NIH
OHSRP

VOL 3 ISSUE 1

Letter from the OHSRP Director

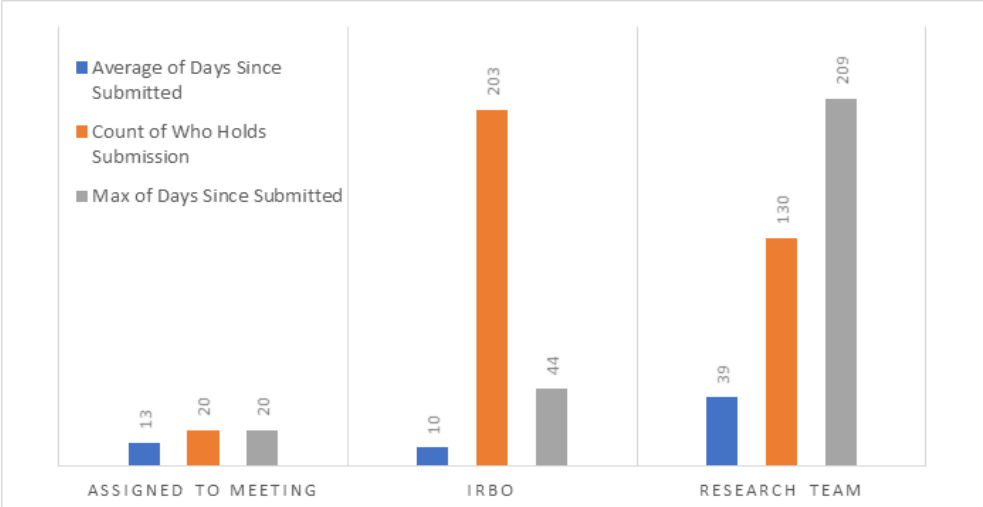
One of our first initiatives in re-organizing OHSRP was to develop a new set of policies that reflected the new organizational structure and incorporated the requirements of the revised Common Rule. At times, it was a grueling undertaking, I am pleased to say that the process was completed this past quarter. The new policies are really something of which we can all be proud. They will serve the NIH community well for the foreseeable future and are outstanding examples for the rest of the regulated community. A huge shout out to Heather Bridge who led this effort, and extra special thanks to Carrie Kennedy in OGC for the enormous effort she put into helping us get this right. Thank you to the many, many individuals we tapped over the past 2 years to review, critique, edit and often re-review specific chapters. The new policies are now posted in the NIH Manual.

Continuous process improvement:

OHSRP is committed to continuous process improvement. Our goal is to provide timely, consistent and compliant reviews. As discussed in detail in the IRBO Update section of the newsletter, IRBO is changing parts of its internal workflow to better accomplish these goals. Teams of IRB staff analysts will be assigned to review submissions from a subset of ICs. In this way, analysts will develop greater familiarity with the investigators and studies, and more stable relationships can be formed between the office and study teams. Our sincere hope is that this change will lead to greater consistency for the investigators in the pre-review and review process. Once in place, we would welcome your feedback as to how this impacts your experience with the office.

We need to hear from you!

