Scientific Review by the Ethics Committee

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Dear Practical Ethicist,

On my review board, we have a lot of discussion about how much "scientific review" we should be doing. Some members feel that if the protocol has been funded through a competitive grant process, the scientific review has already been done and we don't have to worry about it. What is the role of the IRB/IEC as it relates to scientific review?

Signed,

Making a Review Scientific

Dear MARS,

This is a question that a lot of IRB/IECs struggle with.

There are different types of scientific review. One form of scientific review is *peer review*, conducted by funding agencies, journals, and regulatory agencies. The goal is to improve the quality of the science by having other experts in the field critique a scientific proposal or publication, and provide constructive suggestions, recommendations, or requirements for improvement. Any study or publication can undergo additional peer review and become a better study or better publication. Another form of scientific review is *merit review*, conducted by funding agencies and scholarly journals. Merit review is intended to determine how to distribute a scarce resource, which scientific projects deserve tax dollars, or which publications deserve journal pages. The intensity of merit review depends on the availability of resources and the number of scientific proposals or publications competing for those resources.

Neither peer review nor merit review, as conducted by the Food and Drug Administration (FDA), National Science Foundation (NSF), or the National Institutes of Health (NIH), is part of the IRB/IEC's function. The IRB/IEC is not in the business of deciding how to best use scarce resources nor in the business of improving the science of research that meets the ethical standards of the regulatory criteria for approval. Whereas IRB/IEC review is based on specific criteria for approval, scientific peer review and scientific merit review are based on making science better and more useful to society, respectively.

There are those who say that the better the science, the more ethical the research—in other words, the greater the potential scientific benefit, the more ethical the research. However, this leads to the illogical conclusion that to best minimize risk, we should disapprove all research if there is anyone who can come up with a way to make the science better.

The IRB/IEC needs to determine whether the regulatory criteria for approval are met. These determinations are ethical criteria and not scientific criteria. They are judgment calls. They require the IRB/IEC to make decisions about how low a risk is low enough ("minimized"), what is "reasonable," what is "important," what is "equitable," when influence is "undue," and so on. None of these judgment calls is a scientific decision. However, making these decisions requires that the IRB membership know scientific information about the research. This is the *scientific* review required by IRB/IECs.

The first part of scientific review needed by IRB/IECs is the input from one or more individuals with scientific or scholarly expertise in the research who can determine the answers to these questions based on the information submitted to the IRB/IEC:

1. Is there a safer way to perform the research that would still accomplish the research aims?
2. Are there procedures that would reduce subject risks without negatively affecting the research?
3. Does the protocol accurately describe the risks?
4. Does the protocol accurately describe the benefits?
5. Is the protocol likely to yield the knowledge proposed to result?

If the answers to the first two questions are "no" and the answers to the last three questions are "yes," then the investigator has provided the IRB with sufficient information to determine whether the regulatory criteria for approval are met. Otherwise, the individuals with scientific or scholarly expertise can fill in the gaps or guide the IRB on where to get additional information.

Review by an external agency, such as NIH or FDA, might give weight to the fifth question being answered "yes." However, these reviews are unlikely to provide the IRB/IEC with answers to the first four questions, because the review conducted by these agencies is peer review and merit review, and does not answer to the risk, benefit, and procedural questions that the IRB needs to answer to determine whether research meets the regulatory criteria for approval.

In my experience, discussions at IRB/IEC meetings commonly bounce between scientific review/ ascertainment and consideration of the regulatory criteria. The discussion of scientific review/ascertainment may be dominated by the IRB/IEC members with scientific expertise. Too often, scientific members consider their review to

be done once they have explained the science to themselves, and discussion of the regulatory criteria is limited. This leads to several problems. Nonscientific members do not participate in the scientific review/ascertainment and often feel that their role in the ethical review of research is to evaluate the language and consent document. Scientific review ascertains the facts but may not adequately explain the relevance of those facts to everyone around the table, leaving both scientific and nonscientific members disenfranchised. IRB/IEC members decide that criteria for approval are met without sufficient background information or understanding. When ascertaining the facts of the research requires a lot of energy, IRB/IEC members may give insufficient attention to the work of evaluating the regulatory criteria for approval once they have ascertained the facts. Most experienced IRB staff members can probably identify with one or more of these situations.

One way to avoid this problem is to have the IRB/IEC discussion separate scientific ascertainment/understanding from the ethical review. The discussion starts with presentation of an assigned reviewer to answer the scientific questions, and to answer related questions from the Board. Scientific and nonscientific members should freely ask questions so that all members present at the meeting understand what the risks and benefits mean, and know what the procedures involve. After the IRB/IEC ascertains the risks and potential benefits of the research, and the knowledge expected to result, and all IRB/IEC members understand the information, the scientific review required of the IRB/IEC ends. Next, the chair or primary presenter asks the question, "What regulatory criteria for approval, if any, are not met?" At this point, the ethical review begins.

P. Ethicist

Author Biographies

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Jeffrey A. Cooper, MD, MMM, is a physician, basic science investigator, clinical investigator, and manager with many years of ethical review experience as a member and chair of an IRB. He left medical practice in 2002 to help start the Association for Accreditation of Human Research Protection Programs, Inc. (AAHRPP), where he was responsible for the development and operation of the accreditation process. He is currently vice president for Global Consulting at WIRB-Copernicus Group.

Lindsay McNair, MD, MPH, MSBioethics, is a physician, clinical investigator, and former academic IRB member who has spent most of her career working in clinical research for the pharmaceutical and biotechnology industry, with a specific interest in ethical drug development research. She is an adjunct faculty member at Boston University and is currently the chief clinical research officer and president of Consulting Services for the WIRB-Copernicus Group.