Northwestern

IRB Operations and Membership

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Overview

We intend to cover the following:

- Regulatory requirements that inform the constitution of IRB Panels and meetings.
- The logistics of submission review, assignments, meeting conduct and post-meeting communication.
- The process for panel member application, training, and supporting tools.
- The regulatory requirements and considerations for conducting reviews.
- IRB member personal history and experience

IRB Membership

- The “Regs” of IRB Formation: §46.107
  - Composition: At least 5 members with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution (Representation)
  - Diverse Experience and Expertise:
    - With consideration for regular review of vulnerable populations; e.g. institution who commonly reviews human research involving children should consider inclusion of members with background in pediatrics

IRB Membership

- The “Regs” of IRB Formation: §46.107
  - Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in non-scientific areas.
  - Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.
  - No IRB may have a member participate in the IRB’s initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.
  - An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

Northwestern University IRB

- 5 Biomedical panels (A,B,C,D,Q) and 1 Social-Behavioral Panel (E). We will be creating an additional Biomedical panel by the end of the fiscal year.
  - Calendar Rotation:
    - 4 of the Biomedical panels meet once per month
    - The Biomedical panel that reviews continuing reviews meets weekly.
  - Duration:
    - Monthly panel meetings: 2-3 hours (Thursdays and/or Fridays from 2-5pm)
    - Weekly panel meets: 1-1.5 hours. (Mondays at 11:30-1pm)
  - Composition and Quorum:
    - Each panel roster has about 6 voting members,10 alternates
    - In the event that the voting member is unable to attend the meeting, their alternate can vote at the meeting to meet Quorum.
    - Quorum is met when the majority (over 50%) of voting members are present.

IRB Panel Member Commitment & Responsibilities

- New projects are assigned to two reviewers with the goal of matching study content with reviewer's expertise, but it's often not possible to match up neatly.
- Each member is assigned about 2-4 submissions per meeting, including a mix of new projects, MODs, or RNIs.
- Panel membership lasts for a 3 year term, and is renewed for as long as a member wishes to continue.
- We have developed a 360 degree member review process for continuing education and feedback.
- Panel members, both voting members and alternates are expected to attend about 8-9 meetings per year out of 12.
- New members are identified in a multitude of ways, sometimes they are suggested by Department Chairs, sometimes they are directly solicited by the IRB Office, sometimes they are recommended by current members, we welcome interested parties to inquire about membership directly.

Prospective IRB Members

- A prospective member will begin by submitting a member application and their CV.
- Next a prospective member will observe a panel meeting. We consider those interested in observing to observe a panel meeting even if not interested in pursuing membership.
- Then there will be an informal interview with the associate director to learn more about their background, experience, interest, and availability, as well as discuss the panel meeting observation and IRB membership expectations.
- We have a training program for new IRB members called I-POEM that includes elaborate training materials, a checklist for material review, materials to aid reviews, and a mentorship program.
- The mentorship is informal and includes pairing up to IRB members on the review of new projects and encouraging communication to share their observations and questions.
- Our IRB Senior Analysts also serve as a reliable resource for new members learning how to carry out reviews and use the eIRB system.
- MyHR training will help introduce the training available: Navigating Human Research Ethics & Regulatory Review with the Institutional Review Board Office

The Lifecycle of a Submission

- Submissions are assigned in the order that they are received
  - There are about 150 total internal submissions in our **unassigned** inbox on any given day. These comprise both Biomedical (80%) and Social Behavioral (20%) and are for studies where Northwestern serves as the IRB of record.
  - There are about 130 total external submissions in our queue to be assigned to an Analyst on any given day.
  - Submissions are usually assigned 1-2 weeks after they are received. This is because each Analyst already has a lengthy queue of submissions that they are working through.

The Lifecycle of a Submission: Pre-Review

- Pre-review will begin within a week after it has been assigned to an analyst.
  - You can identify the Analyst/Coordinator assigned to your submission by viewing the field in the upper right-hand side of the submission dashboard.
- Expedited vs. Full Board:
  - Studies that are minimal risk and fit an expedited or exempt category are reviewed outside of a panel meeting. Studies that are greater than minimal risk or don't meet an expedited/exempt category are reviewed by a full board panel.
  - MOD submissions are sent to full board if the overall study is greater than minimal risk, and there is either a change in study design such as inclusion/exclusion criteria or there is a change in risk information or an impact to the risk/benefit ratio.
  - For submissions requiring full board review, the Analyst will carry out a pre-review to make sure that the submission is complete and ready to be assigned to a meeting.

The Lifecycle of a Submission: Panel Meeting Review

- Monthly meeting agendas are usually filled up 3-4 weeks ahead of time.
- Panel members are assigned reviews 2 weeks before the meeting. Each member is assigned about 2-4 submissions per meeting.
- Questions from reviewers may be sent before the meeting via a comment. Responding is optional, it but will likely reduce the chances of deferral. Responding to questions does not guarantee that the study will be approved but may help avoid deferral.
- Determination letters are usually sent out between 1-3 business days, or up to a week, after a meeting.

Reviewer Tools

When reviewing a study in the eIRB+ system, panel members are required to complete the reviewer sheet imbedded in the system which ask for free to text to document the following:

- Purpose of the study
- Summary of study procedures
- Summary off risks and how they are minimized
- Summary of any potential benefits to subjects and/or society:
- Summary of study's data and safety monitoring plan (if applicable):

We also have a suite of worksheets and checklists that Analysts will provide to reviewers as applicable.

- **EXAMPLES: minors, pregnant women, prisoners, cognitive impairment, IND, IDE. Waivers**

111 Criteria

1) Risks to subjects are minimized

2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.

3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted.

4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative

5) Informed consent will be appropriately documented or appropriately waived

6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

Continuing Reviews

- Continuing Reviews that require full board review are reviewed by panel Q, which meets every Monday from 11:30 am to 1pm.
- Panel Q agendas have about 10-15 items and assignments are sent out on Wednesday, the week prior to the Monday.
- There is no rhyme or reason for why this panel is called Panel Q
- On occasion, and to the discretion of the IRB Managers and Panel Chair, particularly time-sensitive submissions are reviewed at panel Q in addition to Continuing Reviews.

Pending vs. Deferral

- In general, the difference between a pending determination (modifications required) and a deferral is whether the panel can attest the study/submission meets the 111 criteria. Pending determinations usually entail specific change requests while deferral determinations usually involve open-ended questions, or there are significant changes required or gaps in understanding of the study.

- Deferred submissions are always returned to the same panel that carried out the first review so it's best to try to have a response submitted about 2 weeks after the letter is received in order for it to be placed on the next available agenda.

IRB Member Perspective

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- Position and history at Northwestern and your (research) career in general
- History as a panel member and/or Chair
- Personal experience working as a panel member (challenges, education, or benefits)
- Experience working with IRB Office and the IRB member retreat

Questions?

Resources

- **Becoming an IRB Member**
- **Checklists and Worksheets**
- **Human Research Protections Training**