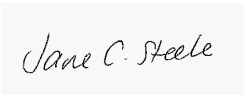
RESEARCH & INNOVATION SERVICES

UNIVERSITY OF SUSSEX

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Reporting Protocol and Good Clinical Practice Deviations and Breaches

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1. Purpose and scope

This Standard Operating Procedure (SOP) describes the procedure to be followed for reporting breaches of Good Clinical Practice (GCP) or the approved research protocol, arising in research studies conducted under the UK Policy Framework for Health and Social Care Research and sponsored by the University of Sussex.

This SOP applies to Clinical Trials of an Investigational Medicinal Product (CTIMPs), regulated under the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025; Clinical Investigations of a Medical Device (IMDs), regulated under the UK Medical Device Regulations 2002; and other health and social care research falling within the scope of the UK Policy Framework for Health and Social Care Research.

It applies to all Chief Investigators (CIs), Principal Investigators (PIs), research teams, and members of the Research Ethics, Integrity and Governance (REIG) team involved in the sponsorship, conduct, or oversight of such studies.

This SOP is intended to ensure that deviations are identified promptly, classified consistently, escalated appropriately, and reported to the relevant Research Ethics Committee (REC) and, where applicable, the Medicines and Healthcare products Regulatory Agency (MHRA), within statutory or regulatory timeframes. The principles of Good Clinical Practice referred to throughout this SOP are those set out in the International Council for Harmonisation Guideline for Good Clinical Practice E6(R3).

This SOP should be used in conjunction with the relevant University of Sussex research governance procedures, the University of Sussex Code of Practice for Research, and the study-specific protocol and risk assessment.

2. Abbreviations

CAPA	Corrective and Preventative Action
CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
GCP	Good Clinical Practice
HSC SSC	University of Sussex Health and Social Care Sponsorship Sub-Committee
IMD	Clinical Investigation of a Medical Device
ISF	Investigator Site File
MHRA	Medicines and Healthcare products Regulatory Agency
PI	Principal Investigator
REC	Research Ethics Committee
REIG	Research Ethics, Integrity and Governance
SOP	Standard Operating Procedure
T/SMF	Trial or Study Master File (T/SMF)
USM	Urgent Safety Measure

3. Background

A deviation is the general term for any departure from the approved protocol, from the principles of GCP, or both. The terms 'minor deviation' and 'minor breach' are used interchangeably to refer to deviations that do not meet the threshold of a serious breach and will be referred to throughout this document as minor breaches.

A serious breach is a breach of the protocol or of the principles of GCP which is likely to affect to a significant degree: (a) the safety or physical or mental integrity of research participants; or (b) the reliability, robustness or scientific value of the data generated.

Most breaches do not meet the threshold of a serious breach and are managed locally, with no requirement to notify the MHRA or the REC.

For non-CTIMPS, minor breaches should be documented in the Trial or Study Master File (T/SMF) and, where relevant, the Investigator Site File (ISF) and the Case Report Form, and reported to the sponsor within 7 days. There is no statutory duty to notify the MHRA of a serious breach in non-CTIMPs however, the HRA's standard conditions of REC favourable opinion require the sponsor to notify the REC.

For CTIMPs, minor breaches should similarly be documented in the T/SMF and, where relevant, , the Investigator Site File (ISF) and the Case Report Form, and reported to the sponsor within 7 days. The sponsor has a statutory responsibility to inform the MHRA and the REC within 7 days of becoming aware of any serious breach.

Clinical Investigations of a Medical Device (IMDs) follow a separate MHRA requirement and sponsors must notify the MHRA of all breaches (not just serious breaches) as soon as they are aware of the breach. In the case of a serious breach, the REC will also be informed.

4. Responsibilities

☐ The CI is responsible for:

- Monitoring the research, including its conduct, participants' safety and well-being and the ongoing suitability of the approved protocol.
- Monitoring adherence to the study protocol and GCP.
- Implementing, or supporting research sites to implement, any Urgent Safety Measure (USM) necessary to protect participants, and notifying the sponsor immediately where a USM has been taken.
- Adhering to the sponsor's and regulatory reporting requirements for breaches, as laid out in this SOP.
- Ensuring that all deviations are documented and reported to the sponsor within one (1) working day (serious breaches) or five (5) working days (minor breaches) of the CI or PI becoming aware.
- Ensuring that any CAPA are complete.

