Office of Human Research Ethics Training Tips

How to Review & Present Protocols as the Presenter

Effective September 1, 2016 Required Use

I. **Pre-Meeting:**

a. Begin early, so you have time to get answers to any questions you may have about the research.
b. Reading the consent form first. , 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.
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
    iii. Is this a new drug or new indication or route of administration for an approved drug?
g. Identify and resolve, if possible, deferrable issues ***PRIOR*** to the meeting. Communicate with the study team or IRB Analyst ***early*** 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. **Draft recommended solutions** to controverted issues for presentation at the meeting.

II. **At the Meeting:**

a. **Be brief**: Present key issues as outlined below.
b. **Provide a 3-5 minute review of key points in your oral presentation .**

    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; and
    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. Declaration of Concordance if NIH funded,
    iii. If children in the study, what is your recommendation for risk level and number of parent signatures
    iv. 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.
    v. Recommend any stipulations citing specific sections to be modified. All stips should be entered in the appropriate section.

d. **Make your final motion to:**

i. Approve, including period of approval, approval for LAR or not; child risk level & number of parents to sign the consent and any other regulatory findings as appropriate.
ii. Based on the risk assessment by the IRB, the approval period can be 1-year or less than 1-year or can be less (3, 6, or 9-months), or after enrollment of "X" number of subjects.
iii. Approve with stipulations
iv. Defer/Table (**If it does not meet the 111 Criteria: You MUST defer the study!**)
v. Disapprove

Guidelines for using Reviewer Checklists:

1. Prefer that checklists be completed electronically.
2. If checklists completed electronically, email to IRB Analyst prior to IRB meeting. Checklists will be scanned and uploaded to IRBIS as OHRE attachment following meeting.
3. If paper checklist used, to be collected by the admin assistant **following** presentation. Checklists will be scanned and uploaded to IRBIS as OHRE attachment following meeting.
4. Presenting a study:
    a. Primary/Secondary Reviewer Summary (in IRBIS): Use to summarize study for presentation to committee
    b. Reviewer Checklist: Use to present overall review (concerns)
    c. Complete presentation by reviewing all stipulations entered. Committee to collectively agree to accept, remove or revise each stipulation.
5. *Members should not alter stipulations in IRBIS during the meeting unless requested to do so by Chair.*

- **Initial Application Checklist**
    - Both Primary & Secondary Reviewer need to complete checklist & submit before 8am the day of the meeting
    - Add a stip for any answers with (*), concerns or questions you want to raise with the full board
    - Don't forget to complete the Regulatory Findings on page 3
    - As appropriate, complete the Additional Considerations checklist for:
        - Prisoners
        - Department of Defense Research (DOD)
        - Department of Navy Research (DON)
        - Department of Justice Research (DOJ)
        - Bureau of Prison (BOP) Research
        - Environmental Protection Agency (EPA) Research
        - Department of Energy (DOE)
        - Department of Education (ED)
    - Complete the recommendations section

Renewal Application Checklist: Only the Primary Reviewer completes & submits before 8am the day of the meeting

- **Modifications Checklist:**
    - Only the Primary Reviewer completes & submits before 8am the day of the meeting
    - Should the modification include the addition of a vulnerable population or the addition of one of the sponsors listed below, complete the appropriate checklist.
        - Prisoners
        - Department of Defense Research (DOD)
        - Department of Navy Research (DON)
        - Department of Justice Research (DOJ)
        - Bureau of Prison (BOP) Research
        - Environmental Protection Agency (EPA) Research
        - Department of Energy (DOE)
        - Department of Education (ED)

Email your completed checklist by 8am on meeting day to your IRB Analyst who will upload it into IRBIS.