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APPROVAL NOTICE

DATE:	7/31/2015
TO:	GARY MATHERN NEUROSURGERY
FROM:	JAMES MC GOUGH, MD Chair, MIRB3
RE:	IRB#13-001213-AM-00001 Addition of consent forms translated into Spanish by UCLA Interpreter Services UCLA Rare Brain Disease Tissue Bank Version: Version 08.01.13/ Dated August 2013

The UCLA Institutional Review Board (UCLA IRB) has approved the above-referenced study. UCLA's Federalwide Assurance (FWA) with Department of Health and Human Services is FWA00004642.

Submission and Review Information

Type of Submission	Amendment
Type of Review	IRB Review: Expedited
Approval Date	7/30/2015
Expiration Date of the Study	6/24/2016
	1) NIH-NINDS NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND S *Grant PI*: GARY MATHERN *Grant Title*: "Pathophysiology of Developing Dysplastic Human Cortex" *Grant Number*: RO1 NS38992

Funding Source(s)	2) NIH-NINDS NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND S *Grant PI*: GARY MATHERN *Grant Title*: Molecular characterization of Hemimegalencephaly *Grant Number*: 1 R01 NS 083823-01 3) Other: VRS DNRS / Rasmussen encephalitis research *Grant PI*: GARY MATHERN
Initial IRB Approval Type	IRB Review: Expedited

Specific Conditions for Approval

-- **Translations Needed** - Please submit translated copies of your recruitment, screening, and consent documents as an amendment(s) before recruiting or consenting any subjects for whom these translations are required. [If medical study being conducted in CA--Be sure and provide subjects with the appropriately translated Research Participant's Bill of Rights. Numerous translations are available for download on the HRPP website at http://www.ohrpp.research.ucla.edu/pages/bill-of-rights.]

-- **Research Participants Bill of Rights** - By California law, a copy of the Research Participants Bill of Rights in a language in which the participant is fluent must be given to all research participants in this study as there is a real or foreseeable risk of biomedical harm. Numerous translations are available for download on the HRPP website at http://www.ohrpp.research.ucla.edu/pages/bill-of-rights.

Regulatory Determinations

-- **Children as Subjects** - The UCLA IRB determined that the research meets the requirements of 45 CFR 46.404 for research involving children as subjects.

-- **Surrogate Consent** - The UCLA IRB approved the use of surrogate consent in a non-emergency situation in accordance with CA Health & Safety Code 24178.

-- **Expedited Review Category(ies)** - The UCLA IRB determined that the research meets the requirements for expedited review per 45 CFR 46.110 categories 2 and 3.

Currently approved recruitment and/or consent documents:

Document Name	Document Version #
13-001213_Tissue Bank Child Assent.pdf.pdf	0.01
13-001213_Tissue Bank Adult Consent Spanish.pdf.pdf	0.01
13-001213_Tissue Bank Informed Consent - Adult Subject.pdf.pdf	0.01

13-001213_Informed Consent Verification Checklist.pdf.pdf	0.01
13-001213_Tissue Bank Informed Consent - Parental-Youth Consent.pdf.pdf	0.01
13-001213_Tissue Bank Parental-Youth Consent Spanish.pdf.pdf	0.01

Important Note: Approval by the Institutional Review Board does not, in and of itself, constitute approval for the implementation of this research. Other UCLA clearances and approvals or other external agency or collaborating institutional approvals may be required before study activities are initiated. Research undertaken in conjunction with outside entities, such as drug or device companies, are typically contractual in nature and require an agreement between the University and the entity.

General Conditions of Approval
As indicated in the PI Assurances as part of the IRB requirements for approval, the PI has ultimate responsibility for the conduct of the study, the ethical performance of the project, the protection of the rights and welfare of human subjects, and strict adherence to any stipulations imposed by the IRB.

The PI and study team will comply with all UCLA policies and procedures, as well as with all applicable Federal, State, and local laws regarding the protection of human subjects in research, including, but not limited to, the following:

- Ensuring that the personnel performing the project are qualified, appropriately trained, and will adhere to the provisions of the approved protocol,
- Implementing no changes in the approved protocol or consent process or documents without prior IRB approval (except in an emergency, if necessary to safeguard the well-being of human subjects and then notifying the IRB as soon as possible afterwards),
- Obtaining the legally effective informed consent from human subjects of their legally responsible representative, and using only the currently approved consent process and stamped consent documents, as appropriate, with human subjects,
- Reporting serious or unexpected adverse events as well as protocol violations or other incidents related to the protocol to the IRB according to the OHRPP reporting requirements.
- Assuring that adequate resources to protect research participants (i.e., personnel, funding, time, equipment and space) are in place before implementing the research project, and that the research will stop if adequate resources become unavailable.
- Arranging for a co-investigator to assume direct responsibility of the study if the PI will be unavailable to direct this research personally, for example, when on sabbatical leave or vacation or other absences. Either this person is named as co-investigator in this application, or advising IRB via webIRB in advance of such arrangements.