NIH Office of Intramural Research
Office of Human Subjects Research Protections

IRB Member Newsletter

December 2021, Volume 5

Happy Holidays!

Happy New Year!

Flying Colors

NIH completed the site visit for reaccreditation of its Human Research Protection Program (HRPP) in early December. This was a major accomplishment on the path to seeking reaccreditation of the Intramural Research Program's (IRP) HRPP. Earlier this year, OHSRP submitted two written applications that included our policies, checklists and other documents to AAHRPP which demonstrate that our HRPP meets AAHRPP accreditation standards. The review of our paper applications by our Step 1 reviewer went very well. On paper, at least, AAHRPP had confirmed that our program is accreditable.

The purpose of the site visit in early December was to confirm that our practice met what we stated on paper. The site visit was comprised of two types of review, first a review of records and second, interviews of over 100 of our staff from across the NIH IRP. The interviews included IRB members from both of our IRB panels, the NIH IRB and the Research Compliance Review Committee (RCRC). If you were selected to be interviewed by AAHRPP, you attended both a prep session and an interview with a group of your peers and with 2 members of the site visit team. The Site Visitors were our peers from other accredited institutions. This year's Site Visitors were:

- Delia Wolf Christiani, MD, JD, MSCI - Team Leader and Step 1 Reviewer
  Associate Dean, Regulatory Affairs & Research Compliance
  Harvard T. H. Chan School of Public Health and Harvard University Faculty of Medicine;

- John Bertolatus, MD
  Assoc Professor Emeritus/IRB Chair, Human Subjects Office
  The University of Iowa;

- Michele Kennett, JD, MSN, LLM
  Associate Vice Chancellor, Research
  The Curators of the University of Missouri; and

- Joshua Fedewa, MS, CIP
  Director, Institutional Review Board
  The University of Texas Southwestern Medical Center

Flying Colors

This year, the site visit was held virtually via Zoom (a first for the NIH, normally these are in-person visits). The Site Visit was a big success due in large part to the interviews. At the end of the visit, our site visitors provided us the preliminary results of the visit. They started out with commendations: They said our HRPP demonstrated 3 strengths: 1) The newly transformed HRPP including the newly established IRB in 2018, a comprehensive HRPP equipped by strong leadership, and with knowledgeable and competent staff. During the interviews, the Site Visitors heard many praises about the new program; 2) The rigorous Scientific Review process that enhanced IRB review and resources; and 3) The exemplary consenting process onsite for investigators. The Site Visitors were particularly impressed with the resources to educate researchers and to enhance their skills to improve and perform informed consent.

There was only one minor concern raised by the Site Visitors. The concern was focused on the return of the results of the annual self-evaluation to IRB members. The Site Visitors felt that it would be helpful to members if the aggregate results of the self-evaluation are returned to the members. These results will help you compare your individual responses against the aggregate results. NIH appreciated this helpful feedback and plans to provide you with the aggregate results of the annual member self-evaluation going forward.

Given the breadth and depth of the recent changes to our HRPP, to our IRB and to IRB operations, this site visit was a huge endorsement of how far we have come in such a short period of time and where we are headed. We are well on our way to achieving our vision for our

HRPP, namely that: “We will promote the safe and ethical conduct of human subjects research by

- providing timely, consistent and compliant reviews
- educating our community
- communicating effectively and responsively
- collaborating with stakeholders

and thus, will be recognized as national leaders in human subjects protections.”

Thank you, the IRB and especially to our Chairs, members and staff who participated in the site visit for helping us come through this undertaking with flying colors! We have a few more minor steps before our reaccreditation will be considered by the AAHRPP Council in March 2022. We anticipate full accreditation at that time and will update you when we receive our formal notice.

AAHRPP
Association for the Accreditation of Human Research Protection Programs, Inc.®

Membership Update

We currently have 114 members of the NIH IRB. Our IRB has now been up and running for 3 years! When you are appointed as a new member, you have an initial one-year appointment. Please refer to the appointment letter that you were sent when first on-boarded to see your appointment term and designated role (physician scientist, other scientist or non-scientist) on the IRB. After your first term, members may be re-appointed for a three-year term. If your commitments change and you are no longer able to serve as an IRB member during your term, please let Nicole Grant and/or Tiffany Gommel know that you would like to end your membership early.

To Defer, or Not to Defer: Knowing where to draw the line

In reviewing initial applications, continuing reviews and amendments, federal regulations and HRPP Policy state that, as a convened board, we can vote to approve as submitted, approve with modifications (stipulations or defer) or disapprove the research. Most often, voting decisions fall between approving with stipulations and deferring. And while voting decisions can sometimes be very clear cut, we run the risk of occasionally approving items with stipulations when, perhaps, they really should have been deferred (as demonstrated by the Office for Human Research Protection's (OHRP) Division of Compliance Oversight's Compliance Oversight Determinations).

