results (or information about potential health conditions related to these findings) can be shared with subjects, their family members, or their health providers, unless and until they are obtained from a laboratory that is certified as CLIA-compliant. If the genetic/genomic result was not generated in a CLIA-compliant lab, then the result must be confirmed in a CLIA-compliant lab, prior to be returned to the participant. Accordingly, if a new specimen must be collected for CLIA confirmation, the investigator should not reveal information about the potential mutation to the participant, until after a CLIA-confirmed result is obtained.

If subject will be referred out for CLIA confirmation, the external lab must not provide the research result directly to the subject. Instead, it must be provided to the NIH investigator and/or the NIH staff person who has been designated to inform the study participant of the results. Prior to providing the CLIA-confirmed results to a subject's health provider or family member, the investigator must first obtain a signed release of information from the subject.

## GENETIC TESTING/GENOMIC RESEARCH, RETURN OF RESULTS, AND RISKS

### Protocol Requirements

The following delineates the minimum content which should be addressed in IRB-approved protocols that involve genetic testing or whole exome or genome sequencing (WES or WGS).

- Describes the **type of genetic testing/genomic research testing** that will be conducted
    - Names what type of biospecimens will be used to conduct the research

- States what type of specimens or data will be generated, e.g., DNA, RNA, genetic, WGS, WES
- Explains the genetic/genomic analyses that will be conducted
- Discusses the purpose of the genetic testing/genomic research

- States whether **genetic/genomic results will be returned** to subjects or not
  - If results will be returned, addresses whether primary findings, secondary findings or both will be returned
  - If secondary findings will be returned, discusses what type of secondary findings investigators will query the data for, e.g., those specified by the ACMG
  - Specifies the time frame under which sequencing and return of results will occur, i.e., within a short time relative to collection of specimens or at some unspecified date in the future
- If results will be returned, provides **detail about the plan for obtaining and returning results:**
  - Articulates whether subjects will be notified of the result, regardless of what the result is, or only if the result is positive for a genetic mutation
  - Describes how subjects will be contacted, who will receive the results, and how results will be provided
    - The result must be provided directly to the research subject or their legal guardian
    - Return of results must include a verbal conversation
    - A result may also be shared with the subject's health provider or family member after obtaining a release of medical information
    - Affirms that subjects will have the option to decline to receive results upon being contacted
  - If the original testing or sequencing will not occur in a CLIA-certified lab, outlines a plan to obtain a new specimen and send it for confirmation
    - States that confirmatory testing will be conducted at no cost to the research subject
  - Defines who at NIH will provide the results to the subject, free of charge, and whether an NIH or external genetic counselor will be involved in the discussion
- **If results will be returned, articulates the specific risks** associated with the return of genetic/genomic results, including the subject's results being available in the medical record, when applicable
- **If no results will be returned, discusses risks** associated with a potential data breach of the research record or possible re-identification due to sharing the genomic data in a repository, when applicable

For more detailed guidance, see "Description of the scope of genetic/genomic analysis", "Management of Primary Results" and "Return of Secondary Genomic Research Results" and "Genetic counseling" in the NIH Protocol Templates. Please note that the requirements described in the

protocol template must be followed for new protocols which involve genomic research or as part of modifications to existing protocols to add genomic research, approved on or after October 1, 2022.

**Consent Requirements**

The following delineates the minimum content expected in consent forms associated with IRB-approved protocols that involve genetic testing or whole exome or genome sequencing (WES or WGS).

- Names **what type of biospecimens** will be used to conduct the genetic/genomic research
- Explains the **type of genetic testing/genomic research** that will be conducted
    - Discusses the purpose of the genetic testing/genomic research
    - Defines what DNA/RNA/genes are or what whole genome (exome) sequencing is, as applicable
    - States what type of specimens or data will be generated, e.g., DNA, RNA, genetic, WGS, WES
- States **whether primary findings will be returned** or if the analyses are for **research purposes only**
- Addresses **whether clinically-actionable secondary findings will be returned** (Does not refer to "incidental results".)
    - If yes, discusses what type of secondary findings will be returned, e.g., results consistent with the ACMG
- If results will be returned, provides **detail about the plan for obtaining and returning results**:
    - Articulates whether subjects will be notified of the result, regardless of what the result is, or only if the result is positive for a genetic mutation
    - Specifies the time frame under which testing/sequencing and return of results will occur, i.e., within a short time relative to collection of specimens or at some unspecified date in the future
    - Describes how subjects will be contacted, who will receive the results, e.g., the subject or legal guardian, and how results will be provided
        - Specifies that the result will only be provided to the research subject or their legal guardian, unless the subject signs a release to allow their health provider or additional individuals to be notified
        - Promises that subjects will have the option to decline to receive results if they choose not to upon being contacted
    - If the original testing or sequencing will not occur in a CLIA-certified lab, outlines a plan to obtain a new specimen and send it for confirmation
        - States that confirmatory testing will be conducted at no cost to the research subject
    - States who at NIH will share the results with the subject, i.e., whether an NIH or external

genetic counselor will be involved in the discussion

- **If results will be returned, articulates risks associated with the return of results**, including the subject's results being available in their medical record, when applicable
- **If no results will be returned, discusses risks** associated with a potential data breach of the research record or possible re-identification as a result of sharing the genomic data in a repository, when applicable

