

Application of Federal Regulations to IRB Review of HIV Prevention Research:

Case Studies of Research on U.S.
Immigrants

E. Doyle McCarthy

2. Relevant Texts

- Loue & Pike (2010) chapter 1, on human rights, international guidelines, and HIV research.
- Loue & Pike (2010) chapter 2, U.S. Regulations and HIV Research , that includes selections (on p. 19) from the 1984 HHS document, “Guidelines for IRBs for AIDS Studies.”
- A complete set of the Guidelines for IRBs for AIDS Studies (chapter 5, section F) has also been provided for you as a resource this week.

3. OHRP Guidelines for IRB Review of AIDS/HIV Research

1st I will use the 1984 Guidelines as a framework for thinking about the primary ways that IRBs are expected to insure protections to HIV/AIDS research participants.

2nd I will also use for our discussion—from my own IRB experience—a research group that raises similar issues and concerns for IRBs—U.S. immigrants. Thinking about immigrants has helped me think about participants with HIV/AIDS.

4. Three U.S. Immigrant Case Studies

- An interview study of the monies (“remittances”) sent by Mexican immigrants living in NYC to their families living in Mexico.
- An interview study of the health and medical practices of parents and children from West Africa, residing in the Bronx NYC.
- An interview study of Asian-American child-rearing among Asian immigrant families, with a focus on child abuse.

5. Summary of some leading issues identified in the OHRP Guidelines on HIV/AIDS

- That participants be informed of positive antibody test results.
- That they be informed of significant research findings developed during the course of the research process .
- That participants be informed about the limits of confidentiality (e.g., laws requiring reports of positive test results, including researchers' reports to third parties).
- That researchers inform participants of the ways participants' personal identifiers (names, medical charts numbers, etc.) are kept separate from research data.
- That researchers minimize the recording of data from medical records.

[Full listing appears in Loue & Pike 20 p. 19; cf. OHRP Guidelines.]

6. Confidentiality

...as well as its limits, is important because of the possible consequences of breach of confidentiality (loss of a job or medical insurance were cited); protecting names and personal identifiers is discussed; exceptions such as lawful reporting by researchers to persons & agencies.

FULLY INFORMED CONSENT

...at all stages of the research; the need for full information contributes to both participants' risks and benefits ; the problems attendant upon a participant's medical condition to fully give consent (e.g., medications, dementia, end-of-life conditions).

7. ETHICAL CONCERNS Involved with AIDS Research

The *Guidelines* stress the following:

- **Privacy**
 - A person's control over the extent, timing, & circumstances of sharing oneself (physically, behaviorally, or intellectually) with others; the right to limit access by others to aspects of one's person.
 - Many consider privacy a basic human right & maintaining confidentiality a professional obligation.
- **Confidentiality of Data**
 - The treatment of information disclosed in a relationship of trust. The expectation is that disclosure requires a subject's consent.
- **Justice**
 - Fairness in the distribution of benefits & risks of the research

8. Why these 3 ethical concerns?

1st The origins of IRBs in the 1974 National Research Act of 1974 & the 1979 Belmont Report: concern with violations and exploitations of research participants; the laws set out to change these violations.

2nd The 3 “ethical concerns” stress values that were abused: privacy, confidentiality, justice.

9. 1979 Belmont Report

- **Respect for Persons.** The principle of respect for persons...divides into two separate moral requirements: the requirements to acknowledge autonomy and to protect those with diminished autonomy.
- **Beneficence.** Two general rules have been formulated as complementary expressions of beneficent actions: (1) do no harm and (2) maximize possible benefits and minimize possible harms.
- **Justice.** Who ought to receive the benefits of research and bear its burdens? This is a question of justice in the sense of "fairness in distribution" or "what is deserved." An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly.

10. Both groups are “socially marginal”

- because they are discriminated against
- because their status or condition disproportionately affects certain populations: gays and bisexuals (in the case of AIDS); racial and ethnic minorities (in the case of both);
- many (not all, of course) immigrant groups and HIV-infected persons are economically and/or educationally disadvantaged, and may need special social supports and/or services to be able to participate in research.
- both groups are also characterized by mistrust and fear of authorities and institutions (including the government, the medical and scientific establishments).

