STANDARD OPERATING PROCEDURE:

Monitoring Visit

SOP REFERENCE NUMBER	CLPG19 SOP 11 - Monitoring Visit
VERSION NUMBER	Version 1
REPLACES SEPT DOCUMENT	SOP 6 - Monitoring Visit (V1.0: 4 August 2014)
REPLACES NEP DOCUMENT	STANDARD OPERATING PROCEDURE: Monitoring Visit v2
KEY CHANGES FROM PREVIOUS VERSION	Updated for EPUT
AUTHOR	Research & Development Manager
CONSULTATION GROUPS	
IMPLEMENTATION DATE	
AMENDMENT DATE(S)	
LAST REVIEW DATE	
NEXT REVIEW DATE	
APPROVAL BY CLINICAL GOVERNANCE & QUALITY SUB-COMMITTEE	March 2018
RATIFICATION BY QUALITY COMMITTEE	April 2018
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SOP SUMMARY

Policy to describe the preparation for and procedure to follow during and following monitoring visits.

The Trust monitors the implementation of and compliance with this policy in the following ways:

Monitoring of implementation and compliance with this procedure will be undertaken by the Executive Medical Director, Research manager, Research lead, R&D department staff and R&D group.

Services	Applicable	Comments
Trustwide	✓	
Essex MH&LD		
CHS		

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1. BACKGROUND

According to ICH 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.

2. PURPOSE

To describe the preparation and procedure to follow during and following monitoring visits.

3. 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 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.

3.1 Preparing for the Monitoring Visit

- The Site File, all Case Report Forms 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
- All Research staff working on the study and the Principal Investigator should be informed that the monitoring visit is scheduled
- A room or desk should be booked for the use of the Monitor during the visit
- The Monitor should inform Research staff if they plan to visit other departments (e.g. Pharmacy) during the monitoring visit

3.2 During the Monitoring Visit

- A member of the Research Team should be available to meet the Monitor and ensure that all Case Report Forms and required source data are available
- If required, the Principal Investigator should be available for at least part of the monitoring visit
- The Monitor will normally require time to review the Case Report Forms and source data alone and then arrange to meet a member of the Research team and/or the Principal Investigator afterwards to discuss any problems or outstanding issues
- The specific activities of a Monitor are listed in ICH GCP (1996) section 5.18.4

3.3 Following the Monitoring Visit

- All source documents should be returned to the respective departments
- The Monitor will submit a written report to the Principal Investigator 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
- A member of the Research Team should address all outstanding actions promptly

4. OTHER RELATED PROCEDURES

None

5. REFERENCES

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