

Reviewing Proposals Talking Points

WSIRB Review Documents

- **Review Worksheet** (renamed from Presentation Guide)
Intended to be used by all Board Members when reviewing proposals. Primary Reviewer is asked to complete the Worksheet and distribute last page, *Regulatory Determinations and Disposition Recommendation*, to Board Members before their presentation: provides a summary of regulatory determinations required to be documented in the meeting minutes, and to be included in the motion for vote.
- **Consent Form Checklist** (new)
Includes elements required by federal regulations (*) and other elements required by WSIRB. Not necessarily all inclusive list, there may be other elements that the Board could require depending on the research.
- **Presentation Guidelines for Primary Reviewers**
Outlines the structure for Primary Reviewers to follow for their presentation. Provide only brief summary of the protocol—remember everyone has (or should have) read the proposal. With heavier agendas, it is unnecessary to go into detail about aspects of the study that are okay. If there is an issue with something, may want to discuss in more detail.

Presentations should focus on:

- Significant, unresolved issues
- Regulatory determinations regarding vulnerable populations; waivers of consent/assent/parental permission/authorization
- Risk/potential benefit assessment
- Adequacy of recruitment/consent documents
- Conclude with motion for voted that includes risk determination, Subpart determinations, waiver approvals, disposition, approval conditions, and approval period

Beyond Checklists and Regulatory Compliance: “Making Compliance Meaningful”

Insights from a talk given by Dr. James DuBois, Ph.D. philosophy, Dr.Sc. psychology, St. Louis University, Department Chair of Health Care Ethics.

- Need for more empirical studies and data to assess whether or not regulatory and other Board requirements are actually meeting our ethical duties as identified in the Belmont Report (respect for persons, beneficence, justice).
i.e.
 - Do payments cause participants to ignore risks?
 - What processes of consent enhance the understanding of consent information?

- Points regarding research review:
 - Regulations are often followed “mindlessly” by IRBs, the point or ethical intent behind the regulation is forgotten
 - When reviewing research, reviewers should focus on deciding what is the ethical or right way to do something first, based on Belmont principles, then look to the regulations. In most cases, ethics will fit within the regulatory framework—there is flexibility.
 - Most often, IRBs are driven by regulatory compliance with the assumption that compliance ensures ethics, but DuBois argues this is backwards
 - Regulations should be seen as tools to help apply principles of respect for persons; beneficence; justice
 - Need to recognize that IRBs must go beyond regulatory compliance--
 - requiring extra protections during consent process for vulnerable populations not specifically identified in the regulations (cognitively impaired).
 - Also need to recognize that strict application of regulations in some instances may hinder research without enhancing the protection of human subjects, or makes it difficult to do the most ethical thing:
 - Literal, strict interpretation of Subpart B, special protections for pregnant women, do not appear to allow women to participate in many social/behavioral studies because research may not lead to “important biomedical knowledge that cannot be obtained by any other means.”

Suggested method for reviewing proposals

Frequently recommended in human subjects training, including *Institutional Review Board Member Handbook*, by Amdur and Bankert.

- 3 steps:
 - Read the consent documents first, prior to reading the proposal (don't make revisions). Evaluate whether the consent form can stand alone as a document in clearly describing what is involved and what the subject will experience as a participant
 - Next, read the application (using the Review Worksheet), identifying issues and concerns.
 - Re-read the consent documents, making revisions as necessary (using Consent Form Checklist).
- Only applicable when project involves obtaining consent.
- Strength of approach is that it focuses on information the subjects receive about the study, ensuring that subjects have adequate and accurate information to make an informed decision about their participation—rather than focusing on study design issues, which can sometimes lead discussions astray.