

STANDARD OPERATING PROCEDURE (SOP)

**TITLE: MANAGEMENT OF REMOTE AND ON-SITE
MONITORING VISITS**



**DO NOT USE THIS SOP IN PRINTED FORM WITHOUT FIRST CHECKING IT IS THE
LATEST VERSION**

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TITLE: MANAGEMENT OF REMOTE AND ON-SITE MONITORING VISITS



1. PURPOSE:

The purpose of this SOP is to establish a standard procedure for the management of remote and on-site monitoring visits, which are conducted to assure protection of rights and safety of human subjects, and quality integrity of clinical trial results.

2. SCOPE:

All clinical trials conducted at Epworth.

This SOP can be used as guidance for other clinical research projects where monitoring is required at the discretion of either the Sponsor, Investigator or the approving HREC.

3. APPLICABILITY:

This applies to all Epworth employees, non-employed staff and Visiting Medical Officers (VMOs) and to all relevant external persons or parties engaged in the research activity at Epworth.

4. GLOSSARY OF TERMS:

Please refer to Epworth SOP Glossary of Terms (see [Related Documents](#)).

5. PROCEDURE:

The Principal Investigator (PI) is responsible for ensuring monitoring visits for the clinical trial is conducted in accordance with this SOP. The PI can delegate at his/her discretion certain trial duties to individuals where appropriately qualified by education, training and experience (see also [SOP-TM-14 Delegation of Duties](#)). Delegation of trial activities must be recorded on the delegation log. The PI remains responsible for any delegated activity.

5.1 On-site Monitoring Visit

5.1.1 Visit Preparation

- The Sponsor (designee/Monitor) should provide at least 2 weeks notice prior to the intended visit.
- Upon notification from the Sponsor (designee/Monitor) of the scheduling of an upcoming monitoring visit, all involved trial personnel will be notified of the planned dates for the visit. Visit dates and availability of key personnel will be confirmed with site personnel and the Sponsor (designee). An appropriate work area for the monitoring visit will be reserved.
- Previous monitoring report(s) should be reviewed if relevant (or initiation report if first monitoring visit), recent telephone contact reports or e-mails and establish outstanding actions.
- All regulatory documentation and case report forms (CRFs) should be up to date and available for review at the monitoring visit.

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- All data queries received prior to the visit date should have been resolved prior to the monitoring visit.
- All the necessary data, including trial participant medical records, should be available for review at the time of the monitoring visit (see also *SOP-TM-07 Source Document Management*).
- See [APPENDIX A](#) for instructions on how to set-up Monitor access to Epworth Scanned Medical Records (SMR). If required at least 5 business days notice is required to set-up access to Epworth SMR.
- If direct access to the SMR is not possible, the PI or delegate should print the relevant SMR documents and certify them as a true copy. These copies of the SMRs will be filed in the participant folder before each monitoring visit.
- The investigational product (IP) should be securely stored according to the instructions in the protocol (e.g., temperature or light specifications) and all accountability records should be updated for the monitoring visit. See [SOP-TM-04](#) for procedures related to receipt, storage, dispensing, return and destruction of investigational medicinal products.
- Prior to the Monitor's arrival, the Investigator Study File (ISF) will be checked to ensure it is up-to-date and available for when the Monitor arrives.

5.1.2 On-site Visit

- The PI and trial team should allow time to discuss and answer any queries raised, and if possible, make any necessary corrections during the visit.
- At the end of the monitoring period, the Monitor should sign the Site Visit Log which is filed in the ISF and meet with site personnel for debriefing. The Monitor will review the findings of the monitoring visit

5.2 Remote Monitoring

In agreement with Sponsor and PI monitoring activities may take place remotely. Written documentation of the terms of this arrangement including any associated costs must be filed in the ISF.

The conduct of remote monitoring visits should not replace the conduct of on-site visits entirely.

SiteDocs Portal (SiteDocs) is the preferred platform for facilitating remote monitoring activities at Epworth.

5.2.1 Preparation

- The conduct of remote monitoring visits should be no more frequent than on-site visits.

