

Title: COVID-19: Surgical Implications Study

Sponsor Name: None

PI Name: Kaafarani, Haytham M

Protocol #: 2020P000794

Type: Initial Review (IR)

Date Received:

Study Staff Added

Name	Role	Degree	Organization	Citi Certified
Alser, Osaïd	Co-Investigator		MGH > Surgery > Trauma Unit	10/05/19
Bankhead-Kendall, Brittany	Co-Investigator		Partners	05/27/19
Breen, Kerry	Research Coordinator/Manager		MGH > Surgery > Trauma Unit	07/24/18
Kaafarani, Haytham	Principal Investigator MD, MPH		MGH > Surgery > Trauma Unit	02/13/18
Mashbari, Hassan	Co-Investigator		MGH > Surgery	07/26/19

Signatures

Initial Review

Title:

COVID-19: Surgical Implications Study

The Partners Human Research Committee has created several forms for review of human subjects research. This questionnaire includes a series of questions to identify the form (s) you need to complete for your research project.

1. Intervention/Interaction
2. Health / Medical Information
3. Excess Human Material and Related Health / Medical Information
4. Secondary Use of Research Samples and/or Data (samples/data from another research study)
5. Research Data Repository (collecting and storing health/medical information for future research)
6. Tissue or Sample Repository
7. Coordinating Center / Core Labs
8. Emergency / Single Patient Use of Investigational Products

1. Intervention and/or Interaction

Does your research involve an **intervention** and/or **interaction** with subjects for the collection of specimens or biological material or data (including health or clinical data, surveys, focus groups or observation or behavior)?

NOTE: Do not answer YES if this protocol is to establish a Research Data Repository or Sample/Tissue Repository. There are separate forms for Data and Tissue Repositories.

- Yes No

2. Health / Medical Information

Is your research limited to the use of health / medical information?

- Yes No

Sponsor Funding: None

Select the source of funding that will be used to support the proposed research:

- Government / Foundation / Other Non-Profit
 Corporate
 Institutional Award
 Department Funds
 None

Is this the primary source of funding?

- Yes No Not applicable

Health / Medical Records

The Health/Medical Records specialized form is to be used for studies that are limited in scope to review of health or medical information from medical records or other sources, including use of datasets that were not collected for research purposes, e.g., CMS or other third party insurer datasets.

Do not use the health/medical records form for research that involves contacting subjects, e.g., a follow-up phone call for patient status.

More detailed descriptions of specific questions/categories below can be found in the Research Navigator "Specialized Forms" section. See [Research Navigator](#).

1. Purpose

Briefly describe the purpose of the research:

To describe the management and outcomes of confirmed COVID-19 patients who have a surgical issue (operative and non-operative management).

We will be collaborating on a GlobalSurg project [<https://globalsurg.org/>] on COVID19, which will be open to ALL centers worldwide who have COVID+ patients requiring an operation. This project is extremely important to get the data out there on how each hospital is managing these novel cases, surgeons around the world stand to benefit from this.

Data resulting from this research will be used for the following.

Check all that apply.

- Publication
 Oral Presentation
 Other

Will data resulting from this research ever be submitted to the FDA?

- Yes No
-

2. Study Population

Check all that apply.

- Patients

Describe medical condition/diagnosis to be studied:

COVID+ patients who have a surgical problem

- Healthcare Providers

NOTE: Healthcare providers may be considered subjects if you are studying provider behavior or performance, or analyzing patient outcomes based on provider. In such cases, you must consider the privacy risks and privacy rights of providers and address these in the waiver of consent / authorization section.

- Other

Age

Check all that apply.

- Children (less than 18 years of age)
 Adults (18 years and older)
 Unknown

Gender

Check all that apply.

- Male
 Female
 Unknown
-

3. Source of Health / Medical Information

Indicate:

- Partners Sites

Partners Sites

Check all that apply.

- BWH
 BWFH
 MEE
 MGH
 McLean
 NWH
 NSMC

- PCHI
- SERI
- SRH
- Other Partners Site

- Non-Partners Sites

Non-Partners Sites

Check all that apply.

