Partners Human Research Committee
Partners Human Research Office
116 Huntington Avenue, Suite 1002
Boston, MA 02116
Tel: (617) 424-4100
Fax: (617) 424-4199

Application: Notification of IRB Approval/Activation

Protocol #: 2011-P-001563/1; BWH

Date: 08/04/2011

To: Robert Burakoff, MD, MPH
Medicine
PB-A-123

From: LaNeia G Thomas
PHS Research Management
HN-116 10-1024L

Title of Protocol:	Esophageal Impedance in the Evaluation of Patients with Severe Pulmonary Disease
Version Date:	07/20/2011
Sponsor/Funding Support:	None
IRB Review Type:	Expedited
Minimal Risk:	45 CFR46.110 and 21 CFR56.110
Expedited 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).
IRB Approval Date:	08/02/2011
Approval Effective Date:	08/04/2011
IRB Expiration Date:	08/02/2013

This Project has been reviewed and approved by the BWH IRB. During the review of this Project, the IRB specifically considered (i) the risks and anticipated benefits, if any, to subjects; (ii) the selection of subjects; (iii) the procedures for securing and documenting informed consent; (iv) the safety of subjects; and (v) the privacy of subjects and confidentiality of the data.

NOTES: The IRB has reviewed and approved this study for research limited to the use of health/medical records.

As Principal Investigator you are responsible for the following:

1. Submission in writing of any and all changes to this project (e.g., protocol, recruitment materials, consent form, study completion, etc.) to the IRB for review and approval prior to initiation of the change(s), except where necessary to eliminate apparent immediate hazards to the subject(s). Changes made to eliminate apparent immediate hazards to subjects must be reported to the IRB.
2. Submission in writing of any and all adverse event(s) that occur during the course of this project in accordance with the IRB's policy on adverse event reporting.
3. Submission in writing of any and all unanticipated problems involving risks to subjects or others.
4. Use of only IRB approved copies of the consent form(s), questionnaire(s), letter(s), advertisement(s), etc. in your research. Do not use expired consent forms.

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5. Informing all physicians listed on the project of changes, adverse events, and unanticipated problems.

The IRB can and will terminate projects that are not in compliance with these requirements. Direct questions, correspondence and forms (e.g., continuing reviews, amendments, adverse events, safety reports) to LaNeia G Thomas, 617-424-4120.

cc: Wai-Kit Lo, Medical Services