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Note from the OHSRP Director

In our last newsletter, I shared with you the OHSRP Vision Statement that reflects the priorities and values of the Office of Human Research Protections. As we enter 2021, I would like to outline how we plan to work towards making this vision a reality.

Process Improvement: The IRB review of research protocols is the bread and butter activity of the office and is a critical step that enables the actual operationalizing of the research idea. During 2020, we developed key performance indicators that are assessed at regular intervals and used to identify bottlenecks and areas of concern. The upcoming year will be marked by ongoing efforts of continued process improvement, stressing not only the need for timeliness, but consistency across reviewers. We are also focusing on improving our communication, so that during and after the review, the intent of the IRB is clearly and effectively communicated back to the research team.

eIRB system: We continue to assess whether to replace iRIS with a new IRB submission system. We have completed an extensive series of sessions with stakeholders across the NIH IRP. Our next step is to finalize system requirements and solicit proposals from vendors. Our hope is that we can identify a system that will streamline both the submission and review process while meeting some of the unique needs of the intramural program.

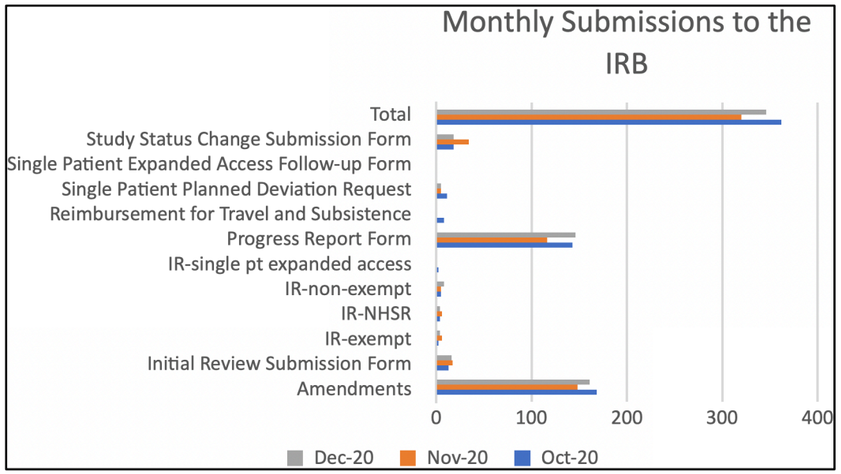
Education: We will continue with our monthly OHSRP NIH wide education series. These have been a useful forum to widely disseminate information on topics of broad interest to the intramural research community. In addition, we will continue to offer targeted sessions on request, as well as develop guideline documents and other written materials to support our researchers and IRB members. If you have ideas for topics you would like to see addressed, please email those to the IRB inbox.

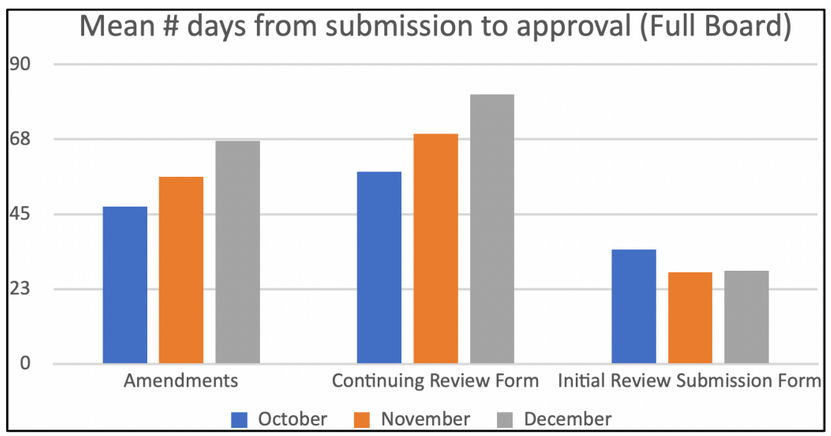
Policy: By the time this newsletter is published, we will have finalized the entire set of revised HRPP policies. This has been a massive effort that has resulted in a robust set of policies that will serve the community well going forward. Over the next year, we will be developing guidance documents to help researchers implement the policies.

