



1. Project Identification

1.1 * Short Title:

EGS in COVID era

1.2 * Full Title of Project:

Hospital course and outcomes of emergency general surgery patients admitted during the COVID era

1.3 * Principal Investigator (PI):

[Marc De Moya](#)

1.3.1 * Does the Principal Investigator, their immediate family members (spouse and dependent children) or their significant other have a "Significant Financial Interest" with the sponsors of this research or that might affect the result of this research?

Yes No

1.3.2 * Does the Principal Investigator need to access Epic for this project?

Yes No

1.3.3 * Will the Principal Investigator be involved with any of the following:

- Screening subjects for entry into a magnetic environment for MRI
- Entry into a magnetic environment for MRI
- None of the above

1.4 * Will there be other project team members in addition to the Principal Investigator?

Yes No

2. Project Team

2. Project Team Members Other Than PI:

1 For projects relying on another IRB for review: add only MCW/Froedtert Hospital/Versiti, Inc. project team members.

	Last Name	First Name	Primary Organization	Department	Position	Is Primary Contact	Can I Email	Receives Project	Role	Consenting Subjects	MRI Involvement?	Human Subject?	Material?	FI
View	Brandolino	Amy	Medical College of Wisconsin	Surgery	Clinical Research Coordinator III	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Key Personnel	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
View	Karamil	Basim	Medical College of Wisconsin	Surgery	Research Fellow	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Key Personnel	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
View	Morris	Rachel	Medical College of Wisconsin	Surgery	Assistant Professor	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Key Personnel	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
View	Murphy	Amy	MCW AH	Non-MCW		<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Key Personnel	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
View	Pearl	Joshua	MCW AH	Surgery	Instructor	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Key Personnel	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3. Project Category

3.1 * Which category best describes the type of project you are submitting for review?

- Case Report**[†] – Involves a description of routine medical care for three patients or less
- Quality Improvement**[†] – The entire project is initiated, overseen, and analyzed by an official Froedtert Health Entity Quality Assurance committee
- Research Project**[†] - Including clinical trials, record reviews, specimen reviews, surveys, etc.
- Research Project plus distant bank**[†] - No banking at a local project site

- Research Project plus creating a new local bank[†]** - At least one at a local project site *Note: see 3.1.1 below
- Research Project requesting reliance on another IRB[†]** - An IRB other than the MCW IRB will serve as the IRB of record for this project.
- Creating a new local bank[†]** - No research project being proposed in this submission
- Treatment Use[†]** - Use of investigational drugs, medical devices, biologics or Humanitarian Use Devices (HUDs) solely for clinical purposes with no elements of research or research data collection
- Emergency Use[†]** - Use of an investigational drug, medical device, biologic or Humanitarian Use Device (HUD) – after-the-fact report to the IRB
- Not Human Subjects Research[†]** – The project will not interact/intervene with living human beings

3.2 * Does the proposed project involve any of the following features?

(check all that apply)

- Deception projects
- Direct contact with subjects
- Human Source Material (human blood, tissues, cell lines)
- None of the above

3. Project Elements

3.3 * Does this project involve any of the following elements?

(check all that apply)

- 100% of subjects are known to be deceased, e.g., work with cadavers or biospecimens of deceased persons; record reviews where all subjects are demonstrably deceased
- In-vitro or laboratory diagnostic tests in the absence of FDA approval and/or CLIA certification: chemistry, drug monitoring, immunological/hematologic, tumor marker, genetic disorder, infectious disease, microorganism, bio-threat tests
- Dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus from any source, commercial or otherwise
- More than one site. Project activity will take place at other institutions or locations that are not under the supervision of the PI listed on this IRB application.

