



University of Maryland, Baltimore
Institutional Review Board (IRB)
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New Study Approval Notification

Date: February 10, 2011

To: Erik von Rosenvinge
From: IRB Chair/Vice Chair: Robert Rosenthal
RE: HP-00048528
Risk designation: Minimal Risk
Submission Date: 12/28/2010
Original Version #: N/A

Approval for this project is valid from 2/10/2011 to 2/9/2012

This is to certify that the University of Maryland, Baltimore (UMB) Institutional Review Board (IRB) has fully approved the above referenced protocol entitled, "*Clostridium difficile*-Associated Disease: UMMC's compliance with the May 2010 SHEA/IDSA Guidelines."

The IRB has determined that this protocol qualifies for expedited review pursuant to Federal regulations 45 CFR 46.110, 21 CFR 56.110, & 38 CFR 16.110 category(ies).

(5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

Please be aware that only valid IRB-approved informed consent forms may be used when written informed consent is required.

Below is a list of the documents attached to your application that also have been approved:

Eligibility Checklist for HP-00048528 v12-27-2010-1293486445028

SHEA-IDSA position paper 1995

Update on *Clostridium difficile* infection

A Predominantly Clonal Multi-Institutional Outbreak of *Clostridium difficile* –Associated Diarrhea with High Morbidity and Mortality

Clinical Practice Guidelines for *Clostridium difficile* Infection in Adults: 2010 Update by the Society for Healthcare Epidemiology of America (SHEA) and the Infectious Diseases Society of America (IDSA)

Reassessment of *Clostridium difficile* Susceptibility to Metronidazole and Vancomycin

A Comparison of Vancomycin and Metronidazole for the Treatment of *Clostridium difficile*–Associated Diarrhea, Stratified by Disease Severity

Recommendations for Preventing the Spread of Vancomycin Resistance Recommendations of the Hospital Infection Control Practices Advisory Committee (HICPAC)

1984 Treatment of Antibiotic-Associated Pseudomembranous Colitis

Severe *Clostridium difficile*–Associated Disease in Populations Previously at Low Risk— Four States, 2005

Hypervirulent *Clostridium difficile* Strains in Hospitalized Patients, Canada

Investigators are reminded that the IRB must be notified of any changes in the study. In addition, the PI is responsible for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject (45 CFR 46.103(4)(iii)).

DHHS regulations at 45 CFR 46.109 (e) require that **continuing review** of research be conducted by the IRB at intervals appropriate to the degree of risk and **not less than once per year**. The regulations make **no provision for any grace period extending the conduct of the research beyond the expiration date of IRB approval**. You will receive continuing review email reminder notices prior to study expiration; however, it is your responsibility to submit your continuing review report in a timely manner to allow adequate time for substantive and meaningful IRB review and assure that this study is not conducted beyond the expiration date. Investigators should submit continuing review reports in the electronic system at least six weeks prior to the IRB expiration date.

In addition, you must inform the IRB of any new and significant information that may impact a research participants' safety or willingness to continue in your study and any unanticipated problems involving risks to participants or others.

Research activity involving veterans or the Baltimore VA Maryland Healthcare System (BVAMHCS) as a site, must also be approved by the BVAMHCS Research and Development Committee prior to initiation. Contact the VA Research Office at 410-605-7131 for assistance.

The UMB IRB is organized and operated according to guidelines of the International Council on Harmonization, the United States Office for Human Research Protections and the United States Code of Federal Regulations and operates under Federal Wide Assurance No. FWA00007145.