

Research with Biological Data Collected in Social Surveys: The Role of IRBs in Informed Consent

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IRBs and informed consent

I Important distinctions

- ✓ Physical biospecimens (normal/diseased tissue, nail clippings, urine, blood, etc.)
- ✓ DNA sample
- ✓ Images
- ✓ Information/data obtained from biospecimens/DNA sample and/or images
- ✓ Information/data obtained from other sources (questionnaires, medical records, other data bases)

IRBs and informed consent

- | Is IRB review and informed consent required? Can the criteria for an IRB-approved waiver of consent be met?
- | Is participation in biospecimen/data collection optional?
- | What is the permissible scope of consent, re: present and future use of biospecimens and/or data? (specific, tiered, broad, open, opt-in/opt-out) Ability to direct future use of stored samples?
- | Single, segmented, or separate consents?

IRBs and informed consent

- | Consent from family members for genetic/genomic research?
- | Surrogate authorization for decisionally impaired adults?
- | Biospecimen/data collection from children?
Parental permission/child assent?
- | What information and how much in the consent form?

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- | Will biospecimens and/or data be shared?
- | Who will have access to biospecimens and/or data? Only researchers within the original research group, or others?
- | Should participants be given the opportunity to opt out from sharing biospecimens and data with researchers (including from private industry) not affiliated with the study?

What information and how much in the consent form?

- | Will genetic/genomic research be conducted?
Some consent forms vague about the fact that
 - √DNA is being collected
 - √Genetic/genomic research will be conducted
 - √DNA samples/cell lines and/or genetic/genomic information will be stored and shared

What information and how much in the consent form?

I Personal Genome Project

- ✓ “The main scientific goal of this study is to explore ways to connect human genetic information and human phenotype information, i.e. human DNA sequence, medical information, and physical traits, so that such data can be used for hypothesis-generating research and computational efforts worldwide.”

http://arep.med.harvard.edu/PGP/Consent08/PG_Consent_15Apr2008.pdf

What information and how much in the consent form?

I Privacy/confidentiality:

- ✓ NIH cooperative group treatment trial collecting biospecimens for correlative genetic biomarker studies: “We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.”

What information and how much in the consent form?

I Privacy/confidentiality:

- ✓ Boston University – The Framingham Heart Study
http://www.framinghamheartstudy.org/research/pdfs/consent/bdc_cell_line_creation.pdf

What information and how much in the consent form?

- ✓ **Confidentiality.** Information obtained during this study will be treated as strictly confidential. A code number will be assigned to you and to your personally identifying information. Cell lines will be stored at a central site. Files linking names to samples will be kept locked and accessible only to the Framingham Heart Study (FHS) data managers. The coded samples will be stored securely and kept until no longer of scientific value. The risk in providing this sample is minimal.

What information and how much in the consent form?

- ✓ Data and DNA will be distributed to the FHS researchers and other qualified researchers interested in the genetics of heart and blood vessel diseases, lung and blood diseases, stroke, memory loss, joint disease, bone loss, deafness, cancer, and other major diseases and health conditions. The researchers will be given the DNA without any personally identifying information. Information gained from research on your DNA may be used for the development of diagnostic procedures or new treatments for major diseases. Your DNA will not be sold to any person, institution, or company for financial gain or commercial profit. However, neither you nor your heirs will gain financially from discoveries made using the information and/or specimens that you provide.

Boston University – The Framingham Heart Study

What information and how much in the consent form?

- ✓ When study results are published, your name and any other identifying information will not be revealed. You will be informed through periodic publications from the FHS of some findings about genetics, cardiovascular disease or other health conditions generated from the DNA analyses.

Boston University – The Framingham Heart Study

What information and how much in the consent form?

- ✓ To help us further protect your privacy, the investigators have obtained a Confidentiality Certificate from the Department of Health and Human Services (DHHS). With this Certificate, the investigators cannot be forced (for example by court subpoena) to disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes. You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research.

Boston University – The Framingham Heart Study

What information and how much in the consent form?

- ✓ Note however, that if an insurer or employer learns about your participation, and obtains your consent to receive research information, then the investigator may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy. Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

Boston University – The Framingham Heart Study

Horizon issues

- I Myth of IRB harmonization? Factors that may affect variation re: consent policies and practices:
 - ✓ Type of research
 - ✓ Characteristics of research population
 - ✓ Institutional culture, norms, policies
 - ✓ External requirements, (research sponsor, consortium/cooperative group studies, central IRB, federal/state law)
 - ✓ Differing values and interests that shape the interpretation and application of regulations, statutes, guidance, and policy recommendations

Horizon issues

I Myth of IRB harmonization?

✓ Genetic research: survey of IRB practices for SWISS (Siblings with Ischemic Stroke Study)

∅ 2003/40% of sites reported IRBs prohibit surrogate authorization to enroll impaired adults as probands in non-beneficial genetic research; 2007: 35% prohibited surrogate authorization

∅ No regulatory prohibition re: surrogate authorization in genetic research

Horizon issues

I Myth of IRB harmonization?

✓ SWISS investigator definition of risks:

- ∅ Letter of invitation for sibling participation
- ∅ Participant provides double-coded blood sample for genome-wide scan and linkage analysis
- ∅ Authors did not seek explanation IRB policies/practices

Horizon issues

- | Cross-border data sharing (consent/privacy issues, nomenclature)
- | Inconsistent use of nomenclature
 - √ Identified, coded, de-identified, anonymous, anonymized
- | Multi-center/consortium trials
- | Return of research results

Horizon issues

- | Impact of Genetic Information Nondiscrimination Act (GINA) and implementing regulations
- | Electronic medical records: will patient-control paradigm in clinical context impact research context re: who uses, for what purposes, audit trails, etc.?

Horizon issues

I Myth of genomic anonymity

- ✓ What impact will ability to re-identify individuals using aggregate databases have on
 - ∅ consent approaches for prospective collection of biospecimens and/or data?
 - ∅ concept of risk?
 - ∅ privacy/confidentiality information in consent documents?
 - ∅ IRB policies re: waiver of consent for future secondary research?

References

- | 45 CFR 46 (Common Rule)
- | 2008/2004 OHRP Guidance on coded private information or biological specimens
- | 2006 FDA Guidance, *In vitro* diagnostic device studies
- | 2008 OHRP Guidance, Engagement of institutions in humans subjects research

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