

Stanford University School of Medicine
Responsible Conduct of Research
Session 6: Tissue Use
Makeup Cases

Please choose one case and write a 3-5 page paper that answers the questions that accompany the case. E-mail the paper to tobinsl@stanford.edu with your name in the subject line. Your paper is due at noon on the last day of class for the quarter.

Case 1

By Sally Tobin

A physician researcher has spent many years gathering tissue samples from women with breast cancer. All donors gave permission for their samples to be held in a tissue bank to be used to investigate causes of and treatments for breast cancer. The researcher has been offered a faculty position at another academic medical center and wishes to take the tissue bank with him. He reasons that the participants, most of whom were his patients, donated their samples for his research. His current institution disputes this plan and says that the tissue bank must remain there. Many of the tissue donors write letters supporting their desire to have their samples go to the new institution with the researcher, rather than remain at the current institution.

Who are the stakeholders in this situation?

Does the researcher have a say in the location of a tissue collection?

What if the tissue bank has been funded by an ongoing federal grant that the researcher will move to the new institution?

What if the tissue bank contains samples from several researchers and has been used for many different projects directed by other investigators?

Should the wishes of the tissue donors influence the location of the tissue bank?

How would you balance the interests of the various parties?

Case 2

By Sally Tobin

A commercial tissue bank has a valuable collection of tissue samples from patients with prostate cancer. The bank has followed appropriate procedures for its IRB to review requests for tissue and collection of new tissue samples. All of their samples are labeled only with random number codes, and no personal identifying information is released to those who request tissue samples.

A researcher requests 150 prostate cancer tissue samples from the bank. The researcher plans to carry out a pilot study that will involve immunostaining of tissue sections to determine whether certain proteins encoded by genes located on the Y chromosome are expressed in the samples. The researcher also plans to look at the Y chromosome subtypes to see whether some might be overrepresented in prostate cancer patients, compared with their prevalence in the population.

Because the tissue samples are small, the researcher uses his own DNA and samples from male members of his laboratory to work out the genotyping techniques and as controls in each experiment. Suddenly he realizes that the Y chromosome profile of one of the donors matches his own exactly, and that the tissue donor may be related to him. He realizes that he may have the technical ability to identify the donor.

What should the researcher do at this point?

Should he notify anyone?

Use of the tissue samples was not considered human subjects research. But now that at least one sample may be identifiable, does that change the status of his project?

How can he proceed to carry out his project without generating identifiable information about additional tissue donors?

What should prospective tissue donors be told about risks to their confidentiality?

Case 3

By Sally Tobin

A medical student is doing a rotation in a research lab and is genotyping DNA samples for mutations that are associated with adult onset loss of hearing. The mutations are dominant, so on average, half the offspring of an affected person will inherit the mutation and will experience symptoms of the condition as they reach middle age. The student has been interacting with the affected patients and their family members to draw blood for DNA samples. One of the donors is still too young to show symptoms, and he asks the student to tell him whether or not he will be affected. The student reasons that the test is pretty straightforward, so he tells the donor that he does carry the mutation. The donor then wishes the student to test his young daughter. The student mentions this to his advisor.

As the student's advisor, what concerns do you have?

What do you tell the student?

Should the daughter be tested? Should her father be given the results?

Would it make a difference if there was a treatment that would be effective if administered during childhood?

If the results are to be released to the father, how should this be handled?