Molecular Analysis of Human Epileptic Tissue

Informed Consent

Principal Investigator- Harry Chugani, M.D.

Co-Investigators-

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Jeffrey Loeb, M.D., Ph.D.	Craig Watson, M.D.
Jose Rafols, Ph.D.	

A Introduction and Purpose:

The purpose of this research study is to learn more about the causes of epilepsy so that we can develop better treatments. My physician at the Detroit Medical Center has asked me to consider participating in this medical research study because I am undergoing epilepsy surgery. 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 my brain that may be related to seizures. The studies being performed will relate to epilepsy and disorders in the brain that contribute to epilepsy.

B Procedure:

My doctor will not remove more tissue than needed for my care, at the time of surgery. I will read the question and answer sheet called, "How Tissue Is Used for Research" to learn more about tissue research. My 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 my 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 my name. The tissue will be stored frozen as long as it remains usable. As such, the tissue will also be available to you should you need it in the future. Collaborators will have access to the tissues only after obtaining permission from the University. I will be treated according to the recommendation of my doctor.

C Benefits:

The potential benefits of research using this tissue include learning more about what causes epilepsy, how to prevent it, how to treat it, and how to cure it. If these results do become clinically relevant, I will be informed. I can also ask for the results of the studies done with my tissues if in the future this information may be helpful to my care.

D Risks:

There are very few risks to me from the examination of tissues after surgery. The greatest, foreseeable risk is the unlikely event that health information could potentially be used to discriminate against me or members of my family in matters pertaining to access to health insurance or employment. My records, name, address and phone number will be kept private and confidential. The chance that this information will accidentally be given to someone else is very small.

E Costs:

There will be no cost to me for participating in this study.

F Compensation:

In the event that I become injured as a result of taking part in this study, treatment will be offered to me, or I will be given information about where to receive medical care; but I or my insurance company will be responsible for the costs. No reimbursement, compensation or free medical care is offered by Wayne State University or The Detroit Medical Center.

G Confidentiality:

All information collected about me will be kept confidential to the extent permitted by law. I will be identified in the research records by a code number. Information which identifies me personally will not be released without my written permission, however, my records may be reviewed by the study sponsor, its agents, the Wayne State University Human Investigation Committee, and appropriate federal agencies. Information from this study may be published, but my identity will be kept confidential in any publications.

H Voluntary Participation/Withdrawal:

Taking part in this study is voluntary. I can choose not to participate in this study without affecting the present or future health care I may receive. I can also ask that the tissue samples be destroyed at any time.

I Questions:

If I have any questions concerning my participation in this study now or in the future, Dr. Harry Chugani or one of his associates can be contacted at phone 313 993-7101. If I have any questions or problems regarding my rights as a research subject, the Chairperson of the Human Investigation Committee (HIC) can be contacted at 313-577-1628.

J Consent to Participate in a Research Trial;

My signature below indicates that I have read or had read to me all of the above information about the research study and the likelihood of benefits to me. The content and meaning of this information have been explained and are understood. All my questions have been answered. I hereby consent for the research study. My refusal will not affect my care and I can withdraw my participation at any time. I will be given a copy of this consent form.

Signature of Study Subject	Date
Printed Name of Study Subject	Date
Assent of Child if age 13 or older	Date
Signature of Legally Authorized Representative	Date
Relationship to Subject	
Signature of Witness	Date
Signature of Investigator/Designee Obtaining Informed Consent	Date

APPROVAL PERIOD

JUL 0 8 '10 JUL 0 7 '11

HUMAN INVESTIGATION COMMITTEE