

## Partners Human Research

Partners HealthCare 399 Revolution Drive, Suite 710 Somerville, MA 02145

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## **Notification of IRB Review**

Protocol #: 2020P002447

Date: July 31, 2020

To: Kaafarani, Haytham, MD, MPH

MGH

Partners > MGH > Surgery > Trauma Unit

From: Partners Human Research

399 Revolution Drive, Suite 710

Somerville, MA 02145

Title of Protocol: GlobalSurg-CovidSurg Week: Determining the optimal timing for

surgery following SARS-CoV-2 infection

Version/Number:

Version Date:

IRB Review Type: Expedited
IRB Review Action: Exempt
IRB Approval Date: 07/30/2020
Approval/Activation 07/31/2020

Date:

07/31/2020

Next Review: Exempt Check In

IRB Expiration Date: 07/30/2023

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 <u>MGB's</u> Expansion Plan of Clinical Research.

## Research-Related Use of Health Medical Records

As Principal Investigator, you are responsible for the following:

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- 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 Fausta Figueroa | Tel: 857-282-1909 | Email: FFIGUEROA@PARTNERS.ORG

cc:

Kerry Breen, Research Coordinator/Manager, Trauma Unit, Surgery

Haytham Kaafarani, MD, MPH, Principal Investigator, Trauma Unit, Surgery