Montefiore Medical Center
Albert Einstein College of Medicine of Yeshiva University

Individual's Informed Consent to Participate as a Subject in Clinical Research

TITLE OF STUDY:	The EpiNet Project: An International Pilot Study		
PRINCIPAL INVESTIGATOR:	Alexis Boro, M.D.	**TELEPHONE NO.:**	(718) 920-4898
OFFICIAL ADDRESS:	Montefiore Medical Center 111 East 210th St. Bronx, New York 10467	**IRB#:**	IRB# 10-04-109E

By signing this form you have agreed to participate as a subject in The EpiNet Project: An International Pilot Study

After reading and listening to an explanation of the following information, you should ask all the questions you want to ask. You will be given a copy of this form whether or not you agree to participate in this study.

1. The **PURPOSE** of the research
2. The **PROCEDURES** involved and duration of your participation
3. The **RISKS** that you will be taking, if any
4. The **BENEFITS** that may result to you or to others
5. Any **ALTERNATIVE** procedures or courses of treatment that may be available

APPROVED
IRB
7/31/11 through 7/30/12

PURPOSE AND BACKGROUND:
This study is a first step in developing an international database of patients who might be interested in joining research studies that deal with questions such as which seizure medications work best for which kinds of seizures, which combinations of medications work best for those who are taking more than one medication and when it would be best to stop taking medications once someone has been seizure free, At this stage we are only testing the database. If this stage of the investigation is successful, the database will be used to plan studies and identify patients who may be invited to participate.

This project was initiated by investigators at the University of Auckland, New Zealand. About 10 medical centers in at least five countries will be enrolling patients. You are being asked to participate in this study because you have seizures and take medication to prevent seizures. This pilot study will last between six months to a year and a half. We are hoping to enroll approximately 500 subjects in this phase of the study, with about 50 subjects coming from Montefiore Medical Center.

PROCEDURES: If you agree to participate in this study, a Montefiore doctor will fill in an electronic form on a website which only we can log onto. The information that will be entered onto the website and stored in the database includes your name, date of birth, gender, ethnicity, what type of seizures you have, how often your seizures occur, what tests you have completed (MRI, EEG, CT, etc) and the results of these diagnostic tests along with the medications that you are using or have taken in the past and when these medications were changed. Your information may be updated each time you come in to see your doctor for the next year.

If you agree to participate in this study, your data will be kept in the database in the database to determine if you may be eligible for our future studies. You may be contacted in the future to discuss the possibility of participating in separate studies, but you will in no way be obligated to participate.

RISKS AND DISCOMFORTS: Participation in research may involve a loss of privacy. However, the research investigators will do everything possible to protect your confidentiality.

PATIENT CONFIDENTIALITY: Participation in research may involve a loss of privacy. However, the investigators will do everything possible to protect your confidentiality. Only the investigator entering the data will have access to your

medical chart and your name. Investigators at other participating sites will be able to see a summary of your current and past medications and tests results but will not have access to your name. The data will be de-identified. That is, any personal information which exists in your medical record (such as name, address and social security number) will not be seen by anyone other than the investigators here at Montefiore Medical Center.

Finally, any information from this study that is used in publications will contain no identifying information.

WILL THERE BE ANY COST TO ME? There will be no costs for your participation in this study.

BENEFITS: There are no direct benefits to you for your participation in this study. This study may provide an international resource that help in the treatment of epilepsy. This may bring benefit to people in the future.

ALTERNATIVES: You do not have to participate in the research study.

REIMBURSEMENT: You will receive no reimbursement for enrolling in this pilot study.

WITHDRAWAL: Your participation in this study is voluntary. You may be a participant in it only if you wish, and you may withdraw from the study at any time. If you choose to withdraw from the study your information will be removed from the website database and you will not be contacted about additional studies related to the EpiNet Project. Your treatment by doctors and staff at the hospitals involved in this study, now and in the future, will not be affected in any way if you refuse to participate or if you enter the program and withdraw later. You do not waive any of your legal rights or benefits to which you are otherwise entitled by signing this document.

WHO MAY SEE MY RECORDS?

- The research records will be kept private and your name will not be used in any written or verbal reports.
- Your research records and epilepsy medical records may be seen by members of the research team, the company conducting the study and other hospitals that participate in this study.
- The research study doctor and research staff will review your medical records and will keep the information private.
- All records will be identified only by a number known only to the research study doctors. The research records will be kept in a secured manner and computer records will be password protected.
- The people who reviewed this research study as members of the Albert Einstein College of Medicine and Montefiore Medical Center Institutional Review Board may also review your research and medical records.
- The Office for Human Research Protections (OHRP) may also review your research study records.
- All of these groups have been requested to keep your information private.

WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?

Research Study Doctor's Name:

Dr. Alexis D. Boro
111 East 210th Street Room-H009
Bronx, NY 10467
718-920-4898

- If you have any questions about this research project you can call the research study doctor above.

- If you have questions regarding your rights as a research subject, you may also call the Administrator of The Albert Einstein College of Medicine Committee on Clinical Investigations at (718) 430-2253 or the Montefiore Medical Center Institutional Review Board at (718) 798-0406, Monday through Friday between 9 A.M. and 5 P.M.

CONFIDENTIALITY

Records of this study will be kept confidential and you will not be identified in any written or verbal reports with the following possible exceptions: Research personnel authorized by the Principal Investigator may see your records. Your research records will be kept in a secure manner and computer records will be password protected. The U.S. Food and

Drug Administration (FDA), Office of Human Research Protections (OHRP), the Institutional Review Board (IRB) of Montefiore Medical Center and collaborating groups may inspect your records.

QUESTIONS RELATED TO THE RESEARCH

, You may call the supervisor of this study Dr. Boro at (718) 920-4898 if you have any questions. If you have questions regarding your rights as a research subject, you may call the Montefiore Medical Center Institutional Review Board at (718) 798-0406 Monday through Friday between 9am and 5pm.

□ Please contact me about future studies.

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Printed Name of Participant

_____ _____
Signature of Participant Date

_____
Printed Name of Individual Conducting Informed Consent Process

_____ _____
Signature of Individual Conducting Informed Consent Process Date

APPROVED
IRB
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