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Informed Consent for Use of Stored Specimens

Year

1997

Description

This case discusses issues in ethics such as treatment of human research subjects, ethical research methods, use of informed consent, privacy and confidentiality.

Body

Part 1

Part 2

Part 3

Part 1

Dr. Samantha Smith and Dr. Joyce Jones have collaborated on an epidemiologic study to identify determinants of preterm birth (delivery before 37 completed weeks of gestation). Over five years, the project team recruited 10,000 women into the study from prenatal care clinics in South Carolina. The study participants provided genital tract, blood and urine specimens, all of which were frozen and stored. They collected a great deal of other information through interviews with the participants and review of their medical charts, including social, demographic, health behavior

and health history information.

All study forms and specimens were coded with identification numbers rather than the women's names. The links between the identification numbers and names were kept locked up and separate from all other study materials.

The consent form signed by the women in the study described in a general way the analyses planned on the biological specimens. For example, genital tract specimens were to be analyzed for the presence of infections, blood samples were to be analyzed for levels of different vitamins, and urine was to be checked for cotinine (a marker of exposure to cigarette smoke).

It has now been five years since the end of data collection for the study, and Smith has become very interested in studying potential genetic causes of preterm delivery. She realizes that this cohort of women, from whom a great deal of information has been collected, provides a unique opportunity to conduct an investigation of her hypothesis with minimal additional work or funding.

Smith is eager to proceed with a genetic analysis using the participants' stored blood specimens. However, Jones is concerned. "Sandy, the consent form that these women signed did not mention the possibility that we might do this genetic analysis. We'll have to contact them again and ask for their permission."

Smith thinks that contacting the women would be too difficult. "But, Joyce, that's unreasonable. You know the logistical challenges we face in trying to find these women -- some of the participants were recruited as long as a decade ago. We should just go ahead with the analysis. It's not that big a deal. It wouldn't make sense to pass up this opportunity."

Discussion Questions

1. Are Smith and Jones obligated to recontact the participants to ask for permission to do a genetic analysis using their specimens?

Part 2

Smith thinks of a way around having to ask the women for permission to do the additional analysis. "Joyce, how about making the specimens anonymous by destroying the links between the names and the identification numbers before we proceed with the analysis? Then we won't need to ask for consent; in fact, we won't even be able to."

Jones doesn't agree. "No, I still think we need to recontact them to ask for their permission to analyze their specimens. Besides, if we destroy the links between the names and numbers, that would interfere with conducting further follow-up studies. And what if we want to give them the results of our analyses?"

Discussion Questions

1. Should the investigators destroy the links between the names and identification numbers before proceeding with the genetic analysis?
2. If they do decide to destroy the links, are they still obligated to recontact the subjects first to ask their permission to do the additional analysis?
3. Do they have an obligation to inform the women of any results of the genetic analysis?

Part 3

Suppose that when the study was originally conceived, Smith and Jones had foreseen the possibility of wanting to conduct further analyses on the subjects' specimens. Therefore, they had included in the consent form the following statement: "If any specimens remain, additional tests may be done for research purposes such as tests to look at factors in your blood that might affect pregnancy or health."

Discussion Questions

1. Does the statement in the consent form provide adequate informed consent regarding the planned genetic analysis?

Notes

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