VIRGINIA COMMONWEALTH UNIVERSITY

VCU

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DATE: October 11, 2013

TO: Pingle Reddy, MD
Anesthesiology
Box 980695

FROM: Lea Ann Hansen, Pharm D Lea Ann Hansen, Pharm D/DSA
Chairperson, VCU IRB Panel D
Box 980568

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RE: **VCU IRB #: HM15391**
Title: The Effect of Intensive Insulin Therapy During Cardiac Surgery on Intraoperative Blood Glucose Levels

The following study involving the research use of human subjects was ***approved*** by the VCU IRB on October 11, 2013 according to 45 CFR 46.108(b). The changes requested by the Panel received in the Office of Research Subjects Protection on October 8, 2013 satisfactorily meet the stipulations set forth in the September 19, 2013 IRB Panel meeting. This approval includes the following items reviewed by this Panel:

PROTOCOL: The Effect of Intensive Insulin Therapy During Cardiac Surgery on Intraoperative Blood Glucose Levels

- Research Plan (dated October 7, 2013; received in ORSP October 8, 2013)

HIPAA PROCESS:

The following pathways for accessing and/or using PHI have been approved:

- Waiver of Authorization: The three criteria for waiver of authorization have been met [45 CFR 164.512(i)(1)(i)]

CONSENT/ASSENT:

- All four conditions for waiver of consent have been met. See §45 CFR 46.116(d). The IRB Panel has waived all elements of consent.

ADDITIONAL DOCUMENTS:

- VCU IRB Study Personnel Roster (Version date: July 9, 2013; received in ORSP July 22, 2013)

This approval expires on September 18, 2014 Federal Regulations/VCU Policy and Procedures require continuing review prior to continuation of approval past that date. Continuing Review report forms will be mailed to you prior to the scheduled review.

If you have any questions, please contact Dr. Lea Ann Hansen, Chairperson, VCU IRB Panel D, at leaann.hansen@gmail.com or 804-393-0498; or you may contact Dawn Anderson, IRB Administrator, VCU Office of Research Subjects Protection, at IRBPanelD@vcu.edu or 827-1445.

Attachment – Conditions of Approval

Conditions of Approval:

In order to comply with federal regulations, industry standards, and the terms of this approval, the investigator must *(as applicable):*

1. Conduct the research as described in and required by the Protocol.

2. Obtain informed consent from all subjects without coercion or undue influence, and provide the potential subject sufficient opportunity to consider whether or not to participate (unless Waiver of Consent is specifically approved or research is exempt).

3. Document informed consent using only the most recently dated consent form bearing the VCU IRB "APPROVED" stamp (unless Waiver of Consent is specifically approved).

4. Provide non-English speaking patients with a translation of the approved Consent Form in the research participant's first language. The Panel must approve the translated version.

5. Obtain prior approval from VCU IRB before implementing any changes whatsoever in the approved protocol or consent form, unless such changes are necessary to protect the safety of human research participants (e.g., permanent/temporary change of PI, addition of performance/collaborative sites, request to include newly incarcerated participants or participants that are wards of the state, addition/deletion of participant groups, etc.). Any departure from these approved documents must be reported to the VCU IRB immediately as an Unanticipated Problem (see #7).

6. Monitor all problems (anticipated and unanticipated) associated with risk to research participants or others.

7. Report Unanticipated Problems (UPs), including protocol deviations, following the VCU IRB requirements and timelines detailed in VCU IRB WPP VIII-7):

8. Obtain prior approval from the VCU IRB before use of any advertisement or other material for recruitment of research participants.

9. Promptly report and/or respond to all inquiries by the VCU IRB concerning the conduct of the approved research when so requested.

10. All protocols that administer acute medical treatment to human research participants must have an emergency preparedness plan. Please refer to VCU guidance on http:/www.research.vcu.edu/irb/guidance.htm.

11. The VCU IRBs operate under the regulatory authorities as described within:
    a) U.S. Department of Health and Human Services Title 45 CFR 46, Subparts A, B, C, and D (for all research, regardless of source of funding) and related guidance documents.
    b) U.S. Food and Drug Administration Chapter I of Title 21 CFR 50 and 56 (for FDA regulated research only) and related guidance documents.
    c) Commonwealth of Virginia Code of Virginia 32.1 Chapter 5.1 Human Research (for all research).