- DFCI
- Partners in Health
- Shriners Hospitals for Children
- Other Non-Partners Sites

Enter the other non-Partners sources of health / medical information. Enter all sites.

open study for all hospitals with COVID-19 patients to join. Hospitals will be responsible to provide their own IRB before uploading data.

Note: If the institution/entity providing the data requires you to sign a data use or other agreement, the agreement must be reviewed by Research Management. Please make sure to initiate the DUA following the directions on this page in the Navigator:

[https://partnershealthcare.sharepoint.com/sites/phrml/initiate/imcdc/Pages/Data-Use-Agreements-\(DUAs\).aspx](https://partnershealthcare.sharepoint.com/sites/phrml/initiate/imcdc/Pages/Data-Use-Agreements-(DUAs).aspx)

PHS HIPAA policies apply to protected health information (PHI) received from non-PHS entities that is stored at Partners for research purposes.

- NeuroNext or Stride Network
-

4. Data To Be Collected / Obtained

Check all that apply.

Administrative:

- Billing data
- Coded encounter data (diagnoses, procedures, dates)
- Demographic data (age, gender, vital status)

Health / Medical:

- Allergies
- Discharge Summary
- Doctors Orders
- History / Physical
- Immunizations
- Medication List
- Office / Clinic Notes
- Operative / Procedure Notes (e.g. endoscopy)
- Pharmacy
- Problem List

Health/Medical Reports/Results:

- Blood Bank
- Laboratory
- Pathology reports (reports only). Complete the Excess Human Material form for use of tissue/slides instead of this form.
- Radiology
- Clinical Genetic Data

Sensitive/Personal Information:

- HIV Status
- Mental Health
- Reproductive History (e.g., abortions)
- Sexual Behavior / Sexually Transmitted Diseases
- Substance Abuse (e.g., drug or alcohol abuse)
- Other potentially stigmatizing behaviors (such as illegal activities) or information

Will any sensitive/personal information listed above be collected?

- Yes No

Explain why the sensitive/personal data checked above is needed to achieve the goals of the study:

HIV status is important, as these patients will be immunosuppressed.

Other Health/Medical Information:

- Other

Note: The HIPAA Privacy Rule requires Partners and its affiliated hospitals and providers to make all reasonable efforts to use or release only the "minimum necessary" identifiable health care information to achieve the intended purpose. The minimum necessary standard applies to research limited to health/medical information collected with a waiver of authorization.

Have you created a data collection form or other tool for data collection?

- Yes No

NOTE: Attach a data collection form in the Attachments section of this application using the Attachment type "Data Collection Form."

5. Data To Be Requested From The Following Time Period (Encounter Dates)

Indicate the time period of interest for your study, e.g. 01/01/2000 - 01/01/2024. Prospective reviews are allowed for most studies limited to health/medical information, usually limited to 5-7 years in the future. The end date can be extended by amendment.

From (mm/yyyy):

12/2019

To (mm/yyyy):

For future data, use anticipated project end date.

12/2022

6. Protected (Identifiable) Health Information

PHI refers to health/medical information that is accompanied by any of the listed 18 HIPAA identifiers or by a code where the key to the code that links to the identifiers is accessible to investigators. Note that if any part of an identifier, e.g. patient initials, is included in a code number, the code number itself is then considered an identifier under HIPAA. DE-IDENTIFIED DATA (without any identifiers or codes that link back to individuals) are not considered PHI, and are not subject to HIPAA regulations.

