

# OHSRP NEWSLETTER

Winter Edition

March 2025



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## LETTER FROM THE OHSRP DIRECTOR

As 2025 gets underway, I wanted to take the opportunity to review our activities of 2024. The intramural research program was busy. Table 1 breaks down the number of forms reviewed by the IRB by review path and form type. Committee review refers to those that were reviewed by the convened IRB (full board review) whereas exempt and expedited forms are reviewed by a non-committee process (designated review). A total of 6289 forms were reviewed and approved by the IRB in 2024, including 193 new protocols across all ICs. Figure 1 shows the number of submissions (as opposed to approvals) to the IRB by each IC, broken down by form type. Not surprisingly, NCI took first place by a hefty margin, with NHLBI and NIAID leading the remaining ICs.

Row Labels	Count of Request Type
<b>Committee</b>	
Continuing Review	502
Initial Study	64
Modification and Continuing Review	148
<b>Exempt</b>	
Initial Study	47
<b>Expedited</b>	
Continuing Review	829
Initial Study	81
Modification and Continuing Review	192
<b>External IRB</b>	
Initial Study	1
IRB Site	10
<b>IRB Site</b>	
IRB Site	25
Modification / Update	156
<b>Modification / Update</b>	
Modification / Update	4148
<b>Not Human Research</b>	
Initial Study	86
<b>Grand Total</b>	<b>6289</b>

Table 1: Total number of forms reviewed by the IRB by review path and form type

# LETTER FROM THE OHSRP DIRECTOR, CONTINUED

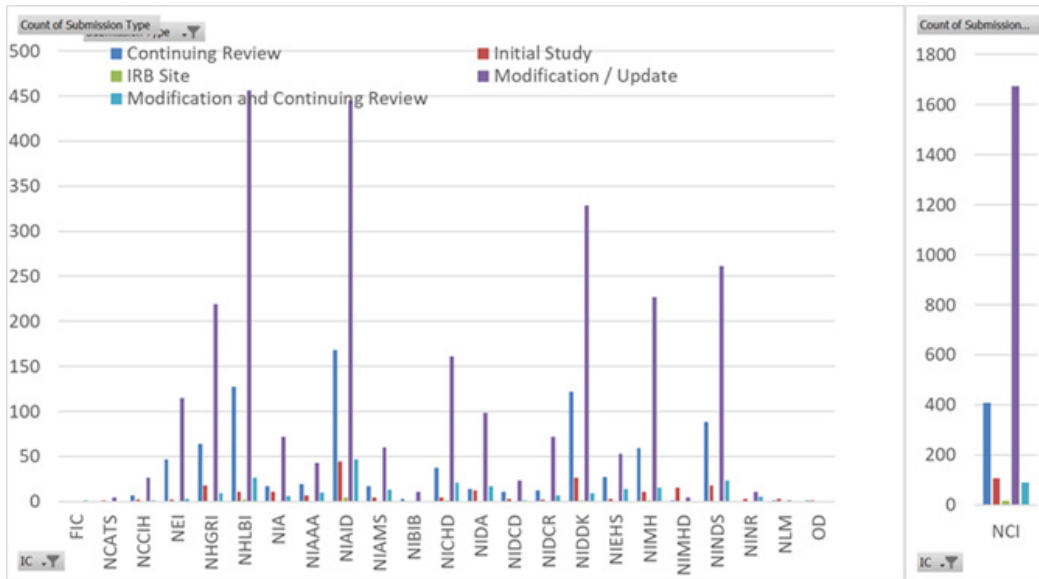


Figure 1: Submissions to the IRB in CY 2024, by IC and form type

Figure 2 shows the number of days from submission to the IRB to final approval, by form type and review path.

