Author's Commentary on "Informed Consent for Use of Stored Specimens"

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This case concerns the appropriate use of stored biological specimens from research with human subjects. Parts 1 and 2 describe a scenario in which the investigators have finished their originally planned analyses on the stored samples and now wish to conduct further analyses that were not described when they obtained consent from the participants in the study. This scenario may happen more often today because of the development of new technologies for analyzing biological specimens that were not anticipated when samples were first collected.

In Part 1, Smith's desire to pursue this research area, which could be beneficial to her career, and society's interest in increasing knowledge about the causes of preterm birth are conflicting with the right of the participants to make informed decisions concerning the types of research activities in which they participate. Smith wants to take advantage of a unique opportunity to conduct important research with little additional effort or funding. She fears that a requirement to obtain permission from the participants to do additional analyses of their specimens will make it impossible to conduct the research at all.

The women who participated in the study probably assumed that the biological specimens they provided would not be used for any purposes other than those specified on the consent form. The informed consent process should allow prospective participants in a study to make informed decisions about whether or not to participate in research activities, based on knowledge of the nature and purpose of the study and of its risks and benefits. Some women may not have agreed to participate in the study if they knew it would contribute to knowledge of genetic causes of adverse pregnancy outcomes. They may feel that this type of research could lead to discrimination against groups of people or to less attention to prevention programs if preterm birth is perceived as primarily a genetic problem rather than the result of modifiable factors.

If Smith proceeds with the genetic analysis, she will presumably contribute to knowledge of causes of preterm birth, and she may expect that her reputation as a researcher will be enhanced. However, she may have doubts about whether her decision was ethical. There is a risk that results of the genetic analysis could be linked to the participants individually and threaten their ability to get or maintain health insurance or employment if it is discovered that they are genetically susceptible to preterm delivery. Also, there are possible adverse consequences for Smith's relationships with women who agreed to participate in the original study. If the women find out that their specimens were used for such a purpose without their permission, some of them may feel betrayed by the researchers and may develop a mistrust of scientists and the scientific process. Other members of the public who learn the details of the consent process may also become less trusting of the scientific enterprise, thus jeopardizing public support for science.

Smith has an obligation to fully disclose to women who agreed to be in her study what she intends to do with the samples she collected from them. She should respect the women's rights to make informed decisions regarding their participation in research studies. However, she might argue that the need for informed consent is not the same for research on stored samples as it is for research that more personally involves the participants. In Part 2, Smith raises the possibility of avoiding the need to obtain consent for the genetic analyses by destroying identifiers. Making the specimens anonymous would alleviate many of the concerns about confidentiality. However, even if the specimens are "anonymized," as long as each specimen is linked to other information obtained from the women (for example, age, race and date and site of recruitment), the danger of deductive disclosure remains. When specimens are currently linked to names, the issue also arises of whether it is appropriate to pass up the opportunity to obtain informed consent (by destroying the links). Additionally, as Jones points out, making the specimens anonymous means that the investigators will be unable to provide specific information on the results of the genetic analysis to individual women in the study, or to obtain more information about the women for use in follow-up research.

Several points must be considered regarding whether the investigators should inform women of their individual results. First, it is important to consider the accuracy of a genetic test and how predictive a genetic marker is. In other words, how likely is it that a woman who is determined to have increased susceptibility to preterm delivery will actually deliver prematurely if she becomes pregnant? The

women should be asked, preferably before they agree to participate in the research, whether they would want to receive their specific results. Some women may prefer not to know. If results are shared with the women, counseling would be important. In the specific case of studies on preterm delivery, any specific individual results will not be particularly relevant to women who are past reproductive age or who do not plan to have more children. However, this information may be relevant if the women's children are likely to be at higher risk of preterm delivery.

In Part 3, the scenario is changed to suppose that the investigators anticipated the desire to do genetic research and included a statement in the consent form to that effect. Although this statement is technically accurate, it is quite vague, and it is likely that most participants will not understand that their samples may be used eventually for genetic research. Even if the consent form had informed the participants that the investigators would "look at genes," this phrase may still be inadequate without further explanation of the potential consequences of genetic research. It may be desirable to ask participants whether they agree to have the links between their names and the identification numbers preserved, and, if links are kept, whether they would want to know any specific results concerning genetic analyses. Alternatively, if the specimens were made anonymous, it may be appropriate to ask participants if they agree to have the links destroyed and to inform them that in that case it would not be possible to provide them with specific results.

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