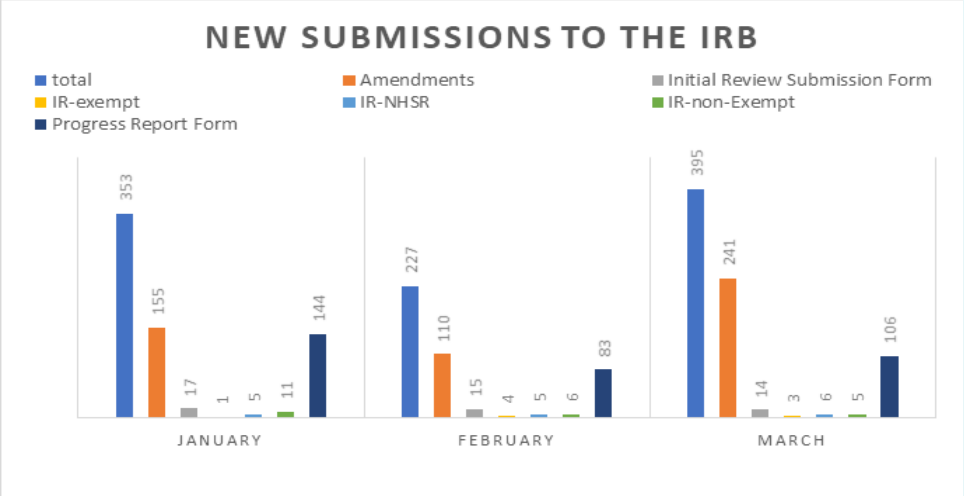
The time that a submission takes to get from start to finish involves both the IRBO and the research team. We need your help to make this process go as smoothly as possible. The OHSRP leadership team looks at our in-process submission queue every week. We have observed a consistent trend of research teams sitting on submissions that have been returned to them for corrections for increasingly long periods of time. For example, the queue on April 12 contained 353 submissions, of which the 37 submission that have been in the queue the longest have been sitting with the research team for period ranging from 13-209 days waiting for the PI to respond to a query from the IRBO. Of the 50 submissions sitting in the queue the longest, 46 are with the research team. The graphic below illustrates this point. Currently, there are 203 submissions with the IRBO, the mean number of days since submission is 10 days, with a maximum of 44 days. In contrast, there are 130 submissions that have been returned to research teams, the mean number of days since submission is 130, with a maximum of 209.

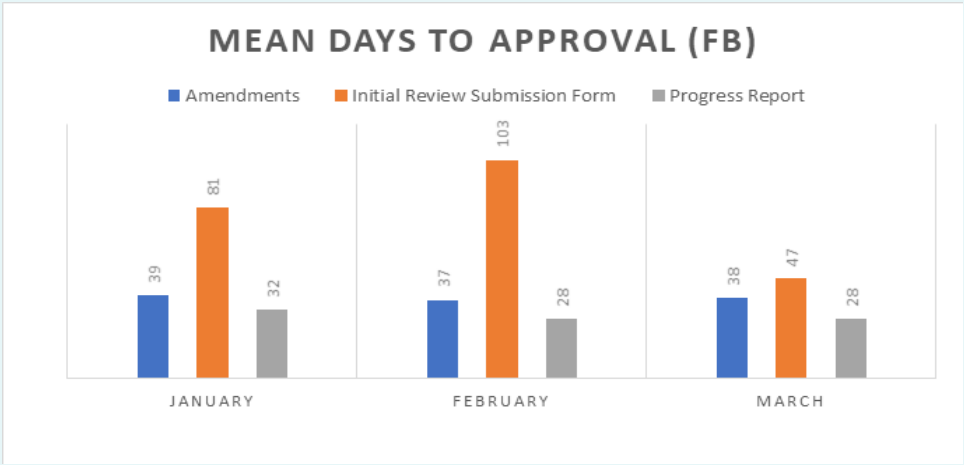


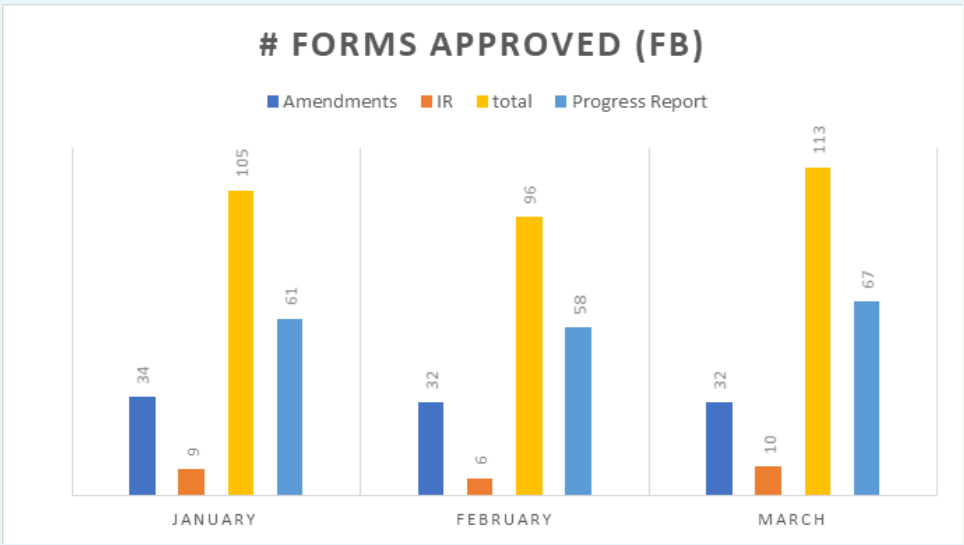
In the near future, we will be instituting a non-responsive policy. If a study team fails to respond to a request for a submission correction within 30 days, the IRB will prompt the investigator to respond or provide a justification for the delay. Understandable delays may occur for a number of reasons, for instance, the study is with the FDA or the sponsor awaiting additional approvals or information. However, if there remains no response within a week of the prompt, the IRB will administratively withdraw the action. We will provide ample notification to the research community as to when this policy will go into effect.

