

Key Information for: West Virginia University Tissue Bank for Neurological Diseases

You are being asked to participate in the research described below. This page provides key information that may help you to make this decision; more detailed information can be found after this section.

Why is this research being done and what is involved?

- The purpose of this study is to collect, store and distribute brain, spinal cord, muscle, nerve, and/or cerebrospinal fluid samples from subjects with neurological diseases and subjects without medical conditions so that they may be studied by researchers to advance medical science and our understanding of these diseases.
- You will be asked to voluntarily complete, either over the phone or on paper, a questionnaire related to the decedent's medical and family history.
- Your participation in this study will take less than 1 hour to complete should you complete the survey.

Do I have to participate and what are the risks involved?

Participation in this research study is completely voluntary and you are free to withdraw from the research at any time. If you do not wish to participate, there is no alternative study. You may or may not directly benefit from participating in this research.

Risks from participation in this study include a small risk that the decedent identity may be inadvertently identified outside of the research.

Who can I talk to if I have questions or concerns?

If you have any questions or concerns about this research or would want to withdrawal from the study, you can contact Rudolph Castellani, MD at 304-293-0287 from the Dept. of Pathology, Anatomy and Laboratory Medicine at West Virginia University.

For more information, please see the Informed Consent Form.

Informed Consent for Research | Minimal Risk (Autopsy)

Principal Investigator (PI) 	Rudolph Castellani, MD
Department 	Department of Pathology, Anatomy and Laboratory Medicine.
Co-Investigator(s) 	Peter Perrotta MD, James Coad MD and Jacqueline Karakiozis.
Sponsor or Funding Source 	Department of Pathology, Anatomy and Laboratory Medicine.
WVU IRB Protocol # 	1811349401
Study Title 	West Virginia University Tissue Bank for Neurological Diseases.

Introduction

You, _____, have been asked to participate in this research study, which has been explained to you by _____. This study is being conducted by Rudolph Castellani, MD in the Department of Pathology, Anatomy and Laboratory Medicine at West Virginia University, along with Peter Perrotta MD, James Coad MD and Jacqueline Karakiozis MLT (ASCP). Funding for this research is provided by the Department of Pathology, Anatomy and Laboratory Medicine.

Purpose

The purpose of this study is to collect, store and distribute brain, spinal cord, muscle, nerve, and/or cerebrospinal fluid samples from subjects with neurological diseases and subjects without medical conditions so that they may be studied by researchers to advance medical science and our understanding of these diseases. As a Tissue Bank, this study expects to continue overtime to enroll subjects without limiting enrollment, as increased participation will enhance the tissue bank's quality.

Description of Procedures

This study involves your donating the decedent's brain, spinal cord, muscle, nerve, and/or cerebrospinal fluid. While the Tissue Bank serves as a collection of tissues for researcher to use and does not specifically do the research work, the Tissue Bank may performed tests on the donated specimens to confirm any diagnosis or properly characterize it prior to giving it to the researchers.

Cells from the tissues may also be grown to better understand the biology of neurological diseases. In addition, DNA/RNA (genetic part of the cells) and/or proteins may be collected for use in some of these research studies.

By participating in this study, you will be agreeing to allow access to the decedent's medical records in order for the tissue bank to fully understand the decedent's medical history, which may include information about their family's medical history.

I understand that I will be asked to voluntarily complete, either over the phone or on paper, a questionnaire related to the decedent's medical and family history. I understand that I will be able to see the questions prior to signing this consent form if I want to and that I do not need to answer each question. I understand that I am under no obligation to complete this survey to participate in this study, and that I can complete all or part of it at my discretion.

The decedent's brain, spinal cord, muscle, nerve, and/or cerebrospinal fluid will be made available to researchers either immediately or preserved in the Tissue Bank located within the Pathology Department at West Virginia University for future use. In addition, the samples may be shared with private biotechnology companies who may use it for research and development purposes only.

Prior to the release of any specimens, future researchers will be required to have a reviewed and approved Institutional Review Board protocol for the conduct of their research.