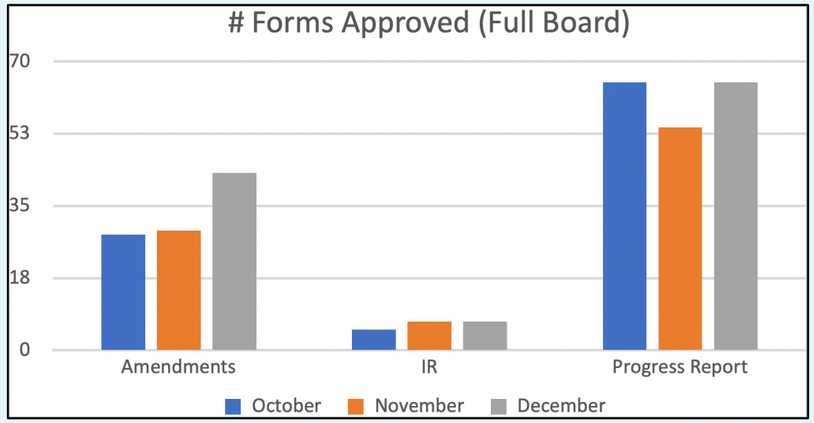
The protection of human subjects is a responsibility that is shared between the IRB, the investigator, the institution and the sponsor. Optimal functioning requires effective communication between all parties. This starts with submitting a well written, complete protocol. This not only greatly facilitates and shortens the review timeline, it enables the IRB reviewer to clearly understand what the research team is doing, why they are doing it, and therefore make the required determinations.

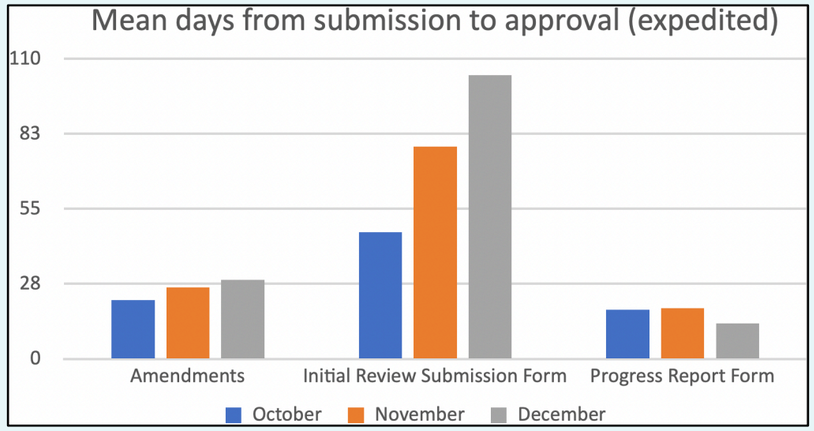
Ultimately, human subjects protections occurs at the bedside. In the words of Henry Beecher "....there is the more reliable safeguard provided by the presence of an intelligent, informed, conscientious, compassionate, responsible investigator."

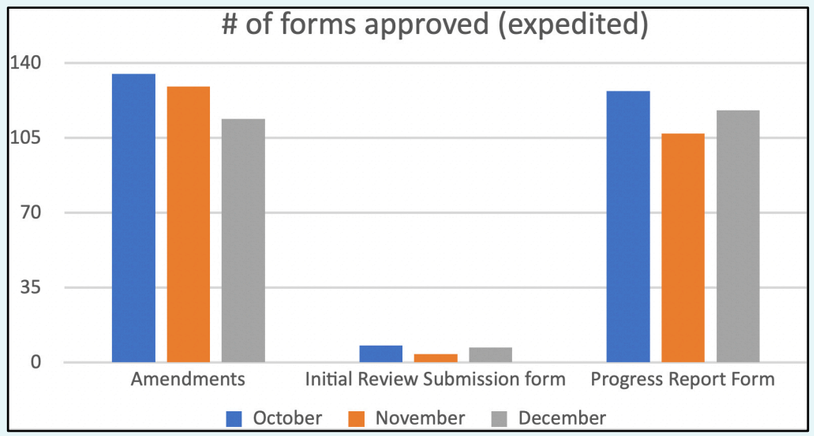
Q4 Metrics











IRBO Update

Happy New Year from the IRBO staff! 2020 has been an unprecedented year in more ways than one! After over nine months of the IRBO functioning 100% via telework, including holding all IRB meeting virtually, much of the staff can confidently say that they now know more things about platforms like Zoom, MS Teams, Webex and Skype than they ever expected (or wanted) to know.

We are thrilled to announce the newest IRB analyst to join our office, Temi Adewuyi; she most recently hails from George Washington University.

