

10/13/01

USAAL2 - 21406

second
Time
in AL

participants so far

Consent to Participate in a Genetic Study

Description of the study.

We are inviting you to participate in a study designed to create a very large molecular genetic database (a genealogy that is based on an individual's DNA) that will link the molecular DNA information to known written pedigrees. This study will verify molecular methods to determine how individuals and populations are genetically related and to verify written pedigrees and other scientific questions. This study is scheduled to continue for at least six years and participation is voluntary. You will be required to supply a record of your known genealogy and a blood sample that will be used to obtain DNA. The DNA will be used to produce molecular genetic data that will be assembled into a large database.

Procedures. This study involves:

- Submission of a record of your own genealogy in the form of a 4-generation pedigree chart or a data disk containing a GEDCOM file from Ancestral File.
- Donation of a small blood sample drawn by a professional nurse, phlebotomist, or medical technician. The amount of blood taken from your arm is about 8 cc (approximately 2 Tbsp).

Voluntary Participation.

Participation in this study is voluntary. You have the right to end your participation at any time, and to decide whether the material already collected can remain part of the study or must be destroyed. You also have the right to determine which of the above procedures you are willing to complete. Your privacy will be preserved in any scientific publication of the data, and we will not provide genetic information back to you, except in the unusual circumstances listed in Other General Issues, below.

Alternative Approaches. Participation is voluntary, and alternatively, you may choose not to participate.

Risks, Inconvenience, and Discomfort. There is no significant physical risk to your health for participating in this study. There is a possibility that your arm will be bruised at the site where your blood is drawn. In the event you are injured during the blood draw, we will provide transportation to the local hospital emergency room or medical facility of your choice. Generating the genealogical data disk and providing a blood sample will be an inconvenience, since in total they will take about an hour of your time, and a small amount of local travel may be required.

Benefits. There will be no immediate benefit to you for participating in this study. If desired, a small compensation will be offered for your time.

Research Subject's Rights. Participation in this study is voluntary. You may ask questions at any time during your participation, as noted below.

Other General Issues Related to This Proposal

1. Future research. Our specific research plans have been summarized in the first paragraph of this document. In the course of the research, we will obtain samples of your cells. While we will do some testing immediately, we may store your DNA from your cells in the freezer for future studies. In addition, certain information will be stored in your research record. Samples will not be used for other research purposes without your prior permission. The risks involved in future research may differ from the risks involved in this study. If you agree to the use of our sample in future research, you will be able to discuss any concerns you have about this research with a genetic counselor.
2. Unanticipated medical information. During the course of this investigation, it is possible (although not likely) that we will obtain unanticipated information about your health or genetic background. If this information is considered to be relevant to your healthcare, we will provide it either to you or to your physician only at your request. This information will not compromise any other individual in the database.
3. Family relationships. In the course of this study, it is possible that we may learn information about relationships within the family, such as adoption or paternity that is medically relevant. We will not ordinarily provide this type of information to any member of the family. However, we may make exceptions under an extraordinary circumstance if this information were required for the medical care of the individuals involved. If we are convinced that this is necessary, we will provide the information to the physician who is providing medical care to the patient.
4. Maintenance of confidentiality. Any information collected or discovered about you or your family is considered strictly confidential and private. Medical records containing this information will be housed in a locked and secured office at Brigham Young University. You control release of any information contained in these files. Access by others, including family members, is possible only through your written approval.

There may be additional risks that we cannot predict at this time.

Development of genetic tests. It is possible that this study will result in a test or tests that may someday be useful in genetic diagnosis of some disorder. If such a test is developed, you will not be compensated beyond that described above.

Collection of, Research on, and Storage of Genetic Material. It should be clear to you that your blood sample will only be used for research and development of a correlated genetic and genealogical database. No other testing or research will be conducted on your sample unless you specifically give permission (as indicated below). The DNA isolated from your blood sample will be stored in freezers contained in secure buildings at Brigham Young University. The samples will be labeled and stored by codes defined by us. The only individual who will have access to the codes will be the principal investigator of this study, Scott R. Woodward, Ph.D.

Researchers within as well as outside of Brigham Young University may be interested in using DNA samples to pursue their own individual research projects. Those who provide the samples, namely you, can control the use of any DNA samples. Unless you specifically refuse, we will contact you about future studies that may take place. Therefore, we ask your guidance and concurrence if the occasion should arise concerning future use of your DNA samples in any other studies.

I give my permission to use my DNA sample in future studies under the following condition:

(Check one of the following options)

_____ **I give my permission to use my DNA sample in future research studies judged as important by the investigators.**

_____ **I wish to be contacted if further studies with my sample are considered. After the study has been explained, I will then decide if I want my samples to be included in the study.**

_____ **Under no circumstances shall my sample be used for future studies.**

Contacts. This study is supervised by the principal investigator, Scott R. Woodward, PhD. Dr. Woodward can be contacted at 801-378-6259 with any questions you may have concerning the research and your rights as a research subject. In addition, if you have any questions that you wish to direct to an impartial third party, you may contact Dr. Shane Shulthies, Chair of the Human Subjects Institutional Review Board, 135 TLRB, Brigham Young University, Provo, UT 84602; phone: 801-378-5490.

I have read, understood and received a copy of the above consent, and desire of my own free will and volition to participate in this study and accept the benefits and risks relating to the study.

Your Name (Print)

Date

Gender: M F

Permanent Address (Street, City, State, ZIP)

Phone

Email Address

Your Signature

Witness Signature