

Community-based genetic studies: experiences from donor recruitment to social impact

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ESF-UB Conference in Biomedicine
Biobanks: Introduction and Next Steps
Hotel Eden Roc, Sant Feliu de Guixols (Costa Brava)
Spain
November 3, 2008

Roadmap

- Emergence of Public Participation as a Biomedical Ethics Concern
- US Case of Community Engagement: the International HapMap Project
- Moving Forward: Creating a Process for Participation

Shift Towards Public Participation

- Inclusion of lay members on the UK government's scientific advisory committees;
- Public debate initiated and funded by federal agencies (eg. GM foods debate in Europe; Racial categories by NIGMS);
- Research funded activities by major biomedical organizations (eg. the Royal Society, the Office of Science and Innovation);
- Public education programs (eg. Genetics and Society; Museum exhibits);
- Entrée of social scientists into ethics related research.

Protection for “Communities” in Biomedical Research

- What is a community?
- What is the status of communities in research ethics?
- What is the status of the individual patient in relationship to the community?
- What are the ethical obligations of researchers to communities?

Social Studies of Science

- Question assumptions ,dispelling myths, challenging established 'truths', and expanding the potential for greater truth
- Highlighting voices that hitherto have been marginalized and excluded from debate
- Reduce the alienation of lived reality from the creation of policy relevant knowledge

Boundary Work

- Thomas Gieryn's theory on boundary work (Gieryn 1983; 1985).
- Addresses the lack of parity between scientific expertise and general lay public.
- Signifies the discursive work that is done by scientists to demarcate and create a boundary between science and non-science.
- Used to describe the work that is done by scientists – and its implications of social boundaries and community identity

Co-production

Sheila Jasanoff, 2004 – States of Knowledge

- Knowledge is not simply a reflection of reality, but is constructed along with social order (including, but not limited to relationships of power and dominance, also legitimate interpretations of how the world works)
- Identifying how knowledge is co-produced with social order allows for expansion of terrain for the creation of new knowledge and thus, new social orders

Pendulum Shifts

- Protective Exclusion
- Protective Inclusion
 - Patient Advocacy Groups
 - Act-Up
 - PXE International
 - Researcher Led Engagements

“Tuskegee Study of Untreated Syphilis in the Negro Male” 1932-1972

- Study conducted by the U.S. Public Health Service in Macon County, Alabama
- Study objective: To study the “natural history” of syphilis in black men.
- 600 black males recruited: 399 with syphilis; 201 without disease
- Subjects told they were being treated for “bad blood”
- Treatment for subjects with syphilis was withheld



United States
of America

Congressional Record

PROCEEDINGS AND DEBATES OF THE *103rd* CONGRESS, FIRST SESSION

NIH Revitalization Act of 1993

The inclusion of women and members of minority groups and their subpopulations must be addressed in developing a research design appropriate to the scientific objectives of the study. The research plan should describe the composition of the proposed study population in terms of gender and racial/ethnic group, and provide a rationale for selection of such subjects. The plan should contain a description of the proposed outreach programs for recruiting women and minorities as participants.

Patient Advocacy Groups



- In March the U.S Food and Drug Administration (FDA) approved AZT as the first antiretroviral drug to be used as a treatment for AIDS
- Act-Up founded in NYC in March 1987
- Held first demonstration on Wall Street March 24, 1987
- Demanded better access to drugs as well as cheaper prices, public education about AIDS and the prohibition of AIDS-related discrimination.

Patient Advocacy Groups



“Clinical trials are healthcare, too!”





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PXE International, Inc holds the world's largest collections of blood and tissue from people affected by PXE and their immediate relatives. It is the only centralized repository in the world. We are using these samples to classify the mutations in the gene responsible for PXE. PXE International established the Blood and Tissue Bank to make certain that your privacy and confidentiality are protected and your samples are available to any approved research project.

Consent vs. Consultation: Language Matters

- Community Consent – Modeled after individual informed consent- the ability to say no to research – Native Peoples
- Community Consultation – Introduces proposed research to achieve community support – Act Up
- Community Engagement – Active co-partnership throughout the research process and beyond – HapMap Project

International HapMap Project



- Research on genetic factors contributing to variation in response to environmental factors, in susceptibility to disease, and in the effectiveness of and adverse responses to drugs and vaccines.
- Effort to incorporate genetic diversity.

