

Additional Items for Informed Consent for Research Involving DNA

Add to Procedures Section when there are No identifiers linked to the DNA sample (i.e., name, initials, medical record number, code):

- Sample will be used for genetic research
- Where the sample is stored
- Who has access to the sample
- If sample/data will be used for other purposes than this research, if so, what purposes.
- Inform the subject that since there are no identifiers:
 - They will not be told the results of the study
 - They will not be able to withdraw sample at a later date

Add to Procedures Section when there ARE identifiers:

- How the sample is linked to the subject
- What the security measures are for storage of samples/data
- Who has access to samples/data
 - Investigator
 - If others, list the others -- Specify who and under what conditions
- If sample/data will be used for other purposes than this research
 - If so, what are the other purposes?
 - Will a new consent be obtained for this research?
- If sample/data will be destroyed at a future date -- When?
- If subjects will be contacted at a future date for more information:
 - What kind of information
 - How subjects will be contacted
- If there are limitations to withdrawal of consent for use of sample/data, describe.
- If research findings are disclosed, state:
 - To whom this information can be released.
 - How disclosure will be done.
 - If there is no useful information of relevance to subjects.
 - If genetic counseling will be available provided there is useful clinical

information.

- If subjects can choose not to receive research results. Can they change their choice?

- Under what circumstances the information will be released to others.

- If there is a possibility of commercial value, state:

- If the subjects will receive a portion of profits.

- If they will be asked to waive control over sample/data. If they refuse, will they be allowed to participate?

If any of the following apply to your research project, then address:

- Are there special considerations related to:

- Psychological risk

-Anxiety about discovery of unwanted and uncertain information about future disease risks

-Impact of no effective therapy

-Stress for family members

- Social risks

-Stigmatization

-Discrimination

- Labeling

- Family relationships

- Confidentiality

- Insurability

- Employment

- Paternity suits

- Unknown risks