General IRB Member Questions

1. **How long have you been an IRB member?**
2. **Do you feel all members of the committee are respected and opinions valued equally?**
3. **Do you participate in discussions?**
4. **Is the burden of your IRB responsibilities too much for your other daily tasks?**
5. **Describe your review process. How do IRB discussions work?**
6. **Do you feel the IRB is adequately staffed?**
7. **How are board members trained for their role?**

   All new members must undergo an orientation training session and observe at least one convened board meeting. Each new member must also complete the CITI training for Human Subject Research, Responsible Conduct of Research and IRB Members. Continuing education topics are presented at the beginning of each IRB meeting.

8. **What are you provided with prior to the meeting to conduct your review?**

   All members of the committee receive an email notification that the agenda is ready one week prior to the meeting. All members of the committee have access to the full materials on the agenda through the PittPRO system.

9. **Does everyone on the IRB have access to the meeting materials or just the reviewers?**

   All members of the committee can view the full agenda whether they are assigned as a reviewer or not. This includes all materials for each new protocol, modification, continuing review or reportable new information.

10. **Does the IRB discuss if the study staff is qualified?**

    The IRB ensures that the study team is adequately qualified to carry out the procedures described in the protocol, including ensuring that the proper person is conducting the informed consent process according to Obtaining Informed Consent guidance.

11. **What is the role of an Institutional Official?**

    The I/O must be an individual who is legally authorized to act for the institution and can assure the institution will act according to the terms of the FWA. This person ensures that the HRPP has the resources and support essential to function in compliance with all requirements of human subject research.

12. **Who is the Institutional Official?**

    University of Pittsburgh: Bill Yates, PhD - Vice Chancellor for Research Protections
    UPMC: Barbara Barnes, MD - Vice President for Sponsored Programs, for Research Support
    MWRI: Yoel Sadovsky, MD - Executive Director, Magee-Womens Research Institute
    UPMC Cancer Centers: Charles Bogosta - Executive Vice President

IRB Reviews

1. **Who conducts expedited review at your institution?**

The University of Pittsburgh IRB has a designated team to conduct expedited reviews. All analysts on the team are trained as IRB members and are designated by the IRB chair to conduct these reviews.

2. **What aspects to you consider when you review a protocol?**

   IRB members take in consideration the Criteria for IRB approval, elements of informed consent and any applicable subparts when reviewing a protocol. Checklists to ensure compliance with all of the requirements therein are available in the PittPRO Library.

3. **How does the committee determine if a protocol is minimal risk?**

   Through review of the protocol and discussion at the meeting, the committee determines if the procedures being performed for the research exceed the definition of minimal risk:

   > "minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests"

4. **How is it determined who performs the review of the protocol?**

   The IRB is required to include persons knowledgeable about and experienced in working with subjects in the protocol under review. Full Board analysts ensure that this criterion is met when assigning protocols to a particular committee for review.

5. **Does the PI of a protocol ever attend the IRB meeting? How does that work?**

   Although we don't typically have researchers at the meeting, they are always welcome to be on hand for the committee meeting to provide information and answer questions about a protocol under review. Once the information has been given and questions answered, the researchers cannot be present for the committee's discussion or vote on the protocol.

6. **What actions can a committee take when reviewing a protocol?**

   The committee can vote to grant full approval, approval subject to modifications, deferral or disapproval of a protocol. Definitions of each of these terms can be found in the Meeting Activities section of the IRB P&P. A protocol may also be tabled if there is insufficient information or expertise available to review in an adequate manner.

7. **Who makes the decision to stop a study?**

   There are multiple reasons that a study may be suspended or terminated. Suspensions or terminations may be investigator/sponsor initiated or IRB initiated. Detailed information can be found in Chapter 19 – Suspensions and Terminations.

8. **How does the IRB review researchers' response to comments?**

If the protocol is **approved subject to modifications**, the response is reviewed by the IRB Analyst and the IRB Vice Chair and granted approval if satisfactory. If the protocol is **deferred**, the response (when possible) is sent to the same committee, same reviewers for consideration.

9. **What happens if a reviewer is not present to discuss a protocol?**

   The committee will decide if they feel they have adequate expertise to discuss the protocol. If they decide that they do not, the protocol will be tabled and reassigned to a future meeting with adequate expertise.

10. **How is continuing review different from initial review?**

    Initial review is the committee's first consideration of a new protocol. The re-review of a deferral is considered to be a part of the initial review. **Continuing Review** is the (at least) annual progress of a previously approved protocol.