International HapMap Project



- Yoruba in Ibadan, Nigeria
- Japanese in Tokyo
- Han Chinese in Beijing
- Utah residents with ancestry from northern and western Europe

International HapMap Project



- Maasai in Kinyawa, Kenya
- Luhya in Webuye, Kenya
- Chinese in Metropolitan Denver, CO, USA
- Gujarati Indians in Houston, TX, USA
- Toscani in Italia
- Mexican Ancestry in Los Angeles, CA, USA
- African Ancestry in OK, USA

International HapMap Project



INFORMED CONSENT

- provide oral and written information to ensure voluntary and informed decisions
- consent to participate in the HapMap itself, and in future genetic variation studies
- no medical information
- Anonymous; de-linked identifiers- no withdrawal once samples are submitted

Consent Form Template

- What is this project about?
- Why are we doing this project?
- How will the samples be used?
- What will happen if I decide to give a sample?
- Will there be any costs or payments?
- How will you protect my privacy?
- What are the benefits of giving a sample?
- What are the risks of giving a sample?
- Are there any risks to my community or group?
- Can I change my mind after I give a sample?
- How will I find out what happens with this project?

Are there any risks
to my community or group?

“We will work to make sure that the ethnic or geographic identity of your community is described as carefully as possible--in the sample collection, in the database, in the HapMap, and in any articles researchers write about the HapMap.”

International HapMap Project



COMMUNITY ENGAGEMENT PROCESS

- Work with anthropologists and other social scientists familiar with populations
- Focus groups sessions explaining project and fielding concerns
- Town Hall Meeting to describe results from focus groups and offer opportunity to voice further concerns
- Creation of Community Advisory Groups

Community Advisory Groups

- Establishes its own procedures and decides its own membership and leadership structure, consistent with local cultural norms
- Liaison between the Coriell Institute for Medical Research and the donor community
- Report general progress of the HapMap Project, how the HapMap is being used, and how the stored samples are being used

Negotiating History and Mistrust

“I know what you are saying. They think they found something with my mom...some kind of cancer... and I suppose if there was a chance they could discover a cure for it... but...no, I don't think I would ever tell anyone to give their blood for research...genetics research. Once you give it away, you don't know what they'll use it for...just look at history.”

Return of Results

“Well, yes, (laugh). I’ve already asked (name omitted) to be tested. I would love to find out about where all this leads. I mean really find out. I’ve heard all of my family’s stories, but it would interesting to me to find out for sure... But, I see this as private. It is for me and no one else”

Citizenship and Belonging

“I think it is great that we are being asked to join...to participate in the genetic study. If it helps to find cures to disease, I think we should all sign up. You know, for such a long time, we were never asked to participate in anything...treated like second class citizens. Now, we have finally been invited...we have a duty to help.”

Questions of Inclusion: Who is Chinese?

“I think it is great that they have taken an interest in Chinese American heritage. This will be very interesting to see who are the real Chinese. They are right to focus on the Han Chinese and to discover our unique genetic background.”

“Who really can participate in this research? I am still confused and worried because there are many Chinese from Vietnam for example, who are really Chinese but probably won't know anything about this project....”

Reciprocity

“I was confused about the goal of the community engagement...and, uh, specifically, what will these meetings do for our community? We all know the harsh history in America of race ...what do scientists hope to accomplish? ...will our community be better, stronger with genetic research?”

Social Factors and Implications

- Goals of community engagement not tethered to processes of individual informed consent
- Acknowledging local history is critical to effective communication and identifying stakes
- Creating biobanks not only relies on interpreting the social landscape but may also create new formations

Public Participation in Science: Addressing the Critical Questions

- Who constitute the publics of importance?
- What determines the structure of representation for a group? Who has the authority to speak?
- How does public participation differ from the issues related to individual informed consent?
- What responsibilities does the public or community have to science and scientists?
- What responsibilities do scientists have to communities?

Creating New Forms of Public Engagement

- Adopting new forms of citizen participation where scientists collaborate with social scientists and community leaders to encourage effective dialogue;
- Identification of the context and local history that inform the relationships between scientific researchers, the public and governmental agencies;
- Creation of a process that allows for the identification of pertinent key population specific issues;
- Sustaining ongoing relationships with communities;