- Names, including initials
- Social security numbers
- Medical record numbers
- Addresses by street location
- Addresses by city, county, precinct, zip code
- All elements of dates (except year) related directly to individuals including, but not limited to, dates of birth, death, admission, discharge, or any service
- All ages over 89 and all elements of dates (including year) indicative of such age
- Telephone numbers
- FAX numbers
- Electronic email addresses
- Web URLs
- Internet protocol (IP) addresses
- Account numbers
- Certificate/license numbers
- Vehicle identification numbers and serial numbers including license plates
- Medical device identifiers and serial numbers
- Biometric identifiers, including finger and voice prints
- Full face photographs and any other comparable images
- Any other unique identifying numbers, characteristics or codes including, but not limited to, globally unique identifiers (GUID) and universally unique identifiers (UUID) or equivalent

Will you be recording any of the identifiers listed above with the data or using a code to link the data to any of the identifiers? If yes, under the HIPAA Privacy Rule provisions the data cannot be considered de-identified and authorization from the subject or a waiver of authorization must be granted by the IRB. When answering this question, consider the need for recording dates or retaining direct identifiers, such as name and/or medical record number, to link data from multiple sources, to avoid duplicating records, or for QA purposes.

NOTE: If you are recording medical record number or other identifiers, even if temporarily for QA purposes or to avoid duplicating records, then answer "Yes".

- Yes No

Check the identifiers that will be recorded with or linked by code to the data.

- Name, including initials
- Social Security Number
- Medical record number
- Address by street location
- Address by city, county, precinct, zip code
- All elements of dates (except year) related directly to individuals, including, but not limited to, dates of birth, death, admission, discharge, or any service
- All ages over 89 and all elements of dates (including year) indicative of such age [Note: Consider substituting range, e.g., 89+, for actual age.]
- Telephone number
- Fax number
- Electronic email address

- Web URLs
- Internet protocol (IP) address
- Health plan beneficiary number
- Account number
- Certificate / license number
- Vehicle identification number and serial number, including license plate number
- Medical device identifiers and serial numbers
- Biometric identifiers, including finger and voice prints
- Full face photographic images and any other comparable images
- Any other unique identifying number, characteristic, or code (e.g., Pathology Accession #, Code #), including, but not limited to, globally unique identifier (GUID) and universally unique identifier (UUID) or equivalent

Will identifiers be removed from the data and destroyed after all of the data has been collected, the study has been completed, or all regulatory and sponsor obligations have been met? **Note:** Federal regulations mandate that, under a Waiver of Consent/Authorization, identifiers be destroyed as early as possible. De-identified datasets may be retained indefinitely.

For guidance, see the PHRC [Recordkeeping and Record Retention Requirements](#).

- Yes No

6A. Waiver of Informed Consent / Authorization

Explain why it would be impossible to conduct the research without access to and use of identifiable health / medical information. For example, the data cannot be obtained from electronic health / medical records or databases without access to identifiers or identifiers are needed for prospective data collection.

Eligible patients cannot be identified and data cannot be obtained from electronic medical records without access to identifiers. Identifiable health and medical information will be collected temporarily to ensure the integrity of the study and to avoid duplicates. Upon completion of the data collection, identifiers will be removed.

Explain why the risk to subjects, specifically the risk to privacy, is no more than minimal risk. When addressing this question, describe the measures you have put in place to protect the privacy of subjects and confidentiality of the data; for example: (1) identifiable health information will be stored on a computer on the Partners network with password protections enabled and anti-virus software or an encrypted laptop and access to identifiable data will be limited to study staff by use of password protected files or restricted shared file areas; (2) name and/or medical record number will be replaced with a study ID or code and the key to the code stored in a password protected file; (3) direct identifiers, such as name and medical record number, will be removed once all of the data is collected and analysis performed on de-identified data.

(1) identifiable health information will be stored on a computer on the Partners network with password protections enabled and anti-virus software and access to identifiable data will be limited to study staff by use of password protected files or restricted shared file areas

(2) medical record number will be replaced with a study ID or code and the key to the code stored in a password protected file

(3) direct identifiers, such as medical record number, will be removed once all of the data is collected and analysis performed on de-identified data.

Explain why the research could not practicably be carried out without the waiver of consent /

authorization. When addressing this question, consider the difficulty in locating individuals who may have moved, the number of subjects and cost and use of limited resources of locating individuals and sending letters and consent forms, and the impact on the scientific validity of the study if you could use only data of individuals from whom you were able to obtain informed consent.

