**New Research Proposal Submission Form**

Please fill it in DOCX software and send it as PDF (If any part is deleted, this form will be rejected)

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| **1. Principal investigator** | | | | | |
| \*\*\* | | | | | **Name** |
| Non-MOH | MOH | **Affiliation** | Non-Saudi | Saudi | **Nationality** |
| \*\*\* | | **Email** | \*\*\* | | **Affiliation name** |
|  | | **Signature** | \*\*\* | | **Mobile No.** |
|  | |  | \*\*\* | | **Date** |

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| **2. Supervisor (for undergraduate and postgraduate students)** | | | | | |
|  | **Signature** |  | **Affiliation Email** |  | **Name** |

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| **3. Research information** | | | | | | | | | | | |
| Other: | | | Professional | Post-graduate | | | | | Under-graduate | | **Purpose of research** |
| Outcomes of surgery in COVID-19 infection: international cohort study (CovidSurg) | | | | | | | | | | | **Research title** |
| Non-medical | Medical secondary research  (review, meta-analyses) | | | | | Medical primary research  (biomedical, clinical, health service, sociocultural research) | | | | | **Research type** |
| Surgery | | | | | | | | | | | **Research specialty** |
| Both institutions | | | Out MOH institutions | | | | | In MOH institutions | | | **Research site** |
| Name: | | | | | | | Multi-site | | | One site | **Affiliation Name** |
| If yes, name of the funding institution: | | | | | | | | | | No | **Research fund** |
| Approved | | Yes | | | No | | | | | **Has the study been previously reviewed by another research ethics committee?** | |
| Rejected | |

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| **4. Research proposal summary (300 words)** |
| ***Study objectives.***  To determine 30-day mortality in patients with COVID-19 infection who undergo surgery.  ***Methods. (Sample size and sampling technique)***  This study is a descriptive, analytical, non-interventional, prospective study on a cohort of all patients with COVID-19 infection who either underwent surgery or are planned to have surgery during 30 days from the onset of the infection. Retrospective data will be included for patients who had the inclusion criteria prior to surgery.  ***Statistical analyses.***  The statistical analysis will include description of the primary and secondary outcomes in the cohort. Multivariable modelling will be undertaken to identify risk factors (Appendix 1- Data Extraction Sheet) for 30-days mortality. Analyses will be stratified according to whether or not diagnosis of COVID-19 was confirmed by a lab test.  ***Study importance and benefits.***  Assessing surgical outcomes in patients with COVID-19 infection is significantly important in order to inform clinical practice during this pandemic and in future similar settings, consequently, improving clinical care for those patients. |

*All parts should be filled mandatory.*

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| **5. Research project duration** |
| ***Table.***  Overall, we plan to close data collection/entry in September 2020.  ***Gantt Chart.*** |