During this last quarter, we shared some new information, in the form of revised protocol and consent templates, new guidance, and presentations, with the research community. We have highlighted the key points below.

October 30, 2020 - Changes to the Protocol Templates and Consent Library (Notification)

The Consent Library on the OHSRP website was updated to include the *Public Readiness and Emergency Preparedness (PREP) Act* research inquiry language; new, OGC-approved *Privacy Act* language (to be used for any protocol when subjects will not come to or be registered in the Clinical Center (CC)); and revised language about the risk associated with genomic testing.

The *Interventional Drug and Device Clinical Trials protocol template, the Natural History and Observational Trials protocol template, the Secondary Research protocol template, & the Repositories protocol template* were all updated under Templates and Forms to be consistent with the new versions of the OHSRP policies. In particular, the sections regarding the inclusion of vulnerable populations and pregnant women; the consent processes; recruitment; and compensation were all revised. When writing a new investigator-initiated protocol, you are expected to use the current version of the applicable protocol template document posted on the website. If a sponsor requires additional content, it is fine to add the sections mandated by the sponsor to the version of the NIH template that you are using. This will help to ensure that all of the required content to approve the protocol is included and hopefully greatly reduce the amount of time that it takes for your protocol to go from review to approval

Please note that if a new policy is distributed which impacts what is written in the current version of the protocol, one does not need to immediately submit an amendment; rather plan on updating the protocol when submitting the next planned amendment to the IRB. Once all of our policies have been approved and posted on the website, we will provide a target date for submitting amendments to get existing protocols up to date.

Do you have questions for the IRBO?

REMINDER - If you have general questions for the IRBO, we ask that you please email the NIH IRB email address (IRB@od.nih.gov). This email has been set up for IRBO staff to review and triage to the appropriate individuals within OHSRP/IRBO, accordingly. The IRBO staff who support this mailbox are expected to respond within 24 hours of receipt of the email.

If you have questions about a specific request for correction or a stipulation(s) sent to you in an outcome letter via iRIS, please contact the IRB Analyst who is assigned to that action (Initial Review, Amendment, Continuing Review, etc.) via email directly.

Of note - the IRBO staff consult with each other and involve leadership when necessary before responding to challenging questions. Therefore, please only contact one email address at a time to ensure efficiency and avoid inconsistent guidance. We have noticed many individuals will email the NIH IRB email address, then send a separate email to the IRB Director, and then send a separate email to the Executive Chair; this is causing a delay in responsiveness and more work for everyone.

November 17, 2020-Informed Consent Procedures in the Era of COVID-19: Beyond the Use of a Standard Written Consent Document (Presentation)

At the November OHSRP Education Series Session, Informed Consent Procedures in the Era of COVID-19: Beyond the Use of a Standard Written Consent Document, the speaker, Julie Eiserman, discussed the DHHS human subjects research protection regulations for informed consent in light of the unique challenges in conducting human subjects research during the COVID-19 pandemic. The presentation included a review of the definition and applicability of and the criteria for approval for legally effective informed consent; assent; waiver of consent or assent; alteration of informed consent; documentation of informed consent; and waiver of documentation of consent. It also provided alternatives to conducting in person informed consent with collection of a signature and the context in which these alternative procedures might be appropriate. Finally, the presentation covered the meaning of electronic informed consent (eConsent) (currently not approvable at NIH in most cases), and the use of a finger, stylus or mouse to create a signature on on-line consent form (currently approvable at NIH).

November 24, 2020-Guidance about the Consent Process for Virtual Research

As this pandemic has worn on, OHSRP staff have received many questions regarding telehealth visits, remote consent, electronic consent, and what level of detail about consent needs to be included in the protocol. While there is currently no 21 Part 11 compliant system for electronic consent in the Intramural Research Program, investigators have asked if they can use Adobe, DocuSign, and other platforms to obtain signatures on consent documents. We have developed a brief guidance document, Guidance about the Consent Process for Virtual Research, which will hopefully address your questions.