For more detailed guidance and consent template language, see "Genomic Sequencing", "Secondary

## PROTOCOL AND CONSENT REQUIREMENTS ASSOCIATED WITH THE GENOMIC DATA SHARING (GDS) POLICY

The Genomic Data Sharing (GDS) Policy went into effect in the NIH Intramural Research Program on August 31, 2015. This policy includes other protocol and consent requirements for studies that generate large-scale genetic/genomic data. Both the NIH Protocol Templates and the NIH Consent Templates include instructions and template language that must be addressed in applicable studies.

**If the Genomic Data Sharing (GDS) Policy applies and the data that will be shared are associated with specimens that were collected on or after Aug. 31, 2015:**

The **protocol** must state that the Genomic Data Sharing Policy applies. It should also specify that de-identified or anonymized genetic/genomic data will be shared in a genomic repository for future research. The relevant **consent form** must explain that genetic or genomic data will be deposited in a repository to allow sharing for research purposes. The **consent form** must also reference the plan to share genomic summary level results in a repository with unrestricted access unless the PI deems the data to be sensitive.

**If the Genomic Data Sharing (GDS) Policy applies and the data that will be shared are associated with specimens that were collected before Aug. 31, 2015:**

The **protocol** must state that genetic/genomic data will be generated as part of the research. In addition, the plan to deposit genetic/genomic data in a repository for sharing for future research cannot be inconsistent with what was stated in the original IRB-approved **protocol** that was used to collect the specimens. Futhermore, the plan to deposit genetic/genomic data in a repository for sharing for future research cannot be inconsistent with the content in the **consent form** signed by study subjects (when the specimens were collected with informed consent).

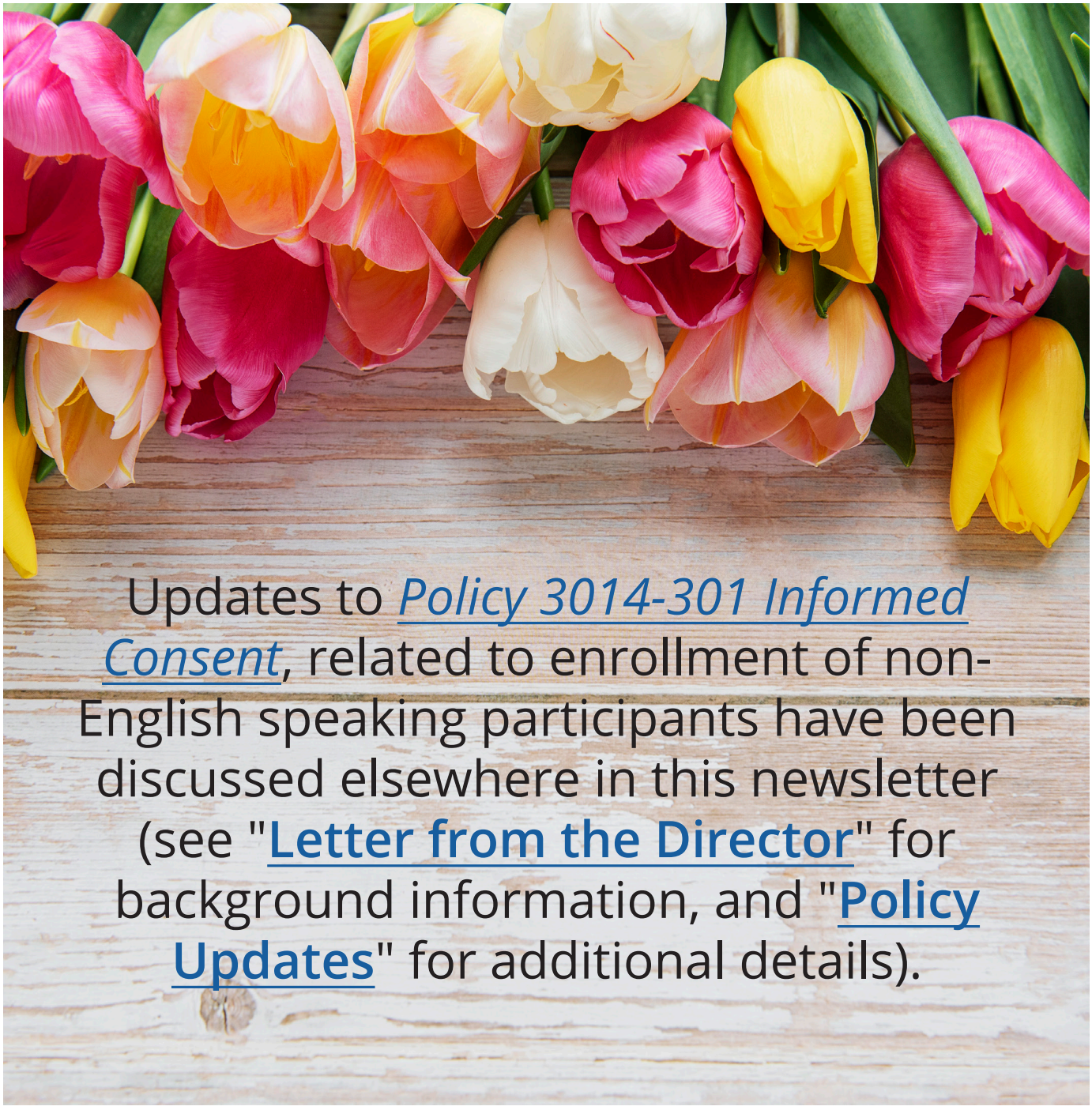
**If application of the Genomic Data Sharing (GDS) Policy is not required, but a journal is requiring sharing or the study team plans to share the genetic/genomic data per the NIH Data Management and Sharing Policy, etc.:**

