

Title: GlobalSurg-CovidSurg Week: Determining the optimal timing for surgery following SARS-CoV-2 infection

Sponsor Name: None

PI Name: Kaafarani, Haytham M

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Study Staff

Name	Role	Degree	Organization	Citi Certified
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Breen, Kerry	Research Coordinator/Manager		MGH > Surgery > Trauma Unit	07/24/18
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Kaafarani, Haytham	Principal Investigator	MD, MPH	MGH > Surgery > Trauma Unit	02/13/18
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Signatures

PI Name: Kaafarani, Haytham M, MD, MPH

Authenticated: July 29, 2020

Initial Review

Title:

GlobalSurg-CovidSurg Week: Determining the optimal timing for surgery following SARS-CoV-2 infection

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

COVID-19/SARS-CoV-2

Is this research related in any way to the novel coronavirus, COVID-19, SARS-CoV-2 or, any impact or consequences related to the outbreak and pandemic?

- 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:

The primary purpose of this study is to determine the optimal timing for surgery following SARS-CoV-2 infection. We will compare mortality and many other outcomes between patients preoperatively infected with SARS-CoV-2 and those presumed to be unexposed at the time of surgery. This will be an

international multi-center collaboration led by GlobalSurg based at the University of Birmingham in the United Kingdom.

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:

Any operation (elective or emergency) done in an operating room by a surgeon, excluding minor procedures

- 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
 - 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

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):

10/1/2020

To (mm/yyyy):

For future data, use anticipated project end date.

12/1/2020

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.

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

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.

The primary storage of the data will be in the REDCap maintained by GlobalSurg (University of Birmingham). The REDCap will be accessed on the encrypted and password-protected laptops of the study staff using password-protected accounts while connected to VPN or desktop partners computers located at 165 Cambridge Street, Suite 810 - Trauma Administrative Office at MGH. No data will be stored on the study staff's laptops. An excel for tracking the patients with identifiers will be stored on TRAUMARS2, a secured shared drive hosted by Partners which can only be accessed via VPN by authorized personnel only who are given access by one keygiver. The file will be encrypted and password protected, and only study staff listed on this protocol will know the password.

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 listed on Insight.

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 (University of Birmingham). The security details of this REDCap are under "Other" in attachments.

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)

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](#).**

A limited data set will be uploaded to the REDCap maintained by GlobalSurg (University of Birmingham). The security details of this REDCap are under "Other" in attachments named "REDCap letter by GlobalSurg".

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/phrmlnitiat/imcdc/Pages/Data-Use-Agreements-\(DUAs\).aspx](https://partnershealthcare.sharepoint.com/sites/phrmlnitiat/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	Mode
COVIDSurg-Week CRF v1 (Data Collection Form)	Electronic
REDCap Letter GlobalSurg (Other)	Electronic

Case Report Form

Baseline	
Age	<52 weeks, 1-4 years, 5-9 years, 10-17 years, 18-29 years, 30-39 years, 40-49 years, 50-59 years, 60-69 years, 70-79 years, 80-89 years, ≥90 years
Sex	>Female >Male >Ambiguous
ASA	>Grade I >Grade II >Grade III >Grade IV >Grade V
Revised Cardiac Risk Index	>History of ischemic heart disease >History of congestive heart failure >History of cerebrovascular disease >Pre-operative treatment with insulin >Pre-operative creatinine >2 mg/dL / 176.8 μmol/L
Respiratory comorbidities	>Current smoker or smoked in last 6 weeks >Ex-smoker (stopped ≥6 weeks ago) >Asthma >COPD >Other respiratory comorbidity
SARS-CoV-2 status	
Hot/cold unit	<p>Operating theatre</p> <p>>Cold: dedicated theatre for non-SARS-CoV-2 elective surgery patients, segregated from COVID-19 patients</p> <p>>Hot: area shared by elective surgery patients and COVID-19 patients</p> <p>Intensive care unit</p> <p>>Cold: dedicated ICU for non-SARS-CoV-2 elective surgery patients, segregated from COVID-19 patients</p> <p>>Hot: area shared by elective surgery patients and COVID-19 patients</p> <p>>Not applicable</p> <p>Postoperative ward</p> <p>>Cold: dedicated ward for non-SARS-CoV-2 elective surgery patients, segregated from COVID-19 patients</p> <p>>Hot: area shared by elective surgery patients and COVID-19 patients</p>

