

Title: STORAGE OF BIOLOGICAL MATERIAL FOR THE DISCOVERY AND CHARACTERIZATION OF GENES INVOLVED IN HEREDITARY DISEASE PREDISPOSITION

Ohio State University

OSU Protocol Number 2004H0136

ADULT CONSENT

I, _____, hereby authorize or direct Albert de la Chapelle, M.D., Ph.D. or associates or assistants of his choosing, to perform the following procedure if necessary and hereby authorize associates or assistants of his choosing to store the DNA and other biological material in the Genetics Sample Bank (Director A. de la Chapelle, MD, PhD) of

(myself; or subject name)

THE EXPERIMENTAL (RESEARCH) PORTION OF THE STUDY:

The research portion of this study is to store biological material (DNA, RNA, and/or protein) from individuals with a personal or family history of a disease or condition that may be hereditary. I understand that my or my deceased relative's biological material will be stored for twenty years. I also understand that while my or my deceased relative's biological material is stored at OSU it may be included in research studies to find genes that cause an increased risk for my or my family's inherited disease. I understand that I will not be asked to consent to each study as it is conducted; instead this will serve as my consent to all future studies. No other types of research will be performed on the stored samples and identified samples will not be released to other investigators for other unrelated research.

Participation in this study will be discussed with me by a clinical geneticist, a genetic counselor, or an associate of their choosing. If I choose to store my or my deceased relative's biological material, a detailed family history will be obtained along with my or my deceased relative's medical history.

I understand that my or my deceased relative's sample will be discarded after twenty years. Since the researchers are storing DNA, RNA, and protein, they will not likely run out of the biological material before the twenty year period expires; however, the researchers cannot guarantee the quality of the sample over time. I understand that my or my deceased relative's stored material will be available for the personal use of me or my family during that twenty year period.

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In this consent form, I have the option of naming a “Family Member Contact” person who can receive results or make decisions about my or my deceased relative’s stored biological material if I am unable to do so myself. The Family Member Contact person can be another family member, friend, or a physician.

I understand that if I choose to store my or my deceased relative’s biological material at OSU, it will be included in research studies about the genetics of the disease or condition in myself or my family. I understand that any research study conducted on my or my deceased relative’s sample will have the approval of the Division of Human Genetics based upon scientific merit, potential risks and benefits to my family or me, and qualifications of the laboratory.

I understand that I can choose whether or not to allow researchers to study my or my deceased relative’s biological material with an identifying code number linked to my name, or anonymously. If I allow researchers to study my or my deceased relative’s biological material with a code number, I can decide whether or not to be told any clinically relevant research results (meaning that the result may change recommendations for my health care) that become available in the future. If I allow researchers to use my or my deceased relative’s biological material anonymously, results cannot be linked to me and I do not have the option of receiving research results.

I understand that researchers may never find any clinically relevant research results using my or my deceased relative’s stored biological material. I also understand that if the researchers do find clinically relevant results, I will be told the overall research finding and offered participation in a follow-up test where my research results would be confirmed in a clinical laboratory. Research results cannot be used for clinical care in the United States, therefore confirmation of research results in a clinical laboratory is available at my cost.

Researchers may make incidental findings during genetic studies. For example, it is sometimes learned that some family members are not biologically related to each other or are related in a different way than expected. In all instances, I will not be informed of this type of incidental finding.

If I decide to receive any future research results, it is the responsibility of me and/or my Family Member Contact person to maintain a current address and phone number with the researchers. The researchers will not attempt to contact me or my Family Member Contact person beyond the most current address that has been provided, regardless of the results.

I can withdraw my consent at any time. If I withdraw from the study, my or my deceased relative’s stored biological material will be destroyed by the storage facility and by any researchers working with the sample. In addition, researchers will remove any information about me or my deceased relative from the research files and computer database to the extent possible. Any results obtained before I withdraw from the study will be handled as directed by me in this consent form.

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All information collected about people who choose to take part in this research program will be kept confidential to the extent possible. None of the information collected during this study will be included in my medical records at the Ohio State University Medical Center. All collected information will be stored in locked research files or in locked files in the Division of Human Genetics. All laboratory specimens are identified only by a code number. Samples will be destroyed after 20 years of storage.