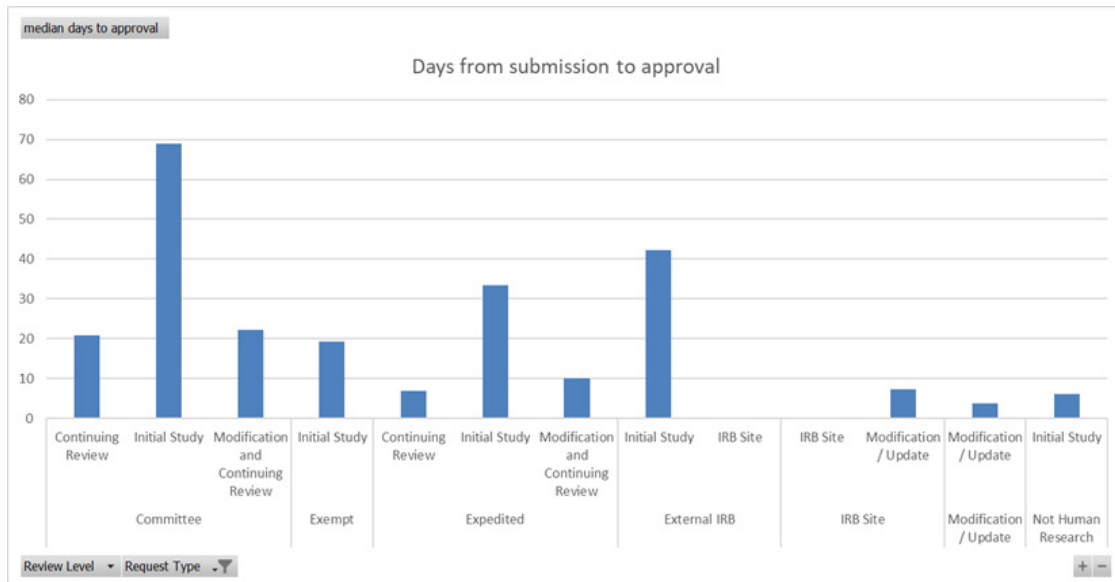


Figure 2: Days from submission to final IRB approval

## LETTER FROM THE OHSRP DIRECTOR, CONTINUED

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We are in the process of rebuilding our dashboards. I am hopeful they will go live soon. Once available, they will be accessible on our website and you will be able to see our metrics in real time. In other news, the NIH IRB is soon to be the official IRB of record for the Health Research Services Administration (HRSA). HRSA has a small portfolio of intramural research, and they approached us to see if we could help them out with IRB review and advice. We are excited to be able to extend our expertise and services to a sister HHS agency.

Our initiatives for 2025 include outreach activities to our research participant community to increase awareness of the IRB. We hope to have a pamphlet available to give to individuals as they enroll in our studies. We are also actively working on ways in which informed consent documents can be improved so that our participants can make the best decision as to whether (or not) to join a study. This is an area in which I think AI can really make a difference.

Along with the rest of NIH, we lost staff with the recent termination of probationary employees. Five members of OHSRP were let go, including one that had worked with us for 5 years as a contractor and had recently come on board as a federal employee. These individuals were valued members of our team and performed critical functions that are not easily reassigned. While we will work to minimize the impact, I have no question that this will affect our operations and hinder our efforts to reduce turnaround times. In addition, some of the initiatives we hoped to make progress on in 2025 are likely going to be on hold.

Lastly, we greatly appreciate everyone's effort to comply with the translation policy. For the period March through December, 319 consents were translated. This extra effort contributes greatly to assuring that individuals fully understand what it means to participate in research.

—Jonathan M. Green, MD, MBA  
DIRECTOR

## IRBO UPDATES

### GOLD STAR AWARD

This issue's Gold Star award goes to Dr. William A. Gahl, MD, PhD, in the Human Biochemical Genetics Section; Dr. Marjan Huizing, PhD; Andrea Ashton, Research Nurse; and the rest of the research team in **NHLBI** and **NIDDK**. In September 2024, the research team submitted an initial review for a phase 2, open-label, single-arm study of oral N-Acetyl-D-Mannosamine (ManNAc) for use in subjects with primary focal segmental glomerulosclerosis (FSGS). The study's objectives are to characterize the long-term safety, tolerability, pharmacokinetics, and efficacy of ManNAc for proteinuria reduction. The analyst's only stipulations were related to the readability of the consent form as part of the IRBO Partnership for Informed Consent Optimization (PICO). The team responded to the stips the next day. The protocol was reviewed by the full board in October 2024. The full board requested that another exclusionary condition be added along with two other minor edits to the protocol as well as additional changes to the consent form. The team returned the corrections later that day and final approval was granted soon after. **Congratulations to Dr. Gahl, Dr. Huizing, Ms. Ashton, and the other members of the research team!**



