North Bristol NHS Trust

Standard Operating Procedure

Monitoring

REFERENCE:	RI/QMS/SOP/014
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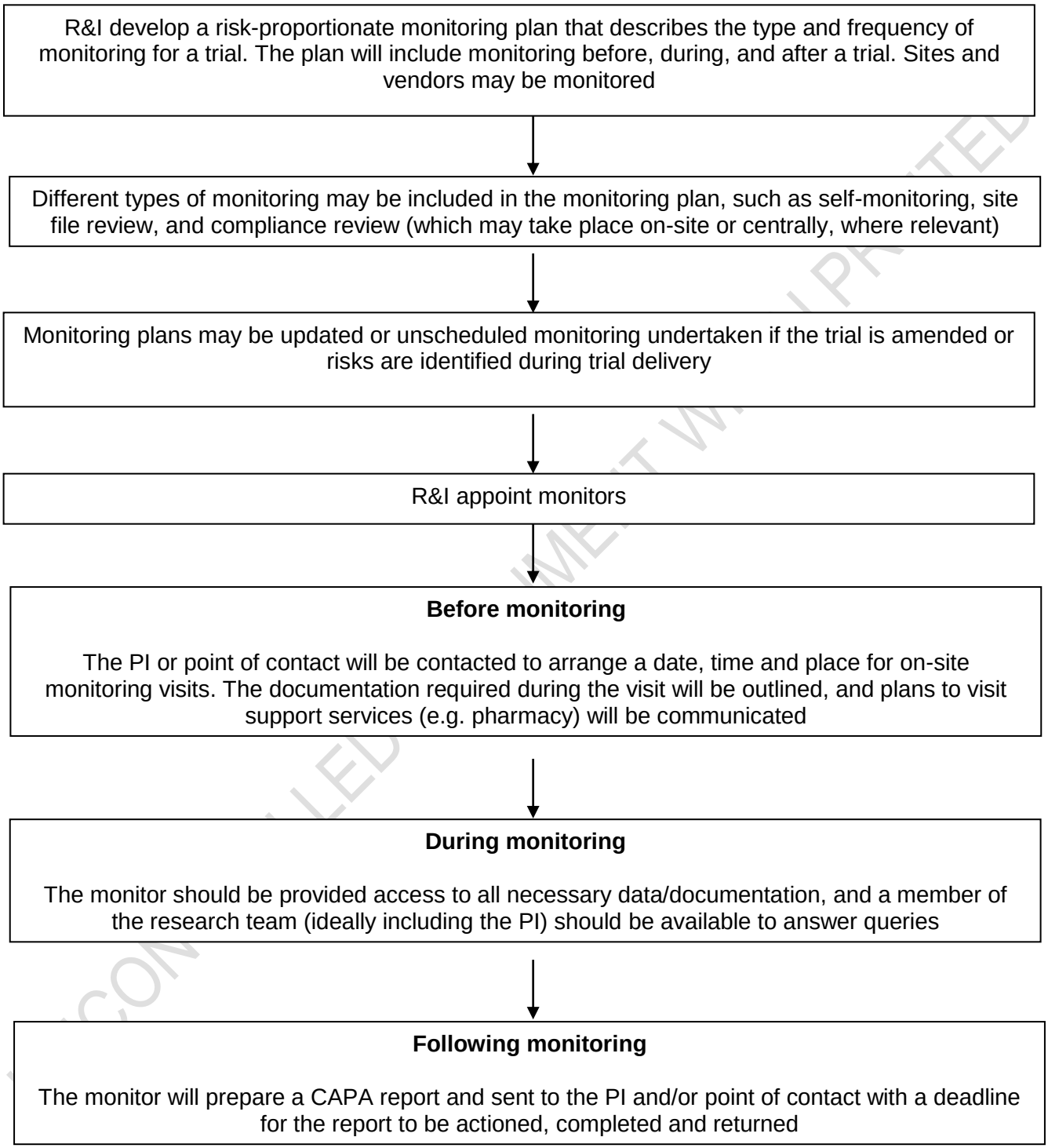
Document Version History

VERSION NUMBER	EFFECTIVE DATE	REASON FOR CHANGE
1.0	N/A	Prior to implementation of this SOP, a draft monitoring SOP was in use. To avoid any confusion with version control, the new published SOP was coded version 2.0.
2.0	13-06-16	Clarification that monitoring plans and risk assessment for NBT-sponsored CTIMPs will be reviewed on an annual basis. Separate guidance produced on preparation of a monitoring plan

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

Current versions of all Research & Innovation SOPs and accompanying documents are available online. If you are reading this document in printed form, please check that the version number and date match the most recent version on the Research & Innovation website: www.nbt.nhs.uk/research

i. SOP Flowchart



1. PURPOSE AND SCOPE

This SOP describes the risk-based procedures that will be used by R&I to monitor CTIMPs sponsored by NBT. The SOP also outlines the procedures to follow in preparation for, during and following the monitoring.

Monitoring is an integral role in the quality control of a research study and is designed to verify the quality of the study. According to ICH GCP (paragraph 5.18.1), the purpose of monitoring is to verify that:

(a) The rights and well-being of the human subjects are protected;

(b) The reported trial data are accurate, complete, and verifiable from source documents; and

(c) The conduct of the trial is in compliance with the currently approved protocol/amendments, with GCP, and with the applicable regulatory requirements.

Although this SOP focuses on CTIMPs sponsored by NBT, the principles in the SOP apply to all research sponsored by NBT.

Guidance relating to the preparation of a monitoring plan is provided in the Guidance Document: Preparation of a Monitoring Plan (RI/QMS/SOP014a), which is available on the R&I website.

