Boston University Medical Center

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Office of the Institutional Review Board
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Title of Study: BIOMARKERS OF LUNG INJURY WITH LOW TIDAL VOLUME VENTILATION COMPARED WITH AIRWAY PRESSURE RELEASE VENTILATION In Trauma Patients
Protocol Number: H-31059

RE: New Protocol
Review Type: Full Board
Action: Approved

Date of Action: July 7, 2011
Date Revisions Were Accepted: August 10, 2011
Date of Expiration: July 6, 2012

Funding Source: Department of Defense
Award #: Pending

Funding Source: NIH/BU Clinical Translational Institute
Award #: UL1RR025771

Protocol Version #: 1.2
Consent Version #: 1.2

- 1-BIOMARKERS OF LUNG INJURY WITH LOW TIDAL VOLUME VENTILATION COMPARED WITH AIRWAY PRESSURE RELEASE VENTILATION In Trauma Patients

Dear Suresh Agarwal, MD:

At the July 7, 2011 Panel Green Institutional Review Board (IRB) meeting, chaired by Dr. Lynn Borgatta, the above referenced protocol was reviewed. It has been determined that this study meets the requirements set forth by the IRB and is hereby approved. This protocol is valid through the expiration date indicated above.

This approval corresponds with the versions of the protocol and consent form(s) indicated above.

Protocol Specific Determinations and Findings

- The Board has approved the request to consent subjects through a Legally Authorized Representative (LAR).

- Please see the approved and stamped HIPAA Preparatory to Research Form (v1.1) in Other Study Documents.

Requirements

The study may not continue after the approval period without additional IRB review and approval for continuation. You will receive an email renewal reminder notice prior to study expiration;

however, it is your responsibility to assure that this study is not conducted beyond the expiration date.

Please be aware that only IRB-approved informed consent forms, validated with current approval dates generated by the INSPIR system, may be used when informed consent is required.

Any changes to the approved protocol or informed consent documents must be reviewed and approved prior to implementation unless the change is necessary for the safety of subjects.

You must report to the IRB unanticipated problems involving risk to subjects or others according to the process posted on the IRB website (www.bumc.bu.edu/irb). The IRB must also be informed of any new or significant information that might impact a research participant's safety or willingness to continue in your study.

Investigators are required to ensure that all HIPAA requirements have been met prior to initiating this study. Once approved, validated HIPAA forms may be found within INSPIR under Study Documents.
It is the responsibility of the PI to ensure that all required institutional approvals have been obtained prior to initiating any research activities.

Sincerely yours,

Signature applied by Jeffrey Yu on 08/10/2011 04:29:59 PM EDT

Senior IRB Analyst