The **protocol** must address that genetic/genomic data will be generated. In addition, the plan to deposit genetic/genomic data in a repository for sharing for future research cannot be **inconsistent with** the content in the **consent form** signed by study subjects (when the specimens were collected with informed consent).

For more information about the required protocol content for studies that must comply with

the Genomic Data Sharing Policy, see "Human Data Sharing, Including Genomic Data Sharing, and Publication" in the NIH Protocol Templates. For examples of consent language that meet the requirements of this policy, see the repository language under "Will your specimens or data be shared with other researchers for use in other studies" and the instructions about "genomic summary results" in the NIH Consent Templates.

## POLICY UPDATE REMINDER



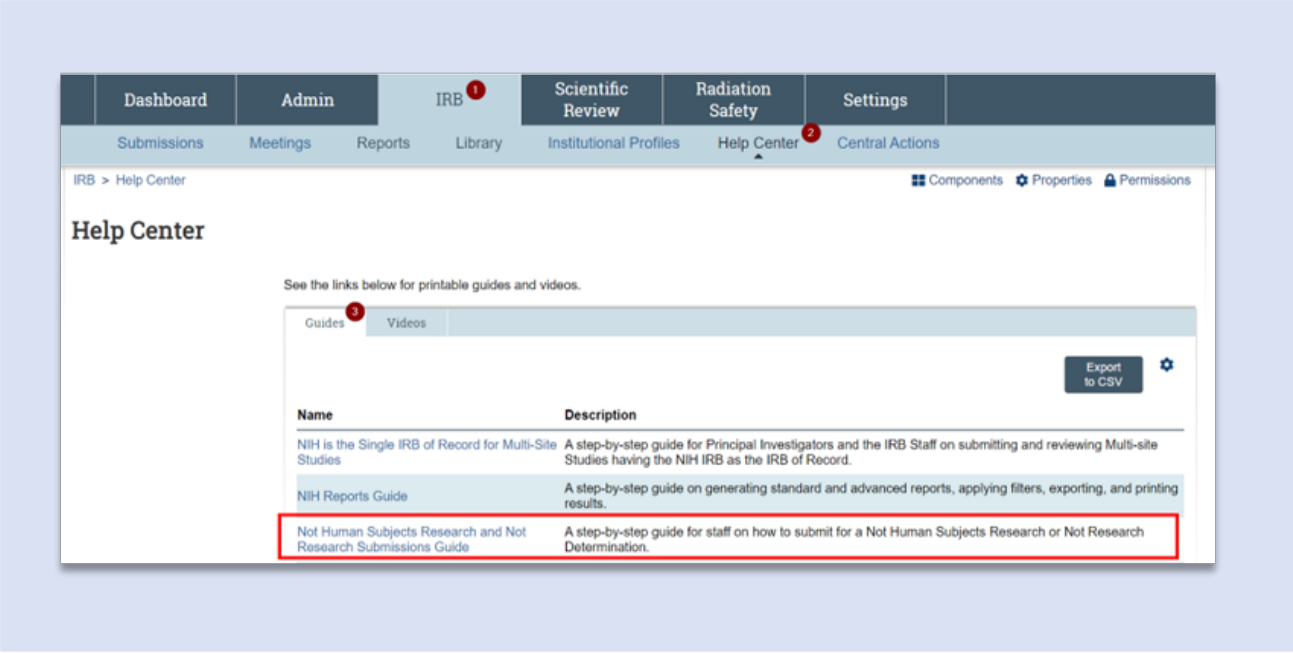
## PROTECT SYSTEM: SUPPORT & EDUCATION

***Update* iRIS System Has Been Archived**

iRIS has been taken offline and archived (unavailable to users) as of May 31, 2024, nearly 18 months after the implementation of the PROTECT system. This has allowed users the time to download any needed information and documents out of iRIS. Please delete any bookmarks to the iRIS system that you may have saved as they can no longer be used.