It would not be feasible or practical to contact these patients or their families, many of these patients will be ventilated and unable to consent. Due to the nature of this observational chart review study, it will also have impact on the scientific validity of the study if we could only use data of individuals from whom we were able to obtain informed consent. In addition, we plan to involve multiple sites as able, it will not be feasible to consent all patients with COVID19.

NOTE: “Only in a few research studies would it be impossible to obtain informed consent; however in many studies the financial cost would be prohibitive and a potentially poor use of limited research resources.” *Ensuring Voluntary Informed Consent and Protecting Privacy and Confidentiality, National Bioethics Advisory Commission.*

Explain why the rights and welfare of the subjects will not be adversely affected by the waiver of consent / authorization. When addressing this question, consider the individual's right to privacy and the measures you have put in place to protect the privacy of subjects and confidentiality of any data and any health/medical implications for subjects; for example: (1) identifiable data will be stored securely with access limited to study staff; (2) information resulting from this study will not have any important health/medical implications for subjects.

The rights and the welfare of the subjects will not be adversely affected by the waiver of consent since the study does not involve interaction with the patients, their care or their rights and welfare. Identifiable data will be stored securely with access limited to study staff.

NOTE: If the research uncovers information about the subjects that has important health / medical implications for them, contact the PHRC to discuss the appropriate process for providing subjects with additional pertinent information.

Are healthcare providers also subjects of the research?

- Yes No

7. Research Data

How will research data be recorded and stored?

- Electronically

Electronic Research Data

What type of device will the research data be accessed and stored on?

Check all that apply.

- Cloud (e.g., OneDrive, Dropbox, Amazon S3, Azure, etc.)
 Desktop computer
 Portable device i.e., Laptop, Netbook, Tablet, iPod computer, Cell/Smart phone
 USB Flash/Thumb, External Hard Drive
 Other device

Describe other device:

RedCap maintained by GlobalSurg - no HIPAA identifiers included

Portable devices can include cell phone/smart phones, laptops, iPad/tablet computers, iPods or any other electronic device that can communicate wirelessly. For information on portable device security, refer to the [Partners Portable Device Security Handbook](#) (PHS Internal only link)

Where is the primary storage location of the device(s)? For example, the desktop computer is located in the PI's locked office on White 1; the laptop is stored in office 123 of White 1 and is secured to a desk with a laptop lock; the hard drive is stored in a locked cabinet in office 123 on White 1 and access is limited to study staff only, etc.

We will store the data on Partners maintained RedCap. The desktop computer for the database is located in the Trauma Administrative Office located at 165 Cambridge Street, Suite 810 in the Charles River Plaza. The computer is secured with a password and has active antivirus software. The office is only accessible for employees with an MGH badge with authorization for the office, granted by the office manager.

Who will have access to the electronic research data stored at PHS? For example, PI, PHS study staff, non-PHS research collaborators who will access data onsite or remotely. There are both IRB and institutional policies regarding how non-PHS collaborators can access PHS electronic systems, whether clinical or research. Describe in detail if requesting non-PHS, research collaborator access to electronic data stored on PHS systems.

Note: For more information, see PHRC guidance regarding [Non-BWH/Non-MGH Employees as Co-Investigators/Study Staff](#) and [Collaborators](#).

Access will be limited to study staff.

NOTE:

- All computers and portable devices must have password protections enabled;
- All computers must have active anti-virus software;
- Laptops, tablet, netbook computers, and USB Flash/Thumb drives must be full disk encrypted;
- If data will be transmitted outside the Partners firewall, data must be encrypted during transit with the use of SSL/https.

Will data be uploaded to a website/server?

Yes No

Will the data be uploaded using a wireless network?

Yes No

Will the data be uploaded outside of the Partners Firewall/computer network? If sending identifiable sensitive/confidential information, please contact [Research Information Security](#).

Yes No

Will the website/server be located in a Partners facility and maintained by Partners IS?

Yes No

Describe security measures in place to protect the data on the server:

Data is entered via a password protected REDCap, maintained by GlobalSurg.

Paper

8. Sending Health / Medical Information to Collaborators Outside Partners

Will any health / medical information be sent to collaborators outside Partners?

