

The Protection of Human Subjects in Anthropological Research.

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Quiz:

- a) *Professor Cattivo is beginning a new project, interviewing Latin American domestic workers in Boston on their transnational ties to their homelands. "I don't have to present my research to my university's Institutional Review Board (IRB) since it is ethnographic, not biomedical, and clearly exempt from the regulations." Is the professor right?*

- b) *Graduate student Vabene is about to leave for Africa to conduct her dissertation research on tourist art sold in airports. "I don't have to present my research to my IRB since it is part of my education." Is the student correct?*

- c) *Professor Scrivamolto and his students are frustrated. They are eager to begin their classroom project of ethnographically interviewing exotic dancers at the local nightclub on gender roles and sexuality, but the IRB chair, in an informal conversation, advised them against presenting the project for approval. The chair said the IRB would be concerned that the research could embarrass the dancers, who are all also students, and would not be likely to approve it. Was the chair acting in accord with the regulations?*

- d) *Professor Parola is really upset. She is in the third year of her NSF-supported sociolinguistic research on Japanese children's use of verb tenses for everyday activities, asking questions like "How would you say 'the pencil fell from the desk'". Dr. Parola just changed universities and her new institution is insisting that she have a Japanese IRB review her research, and that she get signed informed consent from the parents of the children in accordance with Subpart D of the regulations. Neither her old institution nor the funding agency required these things. The consent form suggested by the IRB is full of vague alarms more suitable for biomedical problems, and she is concerned that the form itself will frighten away potential respondents. What should the researcher do?*

If you answered that A and B are wrong, you are correct. While much ethnographic research, like much of social and behavioral research in general, can be exempt from the regulations, the researcher has a clear conflict of interest in making that determination. Institutions should have an independent authority make the decision. While classroom exercises are normally exempt from federal oversight, the research involved in a dissertation should be reviewed as research by the institution to make sure it follows institutional regulations.

Example C is about a course requirement and not about human research intended to advance knowledge through publication. While coursework is not covered by the regulations, many institutions extend their implementation to cover a wider range of research activities than the policy calls for. This review should be reasonable and should follow the principle that oversight of research should be commensurate with real risks of harm to human research participants ("subjects"). People who perform in public, like the respondents in C, expect to be observed. The IRB should make sure that the normal confidentiality of respondents is respected without

preventing the research from progressing. In this case the chair was improperly interpreting the regulations by being excessively strict.

How about poor Professor Parola? This case is more complex, and requires a bit more information to comprehend. Two issues are raised, that of parental consent for research with children, and the requirement for foreign IRB review. The federal government's human subjects regulations are known as the "Common Rule", which is actually "Subpart A" of a total of four parts: Subpart B pertains to research involving fetuses, pregnant women and human in-vitro fertilization; Subpart C pertains to research with prisoners; and Subpart D pertains to research involving children. The subparts contain additional, stricter informed consent provisions. The Department of Health and Human Services (DHHS) has adopted the subparts, but the National Science Foundation has not. Therefore the first institution was following the regulations by not demanding additional protections, especially in light of the innocuous nature of the research which involved no harm to the participating children.

However, many institutions have signed "Assurances" with DHHS in which they agree to apply the regulations, including all the subparts, to all research conducted under their name. Under the new "Federal Wide Assurance" that will replace the older "Multiple Project Assurances", institutions will be free to suit the level of oversight to the cognizant (i.e., funding) federal agency's custom. Research like Dr. Parola's, which is funded by an agency which has not adopted Subpart D, need not be subject to these extra provisions. They do not afford any extra protection since there is not much risk of harm to protect against in the first place.

How about the need for a foreign IRB to review research conducted in a foreign setting? This makes sense for biomedical research, since the risks are usually more substantial than they are for social and behavioral research, and IRBs are likely to exist. Even where a foreign IRB exists, they often refuse to deal with social science. The regulations mention foreign IRBs but place the primary responsibility for review with the US institution receiving the federal funding. That institution's IRB has the responsibility to get the appropriate expertise to review the research.

The regulations seem complex and daunting, but in fact they allow a fair amount of flexibility. That assumes they are administered by people with common sense who understand that research is a public good, and should not be impeded without a clearly defined risk of harm. The National Science Foundation is preparing an extensive guidance document on these issues, which will soon be posted on our web site, <http://www.nsf.gov/bfa/cpo/policy/guidance.htm#human>.

Glossary

The Common Rule: The federal regulation governing the protection of human subjects in research. Sixteen federal agencies have agreed to implement this rule in a cooperative, coordinated fashion. It is available as Subpart A at <http://ohrp.osophs.dhhs.gov/> under "Policy guidance".

Federal Wide Assurance: A contract signed with DHHS by institutions affirming that they will abide by the human subjects regulations. It allows institutions to apply the Subparts selectively, depending on the agency funding the research and the level or risk to subjects.

OHRP: Office of Human Research Protection, the most powerful government watchdog office over human subjects in research. Housed in the Office of the Secretary of HHS.

<http://ohrp.osophs.dhhs.gov/>.

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