A DNA Dilemma

Year
2002
Description

This case discusses issues of responsibilities, human subject research ethics and regulations, and responsibility of institutions.

Body

Fan Chen, a new post-graduate researcher in Dr. Thomas's laboratory, is studying the genetics of a neurological disorder. Fan is still learning English and adjusting to a new culture and research environment. Mark Adams, a graduate student in Thomas's laboratory, is studying the genetics of breast cancer. Thomas and Mark have worked very hard to get IRB approval to collect human DNA samples from breast cancer patients and their family members. Through this process, Mark has learned a great deal about human subject research. According to the IRB-approved protocol, blood will be drawn, DNA extracted and samples coded by clinical laboratory technicians with no connection to the Thomas laboratory. The linking identifiers for each sample will be locked in a file cabinet, and only two clinicians, who are not involved in the research study, will have access to the files. This arrangement is intended to maintain the donors' confidentiality and is outlined in the consent form. Thomas's laboratory receives only the vials of donor DNA number-coded with highly visible red tags attached to each tube.

One morning, as Mark enters the laboratory, he walks past Fan's bench and greets him. Something catches Mark's eye. Mark notices the red-tagged tubes in a bucket of ice sitting on Fan's bench. Mark knows that Fan is not working on the breast cancer study. At first, Mark believes there has just been a mistake or a misunderstanding. He explains to Fan that the red-tagged tubes contain DNA
samples collected for use in the breast cancer study. Fan replies that Thomas authorized the use of a small amount of the breast cancer DNA as a control in the neurology study and shows Mark a handwritten note from Thomas that confirms Fan's account.

Mark feels uneasy about this use of the breast cancer DNA. He returns to his desk to review an unsigned consent form he has on file, which is just like the one that every donor signs before participating in the study. He notes that the consent form does not state that the DNA will be used in other studies; however, Mark also notices that the consent form does not directly indicate that the samples will not be used in other studies, either. Mark keeps coming back to the introductory statement of the consent form, which contains the following wording: "...you are being asked to participate in a breast cancer study to test for..." He can't seem to dismiss this statement.

**Discussion Questions**

1. What should Mark do?
2. What is Fan's responsibility?
3. Suppose that Mark ignores Fan's use of the DNA, but later he hears that Fan is planning to publish a paper based on some of the results he obtained from the use of the DNA. Does this development change what you think Mark should do?
4. What if Mark ignores Fan's use of the DNA and Mark hears nothing of it thereafter?
5. What are the institution's roles and responsibilities?

**Notes**

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**Contributors**

Brian Schrag

**Editor(s)**

Brian Schrag

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**Case Study / Scenario**