

How can the investigator help the IRB in its scientific review?*

1. Write a clear, concise background and justification section of your protocol. Include discussions (with references) of why this research question is an important one to ask at this time in the understanding of the disease or condition or situation.
2. Write a clear, concise methods section of your protocol, describing how the study question will be answered. Indicate how you plan to analyze the data collected to answer the study question. Justify the number of human subjects you plan to recruit in order to answer the study question.
3. Thoroughly describe what the risks, harms and benefits to subjects are. Honestly assess whether and how the benefits outweigh the risks (Hint: a simple restatement that the benefits outweigh the risks is not adequate!) Describe how you will monitor the subjects to assure their safety, and to be able to identify any harms that may occur. Include a description of your data safety monitoring plan (if applicable).
4. Respond to questions that the IRB asks either prior to its review or after the review, the IRB members are intelligent, and that they may not know your field as well as you do. The reviewers are examining basic concepts, not a peer review. The IRB is simply doing the job that it is charged to do, by the Federal Regulations. The IRB is not questioning your expertise, but rather needs more detail on an aspect of your discipline).
5. Develop and/or participate in a departmental review of science.
6. If you believe that the IRB is lacking in expertise in your particular topic area, consider becoming a member of the IRB or recommending use of a consultant.

* (From Clinical Research Times, *Scientific Review and the IRB* by Susan Fish, PharmD., M.P.H, 2004,
<https://dcc2.bumc.bu.edu/ocr/ClinicalResearchNewsletter/article.aspx?article=24>

*A white paper on IRB review of scientific merit by Michael Shapiro J.D., is being reviewed by the USC faculty senate.