**Module 5 Activity: Data Ownership**

**Read and complete these cases from the U.S. Department of Health and Human Services, Office of Research Integrity Columbia University, Responsible Conduct of Research Course Portal. Course 6: Data Acquisition and Management** <http://ori.hhs.gov/education/products/columbia>

**Case Study 1: Share and Share Alike?**

Jim is a graduate student in the department of genetics. For his thesis research, he is mapping a gene involved in blood-sugar homeostasis. His work is part of a larger, multi-center study of the genetics of obesity. The larger study involves several thousand patients and includes information such as socioeconomic class, self-identified ethnicity, activity level, weight, and other medical data. Blood and DNA samples are maintained in Jim's lab along with a database that links unique identifiers - but not patient names - with the data. The study coordinator at each site has access to the encryption key; however, the students and other researchers working on the project do not. Researchers may use the database to retrieve and enter data pertaining to the samples, but they cannot learn the identity of the individuals in the study.

The subject/patients involved in the study were recruited at various study sites. On first contact with a potential participant, a genetic counselor explains the study and arranges for a meeting to begin the informed-consent process. During this meeting, participants learn about the aims of the project, their role as subjects, and the risks and benefits involved in participation. The consent forms state that blood and DNA samples and the resulting data will be anonymized, that subjects may withdraw at any time, and that samples will be used exclusively for this study. If individual participants' samples are to be used in unrelated research, they must be recontacted and they must go through a second consent process, specific to the new study.

Jim's project involves a subset of several hundred samples from the obesity study. One day, Renee, one of the other graduate students in the lab, approaches Jim and starts asking questions about the samples he's working with. She explains that for her work on sickle-cell anemia and mutations in a hemoglobin gene in African-Americans she needs 50 ethnically matched control samples. Since Jim has access to such a large collection of samples, Renee asks if she can take small aliquots of some of his samples from the obesity study. She tells Jim that she will not be looking at disease in these patients and is not really doing a "study" on them. She just needs them as controls, and she doesn't even need that much DNA. "Which box are they in?" Renee asks, as she heads for the freezer. Renee was standing at the freezer with the door open when Jim said, "I'd be happy to tell you more about our samples, Renee, but you had better talk to Jane, the study coordinator, about getting consent from the obesity-study participants if you really want to use them for your study." He went on, "Another option, which might be faster, is to just order a set of anonymous samples from a commercial DNA bank. It would really be a pain to recontact all of those people just for a set of controls."

***This case was adapted from Schrag B, "Share and Share Alike?" Research Ethics: Cases and Commentaries. Volume 6, Section 7. Brian Schrag, ed. Association for Practical and Professional Ethics Bloomington, Indiana, February, 2002. Prepared under NSF grant No. SES-9817880***

**Case Study 2: Who Owns Research Data?**

Jessica Banks, a Ph.D. student working with Professor Brian Hayward, a sociologist studying urban sprawl, has recently defended her dissertation and is now ready to file it and leave for her new job. During her second year, when starting research with Hayward, Banks divided her time among three projects. Then, in her third year, after consultation with Hayward, she decided to continue and expand upon one of the three lines of investigation for her dissertation research. This was also the project most closely related to Hayward's grant at the time. Later, Banks's experimental plan and early results were included in Hayward's grant renewal. The other two promising lines of research were left incomplete. Banks's new job is a tenure-track position in a midsize Western liberal-arts college.

Shortly before leaving for her job, Banks comes to Hayward's office to make copies of research data stored only on Hayward's computer using special software, which she also plans to copy. Although her new faculty position will place a heavy emphasis on teaching, she is looking forward to continuing to do some research as well. In particular, she is eager to pick up where she left off with the two incomplete projects she worked on earlier. Hayward comes in as Banks is downloading her material, and asks her what she is doing. She tells him, and he then says to her that she cannot take the data. "They belong to me," he says. Banks is confused. "But I did the work, and I wanted to follow up on it. I can't do that without the data." Hayward is adamant. "I'm sorry, but you should understand this. Our research project was a joint enterprise, and all the work you did was funded by money I brought in via grants. The data do not belong to you or to me; they actually belong to the university, and the work will be continued with other students. I've already talked to one of the new students about working on those projects this fall." Banks, seeing her plans fall apart around her, protests, but Hayward is implacable.

After a few minutes, she stalks away. Later that afternoon, Banks gets together with her classmate Paul Larson, and she tells him about her run-in with Hayward. "Look," Larson says. "Hayward has no right to deny you access to data. You did the work that generated all the data." "I know!" Banks says. "But Hayward wouldn't listen to that argument when I made it." "Here's my suggestion," Larson says after some reflection. "Just stop by his office and copy it sometime during the weekend. I happen to know Hayward will be out of town, so he'll never know. That's the fair thing to do." Banks seems uncertain, but she says she'll think about Larson's suggestion and decide before the weekend.

***This case was adapted from “The Jessica Banks Case”. Moral Reasoning in Scientific Research: Cases for Teaching and Assessment. Developed by Muriel J. Bebeau, University of Minnesota with Kenneth D. Pimple, Karen M.T. Muskavitch, Sandra Borden, and David H. Smith, Indiana University. Indiana University, December 1995, pages 21-29. Developed for project entitled “Teaching Research Ethics: A Workshop at Indiana University.”***

Questions

1. Why are data held in such a way that certain individuals working on a research study do not have access to personal information about the material?
2. What is a consent form?
3. What does it mean to have data anonymized?
4. Why shouldn’t Renee be able to use the samples, since she is not studying any disease associated with the blood samples?
5. What other options does Renee have besides ordering anonymous samples from a DNA bank?

Case 1: Questions for Further Reflection

1. Do you know the procedures involved in collecting data with human subjects? If not, how would you find out?
2. Why should we protect data collected from human subjects?

Case Study 2: Who Owns Research Data?

1. Who owns federally-sponsored research data?
2. How could this problem of access to the research notebooks and manuals have been avoided?
3. Under what conditions should copying of data have been done?

Case 2: Questions for Further Reflection

1. Are there ways in which you do not treat data as if it belonged to the academic institution, with the principal investigator as the steward?
2. Are the policies of data ownership clearly defined in research projects in which you are engaged?