Title of Study: The EpiNet Project

Consent to be part of a Research Repository
The University of Texas Health Science Center at San Antonio (UTHSCSA)
To be conducted at
University of Texas Health Science Center at San Antonio,
University Health System (UHS),
Baptist Health System

Information about this form

If you are providing consent for someone else, for example your child, your next-of-kin or someone for whom you are the legal guardian or are designated as a surrogate decision maker on a medical power of attorney, please note that in the sections that follow the word "you" refers to the person you are providing consent for.

You may be eligible to take part in a research study. This form gives you important information about the study.

Please take time to review this information carefully. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or a doctor) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

Voluntary Participation - You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are entitled.

General Information – "Who is conducting this research?"

Principal Investigator
The Principal Investigator (PI) is the researcher directing the local collection of materials. The PI is responsible for protecting your rights, safety and welfare as a participant in the research. The PI for this study is Alexander Papanastassiou, M.D., Department of Neurosurgery, University of Texas Health Science Center San Antonio.

If you require further information regarding the financial arrangements described in this paragraph, you should discuss the matter with the Principal Investigator.

Study Sponsor:
The EpiNet project is being funded from a variety of sources. Funds are channelled through the A+ Trust at Auckland Hospital, via the EpiNet sub-trust. To date, funding has been obtained from grants from the Neurological Foundation of New Zealand, the A+ trust, the Julius Brendel trust, and research funds of the neurology department at Auckland Hospital. We have also obtained donations from benefactors and pharmaceutical companies, which have entered a sponsorship arrangement whereby they have provided unrestricted educational grants. The funding is for the project to administer the database, there is no funding for conducting this project locally.

Purpose of this study – "Why is this study being done?"

The EpiNet study group has been established to undertake multi-institutional clinical research in epilepsy. The EpiNet study group comprises an international consortium of epileptologists, neurologists, and neurosurgeons who intend to study questions that are too difficult for one center to study on its own.

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The EpiNet study group has created a secure, international epilepsy database that can be accessed via the internet. The database has been established to follow large groups of patients with specific types of epilepsy or specific problems. We want to run large, simple, pragmatic, investigator-led, multinational trials on a low budget.

You are being asked to participate in this research repository. A research repository is a special type of research also known as a tissue bank or data registry. A repository provides a way for researchers to store samples of tissues (for example, blood, tissue specimens obtained from biopsies, and tissues or organs removed during surgery) and medical information (for example, information from your medical record about your condition) about a person for future use in research studies. In this consent form, tissues of all types will be referred to as "tissue" and private medical information will be referred to as "data". Together, tissues and data stored in a repository are referred to as "materials".

Materials from a repository can be used in research to help find out more about the causes of disease, how to prevent it, and how to treat it. Storing tissue and information about the person who provided the tissue in a repository is one way that researchers plan for new research.

This research repository was designed because we want to learn about epilepsy. Many questions regarding medications and surgery for epilepsy remain unanswered, and the EpiNet study group hopes to address these questions by collecting information about the effects and side-effects of various treatments.. However, the specifics of future research studies using this repository are unknown at this time.

Your materials may be helpful for research whether or not you have the disease or condition that is the focus of this repository.

There may be potential commercial benefits from the repository's use of your materials. There are no plans to provide you with money or other compensation.

The repository is maintained on a central server in Auckland, New Zealand, at:
Auckland City Hospital
2 Park Road
Grafton
Auckland 1023

EpiNet is registered as a sub-trust of the A+ charitable trust, which is based at Auckland Hospital, Auckland, New Zealand. Dr Peter Bergin, Chair of the EpiNet International Steering Committee is responsible for the repository.

You may discontinue all further participation in this research repository at any time and request that your currently stored materials no longer be used. Contact the repository at the address provided above, or contact your study doctor to notify them of your decision. After you discontinue participation, the repository will not collect any new materials from you and will not use your banked specimens or identifiable information for any new research purposes.

Information about Study Participants – "Who is participating in this research?"

You are being asked to be a participant in this study because you are being treated for epilepsy. This study is open-ended and involves all of the patients being treated for epilepsy at multiple centers around the world. We expect the study to includes tens of thousands of patients.

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Information about Study Procedures – "What will be done if you decide to be in the research?"

