Brian Schrag's Commentary on "Share and Share Alike?"

Commentary On
Share and Share Alike?

In this case, participants in an obesity study agreed to provide blood and DNA samples, given their understanding of the nature and purpose of the study, that the samples and data would be anonymized, that the samples would be used exclusively for this study, and that subjects may withdraw at any time.

The case statement is ambiguous regarding whether the subjects have further explicitly agreed that if their samples are to be used in unrelated research, the individual participants must be recontacted and provide a second consent specific to the new study or whether the case author simply assumes that is an implication of the previously stated elements of the agreement.

If Renee has her way, the subjects in the first research project will be essentially cast as control subjects in a completely different research project. It is important to remember that control subjects in research are still research subjects and the same ethical safeguards should apply to them as to any other subjects. In some cases, although perhaps not this one, the control subjects are subject to greater dangers than the experimental subjects.

It is generally understood that research subjects' informed and voluntary consent can neither be informed nor voluntary if the subjects do not have some understanding of the research project in which they are participating. Since the subjects would not even be aware of the second project, they could not be assumed to understand the study and hence could not be assumed to give informed consent. Nor could they have the option of withdrawing from a project in which they did not even know they were participating. Renee's proposed procedure thus strips them of the minimal ethical safeguards for research subjects. She fails to treat them with the respect due human participants in research. That is also an argument for claiming that there is at least an implicit agreement in the original informed consent that if

their samples are to be used in unrelated research, the individual participants must be recontacted and provide a second consent specific to the new study.

The action of enrolling them in the second study also violates the terms of their original agreement, namely, that their samples will be used exclusively for the original study. If we interpret the case to indicate there was an explicit agreement that if their samples are to be used in unrelated research, the individual participants must be recontacted and provide a second consent specific to the new study, then Renee's action is a violation of their original agreement.

The data are anonymous because anonymity was one of the conditions of giving consent. The irony here is that Renee seems to assume that since the data are anonymous, that justifies the use of data without consent.

It may well be true that it would be more convenient for Renee to use these samples without the subjects' consent rather than to go through the procedure of contacting all the subjects (which may already be a violation of their confidentiality) or do as Jim suggests and obtain anonymous samples from a DNA bank. That it is most convenient does not morally justify doing it, however. There are higher moral considerations than convenience, in life in general, and in research science, in particular. That is one of the things that some scientists in Nazi Germany and in the Tuskegee syphilis study failed to understand and that has led to explicit guidelines on research on human subjects.

For all the above reasons, it is irrelevant if the consent forms are not explicit regarding the use of samples; it is irrelevant that Renee does not intend to "study" the samples; it is irrelevant that she and Jim are in the same lab.

Jim has the benefit of these data to conduct his research as a result of the subjects' agreement. He correctly perceives that he has a responsibility to protect the subjects from anyone who would violate that agreement. It is a responsibility that arises from the moral duty of anyone who gives a promise. That duty is not overridden by considerations of convenience. The moral obligation is even more stringent since the violation of this duty harms not only the subjects but, as a practice, could harm the functioning of the scientific community and all members of society who benefit from such research. His study coordinator is bound by the same duty. Jim acts wisely in suggesting an appropriate alternate action to Renee.