- Any part of the project takes place in another country. Check here if the PI is the lead PI for a multi-site project where one or more sites are in another country or if any project related work or oversight work is being done in another country.
- Application to waive informed consent requirements for certain types of planned emergency medicine research [(21 CFR 50.24 or 45 CFR 46 Waiver of Informed Consent Requirements in Certain Emergency Research) or (FR doc. 96.24968)]
- Research using the internet as a source of information or a survey tool
- None of the above

3.4 * Does this project involve ONLY one or more of the following minimal risk activities?

(check all that apply)

- Biospecimens collected for non-research purposes
- Blood draws with collection limited to finger, heel or ear stick, or venipuncture
- Educational
- Non-invasive collection of biospecimens
- Non-invasive Procedures
- Psychosocial Interventions
- Records collected for non-research purposes
- Surveys, questionnaires, interviews, focus groups, or observation of behavior
- Voice, Image or digital recording for research purposes
- No, my project involves activities which are not minimal risk, or the identified activity no longer qualifies as minimal risk

3.5 * Use of Identifiers - indicate the level of "subject identification" you require to BEGIN this work.

- If any element of your records, data files, or administrative records contains an identifier, you should select Identified Data.
- If you plan to de-identify data at any time other than the first day you access the information, you should select Identified Data.
- If different levels apply, choose the "most identified" one, e.g., if level A and level B apply, choose level A.

A - IDENTIFIED DATA: Utilizes one or more identifiers, including those defined by HIPAA Privacy Rule but not using a "limited data set." See help text for complete listing.

B - CODED DATA, KEY held by project team: Data is coded; **and** key code held by any person at MCW, Froedtert Hospital, Children's Hospital of Wisconsin, or Versiti, Inc. whether or not they are part of the project team.

- **C - CODED DATA, KEY not held by project team:** Data is coded; key code not held by any MCW/Froedtert faculty member, employee, fellow, resident, or student; key code not held by any member of the project team; **and** the key code will never be accessible to any member of the project team.
- **D - LIMITED DATA SET:** The only HIPAA identifiers utilized are dates or certain allowable geographic subdivisions; an IRB "limited data set" data use agreement has been executed by the PI; and is uploaded into this IRB application.
- **E - DE-IDENTIFICATION PROCESS:** The IRB application describes how the project team will de-identify data in one of two approvable methods: 1) reliance on an MCW/FH IRB-sanctioned "honest broker" or 2) receiving coded data/specimens without identifiers and without a key code. For details see "Two ways to de-identify data or biospecimens for IRB purposes." To use these options, no code keys may be created or saved and the resulting dataset can never be re-identified. In addition, a complete list of project variables must be uploaded in Section 52.
- **F - ANONYMIZED:** The investigator receives data in anonymized form and no other party has the potential to re-identify data (i.e. no code key exists anywhere in the world). In this case, the IRB application must include a detailed description of how the data was collected, e.g., anonymous surveys, or who provided the anonymized data or biospecimens, so the IRB can verify the source and the irreversibility of anonymization. In addition, a complete list of variables, e.g., data recording sheet, Case Report Form, anything that summarizes all the information that will be recorded, must be included in Section 52 Attached Documents.

3F. Records Research - Part I

You received this section because in Section 3. Project Elements, Question 3.4, you checked "Records collected for non-research purposes"

3F.1 * For what purpose were the records originally created?

(check all that apply)

Clinical Care

* Identify the Sources:

Medical College of Wisconsin

Froedtert Hospital Campus (including all speciality clinics, the Cancer Center and the Eye Institute)

Versiti, Inc. and Blood Research Institute

Other

- Quality assurance
- School or teaching records
- Billing or insurance
- Program administration
- Hospital or community surveillance
- Different research project
- Other

3F. Records Research - Part II

3F.2 * Do you plan to use/analyze records created before the date of IRB approval (retrospective records)? (i.e., NO additional cases created after that date, and NO opportunity to include follow-up information created after that date)

Yes No

If Yes,

*** 3F.2.1 What is the date for the earliest records you will access?**
1/1/2019

3F.3 * Do you plan to access records created after the date of IRB approval (prospective records)?

