MONTEFIORE MEDICAL CENTER
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OFFICE OF RESEARCH AND
SPONSORED PROGRAMS
OFFICE OF
INSTITUTIONAL REVIEW BOARD

MONTEFIORE

July 31, 2010

Principal Investigator: Dr. Alexis Boro, Department: NEUROLOGY
Protocol Number: 10-04-109E
The EpiNet Project: An International Pilot Study

Federal Wide Assurance: 00002558 Study will appear on the IRB Agenda of: 08/27/2010

Dear Dr. Boro:

Montefiore Medical Center's Institutional Review Board (IRB) has approved the above-referenced study, on the
basis of its scientific merit and risk:benefit ratio, in accordance with the expedited review categories under 45 CFR 46.110 and 21 CFR 56.110.

IRB approval for this study will expire on **7/30/11**.

Approved Items:
- HIPAA Authorization has been acknowledged. Subjects are required to sign a HIPAA authorization in addition to the consent form.
- Protocol Version 16 November 2009.
- Individual's Informed Consent Version, dated 29 July 2010.

Recertification of this protocol will require the submission of a progress report and is subject to the review and approval of the IRB. Please note that Spanish-speaking subjects may not be enrolled until a fully translated consent form has been approved by the IRB.

Please do not hesitate to contact me at 798-0406, ext. 225 if you need additional information.

Sincerely,

Elizabeth Paljevic

Elizabeth Paljevic
Research Administration
Institutional Review Board

INVESTIGATOR, please note the following:
1. Use only IRB approved copies of the consent form(s), questionnaire(s), letter(s), advertisement(s), etc in your research. Do not use expired consent forms.
2. Any modifications or changes made to the study must be submitted to the irb for review prior the initiation of said modifications or changes.
3. Any serious and/or unexpected adverse event in a study subject and /or death of a subject is to be reported to the irb within 48 hours followed by a written report within 10 working days of the event.
be initiated.