Approving with Stipulations

Approving with stipulations means the criteria for IRB approval, as defined by 45 CFR 46.111 and Policy 204, will be met provided the study team:

- Makes minor changes specifically requested by the board to an initial application, amendment or continuing review; or
- Confirms specific assumptions made by the board regarding how the research will be conducted

Examples of modifications that might be required as a stipulation for approval include:

- Confirming that routine MRI screening procedures will be conducted
- Requiring editorial revisions to the consent document(s)
- Requesting documentation that confirms the 30-day IND waiting period has passed without any clinical holds
- Requesting that the IRB application be updated to reflect subject payments consistent with the study protocol and informed consent document
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Deferring Research

Anytime the board is unable to make a determination about whether a review item satisfies all the criteria for approval, the item should be deferred to a subsequent board meeting pending the resolution of substantive issues (i.e., deferred). In contrast to approving a review item with stipulations, deferring an item generally means that:

- Not enough information was included in the initial application, amendment or continuing review

to understand how the research will be conducted (and therefore simply confirming an assumption is not possible); or

- The changes required by the board in order for the item to meet the criteria for approval are substantial.

Examples of clarifications that might defer a review item include:

- Providing justification for the use of placebo
- Clarifying how and when data and safety monitoring will occur
- Identifying study procedures that the control group will undergo
- Clarifying how subjects will be screened for participation
- Requiring an additional consent or assent form be created

If, during your review of the actions assigned to your meeting, you have questions about the material, please reach out to the PI/ study team in advance of the meeting via email to ask your question(s). When you do this, please copy the analyst and chair assigned to that meeting so all are in the loop. The chairs will also blind copy the assigned reviewer(s) with any questions that they ask the study team.

Deferral Prevention Program

If you don't feel comfortable contacting the PI/ study team directly, you can email your questions to the analyst assigned to the meeting and s/he will send your queries to the team.

Remember, the meeting is the place to make decisions, not get answers to questions. By getting the information we need prior to the meeting, we will hopefully reduce the number of times we need to defer a review.

Key Considerations

Given the descriptions above, in preparing to vote on a review item (or make recommendations as primary reviewer), ask yourself the following:

1) **Do you have a clear picture of what the research entails and what the board is approving?** If yes, and the board is able to clearly and specifically articulate what changes must be made to the IRB application, it might be appropriate to approve with stipulations.

Given the descriptions above, in preparing to vote on a review item (or make recommendations as primary reviewer), ask yourself the following:

1) **Do you have a clear picture of what the research entails and what the board is approving?** If yes, and the board is able to clearly and specifically articulate what changes must be made to the IRB application, it might be appropriate to approve with stipulations.

2) **How will clarifications or modifications be posed to the study team?** The more open-ended a question or clarification is, the more likely the review item should be deferred. Asking a study team, for example, to clarify how subjects will be monitored for signs of suicidal ideation is very different that asking study teams to confirm that a suicide assessment measure will be reviewed by an appropriately delegated study team member at applicable intervals.

3) **Do a lot of minor changes equate to substantive changes?** While it may be permissible to approve a review item with stipulations pending a laundry list of minor modifications, care should be taken in doing so as the longer the list of required changes, the less likely the review item meets the criteria for approval. Ultimately, this will depend on the nature and scope of the approval conditions set forth by the board (e.g., requesting several editorial changes to a consent document vs. clarifying several procedural inconsistencies among the application, protocol and consent).

Questions? Contact your IRBO Team Lead, the Executive Chair, Nicole Grant or the IRBO Director, Tiffany Gommel. Additional information can also be found in OHRP's Guidance on IRB Approval of Research with Conditions.

IRB Scheduler

Confused by the colors on the IRB scheduler? When you go to sign up, please look for meetings that are yellow or blue. If the slots are all full (or full for your category of member), then the color will be red. The meetings that appear in green are ones you are already signed up for.

The meetings in yellow are the ones where quorum is not met yet; please focus on signing up for those in particular when selecting your meetings to attend.

We count on you to attend the meetings that you have signed up for. If you have a change in your schedule and cannot attend a meeting you have signed up for, please remove yourself ASAP from that meeting so that another member can sign up. The meeting is closed to addition/removal of members a week prior to the meeting date as that is when the agenda is finalized, and you are notified via email about the agenda.

It's that time again!

We have sent out the IRB Member Annual

Survey to you all via email. Please take 5 minutes to respond to this survey if you have not already done so. Here is the link for the IRB survey. And if you are a member of the RCRC, please also complete the survey at this link. Please complete the survey at this link. Please complete the survey(s) by December 31, 2021

Per Policy 103, many of us will all need to take our CITI Biomedical training refresher course. The CITI training must be taken every 3 years by all IRB members. Many of us took this training in January 2019 when the revised Common Rule went into effect, so will be expiring in January 2022. Please visit this page to view training records and to access the CITI website to take your refresher course.