Was the patient asked to self-isolate	<ul style="list-style-type: none"> >No >Before hospital admission only >After discharge from hospital only >Both before hospital admission and after discharge from hospital <p><i>If yes, duration of preoperative and postoperative isolation in days</i></p>
Were any of the following used to screen the patient for SARS-CoV-2 in the 7 days before surgery <i>(tick all that apply)</i>	<ul style="list-style-type: none"> >CT thorax scan >Chest x-ray >Swab >> how many negative swabs / positive swabs & timing of the last swab >Antibody test >Clinical screening (history, examination)
SARS-CoV-2 diagnosis	<ul style="list-style-type: none"> >None >Preoperative (at any time) >Postoperative (within 30 days after surgery)
<i>If SARS-CoV-2 +ve</i> How was the diagnosis made <i>(tick all that apply)</i>	<ul style="list-style-type: none"> >Positive swab >CT thorax >IgG antibody positive >IgM antibody positive >Clinical diagnosis
<i>If preoperative infection</i> How long before surgery was the diagnosis	<ul style="list-style-type: none"> >Day of surgery >1-7 days before surgery >8-14 days before surgery >15-28 days before surgery >5-6 weeks before surgery >7-8 weeks before surgery >3-4 months before surgery >5-6 months before surgery >6+ months before surgery
<i>If preoperative infection</i> Was the SARS-CoV-2 infection symptomatic*	<ul style="list-style-type: none"> >Yes- but all symptoms had resolved before the day of surgery >Yes- and some symptoms were ongoing on the day of surgery >No- the patient did not have symptoms <p>*this includes both respiratory and non-respiratory symptoms</p>
<i>If symptomatic infection</i> What symptoms did the patient have <i>(tick all that apply)</i>	<ul style="list-style-type: none"> >Respiratory symptoms (e.g. cough, shortness of breath) >Non-respiratory symptoms (e.g. fever, diarrhoea, fatigue)
<i>If symptomatic infection</i> Did the patient require hospital treatment for SARS-CoV-2	<ul style="list-style-type: none"> >No >Yes- did not require non-invasive or mechanical ventilation >Yes- required non-invasive or mechanical ventilation

<i>If postoperative infection</i> Was dexamethasone administered in the 10 days following infection	>No >Yes >> enter dose, duration
Intraoperative	
Urgency	>Elective >Emergency
Day-case surgery	>Performed as day-case (no overnight admission) >Performed with overnight admission
Procedure	Dropdown menu of procedures
Anaesthesia <i>Tick all that apply</i>	>Local >Nerve block >Spinal >Epidural >General
Indication	>Benign >Malignancy >> curative or palliative procedure >Trauma >Obstetric >Complication of COVID-19 >> free text field to describe
<i>If abdominal surgery</i> Operative approach	>Planned and performed as open >Planned and performed as laparoscopic (includes laparoscopic assisted cases) >Planned and performed as robotic >Laparoscopic converted to open >Robotic converted to open >Hybrid (e.g. laparoscopic abdomen, open chest)
How was the majority of the cost of surgery supported?	> Public insurance (funded by government) > Private insurance (insurance paid for by the patient) > Corporate insurance (funded by patient's employer) > External funds or grants awarded by charities/NGOs > Out of pocket payments (patient paid the hospital directly) > Other (free text)
Outcomes	
Mortality	>Alive at 30 days >Died in-hospital, within 30 days of surgery >Died after discharge, within 30 days of surgery

Complications	>None >Pneumonia >Acute respiratory distress syndrome >Unexpected ventilation >Pulmonary embolism >Deep vein thrombosis
Clavien-Dindo	>Grade I >Grade II >Grade IIIa/b >Grade IVa/b >Grade V



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19 March 2020

To Whom It May Concern:

RE: Outcomes of surgery in COVID-19 infection: international cohort study (CovidSurg)

I am writing to give further information about the secure online REDCap database which will be used to collect data for the CovidSurg database.