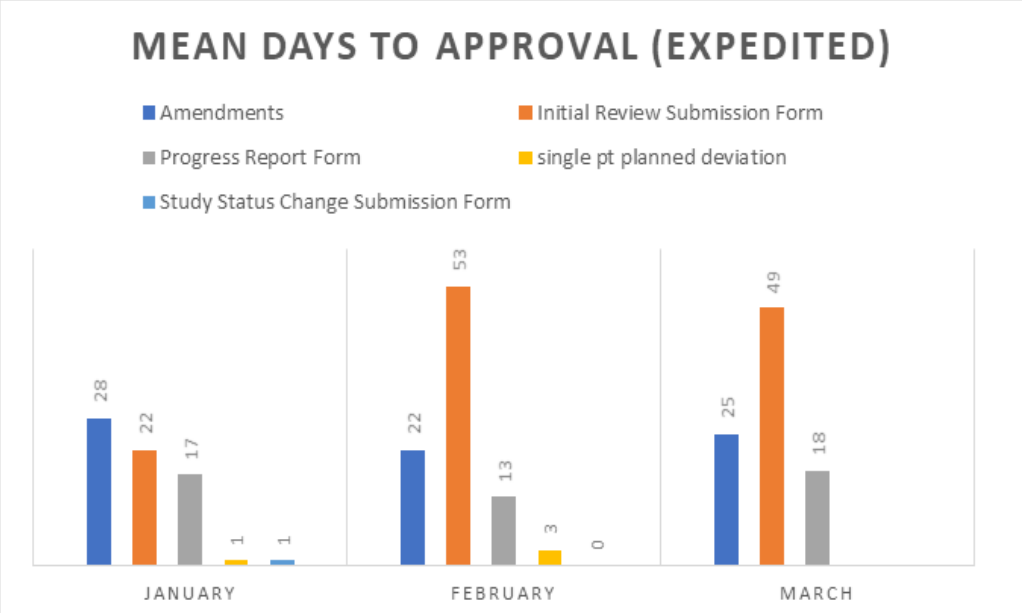
Metrics and Dashboard

We are very close to deploying an interactive dashboard that will allow you to look at submission and approval volumes, as well as turnaround times. You will be able to get not just overall information, but data specific to your IC as well as for each review and submission type. We hope that this information will be of use to you. This should be live within the next month. In the meantime, here are our metrics from first quarter 2021.