Your participation in this study will take less than 1 hour to complete should you complete the survey questionnaire.

Risks and Discomforts

Tissue donation after death is not considered to place risk the decedent at risk and does not interfere with normal viewing at a funeral. There is a small risk that the decedent identity may be inadvertently identified outside of the research setting.

In addition, there is always the risk of uncommon or currently unforeseeable events.

Alternatives

There are no alternatives to this study, and we do not have to participate in this study.

Benefits

While we may not directly benefit from participating in this research, the knowledge gained from this study may eventually benefit others by learning about various neurological diseases.

Financial Considerations

I understand that the decedent's family nor myself (*we*) will not receive any financial benefit from this research, nor will we have to pay any costs associated with the storage of the brain, spinal cord, muscle, nerve, and/or cerebrospinal fluid or the research conducted on these tissues. I understand that we will not have any rights to the research results obtained from the tissues. As a result of these research activities, the investigators or others engaged in these research activities may derive economic benefits from the use of the brain, spinal cord, muscle, nerve, and/or cerebrospinal fluid. I understand that information obtained from these tissues may be used in the development of a commercial product.

Your data, health information, research results, specimens, genomic data, or any and all other information related to this research study used in this research study may contribute to a new discovery or treatment. In some instances, the decedent's data, the decedent's health information, the decedent's research results, the decedent's specimens, any discoveries or treatments, or any other information related to this research study, even if identifiers are removed, may be of commercial value and may be sold, patented, or licensed by the investigators and/or West Virginia University for use in other research or the development of new products. You will not retain any property rights nor will you share in any money or commercial profit that the investigators, researchers, specimen recipients, West Virginia University, and/or their agents may realize.

Confidentiality

Some medical research requires identifying the person donating the brain, spinal cord, muscle, nerve, and/or cerebrospinal fluid in order to correlate the research findings with the person's medical records. In this setting, there is a small risk that the decedent identity may be inadvertently identified outside of the research setting. I willingly consent for their brain, spinal cord, muscle, nerve, and/or cerebrospinal fluid to be used in such projects. These studies

may involve developing new knowledge that could affect the decedent's family if he/she were identified as the donor. Studies that would require the decedent's identification to use his/her specimens will be reviewed by the Institutional Review Board for the Protection of Human Subjects (IRB) at West Virginia University prior to the release of any identifying information with the decedent's tissue samples. For these research projects, I give my consent for the use of the decedent's identifiers, brain, spinal cord, muscle, nerve, and/or cerebrospinal fluid. The decedent's identifiers might be subsequently removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens can be used for future research studies or distributed to another investigator for future research studies without additional informed consent.

When possible, some medical research does not require identifying the person donating the brain, spinal cord, muscle, nerve, and/or cerebrospinal fluid. In this setting, there is a small risk that the decedent may be inadvertently identified to or by the researcher. Information about the decedent's donated tissues will be collected from the decedent's medical records and any information identifying the decedent will be removed and coded (de-identified) to protect their privacy. The Tissue Bank will not provide information that identifies the decedent to any researchers, unless specifically authorized by the Institutional Review Board for the Protection of Human Subjects (IRB) at West Virginia University under a separate research protocol. The researchers will only receive information such as diagnosis, physical examination, laboratory and radiology studies, treatments, treatment responses, age, gender, ethnic background and other medical information. While not intended, it is possible that participation in the Tissue Bank may be referenced, noted or documented in the decedent's medical records. The Tissue Bank may also collect de-identified follow-up information in order to help researchers correlate tissue markers with the decedent's clinical course and outcomes. For those research projects that can be performed without identifying the decedent, I willingly consent for their brain, spinal cord, muscle, nerve, and/or cerebrospinal fluid to be used.

