

## **Threats to Respondents and Survey Staff Involved in Human Rights Field Research: An Overview**

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### **Abstract**

Scientists in many sociological fields are keen to complete research among the target population of interest, and many such studies are monitored by an Internal Review Board (IRB) to ensure proper ethical and methodological standards are met. Research about human rights violations, however, involves complicated ethical considerations related to potential harm to both respondents and survey staff members. Additionally, such research might not even fall under the purview of an IRB, leaving all ethical considerations the responsibility of the researchers alone. Alternatively, an IRB reviewing such research might not understand the special needs of the population, such as verbal informed consent procedures for illiterate respondents. This presentation and paper will consider the landscape of human rights research, the relationship of human rights research to IRB review protocols, and the complicated ethical problems involved in working with victims of human rights violations.

**Key Words:** Human Rights ; Internal Review Board ; Ethics ; Survey Methods ; Questionnaire Design ; Informed Consent

Within the past decade, and with the expansion of biomedical research in developing countries, researchers have contemplated the need to expand Institutional Review Board (IRB) standards into the conduct of international research. In July 2011, the U.S. federal government proposed changes to the "Common Rule" (8). The sponsoring agency proposes that it is time to discuss either revisions to the "Common Rule" to support the special requirements for international research—specifically in the area of human rights—or to discuss the development of an *international* review board to protect the needs of survey and research participants in developing countries.

Many sociological studies, in developing countries, are monitored by IRBs to ensure that proper ethical and methodological standards are met. However, research concerning human rights violations involves complicated ethical considerations related to potential harm both to respondents and survey staff. Such research might not necessarily fall under the purview of an IRB, leaving all ethical considerations to the researchers. An IRB reviewing such research might not understand the special needs of the population, such as verbal informed consent procedures for illiterate respondents. We will

consider the landscape of human rights research, the relationship of human rights research to IRB review protocols, and the complicated ethical problems involved in working with victims of human rights violations.

It is generally accepted that "(t)he purpose of an IRB review is to assure, both in advance and by periodic review, that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in a research study."<sup>(7)</sup> The gradual acceptance of the IRB evolved from societies becoming more conscious that scientific research should be therapeutic in nature and should not have any adverse physical and/or psychological effects on the participants. This consciousness arose with the discovery of unethical experiments involving human subjects performed by the German, Japanese, and British on either prisoners and/or civilians during WWII and the 1960 Milgram physiological studies in the United States. In 1964, the Declaration of Helsinki, based on the Nuremberg Code, was a major step towards the implementation of the institutional review board (IRB) process.

Generally, the IRB focuses on the responsibilities and requirements of who, what, where, when, and how of reporting results and the possible changes to the research. (1) The researchers are required to provide a detailed description of who is responsible for promptly reporting (a) unanticipated problems involving risks to subjects or others; (b) any serious or continuing noncompliance, and (c) any suspension or termination of IRB approval.

Most rules that govern IRBs, and still exist even in the proposed changes of the "Common Rule,"<sup>(8)</sup> focus on biomedical and survey research. But even these rules do not always take into consideration the special needs requirements in developing countries. The Hyder, et al (2004) study "...explore(d) the experiences and attitudes of researchers from developing countries regarding the role of institutional review boards (IRB) in ensuring the adequacy of ethical standards in research conducted in those countries." In this self-reported survey research, "(t)he majority (95%) reported that US ethical guidelines ensure high ethical standards in research, and more than two thirds of the researchers agreed that developing country collaborators rely on US ethical regulations for guidance." However, 83% of these researchers indicated that US IRBs were insensitive to local culture and more concerned with politics.

In other words, even when focusing on biomedical research, the IRB requirements fall short of supporting high ethical standards for human research in developing countries. Fitzgerald (2003) acknowledged this failing when he proposed additional questions

an IRB might pose to individuals doing biomedical research in developing countries.

1. Is there a viable IRB for the country that will review the protocol; if so, how can it be contacted?
2. What is the principal investigator's relationship with the community from which the research volunteers will be RECRUITED?
3. Does the research protocol address ethical challenges of conducting research in a developing country?
4. Is the purpose of the research responding to the health needs of the host country?
5. When negotiating informed consent, how will the investigators ensure that the research volunteers understand the consent procedure?
6. What exactly is the local standard of medical care?
7. Are the risks to the volunteers acceptable in the social context of the host country?
8. Does anyone else in the host country know about the research?
9. What public action will result from the findings of the research study?
10. Is capacity building an essential element of the research protocol?

Fitzgerald (2003) focused on approval of the research by the local community to ensure that both the subjects and the community understand the potential benefits of the research. However, even with these additional requirements, the sponsoring agency suggests the following additional IRB requirements for human rights research:

1. Cross-cultural population needs
  - A. Consideration for both literate and illiterate respondents. Verbal informed consent procedures for illiterate respondents, and all verbal consent in a variety of local dialects
  - B. Making the participant comfortable with the research questions and securing the need for privacy and confidentiality, especially for women.
2. Any additional special needs of the population such as reassuring the participants of physical and psychological safety.
3. Addressing any other possible complicated ethical problems involved in working with victims of human rights violations such as the lack of social support services when there is potential harm to respondent.

Outside of IRB requirements, human rights research must also consider the possibility of unforeseen but potential harm to respondents and/or to survey staff members.

1. Concern of reprisal or retribution from perpetrators to both the participant and staff members.
2. Possible rejection by society/family/community for the participant due to knowledge of certain situations (e.g., The social stigma for being raped may create a situation where a

woman is rejected by her husband and family or make it difficult for her to find a husband in the future.)

