A Question of Consent

Question

You are asked to edit a manuscript written by several members of a clinical service and a resident who works with them. You have worked with these authors on previous occasions and know that they write fairly well, so you expect few problems with the manuscript. However, in the methods section the authors state that they have used blood stored from a previous research study in their current analysis, and they do not mention having obtained institutional review board (IRB) approval to do so. When you ask them about it, they say that they didn't think they needed it — that they got approval for the previous study and the current work could easily be viewed as an extension of the first protocol. Would you find it necessary to include a statement to this effect in the cover letter to the journal? Would this be your role, or would you expect and rely on the resident to follow through on conferring with the residency director or an IRB representative?

Solutions

The question here is the nature of the original informed consent. Assuming that the patients consented to use of the blood samples for the first study, were they also informed at that time of any plans to use the same blood for a later study? If the donors were not so informed, IRB approval would be required again. In the unlikely event that the authors have completed their new analysis of the previously collected blood samples and neither the principal author,

the department chief, nor a research director has ensured that informed consent has been appropriately obtained, you may or may not choose to police this matter. If you have advised the authors to seek consultation from the IRB and they want to submit the paper anyway, without IRB approval, on the basis that they consider the consent from the previous study still valid, you can only trust that the authors will follow through at the next stage in the process of bringing research results to publication.

At this point, it remains for the journal reviewer or even the journal's chief editor to note the absence of the IRB statement in the methods section for a study involving human or animal subjects. Once the journal requests that the authors produce the informed-consent document, the situation should become clear and correctable.

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As an author's editor who had worked with these authors before, I would talk with them about what they probably already know: that principal investigators and their coworkers should always think about obtaining consent from their patients. Principal investigators should remember that federal law requires researchers to obtain, through the local IRB, approval of almost all research projects that involve patients. I would remind the authors that the public (and some members of Congress) have accused the medical profession of failing to police itself and that such carelessness, if discovered, might further erode the public's attitude toward scientific research. I would suggest that a simple call to the administrator of the IRB is always appropriate and could have quickly settled whether submission of a new application was necessary.

I would ask the representative author to go, hat in hand, to the IRB and explain why approval had not been requested before the present study began. I would suggest asking the IRB whether approval for this study might be expedited on the grounds that the present research involved prospectively collected residual specimens from a previously approved study. But before going to the IRB, the authors will need to have pulled charts to verify that the amounts of blood drawn were within specified time limits from patients of specified age, weight, and medical condition; they will have had to verify those exact human-subjects research protocol specifications previously with the institution's administrator or chair of the IRB. If they cannot show that those conditions were met, they will probably need to submit a new application to the IRB for review.

Provided that they were still speaking to me, I would tell the representative author one piece of good news: If the research does fall within the expedited categories, such as a project that involved a questionnaire or survey or a previously approved project involving reanalysis of the same data, the IRB will usually move quickly to approve it.

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If the work reported was truly an extension of the initial project and was included in the initial informed consent, there would be no problem. The editor should ask that a statement reflecting IRB review be added to the methods.

If the work was not closely related, IRB review should be questioned, and the authors should furnish some evidence that the IRB has been consulted (such as an amendment or reapproval).

The institution should make investigators aware that use of samples collected for previous research requires some type of IRB review. The IRB would decide whether further consent was necessary or whether consent could be waived for the additional use of the collected data.

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New Question: A Question of Terminology

A physician studies the prevalence among his patients of a common condition that is receiving attention in the popular media. He finds that the distribution of the condition among ethnic groups differs from that previously reported and does not seem attributable to the demographics of the population he is studying. The physician therefore believes that his finding would be useful to others and wishes to publish it. However, the commonly used US Census Bureau designations "American Indian or Alaskan Native", "Asian or Pacific Islander", "Black, not of Hispanic origin", "Hispanic", "White, not of Hispanic origin", and "Other or Unknown" are not sufficiently specific to describe at least 2 subpopulations of the affected patients — one in which all appear to have Irish surnames and another in which all are of Caribbean origin. The physician consults you, an editor, about how to proceed.

The situations described as New Questions in this column are not necessarily based on actual situations, and the ones that are may have been modified to focus the question. Send your responses to the new question to Della Mundy, Kaiser Foundation Research Institute, Department of Medical Editing, 1800 Harrison Street, 16th Floor, Oakland CA 94612-3429; telephone 510-987-3573; fax 510-873-5131; e-mail della.mundy@ncal.kaiperm.org.