THIS IS DONE AS PART OF AN INVESTIGATION ENTITLED:

STORAGE OF BIOLOGICAL MATERIAL FOR THE DISCOVERY AND CHARACTERIZATION OF GENES INVOLVED IN HEREDITARY DISEASE PREDISPOSITION

PURPOSE OF PROCEDURE:

Check one or more of the following:

- ف I have been invited to donate approximately four tablespoons of blood (20 – 40 ml) so that OSU Medical Center can store my biological material.
- ف I have been invited to donate a cheek cell sample so that OSU Medical Center can store my biological material. To collect a cheek cell sample, I will be asked to rub a soft brush on the inside of my cheek, or rinse my mouth with sterile water or a commercially available mouthwash (like Scope). These samples can be collected at home or at OSUMC with a provided kit, and sent back to OSUMC at their expense. If I donate a cheek cell sample, only DNA and possibly RNA will be stored.
- ف I have been invited to donate a saliva sample so that OSU Medical Center can store my biological material. To collect a saliva sample, I will be asked to spit 2 milliliters (about half of a teaspoon) of saliva into a cup that will be provided as part of a saliva collection kit. This can be done at OSUMC, or this kit can be used at home and sent back to OSUMC at their cost. If I donate a saliva sample, only DNA and possibly RNA will be stored.
- ف I have been invited to release my fresh/frozen or paraffin-embedded tissue so that OSU Medical Center can store my biological material.
- ف I have been asked to release my deceased relative's paraffin-embedded tissue block so that OSU Medical Center can store his/her biological material.

By storing my biological material at OSU, I allow my or my deceased relative's sample to be used for any research studies relating to the genetics of my or my family's disease or condition. I can decide whether or not I would like to hear the overall results of these research studies if they are clinically relevant (could affect my or my family member's health). In addition, I will

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have access to my or my deceased relative's stored biological material for a twenty-year period if I need it for any reason.

POSSIBLE APPROPRIATE ALTERNATIVE METHODS OF TREATMENT:

There are no treatment aspects to this study, therefore, my medical care will be the same if I choose to participate in this study or not. If I choose not to participate in this study, my doctor will continue to give me the best care possible.

I have been informed that DNA storage is available through commercial laboratories at my own cost. This will ensure that the DNA is available for as long as necessary and samples will not be used in any research studies. If I am interested in this option, I can be provided with the contact information for such laboratories.

DISCOMFORTS AND RISKS MOST LIKELY TO BE EXPECTED FROM THIS STUDY:

Discomforts and risks depend on the type of biological material being donated. Tissue will usually be obtained during another medical procedure (i.e. scheduled surgery or prior surgery) so this will not add any additional risk. Discomforts and risks of the blood draw that occur most frequently are temporary discomfort with the needle stick, bruising, and minimal bleeding. Less frequent risks of the blood draw are prolonged bleeding and/or discomfort, infection, possible fainting, or collection of blood in the tissues of the arm (hematoma). A cheek swab involves gently rubbing a soft brush on the inside of each cheek. The risks of this procedure are minimal, but I may have some mild, temporary irritation of my cheek. There are no known risks associated with collecting a saliva sample or a mouthwash sample.

Financial Risks:

I understand that I will not be responsible for the cost of sample storage. However, if my blood is drawn outside of the OSU Medical Center, I may be responsible for the cost of my blood draw. There are no treatment aspects to this study so I will be financially responsible for any screening procedures or treatment that I elect to pursue. In the unlikely event that any profitable discoveries are made using my biological material, I understand that I will not receive any personal financial benefit. In the event that a clinically relevant research genetic finding is made and I have elected to receive preliminary results, I will be given the results in the context of genetic counseling and offered the opportunity to confirm the result in a clinical laboratory if such a test is available. The cost of genetic counseling and the cost of the clinical confirmation genetic testing will be my responsibility.

