

Issues to be Addressed in Obtaining Informed Consent Involving DNA Banking and Genetic Research

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- Purpose of Study**
 - ✧ Inform subjects that the sample will be used for genetic research

- Duration**
 - ✧ Inform subjects how long sample will be stored

- Control and Ownership of the Specimens/Materials**
 - ✧ Explain who owns materials
 - ✧ Inform subjects if research could lead to commercially valuable product
 - ✧ Indicate whether subjects will receive a portion of profits

- Subject Access to Genetic Information**
 - ✧ Inform subjects regarding what information entitled to receive
 - ✧ Inform subjects if results will not be provided and explain why
 - ✧ If findings are to be disclosed, describe disclosure procedures (e.g., genetic counseling)
 - ✧ Indicate at what point in research the findings will be disclosed (e.g., interim results)
 - ✧ Indicate policy regarding disclosure of incidental findings

- Secondary Use**
 - ✧ Inform subjects if subsequent investigators may be given access to samples with direct or indirect identifiers
 - ✧ Give subjects option of consenting now to future second use
 - ✧ Inform subjects they may be re-contacted or
 - ✧ Give subjects option to indicate if willing to be re-contacted
 - ✧ Subjects may want to limit use of sample

- Alternatives**
 - ✧ One alternative is to not participate in the study

- Risks**
 - ✧ Social Risks: Breach of confidentiality could impact insurability, employability, reproduction plans, family relationships, immigration status, paternity suits, stigmatization
 - ✧ Psychological Risks: If information is disclosed, impact of learning results; impact if no effective therapy exists; psychological stress for family members
 - ✧ Physical Risks: Physical risks associated with collecting samples for research purposes and/or for gene therapy procedures
 - ✧ Unknown Risks: Subjects should be informed that there may be risks that at this time are not known

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- ❑ **Examples of Variables Impacting Risks**
 - ⊞ What is the current state of the art with respect to the gene and disease being studied?
 - ⊞ Will identifiers be linked directly or indirectly to the samples?
 - ⊞ Are safeguards for maintaining confidentiality adequate?
 - ⊞ Has the investigator obtained a HHS approved Certificate of Confidentiality?
 - ⊞ Will subjects be informed of results of test?
 - ⊞ Does an effective intervention/therapy exist?
 - ⊞ Will PI be collecting more tissue than needed for clinical purposes?
 - ⊞ Does research involve gene therapy?
 - ⊞ Are family members included in the study?

- ❑ **Benefits**
 - ⊞ Inform subject of no direct benefit, if applicable
 - ⊞ Inform subjects of uncertainties regarding benefits
 - ⊞ Include other potential benefits as appropriate: advancement of knowledge; clinical relevance to individual, family, or society as a whole; long term benefit if investigator plans to re-contact subjects to disclose clinically relevant information

- ❑ **Confidentiality and privacy**
 - ⊞ Address procedures for maintaining confidentiality
 - For example, explain whether there are identifiers linked to data/material
 - Describe plans for physical security of data/sample
 - Indicate if a Certificate of Confidentiality has been obtained
 - ⊞ Address limits to confidentiality (e.g., who will have access and under what circumstances)
 - For example, indicate which third parties (e.g., family, third party payers, employers, subject's physician) would have access
 - Pedigree studies can assure names can not be published, but demographic information may lead to identification
 - ⊞ If possibility that cannot publish without disclosing individual names, need permission to publish names

- ❑ **Costs to Subject**
 - ⊞ Inform subject of any costs of participation not covered in study such as the costs of genetic counseling or psycho/social counseling

- ❑ **Significant new findings**
 - ⊞ Discuss policy regarding willingness to inform subjects if later tests have clinical relevance

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- ❑ **Withdrawal from research study**
 - ✧ Inform subjects of rights to withdraw without penalty and include procedures for doing so
 - ✧ Inform subjects of procedures for subsequently requesting that samples/materials be destroyed, or
 - ✧ Inform subjects of procedures for subsequently requesting that identifiers be removed from materials
 - ✧ Describe any limitations on ability of subjects to withdraw data or DNA samples

- ❑ **Number of subjects**

- ❑ **What else do you need to know**
 - ✧ Inform subjects of the Genetic Information Nondiscrimination Act (GINA) which generally makes it illegal for health insurance companies, group health plans and most employers to discriminate against subjects based on their genetic information.
 - ✧ If genetic testing is anticipated and the data is to be submitted to the data base for the National Institutes of Health (NIH) Genome-Wide Association Studies (GWAS), inform subjects that de-identified genotype or phenotype data will be submitted to the GWAS data base.

References

- ✧ Clayton, Ellen Wright; Karen K. Steinberg; Muin J. Khoury; Elizabeth Thomson; Lori Andrews; Mary Jo Ellis Kahn; Loretta M. Kopelman; Joan O. Weiss. "Informed Consent for Genetic Research on Stored Tissue Samples." *Journal of American Medical Association* 13 Dec. 1995: 1786-1792.

- ✧ Glass, Kathleen Cranley, Charles Weijer, Roberta M. Palmour, Stanley H. Shapro, Trudo M. Lemmens, and Karen Lebacqz. "Structuring the Review of Human Genetics Protocols: Gene Localization and Identification Studies." *IRB A Review of Human Subjects Research* July-Aug. 1996.

- ✧ Fred Hutchinson Cancer Research Center, Institutional Review Board, *Genetic Research Guidelines*. Seattle, Washington: 12 July 1995, provided by Karen Hansen.

- ✧ *Office for Protection from Research Risks (OPRR): Protecting Human Research Subjects, Institutional Review Board Guidebook*. National Institutes of Health, 1993.

- ✧ Summary and Guidance regarding the Genetic Information Nondiscrimination Act of 2008 (GINA), University of Kentucky, Office of Research Integrity at <http://www.research.uky.edu/ori/ORIForms/D101-GINA.pdf>.

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- ✧ University of Kentucky, Office of Research Integrity, Instruction page for the Medical IRB informed consent form under the section DNA Banking and Genetic Research (#12) which can be found on the ORI website under <http://www.research.uky.edu/ori/FormsHELP/S2C.htm>, or the Instruction page for the Nonmedical IRB informed consent form under the section DNA Banking and Genetic Research (#8), http://www.rgs.uky.edu/ori/FormsHELP/S2C_NM.htm.
- ✧ Weir, Robert F., and Jay R. Horton. "DNA Banking and Informed Consent -- Part 1," *IRB, A Review of Human Subjects Research* July-Aug. 1995.
- ✧ Weir, Robert F., and Jay R. Horton. "DNA Banking and Informed Consent -- Part 2," *IRB, A Review of Human Subjects Research* Sept.-Dec. 1995.