1) Introduction

1.1)
This Standard Operating Procedure (SOP) describes the process of remote monitoring for research studies that are HOSTED by the University Hospitals of Leicester NHS Trust (UHL) or for where the UHL is a Research SITE.

1.2)
A Sponsor is required to regularly monitor the progress of research activity in accordance with relevant legislation and guidelines. As a host organisation we are required to have oversight of Principal Investigator (PI) activity. We are also required to enable monitoring / audit of site files as requested by the Sponsor. The expectation is that the study's Investigator Site Files (ISF) are maintained and are 'inspection ready' at all times. This extends to any electronic versions or holdings of ISF documents.

1.3)
The Sponsor or designated Monitor / Clinical Research Organisation (CRO) will establish and maintain a line of communication with the PI throughout the duration of the study which is inclusive of monitoring. For the purpose of clarity for this SOP the remote monitoring will ensure that;

- The rights and well-being of human participants are protected
- The reported study data is accurate, complete and verifiable by source documents.
- The conduct of the study is in compliance with the currently approved protocol and or amendment(s), with ICH GCP and regulatory requirements, legal directives, frameworks, policies and guidelines with the applicable iteration of the Declaration of Helsinki.

2) Scope

2.1)
This SOP applies to research HOSTED by the UHL or where the UHL is a Research SITE. The purpose of this SOP is to give guidance on the process of preparation, organisation and the conduct of remote monitoring processes directed by the external Sponsor or CRO.

3) Procedures

3.1) Monitoring Plan

3.1.1)
The research Sponsor or CRO will be responsible for detailing the monitoring schedule for the research study. The method of monitoring may change as a result of external circumstances (e.g. COVID-19 Pandemic). In these cases, Sponsors, their delegates and sites will need to be appropriately flexible. Sponsors should amend monitoring arrangements where it is deemed appropriate and necessary with remote monitoring being a preferred method.

3.1.2)
Occasionally it may be both necessary or in the best interest of the study to deviate from the planned risk assessed monitoring schedule and to commence a programme of remote monitoring. Should this be the case a file note should be placed in the ISF fully detailing the planned deviation from the original monitoring schedule.

All monitoring personnel must have evidence of qualification, training and/or experience where necessary regardless of the schedule of monitoring that they are undertaking.

3.1.3)
Where it is deemed essential by the Sponsor to complete on site monitoring activities this may be accommodated within some departments. However, any onsite monitoring should be agreed in writing and reaffirmed 7 days prior to any scheduled visit although this may be subject to change depending on local situation and to ensure that the visit continues to be in line with the current Government guidelines. In relation to pandemic situations visits should be sensitive to both National and local lockdown restrictions. External Monitors should be identified and agreed prior to any visit and only those who have been agreed may attend.

3.2) Monitoring Preparation

3.2.1)
On receipt of notification from the Sponsor or CRO of the requirement for remote monitoring an agenda and monitoring schedule should be provided to the site study team. In order to facilitate remote monitoring the study team must notify corporate R&I of the remote monitoring notification and restricted temporary access will be granted to EDGE in order that the study Monitor can view and review relevant study documents.

3.2.2)
It is the monitors' responsibility to communicate with the site the documentation that is required to complete the remote monitoring process. The Monitor must communicate in writing any documentation that they will require to complete the monitoring review a minimum of 7 days prior to the review date. The site research team will then endeavour to upload copies of requested documents anonymising as appropriate. All documents required for review will be placed on EDGE within the specific study RED LEVEL in a file named 'REMOTE MONITORING'. A copy of the monitoring request should be uploaded alongside the schedule and requested review documents. All documents should be named using the naming convention detailed in the general documents section of EDGE.

3.2.3)
The minimum documents required but are not limited to the following;

- Current delegation log
- Protocol – signature page
- Local Pharmacy Manual/ Laboratory Manual (where appropriate)
- IMP storage temperature log
- Screening Log
- Enrolment log
- Local approvals and accreditations where applicable
- Selected Case Report Forms identified by the Monitor prior to the remote monitoring visit which are not available electronically. Access to medical records for source data verification SDV will be as described in the video conferencing section 3.4 outlined below. To note it is not considered reasonable that 100% CRF SDV will be completed remotely.

3.2.4)
During the remote monitoring process, it is imperative that both regulatory and legislative requirements are considered and observed. If documentation with patient identifiers is required a system must be in place that complies with the relevant Information Governance legislation (Data Protection Act 2018) to ensure that any information shared is restricted to the Monitor and is not downloaded or shared from the EDGE database. To mitigate risk, documents should be uploaded in pdf and assurance should be ascertained that a .pdf download blocker has been installed on the device(s) used

in the monitoring process. It is the Monitors responsibility to ensure the confidentiality of any data shared with them on EDGE. All processes should be in line with the Monitor use of EDGE Risk Assessment (Appendix 1) Confirmation that the Monitor has downloaded such a blocker must be received prior to EDGE access being granted.