### Understanding What Types of Studies Meet the Criteria for an Exemption

The IRBO focus for this issue is to provide helpful details about what types of studies might be eligible for an exemption from IRB review and approval. We will also discuss the various requirements associated with submitting for an exemption.

The regulations do not explicitly address whether two or more exempt categories can be combined to be able to provide an exempt determination for one project. However, Secretary's Advisory Committee on Human Research Protections (SACHRP) has stated that combinations are acceptable. The NIH IRBO has been applying this flexibility to allow studies that involve multiple methods (covered under more than one exemption) to be determined to be exempt. All procedures involved in an exempt study must meet the exempt criteria and not conflict with any part of the regulations to qualify. There are currently six exempt categories under the revised Common Rule that can be utilized at NIH. We are going to focus on the three categories that are most commonly submitted to the NIH IRBO.

#### EXEMPTION CATEGORY 2

Studies that might be able to be determined exempt under Category 2 only include interactions with participants involving educational tests (cognitive, diagnostic, aptitude, achievement); survey procedures; interview procedures; or observation of public behavior. Public behavior refers to behavior taking place in a publicly accessible location in which the subject does not have an expectation of privacy (e.g., a public plaza or park, a street, a building lobby, or a government building). At NIH, most of the studies that are determined to be exempt under category 2 involve

## IRBO UPDATES, CONTINUED

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surveys, interviews and/or focus groups. The data collection process can also involve audio-recording or video-recording.

The project may include collection of identifiers and still be determined to be exempt. If the data is identifiable, and accidental disclosure might put the participants at a risk of criminal charges or civil claims; or be damaging to their financial status, employability, educational advancement or reputation, the protocol must include an adequate plan to protect the privacy of participants during the conduct of the study and maintain the confidentiality of their information, as determined by a designated IRB member. This category cannot be applied to any project that also incorporates other existing, identifiable data associated with the participants. If the surveys, interviews or focus groups will be conducted with minors (those 17 years of age or younger), then the project cannot be exempt. This exemption category cannot be applied to any projects targeting prisoners as the participants. It also cannot be applied to projects involving the observation of the public behavior of minors, if the investigator is participating in the activities being observed.

### EXEMPTION CATEGORY 3

Studies that might be able to be determined exempt under Category 3 involve what the regulators refer to as “benign behavioral interventions”. To qualify as exempt under Category 3, the research interventions must be brief, harmless, painless, not physically invasive, not offensive or embarrassing, and unlikely to have a significant negative lasting impact on the participants. Studies deemed to be exempt under Category 3 cannot involve any biomedical interventions (e.g. collecting biospecimens, performing clinical procedures, or the use of investigational drugs or devices). Data can be collected through verbal responses, written responses (including data entry), audio-recording, or video-recording. At NIH, projects which meet this category often involve completing behavioral tasks; watching videos or looking at images; data entry and/or mouse clicks; and sometimes eye tracking (when conducted via video-recording the position and movement of the eyes).

Just like exemption category 2, the project may include collection of identifiers and still be determined to be exempt. If the data is identifiable, and a breach might put the participants at a risk or be damaging to them, the protocol must include an adequate plan to protect the privacy of participants during the study and maintain the confidentiality of their information, as determined by a designated IRB member. This category cannot be applied to any project that also includes other existing, identifiable data associated with the participants. Participants must be informed about the intervention and data collection methods and agree to them. If the consent is not straightforward about the nature or purpose of the research, the participants must be informed and agree to being deceived about this. If the project will be conducted with minors (those 17 years of age or younger) or targets prisoners as the participants, it cannot be determined to be exempt under this category.