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- Sponsor (designee/Monitor) will notify all involved trial personnel (i.e. PI and/or CRC) of the intention to conduct a remote monitoring visit. This notification should be at least 2 weeks prior to the visit and include the following details:
 - the planned dates of this activity
 - the planned times this activity will be conducted each day (e.g. 9am -4pm)
 - the documents required for review (e.g. data to verify eligibility, trial end points for specified trial participants)
- The study team and Sponsor will agree the platform to be used for the remote monitoring visit including any associated costs (if not previously agreed and documented).
- Where SiteDocs is the agreed platform the trial personnel will ensure the following prior to uploading:
 - the PI or delegate has certified on the first page of the source document that the scanned copy is a true copy of the original source; and
 - Source document includes page numbers (i.e. x of x) on each page to keep track of what is certified. These may need to be recorded on each page if not pre-existing.
- The trial personnel will keep a record of the time taken to prepare and upload supporting documentation for remote monitoring for billing purposes.
- Once uploaded to SiteDocs, the trial personnel will ensure any medical record documents downloaded from Epworth SMR are permanently deleted from the local drive (see also [APPENDIX B](#) for how to extract documents from Epworth SMR).
- The trial personnel will ensure the trial monitor has access to the system by sending an email to the Epworth SiteDocs Portal Administrator (research@epworth.org.au) at least 5 business days prior to the remote monitoring visit with the following information:
 - External user name and email address
 - Epworth study reference number
 - Dates and times of required access
 - Number of participant folders to be accessed (if required for set-up purposes)
- Prior to authorising external user access for this purpose the study team will need to provide evidence/confirmation of the following:
 - HREC application and PICF adequately covers sponsor access to identifiable participant information (e.g. for the purpose of monitoring or audit)
 - Written agreement with Sponsor covering terms of use

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- External user has completed required SiteDocs training (training can be arranged by emailing request@trialdocs.com.au)

5.2.2 Remote Visit

- Remote monitoring activity must only occur on the days and times agreed.
- Once the remote monitoring visit has occurred the sponsor (designee/Monitor) will have their SiteDocs access revoked from the remote monitoring folder.
- Source documents should be removed from the SiteDocs remote monitoring folder once the monitor has completed their remote monitoring visit, unless needed for a future monitoring visit, and providing the data can be subsequently sourced again if required.

5.3 Post-Monitoring Visit Follow-up

- Upon receipt of the Monitoring visit issues (mainly reported in a follow-up letter from the Monitor), the PI, should provide responses and any follow-up information as required in a timely manner.
- Any relevant communication from the Trial Monitor should be filed in the ISF.

6. REFERENCES & RELATED DOCUMENTS:

The Epworth Research Policy, handbook, SOPs and supporting forms and templates can be found on the [Epworth Resources for Researchers](#) webpage.

- [Integrated Addendum to ICH E6\(R1\): Guideline for Good Clinical Practice E6\(R2\) - Annotated with TGA comments](#)

6.1 Related Forms and Templates

- N/A

6.2 Related SOPs

- SOP-TM-04 Investigational Medicinal Product Receipt, Storage, Dispensing, Return And Destruction
- SOP-TM-07 Source Document Management
- SOP-TM-14 Delegation of Duties
- SOP-Glossary-of-Terms

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7. VERSION CONTROL

Document History	
Version	Summary of Changes
1.0	N/A – First Issue
2.0	Section 5.2: Inclusion of guidance for remote monitoring. Appendix A: instructions included on how to set-up Trial Monitor access to BOSSnet for monitoring purposes (previously in SOP-TM-07) Appendix B: inclusion of “how to guide” on exporting documents from BOSSnet. Minor formatting.

APPENDIX A: SETTING-UP TRIAL MONITOR ACCESS TO BOSSNET (ON-SITE MONITORING ONLY)

Access to Epworth SMR (BOSSnet) is strictly controlled to ensure confidentiality of patients' medical and personal information. Clinical Trial Monitors are regarded as "non-staff" and do not have the same level of access to medical records as Epworth employees. If Source Data Verification involves reference to electronic records a temporary account must be created by IT. This temporary account provides restricted access to only those patients identified as participating in the trial to be monitored.

For IT purposes there are two types of non-staff accounts:

- Monitors who **have never had** IT access before and need to have an account created
- Monitors who **have had** IT access before and need to **have their account re-activated prior to any monitoring visit** (e.g. their previous password may have expired between visits).

PROCEDURE

The PI or delegate is responsible for requesting IT access for Clinical Trial Monitors.

Remember to allow at least 5 business days for the account to be created or re-activated by IT.

For monitors who have NEVER monitored at Epworth before:

- This person will need to have a new account **enabled**.
- Go to the IT website *Non-Staff IT Access Request form*:
<https://legacyintranet.epworth.org.au/forms/iscomputeraccess/NonStaffReq.asp>
- In the "staff member's manager" provide Trial Co-ordinator details.
- Cost centre is "Research, Clinical Trials, and Governance". Please pick your division as appropriate for the External Contractor.
- When you click BOSSnet a small text box appears. It asks for you to identify the name of another person who does the same role as the monitor. For this request put your name in this box (see below)

This person will require access to the following applications:

<input type="checkbox"/> Labour Hours Database website - The Labour hours data entry program <small>This provides an icon only. From within the Labour Database, staff will request cost center access from managers.</small>
<input type="checkbox"/> iPM Patient Management System
<input type="checkbox"/> Point of Care
<input checked="" type="checkbox"/> BOSSnet - Clinical Portal If this person does exactly the same role as another person, what is that other person's name? <input type="text" value="Put YOUR name here"/>
This person requires access to these additional applications: <small>Please Note: Access to Standard MS Office (Word, Excel, Powerpoint and Outlook) and eMIMS is given to everyone.</small>

- In the last text box on the form you need to indicate:

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Based on Template SOP v2.3 23Oct2019		
Uncontrolled when downloaded or printed. Please ensure you are working from the current version.		