3. The emotional pain of having to recall the experience (post-traumatic stress) and the stress of the staff member hearing of the human rights abuses.
4. Unforeseen dangers of administering a survey in post-conflict zones.
5. The societal burden when collecting human rights data.
- A. The sample size required for the survey may be difficult to achieve due to unforeseen physical (e.g., a large tree in the road), environmental (e.g., the rainy season), or potentially harmful (e.g., armed conflict) situations.
- B. It is possible the research results may never go back to the country– due to lack of funding or publication issues.
- C. May need permission from traditional and local leader/chief.

The sponsoring agency recommends some of the following features and wording for a human rights consent form (6)

1. Name and describe organization doing research:  
*"We are working with....., a non-governmental organization from the United States."*
2. What the organization is doing:  
*"We are conducting a brief survey of as many households as possible to assess the needs of people living in villages and towns like these..."*
3. Discuss the purpose of the survey
  - A. *"We hope to use this survey to find out what the effects of war have had on mental health and how people in your community are functioning day to day."*
  - B. *"We hope to determine what the most important needs are so we can get better medical help to you and/or your community."*
  - C. *"We want to understand how the wars affected you as well as your family... and what new programs or ideas may help you, your household and your community heal from these wars."*
4. Always discuss confidentiality
  - A. *"You do not need to give us your name at all."*
  - B. *"None of your answers will be shared with anyone else and it will not be possible to know your answers from anyone else's answers."*
  - C. *"You are free to stop at any time during the interview. If a question makes you uncomfortable, we will skip the question and go to the next question."*
5. Relax participants and ensure interest in the person's wellbeing
  - A. *We want ".... to understand what has happened to you personally and to those living in your household during and since the war."*
  - B. *"We have tried to limit any consequences to your safety for answering these questions and feel that there*

*is little risk to you and your family, however there may be risk that we are unaware of."*

6. Indicate what you will NOT provide

A. *"We are not here to provide humanitarian assistance at this time."*

B. *"We want you to understand there may be no benefit to you from this survey but your answers may help the government plan better health services for you, your family and/or your community in the future."*

On July 22, 2011 the US Federal Government has invited comments on some proposed changes to the "Common Rule":

(8)

"The public's input on these matters will be critically important to the government's efforts to ensure that regulations keep up with today's changing research environment, and will be considered by HHS as it develops new proposed rules, which will also be made public for comment."

Questions posed by the sponsoring agency which the sponsoring agency thinks should be discussed:

1. Do researchers need a different set of rules for developing countries? Is the current process too rigid to be used for international studies?
2. Should changes be made which revise the existing risk-based framework to more accurately calibrate the level of review to the level of risk?
3. Should the forms and processes used for informed consent be updated?
- A. Does the volunteer of the research understand the major aspects of the research project and survey questions?
- B. Are U.S. required consent forms are too long and languages too varied to fully cover all aspects of the research for participants to understand? The forms do not guarantee that volunteers have fully understood the objectives, risks, and benefits of the study and the extent of their voluntary participation.
4. Should a mandatory data security and information protection standards for all studies involving identifiable or potentially identifiable data be established?
5. Is it possible to implement a systematic approach to the collection and analysis of data on unanticipated problems and adverse events across all trials to harmonize the complicated array of definitions and reporting requirements, and to make the collection of data more efficient?
6. Is it possible to shorten the amount of time to obtain IRB approval when dealing with a post-conflict situation? Unless a study is on the fast-track for approval, sometimes there is only a short window of time to gain approval for the IRB for human rights research. (e.g., need to administer a survey during a certain season of the year– rainy season in Democratic Republic of the Congo.)

7. Is there a need for an international review board that can respond to human rights research requirements in a timely manner but also have standards for the research? If yes, which organization(s) should work together to create and govern such a board?

The sponsoring agency encourage all parties to make comments both on the Health and Human Services website for proposed changes to the "Common Rule"(8) and to continue this conversation with the authors.

References:

1. " Guidance on Written IRB Procedures" Office for Human Research Protections, Department of Health and Human Services. July 11, 2002.
2. Slater, M., Antley, A., Davison, A., Swapp, D., Guger, C., Baker, C., Pistrang, N., Sanchez-Vives, M. V., "A Virtual Reprise of the Stanley Milgram Obedience Experiments", 2006.
3. Pape, Jean William, "Institutional Review Boards: Consideration in Developing Counties" *Emerging Infectious Diseases*, Vol. 7, No. 3 Supplement, June 2001.
4. Fitzgerald, D. W., Wasunna, A., and Pape, W. J., "Ten Questions Institutional Review Boards Should Ask When Reviewing International Clinical Research Protocols", *IRB: Ethics and HUMAN Research* 25 No. 2 (2003); 14-18.
5. Hyder, A.A., Wali, S.A., Kahn, A. N., Teoh, N. B., Kass, N. E., Dawson, L. "Ethical Review of Health Research: A Perspective From Developing Country Researchers", *Journal of Medical Ethics*. Vol. 30 No. 1. Feb. 2004. p 68-72.
6. Confidential consent form used by StatAid
7. Wikipedia:  
[http://en.wikipedia.org/wiki/Human\\_subject\\_research#World\\_War\\_II](http://en.wikipedia.org/wiki/Human_subject_research#World_War_II)  
[http://en.wikipedia.org/wiki/Institutional\\_review\\_board](http://en.wikipedia.org/wiki/Institutional_review_board)
8. "HHS announces proposal to improve rules protecting human research subjects" July 22, 2011.