### EXEMPTION CATEGORY 4

All studies that meet the criteria for an exemption under Category 4 involve the secondary research use of human data or biospecimens. In this context, “secondary research use” refers to the research use of information or biospecimens that were originally collected for research other than the newly proposed research, or for a non-research purpose (e.g., for a clinical purpose). At NIH, the majority of the studies that are determined to be exempt under category 4 involve secondary research in which the investigator **accesses** identifiable information or biospecimens *temporarily* in order to record de-identified data to be used for analysis. It's important to note that if the research team will download, record, or maintain identifiers that can be linked to the data or biospecimens during any part of the research process, exemption category 4 cannot be applied to the project. For more information about identifiers, please review [Guidance for Determining Whether Data Constitutes Individually Identifiable Information Under 45 CFR 46](#) which can be found on our website. As a part of this exempt project, the investigator must agree they will not attempt to re-identify the data or re-contact the

subject.

A typical example of an exempt category 4 project is a medical chart review in which no identifiers are recorded or maintained for future use during the analysis. In a situation in which all the data is in CRIS, we always suggest that investigators first contact the Office of Biomedical Translational Research Informatics (BTRIS) at [BTRISsupport@nih.gov](mailto:BTRISsupport@nih.gov).

This category can also be applied to studies which will utilize *publicly available*, identifiable data. If the data is truly publicly available, the researchers may maintain the identifiers throughout the life of the project. However, publicly available data only refers to data that anyone can access at any time without any gate-keeping process. We often refer to the websites or repositories that allow access to public data as "open access" websites or repositories.

A study that might meet the criteria under exemption category 4 can utilize data or biospecimens which are not in existence at the time of the exempt determination by the IRBO. However, the original collection must be for a different purpose, e.g. blood is drawn for clinical testing or data is collected under another IRB-approved study and then is shared with the research team conducting the exempt study.

### **REQUIRED HUMAN SUBJECTS RESEARCH TRAINING FOR INVESTIGATORS CONDUCTING EXEMPT STUDIES**

NIH Investigators conducting exempt studies must complete either [the CITI Biomedical 101 Basic course](#) or [the CITI Social-Behavioral-Educational Basic course](#), based on the type of research they are conducting.

### **USING PROTOCOL TEMPLATES WHEN CREATING AN EXEMPT STUDY**

We do encourage investigators to utilize our exempt protocol templates which can be found on the [OHSRP website](#). Investigators

should create a protocol document using the "Collecting Prospective Data from Humans Protocol Template" or the "Retrospective Data or Biospecimen Review Protocol Template", as applicable. Be sure to carefully review the preface of the protocol template and the instructions prior to submitting.

### **INFORMING POTENTIAL PARTICIPANTS ABOUT AN EXEMPT STUDY**

While exempt studies do not need to conduct traditional informed consent as described in the regulations, as an AAHRPP-accredited organization, we do require some type of consent process. There is no requirement to obtain the participant's signature. The consent information can be communicated using a written document or a verbal script. The participant should be able to agree or decline participation after receiving this information. This consent information must be uploaded as a separate document as part of the submission. Minimally, the consent language should include the following information:

- The activity is being conducted for research purposes;
- The purpose of the research;
- If the project involves deception about the nature or purpose of the research, then include that the participants are being provided with some misleading information about the nature or purpose of the research;
- Participation is voluntary;
- A description of the procedures involved (e.g., approximate time commitment; type of research procedures; type and number of questions being asked; any tasks, unique activities, or interventions);
- Provisions made to ensure the privacy of the participant while engaged in the activity and if applicable, the confidentiality of the data;
- Compensation, if applicable; and
- The name and contact information one

of the researchers in case participants have questions.