## *NEW* NHSR AND EXEMPT GUIDES

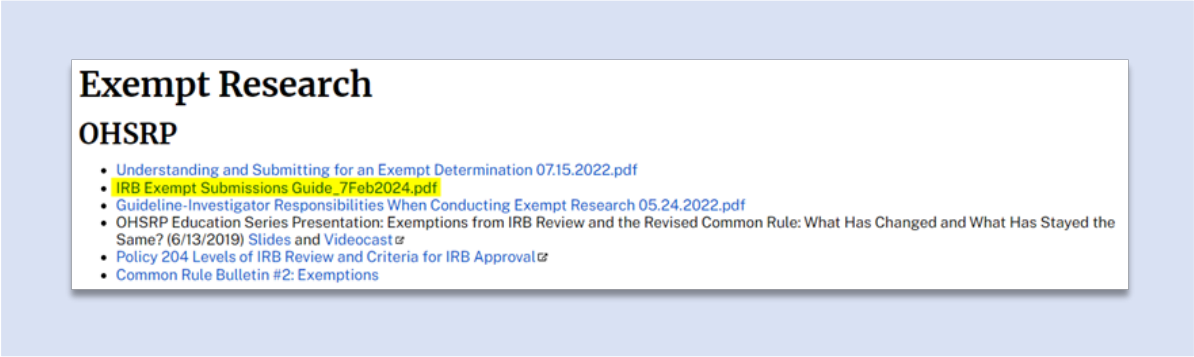
We have released two new user guides for submitting for Exempt Determinations and NHSR/Not Research. They are located in PROTECT with our other user guides:



## EIRB PROJECT COMMUNICATION, CONTINUED

These two new guides are also located on our website here:

https://irbo.nih.gov/confluence/display/ohsrp/Exempt+Research




https://irbo.nih.gov/confluence/display/ohsrp/NHSR+Research


*Revised* Where PROTECT User Guides are stored

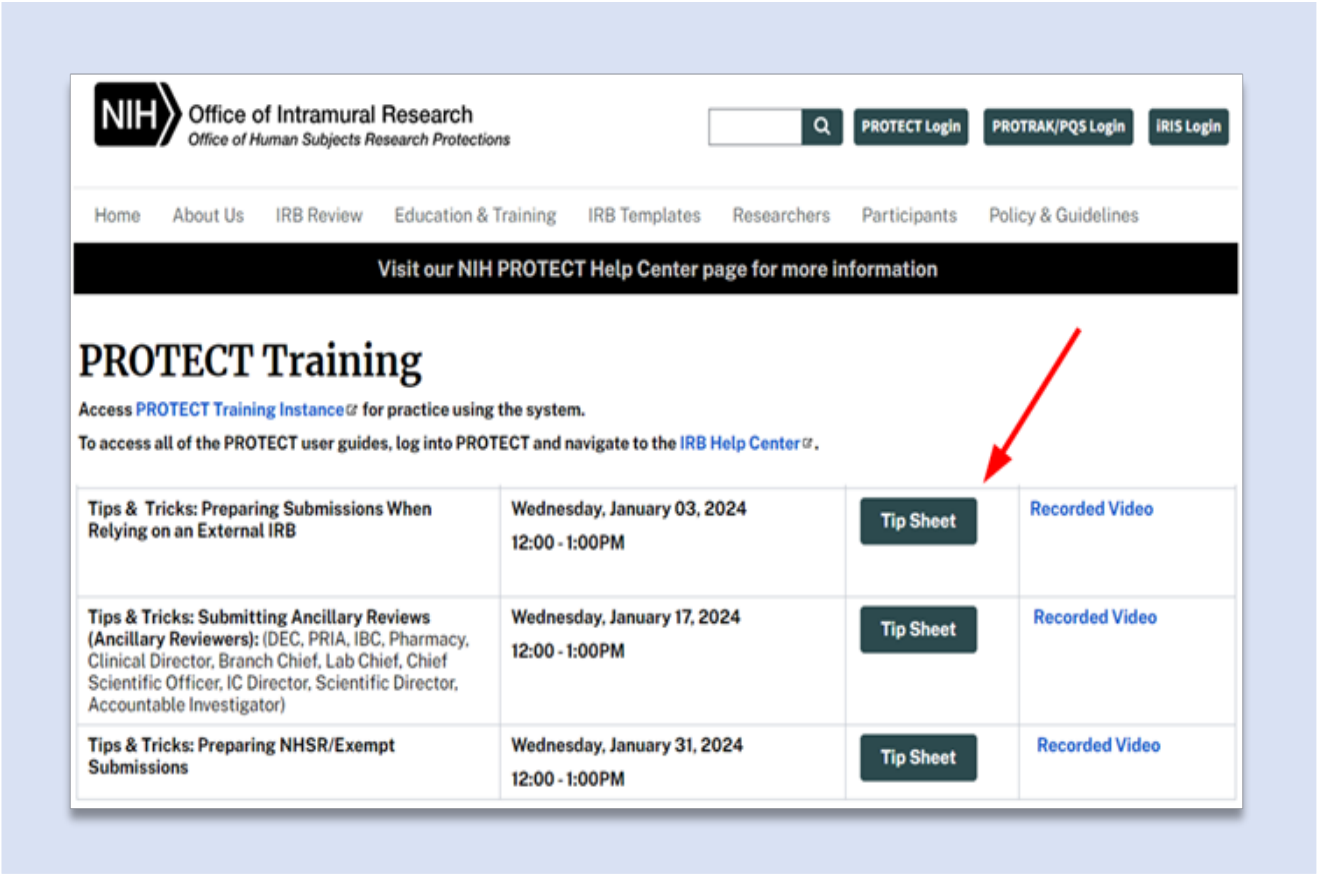
Where PROTECT User Guides are stored The PROTECT User Guides created by HURON were previously located on both our website as well as in the PROTECT system. Now, they are only located in the PROTECT system. This was done to remove redundancy, give access to guides only to PROTECT users since our website is public-facing, and to make ongoing revisions easier.