Yes No

If Yes,

*** 3F.3.1 How will you get permission to access these records?**
(check all that apply)

- Using informed consent
- From an IRB approved bank
- Other

*** 3F.3.1.1 Specify other:**
Minimal Risk Waiver of Consent

3F.4 * Estimate the total number of subject records that you intend to:
(The IRB expects the investigator to provide meaningful estimates and to adhere reasonably to these estimates. It is often better to make a slight over-estimate of numbers.)

Screen, whether you use the record for this project or not.
15,000

Use for this project.

10,000

3F.5 * Explain how you determined the number of records to include in the project at this site.

The Trauma Center at Froedtert & the Medical College of Wisconsin admits some 3,400 patients a year. We anticipate this study to run for 1 year at most and we require each included patient to be matched to subjects admitted to FMLH in the previous year. This is why the screening and use for project number is multiplied by 2, to account for matching. The numbers placed in 3F.4 are an intentional overestimate to avoid non-compliance.

4. Safety and Research Review Committees

4.1 * Does this project include any of the following regulated items or resources? Selections will determine if there are additional review requirements prior to IRB review process beginning, per MCW policy:

(check all that apply)

- Biological Toxins
- Project with a cancer focus (including healthy subjects)
- CTSI Adult Translational Research Unit (facility or resources)
- Human Gene Transfer
- Human stem cells
- Human/Non Human Primate (NHP) Cell Lines, Tissues, or Blood Products
- Microorganisms
- Magnetic Resonance Imaging (MRI) (that is not Standard of Care)
- Radiation therapy, radioactive materials/brachytherapy, CT, X-ray, fluroscopy
- Recombinant DNA (non-Viral vectors)
- Viral Vectors
- None of the above

6. Project Locations

6.1 * Under the direction/supervision of this Principal Investigator, project activities will take place at the following locations:

(check all that apply)

- Froedtert & the Medical College of Wisconsin Hospitals and Health Partners
- Medical College of Wisconsin - Milwaukee Campus
- Medical College of Wisconsin - Green Bay Campus
- Medical College of Wisconsin - Central Wisconsin Campus
- Center for AIDS Intervention Research (CAIR)
- Adult Translational Research Unit (TRU)

- Versiti, Inc.

- Children's Hospital of Wisconsin[†]
- Clement J. Zablocki Veteran's Affairs Medical Center[†]
- UW-Milwaukee[†]
- Marquette University[†]
- Milwaukee School of Engineering[†]
- Other

6.1.1 For all locations other than MCW, Froedtert Hospital, or Versiti, Inc. list the lead collaborator at each institution, their role at each institution, and the name of the institution.

6.2

*** Will any subject recruitment activities or research procedures under the responsibility of this Principal Investigator take place outside of Wisconsin but within the US?**

Yes No

8. National Cancer Institute (NCI) Cooperative Groups

8.1 * Is this project part of a NCI cooperative group?

Yes No

10. Intervention Evaluation

10.1 * Is this research project designed to evaluate the safety or effectiveness of a research treatment/intervention?

- Yes
 No

10.2 * Does the research involve:

(check all that apply)

- Drug: FDA-approved, investigational, or other
 Device: FDA-approved, 510(k), investigational, HUD, or other
 Biologic: FDA-approved, investigational, or other
 Botanical, medical food, or dietary supplement
 None of the above

11. Funding Source

11.1 * Do you have funding to support any of the activities for this project:

- Yes No

12. Project Subject Types

12.0 * Does this project involve any minor subjects, or use of records or biospecimens related to minors? (Minor status is defined by the legal age of consent for the state or country where the research activity takes place; e.g., under 18 years of age in Wisconsin.)