### **OTHER REQUIREMENTS ASSOCIATED WITH EXEMPT STUDIES**

If the exempt research project involves collecting new data directly from humans, the team must also submit individual copies of all supporting materials including recruitment materials (email templates, flyers, scripts); screening questions; instructions to subjects; survey, interview, or focus group questions or scripts; instruments (including screen shots or mock-ups of instructions for any tasks that must be completed); and educational tests, as applicable.

If the research project involves secondary research using data or biospecimens that meets the criteria for an exemption under category 4, the team must also submit a blank data collection form that includes all the data points that will be recorded and used for the analysis.

If the research project involves a retrospective chart review and the team plans to use CRIS for the project, the study team must complete the "Access to CRIS for Exempt Research Form" which can be found on the [Exempt Research page](#) of our website.

For more information about the responsibilities associated with conducting exempt human subjects research, please review "Understanding and Submitting for an Exempt Determination".

### **COLLABORATORS OR SUB-CONTRACTORS IN EXEMPT STUDIES**

If the project will involve staff from other institutions who will conduct human subjects research activities, you should look up whether the organization has an [FWA](#). It is important to note that we do not execute reliance agreements for exempt projects. In most cases, these institutions will be required to obtain an exemption or IRB approval from an external IRB for their role in the NIH project. Some of the activities, which could trigger the need for an FWA and an external determination or approval, are screening for eligibility, "consenting" participants, data collection or review of identifiable data or biospecimens, observation of the data collection process with participants, analysis of identifiable data or interpretation of identifiable data for manuscripts and presentations. In these cases, the team should submit proof of an exemption or IRB approval from the outside institution, prior to starting the project. Some commercial companies may not require external IRB approval or an exempt determination. For help in determining when this is required, please contact your [Team Lead](#) in the IRBO.

## EIRB PROJECT COMMUNICATIONS UPDATES

### Monthly PROTECT Community Calls

Beginning in 2025, the PROTECT Trainers will resume regular monthly check-ins with our system users. During this time, the PROTECT trainers will provide the user community with recent system updates, deliver ongoing educational PROTECT topics, and hold space for users and their system experience. We look forward to this regular time together with you!

Be on the lookout for email reminders of these upcoming sessions. They will also be recorded and located on our website along with any corresponding resources that accompany the class.

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### Housekeeping: Inactive PROTECT Accounts Are Deactivated

Please note that as a part of NIH security requirements, any PROTECT accounts for users who are **NOT PIs or Proxies** and who have **not logged into the PROTECT system in 365 days** will have their accounts inactivated. This also means that system notifications will not go out to these inactive users. We intentionally will not deactivate user accounts if the user is a PI or Proxy on any studies, because they still need to receive system notifications and submit.

- **Existing Submissions:** Any users we inactivate will remain on any of their existing submission forms as their accounts do not “go away” in the system. Their account is just toggled to “inactive”. If you have any users who report no longer being able to login to PROTECT and need their account reactivated, please submit a help desk ticket to request this and we will take care of it for you right away.
  - **Who needs to be on submission forms (Study Team Members):** In addition, we think it is important to remind the community that all NED users are available for selection on submission forms, regardless of whether they have **active** PROTECT accounts. For the most part, it is only the users who wish to login to PROTECT and process submissions who need full, active PROTECT accounts. Please keep this in mind when you are considering if a member of your team needs an active account in PROTECT or not.
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### Reminder: Using Stamped/Watermarked Consents

When consenting participants, if you choose to retrieve your approved consent document from PROTECT, it is important that you are retrieving the stamped, watermarked FINAL PDF consent from the ‘Documents’ tab (NOT the Clean Word version listed under the DRAFT column). **Participants must sign the stamped and watermarked PDF document that displays the latest IRB effective date.**

## POLICY AND ACCREDITATION UPDATES

### In Memoriam

It is with great sadness that we report the loss of Chris Witwer. On December 3rd, Chris passed away peacefully at home following long and difficult illness. She was surrounded by her wife Shi and their two beloved cats. Chris joined OHSRP in June of 2020. Chris worked in the OHSRP office of Policy and Accreditation. She picked up her life and moved cross country in the middle of the COVID pandemic to join us. She quickly made a positive impact on our program, bringing her great attitude, excellent customer service and thoughtful approach to her work.



