UF | Institutional Review Board
UNIVERSITY of FLORIDA

Health Center Institutional Review Board

FWA00005790

PO Box 100173
Gainesville, Florida 32610-0173
Tel: (352) 273-9600
Fax: (352) 273-9614

MEMORANDUM

DATE: September 2, 2010

TO: Baharak Moshiree, M.D.
Box 100214

FROM: R. Peter Iafrate, Pharm.D.
Chairman, IRB - 01

RE: APPROVAL EXPIRES: Tuesday, August 30, 2011

PROJ: #406-2010 EXPEDITED: RETROSPECTIVE ANALYSIS OF TREATMENT OUTCOMES IN PATIENTS WITH BACTERIAL OVERGROWTH SYNDROME DIAGNOSED BY D-XYLOSE BREATH TESTING

You have received IRB approval to conduct the above-listed research study. Approval of this study was granted on August 31, 2010. You have also been approved for a waiver of Informed Consent in accordance with 45 CFR § 46.116(d). This study has been approved as expedited because it meets with applicable conditions and involves only procedures under:

Expedited #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.

You are responsible for applying for RENEWAL of this project prior to the expiration date. Re-approval of this project must be granted before the expiration date, or the project will be automatically suspended. If suspended, you may not do any of the following: (1) enroll or screen any new subjects, (2) perform any study interventions, unless the IRB finds that it is in the best interest of individual subjects to continue participating in research interventions or interactions, (3) collect, use, or report any data, and/or (4) receive any study funding.

The IRB has approved exactly what was submitted. Any change in the research, no matter how minor, may not be initiated without IRB review and approval, except where necessary to eliminate hazards to human subjects. If a change is required due to a potential hazard, that change must be promptly reported to the IRB.

Any (a) serious and unexpected adverse events and (b) unanticipated problems involving risk to subjects or others, must be reported to the IRB, in writing, within 5 working days.

Upon completion of the study, you are REQUIRED to submit a summary of the study and a Study Closure report to the IRB office.

Research records must be retained for a minimum of 3 years after completion of the research; if the study involves medical treatment, it is recommended that they be retained for 8 years. Otherwise you must comply with your institutional record retention policies.

If VAMC patients will be included in this project, or if the project is to be conducted in part on VA premises or performed by a VA employee during VA-compensated time, you must obtain approval from both the VA Subcommittee for Clinical Investigation and the Research and Development Committee before initiating the research.

You are responsible for notifying all parties about the approval of this study, including your co-Investigators and Department Chair. If you have any questions, please telephone the IRB-01 office at (352) 273-9600.

cc: IRB file / VA Research Center / Clinical Research Center

UF | Institutional Review Board
UNIVERSITY of FLORIDA

Health Center Institutional Review Board

FWA00005790

PO Box 100173
Gainesville, Florida 32610-0173
Tel: (352) 273-9600
Fax: (352) 273-9614

MEMORANDUM

DATE: September 2, 2010

TO: Baharak Moshiree, M.D.
Box 100214

PROJ 406-2010 EXPEDITED: RETROSPECTIVE ANALYSIS OF TREATMENT OUTCOMES IN PATIENTS WITH BACTERIAL OVERGROWTH SYNDROME DIAGNOSED BY D-XYLOSE BREATH TESTING

FROM: Keith R. Peter, M.D.
Institutional Review Board Member
Vice Chair, IRB-01

SUBJECT: Waiver of HIPAA Authorization

On August 26, 2010 the IRB reviewed your Waiver of HIPAA Authorization form submitted for Identifying and/or Recruiting Subjects and Enrolling Subjects for compliance with the HIPAA regulations. Your submission has been APPROVED through the expedited review process. A copy of the Waiver of HIPAA Authorization has been stamped with the date of IRB approval and is enclosed.

This Waiver of HIPAA Authorization expires upon completion of the study.

Please track any disclosures of protected health information. The tracking system and form are on the HIPAA/PRIVACY RULE websites at http://privacy.health.ufl.edu/faq/just_the_facts.shtml and http://privacy.health.ufl.edu/policies/hipaamanual/forms.shtml

You are reminded that all records pertaining to HIPAA Waiver of Authorizations must be kept for six (6) years after completion of the study, or longer if indicated in your IRB submission.

Thank you for keeping the IRB informed about your research project, thereby allowing us to keep accurate files. If the IRB staff can be of any further assistance, please feel free to telephone 273-9600.

cc: IRB file