3.2.5)
During monitoring, the research team should make themselves available to the monitor for the entirety of the agreed schedule to answer any questions. It is advised that there is a contact number given to the Monitor to best ensure that contact can be made. The site study team should also ensure that they have the following available as they would with on-site monitoring;

- Trial Master File (TMF) or Investigator Site File (ISF)
- All consent forms
- All case report forms
- Any medical notes as requested by the Monitor prior to the visit.

3.2.6)
Should the Monitor wish to have a virtual meeting with the study team or relevant support services a meeting will be arranged by the site study team using Microsoft Teams or another appropriate platform as agreed in advance with UHL R&I and will be arranged in accordance with the monitoring schedule. Any site room or resource requirements will be met by the study site team. Documentation unable to be uploaded to the EDGE system may be shared in conference call with the Monitor in order that they may validate electronic records. Any shared documents should be appropriately anonymised and should be detailed in the monitoring report for posterity.

3.2.7)
At the end of the monitoring visit notification should be sent from the site study team to corporate R&I RIAdmin@uhl-tr.nhs.uk requesting that any temporary granted EDGE access is revoked. It is essential that the individual details are clear to ensure that the correct access rights are revoked.

3.3) Remote Source Document Verification with video conferencing screen sharing.

3.3.1)
It is not possible to grant remote access to hospital systems to complete Source Document Verification (SDV). Where there is a requirement for SDV documents screens may be shared via remote video conferencing as outlined below. The Sponsor or CRO must have a relevant SOP or equivalent in place to outline any remote monitoring activities.

3.3.2)
Prior to agreeing a monitoring visit and prior to any monitoring activity occurring the following conditions should be satisfied and the Sponsor or CRO must provide an agreement to confirm that:

a) No screen shots will be taken during the process of screen sharing
b) The video conference will not be recorded
c) There will be no printing, emailing or downloading of any records or that this facility is disabled by the system
d) The location of the monitor's access will be agreed, this must be a private location whereby only the monitor has access to the conferencing.
e) The Monitor must confirm that they will be alone in the room/area and will not allow anyone else to see their screen or overhear the conversation. This will be reaffirmed by the study team prior to any sharing.

f) The Monitor must confirm that the device used for the video conferencing has adequate security, including adequate firewalls, secure log-in and passwords etc, and must not be left unattended and accessible.

3.3.3)
Microsoft teams is the approved platform for video conferencing within the UHL. Any other platform, software or system will require prior agreement from the UHL R&I Office with clear indication as to the reasons that MS Teams is not suitable to meet requirements.

3.4) Monitoring schedule deviations

3.4.1)
Any deviations to the monitoring schedule that may include the possibility of additional associated risk must be notified to the Head of Research and Innovation and Datix or other associated reporting may be required.

3.5) Monitoring record

3.5.1)
It is expected that any monitoring remote or otherwise is recorded in the TMF/ISF on the relevant template. For the record of remote monitoring using the EDGE system the record of monitoring should also be uploaded to the relevant 'remote monitoring' electronic file. A file note should be completed for any documentation that was requested to be shared beyond that uploaded to EDGE. A copy of the monitoring record along with any completed corrective action plans should also be filed accordingly.

4) Responsibilities

4.1)

	Responsibility	Undertaken by	Activity
1.	Site Study Team	Site Study Team	Facilitate Remote Monitoring as directed by Sponsor
2.	Site Study Team	Site Study Team with support from R&I	Facilitate access to study record on EDGE if required.

5. Who Guideline Applies To

All staff within UHL and external to UHL who are delivering research.

6. Guideline Standards and Procedures

The SOP is detailed so the process is clearly followed. No flowchart is provided / required.

7. Education and Training

None

8. Monitoring Compliance

8.1)

What will be measured to monitor compliance	How will compliance be monitored	Monitoring Lead	Frequency	Reporting arrangements
Specific research studies	Study monitoring or audit review	Carolyn Maloney	As and when	A report will be issued

9. Supporting Documents and Key References

9.1)

SOP C-2028 – Appendix 1
Data Protection Act 2018

10. Key Words

10.1)

Research, Innovation, Remote, Monitoring, EDGE

11. Contact and Review Details

11.1)

CONTACT AND REVIEW DETAILS	
Guideline Lead (Name and Title) Lisa Wann R&I manager	**Executive Lead** **Medical director**
Details of Changes made during review: **Review and update**	

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This table is used to track the development and approval and dissemination of the document and any changes made on revised / reviewed versions

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