Mass General Brigham IRB
Mass General Brigham
399 Revolution Drive, Suite 710
Somerville, MA 02145
Tel: 857-282-1900
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Notification of IRB Review

Protocol #: 2011P001563

Date:	May 27, 2021
To:	Lo, Wai-Kit, MD, MPH BWH Mass General Brigham > BWH > Medicine > Gastroenterology
From:	Mass General Brigham IRB 399 Revolution Drive, Suite 710 Somerville, MA 02145
Title of Protocol:	Esophageal Impedance in the Evaluation of Patients with Severe Pulmonary Disease
Version/Number:	NA
Version Date:	07/20/2011
Expedited Check in #:	1
IRB Review Type:	Administrative
IRB Review Date	05/27/2021
IRB Review Action:	Noted
Expiration Date:	**05/27/2023**

The MGB IRB has administratively reviewed the Expedited Check-In.

As Principal Investigator, you are responsible for ensuring that this project is conducted in compliance with all applicable federal, state and local laws and regulations, institutional policies, and requirements of the IRB, which include, but are not limited to, the following:

1. Submission of any and all proposed changes to this project (e.g., protocol, recruitment materials, consent form, status of the study, 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 as an unanticipated problem.
2. Submission of Expedited Check-In for re-approval of the project prior to expiration date.
3. Submission of any and all unanticipated problems, including adverse event(s) in accordance with the IRB's policy on reporting unanticipated problems including adverse events.

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4. Obtaining informed consent from subjects or their legally authorized representative prior to initiation of research procedures when and as required by the IRB and, when applicable, documenting informed consent current IRB approved consent form(s) with the IRB-approval stamp in the document footer.
5. Informing all investigators and study staff listed on the project of changes and unanticipated problems, including adverse events, involving risks to subjects or others.
6. When investigator financial disclosure forms are required, submitting updated financial disclosure forms for yourself and for informing all site responsible investigators, co-investigators and any other members of the study staff identified by you as being responsible for the design, conduct, or reporting of this research study of their obligation to submit updated Investigator Financial Disclosure Forms for this protocol to the IRB if (a) they have acquired new financial interests related to the study and/or (b) any of their previously reported financial interests related to the study have changed.

Questions related to this project may be directed to **Monica Granadeno | Tel: 857-282-1912 | Email: MGRANADENO@PARTNERS.ORG**

cc:

Wai-Kit Lo, MD, MPH, Principal Investigator, Gastroenterology, Medicine

Walter Chan, MD, MPH, Co-Investigator, Gastroenterology, Medicine