Office of Human Research Ethics Training Tips

Primary Reviewer Presentation Tips

Pre-Meeting:

- Begin preparation by reading the Consent Form first, should give you a good overview of the study
- 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.
- Contact the PI with any questions.

At the Meeting:

- **Be brief**: Do not read through the entire Checklist. Discuss only important issues as outlined below:
- Provide a 3-5 minute review of key points in your oral presentation:
  - Short description of the study objectives,
  - Identification & recruitment 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, pregnant women, prisoners, adults incapable of consent and IND/IDE status of investigational drugs/devices/biologics; LAR or Declaration of Concordance, NSR determination
  - Recommend stipulations

- **Continuing Review - need to include in the minutes**

  Assess whether the study is proceeding as expected, using information in the progress report
  - Is the number of subjects enrolled ≤ the number approved?
  - Have there been unanticipated problems that suggest a change in risk: benefit?
  - Are there trends in protocol deviations that may need to be addressed?
  - Do monitoring reports or Data Safety Monitoring Committee reports suggest issues that may need to be addressed?
  - Is there new information that changes risk: benefit ratio?
  - Is the consent form adequate and up-to-date?
  - Are there changes requested for the upcoming approval period?
  - Category 9 eligibility
  - Re-consenting subjects needed?

  Make the final motion, including period of approval based on level of risk. Does not have to be 12-months, can be less, i.e., after enrollment of "X" number subjects; or 3, 6 9-months.

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)