

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

By Dennis J. Mazur and Norman M. Goldfarb

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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