

## RESEARCH CONSENT FORM

**Protocol Title:** University of Maryland Brain and Tissue Bank  
– Autopsy Consent

**Study No.:** HP-00042077

**Principal Investigator:** Thomas G. Blanchard, Ph. D. 410-706-1755

**Sponsor:** National Institutes of Health

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- This is a research study. Your participation is voluntary and is based on your decision to participate. The staff of the University of Maryland Brain and Tissue Bank is available at all times to answer questions regarding the project and your participation.
  - Under certain circumstance you may be giving consent for someone other than yourself to participate in this project, for example, a child or someone unable to provide consent themselves or someone who is deceased, then the word “you” in this consent form means that person.

### PURPOSE OF STUDY

- Human tissue is required for studies that may lead to development of new treatments and prevention of developmental disorders such as adrenoleukodystrophy, autism, chromosomal disorders, dystonia, Fragile X syndrome, in-born-errors of metabolism, sudden unexpected death in infancy, Rett syndrome and many other disorders. The University of Maryland Brain and Tissue Bank was established by the National Institutes of Health to serve as a repository of rare tissues collected at the time of death.
- The Brain and Tissue Bank also collects and distributes tissue from individuals of any age as part of its expanded role as a member of the NIH NeuroBioBank network.
- The purpose of the Brain and Tissue Bank is to systematically collect, store, and distribute brain and other tissues to researchers worldwide who are dedicated to improve understanding, care and treatment of individuals with developmental and neurological disorders.
- Any individual who has such a disorder, or is related to someone with such a disorder, is eligible to donate tissue. In addition, individuals without any disorder may donate tissue to serve as control tissue.
- You will be one of approximately 5000 subjects to be asked to participate in this tissue donation program at the University of Maryland.

## PROCEDURES

- At or near the time of death, the next of kin or a designated person contacts the Brain and Tissue Bank by telephone to inform the Bank that the tissue donor is near death or has died. The recovery of tissue will be arranged by the staff of the Brain and Tissue Bank through pathology departments at medical institutions or at a funeral home once consent for tissue donation has been received. There is no cost to the tissue donor and/or family for donation of tissue.
- The tissue to be collected may include the brain, portions of body organs such as heart, liver, kidney, lung, spine and other tissues affected by the disorder. Skin fibroblast cultures will be established and stored frozen from a sub-set of cases if characteristics or properties of the disorder are expressed in skin cells.
- If there any tissues/organs that you do not want to donate, please list the tissues/organs \_\_\_\_\_ . If there are no restrictions to what tissue may be collected, then write “None” on the following line: \_\_\_\_\_.
- Tissue collection will be arranged within 24 hours. The legal next of kin will be notified if a longer time period is needed.
- Since the Bank depends on the availability of pathologists near the site of the deceased, the Bank cannot give assurance that they will be able to find a pathologist for all cases.
- The tissue will be stored and distributed to qualified researchers by the Bank located at the University of Maryland, Baltimore. The National Institutes of Health may designate successor banks to receive the tissue.
- The tissue will be used solely in medical research related to the disorder of the donor. The specific research projects may be microscopic examination of the tissue, analysis of RNA, DNA or proteins. The studies are designed by the researchers requesting the tissue, although the staff of the Brain and Tissue Bank review the projects for feasibility and evaluate the credentials of the researcher. Most of the researchers are working at US research centers although scientists from foreign institutions may request tissue if they meet the same standards as US researchers.
- Donors are de-identified and assigned unique identification numbers. The identity of the donor is retained by the Bank. The legal next of kin may request that the tissue be disposed of by appropriate and legal processes. Likewise, on the request of the legal next of kin, all medical records will be destroyed. the tissue will be disposed of by appropriate and legal processes
- For a subset of donors, cell cultures may be established for laboratory study. There is a possibility that the cells may be used to establish genetic testing for the disorder of the donor.
- The tissue will be stored for an indefinite period of time and may be used for chemical, histological, and genetic studies as science and knowledge advance. The studies may include efforts to look for an association between a genetic marker and a specific disease or condition, but at this point it is not clear if the genetic marker that may be studied will have predictive value. Genetic data, without donor identifiers, may be stored in central databases. The data may be analyzed by researchers in the scientific community to test new hypotheses and to pool data from

multiple studies to identify potential relationships between DNA sequences and medical disorders.

- It is not possible to predict how soon the tissue will be used for research since it depends on when sufficient number of cases for a particular disorder become available and when a researcher requests tissue from the Bank. Therefore, the Bank is not able to track research results for tissue from a particular donor and provide those results to the family.

### **WHAT ARE MY RESPONSIBILITIES IF I TAKE PART IN THIS RESEARCH?**

- If you take part in this research, the next of kin or the person with power of attorney will be responsible to notify the Bank at or near the time when a tissue donors dies. The Bank will also ask for access to medical records that related to the disorder of the donor.

### **POTENTIAL RISKS/DISCOMFORTS:**

- Tissue donation after death is not considered to inflict pain or risk to the decedent.
- Tissue donation does not interfere with a normal viewing.
- All costs related to tissue recovery are paid by the Bank.
- There is a psychological risk in that the donor may not meet the criteria of the project such as an extended time period after death, or that the donor has developed complicating illnesses that would interfere in the research on the tissue, or the inability of the staff of the Bank to recruit a pathologist to recover the tissue.
- Loss of confidentiality will be minimized by storing data in a secure location such as a locked office and locked cabinet. Electronic data will be password-protected.
- There may be risks in this study which are not yet known.

