

Stanford University School of Medicine
Responsible Conduct of Research
Session 4: Regulatory Basics
Makeup Cases

Please choose one case and write a 3-5 page paper that answers the questions that accompany the case. E-mail your paper to tobinsl@stanford.edu with your name in the subject line. Your paper is due at noon on the last day of class for the quarter.

Case 1

By Sally Tobin

In 1999, Richard Curtin opened a fat envelope addressed to his daughter, who was away at college. In the envelope was a survey from Virginia Commonwealth University (VCU) that was being sent to twins who had been born in Virginia. The survey asked a series of questions, and Curtin was shocked when he noticed that his daughter was being asked very personal questions about him, including whether or not his genitalia were asymmetrical. He felt that the personal nature of these questions was invasive and that the researchers should have recruited him as a study participant and asked him directly if they wanted such information, both to protect his privacy and to enhance their ability to collect accurate information. When he raised his concerns to the VCU IRB, he was told that only his daughter was involved in the study. He then raised the issue with the Federal Office for Protection from Research Risks (OPRR). OPRR conducted an investigation that found problems with the VCU IRB, and all human subjects research by all investigators at VCU was suspended until the problems could be corrected.

Do you think that Richard Curtin was being treated as a research subject for the purposes of the VCU study, even though they did not plan to contact him directly? Or do you think he was just being overly sensitive about his privacy?

Many genetic research studies involve the entire families. Researchers have always requested informed consent from all the family members who were being contacted directly (and assent from children). But what is the appropriate approach for researchers who plan to ask the participants in their study about members of their families? Should they obtain consent from all the family members? Should they give their participants brochures about the study that can be given to family members? What should they do if a family member does not wish to be discussed in the study?

How should benefits flowing from the progress of research be balanced with the concerns of the relatives of research subjects?

Does the kind of information that is requested make a difference? Should consent be requested from relatives about some sorts of information (such as about genitalia), but not for others (such as about whether a family member uses a cane)?

Case 2

By Sally Tobin

You wish to carry out a clinical trial of a new drug for HIV. Animal studies have gone very well, and you believe that this drug will be a real breakthrough in treatment. Because HIV is such a devastating disease, you want to recruit trial participants very quickly. You decide that it would serve a variety of ethical principles if you were to carry out the trial by offering prisoners the opportunity to be participants. Because recruitment efforts would be more focused, the trial would move along more quickly and therefore make the drug available at an earlier date. Prisoners with HIV would benefit from this treatment, and their participation in the trial might help them to achieve parole. You write up an IRB application and submit it to your institutional IRB.

Do you think that your institutional IRB will approve this approach?

What factors might they consider in their deliberations?

Are there potential negative aspects to this clinical trial approach? If so, what are they?

On balance, do you believe that such an approach is viable? Why or why not?