Ethnographic Research and IRB-SBS Protocols

INTRODUCTION

The Department of Anthropology has drafted the following guidelines intended to help inform the process of IRB oversight of ethnographic research for the purposes of the ongoing research of our department faculty and students.

WHAT IS ETHNOGRAPHY?

The AAA statement on Ethnography and Institutional Review Boards (2004) provides a useful working definition:

_Ethnography involves the researcher's study of human behavior in the natural settings in which people live. Specifically, ethnography refers to the description of cultural systems or an aspect of culture based on fieldwork in which the investigator is immersed in the ongoing everyday activities of the designated community for the purpose of describing the social context, relationships and processes relevant to the topic under consideration. Ethnographic inquiry focuses attention on beliefs, values, rituals, customs, and behaviors of individuals interacting within socioeconomic, religious, political and geographic environments. Ethnographic analysis is inductive and builds upon the perspectives of the people studied. Ethnography emphasizes the study of persons and communities, in both international and domestic arenas, and involves short or long-term relationships between the researcher and research participants._

Multiple methods are used in ethnographic research. These include but are not limited to the following:

_unobtrusive direct observation, participant observation, structured and unstructured interviewing, focused discussions with individuals and community members, analysis of texts, and audio-visual records. Ethnographic methods can be employed in non-traditional ways in interdisciplinary projects that bridge the sciences and humanities. The complexity and length of ethnographic research engenders an approach to ethics that is both dynamic and flexible. The process of obtaining informed consent may be continuous and incremental throughout the course of the research, and review of consent obtained may be periodic_ (http://www.aaanet.org/stmts/irb.htm page 1).
RISKS vs. BENEFITS OF ETHNOGRAPHIC RESEARCH

The AAA therefore recommends the following with regard to IRB review:

*Review of ethnographic research should be commensurate with the level of risk of harm vs. the potential benefits of each specific research project. The review should consider the likelihood or probability of harm, the severity of harm, and the duration of harm. Each project should be examined on its own merit.*

Unlike experiments and trials in clinical settings, which have clear beginnings and endings, ethnographic research generally is ongoing, at times sporadic, and takes place in dynamic, natural settings, often where participants are able to decline to participate at any point in the process. Just as in daily life, in these natural settings of research there may be a high probability of risk, but the magnitude of such harm, like uncertainty, mild embarrassment or boredom, is usually low. There are, however, instances where the possible magnitude of harm could be high, often in conflictive environments. IRBs should consider the social and cultural environment of each research project, the physical, psychological and political status of the research participants, and the complex power relationships between researchers and participants in particular situations ([http://www.aaanet.org/stmts/irb.htm](http://www.aaanet.org/stmts/irb.htm) p. 2).

ETHNOGRAPHIC RESEARCH AND EXEMPTIONS FROM IRB REVIEW

According to Common Rule ([section 46.101(b)](http://www.aaanet.org/stmts/irb.htm)) certain categories of research may be exempt when:

- “Conducted in established or commonly accepted educational settings, involving normal educational practices;”
- it involves, “the use of educational tests, survey procedures, interview procedures or observation of public behavior” unless the information recorded is individually identifiable and such research poses a risk to informants;
- it involves, “the use of educational tests…survey procedures, interview procedures or observation of public behavior” where the participants are elected or appointed public officials or candidates for public office, or federal statute requires confidentiality of identifiable information;
- it involves the collection or study of existing data, documents, records “if these sources are public or information recorded by the investigator in such a manner that the participants cannot be identified, directly or through identifiers linked to the subjects.”

In cases where a researcher is conducting research that s/he believes qualifies for IRB exemption, the researcher will file a proposal with the IRB indicating the rationale for exemption.
ETHNOGRAPHY AND EXPEDITED REVIEW

Expedited review means that the research poses minimal risk and the research is reviewed by only a subset of the IRB’s members rather than by the full board. Much ethnographic research may qualify for expedited review because it is among the categories of research identified for expedited review in category 7 of guidance issued under the Common Rule (Section 46.110), and normally it involves minimal risk (http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm).

Most ethnographic research involves the observation and interaction of the researcher with adult participants in ordinary life and poses risks not greater in and of themselves than those ordinarily encountered in daily life (http://www.aaanet.org/stmts/irb.htm p. 3).

Category 7 describes most clearly the kind of ethnographic research that our department regularly conducts:

Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (http://www.hhs.gov/ohrp/humansubjects/guidance/expedite98.htm).

PROTOCOLS FOR EXPEDITED REVIEW

When submitting ethnographic research proposals to the IRB for expedited review, stated protocols for practicing informed consent and the rationale behind them shall be clearly delineated. Projects submitted for expedited or regular review should provide the following:

- Explanation of the Research Topic
- Description of the Study Population
- Summary of Research Method Protocols
- Ethical Considerations
- Assessment of Risk
- Documentation of Informed Consent (Written or Alternative)

Ethnographic Research and Informed Consent

Informed consent includes three key components: communication of information, comprehension of information, and voluntary participation.
Informed consent is an interactive process that involves the researcher informing potential participants of the purposes and procedures of the research, the risks and benefits associated with the study, and how the data provided by the participant will be protected and stored. The ethnographer bears the responsibility of ensuring that the participants are fully informed of the intent of the ethnographic research, how the participants' information contributes to the research, and the anticipated risks and benefits the participants may expect to occur as a result of their agreement to participate in the research.

One of the most contentious areas of disagreement between IRBs and ethnographers is the documentation of informed consent. Some IRBs assume that all research resembles clinical, biomedical research and involves a clinician and client/patient in the US, an English-speaking and literate country where individuals, and only individuals, have the right to determine whether or not to participate in research. Yet, much ethnographic research takes place outside of the US, often in developing countries and among populations that may not be literate, and where the group or another individual may determine the right of an individual to participate in research.

At issue is the question of whether written informed consent is required to document participants' consent. It is often not appropriate to obtain consent through a signed form—for example, where people are illiterate or where there is a legacy of human rights abuses creating an atmosphere of fear, or where the act of signing one's name converts a friendly discussion into a hostile circumstance. In these and in other cases, IRBs should consider granting ethnographers waivers to written informed consent, and other appropriate means of obtaining informed consent should be utilized.

The Common Rule clearly allows IRBs to authorize oral informed consent. Section 46.117(c) of the regulations permits 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 46.116(d) authorizes the IRB to waive informed consent or approve a consent procedure that alters or eliminates some or all of the elements of informed consent if four conditions are met: (1) the research is of no more than minimal risk; (2) the change in consent procedures will not harm the respondents; (3) the research could not "practically be carried out without the waiver or alteration;" and (4) whenever appropriate, additional information will be provided to subjects after participation.
These regulations can be interpreted to provide alternative means of obtaining consent. Consent can be assumed in instances where the respondent is free to converse or not with the researcher and is free to determine the level and nature of the interaction between participant and researcher. This in no way absolves the anthropologist from clearly informing participants about the purpose and procedures of the study, its potential risks and benefits, and plans for the use and protection of ethnographic materials gathered during the study. There are also situations in which some community authority must approve the research before any individual community member is asked to participate. In some communities an individual would be put at risk of community sanction if he or she agreed to participate in a research project without the formal approval by community authorities. In some cultural settings, a spouse or male household-head, rather than an individual person, may be the culturally or legally appropriate agent to provide consent. 
(http://www.aaanet.org/stmts/irb.htm , pp 4-5).