A single study database is being used for all hospitals participating in CovidSurg for two reasons. Firstly, we plan to evolve the data collection instruments over time as new hypotheses are developed based on the emerging evidence. A single database will ensure that the same data is consistently collected across all participating hospitals despite rapid changes in data collection instruments. Secondly, we plan to perform regular data analyses throughout the study in order to rapidly disseminate the emerging data. Given this rapid analysis model, if data were collected on separate databases, it would not be feasible to pool datasets for each interval analysis, meaning that any data collected on any parallel databases could not be included in analyses until data collection is completed, and the best use of the data would not be made.

REDCap databases at the University of Birmingham have been successfully used for a number of international studies, including:

- European Society of Coloproctology 2017 Left Colon and Rectal Resection Study (335 participating sites across 49 countries, reference: 2017 European Society of Coloproctology (ESCP) Collaborating Group. *The 2017 European Society of Coloproctology (ESCP) international snapshot audit of left colon, sigmoid and rectal resections - Executive Summary*. *Colorectal Dis.* 2018;20).
- Right Iliac Fossa Treatment Study (290 participating sites across 5 countries, reference: RIFT Study Group on behalf of the West Midlands Research Collaborative. *Identifying children at low-risk of appendicitis: systematic review and prospective, multicentre validation of risk prediction models in children presenting with right iliac fossa pain*. *Lancet Child Adolesc Health* 2020; 4: 271–80).

Hospitals that have already had approval to submit data to the online secure CovidSurg database include:

- University Hospitals Birmingham NHS Foundation Trust, Birmingham, UK.
- Imperial College Healthcare NHS Trust, London, UK.
- Massachusetts General Hospital, Boston, USA.
- Azienda Policlinico Umberto I, Rome, Italy.
- Hospital Universitario del Henares, Madrid, Spain.

The REDCap database used for the CovidSurg study is run by the NIHR Global Health Research Unit on Global Surgery, within the University of Birmingham Virtual Machine architecture which is physically

secured. The architecture is the responsibility of the Storage and Virtualisation Team at the University of Birmingham, Edgbaston, Birmingham, B15 2TT. "At rest" encryption is in place on the database server. Raw data will be stored and will remain at the Birmingham site; it will not be offshored to any other location. The site is physically secure. The virtual hosting service is designed to have no single point of failure with physical redundancy deployed for server, network and storage infrastructure. The virtual server software supports live migration of virtual machines between the physical servers called hosts. Live migration is automatically performed to balance the server load across available infrastructure. On physical server failure the virtual machine is automatically restarted on another host. During host maintenance or intrusive maintenance of the virtual server software, virtual machines are manually migrated to prevent any interruption to service. All physical infrastructure is monitored and automatic alerts generated to systems staff on any failure. All virtual machines are not installed on a single physical server but a range of hosts on which virtual machines automatically live migrate on. Therefore, since there is no one physical location for our machine, it can be considered physically secure. All physical infrastructure and the virtual server software are maintained by the University of Birmingham IT Services. All physical infrastructure is monitored and automatic alerts generated to systems staff on any failure.

The security of the study REDCap database system is governed by the policies of the University of Birmingham UK, in accordance with the requirements of the General Data Protection Regulations (GDPR). The study will be conducted at collaborating sites in accordance with the country-specific data protection requirements. Once data collection is complete, the electronic research files containing anonymised data will be stored on secure non-networked desktop computers for up to 25 years, in line with current regulations. Access will be restricted to the researchers themselves. Personal data will remain securely at local hospitals.

No sensitive or identifiable data will be collected on the database; the patient's clinical team will only upload anonymised data. Access to data will be restricted, each individual collaborator entering data for CovidSurg will have their own username and password. Each patient will be allocated a unique study number at entry. The central research team will not have any access to patient identifiable data. All communication will use this as the identifier. All data will be analysed and reported in summary format. No individual will be identifiable. The anonymised data generated by the study will be held centrally at the University of Birmingham UK, and be analysed by Omar Omar (Senior Statistician, University of Birmingham).

Yours faithfully,



Dmitri Nepogodiev, MBChB
On behalf of the CovidSurg Collaborative