[Medical] Adult Research Informed Consent
Title of Study: *Molecular Analysis of Human Epileptic Tissue*

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313 745-1416

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Purpose

You are being asked to be in a research study because you will be undergoing epilepsy surgery and brain tissue will be removed as a part of this surgery. By examining the tissue removed during surgery, it is hoped that better treatments for this disease can be developed. This study is being conducted at Wayne State University, The University Physicians Group (UPG), and the Detroit Medical Center (DMC). The estimated number of study participants to be enrolled at Wayne State University, the UPG, and the DMC is to be about 30 per year. **Please read this form and ask any questions you may have before agreeing to be in the study.**

In this research study, the researchers listed above will do some tests on the brain tissue removed during surgery. This brain tissue would have been discarded otherwise. Researchers will use special techniques to identify factors, including, but not limited to genes and other molecules, that are expressed in unusually high or low amounts in the brain that maybe related to seizures. The studies being performed will relate to epilepsy and disorders in the brain that contribute to epilepsy. This is an open-ended study.

Study Procedures

If you agree to take part in this research study, your doctor will NOT remove more tissue than needed for your care, at the time of surgery. Your tissue will be processed for analysis and remain in a locked container in a laboratory in Wayne State University. Only the doctors and researchers listed above

will have access to your name and will keep it confidential. The brain tissue will be assigned a number and any research done with the tissue will be done both here and with collaborators outside the University with reference to the number and not with your name. The tissue will be stored frozen as long as it remains usable. As such, and because this is an open-ended study, the tissue will also be available to you, the patient, should you need it in the future. Collaborators who wish to conduct further studies on your tissues will have access to the tissues only after obtaining additional permission from the University.

Benefits

There are no direct benefits for you by participating in this research.

If the study results in doctors learning more about what causes epilepsy, how to prevent it, how to treat it, and how to cure it and the results become clinically relevant to you, you will be informed. You can also ask for the results of the studies done with your tissues if in the future this information may be helpful to your care.

Risks

There are very few risks to you from participating in this research. The only potential risk that might occur would be a breach of confidentiality where the health information could be used to discriminate against you or members of your family in matters pertaining to access to health insurance or employment. Your records, name, address and phone number will be kept private and confidential. The chance that this information will accidentally accessed by someone else is very small.

Study Costs

Participation in this study will be of no cost to you.

Compensation

You will not be compensated for participating in this research study.

Research Involving the Future Use of Biological Specimens

Your specimen will be processed for analysis and remain in a locked container in a laboratory in Wayne State University. Researchers will use special techniques to identify factors, including, but not limited to genes and other molecules, that are expressed in unusually high or low amounts in the brain that maybe related to seizures. The brain tissue will be assigned a number and any research done with the tissue will be done both here and with collaborators outside the University with reference to the number and not with your name. You will be identified in the research records by a code name or number. Information that identifies you personally will not be released without your written permission. However, your records may be reviewed by the study sponsor, the Human Investigation Committee (HIC) at Wayne State University, UPG, DMC, or federal agencies with appropriate regulatory oversight [e.g., Food and Drug Administration (FDA), Office for Human Research Protections (OHRP), Office of Civil Rights (OCR), etc.) may review your records.

Research Related Injuries

In the event that this research related activity results in an injury, treatment will be made available including first aid, emergency treatment, and follow-up care as needed. Cost for such care will be billed in the ordinary manner to you or your insurance company. No reimbursement, compensation, or free medical care is offered by Wayne State University, UPG, and the DMC. If you think that you have suffered a research related injury, contact the PI right away at 313-745-1416.

Confidentiality

All information collected about you during the course of this study will be kept confidential to the extent permitted by law. You will be identified in the research records by a code name or number. Information that identifies you personally will not be released without your written permission. However, your records may be reviewed by the study sponsor, the Human Investigation Committee (HIC) at Wayne State University, the University Physicians Group and the Detroit Medical Center, or federal agencies with appropriate regulatory oversight [e.g., Food and Drug Administration (FDA), Office for Human Research Protections (OHRP), Office of Civil Rights (OCR), etc.) may review your records.

When the results of this research are published or discussed in conferences, no information will be included that would reveal your identity. Information from this study may be published, but your identity will be kept confidential in any publications.

Voluntary Participation/Withdrawal

Taking part in this study is voluntary. You have the right to choose not to take part in this study. You are free to withdraw from participation in this study at any time. Your decisions will not change any present or future relationship with Wayne State University or its affiliates, or other services you are entitled to receive. You can also ask that the tissue samples be destroyed at any time.