- a. Write a specific request for IT to action: "Please enable/re-enable non-staff user access to Windows and BOSSnet for John Smith"
- b. Enter start and stop dates for access to IT services like BOSSnet
- c. List the patients' names and UR numbers. Separate each patient with a semicolon (;) to make it easier for IT to read (see below)

This person requires access to these additional applications:
 Please Note: Access to Standard MS Office (Word, Excel, Powerpoint and Outlook) and eMIMS is given to everyone.

none

This person requires access to the following Departmental or Workgroup folders:
 That is O:\ drive folders, e.g. O:\departments\Day Surgery, or folders under O:\workgroups\

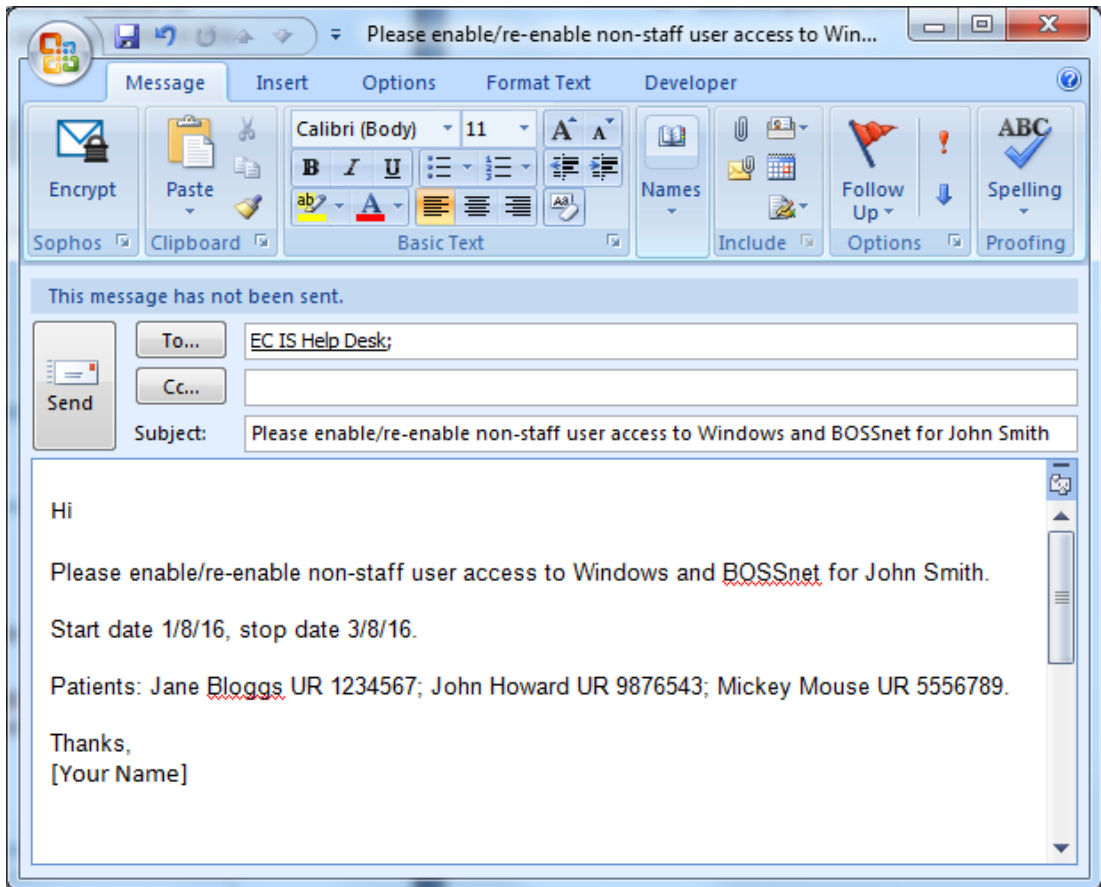
Start date 1/8/16, Stop Date 3/8/16. Jane Blogs UR1234567; John Howard UR 9876543; Mickey Mouse UR 5556789

Submit Request Clear Form

- Requests can take up to 5 business days to be processed.
- Once processed IT Department will provide an email directly to the Trial Monitor containing the appropriate Log-in details.

