[Medical] Documentation of Adolescent Assent Form
(Ages 13-17)

Title: Molecular Analysis of Human Epileptic Tissue

Study Investigator: Jeffrey A. Loeb, M.D., Ph.D.

Why am I here?
This is a research study. Only people who choose to take part are included in research studies. You are being asked to take part in this study because you are undergoing epilepsy surgery and we want to do some tests on the brain tissue removed during the surgery. Please take time to make your decision. Talk to your family about it and be sure to ask questions about anything you don’t understand.

Why are they doing this study?
This study is being done to help us try to find out what is causing your seizures.

What will happen to me?
You will undergo the epilepsy surgery as planned, and only the tissue removed during the surgery will be used for this purpose. No extra procedure will be performed.

How long will I be in the study?
You do not have to make any separate or extra hospital visit regarding this study. We are obtaining your assent so that we can study your brain tissue, removed during the planned epilepsy surgery, as long as it remains usable.

Will the study help me?
We cannot promise you that being in this research study will help you; however, this study may help us in understanding the cause of epilepsy which may be helpful in the future.

Will the study hurt?
This study will not hurt you, as the study involves the brain tissue, already removed during your planned surgery.

What other options are there?
You may choose to not participate in this study.

Do my parents or guardians know about this?
This study was explained to your parents/guardian and they said that you could be in it. You can talk this over with them before you decide.

What about confidentiality?
Your name will not be used in this study; rather a special number will be assigned to your brain tissue and only this number will be used for all the testing. Every reasonable effort will be made to keep your medical records confidential, unless we are required by law to share your information. Also, we do have to let some people look at your study records and maybe your hospital records.
What if I have any questions?
For questions about the study please call Dr. Harry Chugani at (313) 993-2605 or Dr. Jeffrey Loeb at (313) 577-9827. 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.

Do I have to be in the study?
You don’t have to be in this study if you don’t want to or you can stop being in the study at any time. Please discuss your decision with your parents and doctor. No one will be angry if you decide to stop being in the study.
Molecular Analysis of Human Epileptic Tissue

AGREEMENT TO BE IN THE STUDY

Your signature below means that you have read the above information about the study and have had a chance to ask questions to help you understand what you will do in this study. Your signature also means that you have been told that you can change your mind later and withdraw if you want to. By signing this assent form you are not giving up any of your legal rights. You will be given a copy of this form.

_________________________________________________________       ___________________________
Signature of Participant (13 yrs & older)                                      Date

_________________________________________________________
Printed name of Participant (13 yrs & older)

_________________________________________________________       ___________________________
**Signature of Witness (When applicable)                                      Date

_________________________________________________________
Printed Name of Witness

_________________________________________________________       ___________________________
Signature of Person who explained this form                                      Date

_________________________________________________________
Printed Name of Person who explained form

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

Submission Date: 06/29/2011       Page 3 of 3       Participants Initials