5th June 2020

**Monitoring during COVID 19 at GSTFT.**

For everyone’s safety, the Trust is still not in a position to permit any external parties onsite to conduct monitoring visits.

Alternative remote methods of monitoring *may* be available however any changes to monitoring should not increase the burden on NHS sites. Sponsor’s should follow HRA guidance to update changes to monitoring arrangements: <https://www.hra.nhs.uk/covid-19-research/covid-19-guidance-sponsors-sites-and-researchers/>

Below are some common examples of requests and whether the Trust can agree to these methods. Please note that any approved method will need to be reviewed by the research team to ensure adequate resource as some options are more intensive than others.

* **Remote Access to EHR**: Trust e-noting systems are not able to allow CRA’s remote access to electronic health records for source data verification.
* **Uploading to EDGE:** EDGE cannot be used as a trial management database to share source data with sponsors as it is not compliant with the CT regulations. At GSTFT EDGE is considered a document repository and not declared as part of the sponsor or sites’ trial management system.
* **Telephone remote monitoring** is permitted.
* **Shared Screens**: remote SDV via sharing screens is permitted at the Trust where secure platforms are used and CRA’s sign a code of connection (provided by research team prior to remote monitoring visit)
	+ **Access to electronic records** – GSTFT research staff can log into the relevant patient health record and contact third parties (Sponsors/CRAs) via Microsoft teams and share their screens. All third parties must sign up to the code of connection form (via the research team) before sharing screens.
	+ **Paper source** – GSTFT research staff can scan paper source documents to their GSTFT email network and share screens with CRAs/third parties via Microsoft teams. These PDFs must not be uploaded to any external study portal and may not be sent via email. Again all CRAs/third parties must sign up to the code of connection via the research team.

Please note Skype and Zoom are not secure platforms and cannot be used for screen sharing. Any platforms other than Microsoft Teams will require approval from IT governance in advance. Please reach out to the following contacts with details of the platform to be used for review:

* + Non-commercial trials: r&d@gstt.nhs.uk.
	+ Commercial trials: KHPCTOamendments@kcl.ac.uk

**Amendments**

Please continue to send all amendments / Urgent Safety Measures to the following emails accounts:

* + Non-commercial trials: r&d@gstt.nhs.uk.
	+ Commercial trials: KHPCTOamendments@kcl.ac.uk