NIH
OHSRP

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IRB MEMBER UPDATE

Message from the OHSRP Director, Jonathan Green, and Executive Chair, Nicole Grant

Expectations of All IRB Members

We are very grateful for your willingness to participate as members of the NIH Intramural IRB. Your efforts are critical to the mission of the NIH. I would like to take this opportunity to review our expectations and provide additional explanation as to why this is so important.

Attend 1 meeting a month

Our expectation of all members is that they will make every effort to attend one meeting each month. We realize that life happens, and sometimes you will not be able to attend a meeting, and of course that is fine. But we are finding that many members come very infrequently. This poses a problem for several reasons.

1. **Experience counts:** In our experience, it takes the average reviewer

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about a year to become a good IRB reviewer. The IRB review process is not intuitive, even (and perhaps particularly so) for people that are experienced grant and/or manuscript reviewers. It takes practice and that can only happen by regular attendance at meetings. Although many of you were members of the legacy IRBs, our processes and expectations are very different, so essentially, everyone is a new reviewer.

2. **Distribution of expertise:** It is critical that we have wide expertise and that it is distributed across all the meetings. When a study has completed the IRBO pre-review process and is ready for committee review, we look at the upcoming meetings to find the relevant expertise. If no one has signed up, we cannot match the protocol to the expertise. Ideally, expertise is distributed somewhat evenly across the month. If we have 10 oncologists, but only one comes each month...then we cannot review those studies in a timely manner.

3. **Quorum, quorum, quorum:** We cannot meet if we don't have quorum. If we can't meet, we can't review, and researchers can't do their work. We currently are holding 4 meetings per week, which means we need at a minimum 16 people each week (not counting Chairs) to sign up. Given that we currently have 170 members on the roster, this should not be a problem. However, as many people are not signing up, we are struggling to meet quorum for many meetings.

4. **It's not that much work:** The advantage of frequent meetings is the agendas are short. In general, no more 6 agenda items per meeting are scheduled. This is not that much to do each month.

5. **Sign up in advance:** We need to know who is coming in advance of assigning protocols to the meeting agendas. We will open scheduling for a 3-month period in advance of the meetings. Please go into the scheduler and select the meetings you plan on attending for the entire block of time that scheduling is open. If your plans change, you can remove yourself from the meeting and choose another date.

Going forward, we will be reviewing members attendance and will contact individuals that are not attending on a regular basis. For those members whose other commitments are such that they cannot regularly attend, it may be best to step off the committee and come back when time allows.

Requesting Changes to Previously Approved Content at the Time of Continuing Review

Continuing review provides the IRB the opportunity to monitor the research and ensure that the research continues to adequately protect subjects and meet the criteria for IRB approval, as defined by 45 CFR 46.111 and 21 CFR 56.111. Please be reminded that the protocol, recruitment and con-sent documentation reviewed during this process have been previously approved by the board (or the board's designee). Revisions to these materials at the time of continuing review should be limited to those based on a) new information provided during the review period; or b) continuing to meet the criteria for IRB approval.

Adequately Preparing for Your Next Board Meeting

It is essential that every member is prepared when they attend the meeting. The meeting is the time for making decisions, and if reviewers are not prepared, then we cannot move protocols forward. The agenda is released a week ahead of the meeting, which should provide adequate time to review prior to the meeting date.

Think of your assigned board as your "team" and your next board meeting as your next competition. All board members have a role to play on 'the team' and each 'competition' is comprised of an agenda, with a varying number of items that you need to review. Just as any athlete will tell you, Olympian or not, adequate preparation of each team player is critical to the success of the entire team. The better prepared each team player is for a board meeting, the more effective and efficient the review of the agenda.

Preparation for each board meeting should start with the IRBO analyst's outlook meeting invitation confirming the date and time of the next scheduled board meeting, which typically arrives about a week prior to the scheduled meeting. **Board members who are unable to attend the meeting, will arrive late, or need to leave early should notify the analyst as soon as possible.** With proper notice, the IRBO staff can typically accommodate absences by re-arranging the order of the agenda, confirming attendance of other board members, or seeking attendance by alternate members, as appropriate.

Once the agenda for a scheduled meeting has been distributed (typically 7 days in advance of the meeting), all board members attending the meeting, regardless of their role, are expected to review all materials for each agenda item. Pre-meeting reviews should be thorough enough for board members to thoughtfully discuss agenda items at the convened meeting and allow for meeting time to be dedicated to discussion and decision-making, not exhaustive content review.