## POST GO-LIVE EDUCATION SERIES

We continue to deliver post go-live PROTECT education classes that dive into more specific class topics. Sessions are recorded and posted for later viewing or sharing with new hires as part of orienting them. Each class is also accompanied by a Tip Sheet on the topic.

*Classes, recordings, and tip sheets can be found here:*
PROTECT Training (nih.gov)

***NOTE:*** All Tip Sheets that accompanied these classes have been relocated on our website next to each respective class:

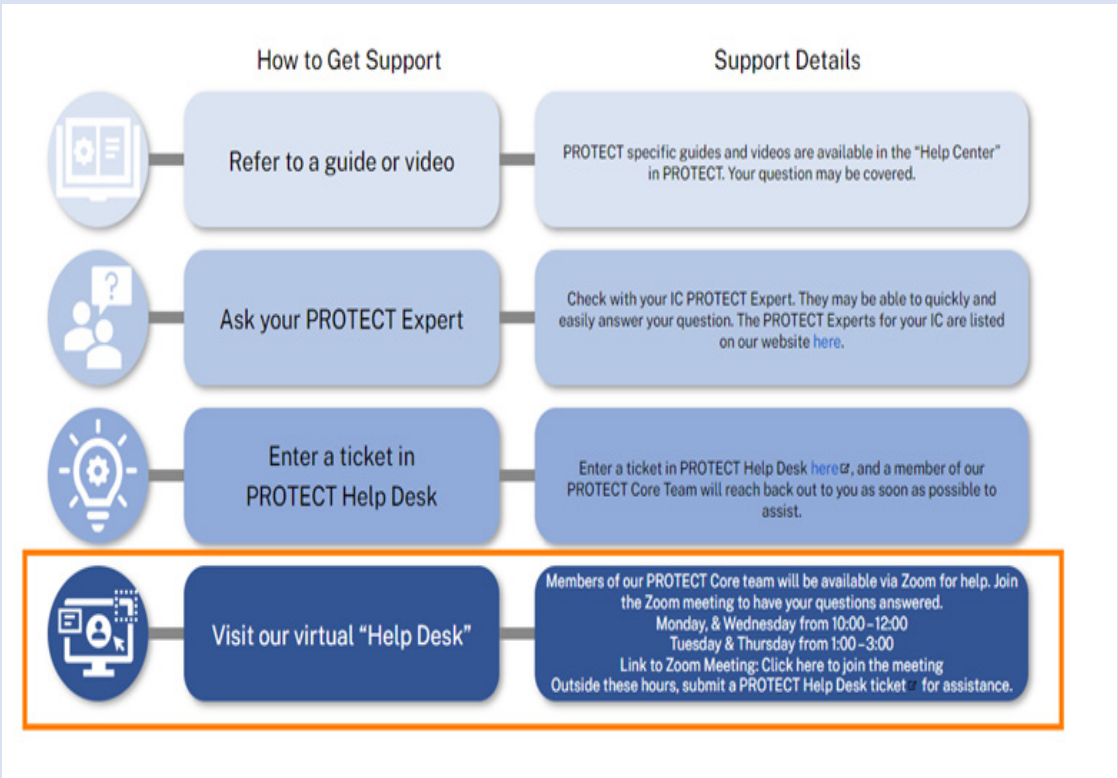


## ONGOING PROTECT SUPPORT

Our trainers continue to offer PROTECT support Monday to Friday 8am-4:30pm (EST) in a variety of ways so that users can get the help they need, when they need it, and in the way that works best for them. The best way to get help is either by attending our PROTECT'Live' Help Desk Hours, or via submitting a Help Desk Support ticket.