### **POTENTIAL BENEFITS**

- You will receive no direct benefit from participation in this tissue donation program. However, your participation may help the investigators better understand the underlying basis for developmental disorders. There also will be no direct benefit to the donor of the tissue. However, research findings may benefit the health of future generations.
- If the tissue donor is your child, you need to decide if your child's participation in this research study is in your child's best interest.

### **ALTERNATIVES TO PARTICIPATION**

- This is not a treatment study. Your alternative is to not take part. If you choose not to take part and if you are a patient at the University of Maryland, Baltimore, your healthcare at University of Maryland, Baltimore will not be affected.

### **COSTS TO PARTICIPANTS**

- It will not cost you anything to take part in this study. The Bank will pay all charges related to tissue recovery.

### **CONFIDENTIALITY AND ACCESS TO RECORDS**

- Efforts will be made to limit your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization. If NIH transfers the responsibility of the Brain and Tissue Bank to another organization, the confidential records will also be transferred. That organization is expected to agree to the same confidentiality rules as the University of Maryland, Baltimore site
- The data from the study may be published. However, you will not be identified by name. People designated from the institutions where the study is being conducted and people from the sponsor will be allowed to inspect sections of your medical and research records related to the study. Everyone using study information will work to keep your personal information confidential. Your personal information will not be given out unless required by law.

### **RIGHT TO WITHDRAW**

- Your participation in this study is voluntary. You do not have to take part in this research. You are free to withdraw your consent at anytime. Refusal to take part or to stop taking part in the study will involve no penalty or loss of benefits to which you are otherwise entitled. If you decide to stop taking part, or if you have questions, concerns, or complaints, or if you need to report a medical injury related to the research, please contact the investigator Thomas G. Blanchard, Ph.D., 410-706-1755.
- If you withdraw from this study, already collected data may not be removed from the study database. For example, if you donated surgical specimens and then withdraw your consent for donating autopsy tissue, data obtained with the surgical tissue will be retained.
- You will be told of any significant new findings which develop during the study which may affect your willingness to participate in the study.

### **CAN I BE REMOVED FROM THE RESEARCH?**

- The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include failure to sign tissue donation form, access to medical records form, or if you develop additional complicating disorders that diminishes the value of the tissue for research. The sponsor can also end the research study early. The study doctor will tell you about this and you will have the chance to ask questions if this were to happen.

**UNIVERSITY STATEMENT CONCERNING RESEARCH RISKS**

- The University is committed to providing participants in its research all rights due them under State and federal law. You give up none of your legal rights by signing this consent form or by participating in the research project. This research has been reviewed and approved by the Institutional Review Board (IRB). Please call the Institutional Review Board (IRB) if you have questions about your rights as a research participant.
- The research described in this consent form has been classified as minimal risk by the IRB of the University of Maryland, Baltimore (UMB). The IRB is a group of scientists, physicians, experts, and other persons. The IRB's membership includes persons who are not affiliated with UMB and persons who do not conduct research projects. The IRB's decision that the research is minimal risk does not mean that the research is risk-free. You are assuming risks of injury as a result of research participation, as discussed in the consent form.
- If you are harmed as a result of the negligence of a researcher, you can make a claim for compensation. If you have questions, concerns, complaints, or believe you have been harmed through participation in this research study as a result of researcher negligence, you can contact members of the IRB or the staff of the Human Research Protections Office (HRPO) to ask questions, discuss problems or concerns, obtain information, or offer input about your rights as a research participant. The contact information for the IRB and the HRPO is:

University of Maryland Baltimore  
Human Research Protections Office  
620 W. Lexington Street, Second Floor  
Baltimore, MD 21201  
410-706-5037

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

If you agree to participate in this study, please sign below.

If Participant is a living adult who is registering as a future tissue donor, please complete section 1.

If Participant is a living minor child or dependent adult, whose parent or guardian is registering the participant as a future tissue donor, please complete section 2.

If Participant is deceased, please complete section 3.

**Section 1:**

\_\_\_\_\_  
Name of Participant (Print)

\_\_\_\_\_  
Signature of Participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Phone Number of Participant

\_\_\_\_\_  
Witness (Print)

\_\_\_\_\_  
Witness Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Telephone Number of Witness





**Section 2:**

\_\_\_\_\_  
Name of Minor Child or Dependent Adult Participant (Print)      Date of Birth

\_\_\_\_\_  
Name of Parent/Guardian (Print)      Relation to Participant

\_\_\_\_\_  
Signature of Parent/Guardian (Print)      Date      Telephone number of Parent/Guardian

**Section 3:**

\_\_\_\_\_  
Name of Deceased Participant (Print)

\_\_\_\_\_  
Name of Kin/Guardian (Print)      Relation to Deceased Participant

\_\_\_\_\_  
Signature of Kin/Guardian      Date

\_\_\_\_\_  
Telephone number of Kin/Guardian

\_\_\_\_\_  
Investigator or Designee of the Brain and Tissue Bank Obtaining Consent Signature

Date: \_\_\_\_\_