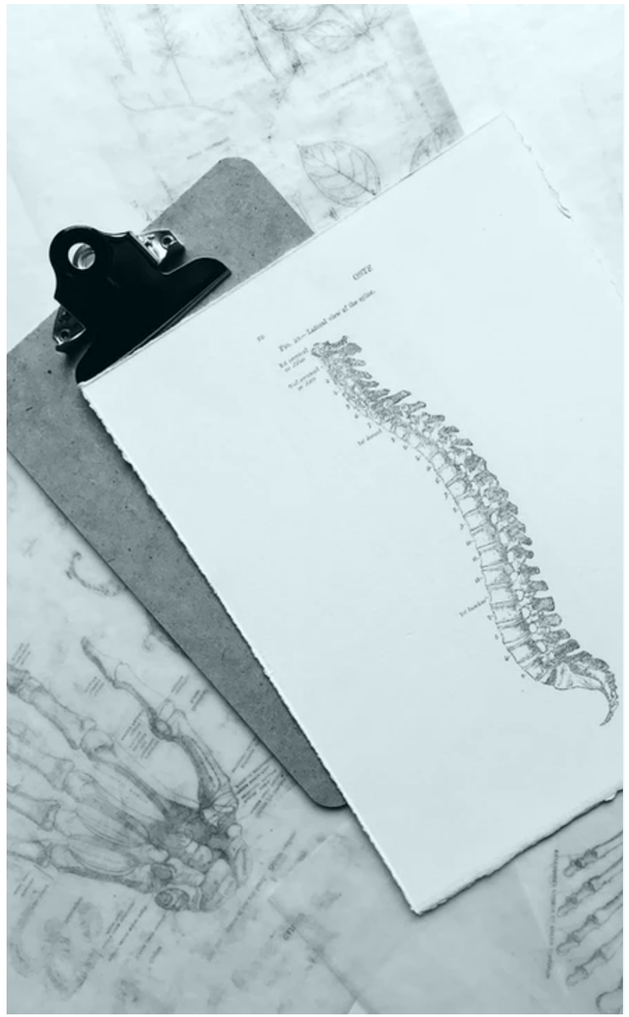
The main takeaways of this guidance are addressed below. If the changes to how you conduct consent and research activities will be only temporary or affect a few subjects, e.g. due to the pandemic, you can submit them to the IRB on a single patient planned deviation request form, rather than as an amendment to the protocol.

If they will be permanent or affect all subjects, the protocol should be amended and approved by the IRB prior to implementation. If the protocol is under an IND, the plan needs to be approved by the IND sponsor prior to IRB submission. If you are adding a remote consent process, you should amend the protocol to describe which subjects will be consented in this new manner; the type of consent process that will be utilized, i.e. telephone, a remote videoconferencing platform, etc.; how the consent form will be shared, i.e. on paper or electronically, etc.; whether not there will be a verbal consent process; and if and how you intend to collect subject signatures, e.g. via pen, finger, stylus, or mouse or if you are requesting a waiver of documentation (signature). The protocol must also be revised to describe the details of the new plan, e.g. which subjects will participate in the modified research plan; how and when you will communicate with subjects and local MDs; and what procedures/ treatment will occur locally or be omitted, if applicable. NIH investigators may use only an NIH-approved virtual platform when communicating with subjects, e.g. MS Teams.

In addition, the NIH Clinical Center is in the early stages of implementing a new application to facilitate the collection of signatures from research study participants, investigators, and witnesses as necessary on informed consent documents, including protocol consents. This platform is called iMed Consent and is secure platform that will be made accessible through a link in the CRIS system. Signature pad devices are being deployed and connected to Thin Clients and Workstations on Wheels (WoWs) in patient care areas throughout the Clinical Center. The application also supports signature capture through mobile devices. These devices will be used to collect signatures during the informed consent process. The subject has access to a touchscreen to use a mouse, stylus, or finger to create a signature. Once completed, the fully executed consent document will be automatically uploaded to CRIS. The system is currently in use by only a few research teams as early adopters and will next be implemented for all non-protocol consent informed consent documents (procedures, transfusion, etc.). During 2021, institutes will be contacted individually to begin implementation. For more specific information regarding the iMed Consent, please contact Tricia Coffey, the Chief of the CC Health Information Management Department.

December 16, 2020-Revisions to the NIH Consent and Assent templates

We have posted revised consent and assent templates on the OHSRP website. If your current consent forms have already been moved to the new consent templates, new changes are not required at this time. However, you are welcome to make these updates with your next amendment, if you wish. If your consents are still on the old templates, please submit an amendment to update them to the new templates by **March 31, 2021**. Use the "Common Rule Consent" templates to update consents for protocols that were initially approved before January 21, 2019. Whenever you are creating a new consent document, please start with the current version of the appropriate template posted on the website.



