Mishandling of Research Data

Two lawsuits against Arizona State University allege that research subjects’ blood samples were mishandled and that additional studies were done without the donors’ consent. Northern Arizona’s Havasupai Tribe and 52 individual tribe members filed the lawsuits totaling $75 million against Arizona State University (ASU), the Arizona Board of Regents, and three ASU professors in 2004.

ASU researchers developed the original project in 1989 to study the prevalence of diabetes in the Havasupai Tribe. The study consisted of three parts: diabetes education, collection of blood samples, and genetic testing to identify which genes in the Havasupai caused diabetes. The 180-plus tribal members, who donated blood samples in the early 1990s, say that they gave blood specifically for the diabetes project and that they did not give informed consent to any other research.

In 2003, following allegations that a student’s research included the unauthorized use of Havasupai blood samples, ASU commissioned an independent investigation.

The independent investigator discovered that unauthorized studies, experiments, and projects involving the Havasupai blood samples had been conducted by various universities and laboratories throughout the country. The studies resulted in at least 23 scholarly papers, articles, and dissertations, 15 of which dealt with subjects that had nothing to do with the original study, diabetes. Instead, those papers focused on schizophrenia, inbreeding, and theories about ancient human population migration to North America.

The Havasupai lawsuits claim that it was a lack of oversight by ASU’s Institutional Review Board and violation of federal law that allowed the unauthorized studies using the blood samples to occur. The two federal lawsuits were combined and transferred to the Maricopa County Superior Court last November. You can read more about this case at www.irbforum.com/forum/read/2/54/54.

IRS Regulations on Compensation of Research Participants

IRS regulations require that compensation to research participants be documented and that compensation in excess of $75 per participant be reported. These regulations create challenges for researchers because of the potential impact on the recruitment of research participants.

The Controller’s, Purchasing, and Research Assurances offices are working to find ways to help researchers deal with these regulations.

The Controller’s Office has introduced a new standardized Research Participant Receipt Form (RPRF). The form is required to document receipt of payment, regardless of the payment type or amount. The form will be confidential and not imaged into public records. Participants will complete the forms with their contact information and signatures. They will also need to provide their social security numbers if they receive compensation worth $75 or more. Additional details are available at www.controller.iastate.edu/controller/what_new.htm.

If you have a currently approved study that will require social security numbers for future payments, you will need to update your informed consent document. Please submit your updated document to the IRB with the Continuing Review and/or Modification Form. It will be reviewed as a minor change and will not require full-board review. If modifying your consent form will make it impracticable to complete your study, please contact the ORA to discuss the possibility of a waiver. Letters of introduction or informational documents for studies declared exempt by the IRB do not need to be changed.