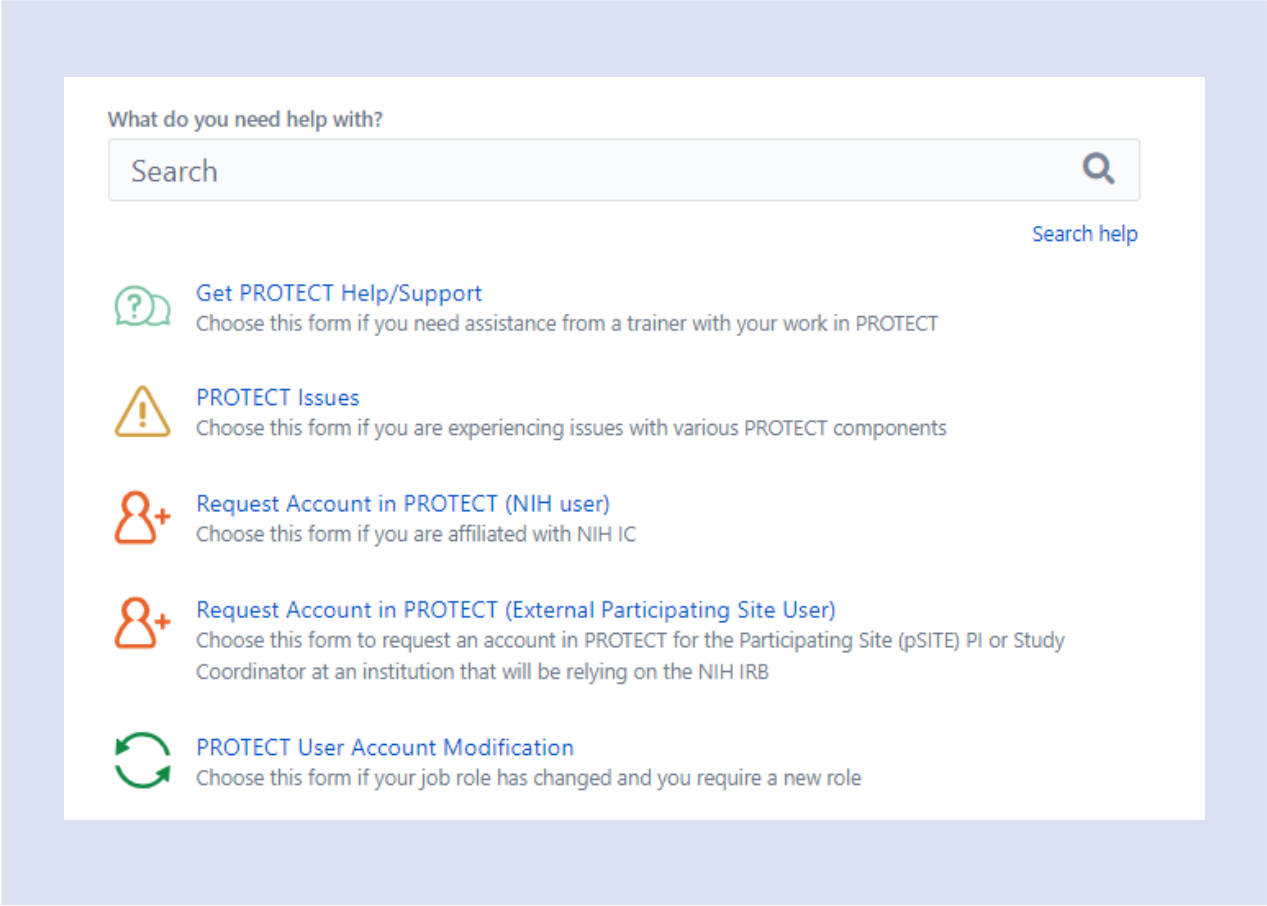
*(See below for how to get help in these two ways.)*

### PROTECT 'LIVE' HELP DESK HOURS



## PROTECT HELP DESK SUPPORT TICKETS

We continue to utilize the Protect Help Desk Support ticketing system for you to submit questions to. This can be found here: [OHSRP IRB PROTECT Help Desk Support](#).



As mentioned above, Manual Chapter 3014-301 Informed Consent has been revised to address several new policy requirements.