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Chris was passionate about making the participant experience as best as it could be, as was evidenced by her work on the Partnership for Consent Optimization (PICO) project to improve the readability of informed consents. This important project is a strategic priority for OHSRP. Chris was an excellent writer. She conducted PICO reviews, assisted Peg Sanders to train staff on how to make consents more readable, and simplified language in the consent library. Chris brought her experience as both a research participant and human research protections professional to this project, and it's success was very personal for her. Going forward, IRBO will lead this initiative. Consent readability training will continue to be led by Peg Sanders and Barbara Weinstein.

Chris also worked closely with Jonathan Green to establish and manage the Protocol Royalty Analysis Committee (PRAC) reviews. Going forward, Heather Bridge will take over this process. Please reach out to Heather for questions related to human research protection policy (MC 3014), for accreditation activities, or any other activities Chris was assisting you with.

Chris was widely respected in the broader Human Research Protections community. Her knowledge of human research protections was an important asset not only to the NIH Intramural Research Program but nationally as well. She was the immediate past Co-Chair of the Certified IRB Professional (CIP) Council. This national body manages the professional certification for IRB professionals. Donations in Chris's memory can be made to [Seal Sitters](#). Her spouse says that this was one of her favorite organizations and volunteer activities.

Chris will be dearly missed by her colleagues and friends not only at the NIH but across the US. It is not surprising that there is so much more to Chris than her work at NIH. To learn more, you can see Chris's obituary here: <https://www.hiltonfh.com/december>



### Policy Updates

Some of the content in this article was covered in the Fall Newsletter. This update compiles what has been happening with the human research protections (HRP) policy series, [Manual Chapter 3014](#). This article provides a digest about the specific policies that have been revised, and what to expect for the remainder of this year.

### WHAT IS HAPPENING

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. 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 past summer and will continue our review through the entire policy series.

### WHAT TO EXPECT

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

In terms of technical revisions, with this review cycle, we are 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.

Policies with **technical revisions**:

- [3014-104 - Managing Research-Related Complaints from Subjects](#) (effective 09/03/2024)
- [3014-107 - Privacy and Confidentiality](#) (effective 06/20/2024)
- [3014-108 - OHSRP Quality Assurance and Quality Improvement Program](#) (effective 09/03/2024)
- [3014-109 - Coverage Under the NIH Federalwide Assurance](#) (effective 01/30/2025)
- [3014-202 - Board Member Financial Conflicts of Interest](#) (effective 01/30/2025)
- [3014-203 - Support of IRB Operations](#) (effective 01/30/2025)
- [3014-204 - Levels of IRB Review and Criteria for IRB Approval of Research](#) (effective 02/05/2025)
- [3014-206 - Maintenance of Records](#) (effective 2/6/2025)
- [3014-207 - Public Health Emergency Research Review Board](#) (effective 2/3/2025)

## POLICY AND ACCREDITATION UPDATES, CONTINUED

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- [3014-302 - Subject Recruitment and Compensation](#) (effective 09/03/2024)
- [3014-303 - Intramural Research Program Telehealth Requirements](#) (effective 2/3/2025)
- [3014-400 - Research Involving Pregnant Women, Human Fetuses, and Neonates](#) (effective 12/23/2024)
- [3014-401 - Research Involving Prisoners](#) (effective 12/19/2024)
- [3014-503 - Data and Safety Monitoring](#) (effective 02/05/2025)
- [3014-700 - International Research](#) (effective 02/05/2025)

Below is a list of policies with **partial revisions** and a brief description of the revisions.

- [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](#) (effective 12/06/2024): 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.
- [MC 3014-205 - Requirements for IRB Submissions](#) (effective 2/18/2025): This revision is 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. This revision also removes the requirement for submission of a high-level summary of events at time of Continuing Review and at Study Closure.
- [3014-403 - Research Involving Adults Who Lack Decision-making Capacity to Consent to Research Participation](#) (effective 12/18/2024) This revision clarifies requirements for seeking assent from adults who lack capacity to consent, when appropriate. The language added to this policy is consistent with long-standing FAQ on this same topic. Note: This revision will be published following technical repairs to the webpage.
- [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.
- [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](mailto: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.

