Office of Human Research Ethics Training Tips

Tips for IRB Members on How to Review Protocol Submissions

§46.111 Criteria for IRB approval of research.

1) **Risks to subjects are minimized**: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(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.** In evaluating risks and benefits, the IRB should **consider only those risks and benefits that may result from the** research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

1. Read the consent form first. You should get a basic understanding of the study. If you do not, then the subjects will not.
2. Read the IRBIS submission.
3. Make notes of your questions based on your reading. You can use the checklist or make your own.
4. If you see a disconnect, check the study protocol &/or investigational brochure (IB)
5. Share your concerns with the primary & secondary reviewers and the chair. They may have already communicated with the investigator & study team and can provide clarification. If not, then perhaps you have identified a concern they can resolve prior to the meeting.
6. Speak up in the meeting: **THERE ARE NO DUMB QUESTIONS AT AN IRB MEETING!**

Study Number:
PI: **Funding Sponsor:** **NIH Concordance Declaration: Y/N**
Phase: ___Pilot ___1 ___2 ___3 ___4
Primary Objective(s) of the study:
Secondary Objective(s) of the study:
Study Design:
Study Population: ___adults only ___minors ____vulnerable populations ___number to be enrolled
Investigational Drug or Device? #_____ Holder of IND/IDE:_____ NSR: Y/N____
Questions/Concerns:
Consent Form Recommendations:
Stipulations: