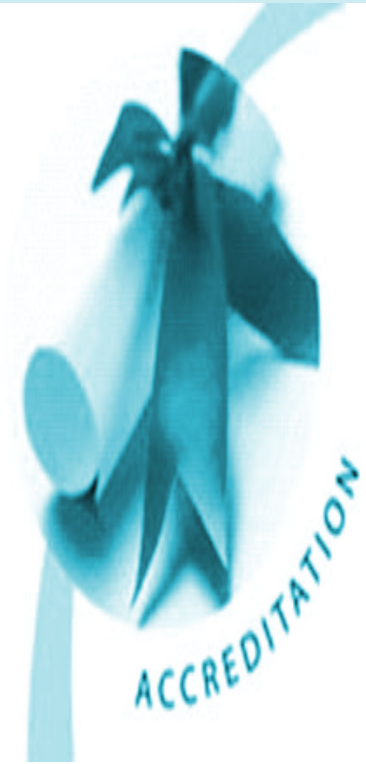
NIH
OHSRP

JUNE 2021

IRB MEMBER UPDATE

Welcome Summertime!

I am sure that each and every one of us is more than ready for a summer where we can finally spend some time with loved ones and perhaps even enjoy some travel. May you all have well deserved R&R this summer, and we look forward to seeing you fully restored at the IRB meetings! If you have not yet signed up for meetings this summer, please take a moment to do that now on the website. We still have a number of meetings where we do not have quorum.



Preparations for AAHRPP Re-Accreditation of the NIH Human Research Protection Program Underway

The NIH Intramural Research Program (IRP) was originally granted full accreditation by the Association for Accreditation of Human Research Protection Programs (AAHRPP) in March 2014. This accreditation program acts as a "gold seal" among HRPPs worldwide, demonstrating an institution's rigorous standards for the protection of human research subjects, as well as their commitment to scientifically and ethically sound research and continuous program improvement. We are now in the process of seeking our second re-accreditation. So far, we submitted the Step 1 application in March which provided AAHRPP our HRPP policies to ensure that they meet the accreditation standards. Fortunately, AAHRPP deemed our policies acceptable with only a few minor additions. Then we were invited to submit the Step 2 application which we submitted on June 1st. This application included the list of active protocols and Principal Investigators, the current IRB roster, and the list of certain NIH staff, by roles specified by the accrediting body. AAHRPP will use these lists to select staff to be interviewed during the upcoming Site Visit. We anticipate that the site visit will take place late this Fall/Winter. We've asked AAHRPP to provide us a tighter visit window and we will update you once we know more. Due to COVID-19, we are not yet sure if the visit will be in-person or virtual.

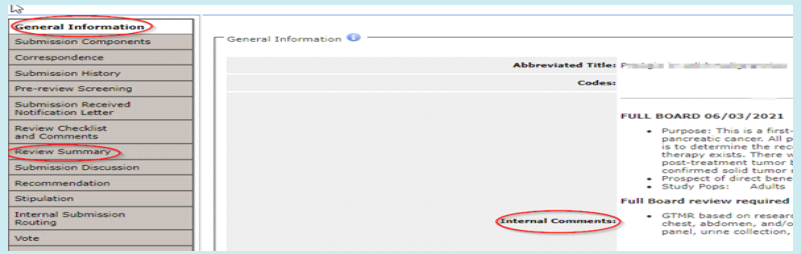
AAHRPP is aware of all the changes to the NIH HRPP and the NIH IRB. We are excited to show off our new program and the new IRB. The site visit is a confirmatory process in which the AAHRPP Site Visitors confirm that our practices reflect our policies and regulatory requirements, and that we meet accreditation standards. It is not an audit. Site Visitors are our peers from other accredited institutions and the process is very collegial. Each interview takes between 15-20 minutes. If you are selected to be interviewed as an IRB member, it is mandatory for you to participate but there is no need to panic. Staff from the OHSRP office of Policy and Accreditation will prepare you for the site visit. You will be interviewed with 2 other IRB members, either a group of scientific IRB members or a group of non-scientific members depending on your role. Be proud to represent the NIH IRB and the important work that you do as a member. You can read more about the accreditation process on the HRPP Accreditation webpage. If you have any questions, please reach out to Heather Bridge.

Tips for Reviewing New Applications

- **Review the Study Protocol 1st and Other Supporting Documents 2nd:** The study protocol is in the driver's seat for all study-related events and review items, so it should be your first pit stop on the road to reviewing a new study. Without knowing the contents of the protocol, we can't adequately review the remainder of the application. Once the protocol has been reviewed, move on to the application and the supporting documents provided within it (including consent documents, recruitment materials and study measures), ensuring the information provided in those documents are consistent with the study protocol.
- In some cases, particularly if you're new to research or are a non-scientific board member, it may be helpful to start with the consent form as this will give you a general overview of the research in lay terms. But that shouldn't be your only review of the consent form, nor should it be the only item you review! Once you've gotten a feel for the study, review the protocol and then circle back around to the consent to ensure it is complete and consistent with the protocol.
- **Jot Notes as You Go**: The most common issues that arise during the review of a new study are incomplete or inconsistent information. As you work your way through the study protocol and any other supporting documents, take a few notes on what procedures, risks and monitoring mechanisms are identified. Reviewing these will help you identify: what information, if anything, is missing; questions or concerns that may need to be discussed during the board meeting; and where inconsistencies lie.
- **Take a Look at the analyst's notes in iRIS:** Once you've completed your review of the protocol and any other supporting documents, review the Analyst's notes in iRIS. The Analyst's notes appear under "Internal Comments" on the study's General Information tab. You can also click on the "Review Summary" to see comments entered by any other board member. Reviewing these beforehand will help cue you in on issues identified by other reviewing board members and adding any issues that haven't already been identified will help streamline the review of the study during the board meeting.

First, go to the agenda of the meeting you are attending. Click the notepad icon to open the protocol action you wish to review:

Next, view the Analyst comments under the internal comments of the "General Information" tab. View all reviewer's comments under the "Review Summary" tab.



Food for Thought - Justice

The Belmont Report identifies basic ethical principles for conducting research that involve human subjects and sets forth guidelines to assure these principles are followed throughout the research process. The last of the Belmont Report's three basic ethical principles, justice, raises questions about who ought to receive the benefits of research and who ought to bear its burdens. Following a provocative discussion of equality and differential treatment, the Belmont Report considers the need to scrutinize whether some classes of people - economically disadvantaged, racial and ethnic minorities, or persons confined to institutions - are systematically selected as research subjects due to their position or vulnerability rather than their connection to the problem being researched.

Today, the principle of justice may demand scrutiny of whether classes of people considered compromised or vulnerable are excluded from participation in clinical trials due to financial and other barriers even though they have a connection to the problem being considered. The Report states that justice demands therapeutic devices and procedures developed from public funds must not provide advantages only to those who can afford them.

A recent blog on the PRIM&R website speaks to this issue of justice and how SACHRP (a committee who advises the Secretary of DHHS) is working to fill the gaps around the principle of justice in the Belmont Report. We look forward to the final recommendation of this committee.

Resources

Check out our updated website with resources for you! We have review resources posted that are specific to you as an IRB member and all of the past IRB Member newsletters.

The NIH IRB Welcomes New Board Members

The NIH IRB would like to welcome the following new board members:

Lauren Reoma, MD,

Chantal Cousineau-Krieger, MD,

Azam Ghafoor, MD,

Alicia Widge, MD,

Contact OHSRP

Phone: (301) 402-3713
Email: irb@od.nih.gov
Website: irbo.nih.gov