The major changes to the templates are described below.

The compensation language section of the consent template has been broken down into 3 discreet sections: Payment, Reimbursement and Cost. The language referring to NIH policies and guidelines has been removed and replaced with simplified language that we hope is easier for subjects to understand. In addition, the sentence about beliefs that may limit the kinds of of medical or research treatments one may want to undergo in has been revised to refer to "interventions" (rather than treatment) and to remove the example of a blood transfusion, as a large number of studies in the IRP do not involve treatment. We have discovered over time that some investigators have been adding the GDS language which states that they plan to deposit the genomic data into both a controlled access database and an open access database, which is not allowed. We have re-organized the GDS language in the consent template to make it clear that you must choose one of the paragraphs as applicable, not both.

We have now revised the assent template to assist the team in making the language in the assent understandable to most children ages 7-13. When crafting assent documents, please consider the age and other characteristics of the minor subjects that might be enrolled, i.e. their potential ability to read and understand the content.

The consent document should be written as close to an 8th grade reading level as possible. Please also

consider using the PRISM readability Toolkit to assist you in meeting the 8th grade reading level target. As such, you may consider having older children (ages 14 and up) sign the regular consent as their assent document, since they should be able to read and understand that document. Please also remember to describe your assent plan with a rationale in your protocol.

Reliance & Single IRB Team

The Reliance & Single IRB Resources section of the IRBO website has been reorganized to provide a single place for NIH study teams to find guidance relating to requests for the NIH IRB to serve as a single IRB and requests to rely on an external IRB. The page includes resources that provide an overview of the reliance and single IRB review process, e.g. educational materials and NIH policies; and then provides specific sub-sections that facilitate requesting an agreement, and accessing appropriate materials depending on whether the study team will be the lead in a project or will be a participating site relying on an external IRB. New materials will be added to assist investigators involved in multi-site studies over the coming months.

The NIH has also recently signed the SMART Agreement with the SMART IRB. SMART stands for Streamlined, Multisite, Accelerated Resources for Trials. This is a national reliance template signed by over 800 institutions and aims to facilitate the reliance process with counterpart institutions. SMART IRB is not an Institutional Review Board (IRB). Therefore, when two or more institutions use the SMART Agreement as part of a collaboration, IRB review could be conducted either by the NIH IRB or an external IRB. For any questions relating to reliance agreements, single IRBs, the use of the SMART agreement, or Federalwide Assurance coverage, please email NIH-Reliance-sIRB@nih.gov for assistance.

Compliance & Training Update

OHSRP is looking forward to the roll-out of new educational tools and sessions as we enter 2021! We closed out the last quarter of 2020 with three OHSRP Educational Seminar sessions that we hope the intramural research community found helpful. Slides and links to the videocasts for all of the OHSRP Education Series sessions can be found in the Presentation Archive on our website. In October, Dr. Jonathan Green and Meredith Mullan from OHSRP presented Transition to a New eIRB [electronic IRB] System: Where We Are Now, and Where We Are going, and in November 2020, Julie Eiserman (OHSRP) addressed the many questions raised lately related to research during the COVID -19 pandemic in her session, Informed Consent Procedures in the Era of COVID-19: Beyond the Use of a Standard Written Consent Document. In December, Dr. Kathy Calzone, Research Geneticist in the Genetics Branch of the Center for Cancer Research at NCI, focused on issues surrounding the NIH Genomic Data Sharing Policy: Applicability to the IRP; Components; Protocol and Consent Content.

This month our Education Series session will feature Dr. Jonathan Green presenting on a topic that has generated many questions for our Office: What Constitutes Secondary Research and When is IRB Review Required for this Research? In February, OHSRP will present Overview and Implementation of the iRIS Multi-site Enhancement.

OHSRP is also expanding the CITI courses and webinars available to individuals with an NIH email address. The Good Laboratory Practice (GLP) course has been added to the list of courses available for those working in NIH labs in Maryland. We are also in the process of augmenting our CITI content to include webinars addressing various issues related to human subjects research. Examples include topics such as the following: Social Media and Research Recruiting; Ethics and Policy Issues CRISPer Gene Editing; 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 as well as a number of webinars that address regulatory changes resulting from the Revised Common Rule. We will send out an announcement once these are available, so stay tuned!