Psychological Risks:

Psychological risks resulting from the storage of biological material are minimal. It is possible that my family members and I could disagree about the future use of my or my deceased relative's biological material. If I die or am unable to make decisions about my or my deceased relative's sample, my family members may disagree with the person that I have chosen as my Family Member Contact. They may also disagree about the future

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use of my or my deceased relative's sample. In all instances, I or the person I name as the Family Member Contact will have control over the use of my or my deceased relative's sample. In addition, I might find that being involved in genetic research causes me anxiety or upset. If I decide to confirm any preliminary research result with clinical genetic testing I will be offered genetic counseling to understand the psychological risks associated with clinical genetic testing.

Insurance risks:

Since no research study can guarantee complete confidentiality and since insurance companies could ask about participation in genetic research if so inclined, my insurance company could learn that I have participated in a research study. It is unclear whether an insurance company would discriminate against someone for participating in a genetic research study since that does not necessarily mean that the individual has any genetic predisposition to disease. Regardless, Federal laws provide legal protection against insurance discrimination for individuals on large, group insurance plans. However, self-insured individuals are not protected by federal laws.

POSSIBLE BENEFITS FOR SUBJECT/SOCIETY:

By storing my or my deceased relative's biological material, my family and I may be able to benefit from future genetic research studies. In addition, the information that is obtained from any genetics research studies will be used scientifically and possibly may be helpful to others.

ANTICIPATED DURATION OF SUBJECT'S PARTICIPATION (including number of visits):

If I choose to participate in the study, I will need to provide informed consent, have a blood draw, provide a cheek cell sample, or provide a saliva sample (if my sample is not already stored at OSU), release my medical records and any available tissue samples, and provide my family and medical history. This may be all done at my genetics consultation, or I may have to make one visit to the doctor's office or hospital to have my blood drawn.

CERTIFICATE OF CONFIDENTIALITY

To help the researchers protect my privacy, they have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify me, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify me, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of Federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

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I understand that a Certificate of Confidentiality does not prevent me or a member of my family from voluntarily releasing information about myself or my involvement in this research. If an insurer, employer, or other person obtains my written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without my consent, information that would identify me or my child as a participant in the research project under the following circumstances: the researchers may provide information to appropriate individuals or agencies if harm to me, harm to others, or child abuse becomes a concern.

I hereby acknowledge that _____ has provided information about the procedure described above, about my rights as a subject and he/she answered all questions to my satisfaction. I understand that I may contact him/her at telephone number 614/293-6694 (Division of Human Genetics) should I have additional questions. He/she has explained the risks described above and I understand them; he/she has also offered to explain all possible risks or complications.

I understand that, where appropriate, the U.S. Food and Drug Administration, a qualified representative of the drug manufacturer, and the National Institutes of Health may inspect records pertaining to this study. I understand further that records obtained during my participation in this study that may contain my, my child's, or my deceased relative's name or other personal identifiers may be made available to the sponsor of this study. Beyond this, I understand that my or my deceased relative's participation will remain confidential.

I understand that I am free to withdraw my consent and participation in this project at any time after notifying the project director without prejudicing future care. No guarantee has been given to me concerning this treatment or procedure.

I understand in signing this form that, beyond giving consent, I am not waiving any legal rights that I might otherwise have, and I am not releasing the investigator, the sponsor, the institution, or its agents from any legal liability for damages that they might otherwise have.

In the event of injury resulting from participation in this study, I understand that immediate medical treatment is available at The Ohio State University Medical Center and that the costs of such treatment will be at my expense; financial compensation beyond that required by law is not available. Questions about this should be directed to the Office of Responsible Research Practices at (614) 688-4792.

I have read and fully understand the consent form. I sign it freely and voluntarily. A copy has been given to me.

Choose one option and initial:

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_____ 1) You can use my or my deceased relative's biological material in genetics research with identifiers, and (check one of the following):

_____ I would like to be contacted in the future if clinically relevant research results become available.

_____ I would not like to be contacted in the future.

OR

_____ 2) You can use my or my deceased relative's biological material in genetics research without identifiers and I realize that I will be unable to receive the results of research performed on unidentified samples.

Date: _____

Time: _____ AM / PM

Signed: _____

Subject consent

Person authorized to consent for subject if required

Witness, if required: _____

I certify that I have personally completed all blanks in this form and explained them to the subject or his/her representative before requesting the subject or his/her representative to sign it.

Date: _____

Signed: _____

(Signature of the Project Director or Authorized Representative)

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