



Office of Human Research Ethics Training Tips

Primary Reviewer Presentation Tips for Initial Reviews: August 2014

Pre-Meeting:

- Identify and resolve difficult issues *PRIOR* to the meeting. Communicate with the study team to reduce the chances of deferral at the meeting.
- Alert the Chair of any controversial issues *PRIOR* to the meeting for **ANY** study on the agenda.
- Prepare recommended solutions to controverted issues for presentation at the meeting.

At the Meeting:

- **Be brief:** Do not read through the entire PR Checklist. Discuss only important issues as outlined below.
- Provide a 3-5 minute review of key points in your oral presentation:
 - One sentence description of the study objectives
 - Identification of subjects; how the consent process will occur
 - Short summary of the study design
 - Short summary of risks, benefits,
 - If applicable:
 - evaluate the pediatric risk level and/or appropriateness of inclusion of children,
 - inclusion of vulnerable groups in the study -- pregnant women, prisoners, adults incapable of consent
 - IND/IDE status of investigational drugs/devices/biologics, remember to consult the information sheet provided by staff
 - Address any conditions of approval, such as:
 - Legally Authorized Representative (LAR)
 - Declaration of Concordance if NIH funded,
 - Category 9 eligibility at the time of Continuing Review to allow future expedited review of the study.
 - Recommend any stipulations citing specific sections to be modified
- Make the final motion to:
 - Approve, including period of approval
 - Based on the risk assessment by the IRB, the approval period can be less than 1-year; can be less, i.e., after enrollment of "X" number of subjects; or 3, 6, or 9-months.
 - Approve with stipulations
 - Defer/Table
 - Disapprove

DO NOT WORDSMITH THE CONSENT!

- If the consent meets all regulatory & ethical requirements, but is not in your preferred writing style, **LEAVE IT ALONE.**
- **DO** change the consent for these reasons:
 - The study activities or risks/benefits/alternatives are misrepresented
 - Standard language needs to be revised/added or required elements are missing
- Make corrections using track changes (but do not use the "insert comment" feature). Download the consent to your computer, turn on track changes, save the file by adding "Reviewer Edits" to the title, save and upload into IRBIS. If you are not the primary reviewer and have recommended changes, please print out the page(s) with your edits and give the paper version to the staff.