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# Model Consent Forms for DNA Linkage Analysis and Storage

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# Model Consent Forms for DNA Linkage Analysis and Storage

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## INTRODUCTION

In 1988, the Great Lakes Regional Genetics Group (GLaRGG) created a standing subcommittee to consider the ethical and legal issues pertinent to the genetics professional community. One of our goals was to provide assistance to geneticists in our region in their consideration of difficult ethical and legal issues related to DNA testing. At the time, few of the regional genetics groups had such committees, and at this time some still do not have them.

At the time of our initial committee discussions, DNA linkage was just beginning to be a part of mainstream genetic testing. There was concern whether a patient was able to understand the nuances of DNA testing, and whether truly informed consent was possible. DNA banking was also a major concern, especially with regard to ownership of the DNA. Today we still perceive a need for greater refinement in the treatment of issues having to do with "ownership" and control over the destiny of DNA samples deposited in laboratories for analysis and/or storage.

In 1990, the committee undertook a project to create template or model DNA consent forms. These forms are not intended to be used as is, but to serve as starting points for consent forms. Although we may have missed some of the potential problems, we hope that by publishing these models, and by facilitating their formulation, we might encourage the use of explicit and detailed consent forms within the genetics community.

The composition of these model consent forms was assisted by our study of forms actually in use in some laboratories of our region, and by our study of the official policies of the American Society of Human Genetics [1990].

## INTRODUCTION TO DNA STORAGE AND LINKAGE ANALYSIS CONSENT FORMS

Genes are made up of deoxyribonucleic acid (DNA). DNA found in the cells of the body contains the "blueprint" for inherited traits. DNA comes from our parents in structures called chromosomes. Usually there are 46 chromosomes in each cell, 23 from each parent. Human diseases are often caused by changes (mutations) in DNA. Often these changes can be traced through a particular family. When an inherited condition occurs in a family, relatives often want to know if they might develop the condition or if they might be carriers of the mutation which causes it. Carriers of a recessive gene have it and may pass it to their children but ordinarily they do not show signs of the condition it may cause when present in a double dose. A dominant condition usually shows itself in any person who inherits it even in a single dose, but sometimes its effects are delayed until adulthood.

Recent advances in DNA technology have produced tests which can find mutations, so that people can know if they have the changed gene or can pass it on to their children. Each test looks at a specific change in DNA. Often several relatives must be studied in order to find these changes. Not all genetic conditions have been studied, but scientists are working to develop more DNA tests. Some people may want to store samples of their DNA, so that it may be used to aid other relatives, should tests become available in the future.

DNA is obtained most commonly from the cells in a sample of blood. Storage of DNA is called "DNA banking." A person who is considering submitting a sample of DNA for analysis should also consider what is to be done with leftover material when the test is completed (storage or disposal).

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(DNA bank letterhead)

**CONSENT FOR DNA ANALYSIS**

I, \_\_\_\_\_ request that an attempt be made to assess the probability that I or my unborn child might have inherited the gene for \_\_\_\_\_. I understand that the DNA for analysis is to be obtained from: a) blood cells, b) skin sample, c) other: \_\_\_\_\_. The methods, discomfort, and risks of obtaining the specimen have been explained to me. I also understand that:

- 1. The test procedure is specific to the genetic condition mentioned above and cannot determine the complete genetic makeup of an individual.
- 2. Lack of cooperation by key relatives in providing blood samples may decrease the accuracy of the test result and/or the ability to perform the test.
- 3. An error in diagnosis may occur if there is anything incorrect in what I say about the biological relationships of relatives involved.
- 4. Sometimes the genetic pattern in a family renders the test results "uninformative" (not clarifying the point in question).
- 5. Even under the best conditions, current technology of this type is imperfect, and may lead to incorrect results.
- 6. The test results, when reported to me, may be distressing.
- 7. I may withdraw my consent at any time without penalty.

When the test has been completed, if there is any remaining unused DNA material (circle one letter):

- a. I wish for it to be stored ("banked") and have submitted the appropriate DNA banking consent form, or
- b. I do not wish to bank the leftover DNA, and prefer that it be destroyed.

All of the above has been discussed with me, and my questions answered by \_\_\_\_\_.

\_\_\_\_\_  
patient signature

\_\_\_\_\_  
witness

\_\_\_\_\_  
date

\_\_\_\_\_  
date

(DNA bank letterhead)

**CONSENT FOR DNA STORAGE**

1. I, \_\_\_\_\_, wish to submit a sample of my blood for the purpose of storing DNA (genetic material) from the cells in the blood. The reason for this is that members of my family have or might have genetic changes associated with the clinical condition \_\_\_\_\_.

The following conditions apply to the DNA:

(circle any and all that you wish)

- A. To be used for any future testing as requested in writing by me.
- B. To be used by members of my immediate family (spouse, descendants, parents, grandparents, sibs and their descendants).
- C. To be used as above only until the time of my death, when the remaining DNA in storage is to be destroyed.
- D. To be used for research purposes without my or my family members' knowledge, at the discretion of \_\_\_\_\_.
- E. To be used without any restrictions.
- F. Other \_\_\_\_\_.

2. I understand that the DNA sample will be stored under the following conditions and limitations (these depend on the specific lab):

- A. Services provided by the bank: (e.g. shipping to other laboratories with/without charges).
- B. Risks associated with banking: (e.g. loss or misplacement of samples, catastrophic events).
- C. Method of maintaining contact between depositor and bank: \_\_\_\_\_.

3. I understand that I may change my mind and withdraw my consent for DNA banking at any time. I also understand that there may be some discomfort and/or bruising associated with drawing blood from a vein in my arm.

All of the above has been discussed with me, and my questions answered by \_\_\_\_\_.

\_\_\_\_\_  
depositor signature

\_\_\_\_\_  
witness

\_\_\_\_\_  
date

\_\_\_\_\_  
date

**REFERENCES**

Ad Hoc Committee on DNA Technology (1988): DNA banking and DNA analysis Points to consider. *Am J Hum Genet* 42:781-783.