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| <h1>ICHT Remote Monitoring and Auditing</h1> | |
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| Approved by: Keith Boland, Senior Clinical Trial Manager | Date: |

| Version | Date | Reason for Change |
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| Version 1.0 | 11 June 2020 | New Procedure |
| Version 2.0 | 18 March 2021 | Change of Process |
| Version 3.0 | 11 October 2021 | New template associated with the SOP |
| Version 4.0 | 09 Feb 2024 | 3yr SOP Review |

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1. PURPOSE

This SOP describes the procedure to facilitate urgent remote monitoring or auditing at Imperial College Healthcare NHS Trusts during exceptional times when on-site visits cannot be facilitated.

This procedure applies to all sponsors, including Imperial College and Imperial College Healthcare NHS studies. This SOP will apply at any time as determined by R&D, the study Principal Investigator or the head of the research department.

2. INTRODUCTION

Remote monitoring and auditing carries information governance risks and additional operational burdens for staff. Therefore, source data verification and other activities which require access to site documentation should be undertaken on site, wherever possible. However, in limited circumstances (e.g. during an emergency or pandemic) it may be necessary to temporarily restrict access to the research site, in which case urgent monitoring or auditing activities will need to be done remotely.

This SOP is designed to ensure that when required, remote monitoring or auditing is conducted according to all applicable regulations, including the Clinical Trials Regulations, Data Protection Act and UK General Data Protection Regulation. Information which may identify the participant as a unique individual (such as full name, address, post code, MRN or NHS number) may not be transferred or stored off site.

During times when site access is restricted, there are likely to be significant burdens on staff and reduced capacity to support usual activities. Accordingly, remote monitoring or auditing will be permitted only where it is urgent. Other monitoring or auditing activities should be deferred wherever possible until access to on-site documentation can resume.

It is the sponsor's responsibility to ensure monitoring activities are consistent with the monitoring plan. If required, and not previously in place, changes to a monitoring plan are now a non-substantial amendment not requiring further study wide review or R&D agreement (i.e. category C). From November 2020, these should be submitted using the amendment tool, sent directly to sites and implemented on the date specified by the sponsor.

3. PROCEDURE

3.1 PowerTrials Monitoring

ICHT have implemented a process to allow for remote access to medical records and monitoring via the cerner and PowerTrials platform. For studies where all study data is accessible via PowerTrials, remote monitoring can be done via PowerTrials. For further information on the process of requesting, granting,

managing and revoking access to studies in PowerTrials for external Monitors, please refer to the separate SOP and contact imperial.powertrials@nhs.net

3.2 Alternative manual remote monitoring

3.2.1 Planning a Remote Visit

The sponsor must ensure that the monitoring plan allows for remote monitoring to be undertaken. The sponsor representative should email the site contact to request a remote monitoring visit. This request should set out the following:

- Proposed date(s) of visit
- Reason for urgency (e.g. safety review, upcoming data lock etc.)
- Specific data required for review (i.e. participant study ID numbers, visits and worksheets, pharmacy records, etc.)
- If video-conference to view documentation or a phone call with study staff is required

The study contact will confirm whether or not the visit can be accommodated. This may require discussion with the PI or other study staff.

3.2.2 Preparation of Study Documentation

A member of the study team will prepare the requested documents so that participant identifiable data (PID) cannot be seen either on webcam or on scans of the relevant documents as pdf files. They are responsible for redacting PID and labelling the scanned records with the participant initials and study ID number.

No permanent changes should be made to the original source documents. The most efficient ways of redacting PID are:

1. Place something removable and opaque (e.g. post-it note) over the PID before it is shown on webcam or before scanning.
2. Remove the PID after scanning using Adobe Acrobat or equivalent software.

Photocopying and redacting PID on the photocopied document is not recommended, as this is usually more time consuming and results in a lower quality scan.

Once complete, if hard copy documents will be used on a webcam then a quality control check should be undertaken by a colleague to ensure that all PID is redacted and would not be viewable on a webcam. It should be ensured that documents are labelled with the participants study ID. These checks should be documented in writing.

When using scanned documents, these should be transferred to a colleague to check that PID has been properly redacted and that each document is labelled with the participant's initials and study ID. The colleague should reply by email to confirm the check has been done.

| Participant Identifiable Information (PID) | |
|--|-----------------------------|
| Information to be redacted | Information that may remain |

| | |
|---|-------------------------|
| Name (first name and surname) including names of relatives / personal carers / GP | Study number (required) |
| Home address / GP address | Initials |
| NHS number | Date of birth / Age |
| MRN number | Sex |

For further information refer to the Trust's Data Security and Protection Policies ([Patient data and confidential patient information - NHS Digital](#)).

3.1. Transfer of Study Documentation

Information should always be transferred using encrypted email via an NHS.net account. This allows secure transfer of files up to 5GB and enables the sender to remove access from the monitor / auditor following the remote visit. Full instructions are available at: [Guidance for sending secure email \(including to patients\)](#)

The recipient (monitor or auditor) will need to create an account via Egress in order to access the documents.

Immediately after the monitoring visit has finished, the sender should follow the instructions to revoke access to the Egress email.

3.2. Meetings, Phone-calls and Teleconferences

If required, the monitor / auditor may meet virtually with the study team via telephone, Microsoft Teams or equivalent video-conferencing software. It is permitted for redacted documentation to be shown on webcam for the monitor/auditor to review during these meetings. A member of the study team should always be present to undertake this activity, documentation should not be left on screen for an indeterminate amount of time and screen shots should not be taken in any circumstances. It is not permitted to allow non-NHS staff remote desktop access. Identifiable patient records must never be shared or discussed using video-conference software.

4. RESPONSIBILITIES

It is the sponsor's responsibility to ensure that any risk assessments for changes to the monitoring plan are undertaken, and that appropriate amendments are in place.

It is the PI and study teams' responsibility to put in place measures to facilitate remote monitoring to ensure that remote monitoring is carried out as per this SOP and that the sponsor and monitors involved are aware of these requirements.

Any deviations from this SOP or information governance breaches must be reported to the Trust Data Protection Office (imperial.dpo@nhs.net) and the Research Governance & Integrity Team (rgit@imperial.ac.uk).

5. REFERENCES

[Patient data and confidential patient information - NHS Digital](#) (Last Cited: 16 May 2023)

[Email Encryption Guide](#) (Last Cited: 16 May 2023)

[Making changes to a research study to manage the impact of COVID-19 - Health Research Authority \(hra.nhs.uk\)](#) (Last Cited: 16 May 2023)

Standard Operating Procedure for Access Management to Cerner PowerTrials for External Clinical Trial Monitors at Imperial College Healthcare NHS Trust (ICHT)

6. APPENDICES

The following Appendices list the following Templates associated to this SOP, which can be found on the SOP which can be found on the [SOP, Associated Documents & Templates page](#).

**Appendix 1 Remote Access, Monitor & Auditor Declaration form –
RGIT_TEMP_071**