2. DEFINITIONS/ABBREVIATIONS

AE	Adverse Event
CAPA	Corrective and Preventative Action
CI	Chief Investigator
CRF	Case Report Form
CTIMP	Clinical Trial of Investigational Medicinal Product
ICH GCP	International Conference on Harmonisation Guidelines for Good Clinical Practice
IMP	Investigational Medicinal Product
NBT	North Bristol NHS Trust
PI	Principal Investigator
PD	Protocol Deviation
R&I	NBT Research & Innovation Office
SOP	Standard Operating Procedure
ICH GCP	International Conference on Harmonisation Guidelines for Good Clinical Practice
Sponsor	The individual, company, institution or organisation, which takes on ultimate responsibility for the initiation, management (or arranging the initiation and management) of and/or financing (or arranging the financing) for that research

3. WHO SHOULD USE THIS SOP

This SOP is applicable to all investigators, research staff, monitors, service support teams, monitors, and R&I staff involved in research.

4. WHEN SHOULD THIS SOP BE USED

This SOP should be used when determining the frequency and type of monitoring required for NBT sponsored CTIMPs.

The SOP should be used when monitoring is being undertaken, in order to determine the procedure for preparing for, completing, and following up the monitoring.

5. PROCEDURE

5.1. Monitoring plan

NBT sponsored CTIMPs will be subject to a sponsorship risk assessment which will be completed prior to regulatory submission (for more information, see SOP on Applying for NBT Sponsorship (RI/QMS/SOP/007). Based on this risk assessment, R&I will determine a risk-proportionate monitoring plan for each trial.

The monitoring plan will document the methods that will be used for monitoring and the frequency of monitoring. As a minimum, the plan will detail the monitoring that will be required before, during and after the trial. This monitoring plan will be communicated to the CI.

The precise requirements of the monitoring plan will be determined on a case by case basis. Not all monitoring may be required to be conducted on site, therefore a proportionate approach should be taken when developing the monitoring plan. Please refer to the guidance document Preparation of a Monitoring Plan (RI/QMS/SOP014a) on the NBT website for further information.

The monitoring plan and sponsorship risk assessment will be reviewed on at least an annual basis throughout the trial by the Sponsor, and updated where necessary (for example, to take account of any trial amendments or risks identified during the conduct of the trial). Where this occurs, the updated plan will be communicated to the CI.

Where a review of the monitoring plan and risk assessment during the trial is not required, to ensure ongoing patient safety and data accuracy, unscheduled monitoring may be undertaken in addition to the monitoring outlined in the initial monitoring plan.

5.2. Monitors

R&I will appoint monitors who are appropriately trained and who have appropriate experience or knowledge to monitor the trial adequately.

The Sponsor may delegate certain monitoring activities to the research team although the Sponsor will hold the ultimate responsibility.

5.3. On-site visits

When on-site monitoring visits take place, the following will apply:

(a) Before the visit:

i. The monitor will notify the PI (or the point of contact, where the monitoring visit is to take place at non-recruiting establishments such as trials units).

ii. A date for the visit will be agreed by the monitor. This will usually be a minimum of two weeks in advance (except where critical risks are identified that need urgent mitigation, where triggered monitoring may be required sooner).

iii. Prior to the visit, the monitor will confirm exactly what documentation they will need available (e.g. site files, medical records)

iv. The monitor will confirm prior to the visit whether any other departments (e.g. Pharmacy) will be visited.

(b) During the visit:

i. The PI or other point of contact should ensure that an appropriate space is booked for use by the monitor during the visit. The monitor will require a quiet space where they can review the documentation.

ii. The research staff should identify if any documentation requested for review is in electronic format, and ensure the monitor has relevant access to these during the visit. If electronic data access is required by the monitor during the visit, the research staff should ensure that someone is available during the visit to provide any necessary training and ongoing Information Technology (IT) support.

iii. A member of the research team should be available to meet the monitor during the visit and to assist with any queries.

iv. Where possible, the PI should be available for at least part of the monitoring visit.

(c) Following the visit:

i. The monitor will prepare a written report in accordance with section 5.4 of this SOP.

5.4. **After monitoring has taken place**

After any monitoring has taken place, the monitor will prepare a written response, which will be submitted to the PI, or any other relevant members of the research team.

Where self-monitoring has taken place, this response will take the form of email feedback.

Where monitoring has included a site file review or compliance review, the response will take the form of a Corrective and Preventative Action (CAPA) report that will be sent via email. This report will include:

(a) Details of what has been reviewed.

(b) Any significant facts/findings, including deviations or deficiencies that have been identified.

(c) Actions to be taken and/or actions recommended to secure compliance.

The CAPA report should be reviewed by the PI and research team, and all actions addressed promptly. The monitor will give a deadline for the actions to be completed. The PI should complete the report to document what actions they have taken, and return it to the monitor by the agreed deadline.

5. DISSEMINATION AND TRAINING

SOPs will be distributed in accordance with the SOP on Preparation of Research SOPs (RI/QMS/SOP/001).

This SOP and any associated templates and forms will be uploaded to the Trust website (www.nbt.nhs.uk/research) and the Managed Learning Environment (MLE) system on the Trust intranet shortly after having been released.

All staff whose activities are subject to this SOP should ensure that they read and understand the content of this SOP.

The training log within the Investigator Site File/Trial Master File should be completed to document that members of staff have read and understood the content of this SOP.

6. RELATED SOPS AND DOCUMENTS

- ICH Secretariat
  Guidelines for Good Clinical Practice (E6 R2, Step 4, 2016)
  www.ich.org

- The following R&I documents are available on the NBT website: www.nbt.nhs.uk/research

RI/QMS/SOP/007	Applying for NBT Sponsorship
RI/QMS/SOP/014a	Preparation of a Monitoring Plan