11. OHRP Guidebook Ch. VI.

On “special classes of subjects”:

- “The federal regulations require that IRBs give special consideration to protecting the welfare of particularly vulnerable subjects, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.”

12. “vulnerable subjects”

- The word “vulnerable,” has special relevance to the IRB review process: meaning susceptible to physical or emotional injury, or open to censure, or liable to succumb to persuasion.
- Included here are: fetuses, women, prisoners, children and minors, the terminally ill, the elderly, minorities [meaning, racial & ethnic minorities], students, employees, the cognitively impaired.

13. *Guidelines*, IRB CONSIDERATIONS

HIV-infected persons “are particularly vulnerable, both because of their disease status and because the disease disproportionately affects certain populations: male homosexuals and bisexuals, intravenous drug users, minorities, and, increasingly, women and children. [See Guidebook Chapter 6, ‘Special Classes of Subjects.’].”

14. Immigrants...Vulnerable?

- HIV-AIDS disproportionately affects many groups of persons who are involved with social & political conflicts (both as participants and as victims).
 - This is the subject of an entire issue (October 2010) of the journal *Forced Migration Review*. As reported there, “the AIDS, Security and Conflict Initiative (ASCI) undertook research over a number of years to examine the connections [HIV/AIDS and forced migrations], to gather evidence and to advance analysis” (www.fmreview.com)
- As already outlined, immigrants are, in many ways, “marginal”
 - Poor, identifiable as non-white, “foreign”-looking and speaking, lacking resources and education, ostracized socially and legally, and “marginalized” by dominant U.S. institutions and communities.

15. Question: How can researchers address these “vulnerabilities”?

How best to recruit them as participants in scientific and medical and social-behavioral studies?

What are the ethical concerns that their participation raises?

16. Some answers (or partial answers)

- 1. Vulnerable groups (socially marginal groups) are best addressed and recruited with the support of community-based organizations.** This is to build up trust as well as to gain access to persons using organizations they already trust.
 - The 3 studies succeeded by doing precisely this: the remittance study first identified organizations the immigrants already used; the West African study is conducting the study in collaboration with a West African community organization; the Asian family study the same; they also used the organization to recruit and to interview in native languages.

17. Some answers cont.

- The **downside** of the involving community organizations should be clear:
 - Researchers need to train organization personnel in “human subjects” protocols.
 - There needs to be careful matching so that prospective recruits are not interviewed by their social workers or family therapists.
 - Confidentiality and privacy issues that arise among staff-recruiters/interviewers need to be emphasized in their training.
 - Prospective participants have to understand that the research study is not one and the same as the community agency.
 - They need to understand that the services they receive are not placed in jeopardy if they do not participate (coercion).

18. More answers...

2 Vulnerable groups require special (if not extraordinary) protections of privacy and confidentiality because they are vulnerable (legally, politically, socially).

3 Vulnerable groups require that researchers make special efforts to understand and to relate to their particular “subjectivities” in their recruitment procedures and in their ongoing communications with them during the study.

19. the particular “subjectivities” of prospective participants

Sources

- Ruth Macklin’s (2008) How independent are IRBs? *Ethics & Human Research* 30, no. 3: 15-19.
- Lisa Eckenwiler’s (2011) Moral reasoning & the review of research involving human subjects. *Kennedy Institute of Ethics Journal* 11, No. 1 (March): 37-69.

20. Addressing groups special subjectivities?

- Review committees like university IRBs often operate on the (false) premise that the scientists and IRB members are in fact knowledgeable of the community and its values in which they operate; this is often not the case. IRB members are typically from social classes and community far removed from those of their university community.
- The requirement of having “community representatives” on IRBs is often not adequately met and local consultants are not often used by IRBs in studies of groups with which IRBs are not familiar.
- IRBs apply their standards as if they are universal standards, despite the fact that several marginal and vulnerable populations follow different standards for judging “good science” or community-university research collaborations.

21. The issues cont.

- IRB members can unknowingly misrepresent the (marginal) others they seek to protect; they/we construct “partial and often distorted pictures of their interests and needs” (Eckenwiler 2011, pp. 47-48);
- “respect for persons” is, thereby, in jeopardy and the possibility of “harm” is more likely, however unknowingly.