

Issues to be Addressed in Obtaining Informed Consent Involving Specimen Collection for Tissue/Specimen Repositories

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Purpose of Repository

- ✧ Inform subjects of the purpose of the repository
- ✧ Provide a specific description of the types of research to be conducted
- ✧ If applicable, inform subjects that samples may be used for genetic research

Duration

- ✧ Inform subjects how long sample will be stored
If indefinite, so state

Procedures

- ✧ Provide a clear description of the operation of the cell repository
- ✧ Inform subjects of conditions under which data & specimens will be released to investigators (e.g. direct or indirect identifiers)

Secondary Use

- ✧ Explain if there will be secondary use only after samples stripped of identifiers or
- ✧ Explain there will be no secondary use
- ✧ Give subjects option now of consenting to future second use
- ✧ Inform subjects they be re-contacted or
- ✧ Give subjects option to indicate if willing to be re-contacted
- ✧ Subjects may want to limit use of sample

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 Information Learned Including Genetic Data

- ✧ 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

Alternatives

- ✧ One alternative is to not provide specimen to repository

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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 transfer procedures
- ⊞ Unknown Risks: Subjects should be informed that there may be risks that at this time are not known

Examples of Variables Impacting Risks

- ⊞ Will identifiers be linked directly or indirectly to the samples?
- ⊞ Are safeguards for protecting privacy and maintaining confidentiality adequate?
- ⊞ Has the repository obtained a HHS approved Certificate of Confidentiality?
- ⊞ Will PI be collecting more tissue than needed for clinical purposes?
- ⊞ Does research involve gene transfer/genetic research?
- ⊞ What is the current state of the art with respect to the gene and disease being studied?
- ⊞ If genetic testing is anticipated, will subjects be informed of results of test?
- ⊞ 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 protecting privacy of subjects and maintaining confidentiality of data
 - 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

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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

Withdrawal from research study

- ✧ Inform subjects whether they may in the future request samples be destroyed
- ✧ 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

- ✧ If genetic testing is anticipated, 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.

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- ✧ 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>.
- ✧ 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.

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