- Yes No

List each collaborator (investigator and institution)

Dmitri Nepogodiev GlobalSurg

Check HIPAA identifiers to be included with the data sent to collaborators.

- Names, including initials
- Social security numbers
- Medical record numbers
- Addresses by street location
- Addresses by city, county, precinct, zip code
- All elements of dates (except year) related directly to individuals including, but not limited to dates of birth, death, admission, discharge, or any service
- All ages over 89 and all elements of dates (including year) indicative of such age
- Telephone numbers
- Fax numbers
- Electronic email addresses
- Web URLs
- Internet protocol (IP) addresses
- Health plan beneficiary numbers
- Account numbers
- Certificate/license numbers
- Vehicle identification numbers and serial numbers, including license plate numbers
- Medical device identifiers and serial numbers
- Biometric identifiers, including finger and voice prints
- Full face photographic images and any other comparable images
- Any other unique identifying number, characteristic, or code, including, but not limited to, globally unique identifier (GUID) and universally unique identifier (UUID), or equivalent
- Other

Explain how health information will be sent securely. Provide details of data transfer that weren't covered in Section 7 (electronic data transfer) or how hard copies (paper, CDs) will be sent using a secure delivery method. **For information on secure file transfer, refer to the [Partners Research Computing website](#).**

No HIPAA identifiers will be shared with GlobalSurg. Data will be entered in the GlobalSurg RedCap.

List each collaborator (investigator and institution)

Dr.Aneel Bhangu GlobalSurg

Check HIPAA identifiers to be included with the data sent to collaborators.

- Names, including initials
- Social security numbers
- Medical record numbers

- Addresses by street location
- Addresses by city, county, precinct, zip code
- All elements of dates (except year) related directly to individuals including, but not limited to dates of birth, death, admission, discharge, or any service
- All ages over 89 and all elements of dates (including year) indicative of such age
- Telephone numbers
- Fax numbers
- Electronic email addresses
- Web URLs
- Internet protocol (IP) addresses
- Health plan beneficiary numbers
- Account numbers
- Certificate/license numbers
- Vehicle identification numbers and serial numbers, including license plate numbers
- Medical device identifiers and serial numbers
- Biometric identifiers, including finger and voice prints
- Full face photographic images and any other comparable images
- Any other unique identifying number, characteristic, or code, including, but not limited to, globally unique identifier (GUID) and universally unique identifier (UUID), or equivalent
- Other

Explain how health information will be sent securely. Provide details of data transfer that weren't covered in Section 7 (electronic data transfer) or how hard copies (paper, CDs) will be sent using a secure delivery method. **For information on secure file transfer, refer to the [Partners Research Computing website](#).**

No HIPAA identifiers will be shared with GlobalSurg. Data will be entered in the GlobalSurg RedCap.

NOTE: Please be aware that as a data set is being sent to external collaborators, a Data Use Agreement (DUA) must be executed between Partners and the entity receiving the data. Please make sure to initiate the DUA following the directions on this page in the Research Navigator: [https://partnershealthcare.sharepoint.com/sites/phrmlInitiate/imcdc/Pages/Data-Use-Agreements-\(DUAs\).aspx](https://partnershealthcare.sharepoint.com/sites/phrmlInitiate/imcdc/Pages/Data-Use-Agreements-(DUAs).aspx)

HIPAA and Limited Data Sets/Tracking Disclosures of Identifiable Health Information (PHI)

1. Tracking is NOT required for disclosure of LIMITED DATA SETS under a DATA USE AGREEMENT. For more information about LIMITED DATA SETS and DATA USE AGREEMENTS, refer to Partners policy "[Limited Data Sets Policy/Data Use Agreements](#)" (PHS Intranet link).

2. Disclosures of PHI to persons or entities outside Partners without the written authorization of the subject must be tracked in accordance with Partners policy "[Accounting of Disclosures](#)" (PHS Intranet link). You may use the [HIPAA Tracking Tool](#). NOTE: A code derived from the subject's name is considered identifiable, for example, a code that contains subject initials.

