Basildon and Thurrock University Hospitals NHS
NHS Foundation Trust

STANDARD OPERATING PROCEDURE FOR RESEARCH

12. Monitoring Visit

1. BACKGROUND

According to ICH Good Clinical Practice (GCP) (5.18.1, 1996) the purposes of study monitoring are to verify that:

- the rights and well-being of human subjects are protected
- the reported trial data are accurate, complete and verifiable from source documents
- the conduct of the trial is in compliance with the current protocol, with GCP and the applicable regulatory requirement(s)

An important part of a monitoring visit is comparing the entries in the case report forms with the original source documents (e.g. laboratory results, patient hospital notes). This procedure is known as Source Data Verification (SDV).

2. PURPOSE

To Standard Operating Procedure (SOP) describe the preparation and procedure to follow during and following monitoring visits.

3. APPLICABLE TO

This SOP is applicable to all monitors, investigators, research and development (R&D) staff and service support teams.

4. PROCEDURE

The Sponsor will appoint Monitors and specify when monitoring visits are to take place. Monitoring visits will be arranged in advance by the Monitor with the site Research Team. The Principal Investigator (PI) and the Research staff working upon the study should be available during the visit. The Monitor will be appropriately trained and should have the scientific and/or clinical knowledge needed to monitor the trial adequately.

The Sponsor will specify the frequency and nature of monitoring visits. ICH GCP (5.18.3) specifies that in general there is a need for on-site monitoring, before, during and after the trial; however, in exceptional circumstances the Sponsor may determine that central monitoring in conjunction with procedures such as Investigator's meetings and training and extensive written guidance can assure appropriate conduct of the trial in accordance with ICH GCP.

4.1 Preparing for the Monitoring Visit

- The Research Officer should be advised of the booked monitoring visit at least 7 days in advance to enable them to check and update the Site File (pharmacy have responsibility to ensure the pharmacy file is up-do date)

- If Electronic Medical Records (EMR) access is required by the Monitor ensure that the Trial Support Officer is available to provide training and on-going IT support during the monitoring visit
- The Site Co-ordinator should be informed of the date of the monitoring visit
- The Site File, all Case Report Forms (CRF) and source documents should be available in readiness for the monitoring visit. If large numbers of patients have been recruited to a specific trial, the Research Staff should agree with the Monitor prior to the visit, which patient notes will be required for Source Data Verification
- The Research Staff overseeing the study should identify if participants case notes are in electronic format (EMR) and should ensure the Monitor has access to all appropriate systems as described below in section 4.2
- All Research Staff working on the study and the PI should be informed that the monitoring visit is scheduled
- An appropriate room or desk (with computer if EMR access is required) should be booked for the use of the Monitor during the visit
- The Monitor should inform Research Staff, in advance, if they plan to visit other departments (e.g. Pharmacy) during the monitoring visit

4.2 Electronic Medical Records Access

- At least seven days prior to monitoring visit, Research Staff should ensure the following have been completed by the Monitor and authorised by the Trust;
    1. Data Security and Confidentiality Undertaking form (DSCU)
    2. Windows Account (IT access)
    3. EMR account
- This will need to be undertaken for each Monitor
- The Associate Director of R&D is the authorised signatory for the IT forms for R&D, the DSCU form will need to be authorised by the Caldecott Guardian
- Either prior to, or on the day of the monitoring visit, ensure sufficient time has been allocated for R&D EMR trainers to train the Monitor on the EMR system, typically 30 minutes
- Post monitoring, R&D will audit the monitors EMR access
- If a Monitor has not accessed their Trust IT account within 30 days, this may need to be re-validated by IT
- At close of study, or when the Monitor ceases employment, all accounts will be disabled
- Monitor EMR access will be limited to read only

Under no circumstances should anyone log onto EMR and give/leave a Monitor unchaperoned access to the system.

4.3 During the Monitoring Visit

- A member of the Research Team should be available to meet the Monitor and ensure that all CRFs and required source data are available
- If required, the PI should be available for at least part of the monitoring visit
- The Monitor will normally require time to review the CRFs and source data alone and then arrange to meet a member of the Research team and/or the PI afterwards to discuss any problems or outstanding issues

- The specific activities of a Monitor are listed in ICH GCP (1996) section 5.18.4

4.4 Following the Monitoring Visit

- All source documents should be returned to the respective departments
- The Monitor will submit a written report to the PI summarising what has been reviewed and stating significant facts/findings, deviations and deficiencies, actions to be taken and/or actions recommended to secure compliance
- The written report should be filed in the Study File
- The Site Co-ordinator should have a copy of the monitoring visit report to enable them to address any significant issues
- A member of the Research Team should address all outstanding actions promptly

5. SUPPORTING DOCUMENTS

Data Security and Confidentiality Undertaking form (DSCU)

Windows Account (IT access) form

EMR account form

6. REFERENCES

ICH Guidelines for Good Clinical Practice, http://ichgcp.net/

7. APPENDICIES

None

8. DOCUMENT HISTORY

Revision Date	Previous Revision Date	Summary of Changes	Changes Marked
July 2014	-	Updated to reflect EMR element of monitoring visits	