The first revision incorporates new regulatory requirements at 21 CFR 50.22 for waiver or alteration of informed consent elements, or waiver to obtain informed consent for FDA-regulated minimal risk research. This new requirement took effect January 22, 2024. This is one of several harmonization efforts by the Food and Drug Administration (FDA) with the 2018 Common Rule. This new requirement replaces the ***2017 FDA Guidance for Sponsors, Investigators and Institutional Review Boards – IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal RisK to Human Subjects*** with the new requirement at 21 CFR 50.22 which states the following:

**§ 50.22 Exception from informed consent requirements for minimal risk clinical investigations.**

The IRB responsible for the review, approval, and continuing review of the clinical investigation described in this section may approve an informed consent procedure that does not include or that alters some or all of the elements of informed consent set forth in § 50.25(a) and (b), or may waive the requirement to obtain informed consent, provided the IRB finds and documents the following:

a. The clinical investigation involves no more than minimal risk to the subjects;

b. The clinical investigation could not practicably be carried out without the requested waiver or alteration;

c. If the clinical investigation involves using identifiable private information or identifiable biospecimens, the clinical investigation could not practicably be carried out without using such information or biospecimens in an identifiable format;

d. The waiver or alteration will not adversely affect the rights and welfare of the subjects; and

e. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

The policy has been revised by adding the citation to 21 CFR 50.22 when discussing waiver or alteration of informed consent for FDA-regulated Research at sections C.13.a., for investigator responsibilities at E.2.f.I., and for IRB responsibilities at section E.5.c. In addition, references to F*DA Guidance for Sponsors, Investigators and Institutional Review Boards – IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects* have been struck from the policy since this guidance is no longer in effect. Investigators seeking waiver or alteration of consent for minimal risk FDA-regulated research should ensure all the criteria under 50.22 will be met.

The next set of revisions comes from the newly consolidated FDA guidance: Informed Consent Guidance for IRBs, Clinical Investigators, and Sponsors (August 2023). These requirements take effect March 1, 2024. First of which is addressed at Section E.2.b.III. which requires that informed consent be provided in language understandable to the subject. The policy already required that the consent document be written at an appropriate reading level for the intended audience. Now, it also requires an explanation of any scientific and medical terms used in the consent document.

The major revision to Policy 301 addresses additional requirements for non-English speaking participants consistent with the same FDA consolidated guidance on informed consent. New requirements to address this are seen at section C.8. and in section E.2.h. In Section C.8.I. we explain the conditions for short-form consent use for minimal risk research. In Section C.8.II. we explain the conditions for short-form consent use for greater than minimal risk research. In Section C.8.III. we explain that short-form consent use must be reported to the IRB as an RNI within 7 days. In addition, for greater than minimal

risk research, the IRB must be informed when the new IRB-approved translated long form consent has been provided to the participant. In Section C.8.IV. we explain that short form consent use may no longer be used for the enrollment of healthy volunteers, and when there is sufficient time to obtain translation of the long form consent document before enrollment of the non-English speaking participant.

In Section E.2.h. we provide additional details to supplement the policy requirements in C.8. above. New requirements are inserted at E.2.h.II., resulting in the reordering of existing requirements in this section. Some examples of new requirements in this section for greater than minimal risks research include: 1) documentation of the rationale for short form consent use in the research record, 2) the requirement to promptly obtain a certified translation of the IRB-approved long form in the language of the subject; 3) once the IRB has approved the newly translated long form consent that it be provided to the participant as soon as possible. When submitting the RNI to the IRB to inform it of short-form consent use, the PI should include the rationale for the use of short form procedures. Lastly, under certain circumstances and at the discretion of the IRB, the PI may be directed to translate the English long form consent document into another language in lieu of short form consent use.

MC 3014-801 Reporting Research events is also being updated to address the new RNIs for reporting short form consent use.

If you were not able to attend the February OHSRP Education Session, ***An Overview of IRB Expectations When non-English Speaking Persons Enroll in Research***, we courage you to review the presentation recording in the **Presentation Archive**. This presentation provides some important supplementary information about IRB expectations, use of interpreters, and additional resources for translation available in the NIH Library.

## ACCREDITATION UPDATES

Thank you to Institute/Center (IC) Association for Accreditation of Human Research Protection Program (AAHRPP) liaisons and to IC Quality Assurance (QA)/Quality Improvement (QI) and monitoring staff for your assistance in gathering AAHRPP accreditation data for the Annual Report. We compiled the report data submitted it to AAHRPP in March 2024. This year was interesting. While we collected only two data points from the ICs for the main report (fewer than ever since we became accredited), we asked more of our QAQI staff. OHSRP took over the annual QAQI survey from ORSC which was a bit of a learning curve for our staff since we are new to using RedCap. This is also our first year getting data out of PROTECT.

Looking forward to next year, we are happy to report that AAHRPP has further refined the type of data it will collect from organizations. This was at the request of accredited organizations. Our thanks to Jonathan Green who contributed to the working group on collecting more meaningful metrics. As a result, we will no longer be asking for budget or staffing data from the ICs, and from the AAHRPP Liaisons. We will still need the assistance of IC AAHRPP Liaisons for re-accreditation and site visits. We will continue to need QA/QI data to be collected annually and that is also likely to be further refined by OHSRP.


