BU R&KEO SOP 008 V1

Title: Monitoring of Clinical Research Projects	
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1. Scope

This Standard Operating Procedure (SOP) applies to all staff undertaking studies sponsored by Bournemouth University (BU), which involve NHS staff, patients, service users and resources.

2. Responsibilities

The *Clinical Governance Advisor (CGA)* is responsible for preparing a monitoring plan and for carrying out internal monitoring on aforementioned projects.

The *Chief Investigator (CI), Principal Investigator (PI), Researchers* and *their research team* are responsible for complying with monitoring requests and making available all the requested documents for review during the visit. They must also be available for queries or clarifications that will aid the monitoring visit.

3. Procedure

3.1 The monitoring process is intended to ensure that all projects sponsored by BU conform to the requirements of Good Clinical Practice (GCP), UK Policy Framework for Health and Social Care Research (2017), and relevant policies and legislation.

3.2 Internal monitoring is implemented as a measure to ensure that:

- The rights, well-being and safety of the study participants are protected;
- Trial data is secure, high quality, accurate, complete and well sourced (and the source documentation is available and accessible);
- The conduct of the trial is in compliance with the current approved version of the protocol and in line with any amendments;
- Approved and appropriately trained personnel are conducting study-related tasks, according to the delegation log;
- Participants have been consented using correct versions of documents;
- GCP is promoted and compliance with the guidelines are met, including but not limited to:
    - Good quality documentation (see BU R&KEO SOP 006);
    - GCP training compliance;
    - Trial Master File (TMF) and Investigator Site File (ISF) maintenance;
    - Equipment and facilities maintenance;
    - Participant recruitment according to protocol inclusion and exclusion criteria;

- Correct consent procedures;
- Participants are receiving all applicable study tests and procedures.

3.3 The CGA will use a pro-forma to monitor studies, using the appropriate document depending on the nature of the study (see appendix document). This will then in turn inform a monitoring report, which staff may discuss with the CGA, prior to implementing the actions.

3.4 An internal monitoring schedule for projects sponsored by BU will be adopted and reviewed continually, in order to ensure it remains fit for purpose. Should there be any requests made for expedited review, or concerns over any aspect of a given study, for example in the interest of participant safety, then the schedule will be altered accordingly.

3.5 BU staff are invited to request monitoring visits by the CGA should they have any concerns regarding a specific project. Likewise, any of the following may trigger a monitoring visit:

- Monitoring of other projects has raised concerns;
- A substantial amendment has changed the risk of a project;
- Non-conformances have been noted by other staff;
- The PI or CI has been changed;
- A serious breach has occurred, or likewise a protocol deviation or violation;
- Any safety concerns have been raised, or multiple SAEs have been reported for the same indication.

If any of the above events take place, then a full risk assessment will likewise take place.

<u>Monitoring Visits</u>

The CGA will carry out two types of monitoring visit:

- An internal monitoring visit on the Sponsor file, at which the CI and Researcher should be present; and
- An external monitoring visit, carried out at a participating site, at which the PI should be present, alongside members of the research team.

3.6 The PI/CI and study Researcher, will be contacted by the CGA to arrange an appropriate time to carry out the monitoring, and will request that all the files and associated documents are made available. Depending on the nature and scope of the study, the monitoring visit may be split over a number of days.

3.7 The PI/CI and Researcher, and any other members of the research team must be available at the end of the visit to answer any queries the CGA may have about the findings, prior to writing the final report. If the PI/CI or appropriate delegate fails to attend, then this shall be considered as non-conformance.

3.8 If a finding does not comply with GCP then this shall be conveyed in the report as non-conformance. This includes, for example; incorrect versions of documents being filed, incorrect versions of consent forms used, and incorrectly completed delegation logs.

3.9 If the finding could (or has the potential to) affect the rights, well-being or safety of study participants, then this may be considered as a *serious breach* (see BU R&KEO SOP 011). If this is the case, then the appropriate actions will be carried out in reporting these to the MHRA.

3.10 Any concerns relating to the financial, data governance, or legal implications of a finding, arising from the monitoring visit, will be highlighted to the appropriate contacts.

Monitoring Report

3.11 The monitoring report will contain not only the findings noted during the visit but also any recommendations and guidance relating to GCP guidelines. The report will be issued electronically (with the original requiring filing in the TMF) and will be sent within 7 days of the visit taking place, unless any of the findings require further discussion.

3.12 The research team will be given the opportunity to feedback on the monitoring visit and procedure so that further improvements can be made to the process.

4. Abbreviations and definitions

CGA	Clinical Governance Advisor
CI	Chief Investigator
GCP	Good Clinical Practice
PI	Principal Investigator
TMF	Trial Master File

5. Related documentation and references

BU RDS SOP 006 - File Management for Clinical Research

BU RDS SOP 011 – Safety Reporting

Sponsor file monitoring form – see appendix document

Monitor Form - participating sites April 2018 - see appendix document

UK Policy Framework for Health and Social Care Research. (2017). Health Research Authority.