11. **How are continuing reviews assigned?**

    Continuing Reviews are given one reviewer at a convened meeting. In general, CRs are sent to Committee I, which is dedicated to the review of CR. In the event of time constraints, CRs are assigned to regularly convened committee

12. **What steps are taken to prevent a lapse in continuing review?**

    The PittPRO system sends reminders that continuing review is coming due.

13. **How is the PI notified that continuing review has lapsed?**

    PittPRO will notify study teams if CR has lapsed. They are informed that all research-related activities must cease until IRB approval has been reinstated. The study team must notify the chair in the event that activities must continue to ensure subject safety.

14. **When is a continuing review necessary?**

    Annual Continuing Review is required for all protocols appearing before the full board. The IRB can assign a shorter approval interval (e.g. 3 months, 6 months) based on the risk-benefit considerations of the protocol or for any reason determined and documented by the committee.

    Expedited protocols approved after 2018 are not subject to the requirement for continuing review unless the IRB has a documented reason as to the why CR would be required.

15. **How are modifications reviewed?**

    Full Board Studies: Minor modifications of studies previously approved by the Full Board that would not materially affect an assessment of the risks and benefits of the study or do not substantially change the specific aims of the study are eligible for expedited review. Examples can be found in Chapter 11 of the IRB P&P. Modifications that do not meet this definition will be reviewed at a convened meeting. FB mods are assigned a primary and secondary reviewer. A consent form reviewer is assigned if there are substantial modifications to the consent form.

Expedited Studies: Modifications to IRB protocols originally approved by the expedited process are re-evaluated to ensure that the submission continues to qualify for expedited review as specified in "Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure." If the research no longer meets these requirements, it will be forwarded for review by a convened IRB Committee

16. **Who determines what is expedited?**

    The Exempt/Expedited Analysts are IRB members who have been extensively trained in the requirements for expedited review. Their comprehensive understanding of the regulations allows them to determine what can be approved through expedited review or if a full committee review is required. The Full Board Analysts are also well versed in the regulations and can also make determinations as to the course of review.

Conflict of Interest

1. **How is conflict of interest identified and who evaluates investigator conflict of interest? How is this managed?**

   Faculty members and certain staff must report conflicts annually through the *My*Disclosures system. Investigators must accurately fill out the Conflict of Interest page in PittPRO. PittPRO will automatically route it to the Conflict of Interest division for review. They will determine if/how a conflict needs to be managed. See the Conflict of Interest Management lesson for more information.

2. **What if an IRB member has a conflict?**

   IRB members with a conflict cannot be assigned as a review or vote upon a study where there is a conflict of interest. The conflicted member must also step out for the discussion of the protocol but can be allowed to answer questions about the protocol. Conflicts can be financial, personal, familial, or any other issue that might be perceived to inhibit a fair and unbiased review of the research

Reportable New Information and Non-Compliance

Review the Reportable New Information Lesson and Chapter 17 for detailed information. The RNI FAQ guidance is also a helpful resource.

1. **What noncompliance needs to be reported to the IRB?**

   Noncompliance that is reportable to the IRB is outlined in Chapter 17. This includes:

   - Noncompliance that meets the definition of an unanticipated problem involving risks to human subjects or others in that it is related or possibly related to the research, is unexpected and places research subjects or others at greater risk of harm (physical, psychological, economic or social) than was previously known or recognized.
   - Noncompliance that may significantly adversely affects the rights or welfare of participants, or significantly compromises the research data.

2. **When are Noncompliance/Deviation logs required?**

   Noncompliance/ Deviation Logs are mandatory in these situations:

- Greater than minimal risk studies
- Studies that meet the federal definition of a “clinical trial”
- Studies for which reporting is required by the funding agency

Logs are not required to be submitted at annual review but must be available upon request. Noncompliance/ Deviation Logs are recommended but non-mandatory for all other studies.

3. How is Reportable New Information reviewed?

A designated IRB staff person and the IRB Chair review the first report and decide that there is no further action required or if additional information and/or review by the convened IRB is required.

HIPAA

Please refer to the multiple guidance documents for detailed HIPAA information. The Informed Consent, HIPAA and Waivers lesson provides information on HIPAA Authorizations.

4. How does HIPAA affect research?

Researchers are obligated comply with HIPAA when they access, use, disclose, and/or create “Protected Health Information” (PHI). Accessing identifiable medical records for research requires a signed HIPAA Authorization or a waiver

5. Define privacy and define confidentiality

Privacy is the Individuals’ right to control access to their information and body. Confidentiality is how that private information provided by individuals will be protected by the researcher from release. The Privacy and Confidentiality guidance provides more information.