OHSRP continues to receive inquiries about investigator training requirements. All NIH study team members who are conducting human subjects research (HSR) on protocols that undergo review by the NIH IRB need to be listed as either the PI or an Associate Investigators in the Study Application. By conducting human subjects research (also referred to as "engaged" investigators in the Study Application), we mean individuals who are obtaining information or biospecimens through intervention or interaction with subjects (including through online platforms); obtaining consent from subjects; or obtaining, using, studying, analyzing, or generating identifiable private information or identifiable biospecimens. Investigators who are automatically, or otherwise, covered by the NIH Federalwide Assurance (FWA) should be listed in Section 3 of the application. Section 6 should list the Site PI of institutions who are relying on the NIH IRB via a reliance agreement, or who are receiving local IRB review e.g., an international site involved in an NIH protocol with in-country IRB review. Section E.2.c of NIH Policy 100, NIH Intramural Research Program's Human Research Protection Program defines which investigators are automatically covered by the NIH FWA. NIH Policy 105, IRB Reliance establishes when the NIH IRB may serve as the reviewing IRB for another institution and NIH Policy 109, FWA Coverage describes when the NIH FWA may be extended by a written agreement. Individuals who are listed in the NIH Enterprise Directory (NED) as Volunteers but who are not specifically listed as Special Volunteers are usually not covered by the NIH FWA and will likely need a written agreement and should contact the Reliance and sIRB Team for guidance.

HSR training requirements are different for those investigators covered by the NIH FWA vs. those not covered by our FWA, and these requirements are explained in Policy 103, Education Program and the accompanying Guidance document. All investigators covered by the NIH FWA who are conducting HSR on protocol(s) reviewed by the NIH IRB must have completed a Collaborative Institutional Training Initiative (CITI) basic training course (i.e. the CITI Biomedical 101 basic course and/or the CITI Social and Behavioral Research Educational Modules based on the type of research that the investigator conducts) through the NIH CITI Portal after January 21, 2019. This includes those investigators conducting HSR that has been deemed to be exempt from review by the NIH IRB. Investigators who conduct HSR on protocols that are not exempt from NIH IRB review (non-exempt HSR) must also have completed or tested out of the CITI Good Clinical Practice (US FDA Focus) course. Investigators who completed the NIAID GCP course prior to June 1, 2019 and whose course has not yet expired will be given credit for the required GCP training. However, when the NIAID GCP expires (3 years from the date of completion), investigators will be required to take or test out of the CITI GCP (US FDA focus course).

When a PI's or AI's training information is missing in iRIS, do not upload the investigator's training records into the submission in iRIS; the IRB analysts have no access to update these records. CITI training completion records must by accessible in the NIH CITI portal so that they will automatically download into the electronic IRB system (iRIS). These records must also be visible and up to date in the training records section of iRIS in order for an investigator to be newly approved or continue to work as research staff on a protocol. If the NIH investigator has an active iRIS account and has taken the appropriate CITI training through the NIH CITI portal, but his or her training is not visible in iRIS, a member of the team should put a ticket into the iRIS helpdesk to get this resolved. Fellows, students, contractors, and Special Volunteers who are covered under the NIH FWA and who have completed the same required CITI training via a non-NIH site, (on or after January 21, 2019 for the basic HSR CITI course(s)), can establish an account in the NIH CITI portal and have their outside records transferred into the NIH CITI portal. (FAQs regarding the process for establishing an account in the NIH CITI portal and transferring outside CITI completion records to the NIH portal can be found here.)

Policy and Accreditation Update

Policy revisions are nearly complete with only one policy (301 Informed Consent) and one tool (CoI Guide) pending final clearance before release. Once these are cleared, we anticipate the final three policies (Informed Consent, Investigator Conflict of Interest, and IRB Member Conflict of Interest) will be released in January 2021. At that time, the final two SOPs will be archived but available on the policy page under the Policy Archive button.

Once the final policies are released, the policy office is turning its full attention to re-accreditation efforts. The Step 1 application will be submitted in March 2021. Ics are in the process of providing data for that submission. In addition, ORC has released the annual QAQI survey, which also collects some of the data needed for the Step 1 application. The accrediting body, AAHRPP, plans to update its application for reaccreditation, and publish it in January 2021. We will review the latest version of the application and inform the Ics if there are any other data points that need to be collected, as soon as that version of the application is published. We thank everyone for assisting in this effort for their hard work on these data calls. As the accreditation process proceeds, we will provide further status updates.

Contact OHSRP

Email - IRB@od.nih.gov

Phone - (301) 402 - 3713