MEAN DAYS TO APPROVAL (EXPEDITED)
Amendments
Initial Review Submission Form
Progress Report Form
single pt planned deviation
Study Status Change Submission Form
28
22
17
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53
13
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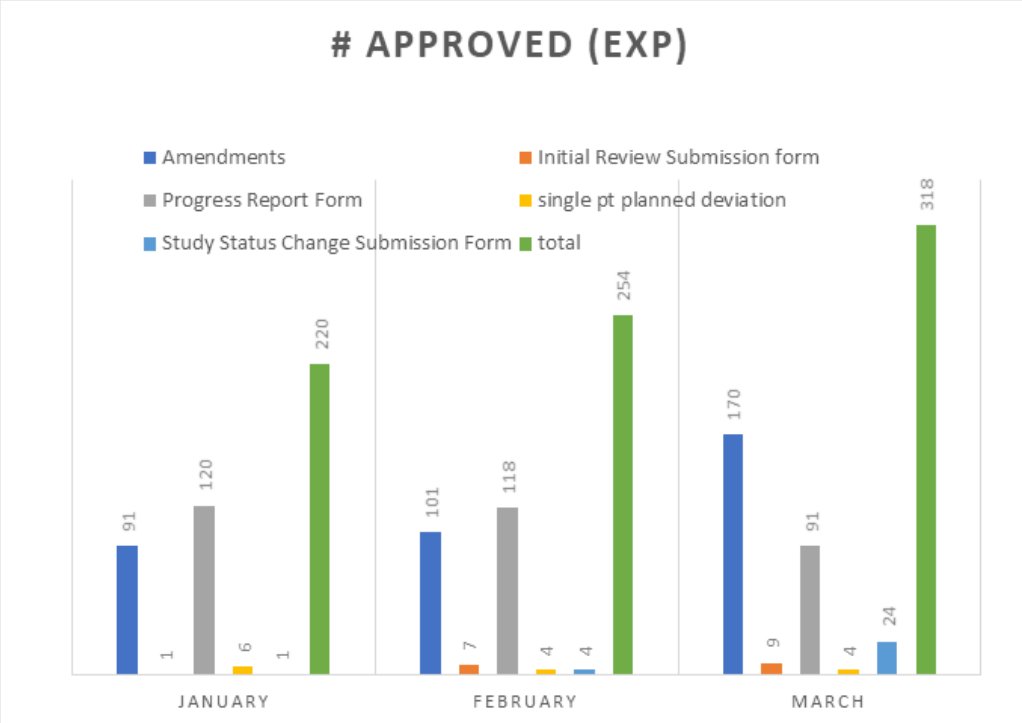
18
JANUARY
FEBRUARY
MARCH


APPROVED (EXP)
Amendments
Initial Review Submission form
Progress Report Form
single pt planned deviation
Study Status Change Submission Form
total
91
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170
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JANUARY
FEBRUARY
MARCH

IRBO Update

Happy Spring from the IRBO staff! We want to announce an exciting change that we plan to implement in the IRBO that will affect you. This change is being made to enhance your experience working with our office; to continue to streamline our practices in order to provide consistent and compliant reviews; and to further increase efficiency. Beginning May 1st, a specific team will be assigned to each Institute/Center (IC). That team will be responsible for supporting the review of all IRB actions (including full board and expedited submissions and requests for determination of exempt and not human subjects research/not research) submitted by a given IC. We will have four teams, each with a Team Lead and two or more analysts. We have divided up the assignment of specific ICs across the four teams based on the average number of submissions to the IRB, so that each team should have a similar workload. To the extent possible, all submissions from your IC will be assigned to your specific team for pre-review and expedited review and approval, when applicable. Please keep in mind in the interest of ensuring timely reviews and balancing workloads, at times, we may need to route a submission to a different team. We will also ask that you go to your designated team as your first point of contact for any questions about a specific action. However, you should continue to email the NIH IRB at irb@od.nih.gov for general questions. **Stay tuned for later this month when we will be sharing the specific IC-IRBO team assignments with the research community!**

We want to use this update to provide some helpful reminders to research teams related to:

- Naming documents in iRIS;
- Creating and updating consent/assent documents and scripts;
- "De-activating" approved consent/assent documents;
- Requirements associated with notifying subjects about a change to the research;
- An important change to the Policy – Research Involving NIH Staff as Subjects; and
- Summarizing events that have occurred as part of the research in the last year as part of Continuing Review.

Naming Documents in iRIS

When uploading and naming documents in iRIS, follow the naming conventions on our website. It is important to not use special characters in document titles in the text boxes, i.e. parentheses, brackets, quotation marks and other symbols. Underscores are not a problem. When you use these types of special characters, you will not get an error message, but it will prevent IRBO staff from being able to open the document. We have to re-name the documents in order to get them to open. When in doubt, try to open the document after saving the name in iRIS to confirm that there are no issues.