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### Accreditation Updates

We are mid-cycle in collecting data for the Association for Accreditation of Human Research Protection Programs (AAHRPP) Annual Report. The annual QAQI survey is being completed by Institute/Center (IC) quality assurance/quality improvement (QAQI) staff. We also kicked off the data call from the IC AAHRPP Liaisons in early January. We are currently compiling the Annual Report to allow time for review by HRPP leadership. Annual Report data gives us a nice snapshot of where our Human Research Protection Program (HRPP) stands each year. AAHRPP aggregates this data from all of its accredited organizations and provides us with useful metrics. These metrics allow us to see how we measure up as an organization as compared to our peer accredited organizations. Given our goal of being the premier research organization in the United States, if not the world, these metrics are very helpful to identify if there are gaps or areas of improvement for our HRPP. We are grateful to the IC staff who assist us each year with these reports. They help us to make our program stronger. Next year we will start our reaccreditation process.



## COMPLIANCE AND TRAINING UPDATES

### Updates Related to the Reportable New Information (RNI) Form

On October 31, 2024, additional flexibilities were released in PROTECT for those submitting RNI forms. These were mentioned in the last newsletter, but they are now live. Below is a review of the updates that we think you will find helpful.

- Previously, only the creator of an RNI could edit or submit the RNI form. Now, PIs and Proxies can edit and submit RNIs created by someone else. This requires that there be a related submission included on the RNI form in item #8.
- There is a new activity on the RNI workspace that allows the IRB Analyst, IRB Director, and RNI Creator to select users from the system to be additional RNI editors on that submission form. On the study team side, this can be done both prior to and after the submission.

The screenshot shows the RNI workspace interface. On the left, a vertical menu contains buttons for 'Edit RNI', 'Printer Version', 'Submit RNI', 'Manage Editors' (highlighted with a red circle and a blue arrow), 'Add Related Submission', 'Add Comment', and 'Discard'. On the right, the 'Manage Editors' section of the form is shown. It includes an information icon and text: 'The following people can edit the details of this new information without being on the editors list and Reported by can also submit:'. Below this is a section titled 'Reported by: ?' with a red circle '1' next to it. Underneath is a heading '1. Additional people who can edit and submit the new information: ?' with a red circle '2' next to it. Below the heading is a search input field and a table with columns for 'First Name', 'Last Name', 'Employer', and 'Title'. The table currently displays 'There are no items to display'.

- Previously, users could not edit RNIs in an Action Required state. This has been revised so that the RNI creator, responsible parties, and additional editors are able to edit RNIs in this state.
- There is a new report available related to RNI submissions. It provides RNIs by category based on which boxes are checked off in item #4 by the RNI submitter and not the IRB determination of the event. Path to locate this report: Under IRB tab → Reports tab → Standard Reports tab → New Information Reports by Category. The RNI that the user has access will be displayed along with category(ies) that the submitter had selected (major protocol deviation, non-compliance, new information, etc.).

### RNI HELP TEXT HAS BEEN UPDATED

In the last newsletter, we mentioned that additional help text was going to be added to the RNI form, and now that has happened! Among other changes, instructions have been updated for the RNI short title section reminding the submitter to include the study number in item #8 of the form. Help text has been added to indicate the type of information that needs to be included in the brief description of the event section and in item #6 where details about the corrective actions that have/will be taken need to be included.

