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