If you decide to take part, you will be asked to sign this consent form.
The following information about you will be collected and stored in the repository: Information about your clinical care will be entered into the EpiNet database, and this will be used to address questions aimed at optimizing clinical care for epilepsy patients. The data that will be entered by your physician into the EpiNet Project database includes existing clinical data in your medical record, as well as future clinical data.

Options to allow other EpiNet users access to your de-identified data

You can choose to participate in one, some, or all the repository procedures listed in this consent. Please initial next to the procedures you agree to take part.

_____ I agree to allow my de-identified data to be accessed by other EpiNet physicians

_____ I do not wish my de-identified data to be accessed by other EpiNet physicians

The materials being put into the repository will be kept indefinitely.
You will not be provided with the results of the studies using your data from this bank. Any results from research conducted in the future on your stored data would be of unclear value and unknown clinical meaning.

Risks – "What are the risks of participation in the research?"

Informational risks related to the repository
Your samples and medical information will be stored with identifying information (such as your name). If this information were unintentionally (by mistake) released it could harm you. The repository is required to protect your private information to prevent unintentional release of your private information. Your name, address, phone number and other identifying information will be taken off anything associated with your medical information and replaced with a code. The key, linking your identity to the code will be kept in a separate, secure location, only accessible by the repository staff.

For more information about risks and side effects, ask one of the researchers or study staff.

We will tell you about any significant new findings which develop during the course of this research which may relate to your willingness to continue taking part.

What if a research-related injury occurs?
The researchers have taken steps to minimize the known or expected risks. However, you may still experience problems, even though the researchers are careful to avoid them. If you believe that you have been harmed, notify the researchers as soon as possible. You may also need to tell your regular doctors.

If you are injured as a result of the research procedures, we have no plans to give you money if you are injured.

If you sign this form, you do not give up your right to seek additional compensation if you are harmed as a result of being in this study.

Benefits – "How could you or others benefit from your taking part in this study?"

The possible benefit of your participating in this study is access to your clinical information by doctors participating in the EpiNet project. You may benefit from discoveries made using the database, but you may not receive any personal benefits from being in this study. We hope the information learned from this study will benefit other people with epilepsy in the future.

Payments – Will there be any payments for participation?

There is no compensation for participating in this study.

Costs – Will taking part in this study cost anything?

There are no costs to you to participate in this study.

Confidentiality – How will your records be kept confidential?

Information we learn about you in this study will be handled in a confidential manner, within the limits of the law. If we publish the results of the study in a scientific journal or book, we will not identify you. The Institutional Review Board and other groups that have the responsibility of monitoring research may want to see study records which identify you as a subject in this study.

Research policies require that private information about you be protected. This is especially true for your health information.

However, the law sometimes allows or requires others to see your information. The information given below describes how your privacy and the confidentiality of your research records will be protected in this study.

What is Protected Health Information (PHI)?
Protected Health Information is information about a person's health that includes information that would make it possible to figure out whose it is. According to the law, you have the right to decide who can see your protected health information. If you choose to take part in this study, you will be giving your permission to the investigators and the research study staff (individuals carrying out the study) to see and use your health information for this research study. In carrying out this research, the health information we will see and use about you will include: your name, birthday, medical record number, medical history, laboratory and imaging data, and information about your treatments.

We will get this information by asking you and looking at your medical records at University Hospital, UT Medicine, or St. Luke's Baptist Hospital.

How will your PHI be shared?
Because this is a research study, we will be unable keep your PHI completely confidential. We may share your health information with people and groups involved in overseeing this research study including:

- the collaborators at other institutions that are involved with the study, however your clinical data will be de-identified by encryption before collaborators at other institutions who are involved with the EpiNet project
- the members of the local research team
- The Institutional Review Board and the Compliance Office of the University of Texas Health Science Center at San Antonio, and other groups that oversee how research studies are carried out.
- The Research offices at the University of Texas Health Science Center at San Antonio, University Health System (UHS), , Baptist Healthcare System.

Parts of your PHI may be photocopied and sent to a central location or it may be transmitted electronically, such as by e-mail or fax.

The groups receiving your health information may not be obligated to keep it private. They may pass information on to other groups or individuals not named here.

If you decide to participate in this study, you will be giving your permission for the groups named above, to collect, use and share your health information. If you choose not to let these groups collect, use and share your health information as explained above, you will not be able to participate in the research study.