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| **6. Research Questions / Research Hypothesis** |
| Is infection with COVID-19 associated with worse outcome (increased morbidity and mortality) in surgical patients? |
| **7. Background to Study / Summary of Literature (max 300 words)** |
| Currently, there is no available data on the impact of surgery performed on patients with COVID-19 infection on the outcomes. One retrospective study from China (1) described the clinical characteristics and outcomes of 34 patients who were unintentionally scheduled for elective surgeries during the incubation period of COVID-19 infection. This study showed that 44% of patients needed ICU care, and mortality was 20%. This report suggests that old age, comorbidities, surgical time, and difficulty of operation may be risk factors for poor outcome in this group of patients. Several brief clinical reports and case-series have described outcomes on patients who underwent emergency surgery, but they are limited by the very small number of patients included (2,3). As more patients all over the world are increasingly affected by this pandemic, multiple recommendations and guidelines have been published (4-7) to support safe and informed decision making by surgeons and other healthcare providers. However, these recommendations and guidelines are opinion of experts and most of them are not evidence-based.  **Reference**:  1- Lei, S., Jiang, F., Su, W., Chen, C., Chen, J., Mei, W., … Xia, Z. (2020). Clinical characteristics and outcomes of patients undergoing surgeries during the incubation period of COVID-19 infection. *EClinicalMedicine*, *000*, 100331. <https://doi.org/10.1016/j.eclinm.2020.100331>  2-Yunhe Gao, MD; Hongqing Xi, MD, PhD; Lin Chen, MD, PhD. ,Emergency surgery in suspected COVID-19 patients with acute abdomen: case series and perspectives 2020 Wolters Kluwer Health , Inc . All rights reserved . 2020  3- Weili Han1, Manhua Zhu, Jun Chen, Jing Zhang, Shengmei Zhu, Tong Li, Hongliu Cai, Qiang Fang, Guoqing Wei, Tingbo Liang, **Lung Transplantation for elderly patients with end-stage COVID-19 Pneumonia ,** 2020 Wolters Kluwer Health , Inc . All rights reserved. 2020  4-Pryor, A. (2020). SAGES AND EAES RECOMMENDATIONS REGARDING SURGICAL RESPONSE TO COVID-19 CRISIS Rationing of Services: Procedural Considerations  5-Zheng, M. H., Facs, L. B., & Fingerhut, A. (2020). Minimally invasive surgery and the novel coronavirus outbreak: lessons learned in China and Italy. https://doi.org/10.1097/SLA.0000000000003924  6-American College of Surgeons COVID 19: Elective Case Triage Guidelines for Surgical Care.  7-American Association of Endocrine Surgeons, Elective Endocrine Surgery. |

*Summarize the relevant literature and explain how the idea for the study evolved. Please include key references*

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| **8. Study objectives** |
| To determine 30-day mortality in patients with COVID-19 infection who undergo surgery. |

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| **9. Study innovation, importance, and benefits** |
| This will inform future risk stratification, decision making, and patient consent. |

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| **10. Study Design** |
| This study is a descriptive, analytical, non-interventional, prospective study (Cohort study) |

*E.g. Cross-sectional study, Case-control study, Randomized Control Trial.*

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| **11. Sample Size Calculation** |
| This study will include all patients with COVID-19 infection who either underwent surgery or are planned to have surgery within 30 days from the onset of the infection in the selected hospitals. Retrospective data will be included for patients who had the inclusion criteria |

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| **12. Study Setting (area)** |
| This study will be conducted in all health facilities that admit and care for COVID19 patients within \*\*\* Region. |

*Specify where the study (data collection) will be conducted.*

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| **13. Study Population** |
| all patients with COVID-19 infection who either underwent surgery or are planned to have surgery within 30 days from the onset of the infection in the selected hospitals. |

*Among whom the study will be carried out?*

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| **14. Sampling Technique** |
| Patient chart review and data extraction will be conducted for all patients with COVID-19 infection who meets the study’s inclusion criteria |

*How the participants will be recruited and selected?*

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| **15. State inclusion and exclusion criteria** |
| ***Inclusion criteria***   * Adults (age ≥18 years) undergoing ANY type of surgery in an operating theatre, this includes obstetrics. * Either before or after surgery: (i) lab test confirmed COVID-19 infection or (ii) clinical diagnosis of COVID-19 infection (no test performed).   ***Exclusion criteria***   * Patients with COVID-19 infection who do not meet the above inclusion criteria |

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| **16. Consent form** | | |
| No explain why not:  This study involves no interaction with patients to minimize risk of disease transmission. Only relevant data will be collected and no personal data are going to be used. However a written information sheet is available if needed | Yes | Will participant be given written information about study details? |
| No explain why not:  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. | Yes | Will participants sign a consent form? |

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| **17. Explain how the participants’ anonymity and confidentiality will be maintained** |
| **No personal data or identifiable patient information will be collected or shared.**  **Collected data will be coded.** |