NOTE: Partners (PHS) is the HIPAA covered entity. PHS includes BWH, BWFH, MEE, MGH, NWH, NSMC, McLean, PCHI and SRH, among others. PHS does not include other Harvard affiliated hospitals, such as BIDMC, DFCI, HSPH, or CHB. Therefore, when PHS investigators send identifiable information to investigators at BIDMC, DFCI, HSPH, CHB or any other institution outside Partners, it is considered a disclosure of protected health information.

Attachments**Name**

Data dictionary_COVID19 (Data Collection Form)

Mode

Electronic

We will not send any HIPAA identifiers to GlobalSurg, any HIPAA identifiers including dates related to patient will be collected internally for MGH research staff.

Hospital Data

- Country
- Hospital size (number of beds)
- Hospital type (public, private, teaching, non-teaching)
- Transfer status
- Transfer origin

Demographics

- Age [in categories]
- Sex
- Race
- Timing of confirmed Covid diagnosis: on admission, inpatient preoperative, inpatient, post operative
 - Specify date/time
- Recent Travel [specify]
- Comorbidities:
 - Ascites,
 - disseminated cancer
 - dyspnea at baseline
 - functional dependence
 - history of COPD
 - hypertension
 - steroid use
 - diabetes
 - Coronary heart disease
 - COPD
 - CKD
 - ventilator requirement within 48 hours preoperatively
 - weight loss >10% in the preceding 6 months
 - Smoker
- Symptoms on admission
 - fever
 - cough
 - haemoptysis
 - sputum
 - myalgia
 - fatigue
 - diarrhea
 - nausea/vomiting
 - abdominal pain

- Immunosuppressant drugs
- preoperative pneumonia
- SOFA score
- Labs:
 - white blood count
 - lymphocyte count
 - hemoglobin
 - albumin
 - alkaline phosphatase
 - BUN
 - Creatinine
 - INR
 - PLT
 - SGOT
 - Sodium
- Imaging: consolidation, ground glass opacity, bilateral pulmonary infiltration
- Chest x-ray results
- CT findings

Surgical details

- Ventilated pre-operatively?
- Diagnosis
- Type of procedure performed
- Booking status
- Organ associated (appendix, esophagus, colon, hepatobiliary, pancreas, small bowel, stomach, other)
- Pre-op & Post-op diagnosis
- Reason for conservative management (if applicable)
- Reoperation

Treatment

- ICU Admission
- Indication for ICU Admission
- Antibiotics
- Antivirals
- Corticosteroids
- IV immunoglobins
- mechanical ventilation
 - specify settings
- P/F ratio

- ECMO
- Dialysis

30-day outcomes

- Respiratory failure
- Cardiac injury
- ARDS
- ICU LOS
- Mortality
- Hospital length of stay

30-day complications

- Superficial surgical site infection
- Deep incisional surgical site infection
- Organ/ space surgical site infection
- Wound dehiscence
- Pneumonia
- Unplanned intubation
- Pulmonary embolism
- Ventilator requirement > 48 hours
- Renal insufficiency
- Acute renal failure
- Urinary tract infection
- Stroke/ cerebrovascular accident
- Coma > 24 hours
- Cardiac arrest requiring CPR
- Myocardial infarction
- Peripheral nerve injury
- Bleeding requiring transfusion
- Graft/ prosthesis/ flap failure
- Deep vein thrombosis
- Sepsis
- Septic shock
- Anastomosis leakage
- Other

** specify date of each complication

End Organ Failure at Discharge

- Alive at discharge
- Tracheostomy

- Oxygen therapy
- Ventilator dependence
- CHF
- Cardiac arrhythmia
- Feeding tube
- Enterostomy
- On Dialysis
- Other

Discharge Status

- Destination
 - Home
 - Home with nursing services
 - Rehabilitation
 - Long term acute care facility (LTAC)
 - Nursing home
 - Refer to another hospital
 - Hospice
 - Death
- Return to ED within 30 days after discharge
- How many days from discharge to ED presentation?
- Readmission within 30 days