MEDICAL COLLEGE OF WISCONSIN

Medical College of Wisconsin /
Froedtert Hospital
Institutional Review Board

To: Charles Cady , MD
CC:

Date: **9/30/2013**

Re: **Project Title**: EMS Use of Ketamine in Excited Delirium: A Case Series
PRO ID: PRO00018649

IRB Approval Date: 9/30/2013

IRB Expiration Date: 9/29/2015

The MCW/FH Institutional Review Board #5 has granted approval for the above-referenced submission in accordance with 45 CFR 46.111 by expedited review, Category **#5**.

Approval has been granted for the following institutions:
Froedtert Hospital including the Clinical Cancer Center
Emergency Physician Ministry Saint Michael's Hospital

The items listed below were submitted and reviewed when the IRB approved this submission. Research must be conducted according to the IRB approved protocol listed below:

Ketamine and Excited Delirium Protocol

The IRB has granted approval of a waiver of HIPAA authorization requirements at 45 CFR 164 and a waiver of informed consent requirements at 45 CFR 46.116 for this project.

Any and all proposed changes to this submission must be reviewed and approved by the IRB prior to implementation. When it is necessary to eliminate hazards to subjects, changes may be made first. This should be followed promptly by a Reportable Event for a protocol deviation and Amendment.

In accordance with federal regulations, continuing approval for this submission is required prior to 9/29/2015. The Continuing Progress Report (CPR) must be received by the IRB with enough time to

allow for review and approval prior to the expiration date. Failure to submit the CPR in a timely manner may result in the expiration of IRB approval.

A Final Report must be submitted to the IRB within 30 days of when all project activities and data analysis have been completed.

All Unanticipated Problems Involving Risks to Subjects or Others (UPIRSO) must be reported promptly to the MCW/FH IRB according to IRB Standard Operating Procedures (SOPs).

If your project involves the use of any Froedtert Health resource such as, space, staff services, supplies/equipment or any ancillary services - lab, pharmacy, radiology, protected health/billing information or specimen requests, OCRICC approval is required before beginning any research activity at those sites.

If you have any questions, please contact the IRB Coordinator II for this IRB Committee, Dee Burns, at 414-955-8464 or dburns@mcw.edu.

Sincerely,

Kathryn Gaudreau
David Clark, PhD

IRB Chair

MCW/FH Institutional Review Board #5