- All minors
 Some adults and some minors
 All adults of legal age

12.1 * Enter the disease/affliction that is the focus of this project (e.g. pancreatic cancer):

Emergency general surgery patients

12.2 * Identify all categories of subject populations that will be included in this project:

(check all that apply)

- Cancer patients
- Inpatients
- Outpatients
- Healthy Subjects (i.e. subjects NOT selected because they have a particular medical condition or history)
- Elderly - age 70 and over
- Employees including faculty, staff, residents or fellows
- Fetuses
- Issues of cognitive or decisional impairment
- Limited or non-reader
- MCW students
- Neonates
- Non-English speaking
- Nursing home residents
- Persons with alcohol or drug use disorders
- Persons with developmental disabilities - neurologic or psychiatric
- Persons with mental illness
- Poor and/or uninsured
- Pregnant women
- Prisoners - see help text
- Terminally ill patients
- Traumatized, sedated, or comatose patients
- Visually / hearing impaired
- Other (SPECIFY)

12.3 * Are the exclusion criteria for this project likely to exclude groups or categories of subjects based on race, socioeconomic status, or insurance coverage?

- Yes No

17. Recruitment Strategies

17.1 * Will potential subjects be identified or screened by searching records of any source outside MCW/FH/CHW/Versiti, Inc.? (e.g., motor vehicle records, military service records, state registries, Medicare files, other hospitals including International hospitals)

Yes No

17.2 * To recruit potential subjects, will you use any of the following:

- Print advertisements (e.g. newspapers, magazines, flyers, posters, brochures)**
- Letters/emails**
- Radio or television advertisements**
- Web solicitations**
- Telephone**
- Recruiting company**
- Physician referrals (includes in-house and/or outside referrals)**
- Approach subjects in-person** (Example: a public place or knocking door-to-door)
- Other strategies (not already covered) to identify, screen, or recruit subjects**
- No recruitment activities**

Instruction: Upload all recruitment materials in Section 52.

19. Protocol Summary

You received this section because the responses you provided in Sections 3, 6, 11, and 12 qualify this project to be a minimal risk project that could be Registered.

Introduction

19.1 * Briefly summarize the background and the history of the proposed project.

On December 31 2019, Chinese authorities reported a cluster of cases of pneumonia. 55% of the cases reported prior to January 1st of 2020 were linked to the Huanan Seafood Wholesale Market in the Chinese province of Wuhan, Hubei, as compared to only 8.6% of future cases. This suggested rapid and consistent human to human transmission requiring strong and swift isolation measures (1). Now known as Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) or coronavirus disease 2019 (COVID-19), the virus has spread rapidly within China and across the globe, creating large outbreaks on all 6 continents. The World Health Organization designated COVID-19 a global pandemic on March 16 2020 (2).

As of April 23rd 2020, the United States has a reported 843,937 total cases and 46,851 deaths. The U.S. is advocating its residents to work from home, avoid discretionary travel, and avoid social gatherings (7). Due to the rapid surge in patients requiring testing and inpatient care and despite the efforts of the federal and local governments, hospitals across the U.S. are starting to experience shortages in vital supplies and devices such as personal protective equipment, ventilators, and ICU beds (8). The consequences of these shortages will not only affect the quality of care provided for COVID-19 patients, but will also impact care provided across the entire healthcare system.

Since the beginning of March, FMLH has started implementing various administrative and clinical policies to help prepare for the anticipated surge in patients requiring inpatient care. FMLH has replaced all outpatient visits with telemedicine, relocated all nonessential staff to work from home, restricted the number of providers present at any time, postponed elective procedures, and restructured some of its units to accommodate the expected surge. Although much research and efforts are currently being directed towards understanding and optimizing the care for and treatment of subjects infected with COVID-19, there has been no study yet examining the impact this will have on the clinical outcomes of none COVID-19 subjects, especially emergency general surgery patients (EGS). We believe there is an urgent need to understand how all these policy changes, shortages, and work restrictions will affect the quality of care for EGS patients admitted to FMLH.

