University of Pennsylvania
Informed Consent & HIPAA Authorization

Title of the Research Study:	A Comprehensive Evaluation of Patients with Suspected Autoimmune Encephalitis
Principal Investigator:	Eric Lancaster, MD, PhD Center for Autoimmune Neurology, 3 W. Gates Phone: 215-349-5313
Study Contact:	Lindsey McCracken Center for Autoimmune Neurology, 3 W. Gates Building Phone: 215-746-8511 Fax: 215-573-4454 Email: Lindsey.McCracken@uphs.upenn.edu
Emergency Contact:	24 Hour Emergency Number: 215-662-6059 Ask for the Neurology resident on call

You have the option to participate in a study about brain diseases caused by antibodies. Your participation is voluntary which means you can choose whether or not to participate, participation in this study is outlined below. If you decide to participate you should send a signed copy of this document to Study Contact above. If you do not understand what you are reading, or have questions regarding the research testing, do not sign it. If you have any questions regarding this research with regard to your participation, please contact Lindsey McCracken at 215-746-8511. If you have questions regarding your rights or welfare as a subject you may contact the Institutional Review Board at 215-898-2614.

What is the purpose of the study?

The purpose of the study is to learn more about antibodies that may cause neurologic diseases. Since 2007 researchers here at the University of Pennsylvania have discovered many new antibodies that cause brain diseases. Some of these antibodies can be detected through commercial testing labs like Quest or the Clinical Pathology Lab at the University of Pennsylvania; others are not yet available through these companies. For this study, we will perform exploratory studies on samples to detect known and unknown antibodies. We will also collect clinical information to compare the findings of lab studies to symptoms you are experiencing.

What am I being asked to do?

Participation in this study is voluntary and involves allowing the study team to collect and store clinical information about your disease from your physician, and leftover cerebral spinal fluid (CSF) and/or blood sent to the William Pepper Lab at the University of Pennsylvania. If you agree to participate we will collect the samples from the lab and clinical information from your treating physician.

The study the study team will obtain any excess cerebral spinal fluid (CSF) directly from the Clinical Pathology Lab. We will only take samples that remain unused after all tests your doctor ordered are complete. Studies will examine these samples for known and unknown antibodies that cause neurologic diseases. There is no cost for these studies and your insurance will not be billed. If you agree, and initial accordingly on Page 2, we will share our research findings with your physician. After these studies are complete your samples will be coded and stored for future research. They will remain in the tissue bank until they are used up, the study ends, or you request in writing that they are withdrawn.

We will also ask your physician to complete a brief questionnaire regarding your neurologic symptoms. This information will include past, present, and future neurologic symptoms, including test results and treatments related to these symptoms. We may also contact you directly to ask about your clinical history. All clinical information will be stored in a coded database, and will not be shared with anyone outside the study team.

What are the risks and benefits of participation?
Your participation in this study could possibly help future patients with similar diseases. There is also a very small chance that the study team could identify antibodies in your CSF or blood that are not available for commercial testing. If you agree, this information will be shared back with your physician so he/she may order more tests. The risks to the study include potential loss of confidentiality. Precautions against this will be taken by the study team, and all your information that is collected with be kept confidential in a password protected online database with limited access by the study team.

Who can see or use my information?
We will collect and store Protected Health Information (PHI) including your name, address, medical record number (MRN), date of birth (DOB), which will be stored in in an independent database only accessible by the PI and Project Manager. Other information including age, sex, and past, current, and future neurologic history including treatments, imaging results, lab results and other related tests and procedures will also be collected and will be stored coded. Only the investigator for the study, the study team and the Institutional Regulatory Board (IRB) may use or share your information. We will not disclose any PHI outside of UPHS. Collaborating researchers will not have access to your clinical information without prior approval from IRB. Once your personal health information is disclosed to others outside of UPHS, it may no longer be covered by federal privacy protection regulations. Your authorization for use of your personal health information for this specific study does not expire, though you can revoke your authorization at any time. You do this by sending written notice to the investigator for the study.

If you agree to participate, complete the section below. Sharing our research findings back with your physician is optional, if you agree please check the box and initial the line next to that section. The participant information box below will be used to locate your CSF and serum sample and to request clinical information, therefore should be completed in its entirety. Your signature at the bottom of the page certifies you have read, understand, and agree to participation in this study. If you have questions about this protocol please contact Lindsey McCracken at 215-746-8511.

☐_____ **I consent to the study team sharing their research findings with my physician**
The study team may contact my physician to share CSF study findings. I understand that these are exploratory findings in the research phase and are not validated by the Clinical Laboratory Improvements Amendment (CLIA). These results may be used by my physician to order additional tests, but will not be used to diagnose, manage, prevent or treat any disease or impairment.

Participant Name	**Date of Birth**
Address *(optional)*	**Telephone Number *(optional)***
Physician Name	**Physician Contact (Telephone, email)**

Signature of Patient Print Name Date

Signature of Personal Representative Print Name Date

Relationship of Personal Representative to Patient