# University of Pennsylvania

## Informed Consent & HIPAA Authorization Form

| | |
|---|---|
| **Protocol Title:** | Proof of Principle for a Diagnostic Blood Test of Recurrent Seizures |
| **Principal Investigator:**<br><br>**Phone:** | John Pollard, MD<br>Department of Neurology<br>3400 Spruce St, 3 W. Gates<br><br>215-349-5166 |
| **Emergency Contact (24-hr):** | Please page the Neurologist on call: (215) 662-6059 |

## What is the purpose of this research study?

You are being asked to participate in this research study because you are part of one of two groups of patients:

1. You are attending your first visit at the Penn Epilepsy Center (PEC) to learn about your seizures or seizure-like events.
2. You have been admitted to the Hospital of the University of Pennsylvania for continuous video Electroencephalography (cVEEG) monitoring.

We hope that this study will help us learn whether a blood test can help doctors diagnose epilepsy (more than one unprovoked seizure). In this form, the word “seizure” refers to the seizure-like events that you experience, regardless of your doctor’s eventual diagnosis.

Please read this form carefully for more information about the study and ask the study team about any questions that you have. If you decide to join the study, you will receive a signed copy of this form for your records.

## How is this study being funded?

The National Institutes of Health (NIH) provided a grant to Cognizance Biomarkers, LLC, to carry out this study. The Principal Investigator, Dr. John Pollard, is a part owner of Cognizance Biomarkers, and the University of Pennsylvania owns the patent for the blood test being studied.

## How long will I be in the study? How many other people will be in the study?

We think that the whole study will last about two years. Your active participation will begin when you sign this consent form and end after you give you last blood sample for research. If you choose to give a single blood sample, this will happen on the same day that you sign this consent form; if you choose to give multiple blood samples, this will happen within one year after you sign this consent form. Please continue reading this form for more information about the blood draws.

We will continue to enroll until 240 people have joined the study in the PEC's outpatient clinic and have given usable blood samples for the study.

At any time, you may decide to leave the study and tell the study team to destroy your blood sample. If you decide to leave the study, please contact the investigator. You may contact him by phone or mail using the address and number at the top of this page.

## What am I being asked to do?

Subjects may join the study at one of two types of visits, described below.

It is important to remember that all blood samples are optional. You may join the study and then decide that you do not want to give blood at any time, for any reason.

1. Subjects who join during an outpatient visit at the PEC

   If you decide to join this study, we will ask you to give a single sample of about one teaspoon (or 15ml) of blood during your first visit to the Penn Epilepsy Center. We will draw the blood through a needle inserted into a vein in one of your arms. This sample will be used for research purposes only (it will not be used for your regular clinical care).

   You may also decide to provide blood samples for research at the following times:

   - If you are admitted to the Hospital of the University of Pennsylvania for cVEEG monitoring at a later date, you may be asked to give up to two blood samples for research per day (12:00am – 11:59pm). These samples would consist of one per day, and an additional sample if you experience a seizure or seizure-like event.

- If you attend one or more follow-up visits at the PEC during the year after you sign this form, you may provide an additional blood sample for research at each visit.

2. Subjects who join during an admission for cVEEG monitoring:

   If you are admitted to the Hospital of the University of Pennsylvania for cVEEG monitoring at a later date, you may be asked to give up to two blood samples for research per day (12:00am – 11:59pm). These samples would consist of one per day, and an additional sample if you experience a seizure or seizure-like event.

   If you attend one or more follow-up visits at the PEC during the year after you sign this form, you may provide an additional blood sample for research at each visit.

Your Medical Record/ Health Information

In order to help the study team understand the results of this experimental blood test, we will collect information from your medical record. This information may include your date of birth, medical conditions and complaints, medications and other forms of treatment, and information about your seizures (including imaging and EEG results and seizure history).

Your treatment will not be any different, and your doctor will not order any extra diagnostic tests if you join this study.

Reports about your health will **not** include your name, address, phone number, or any other piece of information that may identify you. If you choose to withdraw from this study at any time, we will not collect additional information from your medical record and we will destroy any unanalyzed samples that you have donated.

Please continue reading this Informed Consent Form for more information about who will have access to your personal health information and medical record.

## What are the possible risks or discomforts?

There are very few risks to you. The greatest risk is the release of information from your health records. The University of Pennsylvania will protect your records

so that your name, address, and phone number will be kept private. The chance that this information will be given to someone else is very small.

The most common risks associated with drawing blood from a vein include pain, bruising, bleeding, dizziness, and a burning feeling. Rarely, people may also experience fainting or an infection at the site where the needle is inserted to take the blood sample.

