



Mass General Brigham IRB
Mass General Brigham
399 Revolution Drive, Suite 710
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Notification of IRB Review

Protocol #: 2020P003783

Date: November 30, 2020

To: Chan, Walter, 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 Diseases and Motility Registry
Version/Number:
Version Date:

Sponsor/Funding/Support:	Proposal Title:	GI Motility Fund
	Principal Investigator:	Chan, Walter
	Immediate Sponsor:	SUNDRY
	Fund #:	124119

IRB Review Type: Expedited
IRB Review Action: Exempt
IRB Approval Date: 11/30/2020
Approval/Activation Date: 11/30/2020
Next Review: Exempt Check In
IRB Expiration Date: 11/30/2023

The IRB has determined that this project meets the criteria for exemption 45 CFR 46.101(b)(#)

EXEMPTION (4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least ONE of the following criteria is met:

(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined

Note: IRB approval of research does NOT constitute final approval to conduct the research. Human subjects research must be conducted in accordance with [MGB's Expansion Plan of Clinical Research](#)



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Approved for the Use of Medical Records

As Principal Investigator, you are responsible for the following:

1. Ensuring that this project is conducted in compliance with this determination.
2. Ensuring that all study staff have completed the required human research education requirements through the Collaborative Institutional Training Initiative (CITI).
3. Submission of significant proposed changes to this project to ensure that the project continues to meet the criteria for exemption.
4. Submission of Exempt Check-In every 3 years as required by institutional policy.

Questions related to this project may be directed to **Thelma Bennett** | Tel: **857-282-1915** | Email: **TBENNETT1@PARTNERS.ORG**

cc: **Walter Chan, MD, MPH, Principal Investigator, Gastroenterology, Medicine**