Any information about the decedent that is obtained as a result of this research will be kept as confidential as legally possible. The decedent's research records, just like hospital records, may be subpoenaed by court order or may be inspected by federal regulatory authorities without my additional consent. The decedent's research records and results may be inspected reviewed, monitored or audited by West Virginia University, Researchers, West Virginia University's Institutional Review Board (IRB), West Virginia University's ethics committee or federal regulatory authorities, including the Food and Drug Administration (FDA), without your additional consent. . People from these groups may need to look at the medical records to be sure that the data provided to the researcher is correct and that the donation to the Tissue Bank was done correctly. In addition, there are certain instances where the researcher is legally required to give information to the appropriate authorities, include mandatory reporting of infectious diseases.

I agree that de-identified medical and/or genetic information related to the decedent's donated brain, spinal cord, muscle, nerve, and/or cerebrospinal fluid may be released into one or more scientific databases. These databases are large collections of information that are kept on computers and help advance scientific research by allowing other researchers to use the information to better understand diseases and compare results. These databases may be maintained by academic, medical, government or private organizations. While online information will be de-identified, limited identifiers may be needed to link information within these databases that is not released to the public, such as data integration with other data within the West Virginia Clinical and Translational Sciences Institute (WVCTSI).

In any publications that result from research associated with the Tissue Bank, neither the decedents name nor any information from which the decedent might be identified will be published without my consent.

Genetic information, about genes that account for the similarities and differences between each of us, can help researchers understand why some people, but not others, get certain neurological diseases. Studying genes can also help researchers understand why some people, but not others, respond well to certain treatments and not others. In this setting, there is a small risk that this genetic information could in the future identify the decedent to the researcher.

Future genetic research may include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequencing of that specimen).

Genetic Information Nondiscrimination Act (GINA)

A Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this law by May 21, 2010. All employers with 15 or more employees must follow this law as of November 21, 2009. Be aware that this Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

West Virginia's genetic discrimination laws protect patients from discrimination by health insurers or employers. This means that a health plan or insurance company cannot raise your rates based on genetic information about you or commit any other form of illegal discrimination, nor can employers in West Virginia use your genetic information to inform decisions related to hiring or firing you.

HIPAA Authorization

We know that information about the decedent and their health history is private. We are dedicated to protecting the privacy of his/her information. Because of this promise, we must get your written authorization (permission) before we may use or disclose the decedent's protected health information or share it with others for research purposes. This form gives that permission and helps us make sure that you are informed as to how this information will be used or disclosed.

I can decide to sign or not to sign this authorization. However, if I choose not to sign this authorization, the decedent will not be able to take part in this research study.

Persons/Organizations Providing the Information

Myself on behalf of the decedent;

Tissue Bank for Neurological Diseases Principal Investigator and members of its Research Team; and

The following research site(s) carrying out this study and their respective physicians, research and medical staff members, including West Virginia University (WVU); WVU Medicine, West Virginia University Hospitals (WVUHS); University Health Associates (UHA) and UHA affiliated clinics; Mary Babb Randolph Cancer Center; and other medical clinics, hospitals and facilities where the decedent received health care.

Persons/Organizations Receiving the Information

This form will authorize the following person(s), class(es) of persons, and/or organizations to receive the decedent's information in agreement with this study protocol:

- Tissue Bank's Principal Investigator and Research Team;
- The following research site(s) carrying out this study and their respective physicians, research and medical staff members, including West Virginia University (WVU); WVU Medicine, West Virginia University Hospitals (WVUHS); University Health Associates (UHA) and UHA affiliated clinics; Mary Babb Randolph Cancer Center;
- Health care providers who provide services as part of this research study;
- Laboratories and other people and groups that look into your health information as part of this study in agreement with the study protocol;
- The United State Department of Health and Human Services (which includes the National Institutes of Health (NIH), Food and Drug Administration (FDA)) and other groups that have the right to use the information as required by law;
- Foreign Regulatory Agencies;
- Researchers and the people and/or companies that they use to oversee, manage, or conduct the research; and
- The members and staff of any Institutional Review Board (IRB) that oversees this research study, including the West Virginia University Office of Human Research Protection and the West Virginia University Office of Sponsored Programs.

*If during the course of the research, one of the companies or institutions listed above merges with or is purchased by another company or institution, this authorization to use or disclose protected health information will extend to the company or institution.