In the event that you are hurt or injured as a result of participation in this study, please contact the investigator listed the first page of this form.

## What are the possible benefits?

You will not directly benefit from joining this study. We hope that information learned from this study may eventually help doctors diagnose epilepsy and develop more effective treatments for epilepsy.

Your blood may be helpful for research whether you do or do not have epilepsy.

## Will I be paid for being in this study?

You will not be paid for participating in this study.

## What information about me may be collected, used or shared with others?

If you decide to join this study and sign this consent form, the research team may ask you some questions about your medical history and review your medical records. They may also collect future information from your medical records. Researchers will use this information to help them understand the results of tests that they do on your blood. Your authorization for use of your personal health information and medical record for this study does not expire.

No information will be recorded in your medical record as a result of your participation in this study, including the results of the research blood test.

The research team will collect the following information as a result of your participation in this study:

- Name
- Date of birth

- Medical Record Number
- Personal medical history
- Results from examinations, tests, or procedures that you undergo as part of your routine clinical care

## Why is my information being used?

Your information and results of tests and procedures are used to:

- Do the research
- Oversee the research
- See if the research was done right.

## Who may use and share information about me?

The following individuals at the University of Pennsylvania may use or share your information for this research study.

Individuals or organizations responsible for administering the study:

- The Investigator for the study and the research team
- Members of Penn's Office of Human Research
- Other authorized personnel at Penn

## Who, outside of the School of Medicine, might receive my information?

The following groups of people may receive your information associated with the research study:

- Those working under the direction of the investigator for the study, (e.g. under subcontracts).
- The Funding Sponsor (Cognizance Biomarkers, LLC) and organizations supported by the Funding Sponsor, for example the lab processing your blood samples

<u>Oversight organizations that may see your information in the process of inspecting this research</u>

- The Food and Drug Administration
- The Office of Human Research Protections

Once your personal health information is disclosed to others outside the School of Medicine, it may no longer be covered by federal privacy protection regulations.

The Principal Investigator or research team will inform you if there are any additions to the above lists during your participation in the trial. Any additions will be subject to the University of Pennsylvania's procedures developed to protect your privacy.

## How will my confidentiality be protected?

All information that is collected about you during this research study will be kept as confidential (private) as possible. You will be assigned a study ID number, and all blood samples and documents relating to your participation in this study will be labeled with this study ID (and no other identifiable information, like your name). There will be a master list linking study IDs with patients' identifiable information and it will be kept in a locked file, separate from all other study documents. Like all other study information, this master list will be accessible only by authorized members of the research team.

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. In unusual cases, research records may be released in response to an order from a court of law. Participants will not be identified by name in any publication of research results. It is also possible that authorized representatives of federal regulatory authorities and/or the University Research Conduct and Compliance Office may inspect the research records. If this study is being overseen by the Food and Drug Administration (FDA), they may review your research records.

## How long may the School of Medicine use or disclose my personal health information?

Your authorization for use of your personal health information and medical record for this specific study does not expire.

Your information may be held in a research database. However, the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization

- The University of Pennsylvania's Institutional Review Board grants permission
- As permitted by law

## Can I withdraw from the study?

Yes. You may withdraw or take away your permission for the research team to collect your health information at any time. You do this by sending written notice to the investigator for the study. If you withdraw your permission, you will not be able to stay in this study and we will no longer collect information from your medical record. We will also destroy any unused blood samples stored in the Tissue Bank, but we will not destroy information that we have already collected and analyzed. Withdrawal will not interfere with your current or future care.

## What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study.

The study team will give you a signed copy of this Research Consent & HIPAA Authorization Form describing your confidentiality and privacy rights for this study.

By signing this document you are permitting the School of Medicine to use and disclose personal health information collected about you for research purposes as described above.

## Who can I call about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on page one of this form.

If a member of the research team cannot be reached, or if you want to talk with someone other than those working on the study, you may contact the Office of Regulatory Affairs with any questions, concerns or complaints at the University of Pennsylvania by calling (215) 898-2614.

**By signing below, you consent to participate in the procedure described above and have the research team review your medical record.** Your decision to take part in this procedure is a voluntary one and your medical care will not be affected if you refuse. You may terminate your participation anytime without prejudice to present or future care at the University. You will be given a copy of this consent form.

Your Signature: _____

Printed Name: _____

Date: _____

Signature of Person Obtaining Consent: _____

Printed Name: _____

Date: _____

**For subjects unable to give authorization, the authorization is given by the following authorized subject representative:**

Signature of Authorized Subject Representative: _____

Printed Name: _____

Date: _____

**Provide a brief description of above person authority to serve as the subject's authorized representative:**

_____

_____