Rationale/Purpose

19.2 * Describe the reason this project is being proposed. Include why is it significant or important to conduct this project.

There is no debate that the COVID-19 pandemic has significantly overwhelmed healthcare systems across the world and especially the United States. There is an

urgent and immediate need to assess how the new measures, restrictions, and shortages at FMLH are reflected in the quality of care. This study aims to quantify this impact by reporting clinical data and outcomes from EGS patients admitted to FMLH after March 1 and comparing them to matched controls admitted prior to that period.

Given the international nature of this outbreak, this study can bring new and original findings to the medical literature by providing a detailed and comprehensive assessment of the disease status, clinical course, and outcomes of non COVID-19 EGS patients in the COVID era. To our knowledge, such an assessment has not been reported so far.

Objectives or Hypothesis

19.3 * Describe the Aims and Objectives of this project.

1. Describe the clinical course and outcomes of EGS patients admitted during the COVID pandemic
2. Compare the clinical course and outcomes to historical controls
3. Describe the trends in EGS presentation and admissions

19.4 * Describe goals which are empirically measurable.

To understand how the COVID-19 pandemic has affected EGS patients being admitted now, compared to similar patients admitted pre-COVID-19. The goal is to answer how the two groups differ on clinical outcomes and course.

Inclusion/Exclusion Criteria

19.5 * Identify subject selection criteria in inclusion criteria

1. Adult patients (≥ 18 years of age)
2. Emergency general surgery patients that meet the following diagnostic groups: Appendicitis, Cholecystitis, Perforated Diverticulitis, Perforated Viscus, Perforated Peptic Ulcer, Small Bowel Obstruction, Necrotizing Soft Tissue Infection
3. Admitted on and after 1/1/2019

19.6 * Identify subject selection criteria in exclusion criteria

1. < 18 years of age
2. EGS patients from diagnostic groups not mentioned above.

Project Design

19.7 * Provide details of how the project will be performed including a description of what will happen during each visit/activity.

We will identify EGS patients and their controls using the MCW Clinical Research Data Warehouse (PRO00013874) for EGS patients.

Clinical data for this study will also be obtained by searching for eligible participants by querying a cohort discovery tool (i2b2 and/or TriNetX) from the MCW Clinical Research Data Warehouse (PRO00013874) with (a) the following inclusion/exclusion criteria, and (b) seeking IRB approval to extract or access the following clinical information for each identified participant using the Honest Broker tool:

- a. Inclusion: All adult (≥ 18 years old) EGS (Appendicitis, Cholecystitis, Perforated Diverticulitis, and Perforated Viscus) patients admitted after 1/1/2019. / Exclusion: < 18 years old, EGS patients from diagnostic groups not mentioned above
- b. Clinical information to be extracted: demographic characteristics, disease and injury characteristics, information related to hospitalization course (i.e., length of stay, mortality, etc.)

After identifying eligible patients we will perform data abstraction from the Froedtert Hospital medical records program (EPIC). Using Epic, we will collect additional information relating to the patient's clinical presentation, hospital course, medical history, radiological findings, laboratory variables, treatment variables, procedure data, surgical data, clinical outcomes, and discharge information.

The data collected will be entered by a member of the study team into a secured electronic excel spreadsheet created for this project and an online REDCap database in a secure fashion with password protection. Registry files, data downloaded from REDCap, and any other documents containing patient information will be stored on a password protected MCW shared drive on the MCW BOX or OneDrive.

Financial Implications

19.8 * Explain which procedures are research-related.

All activities are research-related.

19.9 * Will there be any costs to the subjects? If yes, then list each item being charged.

No expenses will be incurred in this study and none will be expected to be paid by subjects.

Subject Compensation

19.10 * Will subjects be offered stipends, gifts or compensation for their participation, or reimbursement for project-related expenses?