Consent and Assent Forms and Scripts

Creating Informed Consent and Assent Forms

When creating a new consent or assent form, always start with the latest and appropriate consent template from our website and try to put yourself in the shoes of a possible research subject. Here are some tips to decrease the chance that you will receive stipulations associated with the consent form:

1) Consider whether most research participants will be familiar with the terms that you are using and employ lay/plain language at an 8th grade reading level or less whenever possible.

2) Review the consent form to confirm that information is provided in a logical manner, i.e. ask yourself what you would want to know first, second, third, when considering the research.

3) Try to avoid repetition of the same information in a different way and location in the body of the consent. Consent forms are commonly long, so it is not helpful to repeat concepts.

4) Try to take time away from editing the consent form and come back to it and re-read it again. You will likely notice something you did not when you first read it.

5) Have multiple members of the research team read over the consent form for spelling, grammatical and punctuation errors and provide other edits before calling it final.

Updating Consent and Assent Forms

Thank you to all who submitted their updated consent and assent forms in advance of the March 31, 2021 deadline. As part of our review, we have noticed some things that we wanted to remind you about:

- Please remember to first version off the last approved consent/assent form by creating revisions in the iRIS system. DO NOT USE consent forms that you have saved outside of the iRIS system.
- Before putting the consent/assent form on a new template, confirm that you are choosing the correct template. Important considerations include whether the study was originally approved before Jan. 21, 2019 (Common Rule Consent templates) or on or after Jan. 21, 2019 (Revised Common Rule Consent templates) and the site for enrollment (NIH CC, NIDA, NIEHS, etc.) for the protocol.
    - When NIH is the lead or coordinating site for a multi-site protocol or subjects are being consented at home or in the community and will not be registered at the NIH Clinical Center, use the “Model Consent Template”.
- Copy and paste the current approved consent/assent language into the updated consent/assent template after downloading it and saving it from our website. Most of the errors we find involve research teams copying sections of the most up-to-date template into their old approved consent/assent form.
- Research teams are responsible for the final formatting of consent/assent forms that will be approved, not the IRBO staff.
    - If you unsure about the requirements, review the “Instruction Sheet for Transferring Consents from Old Template to New Template” (Common Rule protocols) or the “General Instructions” in each revised common rule consent template (Revised Common Rule protocols).
    - Prior to uploading a CLEAN consent/assent form into iRIS, check that the formatting matches the appropriate consent/assent template on our website, i.e. in terms of margins, font type and size, subheadings, headers and footers, etc.
    - Remove any signature blocks for populations that are not being enrolled in your study.

    - Update the version date on page one and in the footer to the date that you finish revising the new version.
    - When your study involves multiple consent/assent forms, double-check that the numbering in the footer in the new consent matches the previous consent as before, e.g. 1, 2, 3, etc.
    - Review the page numbers to make sure that they are sequential.
    - Delete any extra spaces and remove any blank pages.
- If you have not submitted your updated consent and assent forms, please make sure to do so as soon as possible so that we can update your consent/assent documents to remove the expiration date.

"De-Activating" Approved Consent/Assent Forms

If you merge consent forms to create one consent form or remove a cohort from your study, please indicate which IRB-approved consent/assent forms need to be "de-activated" in iRIS as part of the amendment. When IRB staff de-activate a consent form, they void it in iRIS to remove the approval. This process also helps to ensure that the research team does not accidently use the wrong version to create a new revised version of the consent/assent. It is also good practice to routinely check the NIH Clinical Research Studies website to ensure that the available consent/assent documents listed on this site are only what are still in use for the study.