Best Practices

- **Complete your reviews in the system in advance:** Properly preparing for a board meeting can be a timely task. Initiate reviews of agenda items at least 2-3 days prior to the scheduled meeting; this allows sufficient 'cushion' time for potentially complicated reviews. Avoid delaying meeting preparation until the night before or day of scheduled board meetings.

- **Get your questions answered ahead of time:** The meeting is about making decisions. If there are issues that require additional information or clarification, it is your responsibility to obtain those prior to the meeting. For example, you don't understand why a certain procedure is being done in a research study, or you are unclear on the dosing regimen of the drug. Reach out to the PI (either directly or through IRBO) and get the information. Do not come to the committee and expect to get clarifications at that time.

- **Review all studies on the agenda:** You are voting on everything so you must be familiar with all the studies on the agenda. Do not rely solely on the "Submission Comments" completed by the analyst to complete your review of the agenda item. These activities in iRIS are only meant to facilitate review of the agenda item during the convened meeting. Independent review of submission materials is necessary to contribute to board discussions effectively. If you are a primary or secondary reviewer, you should perform an in-depth review of that action. For those studies that you are not a primary or secondary reviewer on, you must have reviewed the material in sufficient depth to be able to vote on the criteria for approval.

- **Document your review:** It is enormously helpful to all of us if you document your reviews in iRIS ahead of time. Utilize the 'Reviewer Comments' in iRIS to document questions or clarifications that need to be discussed during the convened meeting. Doing so, with adequate lead time, allows the primary reviewer, board chair and/or IRBO staff to attempt to ascertain additional information from the study team prior to the board meeting. Your review is also how we document in the system that it was performed.

- **Document Revisions:** Extensive consent and recruitment material revisions are best addressed by tracking revisions directly within applicable Word documents prior to the meeting and emailing these tracked documents to the analyst ahead of the meeting. Pre-meeting revisions are routinely carried out by the board specialist and primary reviewer, though all board members are welcome to do so. Note: When requesting revisions and/or clarifications, including those made to consent documents and recruitment materials, limit revisions to those that: a) have a meaningful impact on the protection of research subjects; and b) affect the ability of the research to meet the criteria for approval, as defined by 45 CFR 46.111 and 21 CFR 56.111. Polishing the wording of documents to suit individual preferences does not

Best Practices Summary

1. *Complete your reviews in the system in advance*
2. *Get your questions answered ahead of time*
3. *Review all studies on the agenda*
4. *Document your review*
5. *Document Revisions*
6. *In-meeting courtesy*

necessarily impact the 'approvability' of the research, nor the protection of subjects and can consume significant board time.

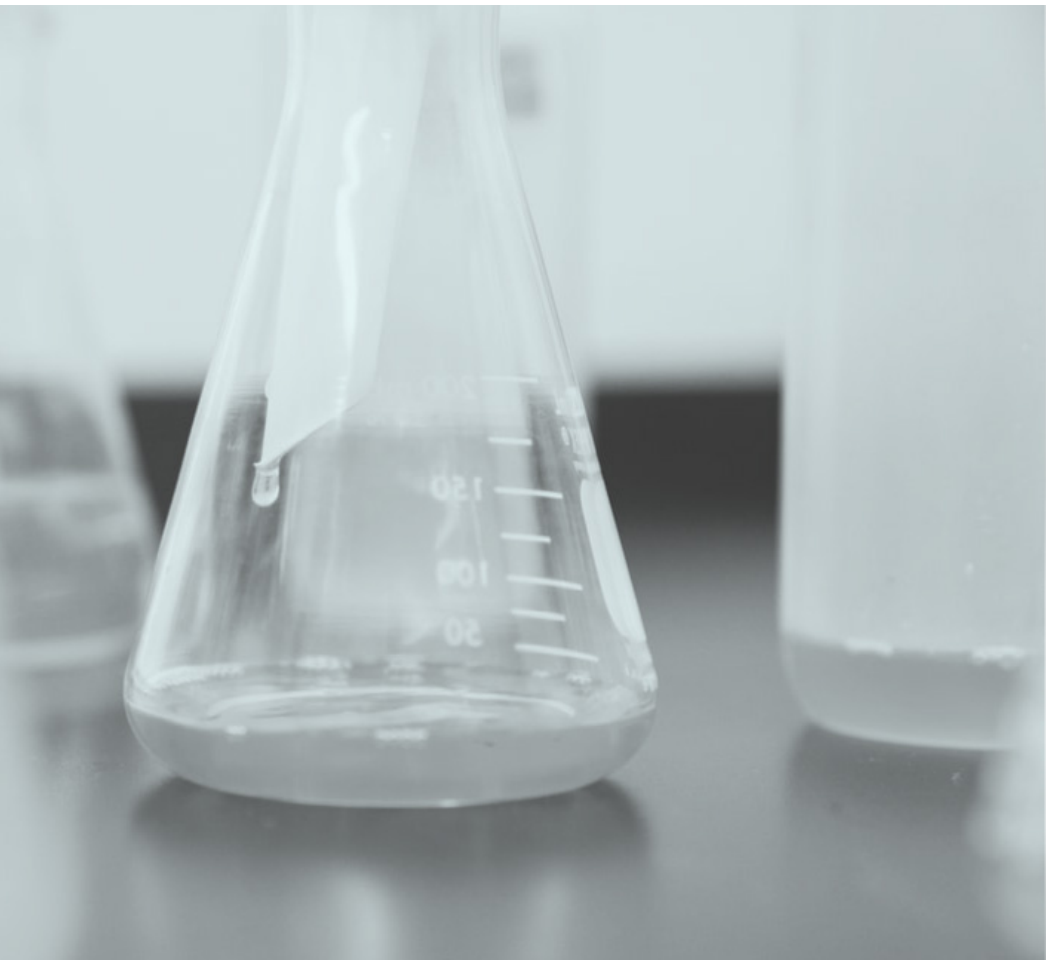
- **During the meeting:** Refrain from interrupting the primary reviewer with questions during their summary, as this can derail the presentation; save questions until either directed following the presentation of each submission document or the open discussion.

