

## Human Subjects protections and anthropology

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*In a letter dated September 22, 2003 the Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP) stated that oral history interviewing activities “do not need to be reviewed by an institutional review board (IRB)” because it does not involve the type of research defined by DHHS regulations.*

*“Free at last from IRB control!” exults anthropology Professor X. “Since cultural anthropology uses open-ended interviewing like oral history, then my research is excluded from IRB oversight also!”*

Is Professor X right? Is cultural anthropology research free from human subjects oversight? Should it be? This article presents my views on this particular issue and on the general topic of human subjects protections in cultural anthropology research. It gives my personal opinion based on ten years of activity as the human subjects specialist at the NSF, and with the Human Subjects Research Subcommittee (HSRS), a government-wide interagency coordinating committee housed in the Office of Science and Technology Policy.

### The Human Subjects Protection System

First let's understand some basics about human subjects protection.

- Everyone involved in research – researchers, research assistants, institutions and funding agencies – should actively foster an “**ethical climate of research**”. This implies, above all, the cardinal rule of human subjects protection: **No one should be harmed because they were involved in research**. This entails two things:
  - The risk of harm in the project's research design must be assessed and minimized, and
  - Research participants (“subjects”) should exercise **informed consent** to understand and accept such risks as are involved in the research.

Practically all universities and research organizations in the US have agreed to follow a set of regulations called “**The Common Rule**” (technically, “Federal Policy for the Protection of Human Subjects”, DHHS' 45 CFR 46 or the equivalent regulations for other federal agencies). The regulations specify how institutional review boards are to be operated; while they specifically apply only to federally funded research, most institutions have voluntarily extended their coverage to all research. So individual researchers have no choice in the matter. You must follow the federal regulations because your employer requires you to (and, after all, your institutional identity legitimizes you to your respondents). Following the regulations makes you a participant in fostering ethical research, and also gives the researcher a measure of protection from potential criticism that the research might ignore the welfare of participants.

The Common Rule has a history born out of the atrocities of the Nazi concentration camps of World War Two, and is focused on biomedical research. I recommend the article by Eleanor Singer and Felice Levine summarizing the recent developments (2003). Up to a few years ago universities interpreted these regulations as primarily applying to biomedical research, keeping a minimal burden of oversight on social and behavioral science research. More recently institutions have tightened their IRB procedures, instituting new requirements for training of researchers and staffs, all of which can become an impediment to anthropological researchers. Many of us have heard “horror stories” of innocent researchers being delayed for months while they tried to satisfy impossible IRB demands, such as for written informed consent documents in impractical circumstances. Thus the oral history ruling seems to many to be a dream solution, something we could use as our very own “get out of jail free” card. Before we attempt to pursue this goal, let’s look at the ruling a bit more closely.

### **The OHRP statement on Oral History**

The Common Rule defines research as a “a systematic investigation ... designed to develop or contribute to generalizable knowledge.” The DHHS developed its ruling on oral history in response to an appeal from the Oral History Association, which defined oral history as a “method of gathering and preserving historical information through recorded interviews with participants in past events and ways of life”. The Oral History Association appeal went on to say that “... *unlike researchers in the biomedical and behavioral sciences they [oral historians] do not reach for generalizable principles of historical or social development, nor do they seek underlying principles or laws of nature...*”. The OHRP letter concurs with this definition of oral history, stating that “...*oral history interviewing activities, in general, are not designed to contribute to generalizable knowledge and, therefore, do not involve research as defined by DHHS regulations...*”.

Does cultural anthropology want to define itself as unconcerned with seeking generalizable knowledge and underlying principles that explain observed behavior? That would be a vision of the discipline at odds with most people’s understanding of anthropology’s mission. “*But it frees us from this noxious oversight by IRBs*” Professor X might argue. Is the tradeoff of our scientific heritage as a field that seeks to create generalizable knowledge worth the avoidance of IRB oversight? Let’s think about some basics:

### **Research participants in cultural anthropology can be harmed**

Respondents can be harmed, even die, because they were involved in cultural anthropology research. For example, several years ago I read a research proposal for a study of political behavior and attitudes in Chiapas, Mexico. Chiapas is the site of the 1994 Zapatista armed uprising, and subsequent internecine violence such as the 1997 Acteal massacre of 46 indigenous men, women and children by indigenous thugs. Some villages in the area contain supporters of diverse political parties, armed and at odds with

one another. If the researcher documented a respondent's political activity in favor of one faction, and this information became available to extremists in an enemy faction, it is not far-fetched to imagine that the respondent's life would be put in danger. **We cannot foster an ethical climate of research by asking for a blanket exemption for all anthropological research.** While the chance of harm may be lower overall for anthropology research as compared with biomedical research, that does not mean that the chance of harm is always negligible. Each project must be examined on its own merit.

