NIHR Global Health Research Unit on Global Surgery

NIHR Global Research Unit on Global Surgery
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RE: CovidSurg-3 study REDCap system

To Whom It May Concern:

I am writing to give further information about the secure online REDCap database which will be used to collect data for the CovidSurg-3 study.

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

- CovidSurg Study (1,040 participating sites across 85 countries), reference: COVIDSurg Collaborative. *Mortality and pulmonary complications in patients undergoing surgery with perioperative SARS-CoV-2 infection: an international cohort study*. Lancet. 2020;396(10243):27-38. doi:10.1016/S0140-6736(20)31182-X.
- GlobalSurg-CovidSurg Week (1,650 participating sites across 116 countries), reference: COVIDSurg Collaborative, GlobalSurg Collaborative. *Timing of surgery following SARS-CoV-2 infection: an international prospective cohort study*. Anaesthesia. 2021 Jun;76(6):748-758.
- 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.

The REDCap database used for the CovidSurg-3 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

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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 on-identifiable data. Access to data will be restricted, each individual collaborator entering data for CovidSurg-3 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 study number. All data will be analysed and reported in summary format. No individual patient data will be identifiable in public reports.

Yours faithfully,

Dmitri Nepogodiev, MBChB MPH
On behalf of the CovidSurg-3 steering group

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