- Yes
- No

Statistical justification for number of subjects

19.11 * Provide detail as to how the number of subjects was chosen. Include a number or range that will give you statistical viability or make your results meaningful.

The Trauma Center at Froedtert & the Medical College of Wisconsin admits some 3,400 patients a year. We anticipate this study to run for 1 year at most, and we require each included patient to be matched to subjects admitted to FMLH in the previous year. This is why the screening and use for project number is multiplied by 2, to account for matching. The numbers placed in 3F.4 are an intentional overestimate to avoid non-compliance.

Statistical Methods and Data Analysis

19.12 * Provide a simple overview of potential statistical tests for analysis.

Admission and management trends will be described. Data collected will be compared to a historical control using propensity score matching to evaluate for differences in outcomes. Patients will be matched according to age, gender, race, mechanism of injury, admission diagnosis, and possibly other variables depending on sample size. Mean length of stay, mortality, complications, 30-day readmission, and hospital disposition will be compared between the two groups.

A multivariate logistic regression will also be performed to determine whether admission date has any effect on presentation and clinical outcomes, and to identify any other independent variables that might be influencing outcomes during this period. Student's t-test and the Mann Whitney U test will be used to compare continuous variables. Chi-squared tests or Fisher's exact test will be used to compare categorical variables. Adjusted odds ratios with 95% CI will be used to report outcome data. Statistical significance is set at $p < 0.05$.

Risks/Safety

19.13 * Identify the risks associated with project including physical, psychosocial, confidentiality, and privacy risks.

Loss of privacy and confidentiality are the potential risks.

19.14 * Identify efforts to minimize the identified risks and how confidentiality will be protected.

Only approved study staff will have access to the data in question and to patient PHI, which will be used to determine eligibility. Identifiable information will come from review of our own trauma registry and MCW Clinical Research Data Warehouse. Data will be collected and stored online through a secure server running the Research Electronic Data Capture (REDCap) web application. REDCap allows team members to enter and store data in a secure server that is hosted and managed by the Medical College of Wisconsin. The information in the final analytic dataset will be deidentified. All electronic data containing patient information will be stored on the secure MCW Box platform or OneDrive.

MCW Box features:

The MCW Box platform is a secure data storage system provided through the Medical College of Wisconsin. The MCW Box platform provides data encryption utilizing 256-bit SSL, SSAFE 16 Type II, and maintains a safe-harbor certification for security. Box sync's encrypted authorization token technology keeps user data secure and work seamlessly with existing MCW desktop encryption systems.

MCW Box is licensed for storage of PHI data as it provides maximum security and allows users to assign different levels of security based on individuals' roles within a project. All files stored on MCW Box are stored within a secure server on the MCW campus and can be synced to MCW owned computers kept in locked offices within Froedtert Hospital.

Content from Box is available remotely through their encrypted website which requires two step verification and login each time the site is accessed. Users have access only to files in which they have been granted access, increasing the security of data storage.

OneDrive is also endorsed by MCW IS and secured.

Benefits

19.15 * Identify any potential benefits to subjects.

There is no direct benefit to subjects analyzed in this study.

19.16 * Identify any potential benefits to science and society.

This study will provide a detailed and comprehensive assessment of the disease status, clinical course, and outcomes of EGS patients admitted in the COVID era. This will help us understand how the quality of care has been affected during this period. This information will prove valuable when planning for future pandemics or disasters. Refer to section 19.1 for a detailed background on the study.

References

19.17 * Briefly summarize findings from previously published data or pilot projects that substantiate the soundness of protocol being proposed; or describe formulation of research questions:

1. Li, Q., Guan, X., Wu, P., Wang, X., Zhou, L., Tong, Y., ... & Xing, X. (2020). Early transmission dynamics in Wuhan, China, of novel coronavirus–infected pneumonia. *New England Journal of Medicine*.

