

Stanford University School of Medicine
Responsible Conduct of Research
Session 5: Human Subjects
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

In 1979, a research team conducted a survey about alcohol use in the Inupiat community of Barrow, Alaska. A total of 88 Inupiat were interviewed about their attitudes and values about the use of alcohol, and their psychological histories (including drinking behavior) were obtained. The study was to focus on alcohol use, detention, and the nature of social change in Barrow, and was initiated by the Director of Public Safety for the North Slope Borough because he was very concerned about the incidence of traumatic deaths due to alcohol use in the community. The researchers worked with several Inupiat community groups as they carried out their study.

Following data collection and submission of a draft report, divergent views from several different segments of the community emerged. The draft report was sent out informally, and was denounced for its “cultural imperialism.” The researchers were asked to participate in reporting the research results to the community. In the midst of this process, the conclusions of the study were picked up by the New York Times under the headline, “Alcohol plagues Eskimos.” The UPI International Wire service entitled its story, “Sudden wealth sparks epidemic of alcoholism.” The Director of Public Safety was fired. As a result of the adverse publicity, the community’s ability to issue bonds to finance public improvements was adversely affected.

Were individuals harmed by the research study? Was the community harmed by the research study? How could these harms have been prevented?

In retrospect, how might the researchers have avoided or reduced the national and international negative social outcomes of the research study?

How can researchers be sure that they are reaching all segments of a complex community during a study’s design phase as well as during the release of results?

Case 2

By Sally Tobin

You are a researcher studying a relatively rare genetic condition, and several families have participated in your research program. You have collected and analyzed blood and tissue samples from both affected and unaffected family members, and you are now ready to publish your work. You have had IRB approval for your study and have received informed consent from everyone who participated in the study. In each family, there were a few family members who declined to participate for different reasons. You have written up the paper for publication and have given the manuscript to one of your coauthors for review.

Your coauthor asks you if it is appropriate to publish the family pedigrees in the article. She is concerned that the pedigree diagrams include family members who chose not to participate in the study. In addition, she mentions that the genotypes of participating family members are noted on the pedigrees, so any family member could learn his or her own genotype, as well as those of their relatives, by looking at the published article.

Is it appropriate for the researcher to publish the pedigrees? What are the arguments in favor of publication?

What about possibly modifying the pedigrees to mask the identities of the family members? What are the pros and cons of this approach? If the pedigrees are masked, should there be a statement in the article about the modifications?

If the researcher feels that the pedigrees should be published without modification, should he seek consent for publication after showing the pedigrees to the family members?

Some journals require approval from the institutional IRB before pedigrees are published. Does this seem reasonable to you? Is this something that can be monitored effectively by the journals?