Requiremnts for Notifying Subjects About a Change to the Research

Often research teams submit amendments which also result in a need to notify the subjects about the change to the research. The changes can be communicated to subjects 1) by re-consenting with the full revised consent form; 2) by sending an information sheet or letter via email or mail; or 3) verbally during a phone call or in person. The PI has discretion to determine the approach and must disclose the planned mode of notification as part of the amendment form. The number of proposed changes and the type (e.g. does it affect risk to the subject?), and complexity of the changes should drive this decision. The IRB then has the option to approve the plan or change the plan. In situations which the research team plans to notify the subjects verbally, the IRB now requires submission of a verbal script. The use of a verbal script allows to IRB the opportunity to ensure that subjects are receiving clear and sufficient information about the change. The use of an approved verbal script also helps to safeguard that all subjects receive the same information. When using an information sheet, letter or verbal script, the expectation is that the documents will only contain the information related to the change and any context needed to understand the change. The IRB does not have templates for these documents or specific rules about how they are written. However, they should be written in such a way that conforms to the method of communication being used, be written at an 8th grade or less level, etc.

Important Change to the Policy – Research Involving NIH Staff as Subjects

On September 9, 2020, a revised HRPP policy, Policy 404 – Research Involving NIH Staff as Subjects, came into effect which specifically applies to the enrollment of NIH staff or immediate family members of the research team in NIH IRP research. In the previous SOP 14F - Research Involving NIH Staff as Subjects, the research team could request that the IRB waive the requirement for an independent consent monitor when staff members are being consented by a non-supervisory co-worker. Under the new policy, a consent monitor or independent observer is always required when NIH staff are being consented to research taking place within their own work unit(s) or conducted by any of their supervisors, regardless of who is conducting consent. Research teams whose approved protocols previously included a request for this waiver are now required to always have a consent monitor present in this circumstance and should remove this language as part of their next submitted amendment.

Summarizing Events at the Time of Continuing Review

As part of completing the Continuing Review form, the PI is asked to:

Provide a high-level summary of the following events that have occurred since the time of the last IRB review (not a line item listing):

- *major and minor protocol deviations*
- *noncompliance reported to the IRB that is not a protocol deviation*
- *adverse events (including serious adverse events) that do not meet the definition of an unanticipated problem (UP), and*
- *all UPs that have been reported to the IRB.*

Please address whether adverse events/serious adverse events/deviations are within expected severity and frequency.

The IRB is requesting that you provide an accounting of only those events which have occurred within the last calendar year, i.e. since the time of the last submitted Continuing Review form. Please do not provide a cumulative accounting of all events that have occurred since the beginning of the study. When providing a table, we are not asking for detailed event information to be shared on a per subject basis, instead whenever possible, group the events into categories and summarize the issues. If you choose to provide a table, copy and paste the table into the Continuing Review form. **Do not upload a separate document with individual events in iRIS.** A separate document is not required and may inadvertently include Private Individually Identifiable (PII) which could result in a breach of confidentiality.

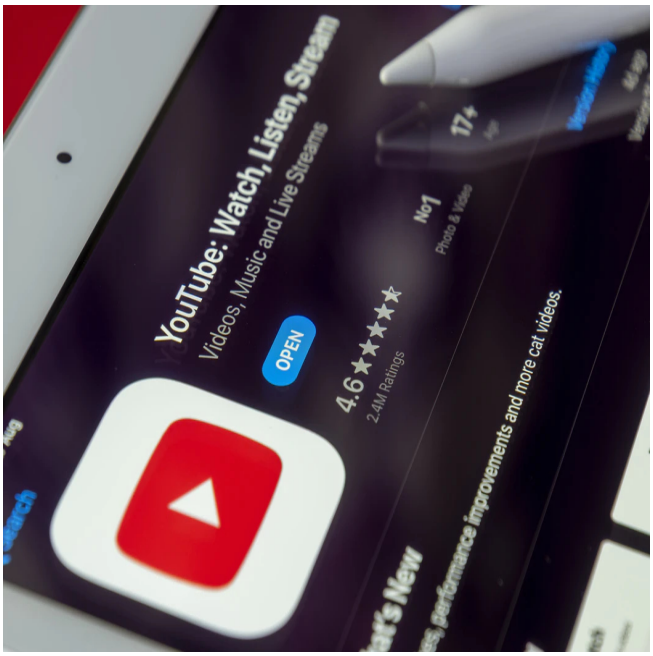
An example of an appropriate summary of deviations is as follows: "There were a total of 10 deviations that have occurred which included 8 out of window visits due to inclement weather or scheduling issues with the participants and 2 participants failed to bring their medication diary to a follow up visit. There were no systemic issues identified with these deviations."