*For example, data will be collected with codes. No data will not be linked to participants. Questionnaire will not include participants’ names, files numbers, mobile phone etc.*

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| **18. Explain how / what data will be collected** |
| **Chart review is the source of all data.**  **(data extraction sheet is attached)** |

*For example, interview, review files etc. Provide copies of relevant documents (questionnaires, data extraction forms etc.).*

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| **19. Outline how the data will be analyzed statistically** |
| The statistical analysis will include description of the primary and secondary outcomes in the cohort through a statistical software program (SPSS version 25). Multivariable modelling will be undertaken to identify risk factors (Appendix 1- Data Extraction Sheet) for 30-days mortality. Analyses will be stratified according to whether or not diagnosis of COVID-19 was confirmed by a lab test. Interim analyses will be performed. The first analysis will be performed once 50 patients have been enrolled. The data will be stored at secured online system |

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| **20. Outline potential risks to participants in the study (including the researchers)** |
| **No patient contact is necessary and only chart review is going to be conducted, so there are no potential risks involved with this study.** |

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| **21. How the potential risks will be prevented?** |
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| **22. How will data be stored securely during and after the study?** |
| **One data extraction form per patient will be filled in and kept securely with the PI.**  **No identifiable patient information will be collected.** |

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| **23. Consent form (if applicable)** |
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| **24. Questionnaire or data extraction form** |
| **The form is attached** |

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| **25. Principal investigator assurance** | | |
| All co-investigators accept their responsibility for the scientific and technical conduct of the proposed research and submission of progress reports if this application is approved. My research project cannot begin until I have received the \*\*\* hospital IRB approval letter. No changes in this study will be implemented until an amendment form has been submitted and approved by the \*\*\* hospital IRB. If the \*\*\* hospital IRB approves this study via expedited or full procedure, I will submit for continuing review as stipulated in the approval letter. If the study or data analysis will exceed the approval period, I will submit a Submission Form for Continuing Review of the \*\*\* hospital IRB Approved Studies in a timely manner (well in advance of the renewal date). I will provide a copy of the signed consent form to the subject or patient. I will retain all signed informed consent documents and study-related records for a minimum of three (3) years (or longer as stipulated by funding agencies) from the date, the study is concluded. In the case of any serious adverse events, I will report in writing to the \*\*\* hospital IRB within 24 hours, and within five (5) working days for all other adverse events and unanticipated problems. I will provide any significant new information obtained during the course of the study and submit reports of new information to the \*\*\* hospital IRB as a Study Amendment. If my study is approved at the Expedited or Full Review levels, I will report to the \*\*\* hospital IRB when this study has closed (no further data collection or analysis). This report will be provided no later than 30 days after the end of the study via the \*\*\* hospital IRB Closing Report Form. I will submit the manuscript of the study for review by the \*\*\* hospital IRB before publication. | | |
| **Date** | **Signature** | **Name of principal investigator** |
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*Please read it carefully before you sign.*

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| **26. Conflict of interest declaration** | | |
| As an investigator/co-investigator, you are required to disclose relationships that could be viewed as presenting a potential conflict of interest in reviewing research applications. Close personal relationship or financial relationship such as employment, consultancy, stock ownership, scholarship, donation and honorarium are the most easily identifiable conflicts of interest. As it is not possible to provide an exhaustive list of conditions that could give rise to a conflict of interest situation, investigators are advised to refer to the “Conflict of Interest Policy”.   * I have no conflict of interest currently and will report such conflicts to the \*\*\* hospital IRB if it should arise during the course of review. * I have not received and will not receive any monetary or other types of incentives from the sponsor for recruiting patients or providing data apart from those processed through the formal study agreement. * I shall disclose and submit my financial agreement with the sponsor to the \*\*\* hospital IRB. | | |
| **Date** | **Signature** | **Name of principal investigator** |
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| **27. Pilot study results** |
| **None** |

**Good Luck**