University of California
San Francisco

Human Research Protection Program
Committee on Human Research

Notification of Review

Principal Investigator
Claus Niemann

Type of Submission: Submission Response for Initial Review Submission Packet
Study Title: Impact of organ donor management on post-transplant renal function in recipients
IRB #: 11-08166
Reference #: 036523

Acknowledgment Date: 1/12/2012

IRB Comments:

1. The IRB agreed that research on brain dead organ donors does not require IRB approval under state or federal regulations. However, they thank you for submitting your study for review, and will make a recommendation to UCSF leadership that such studies be reviewed by the IRB in the future. Note that while the IRB has reviewed the proposal, a formal approval is not required and will not be issued. Your study will not need to be resubmitted for annual continuing reviews.
2. The IRB noted that identifiable data collected on the recipients does require review and is covered by an existing approved IRB application on which you are PI.
3. The IRB concluded that this particular study poses minimal risk and imposition to all involved and agreed that neither the donors' next of kin nor the transplant recipients need to be consented for this research.

For a list of acknowledged study documents, follow these steps:
In iMedRIS, go to My Studies and open the study – Click on the Informed Consent link to obtain a list of approved consent documents and click on the Other Study Documents link for a list of other reviewed documents.