You can access definitions, requirements and guidance associated with reporting research events and non-compliance here or refer to Policy 801 - Reporting Research Events or Policy 802 - Non-Compliance in HSR.

OHRP Video re: Enrolling Children

The DHHS Office for Human Research Protections (OHRP) has posted a new video about research with children on its public outreach website, About Research Participation. This short video provides basic information about why research involving children is important, and what parents should expect if they are considering enrolling their child in a study.

This video "Research with Children: What Parents Need to Know" can be watched here and shared with your research subjects.



Policy Update

Did you know that with the release of Policy 303 Intramural Research Program Telehealth Policy, the HRPP policy series is complete and has been posted? All HRPP SOPs have been retired, archived, and replaced with the new policy series. We are adding a new IRP policy (see "What's new with policies?" below) this Spring. If you have a question about a policy requirement, or just need a quick review of what is new or has changed, go check out the OHSRP Policy page: https://irbo.nih.gov/confluence/pages/viewpage.action?pageId=36241835). In addition to each policy, you will find educational materials, including policy change tables and/or narrated presentations. For example, there is a new narrated presentation for IC DECs and PIs which provides some new tools to help study teams know what must be submitted for their protocol ethics review, (e.g., which study team members must complete an HHS 717-1, and which study team members must complete a COI Certification, and which certification to complete when one is necessary). See Narrated presentation - Investigator Conflict of Interest Tool for DECs and PIs.ppsx. We will continue to add guidance and tools to this page that you will find helpful. After your review of policies and educational materials, if you still have a question, be sure to reach out to IRB@od.nih.gov.

What's new with policies?

- We posted revised versions of Policies 300 Investigator Responsibilities, and 301 Informed Consent at the end of March (effective March 30, 2021). To align HRPP policies with NIH policies regarding trainees, both policies provide further clarification about supervision of trainees (Visiting Fellows, IRTAs and CRTAs) serving as Associate Investigators. The activities of these trainee investigators should be properly supervised; and these investigators may observe or participate in the informed consent process, if they are under direct and constant supervision by a qualified NIH federal employee investigator. However, Visiting Fellows, IRTAs and CRTAs trainees may not sign the

informed consent document. For Policy 300 Investigator Responsibilities, see Section C.h., and for Policy 301 Informed Consent, see Section E.3.XIV.i.

- All HRPP policies now reside in the NIH Manual Chapter system. You will still be able to access them on the OHSRP Policy page: https://irbo.nih.gov/confluence/pages/viewpage.action?pageId=36241835. We are currently replacing each policy document with a link to the policy in Manual Chapter 3014, so the process will feel seamless to the user. The only thing to note is a slight change in the policy numbering with the publication of the policies in the Manual Chapter system. Each policy number will be preceded with the Manual Chapter number 3014. So, Policy 300 will become 3014-300, and Policy 301 will become 3014-301, and so forth. You can also access the policies directly in the OMA system. Manual Chapter 3014 is part of the Intramural policy series 3000 and can be accessed here: https://policymanual.nih.gov/3014. You can also access the new NIH IRP HRPP Policy Glossary here: https://policymanual.nih.gov/3014-001#3c10217c. OMA is also our official repository for archived SOPs and policies that are no longer in effect. Later this year, the archive button on the main OHSRP Policy Page will be replaced with instructions for how to request an archive copy of an SOP or HRPP policy from OMA.

What's Next:

- You should have received an iRIS blast notifying you that Policy 303 IRP Telehealth Requirements has been released. This policy goes into effect on May 3, 2021. Please review the policy and accompanying presentation to learn more. This new policy applies to all NIH sites and is consistent with the Clinical Center MAS Policy on Telehealth (MAS policy M20-1 Utilization of Telehealth/Telemedicine by NIH Healthcare Providers for NIH Clinical Center Patients).

