The University of Nottingham	**Sponsor Standard Operating Procedure**

Title: **TRIAL MONITORING**

SOP ref: **TA012** **Version and date:** **1.0 11th November 2008** **Superseded version and date:** **N/A**	**Effective from date :** **24th November 2008** **Review cycle:** **2yrs after effective date**

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Document history: **1.**	**Modification to previous version:** **1.**

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1. PURPOSE and SCOPE

PURPOSE:
To describe the process of, the topics to be covered and the report for trial monitoring.

SCOPE:
Applicable to all clinical trials.

2. NOTES

2.1 The International Conference on Harmonisation guidelines states that 'the purposes of trial monitoring are to verify that:
- 2.1.1 The rights and well-being of the trial participants are protected
- 2.1.2 The reported trial data are accurate, complete and verifiable from source documents
- 2.1.3 The conduct of the trial is in compliance with the currently approved protocol / amendments, with GCP and with the applicable regulatory requirements'

2.2 It is the responsibility of the Chief Investigator to determine the appropriate extent and nature of monitoring in relation to the trial risk assessment, based on trial objectives, purpose, design, complexity, blinding, size and endpoints of the trial.

2.3 Monitors should be familiar with the trial protocol, the investigational medicinal products used, the consent processes and the Sponsor's SOPs.

2.4 It is the responsibility of the monitor to check and report on the trial conduct, the trial documentation, that procedures have been followed in accordance with the protocol, GCP and with the applicable regulatory requirements.

3. CROSS REFERENCES

3.1	International Conference on Harmonisation GCP guidelines	Section 5.18
3.2	Trial Risk Assessment	SOP TA002
3.3	Site Responsibility (Delegation) Log	RF2 TA008

4. PROCEDURE

The **Chief Investigator** shall:

4.1 Appoint a monitor. This may be one or two persons to cover all sites or a separate monitor as each site. If the latter the local Principal Investigator may be delegated the responsibility of appointing a local monitor. The appointment must be recorded and authorised on the Site Responsibility (Delegation) Log, RF2 TA008.

4.2 In accordance with the trial risk assessment (SOP TA002) determine the frequency, scope and nature of the monitoring and responsibilities to be undertaken by the monitor. This should be documented in a monitoring plan either within the protocol or as a separate document.

4.3 The monitoring plan should take into account and include:
- 4.3.1 the number of participants, overall and at each participating site
- 4.3.2 the duration of the trial and expected accrual rates of participants
- 4.3.3 the number of participating sites and the frequency of visits therein
- 4.3.4 the percentage of source data verification (SDV) to be performed

The **Monitor** shall:

4.4 4.4.1 Familiarise themselves with the monitoring plan, the study protocol, the consent processes, and the processes for the IMP handling and dates of all authorisations.
4.4.2 Review any previous monitoring reports and the outcomes of any corrective action
4.4.3 Contact the site and agree the visit date and scope. Confirm:
4.4.3.1 the purpose and the areas to be covered
4.4.3.2 the documents to be provided by the site. This must include the Trial Master File or Trial Site File as appropriate.
4.4.3.3 the facilities, locations and equipment to be reviewed

4.5 During the monitoring visit and In accordance with the monitoring plan:

4.5.1 Check the responsibility (delegation) log, training records and CVs of all investigators for relevant qualification, GCP and trial specific training and that these are kept up-to-date
4.5.2 Verify that the site has all necessary approvals in place in order to conduct the trial and that no participants were recruited before these were in place
4.5.3 Verify that the current protocol and associated documents are being used and adhered to and that the ICH essential documents are being maintained
4.5.4 Verify that consent was obtained before each participant received any trial related procedures and that only eligible participants were enrolled
4.5.5 Where applicable, verify that IMP handling procedures are being adhered to and that all relevant IMP documentation is in place. Check that IMP supplies are adequate, stored appropriately and accounted for
4.5.6 Check that the source and trial specific documents are accurate, complete, kept up-to-date and maintained and that all data transfers are also accurate
4.5.7 Determine whether serious adverse events are appropriately reported and verified within the applicable regulatory requirements. Ensure that the Sponsor has been informed of any Suspected, Unexpected Serious Adverse Reactions (SUSARs) and that the relevant authorities have been informed
4.5.8 Check that all trial reporting - to trial committees, ethics committee and regulatory authority - has been done and is up to date
4.5.9 Review the facilities and any equipment used for adequacy, maintenance and security

4.6 Discuss with the Principal Investigator the monitoring 'finds' and agree on any necessary corrective actions.

4.7 Compile a monitoring report and pass to the Chief Investigator, retaining a copy for the Trial Site File. Sign and date the report.

The **Chief Investigator** shall:

4.8 Consider the monitoring report outcomes, verify and advise on any necessary actions to be taken. Inform any relevant trial committees (e.g. trial steering committee) and the Sponsor of any significant outcomes and the actions taken.

4.9 File the monitoring report in the Trial Master File.

5. FLOW CHART

Not applicable