January 28, 2014

MADELEINE PAHL
MEDICINE

RE: UCI IRB HS# 2012-9270 *Diffuse Optical Spectroscopy Imaging (DOSI) to Assess Volume Changes During Hemodialysis*

The above-referenced human-subjects research project has been approved by the University of California, Irvine Institutional Review Board (UCI IRB). This approval is limited to the activities described in the approved Protocol Narrative, and extends to the performance of these activities at each respective site identified in the Application for IRB Review. In accordance with this approval, the specific conditions for the conduct of this research are listed below, and informed consent from subjects must be obtained as indicated. Additional conditions for the general conduct of human-subjects research are detailed on the attached sheet.

NOTE: Approval by the Institutional Review Board does not, in and of itself, constitute approval for the implementation of this research. Other institutional clearances and approvals may be required (e.g., EH&S, Radiation Safety, School Dean, other institutional IRBs). 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. Such agreements must be executed by an institutional official in Sponsored Projects, a division in the UCI Office of Research. The University is not obligated to legally defend or indemnify an employee who individually enters into these agreements and investigators are personally liable for contracts they sign. Accordingly, the project should not begin until all required approvals have been obtained.

Questions concerning the approval of this research project may be directed to the Office of Research, 5171 California Avenue, Suite 150, Irvine, CA 92697-7600; 949-824-6068 or 949-824-2125 (biomedical committee) or 949-824-6662 (social-behavioral committee).

Expedited Review: Categories 4,5,6

Ruth A. Mulnard, DNSc, RN, CNRN, CIP, FAAN
Vice Chair, Institutional Review Board

Approval Issued: 1/28/2014
Expiration Date: 1/27/2015
UCI (FWA) 00004071, Approved: January 31, 2003

IRB Determinations as Conditions of Approval:

Informed Consent Determinations:

1. Signed Informed Consent Required
2. Signed UC HIPAA Research Authorization Required
3. Use of Translated Language Consent[1]

[1] *In order to consent subjects who are unable to read and speak English, the English version of the consent form must be translated into appropriate languages once IRB approval is granted. Submit the translated version of the current IRB approved consent form to the IRB for stamping, PRIOR to use.*

APPROVAL CONDITIONS FOR ALL UCI HUMAN RESEARCH PROTOCOLS

UCI RESEARCH POLICIES:
All individuals engaged in human-subjects research are responsible for compliance with all applicable UCI Research Policies (http://www.research.uci.edu/researchpolicies.htm). The Lead Researcher of the study is ultimately responsible for assuring all study team members adhere to applicable policies for the conduct of human-subjects research.

LEAD RESEARCHER RECORDKEEPING RESPONSIBILITIES:
Lead Researchers are responsible for the retention of protocol–related records. The following web pages should be reviewed for more information about the Lead Researcher's recordkeeping responsibilities for the preparation and maintenance of research files: http://www.research.uci.edu/ora/hrpp/leadresearcherrecordkeeping.htm and http://www.research.uci.edu/ora/hrpp/researchauditfile.htm.

PROTOCOL EXPIRATION:
The UCI IRB approval letter references the protocol expiration date under the IRB Chair's signature authorization. A courtesy email will be sent approximately 60 to 90 days prior to expiration reminding the Lead Researcher to apply for continuing review. For studies granted Extended IRB Approval, a courtesy e-mail will be sent annually to verify eligibility for the continuation of extended approval. It is the Lead Researcher's responsibility to apply for continuing review and in order to ensure continuing approval throughout the conduct of the study. Lapses in approval must be avoided to protect the safety and welfare of enrolled subjects.

MODIFICATIONS & AMENDMENTS:
No changes are permissible to the approved protocol or the approved, stamped consent form without the prior review and approval of the UCI IRB. All changes (e.g., a change in procedure, number of subjects, personnel, study locations, new recruitment materials, study instruments, etc.) must be prospectively reviewed and approved by the IRB before they are implemented.

APPROVED VERSIONS OF CONSENT DOCUMENTS, INCLUDING STUDY INFORMATION SHEETS:
Unless a waiver of informed consent is granted by the IRB, the consent documents (consent form; study information sheet) with the UCI IRB approval stamp must be used for consenting all human subjects enrolled in this study. Only the current approved version of the consent documents may be used to consent subjects. Approved consent documents are not to be used beyond their expiration date.

ADVERSE EVENT & UNANTICIPATED PROBLEMS REPORTING:
All unanticipated problem involving risk to subjects or others or serious adverse events must be reported to the UCI IRB in accordance with Federal regulations and UCI policy. See http://www.research.uci.edu/ora/hrpp/adverseexperiences.htm for complete details.

CHANGES IN FINANCIAL INTEREST:
Any changes in the financial relationship between the study sponsor and any of the investigators on the study and/or any new potential conflicts of interest must be reported immediately to the UCI Conflict of Interest Oversight Committee (COIOC). If these changes affect the conduct of the study or result in a change in the text of the currently-approved informed consent document, these changes must also be reported to the UCI IRB via a modification request. Research subject to COIOC oversight is not eligible for Extended IRB Approval.

CLOSING REPORT:
An electronic closing report must be filed with the UCI IRB when the research concludes. See http://www.research.uci.edu/ora/hrpp/closingaprotocol.htm for complete details.

CLINICAL INVESTIGATIONS
If the study involves biomedical interventions and may use UCIMC facilities or resources (including the Plaza and satellite clinics), financial review by the Office of Clinical Research Finance Assessment (CRFA) is required prior to initiation of your clinical investigation. For information about CRFA submission requirements, please consult http://www.research.uci.edu/ora/hrpp/clinicalresearchfinance.htm or go directly to the CRFA website at https://intranet.hs.uci.edu/CRFA/research01.htm.