How will your PHI be protected? Your clinical data will be de-identified by encryption before collaborators at other institutions who are involved with the EpiNet project. Only de-identified data is shared with investigators who is not involved in your clinical care. The Sponsors do not have any right to access any of the data contained in the database. Access to all information will be controlled by the EpiNet steering committee, who will act as the custodian of the composite dataset. Under no circumstances will details that would allow you to be identified be shared with other agencies, such as pharmaceutical companies. If you might be eligible for a research study, your study doctor will be notified by EpiNet. You will not be contacted directly.

If the results of this study are reported in medical journals or at meetings, you will not be identified.

Do you have to allow the use of your health information?
You do not have to allow (authorize) the researchers and other groups to see and share your health information. If you choose not to let the researchers and other groups use your health information, there will be no penalties but you will not be allowed to participate in the study.
After you enroll in this study, you may ask the researchers to stop using your health information at any time . However, you need to say this in writing and send your letter to Alexander Papanastassiou, M.D.; 7703 Floyd Curl Dr. (MC 7843); Medical School Building, 102F; San Antonio, TX 78229-3900. If you tell the researchers to stop using your health information, your participation in the study will end and the study staff will stop collecting new health information from you and about you for this study. However, the study staff will continue to use the health information collected up to the time they receive your letter asking them to stop.

Can you ask to see the PHI that is collected about you for this study?
The federal rules say that you can see the health information that we collect about you and use in this study. Contact the study staff if you have a need to review your PHI collected for this study. You will only have access to your PHI while the EpiNet project is ongoing.

How long will your PHI be used?
By signing this form, you agree to let us use and disclose your health information for purposes of the study until the end of the study. There is no expiration date because repositories by their nature are intended to use stored materials continually. We do not know how long it will take us to finish doing all of the analyses and we will need to use your health information for as long as it takes.

Contact Information – Who can you contact if you have questions, concerns, comments or complaints?

If you have questions now, feel free to ask us. If you have additional questions later or you wish to report a problem or complaint which may be related to this study please contact:

Primary contact:
Janice Jordan, R.N., can be reached at 210-358-8555 or 210-358-4000 after hours.

If primary is not available, contact
Alexander Papanastassiou, M.D. can be reached at 210-358-8555 or 210-358-4000 after hours.

The University of Texas Health Science Center committee that reviews research on human subjects (Institutional Review Board) will answer any questions about your rights as a research subject, and take any concerns, comments or complaints you may wish to offer. You can contact the IRB by calling 210-567-8250, or by mail to IRB, UTHSCSA, Mail Code 7830, 7703 Floyd Curl Drive, San Antonio, TX 78229-3900.

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Research Repository Consent and Authorization Signature Section

If you agree to participate in this research including the use of your protected health information sign below. You will be given a signed copy of this form to keep. You do not waive any of your legal rights by signing this form.

SIGN THIS FORM ONLY IF THE STATEMENTS LISTED BELOW ARE TRUE

- You have read the above information.
- Your questions have been answered to your satisfaction.

Adult Signature Section

You have voluntarily decided to take part in this research study.

Printed Name of Subject	Signature of Subject	Date	Time AM PM
Printed Name of Witness	Signature of Witness	Date	Time AM PM

☐*Check if consent obtained from an individual who can understand & comprehend English but is physically unable to talk or write. Have witness initial below.*
Declaration of witness: I was present for the entire consent process. _____ ←(initials of witness)

Printed Name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date	Time AM PM

☐Consent was obtained from this individual who can understand & comprehend English but is physically unable to talk or write. The method used for communication with the subject was: _____. The specific means by which the subject communicated agreement to participate was: _____

Surrogate Signature Section

You are voluntarily giving your consent for another person to participate in this study because you believe this person would want to take part if able to make the decision and you believe it is in this person's best interest.

Printed Name of Subject	Signature of **Child**, indicating Assent, if Age 7 or Older (If incapable of signing, person obtaining consent should initial here)	Date	Time AM PM
Printed Name of Person Consenting for Subject	Signature of Person Giving Consent ☐Parent/☐Guardian/☐Legally Authorized Representative	Date	Time AM PM
Printed Name of Witness	Witness Signature	Date	Time AM PM
Printed Name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date	Time AM PM