BELMONT REPORT: Guidance for Community Research?

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Belmont’s Guidance for Community Research

• Simple answer to the question: None.
  – spell check shows that the word, ‘community’ does not appear in the Belmont Report.
  – “Because the problems related to social experimentation may differ substantially from those of biomedical and behavioral research, the Commission specifically declines to make any policy determination regarding such research at this time….[T]he Commission believes that the problem ought to be addressed by one of its successor bodies.”
Belmont’s Guidance for Community Research

• But that does not mean:
  – that Belmont did not provide resources for planning and conducting ethical research involving the community.
  – that there was no concern about the community in the design and conduct of research even before the Belmont Report.
• I will discuss these concerns and their evolution.
USPHS Surgeon General’s Memorandum Feb. 8, 1966

– The first federal policy statement requiring committee review of extramural research. This "committee of institutional associates" was the forerunner of the modern IRB.

• No mention of the community.

– Revision of December 1966 added: Investigations must be "in accordance with the laws of the community in which the investigations are conducted."
Surgeon General’s Memo

• Further amendment on May 1, 1969 stated that the membership of the committee should possess in addition to scientific competence "other competencies necessary in the judgment as to the acceptability of the research in terms of institutional regulations, relevant law, standards of professional practice, and community acceptance."
45 CFR 46 promulgated May 30, 1974

- The new language calling for differences in committee membership includes the following: the committee must be composed of not fewer than five persons and must have the capacity to judge the proposal in terms of community attitudes. "The committee must therefore include persons whose primary concerns lie in these areas of legal, professional and community acceptability...."
Community Consultation

• Introduced in 1976.
• Ethical justification of conducting RCTs in VA Hospital System.
  – Determine whether veterans considered it burdensome.
  – Reduce intimidation, ‘fragility.’
• Navajo children: Trial of Vitamin C to reduce incidence of acute illness.
Guidelines for Confidentiality in Research on AIDS: The Hastings Center, 1984

• Community consultation to address concerns about risk held by subject population.
  – Either by IRB or investigators.

• Community Advisory Board to address new issues in confidentiality.
  – Membership to include representatives of the subject populations and of private agencies.
Community Consultation in Socially Sensitive Research: 1988

- To enlist prospective participants as partners in solving difficult problems in ‘sensitive’ research.
- To increase subjects’ perception of justice in the research.
- The *feeling* of control tends to humanize relationships between researchers and participants and thus serves to promote respect for persons.
Ethical principles and policies for clinical research on HIV/AIDS: The Hastings Center, 1991

- Community consultation (CC) should be integral part of the planning and design of clinical trials of nonvalidated therapies.
  - Need for negotiation recognized (eg, choice of comparator).
- CC should not be seen as a way to obtain acceptance of an already agreed upon protocol; it must be a partnership.
- Primary responsibility for initiating and conducting CC rests with the investigator.
- Institutions that regularly conduct clinical trials of therapies for HIV infection should have standing community advisory committees.
Ethical principles and policies for clinical research on HIV/AIDS: The Hastings Center, 1991

• When there is no clearly defined community of prospective subjects or intended beneficiaries, or when different groups claim to represent the community, CC may be problematic. This does not absolve the investigator of the responsibility to accomplish the purposes of CC.

• IRBs that regularly review HIV/AIDS research should seriously consider including among their members representatives of or advocates for populations of prospective subjects and intended beneficiaries.
CIOMS* International Ethical Guidelines: 1993

• *Council for International Organizations of Medical Sciences

• ‘Externally Sponsored Research.’
  • Sponsors’ obligations should be clarified before the research is begun.
  • What, if any resources, facilities, assistance and other goods and services (including capacity-building) will be made available during and after the research.
  • Details should be agreed by the sponsor, officials of the host country, other interested parties and, when relevant, the community from which the subjects are to be drawn.
CIOMS International Ethical Guidelines: 2002

• Requirements of 1993 affirmed and extended.
• Focus remains on research in low resource countries.
• Groups to determine ‘responsiveness,’ ‘reasonably availability’ and sponsors’ obligations should include representatives of communities from which subjects will be drawn and NGOs such as health advocacy groups.
• Capacity building emphasized.
Contemporary community involvements

• Cluster randomized clinical trials.
  – Randomize intact social units such as households, primary care practices, hospital wards, classrooms, neighborhoods, entire communities.
  – Recognition that individuals within such units respond differently than those considered outside such settings.
  – Allows simultaneous evaluations of individual and group responses.
    • Vaccine trials: individual and ‘herd’ immunity.
Contemporary community involvements

• Community-Based Participatory Research (CBPR).

• **Witness for Wellness Program**, for example.
  - Community members involved in the conceptual design, implementation, data analysis and collection, formulation and writing of manuscripts.
  - Program rooted in trust of underserved Los Angeles communities and the academic community.
  - Promotes effective interactions of grass roots communities, CBOs and academia.
THANK YOU!