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"Happy Trials to You"

Ten Questions for an IRB to Ask About the Science behind a Protocol

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While IRB members are not expected to be scientific experts, especially given the broad range of protocols they review, they do need to assess the scientific merits of a protocol to evaluate its suitability for human subjects.

The following 10 questions can assist IRBs in determining whether a study has the scientific merit to justify participation by human subjects:

- 1. Does the IRB have the necessary scientific and statistical expertise on the board or available from consultants to weigh the scientific merits of the study?
- 2. Does the protocol have a clearly stated study question (hypothesis)?
- 3. Does answering the study question have sufficient importance and originality (based on a thorough review of the literature) to justify conducting the study by:
 - a. Creating generalizable knowledge about a disease or medical condition?
 - b. Aiding in early detection of a disease or medical condition?
 - c. Developing a diagnostic method for a disease or medical condition?
 - d. Treating a disease or medical condition?
 - e. Generating new scientific hypotheses that can be tested in subsequent studies?
 - f. Producing some other public benefit?
- 4. Is the study population appropriate to answer the study question?
- 5. Is the size of the study population adequate to generate statistically significant results of public benefit, as demonstrated by sample-size calculations?
- 6. Is the diversity of the study population adequate to answer the study question for the broadest practical range of patients?
- 7. Is the design of the study, including dosing regimens, controls, procedures and tests, sufficient to answer the study question without imposing unnecessary harms, risks or burdens on the study participants?
- 8. Do the investigator and study sponsor have a track record of conducting and publishing scientifically valuable clinical research?
- 9. Is the study likely to yield at least one valuable scientific publication?
- 10. If the study results are negative, will they still have scientific value that merits publication?

Authors

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