

Free, Prior and Informed Consent: A Right of Communities

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History

- Before Nuremberg – late 1800's emerging role of science in medicine. Experiments on human subjects were done in the name of medical progress.
- Nazi experimentation and post-Nuremberg
 - United States v. Karl Brandt et al., "The Medical Case, Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10" (Washington, D.C.: U.S. Government Printing Office, 1949)
- Code of Federal Regulations Title 45 Volume 46, regulations issued by the U.S. Dept of HHS governs federally-funded research in the U.S.

History continued

- Belmont report: in 1974, the National Research Act (Pub. L. 93-348) was signed into law, creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. One of the charges to the Commission was to identify the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and to develop guidelines

Three ethical principles in the Belmont Report

- Respect of persons
 - Requirement to respect autonomy
 - Protect those with reduced autonomy
- Beneficence
 - Do No Harm
 - Maximize Benefits/Minimize Harms
- Justice

Applying the three ethical principles requires free, prior and informed consent

Institutional Review Boards

- Human subject testing requires a review by a board that makes two determinations
 - Is the experiment ethical?
 - Respect
 - Beneficence
 - Justice
 - Has Consent been obtained?

FPIC as a right of community

- Treaties establishing the right of nation-states to prior and informed consent. For example ,the Rotterdam Convention on the Prior and Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade.
- U.N. Declaration of the Rights of Indigenous Peoples establishes the right of indigenous communities to FPIC
- Vermont Constitution

Development and Land Use Issues and Uncertainty

- Communities facing proposed dams, mines, drilling, pipelines, fracking, factories, refineries, clean up (or not) of hazardous facilities, are facing scientific uncertainties about the consequences of these activities.
- These proposed activities are the equivalent of an experiment on the community.

Communities are entitled to be treated ethically

- Respect
- Beneficence
- Justice

- They are therefore, entitled to give or withhold free, prior and informed consent

Basis for Governance

- The legitimacy of government is predicated on the consent of the governed.
- Free, prior and informed consent is the foundation of governance.

Two steps

- We withdraw our consent
- Methods for obtaining Community Free, Prior and Informed Consent

Institutional Review Boards as a Model

- Community based research requires an IRB review.
- Environmental projects should be subject to a similar process. We can institute Community Review Boards to make the determinations of
 - Is this project ethical?
 - Does the proponent of the activity have the free, prior and informed consent of the community?

Violations of Free, Prior and Informed Consent as a Community Matter

- Tufts Golden Rice
- Havasupai Blood misused by Arizona State University researchers

A new decision-making framework

- Environmental Impact Assessments and Health Impact Assessments conducted as information for both
 - the Community Review Board to determine whether it is ethical and
 - for the Community to fulfill the Informed part of consent

A New Role for Public Health Practitioners

- Provide the information on public health impacts so the community can be informed.
- Determine whether this project is ethical according to the Belmont standards.

Community Review Board

- Is this project ethical?
 - Is it respectful of the community?
 - Is it beneficial to the community?
 - Is it just?

An Unethical Project

- If a CRB says the project is unethical it does not proceed.

A Project Deemed to be Ethical

- The project is put before the community for its consent.

Mechanisms for Consent

- Town hall meetings
- Ballot referendums or initiatives
- Any other method for direct democracy.

Consent

- Can be denied
- Can be given with conditions (community benefits agreements)
- Can be given outright

Examples

- The Royal Bank of Canada has said they will not fund any development project in indigenous communities without their free, prior and informed consent.
- Giant Mine clean up

The Work Ahead

- Can CRB's be housed at Universities?
- Can communities create their own?
- What other mechanisms do we have for obtaining free, prior and informed consent?
- What else?

Resources

- <http://sehn.org/we-withdraw-our-consent/>
- <http://sehn.org/democracy-through-informed-consent-januaryfebruary-2012/>
- [http://www.sehn.org/pdf/The%20Principles%20of%20Perpetual%20Care%20\(Giant%20Mine\)%20December%202011.pdf](http://www.sehn.org/pdf/The%20Principles%20of%20Perpetual%20Care%20(Giant%20Mine)%20December%202011.pdf)