USC IRB Members Standards and Responsibilities

Full-Board Member Review Expectations

Purpose

This document provides expectations for the process for reviewing a study during full-board meetings. It describes the overall responsibilities of the IRB analyst (IRBA), non-reviewing member expectations, and expectations for the primary and secondary reviewer.

As described in the Expectations for Board Member Participation in Committee Meetings document disseminated earlier this year, all members are expected to read iStar applications for all studies on the day's meeting agenda. This allows members to engage in the primary purpose of the meeting, to discuss risks and how those risks are being addressed by the study team, as well as any other aspects of the study that demand members' time and attention.

Below, the responsibilities of the IRBA, primary and secondary reviewer, and non-reviewing members.

IRBA Review Responsibilities:

1. Review consent language
2. Ensure template consent language is included/excluded
3. Ensure local context is attended to
4. Ensure Conflict of Interests have been cleared by CIRC
5. Ensure radiology/ancillary committee is on its way or not required

Primary and Secondary Member Review Expectation:

New Studies

1. Summarize the study
2. Speak to only those parts after going/walking briefly through each of those. Describe what you identify as the risks associated with this study that require discussion and the reasons why the study is brought to full board

Review Plan:

1. Objective/hypothesis
2. Study design
3. Participant population/recruitment/how are they finding the patients
4. If there are treatment groups, what are they doing
5. Outcome measure/endpoint
6. Follow-up summary
7. What is the risk associated with all of the above?
8. Sub-categories, if applicable
    a. Device
    b. Drug
    c. Risk
    d. Minors
    e. Pregnant Women/neonates
    f. Prisoners

Tips for Presenting Review:

1. No need to reproduce IRBA/primary review

2. If the analyst has done a good job, use their review/expand as applicable
3. No need to discuss every aspect of every study
4. Be comfortable saying this is a very straightforward study and give a brief description of the study,
    a. Example: This is an investigational study with 2 investigative arms, which include previously approved drugs, etc.
    b. More detail can be given for those studies that require it (e.g., first in human)

Questions to Ask Yourself:

1. Are the issues glaring or problematic?
2. Does it affect the risk determination?
3. Can we alleviate the risk?
4. What do the members really want to hear?

Amendment:

1. Summary of background
2. Focus on amendment

Non-Reviewing Member:

1. Read materials before attending a meeting
2. Focus on risk
3. Stay away from wordsmithing the consent and instead focus on readability or clear communication of risks
4. Use time efficiently

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Expectations for Board Member Participation in Committee Meetings:

Duties, Responsibilities and Education Required

Members are required to possess knowledge of the federal regulations, ethical principles of human subjects research, IRB policies and apply them appropriately. They are also expected to participate in educational sessions and complete required member training. In addition, they are expected to maintain the confidentiality of all IRB information. All conversations outside of a meeting on topics related to a meeting must be directed to the OPRS Director, the IRB Chair, or the Vice President for Research only.

All members will receive an email invitation generated through iStar to attend full board committee meetings. Each member is required to respond to the meeting invitation via iStar and indicate whether they will be attending the meeting. The staff will try to only assign reviews to those who have indicated their intention to attend; however, if attendance is limited or specific expertise is required for the review, a member may be assigned to review a study, irrespective of whether that person indicated his/her/zir intention to attend.

Once assigned a study, the reviewer is expected to post the review in iStar no later than 24 hours prior to the meeting. This gives the other members time to read the review prior to the meeting.

If a member is assigned as a reviewer that person will be expected to complete the review unless extenuating circumstances make it impossible (e.g., work or family emergency). Under those circumstances, the member should inform the IRB analyst as soon as possible so the study can be assigned to another reviewer.

Members who are not responsible for reviewing studies should read all IRB application materials, including the reviews for all matters on the agenda, for example, the meeting minutes and expedited actions, in advance of the meeting so that they are able to participate fully in the meeting discussions.

It is expected that each member will join and attend the meeting **on camera,** from a quiet location with no distractions and a strong internet connection, using a computer or tablet (not phone), and use either computer/tablet or telephone audio. These conditions make it possible for each member to view the agenda and study related materials, participate fully in the discussion, and vote.

During the meeting, each member is expected to:

1. Be fully present, participate in the discussion, and vote using the “raise hand” or “yes” function.
2. Be respectful of other opinions and perspectives.
3. Comply with the USC conflict of interest policy.
4. Disclose conflict of interests for a project subject to IRB review at a convened meeting; refrain from the discussion except to provide information requested by the IRB and leave the room during voting.
5. Keep audio on mute if the member is not presenting or discussing a study. The microphones in the platform are very sensitive and pick up every noise, including background noise.

6. Be courteous to fellow attendees. As everyone is on video, all other members see (and hear) what everyone else is doing. Don't walk around if using a tablet.
7. Have the Chat pod open and monitor the chat conversation during the meeting.
8. Use the Chat to communicate with a co-host if that member needs assistance or if unable to access the chat, send an email to the co-host.
9. Have the Participant pod open and monitor it in order to ensure that you are able to vote using the "raise hand" or "yes" function.
10. Vote using the "raise hand" or "yes" function.

Meetings will be led by the Chair unless a Vice Chair is asked to lead the meeting or take over the meeting when/if the Chair becomes indisposed.

The Director of the IRB or a designee will host or co-host the meeting in order to ensure that the members are admitted to the meeting, are able to participate successfully, and to support the Chair or Vice Chair to manage the technology during the meeting.

The IRB Office will ensure all members have the resources they require (e.g., laptop, tablet, headphones, webcam) in order to participate fully in the IRB meetings.