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AS MODIFIED
May 7, 2008
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RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE: Development of a Correlated Genetic and Genealogical Database

PROTOCOL NO.: SMGF-2008-1
WIRB® Protocol #20031734

SPONSOR: Sorenson Molecular Genealogy Foundation
Salt Lake City, Utah
United States

INVESTIGATOR: Scott R. Woodward, Ph.D.
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Salt Lake City, Utah 84115
United States
801-428-1050 or
1-800-344-7643 office hours 8am – 5pm MST
801-244-2542 (in case of emergencies)

SITE(S): Sorenson Molecular Genealogy Foundation
Suite 200
2480 S Main Street Ste 200
Salt Lake City, Utah 84115
United States

STUDY COORDINATOR: Ugo Perego
801-428-1054

This consent form may contain words that you do not understand. Please ask the study coordinator or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

In this consent form, "you" always refers to the subject. If you are a legally authorized representative, please remember that "you" refers to the study subject.

Description of the Study

You are invited to participate in a research study designed to create a large database of combined genetic and genealogical information. The primary purpose of the database is to link molecular genetic information with written pedigrees. The research study is being conducted by The

Sorenson Molecular Genealogy Foundation, a not-for-profit organization. This study will use molecular testing methods to determine how individuals and populations are genetically related. This information will be added to a database that links genetic markers with family pedigrees. The database is publicly available on the SMGF website (www.smgf.org) and can be a tool to help search for genealogical information.

If you decide to participate, you will be required to supply the following: (1) a record of your known genealogy with as many names, dates of birth, and places of birth as possible, and (2) a biological sample.

DNA will be extracted from your cells and a genetic profile created. The genetic profile derived from your DNA together with your genealogical pedigree will be placed into the SMGF database. All information and samples will be encoded in such a way as to remove your personal identification, however, a link will remain available to the researchers. The information from this study is intended to be used for genealogical services, including the determination of family migration patterns and geographic origins.

Procedures Include the Following

1) Submission of a record of your own genealogy (containing as many generations as possible) in the form of a pedigree chart or an information disk containing that information in a GEDCOM file; and
2) Providing a biological sample. You will be given specific directions by study staff.

Risks, Inconvenience, and Discomfort

Presently, there are no known health risks involved in obtaining the DNA sample.

Despite confidentiality protocols in place, the sponsor cannot guarantee that your genetic test results could never be linked to you. A potential non-health risk is the possibility that the confidentiality of your genetic or genealogical records could be compromised.

There are risks associated with a loss of confidentiality of your genealogical information and genetic testing results. Information about genetic test results may affect your employment, insurance, or family relationships.

Generating and submitting the genealogical information and providing a biological sample may be an inconvenience to you.

Additional risks. There may be additional risks that we cannot predict at this time. If in the future, substantial risks determined by SMGF associated with your participation are identified, you will be contacted.

New Findings

You will be told about any new information that might change your decision to be in this study.

Benefits

There is no immediate benefit to you for participating in this study. We will not routinely provide genetic information back to you. You may be given the opportunity to access your genetic profile and pedigree information after your data has been processed. Notification and instructions will be provided at that time.

Future benefits. Your contribution to this study may benefit you and others who use the public database to further their ancestral research.

Payment for Participation

There will be no payment for your participation.

Alternatives

This is not a treatment study. As such, your alternative is not to participate in this study.

Voluntary Participation/Withdrawal

Participation in this study is strictly voluntary. You may choose not to participate. You also have the right to end your participation at any time, and to decide whether the biological sample, genetic information, or genealogy you provided can remain part of the study or must be destroyed.

Your participation in this study may be stopped at any time by the study coordinator or the sponsor without your consent.

Research Subject's Rights

You may ask questions at any time during your participation.

