NIHR Global Research Unit on Global Surgery Office 15, Floor 2 Institute of Translational Medicine Heritage Building, Mindelsohn Way Birmingham B15 2TH

10 August 2020

RE: GlobalSurg-CovidSurg Week study

To Whom It May Concern,

I am writing to you regarding study approvals for the GlobalSurg-CovidSurg Week study. In order to participate in the study, collaborators must ensure that the study is registered and approved with respect to all applicable local and/or national regulations.

In hospitals which have already participated in either the CovidSurg and/or CovidSurg-Cancer studies, collaborators should discuss with the relevant committee (e.g. research ethics committee or institutional review board) whether the GlobalSurg-CovidSurg Week study can be registered as a substantial amendment to the existing CovidSurg / CovidSurg-Cancer approval.

The reasons why a substantial amendment may be appropriate are:

- All the studies are coordinated by the same research group (CovidSurg Collaborative, based at the University of Birmingham, UK).
- All the studies are focussed on the same topic: the impact of SARS-CoV-2 infection on postoperative outcomes.
- The primary (30-day mortality) and secondary (30-day pulmonary complications) outcome measures remain the same across all studies.
- The principles of the data collection are the same in all the studies. They are all observational studies which do not require any changes to normal patient care. No additional tests or follow-up are required in any of these studies.
- The data collection platform is the same in all the studies. Data can be anonymised and uploaded to a secure, online REDCap database. The same REDCap server will be used for GlobalSurg-CovidSurg Week as for the CovidSurg / CovidSurg-Cancer studies.

The differences between the GlobalSurg-CovidSurg Week study and the CovidSurg / CovidSurg-Cancer studies are:

- Data collection in GlobalSurg-CovidSurg Week will be expanded to include all patients undergoing surgery in order to capture comparator data.
- Whilst the core data points have remained the same, some additional data points have been added on the case report form to address issues raised by the evolving literature on SARS-CoV-2.





Please do not hesitate to contact us with any queries through covidsurg@contacts.bham.ac.uk.

Yours faithfully,

Dr Dmitri Nepogodiev MBChB

Research Fellow NIHR Global Health Research Unit on Global Surgery University of Birmingham, UK

