Office of Human Research Ethics Training Tips

How to Review & Present Protocols as the Presenter

I. **Pre-Meeting:**

a. Begin early, you could have questions & not be able to get answers your questions soon.
b. Start by reading the consent form, it will give you an overview of the study. If you don't understand it, then subjects won't either. Also, great way to see disconnects between it and the protocol.
c. Call the PI or Coordinator with any questions you have. Include information in your summary, so there is not a need to repeat the same question next year.
d. Only ask for clarification or additional information about a study. **NEVER** direct the study team to make any changes to their study at this point. ***Until the IRB votes on stipulations, there are no changes to be made.***
e. Read the following sections of the study submission or protocol:
    i. Primary & secondary objectives
    ii. Study design
    iii. Recruitment
    iv. Safety Plan
f. Read the Investigational Brochure (IB) for:
    i. FDA information on the Investigational New Drug (IND)
    ii. Study drug pregnancy rating
g. Identify and resolve, if possible, deferrable issues ***PRIOR*** to the meeting. Communicate with the study team or IRB Analyst to reduce the chances of deferral at the meeting
h. **Alert the Chair** of any potentially deferrable or controversial issues PRIOR to the meeting for **ANY** study on the agenda.
i. **Prepare recommended solutions** to controverted issues for presentation at the meeting.
j. **Email your completed checklist by 8am on meeting day to your IRB Analyst who will upload it into IRBIS.**

II. **At the Meeting:**

a. **Be brief**: Do not read through the entire Checklist. Discuss only important issues as outlined below.
b. **Provide a 3-5-minute review of key points in your oral presentation** ***(can be your oral presentation outline & uploaded into the Presenter summary block of IRBIS).***
    i. One sentence description of the study objectives,
    ii. **Short** summary of the study design,
    iii. **Short** summary of risks, benefits,
    iv. Identification of subjects **(is a HIPAA waiver needed to ID potential subjects?)**;
    v. how the consent process will occur,
    vi. If applicable:
        1. evaluate the pediatric risk level and/or appropriateness of inclusion of children,
        2. inclusion of vulnerable groups in the study -- pregnant women, prisoners, adults incapable of consent

3. IND/IDE status of investigational drugs/devices/biologics, remember to consult the information sheet provided by staff

c. Address any conditions of approval, such as:
   i. Legally Authorized Representative (LAR)
   ii. If children in the study, what is your recommendation for risk level and number of parent signatures
   iii. Recommend Category 9 eligibility at the time of Continuing Review to allow future expedited review of the study. If the study is no greater than minimal risk and does not involve an IDE/IND.
   iv. Recommend any stipulations citing specific sections to be modified

d. Make the final motion to:
   i. Approve, including period of approval, approval for LAR or not; child risk level & number of parents to sign the consent
   ii. 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.
   iii. Approve with stipulations
   iv. Defer/Table (**If it does not meet the 111 Criteria: You MUST defer the study!**)
   v. Disapprove

Criteria for IRB Approval of Research

§46.111 & §56.111

(a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

(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.

(3) Selection of subjects is equitable. In making this assessment the IRB should take
research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disable persons, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject or the subject's
legally authorized representative, in accordance with, and to the extent required by §46.116.

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117.

(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.**

(b) When some or all of the subjects are likely to **be vulnerable to coercion or undue influence**, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.