PLEASE LIMIT PRESENTATION TO 5 MINUTES,
ALLOW ADDITIONAL 5 MINUTES FOR Q&A WITH THE IRB

Guidelines for Oral Presentation of a Protocol to the IRB

Please prepare to discuss the following items with the board. If you have specific questions for the board relating to your study, please feel free to discuss them at this time as well. Once you present your study to the board, the board members will ask you specific questions relating to your study.

a. Objective of the study

b. Rationale for the study: Why is it being done?

c. Research subjects:
    i. Are the subjects considered vulnerable (children, pregnant, elderly, etc.)?

d. Any unusual aspects about the process of informed consent (e.g. subjects will be decisionally-impaired; request waiver of requirement for assent for minor subjects, non-English speaking subjects, etc.)

e. Potential benefits to subjects

f. Potential risks to subjects, with estimated probabilities of risk(s) (e.g., very unlikely, likely, highly likely)

g. Investigator's assessment of the risk-benefit ratio

h. Tell us about the Data Safety Monitoring Board (DSMB) (is there one, who is on it – specific names of individuals or their titles if the full DSMB has not been compiled at the time of presentation). If no DSMB exists, please explain to the board how you plan to monitor the safety of study participants.

i. Please list the steps you intend to follow to educate the study staff on the study protocol and its requirements. (Include how training will occur, i.e. in person, via online module, etc.)

j. Anything else the IRB should know at this time