



Biomedical Sciences Institutional Review Board

Office of Responsible Research Practices
300 Research Administration Building
1960 Kenny Road
Columbus, OH 43210-1063

Phone (614) 688-8457
Fax (614) 688-0366
www.orrp.osu.edu

September 16, 2011

Protocol Number: 2009H0252
Protocol Title: CCT CORE TREAT FRACTURE STUDY: TIME SAVINGS BY RAPID EMS
ANTIBIOTIC THERAPY FOR FRACTURES, Howard A. Werman, Emergency Medicine
Type of Review: Continuing Review – expedited
IRB Staff Contact: Paul Montesanti
614.292.9804
Montesanti.2@osu.edu

Dear Dr. Werman,

The Biomedical Sciences IRB **APPROVED BY EXPEDITED REVIEW** the above referenced research. The Board was able to provide expedited approval under 45 CFR 46.110(b)(1) because the research meets the applicability criteria and one or more categories of research eligible for expedited review, as indicated below.

Date of IRB Approval: September 13, 2011
Date of IRB Approval Expiration: September 13, 2012
Expedited Review Category: 5

In addition; the research has been approved for a waiver of the consent process and for a waiver of HIPAA Research Authorization (entire research study).

If applicable, informed consent (and HIPAA research authorization) must be obtained from subjects or their legally authorized representatives and documented prior to research involvement. The IRB-approved consent form and process must be used. Changes in the research (e.g., recruitment procedures, advertisements, enrollment numbers, etc.) or informed consent process must be approved by the IRB before they are implemented (except where necessary to eliminate apparent immediate hazards to subjects).

This approval is valid for **one year** from the date of IRB review when approval is granted or modifications are required. The approval will no longer be in effect on the date listed above as the IRB expiration date. A Continuing Review application must be approved within this interval to avoid expiration of IRB approval and cessation of all research activities. A final report must be provided to the IRB and all records relating to the research (including signed consent forms) must be retained and available for audit for at least 3 years after the research has ended.

It is the responsibility of all investigators and research staff to promptly report to the IRB any serious, unexpected and related adverse events and potential unanticipated problems involving risks to subjects or others.

This approval is issued under The Ohio State University's OHRP Federalwide Assurance #00006378. All forms and procedures can be found on the ORRP website – www.orrp.osu.edu. Please feel free to contact the IRB staff contact listed above with any questions or concerns.

Karla Zadnik, OD, PhD, Chair
Biomedical Sciences Institutional Review Board

