BU RDS SOP 005 V2

Title: Deviations, Violations and Serious Breaches	
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Document History

Version	Description of update	Date Effective
1.0	Correction of typographical errors.	25/11/2020

1. Scope

1.1 This Standard Operating Procedure (SOP) applies to all researchers and BU staff participating in *interventional* research projects that are sponsored by Bournemouth University (BU).

1.2 Interventional projects not only include Clinical Trials of Investigational Medicinal Products (CTIMPs), but also studies including medical devices, surgical procedures, non-CTIMP drugs, or any project the Sponsor has deemed *interventional* (i.e. intervening in the patient's[1] care). Studies using technology may be categorised as interventional.

2. Responsibilities

The *Chief Investigator (CI)* is responsible for reporting serious breaches to the Sponsor (via the Clinical Governance Advisor) and the Research Ethics Committee (REC).

The *Sponsor* is responsible for reporting serious breaches in CTIMPs and device studies to the MHRA using the Notification of Serious Breach template provided by the MHRA within 7 days of becoming aware of the breach - http://www.gov.uk/good-clinical-practice-for-clinical-trials#report-a-serious-breach.

They should then file a copy of the notification in the Trial Management File (TMF).

3. Procedure

3.1 A *protocol deviation* is any change, divergence or departure from the study design or procedures defined in the protocol.

Examples of *protocol deviations* include:

- A participant's visit taking place on the incorrect date;
- Missed physical exam as outlined in the protocol for a particular visit;
- Missed or incomplete study procedure (e.g. renal function test).

[1] The term *patient* incorporates all service users.

3.2 A *protocol violation* is defined as any occurrence or event that significantly impacts the completeness, accuracy and/or the reliability of the study data. A violation may also significantly affect a participant's rights, safety or well-being.

Examples of *protocol violations* include:

- Failure to obtain informed consent;
- Failure to report serious adverse events (SAEs) as required in the protocol;
- Investigational Medicinal Product (IMP) labelling or dosing errors.
- Mishandled samples

Protocol deviations and protocol violations should be reported by the participating site's Principal Investigator. They are responsible for informing the Sponsor. The Sponsor should be contacted on researchethics@bournemouth.ac.uk. All correspondence and forms shall be filed in the TMF.

Serious breach reporting

3.3 A *serious breach* is defined as a breach that is likely to affect, or have the potential to affect, to a significant degree:

- The safety, physical or mental integrity of the research participants; and/or
- The scientific value of the research.

Examples of *serious breaches* include:

- Repeatedly failing to carry out a *safety* test on patients;
- Administering IMP to participants that had been stored incorrectly;
- The Investigator purposefully failed to stop trial medication according to protocol, following adverse test results for multiple patients.

3.4 When a serious breach occurs, the CI or delegate must ensure that it is reported to the Sponsor *within 24 hours* of being identified. The Sponsor is contacted on researchgovernance@bournemouth.ac.uk. The Sponsor must complete a Notification of Serious Breach form and send to the MHRA *within 7 calendar days* of being notified of the breach. All correspondence and forms shall be filed in the TMF.

3.5 The CI must also forward the form to the REC that provided the favourable opinion for the study within 7 calendar days, and to the R&D contact(s) at the site(s) where the serious breach occurred, copying in the Clinical Governance Advisor (CGA).

3.6 The CGA is responsible for follow-up notifications to the relevant authorities, and the Sponsor will keep the breach under review so that any corrective actions can be closed and so that they can identify any additional information or follow-up reports that should be forwarded to the MHRA, REC and R&D office(s). The Head of Research Development & Support or the appropriate Deputy Dean for Research & Professional Practice must likewise be informed of serious breaches.

3.7 In assessing the serious breach, the MHRA may request additional information. The CGA should be contacted to forward the requested documents and information when required.

3.8 The Investigator must not implement any deviation from or changes to the protocol without prior agreement from the Sponsor and the necessary approval bodies. If an investigator deviates from the approved protocol, then they must document and explain as to why this occurred and forward this onto the CGA at researchethics@bournemouth.ac.uk.

3.9 The Investigator (Chief or Principal), or Sponsor, may implement a deviation from or change of the protocol in the case of eliminating immediate hazard(s) to a trial participant without REC approval/favourable opinion, but must follow this up in writing with the study Sponsor – this is identified as an Urgent Safety Measure (see BU RDS SOP 011).

3.10 The CI/Sponsor must also contact and discuss the issue with a medical advisor at the MHRA, details on their website.

3.11 The CI must notify the MHRA (in the case of CTIMPs) and REC immediately. They should then submit an amendment to the MHRA (if applicable) and REC *within 3 days*. In this correspondence they should detail the reason(s) for the measures and the measures that were taken, with a description of the event.

Relevant NHS Research & Developments (R&D) and site PIs should be notified of the measures being taken immediately. The notification must be filed in TMF and ISF.

- Email the Sponsor at researchgovernance@bournemouth.ac.uk;
- Email the MHRA clintrialhelpline@mhra.gov.uk, mark the correspondence as 'Urgent Safety Measure', a substantial amendment will then need to be made covering the changes made as part of the Urgent Safety Measure;
- Email the REC who gave the favourable opinion, marking the email as 'Urgent Safety Measure';
- Email the relevant NHS R&D offices, marked as 'Urgent Safety Measure'.

3.12 The CI must discuss the implications of the Urgent Safety Measure on the conduct of the study, with the Sponsor, urgently.

4. Abbreviations and definitions

CGA	Clinical Governance Advisor
CI	Chief Investigator
CTIMP	Clinical Trial of Investigational Medicinal Product
IMP	Investigational Medicinal Product
MHRA	Medicines and Healthcare Products Regulatory Agency
R&D	Research & Development (Trust Research Governance)
REC	Research Ethics Committee
TMF	Trial Master File
SAE	Serious Adverse Event

5. Related documentation and references

MHRA Notification of Serious Breach form - http://www.gov.uk/good-clinical-practice-for-clinical-trials#report-a-serious-breach