Brian Schrag's Commentary on "A DNA Dilemma"

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A DNA Dilemma

The primary issue in this case is the moral justifiability of using DNA and tissue samples from one study in another unrelated study without the donors' knowledge or consent. It is worth making the point that the morally justifiability of such action is not settled by the fact that Dr. Thomas thinks it is acceptable or that the local IRB may have given its approval. As the Tuskegee syphilis study illustrates, the moral justifiability of a practice in research is not settled by the opinion of the research director of a study or a review board.

Neither is the law a sufficient guide to the moral justifiability of the secondary use of DNA and tissue samples without donors' knowledge or consent. Whether a state determines that it is legal to use DNA and tissues samples in secondary studies without the donors' permission (as does California in some circumstances) or whether the state rules that such use is illegal (as does Oregon), that does not settle the question of whether such activity is morally justified. The domains of law and morality are not necessarily congruent.

This case is similar to another case in this volume. (See "Share and Share Alike, p. 131.") It differs in that Dr. Thomas and perhaps the local IRB have approved the use of DNA and tissue samples in an additional, unrelated study without the donors' informed, voluntary consent. The case also differs in that the consent form in this case does not explicitly specify that the samples will be used only in the original study.

In this case, Fan (and apparently Thomas) plan to use the coded DNA samples as a control in a completely unrelated study. If the donors' confidentiality were breached, they could suffer some harm. There is a tendency to think that the use of the subjects' material as a control provides minimal risk of harm to the donors and hence would be acceptable. That, of course, is not always the case. Suppose,

however, for the sake of this discussion, that the element of risk to the donors is minimal. Would the researchers be justified in using this material in the second study, without the donors' informed, voluntary consent?

The informed consent doctrine rests on several different moral principles, two of which -- beneficence and respect for persons -- are especially relevant here. Informed consent allows subjects to protect themselves from harms from a research activity. But even if there is minimal risk of harm to the subject in a research project, there is another moral justification: Obtaining informed consent is also a recognition of a basic respect for persons and their capacity for free choice; in particular, it respects their right to choose whether to cooperate with a particular scientific experiment.

This moral consideration is independent of considerations of the experiment's risks and benefits. Thus it is morally unjustified for the researcher or the IRB to argue that since the research exposes subjects only to minimal risk, it is acceptable to use their DNA samples as controls in an unrelated study without their informed, voluntary consent. The stringency of the obligation to show respect for the choices of human subjects is not lessened by minimal risk to the subjects in a second study or by the fact that it is convenient for the researchers to use their samples.

The issue could have been avoided if the IRB had done its job and insisted that the protocol of the original research study address the issue of the future use of tissue samples, including giving subjects the opportunity to consent or refuse consent to the use of their tissue samples in any secondary research or indicating that in the event of any secondary studies they would be recontacted and given the opportunity to consent or refuse consent to the use of their tissues in such studies. Such consent may not be morally adequate, but it would at least be a necessary step in respecting the persons serving as subjects in the original research.