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### Welcome Our New Compliance Analyst

OHSRP is happy to welcome our newest staff member, Brandi Fields. Brandi started with Compliance and Training as an analyst on January 21st, and most recently she served as a Clinical Research Associate in the Office of Quality Assurance within the NINDS Clinical Trials Unit. Her responsibilities included conducting site initiation visits, performing audits in compliance with FDA regulations, ICH GCP, and NIH policies, and serving as the NINDS DSMB Liaison, ensuring regulatory compliance for intramural DSMBs. Prior to this, she worked as a Quality Assurance Specialist in the Office of Regulatory Affairs at NIAID, where she oversaw regulatory compliance, audits, and the development and implementation of project work instructions. Brandi earned a Bachelor of Science in Public Health from Georgia Southern University and a Master of Clinical Research with a specialization in Regulatory Affairs from The Ohio State University. She is an active member of professional organizations, including the Association of Clinical Research Professionals, the Society of Clinical Research Associates, and the Regulatory Affairs Professional Society. Outside of work, she is passionate about long-distance running, cross-stitching, and actively participating in her sorority, Alpha Kappa Alpha Sorority, Incorporated.

### OHSRP Education Series Sessions

Our 2024 OHSRP Education Series closed out with three very interesting presentations. As previously mentioned, [Policy 403 - Research Involving Adults Who Lack Decision-making Capacity to Consent to Research Participation](#) was updated at the end of 2024 to clarify the requirements for seeking assent from adult subjects who lack capacity to consent, when appropriate. Regarding this topic, our October Education session presented by Dr. David Wendler, *Ethical Importance of Assent in Adults with Decisional Incapacity* was very timely. Dr. Wendler reviewed the ethical basis for obtaining assent in these cases and reminded attendees that decisional capacity is a matter of degree. He also provided helpful information for investigators about what this process could look like. This presentation provided context for the subsequent change to Policy 403. Please visit the NIH videocast page to view [Ethical Importance of Assent in Adults with Decisional Incapacity](#).

Our November OHSRP session featured Dr. Lisa Horowitz who presented *Detecting and Managing Suicide Risk in the Medical Setting: Turning Research into Practice*. This presentation provided ample and very convincing statistics that demonstrate that suicide is a major national and global public health crisis, with significant disparities. Important information that was covered included suicide risk factors, warning signs, and the fact that suicidality often goes undetected, with the majority of those

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who die by suicide having had contact with a medical professional within the prior three months. Dr. Horowitz emphasized that for these reasons, it is key for health care providers to have difficult conversations with their patients that can help save lives. Various helpful tools for suicide risk screening were provided. One of the instruments discussed for screening was the ASQ (Ask Suicide-Screening Questions), and Dr. Horowitz has been involved in validating and implementing this questionnaire in practice. The presentation also provided practical suggestions about how attendees can engage with family, friends and colleagues who they are concerned about. The NIH videocast is available for this presentation: [Detecting and Managing Suicide Risk in the Medical Setting: Turning Research into Practice](#).

The final session for the 2024 Education series, held in December, was presented by Dr. Karina Walters who is Director of the NIH Tribal Health Research Office (THRO). THRO serves 574 Federally Recognized Nations which represent close to 4 million people. The session, *Tribal Health Research Office & Considerations When Conducting Research Involving Indigenous Peoples*, provided an introduction to THRO's mission and values. The session included information about health disparities experienced by indigenous people and the need to harness the power to heal through science. She explained the long history of research abuses that involved this population which also affects efforts to engage with research involving tribal nations. Dr. Walters discussed the *Guiding Principles of Indigenous Data Sovereignty & Research Ethics* as well as key practices for indigenous data governance. As with Dr. Wendler's session in October, this session was very timely as OHSRP hopes to introduce a new HRPP policy specifically addressing the conduct of human subject research involving indigenous peoples. Please visit the NIH videocast page to view [Tribal Health Research Office & Considerations When Conducting Research Involving Indigenous Peoples](#).

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](#).

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**We Invite Your Questions and Suggestions!**



Our Compliance and Training group is always interested in ideas for future educational and training topics, and we invite you to send us ideas. If you would like our staff to provide in-person education to your research group, we are happy to do that as well. Please send your questions, ideas or requests for training to [OHSRPCompliance@od.nih.gov](mailto:OHSRPCompliance@od.nih.gov).