University of California
San Francisco

Human Research Protection Program
Institutional Review Board (IRB)

Full Committee Approval

Principal Investigator
Dr. Claus Niemann, MD

Type of Submission: Submission Response for Initial Review Submission Packet
Study Title: A Randomized Trial of Mild Hypothermia and Machine Perfusion in Deceased Organ Donors for Protection against Delayed Graft Function in Kidney Transplant Recipients

IRB #: 17-21768
Reference #: 185808
Reviewing Committee: Parnassus Panel
Study Risk Assignment: Minimal

Approval Date: 04/17/2017 **Expiration Date:** 04/16/2018

Regulatory Determinations Pertaining to This Approval:

Note: This study involves deceased organ donors and their kidney recipients. The donors are not considered human subjects under Health and Human Services Code of Federal Regulations Title 45 Part 46. The following regulatory determinations were made regarding the recipients only.

This research is not subject to HIPAA rules.

A waiver of informed consent is acceptable because, as detailed in the application: (1) the research involves no more than minimal risk to the organ recipients; (2) the waiver will not adversely affect the rights and welfare of the organ recipients; (3) the research could not practicably be carried out without the waiver; and (4) whenever appropriate, the organ recipients will be provided with additional pertinent information after participation. The waiver of informed consent applies to all persons receiving a kidney managed by this protocol.

This research satisfies the following condition for the involvement of children: 45 CFR 46.404, 21 CFR 50.51: Research not involving greater than minimal risk.

The full board determined that the research poses no greater than minimal risk and is eligible for expedited review in the future under category #9 (continuing review of research, not conducted under an IND or IDE where categories 2 through 8 do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified).

Comment:
Per the Office of Human Research Protections' definition of "engagement in research," the hospitals at which the recipients receive their transplants are *not* engaged in research because they are not performing any research procedures.

All changes to a study must receive UCSF IRB approval before they are implemented. Follow the modification request instructions. The only exception to the requirement for prior UCSF IRB review and approval is when the changes are necessary to eliminate apparent immediate hazards to the subject (45 CFR 46.103.b.4, 21 CFR 56.108.a). In such cases, report the actions taken by following these instructions.

Expiration Notice: The iRIS system will generate an email notification eight weeks prior to the expiration of this study's approval. However, it is your responsibility to ensure that an application for continuing review approval has been submitted by the required time. In addition, you are required to submit a study closeout report at the completion of the project.

Documents Reviewed with this Submission:

Study Document			
Title	Version #	Version Date	Outcome
Letter from UCSF Bioethicist Koenig	Version 1.0	02/20/2017	Approved
Letter from UPenn Bioethicist	Version 1.0	02/16/2017	Approved
Letter from Vanderbilt Bioethicist	Version 1.0	02/16/2017	Approved
Public Citizen complaint letter	Version 1.0	02/16/2017	Approved
UCSF Response re Public Citizen	Version 1.0	02/16/2017	Approved
Study Diagrams	Version 1.0	02/16/2017	Approved
Niemann NEJM 2015 Article on Previous Trial	Version 1.0	02/16/2017	Approved
Niemann Heldens Editorial on Donor Research	Version 1.0	02/16/2017	Approved
Watson_Editorial_NEJM_2015	Version 1.0	02/16/2017	Approved
Feng-2016-American_Journal_of_Transplantation	Version 1.0	02/16/2017	Approved
Abt_et_al-2016-American_Journal_of_Transplantation	Version 1.0	02/16/2017	Approved

For a list of all currently approved documents, follow these steps: Go to My Studies and open the study – Click on Informed Consent to obtain a list of approved consent documents and Other Study Documents for a list of other approved documents.

San Francisco Veterans Affairs Medical Center (SFVAMC): If the SFVAMC is engaged in this research, you must secure approval of the VA Research & Development Committee in addition to UCSF IRB approval and follow all applicable VA and other federal requirements. The IRB website has more information.