Accreditation Update: The Step 1 Application has been submitted to AAHRPP. Thanks to everyone who provided us with data and support during this process! Now we are waiting on AAHRPP's review of our policies and materials. During this review AAHRPP may ask for minor changes to our policies or procedures. We will keep you abreast of these changes if they will impact study teams. Once AAHRPP is satisfied that our policies and procedures meet the AAHRPP accreditation standards, we will be invited to submit a Step 2 Application later this year. The site visit will take place approximately 3 months after the Step 2 application is accepted by AAHRPP. We will begin prepping NIH staff selected by AAHRPP to be interviewed during this time period. If you are selected, we hope you will be honored to represent the NIH IRP and the great work it does.

Compliance and Training Update

The first quarter of CY 2021 featured diverse topics presented as part of the OHSRP Educational Series and was kicked off by OHSRP's Director, Dr. Jonathan Green's session on *Secondary Research: Fact, Fiction, Fears and Fantasies*. This session clarified many of the questions and concerns that are frequently raised by investigators in their communication to the OHSRP. February's session, *iRIS Multi-Site Enhancement: Overview and Implementation*, provided a high-level demonstration of the new eIRB system (iRIS) multi-Site module and was presented by OHSRP's Anthony Marchi with Jeffrey Rollins and Shirley Rojas. This iRIS module provides external research sites with access to iRIS so that they can manage their own research submissions when the NIH IRB serves as the Reviewing IRB for multi-site research. The March session featured Nicole Grant, OHSRP Associate Director and IRB Executive Chair, who discussed Part 1 of 2 presentations on *Responsibilities of the Principal Investigator* that addressed *What You Need to Know & Do Before Your Protocol Starts*. In the April Session, Liz Ness, Director of the NCI CCR Office of Education and Compliance presented Part 2 and addressed *PI Responsibilities Related to Implementation of a Clinical Research Protocol*. Slides and links to the archived videocasts for all of the OHSRP Education Series sessions can be found in the Presentation Archive on our website. If you have suggestions for topics for the OHSRP Education Series, please feel free to contact us via the Compliance and Training mailbox. Additionally, if you have specific questions related to reporting research related events, completing the reportable event form (REF), compliance concerns, or questions about HRPP training requirements for investigators conducting human subjects research reviewed by the NIH IRB, please direct those questions to this same mailbox.

The newsletter for the 4th quarter of 2020 discussed questions that our office receives related to which investigators on protocols under NIH IRB review are covered by the NIH FWA. That newsletter addressed where this information is available in our HRPP policies. More recently, a document titled *FWA Coverage and Training Requirements for Volunteers Serving as AIs on NIH Protocol* has been added under Policy 109 on the Policy section of the OHSRP website. This information sheet addresses which types of NIH volunteers are/are not covered by the NIH FWA and also discusses the human subjects research training requirements based on the investigator's specific volunteer classification.

Additional educational materials have been added to the OHSRP website which now includes a set of FAQs about the European Union General Data Protection Regulation (GDPR). The website also now includes a resource index that provides links to helpful resource material grouped by specific topic (e.g. informed consent, research with FDA regulated test articles, required training for investigators, IRB review processes, participant recruitment, secondary research/ repositories, and vulnerable populations). The index not only includes links to information on our website, but it also provides hyperlinks to relevant federal regulations related to human subjects research protections, guidance documents and other informative external materials. Look for updated FAQS regarding the informed consent process that will be posted soon. Additionally, summary sheets describing PI responsibilities for FDA regulated and non-FDA regulated protocols are being created. Access to new CITI webinars that was pending at the time of the last newsletter is now available via the NIH CITI account portal on the OHSRP website. New webinars to which those with a NED account have access include the following: *Social Media and Research Recruiting; Ethics and Policy Issues CRISPer Gene Editing; FERPA: A quick review of the law for researchers and IRBs; Understanding Consent Requirements and "Key Information" Under the Revised Rule; Informed Consent: A focus on the Process; Preparing for Single IRB under the Common Rule; Artificial Intelligence (AI) and Human Subject Protections; and Working with Your IRB*. CITI webinars that discuss the Revised Common Rule are also available and these include an overview of the revisions as well as specific webinars about revised definitions and revisions to informed consent.

Contact OHSRP

Email - IRB@od.nih.gov

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