

Sixteen Red Flags for the IRB

By Dennis J. Mazur and Norman M. Goldfarb

Before an IRB thoroughly reviews a study, it should ask whether the study's objectives seem realistic, the risks seem reasonable, and the research team seems capable of carrying out the study. If any of the following 16 questions raise a red flag, these fundamental concerns should be addressed before moving on to matters like whether the informed consent describes the risks in clear language, a careful weighing of risks vs. benefits, any particular issues with vulnerable populations, and so on. These red flag issues should be addressed before the IRB performs its detailed review.

Will the study's findings matter?

1. Assuming the investigator completes the study as planned, will it create generalizable knowledge of any significance?
2. Have previous (or current) studies addressed essentially the same hypothesis?
3. Is the study designed in such a way (e.g., with an appropriate study population and adequate statistical power) that the findings will be useful?
4. How likely is it that the study will have a material impact on medical practice?
5. How likely is it that the study will help create knowledge that will support future research that eventually could have a material impact on medical practice?
6. Would negative results be useful?

Do the benefits outweigh the risks?

7. Are the risks clearly much larger than can be justified by the potential benefits?
8. Are the risks too uncertain to even assess?

Is this the right team for the study?

9. Is the study proposal so poorly written that proper conduct of the study is questionable?
10. Has the investigator demonstrated the qualifications and experience necessary to conduct the study, given its risks and complexities?
11. Are the other personnel on the research team qualified?
12. Are support personnel and departments qualified?
13. Will everyone involved give the study adequate attention?
14. How will the study team hold up in the face of problems like serious adverse events or the loss of a team member?
15. How is the situation likely to change over the course of the study?
16. Can any weaknesses be addressed with supervision or assistance from more qualified people?

In answering questions in the first two areas, it helps to be familiar with the science. In answering questions in the third area, it helps to be familiar with people involved. Local IRBs obviously have an advantage in this respect over central IRBs, but even local IRBs might need to consult with site personnel who have direct knowledge of the study team members. If an IRB does not have people qualified to address these fundamental questions, it should obtain assistance.

It is, of course, best to catch any red flags before a study starts, but they can certainly arise during the study and even after the study. After a study is complete, the IRB can do little to protect the participants in that study other than informing them of new information about risks they should watch for. However, post-study red flags can still be useful for future studies and the IRB's review processes in general.

Authors

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