2. World Health Organization (2020, March 11). *Press briefing by WHO Director General*. Retrieved from <https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020>

3. Wang, D., Hu, B., Hu, C., Zhu, F., Liu, X., Zhang, J., ... & Zhao, Y. (2020). Clinical characteristics of 138 hospitalized patients with 2019 novel coronavirus–infected pneumonia in Wuhan, China. *Jama*.

4. Huang, C., Wang, Y., Li, X., Ren, L., Zhao, J., Hu, Y., ... & Cheng, Z. (2020). Clinical features of patients infected with 2019 novel coronavirus in Wuhan, China. *The Lancet*, 395(10223), 497-506.

5. Verity, R., Okell, L. C., Dorigatti, I., Winskill, P., Whittaker, C., Imai, N., ... & Dighe, A. (2020). Estimates of the severity of coronavirus disease 2019: a model-based analysis. *The Lancet Infectious Diseases*.

6. Wu, Z., & McGoogan, J. M. (2020). Characteristics of and important lessons from the coronavirus disease 2019 (COVID-19) outbreak in China: summary of a report of 72 314 cases from the Chinese Center for Disease Control and Prevention. *Jama*.

7. U.S. Office of the President. (2020, March 16). *Press briefing by President Donald J. Trump*. Retrieved from <https://www.whitehouse.gov/briefings-statements/coronavirus-guidelines-america/>

8. Ranney, M. L., Griffeth, V., & Jha, A. K. (2020). Critical Supply Shortages—The Need for Ventilators and Personal Protective Equipment during the Covid-19 Pandemic. *New England Journal of Medicine*.

26. Connecting with a Bank

26.1 * Will this project contribute data, records, or biospecimens to a local bank?

Yes No

26.2 * Will this project access data, records, or biospecimens from a local bank?

Yes No

*** 26.2.1 Cite the PRO for the local bank from which you will access data (records or biospecimens) for this project:**

Bank ID	Bank Title	Principal Investigator	Bank State	Accessing Records	Accessing Biospecimens
PRO00013874	Clinical Research Data Warehouse	Reza Shaker	Approved	<input checked="" type="checkbox"/>	<input type="checkbox"/>

38. Informed Consent

38.1 * Indicate your approach to the informed consent process requirement for this project:

(check all that apply)

- Subjects or parents of minor subjects participate in an informed consent process and sign an informed consent document
- Waiver or Alteration of the Informed Consent Process is granted by the IRB. This option is not permitted for most FDA regulated research.
- Subjects participate in an informed consent process, but a Waiver of Documentation of Informed Consent is granted by the IRB
- None of the above

38.1.1 Please identify which pathways are applicable to this project.

(check all that apply)

- Project will not have direct contact with subjects, and a consent form or process is not required per MCW institutional policy
- Project will have direct contact with subjects, and an informational letter will be provided
- Project qualifies for Approval without the Requirements of Informed Consent under the 2006 FDA guidance regarding In-vitro diagnostic evaluation using de-identified, discard clinical specimens
- Informed consent has already been obtained (i.e. previously IRB approved bank, incoming data form another institution, etc.)

42. HIPAA: Protected Health Information

42.1 * Will potential subjects be identified or screened by searching any kind of pre-existing MEDICAL records before consent is obtained? (e.g., medical records, hospital census or procedure logs, emergency room visit rosters)

Yes No

42.2 * Indicate the HIPAA authorization pathway applicable to this project. Generally, the Health Insurance Portability and Accountability Act (HIPAA) prohibits collecting, accessing, using or disclosing a person's protected health information (PHI) for research without valid authorization. Under some circumstances, a waiver of authorization may be granted by the IRB:

(check all that apply)