The Primary Reviewer Role

Using our team analogy, if the board chair is our team captain, the primary reviewer might be considered our point guard, quarterback or forward. The primary reviewer (as assigned on the meeting agenda) is the board member who takes 'the lead' on the review, presentation and discussion of the assigned agenda item. More specifically, the primary reviewer is responsible for:

- Conducting an in-depth review of the item prior to the board meeting;
- Presenting a summary of the item at the convened meeting;
- Being prepared to answer questions; and
- Making board determination recommendations.

While reviewing assigned agenda items prior to the board meeting, it is best practice for primary reviewers to jot down review notes on important details or issues in a systematic manner, so that the material can be easily referenced and presented at the convened meeting. For example, with new applications, it's best to start with the study protocol, as the protocol content should drive the content of all other submission materials. From there, review and address the IRB application, the content of all other submission materials. From there, the consent document(s) and then any other supporting submission documents.



When and if critical issues arise during a pre-review (e.g., issues that might defer the approval of the research), primary reviewers should attempt to answer questions or gather additional information prior to the convened meeting. Depending on the circumstance, this may include seeking advice from or notifying the IRB Analyst, or if comfortable, contacting the study team directly.

The best approach to presenting the summary at the convened meeting is to utilize the same systematic approach as outlined in the review notes; resist the urge

to jump from document to document as issues are brought up. In fact, utilizing review notes to present the material, rather than shuffling through submission materials directly, is also a more effective way to approach the presentation. Additionally, bear in mind that the presentation should be a summary of important points about the research and items that might be pertinent to the approval criteria only. Having already completed their own pre-review, board members should be familiar with the content; a comprehensive review of all materials is not typically necessary.

Once all important points and materials are summarized, the board chair will then open the discussion on the agenda item to the full committee. At this point, the primary reviewer is responsible for answering questions (to the best of their ability) and actively listening to any concerns or opinions expressed by fellow board members.

Based on the outcome of the open discussion, the primary reviewer is then responsible for making recommendations on the applicable board determinations for members to vote on. Typically, this includes determinations pertaining to approval, vulnerable population categories, length of approval and risk level. In making this recommendation, it's generally expected that primary reviewers have considered this during their pre-meeting review. It's important, however, to recognize that this recommendation might change based on comments or concerns raised during the convened meeting.

The NIH IRB Welcomes New Board Members

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

Smita Jha, MD, endocrinology

Srivandana Akshintala, MB, MS, MPH, pediatric hematology oncology

Alice Chen, MD, MPH, medical oncology

Andrea Gross, MD, pediatric oncology

Geraldine O'Sullivan Coyne, MD, PhD, MRCPI, medical oncology

Margaret Kroen, LCSW-C,

Jeff Carrico, Pharm.D, B.C.P.S

Margarita Aryavand, MSN, CFNP

Denna Zeltzer, MD, pediatrics

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