For monitors who have PREVIOUSLY monitored at Epworth before:

- This monitor will need to have their existing account **re-enabled**. There is a possibility the account has been disabled due to inactivity or mandatory requirement for a password change.
- Current clinical trials staff members now have authorised access to email IT directly (rather than use the form as indicated in section 5.1 for monitors who have never worked here).
- Send an email to the IT helpdesk - ServiceDesk@epworth.org.au
- Put something relevant in the Subject heading, e.g. *Please enable/re-enable non-staff user access to Windows and BOSSnet for John Smith.*
- Provide a start date and a stop date. This is so IT can provide the correct level of restricted access to coincide with the monitor's visit
- List the patients and their UR numbers in the email (see example below)



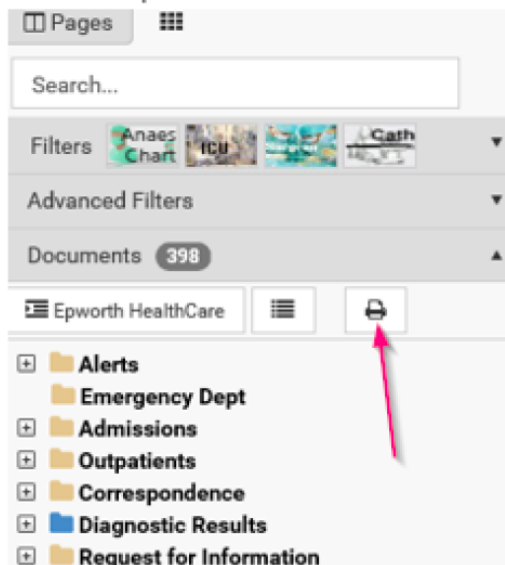
Further information regarding Epworth SMR access and management see:

- Epworth, 2019. [ICT - Acceptable Use of Resources Policy](#)
- Epworth, 2016. [ICT - Password Security Protocol](#)
- Epworth, 2012. [Health Information - Health Records Management Protocol](#)
- Epworth, 2019. [Scanned Medical Records – Access and Management Protocol](#)

APPENDIX B: HOW TO EXPORT DOCUMENTS FROM BOSSNET

1. Begin by searching the patient in BOSSnet and opening their Scanned Medical Record (SMR)

2. Click on the Printer Button



3. This will open to the "Bulk Record Export" page

Bulk Record Export

Previous Searches
Load Previous

Export Structure
Export as simple document list
Epworth HealthCare

Saved Export Templates
Select export template + New

Location
All Locations
Epworth Cliveden Hill Hospital
Epworth Eastern
Epworth Freemasons

Date Range
Clear selections

Episode Selection
 Only current episode: DOA - 29/01/2018, TLC Ward
Filter On Dates

Document Types
 Print Documents
Select the document types to export (Select none to export all)

Results
 Print Results

Document Watermarking
 'DO NOT SCAN' Watermark
 Export Summary Header
 Export Summary Footer

Check Bulk Print Parameters

Episode Selection List:
 DOA: 21/03/2017 11:47:00 AM
DOD: 21/03/2017 11:47:00 AM
Ward: Visiting
 DOA: 26/05/2017 6:43:00 PM
DOD: 26/05/2017 6:43:00 PM
Ward: No Episode
 DOA: 29/03/2017 1:21:00 PM
DOD: 14/06/2017 9:55:00 AM
Ward: ER Bethesda Wing L3 Rehab
 DOA: 3/07/2017 10:00:00 AM
DOD: 3/07/2017 11:00:00 AM
Ward: Richmond Physical Education/Physiotherapy
 DOA: 3/07/2017 11:00:00 AM
DOD: 3/07/2017 12:00:00 PM

Document Types List:
 Admission Details (MR1) - Admission Details (MR1) (MR1)
 Agreement to Participate in a Rehabilitation Program (MR3A) - Agreement to Participate in a Rehabilitation Program (MR3A) (MR3A)
 Agreement to Participate in Rehabilitation Program (eOP3A) - Agreement to Participate in Rehabilitation Program (eOP3A) (OP3A)
 Agreement to Participate in the Transitional Living Centre Program (MR3U) - Agreement to Participate in the Transitional Living Centre Program (MR3U) (MR3U)
 Alerts (MRA1) - Alerts (MRA1) (MRA1)

4. Select / Unselect the below fields to ensure the correct documents are exported

- Select “Epworth Healthcare” under export structure (pink highlighted section below)
- Unselect “watermark”, “header” and “footer” (pink highlighted section below)
- Select / unselect the episode, document type and results as per your request (green highlighted sections below) *NB: If specific admissions are required, the date range can be altered or you can select for a specific episode*

5. Save the document in the allocated location on the o drive with the desired document name

6. Once certified and uploaded to SiteDocs these documents must be **DELETED** from the shared drive.

For further information and training resources on BOSSnet refer to:

<https://intranet.epworth.org.au/BusinessServices/InformationTechnology/SitePages/BOSSnet%20Upgrade.aspx>