*“OK, I see that attempting to claim an exclusion on oral history grounds would violate anthropology's historical sense of mission” Professor X might say. “I also agree that sometimes, rarely, people can actually be harmed through their involvement with cultural anthropology research, and that institutions have the right to oversee the research of employees. Does this mean that we have to accept the current system where cultural anthropology is subject to the issues and standards of biomedical science?”*

### **Interpreting the Common Rule in a Sensible Manner for Social Science Research**

The existing regulations, albeit written mainly to pertain to biomedical research, are actually not that restrictive of social science research. They must be interpreted with sensitivity and common sense, understanding that the regulations were written for the normal situation of clinical research in the US. Cultural anthropologists must educate IRBs that behavior in a clinical setting, where the subject goes to a doctor's office as a supplicant for health care and is asked to participate in research, differs in systematic ways from behavior in an ethnographic setting, where the researcher is a guest on the respondent's home ground. The anthropologist is most often the supplicant, appealing to the respondent for help in documenting local life. While respondents may be paid for their time, these payments are more like reciprocal gifts than wages. In general the anthropologist, while often of higher status than respondents, is still normally a guest in the study community, dependent on the help and generosity of respondents to accomplish the research goals (if not also to house and feed oneself). Thus the request for a signature on an informed consent document would be unprecedented, rude, and actually threatening in many ethnographic situations. The point is, **ethnographic respondents maintain the freedom to engage or disengage from research activities without an inappropriate and in most cases obstructive informed consent form.** This of course in no way absolves the anthropologist from clearly stating the goals of the study and discussing with respondents the publication plans, data management and identity protection strategies as appropriate.

Both IRBs and anthropologists need to educate each other. IRBs should make it clear that:

- **Individual researchers are not free to exclude or exempt themselves from regulatory oversight.**

A researcher has a conflict of interest in excluding the project from IRB oversight. Some institutional authority should review the project to assess whether it is appropriate with the institution's mission. The Common Rule defines a category of research as “exempt”

from the policy, but an institutional official must make the declaration of exemption. The real meaning of “exempt research” is that the project is free from the need for continuing IRB oversight (every 12 months), not that it is free from any oversight.

Anthropological researchers should make sure their IRBs understand that:

- **IRBs have clear authority in the Common Rule to allow oral or situational informed consent.**

Section 117.c of the regulations discusses the waiver of written consent, *either* if the consent document would be the only form linking the subject and the research and if the risk of harm would derive from the breach of confidentiality; *or* if the research is of minimal risk and signing a consent document would be culturally inappropriate in that context. Section 116.d authorizes research with vastly different consent procedures, or no formal consent entirely, if the research is of no more than minimal risk; the change in consent procedures will not hurt the respondents; and the research could not “*practically be carried out without the waiver or alteration*”. A reasonable interpretation of this section allows such normal anthropological procedures as:

- **Implied or Situational consent:** whereby the nature of the situation the respondent is free to converse or not with the researcher, to tell the truth or otherwise, and is free to determine the level and nature of the interaction between participant and researcher. In many ethnographic situations the proffer of a printed form is in and of itself full of threat and danger for informants and by instilling fear and doubt creates harm instead of ensuring informed consent. The fact of the conversation is most often the concrete proof of consent. This is of course also the case in most surveys, telephone or in person, where the researcher contacts the respondent who is free to continue the conversation or break it off and continue with their normal activities.
- **Community consent:** the situation where some community authority must approve the research before any individual community member is asked to participate (otherwise the approached individuals may be at risk of sanction for engaging in anti-community activities).

Is there a role for the American Anthropological Association to defend the interests of cultural anthropologists in the IRB arena? I suggest two things:

- **Develop a list of anthropological research techniques that normally would qualify for expedited review.** The HSRS is currently examining the provision of new guidance for IRBs on expedited and exempt review, and would welcome the professional advice of the AAA. This advice should build on the material in the recent publication of the National Research Council, *Protecting Participants and Facilitating Social and Behavioral Sciences Research* (Citro, Ilgen and Marrett, 2003).
- **Support a design for an anthropologically sensitive human subjects protection system.** This system would be based on several assumptions:

- Research is a national good, which improves human life. Therefore, research should not be impeded without a good reason.
- Research with human participants is a privilege, not a right, and institutional identity legitimizes the researcher, thus institutions have the right to evaluate the research of members to ensure that policies are followed, and researchers cannot declare themselves exempt from policy.
- The weight of bureaucratic oversight should be related to the level of risk of harm (the probability of the harm as related to the severity of the harm). High probability but low magnitude harms, like uncertainty, mild embarrassment or boredom, are often part of daily life and not worth limiting research to ameliorate. Therefore, each research project should be examined for a risk of harm to participants, and research should not be impeded to address minimal risk activities.

Finally, all participants in the human research protection system should work to educate each other and the public about the value to society of research and the importance of ethics in research. Deception in research should always be justified and examined carefully but reasonably for potential harm to respondents. IRBs should schedule educational briefings for researchers and research departments on a regular basis, and researchers should join their IRBs. Service on the IRB is the single best way for anthropologists to improve the human subjects protection system to make it better for anthropological research.

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