Questions

If you have any questions about this study now or in the future, you may contact Dr. Jeffrey Loeb, Dr. Aashit Shah (Director of the Adult Program), or one of his associates at phone 313 745-1416. If you have questions or concerns about your rights as a research participant, the Chair of the Human Investigation Committee can be contacted at (313) 577-1628. If you are unable to contact the research staff, or if you want to talk to someone other than the research staff, you may also call 313 577-1628 to ask questions or voice concerns or complaints.

Consent to Participate in a Research Study

To voluntarily agree to take part in this study, you must sign on the line below. If you choose to take part in this study you may withdraw at any time. You are not giving up any of your legal rights by signing this form. Your signature below indicates that you have read, or had read to you, this entire consent form, including the risks and benefits, and have had all of your questions answered. You will be given a copy of this consent form.

Signature of participant / Legally authorized representative*	Date
Printed name of participant / Legally authorized representative *	Time
Signature of witness**	Date
Printed of witness**	Time
Signature of person obtaining consent	Date
Printed name of person obtaining consent	Time

**Use when participant has had this consent form read to them (i.e., illiterate, legally blind, translated into foreign language).

APPROVAL PERIOD

JUN 14 '12 JUN 13 '13

WAYNE STATE UNIVERSITY
INSTITUTIONAL REVIEW BOARD

Continue to HIPAA Authorization on next page

HIPAA Authorization

A federal regulation, known as the "Health Insurance Portability and Accountability Act (HIPAA)" gives you certain rights concerning the use and disclosure (sharing with others) of your Protected Health Information (PHI). This regulation provides safeguards for the privacy and security of your information. Your permission (authorization) is required for the use and sharing of any protected health information collected as part of this research study. If you are not willing to sign this authorization to use and/or disclose your PHI by the research team, you will not be eligible to take part in this research study.

The principal investigator (PI) and his research team will use your medical records and information created or collected as part of this research study. Your PHI is important for the PI and his research team in order to collect information about you during the study, to be able to contact you if needed, and to provide treatments to you during the study, if required. The PI may send out your study related health information to the sponsor or other entities involved in this study.

Your medical records, which may contain information that directly identifies you, may be reviewed by representatives from groups identified below. The purpose of these reviews is to assure the study is being conducted properly, that data is being obtained correctly or for other uses authorized by law. These reviews occur at the study site or in the PI's research office and can take place anytime during the study or after the study has ended.

The PHI that will be "USED" for this research includes the following: name, elements of dates, medical record number, and any unique identifying numbers or characteristics or code.

The PHI that will be "DISCLOSED" None

Your study information may be **used** or **shared** with the following people or groups:

- The PI, co-investigators, and key personnel of WSU associated with the research project
- WSU's HIC and the Institutional Review Boards (IRB)
- Authorized members of WSU, UPG, and DMC's workforce who may need to access your information in the performance of their duties.
- The study Sponsor or representative, including companies it hires to provide study related services, which include: NIH, NINDS
- Federal agencies with appropriate regulatory oversight (e.g., FDA, OHRP, OCR, etc.) may review your records

Once your information has been released according to this Authorization, it could be released again and may no longer be protected by the HIPAA regulations.

This Authorization does not expire. The research team may need to correct it or provide missing information about you even after the study has ended, and your medical records may be needed to assist in this process.

- During your participation in this study you will have access to your medical record and any study information that is part of that record. The PI is not required to release research information that is not part of your medical record.

You may withdraw (take back) your permission for the **use** and **disclosure** of your PHI for this research at anytime, by **writing** to the PI at the address on the first page of this form. Even if you withdraw your permission, the PI for the research project may still use your PHI that was collected prior to your written request if that information is necessary to the study. If you withdraw your permission for use of your PHI, you will also be withdrawn from the research project. Withdrawing your authorization **will not** affect the health care that will be provided by the Detroit Medical Center and/or the WSU School of Medicine Practice Plans.

Authorization to use and disclose PHI

- By signing this document, you are authorizing the PI to **use** and **disclose** PHI collected about you for the research purposes as described above.

Signature of participant _____ Date _____

Printed name of participant _____

- For participants unable to give Authorization, the following individual is acting on behalf of the research participant (e.g., children, mentally impaired, etc.).

Signature of authorized representative _____ Date _____

Printed name of authorized representative _____ Relationship to the participant _____

Signature of person obtaining Authorization _____ Date _____

Printed name of person obtaining Authorization _____ Time _____