

Dear collaborator,

If you are seeking local approval for COVIDSurg at your hospital in the US, you can use this document as a proof of previous approval in MGH. Please feel free to contact MGH team for support regarding your local approval process if needed.

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COVIDSurg collaborative group



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Notification of IRB Review

Protocol #: 2020P000794

Date: March 15, 2020
To: Kaafarani, Haytham, MD, MPH
MGH
Partners > MGH > Surgery > Trauma Unit

From: Partners Human Research
399 Revolution Drive, Suite 710
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Title of Protocol: COVID-19: Surgical Implications Study
Version/Number:
Version Date:
IRB Review Type: Expedited
IRB Review Action: Exempt
IRB Approval Date: 03/15/2020
Approval/Activation Date: 03/15/2020
IRB Expiration Date: 03/15/2023

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

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



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cc:

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