The Following Information Will Be Used

General and specific patient, specimen demographic, prognostic and treatment related information may be collected in various combinations. This information will come from the decedent's existing medical records and new information (*prospective*) about him/her that is generated or collected over the course of this study. This information may include but is not limited to history and physicals, discharge summaries, clinic visit notes, nursing and medical staff notes, laboratory results, radiology results, EKG results, demographic data, pulmonary tests, imaging scans and study forms. Various combinations of this information will be released to the researchers in a de-identified manner to protect the decedent's privacy.

The Information is Being Disclosed for the Following Reasons

This information may be re-disclosed or used for other purposes as a recipient described in this form is not required by law to protect the privacy of the decedent's information. Carry out the research study explained to me during the informed consent process:

- Ensure that the information relating to the study is available to all parties who may need it for research purposes to develop a better understanding of human disease and treatment.
- Review of the decedent's data for quality assurance purposes.
- Publication of study results (without identifying the decedent).
- Run the business operations of the Institution.

You may Cancel this Authorization at Any Time by Writing to the Principal Investigator

My consent and authorizations, as specified above, will remain active unless I withdraw the decedent's participation in the Tissue Bank for Neurological Diseases. I can change my mind and withdraw my consent/authorization by writing to the Principal Investigator or his designee at:

Rudolph Castellani, MD c/o Jacqueline Karakiozis
West Virginia University Department of Pathology
64 Medical Center Drive, Mailstop 9203
Morgantown, WV, 26506 USA

Only written cancelation of Authorization is permissible.

If you cancel this authorization, any information that was collected already for this study cannot be withdrawn. Once information is disclosed, according to this authorization, the recipient may re-disclose it and then the information may no longer be protected by federal regulations.

I understand that once samples have been sent to a researcher, I will no longer be able to withdraw them. If the Tissue Bank still has any of the decedent's samples in its possession, it will take steps to destroy them.

If I cancel my consent/authorization, any information that was already collected as part of this study cannot be withdrawn. Following any cancellation, the Tissue Bank can continue to collect information needed to complete the analysis and reports for any specimens previously released from the Tissue Bank. Once information is disclosed, according to this authorization, the recipient may disclose it and then the information may no longer be protected by federal regulations.

This authorization will expire at the end of the study unless you cancel it before that time.

Voluntary Participation

Participation in this study is voluntary. You are free to withdraw your consent to participate in this study at any time. If you choose to withdraw your participation from the study, the data collected on you up until that time remains a part of the study database and may not be removed. No additional information will be added to the study database after your withdrawal.

Refusal to participate or withdraw will not affect your future care or status at West Virginia University.

In the event new information becomes available that may affect your willingness to participate in this study, this information will be given to you so that you can make an informed decision about whether or not to continue your participation. The results of any research or incidental study findings, including individual research results, will not be disclosed to the family.

Contact Persons

If you have any questions, concerns, or complaints about this research, you can contact Rudolph Castellani, MD at 304-293-0287 during business hours (Monday-Friday 7:00am-3:30pm). You can also contact Tissue Bank Personnel at 304-293-0287 during business hours.

If you are hurt from being in this research, you should contact Rudolph Castellani, MD at 304-293-1625 during business hours. If injury occurs outside of business hours and is related to your participation in this research, please contact WVU Medicine Operator and ask for the Pathologist On-Call at 304-598-4000.

For information regarding your rights as a participant in research or to talk about the research, contact the WVU Office of Human Research Protection (OHRP) at (304) 293-7073 or by email at IRB@mail.wvu.edu.

Future Contact

Future research may be conducted for which you are eligible. If you are interested in being contacted for future research, please indicate so by completing this section.

Signatures and Authorization

I have been given the opportunity to ask questions about the research and my authorization of HIPAA, and I have received answers concerning areas I did not understand. I willingly consent to having the decedent's brain, spinal cord, muscle, nerve, and/or cerebrospinal fluid banked and used as specified above in this form. Upon signing this form, I will receive a copy via mail.

INFORMATION ONLY