Confidentiality

Your unique personal identity is considered strictly confidential and private. Your unique personal identity will not be disclosed in any general or scientific publication of the data. Samples and files containing this information will be stored in a secure facility. The only individuals who will have access to the codes and genealogy information will be the principal investigator and the others specifically authorized by the Principal Investigator, including the SMGF research staff. Your unique identification and the identity of your recent ancestors is not directly associated with the information in the public database.

Participant Contact

Users of the online database may desire to contact you to ask questions or share information. Contact between database users and project participants is completely voluntary and is brokered by SMGF or a third party, such as an email message sent through the SMGF website. None of your personal or contact information will be shared with database users.

Who else might get this information?

As the sponsor, SMGF may share non-identifiable information with collaborators, including companies that SMGF works with.

Study records may be reviewed by The Western Institutional Review Board® (WIRB®). WIRB is a group of people who perform independent review of research as required by government regulations.

Family relationships. In the course of this study, it is possible that we may learn information about relationships within your family, such as adoption or paternity. We will not provide such information to you or any member of your family.

Collection of, Research on, and Storage of Biological Sample. Your biological sample is intended to be used for research and development of a correlated genetic and genealogical database. At our sole discretion we may have your DNA analyzed by an outside lab. Biological samples will be encoded and labeled with identifiers defined by us. Samples will not be identified by your name.

Questions

If you have questions regarding the research or your rights as a research subject, or if at any time you feel you have experienced a research-related injury, contact:

> Scott R. Woodward, Ph.D. or Ugo Perego, MSc of The Sorenson Molecular Genealogy Foundation, a non-profit corporation, at 801-428-1050, 1-800-344-7643, or 801-244-2542 (emergencies), or write to info@smgf.org.

If you have questions about your rights as a research subject, you may contact:

> Western Institutional Review Board® (WIRB®)
> 3535 Seventh Avenue, SW
> Olympia, Washington 98502
> Telephone: 1-800-562-4789.

WIRB is a group of people who perform independent review of research.

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Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

If you agree to participate in this study, you will receive a signed and dated copy of this consent form for your records.

Source of Funding

Primary funding for this research study will be provided by the Sorenson Molecular Genealogy Foundation.

Consent

I have read the information in this consent form (or it has been read to me). All my questions about the study and my participation in it have been answered. I freely consent to participate in this research study.
By signing this consent form, I have not waived any of the legal rights, which I otherwise would have as a subject in a research study.

Consent and Assent Instructions:

Consent: *Subjects 18 years and older must sign on the subject line below*
For subjects under 18, consent is provided by the Legally Authorized Representative
Assent: *Is not required for subjects 6 years and younger*
Is required for subjects ages 7 through 12 years using the separate Assent Form
Is required for subjects ages 13 through 17 years using the Assent Section below

_____ _____ Gender: **M F**
1. Subject Name (Print) Today's Date

_____
Permanent Mailing Address (Street, City, State, Zip Code)

_____ _____
Phone Email Address

CONSENT SIGNATURE:

_____ _____
2. Subject Signature (18 years and older) Date

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3. Signature of Legally Authorized Representative (when applicable) Date

4. Authority of Subject's Legally Authorized Representative or Relationship to Subject

5. Person Conducting Informed Consent Discussion Signature Date

ASSENT SIGNATURES, For Subjects Ages 13 through 17 years:

Assent:
This research study has been explained to me and I agree to be in this study.

7. Subject's Signature for Assent Date Age (years)

I confirm that I have explained the study to the extent compatible with the subject's understanding, and that the subject has agreed to be in the study.

8. Signature of Person Conducting Assent Discussion Date

----------Use the following only if applicable----------

If this consent form is read to the subject because the subject (or legally authorized representative) is unable to read the form, an impartial witness not affiliated with the research or investigator must be present for the consent and sign the following statement:

I confirm that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject (or the subject's legally authorized representative). The subject (or the subject's legally authorized representative) freely consented to participate in the research study.

Impartial Witness Signature Date

Note: This signature block cannot be used for translations into another language. A translated consent form is necessary for enrolling subjects who do not speak English.