**OHSRP's Compliance and Training staff would love to hear from you! We are interested in your ideas for future OHSRP Education Series sessions. We are also available to conduct in-person or virtual training for groups in the NIH IRP.**

**If your research team or working/interest group would like us to present on specific topics related to human subjects research, compliance, or training, just email us at OHSRPCompliance@od.nih.gov, and we will be glad to contact you to discuss details about what information would be most helpful to your group.**

## UPDATE TO THE REPORTABLE NEW INFORMATION FORM

Updates to Policy 301, *Informed Consent* related to enrollment of non-English speaking participants have been discussed elsewhere in this newsletter (see Letter from the Director for background information, and Policy Updates for additional details). The guidance for obtaining consent to participate in research from non-English speaking participants explains that any use of a short form consent document requires submission of a Reportable New Information form (also known as an RNI in PROTECT within 7 calendar days. To submit this information, check the box on the RNI form labeled as "Short Form Use: Use of the short form consent to enroll a non-English speaking subject." When submitting the RNI to report short form use, please provide justification for using the short form consent process in the description of the event. Additionally, if the research has been determined by the IRB to be not greater than minimal risk, include information about how many times the short form in that language has been used since March 1, 2024. For studies that are greater than minimal risk, the person submitting the RNI should also indicate when it is expected that the translated consent will be provided to the participant and respond to the Compliance and Training analyst's request for clarification by providing the date that the translated long form consent was provided to the participant.

## NIH INVESTIGATOR SEMINAR SERIES

In recent months, the Investigator Seminar Series has focused on topics related to documentation and event reporting within the conduct of 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 November, Liz Ness, Director of the Office of Education and Compliance at the Center for Cancer Research at NCI, presented ***Documentation and Document Management in Clinical Research*** during which she described best practices for clinical research documentation and the importance of source documents and essential documents. During the December session, ***What Investigators Need to Know About Reporting Research Related Incidents to the IRB***, Peg Sanders from OHSRP, addressed which research related events require expedited reporting to the IRB as well as the process for submitting RNI forms in PROTECT. The process of post approval monitoring and subsequent plans for corrective action were addressed in the January 2024 session titled ***Quality Management in Clinical Research***. That session was presented by Deb Grady, Quality Management Coordinator in the Office of Education and Compliance in NCI's Center For Cancer Research who was joined by Sharon Flynn, Director of Patient Safety and Education for NHLBI in the Office of the Clinical Director. February's session, ***NIH Investigators and Multi Site Research***, was presented by Jeff Rollins and Shirley Rojas from OHSRP and focused on the process, considerations, and PI responsibilities when NIH serves as both the Lead Site and Reviewing IRB for a multi-site study.

We hope you will join us for these virtual presentations. A list of topics, dates and Zoom links for upcoming sessions can be found on the OHSRP Investigator Seminar Series Information webpage.

## 2023 OHSRP EDUCATION SERIES SESSIONS

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. After each presentation, a link to the recorded videocast and slides are posted in the Presentation Archive section of the Education and Training page of the OHSRP website

Our October 2023 OHSRP Education Series titled, ***Considerations for Informed Consent in Cell and Gene Therapy Trials,*** featured an outside guest speaker, Daniel Kavanagh, PhD, RAC, who is the Senior Scientific Advisor, Gene Therapy, Vaccines, and Biologics for WCG. The November session focused on ***The Single IRB Model at the NIH: Principles, Processes, and Pitfalls,*** which provided an update on NIH involvement in multisite research, was presented by OHSRP's Shirley Rojas and Jeff Rollins. Dr. Christine Grady, Chief of the Department of Bioethics addressed the topic of paying research participants in the January 2024 presentation. The February session, ***An overview of IRB expectations when non-English speaking persons enroll in research : The importance of ensuring comprehension,*** focused on changes to NIH policy regarding enrollment of non-English speaking participants in NIH research. The three speakers for the February session addressed various aspects of the planned changes and included; Jonathan Green, OHSRP Director; Nancy Muir, Director of the NIH Library located in the Clinical Center; and Brenda Robeless, the Clinical Center Language Interpreters Program Manager. For additional information on this topic please see, "Letter from the Director" for background information, and "Policy Updates" for additional details.

Upcoming sessions in the 2024 OHSRP Education Series include an outside guest speaker this summer, Dr. Sana Loue, Professor of Bioethics at the Case Western Reserve University, School of Medicine in the Department of Bioethics who will be presenting a session titled, ***A Model for the Integration of Cultural Humility into Human Subjects Research***. Dr. Loue explains that cultural humility refers to a lifelong process of self-reflection, self-critique, and learning, requiring humility and active listening, as one seeks to develop and maintain mutually respectful partnerships with communities and patients and right power imbalances and dynamics between health care providers and patients, and between researchers and research participants.