- No Protected Health Information (PHI) will be Accessed or Used For This Project**
- An IRB-Approved Consent Process and Document will be Used** that incorporates the required HIPAA authorization
- Waiver of HIPAA Authorization Is Requested.** Generally, this request should accompany the "Waiver of the Informed Consent Process" at 38.1.
- Research using only information on deceased persons**
- Limited Data Set**, as defined by HIPAA regulations (download "Data Use Agreement" form located on InfoScope HIPAA website, complete it or an equivalent, and upload in Section 52)
- De-identification of data** subject to the IRB's definition and verification of de-identification
- None of the above**

48. Waiver of HIPAA Authorization: Justification

Note: Here "practicable" refers to the size of the burden and/or cost of obtaining authorization from subjects, on a scale from "difficult" to "impossible". Explain how difficult it would be. It is not acceptable to argue that obtaining authorization would be "inconvenient".

48.1 * Is it practicable for the investigator to conduct this project without a waiver of HIPAA authorization?

Yes No

If No,

48.1.1 Explain:

PHI is needed to identify and verify subject eligibility. Additionally, subjects may be deceased or unable to be reached for contact as is with many admitted patients, especially after discharge.

48.2 * Is it practicable for the investigator to conduct this project without access to and use of the identified health information?

Yes No

If No,

48.2.1 Specify:

Identified health information is needed to verify the correct subject for data collection and to avoid duplicate medical chart entry.

49. Waiver of HIPAA Authorization: Safeguards

49.1 * How will subjects' rights and welfare be protected to assure that use or disclosure poses no more than minimal risk?

To ensure that no identifying data is released, we will not disclose the PHI to anyone and the study team members will only record the least information necessary. All identifiers will be kept either electronically via the MCW BOX or OneDrive, or in a locked file cabinet/drawer within a locked office of the study staff.

49.2 * What is the plan to ensure that the identified health information will NOT ever be removed from the institution?

We will not remove any identified health information. Only approved study staff will have access to the identified health information and only de-identified data, per the DCF attached in section 52.1 will be entered into the study's REDCap Project.

50. Waiver of HIPAA Authorization: Procedures

50.1 * Who will have access to the identifiers? (List by name, class or organization)

All approved study staff.

50.2 * How will the identifiers be protected from improper use and disclosure?

Any identifiers will be kept in a locked file cabinet/drawer within a locked office of the research staff or on the MCW BOX platform which is password protected. The PI will have the responsibility of assuring identifiers are protected from improper use and disclosure.

52. Supporting Documents

* Select all items that will be included for IRB review:

52.1 (select all that apply and upload documents in Section 52.1.2, using the prefix in the title of the document. For example, ICF-PRO1234 (document name), IB-PRO1234(document name))

- DA - Data agreements or contracts
- DCF - Data Collection forms/tools
- ADV - Advertisement
- ICF - Informed Consent form
- INF - Informational material for subjects
- SUR - Surveys / Questionnaires
- Other(s) (SPECIFY)

52.1.2 Upload each item specified from 52.1 and 52.1.1 in the section below:

Name	Last Modified Date	Version
Variables to be abstracted.docx	5/6/2020 9:14 AM	0.01
DCF - PRO37735 - Data collection sheet.xlsx	4/23/2020 3:23 PM	0.01

Final Check

(a) Submission Instructions:

- **The Principal Investigator must click the "Submit Application" activity in the workspace to submit this Project for Departmental, Ancillary and/or Safety Committee(s) review. **Once these reviews have been completed, the submission will automatically get routed to the IRB for review.****
 - Clicking "Go to Workspace" does NOT submit this Project for review.
 - Clicking "Go to Workspace" saves your work and exits the SmartForm, taking you back to the Workspace.

(b) **Spelling and Grammar:**

IRB will not accept any application that has not been checked by the submitter for spelling and grammatical errors. Spell checking capability is not available within the eBridge system at this time.

(c) **Attached Documents:**

Make sure all documents have been uploaded before submission.

(d) **Copy and Pasting from Word or PDF:**

If the format of your text is altered when it is pasted into eBridge, please refer to the "[How to Cut & Paste from a Word Document](#)" directions.