☐ The PI at each site is responsible for identifying and reporting breaches occurring at their site to the CI and/or directly to the sponsor without delay.

☐ Members of the research team are responsible for recording all breaches in the T/SMF and, where appropriate, the Investigator Site File (ISF) and the Case Report Form, and for escalating any breach to the CI/PI promptly.

☐ The sponsor is responsible for:

- Ensuring that effective procedures and arrangements are in place for reporting and monitoring research, including its conduct and the ongoing suitability of the approved protocol.
- Receiving deviation reports.
- Assessing whether a reported deviation meets the definition of a serious breach, in consultation with the CI and, where appropriate, external advice.
- Notifying the REC and, where applicable, the MHRA, of breaches within the required timeframe.
- Reporting breaches to the University of Sussex Health and Social Care Sponsorship Sub-Committee (HSC SSC).
- Overseeing implementation of Corrective And Preventative Action (CAPA) and monitoring for breach recurrence.

☐ The HSC SSC is responsible for monitoring the effectiveness of CAPA plans via trends in reported breaches.

5. Procedure

5.1. Identification and classification of deviations

5.1.1. Any member of the research team who identifies a deviation from the protocol or GCP must immediately report it to the CI or PI, as appropriate, and record it in the T/SMF, noting the date, nature, likely cause, and CAPA.

5.1.2. The CI or, where appropriate, the PI must assess the deviation to determine whether it meets the definition of a serious breach, see Section 3.

5.1.3. Where there are actual or potential impacts on participant safety or rights, the CI or PI should take immediate action to safeguard those involved in the study.

5.1.4. Minor breaches should be recorded in the T/SMF and reported to the sponsor via researchsponsorship@sussex.ac.uk using the Deviation Report to Sponsor (see Appendix A).

5.1.5. Serious breaches must be escalated immediately in accordance with Section 5.2.

5.2. Escalating a suspected serious breach

5.2.1. The CI or PI must notify the sponsor representative via researchsponsorship@sussex.ac.uk of a suspected serious breach within one (1) working day of becoming aware of it, using the Deviation Report to Sponsor (see Appendix A).

5.2.2. The notification should include:

- ☐ Study information.
- ☐ When the suspected breach occurred.
- ☐ A deviation report, including any USMs implemented.
- ☐ Deviation classification.

- ☐ Reporting timeframe.

5.2.3. Where immediate risk to participant safety exists, the CI or PI may take a USM without prior sponsor approval to protect participants and must inform the sponsor of the USM taken as soon as possible and no later than 24 hours following implementation.

5.3. Sponsor assessment

5.3.1. Upon receipt of a suspected serious breach notification, a sponsor representative will review the report in consultation with the CI and/or the trial Manager within the CTU, as appropriate, to determine whether the reported issue meets the definition of a serious breach.

5.3.2. If the sponsor obtains clear and unequivocal evidence that a serious breach has occurred, the sponsor will notify the MHRA. Investigation and corrective action may take place simultaneously with, or following notification.

5.3.3. The sponsor representative may seek advice from parties with relevant expertise as appropriate, whilst ensuring there are no unnecessary delays to onward reporting.

5.4. Notification to the REC and MHRA

5.4.1. Where a serious breach is confirmed in a non-CTIMP, a sponsor representative will notify the REC within seven (7) days of the sponsor becoming aware of the breach.

5.4.2. Where a serious breach is confirmed in a CTIMP, the sponsor will notify the REC and the MHRA GCP Team via GCP.SeriousBreaches@mhra.gov.uk within seven (7) days of becoming aware.

5.4.3. For IMDs the sponsor must notify the MHRA of all breaches (not only serious breaches) as soon as they are aware of the breach by sending the completed MHRA Protocol Deviation Tracker to info@mhra.gov.uk. For serious breaches the REC will also be informed.

5.5. Corrective and preventative action

5.5.1. The CI or PI must develop and implement a CAPA plan proportionate to the breach, addressing both the immediate issue and any root cause.

5.5.2. The CAPA plan will be reviewed by the sponsor who may request implementation of further actions.

5.5.3. The CI must ensure that CAPAs are completed in a timely manner.

5.5.4. The HSC SSC will monitor the effectiveness of the CAPA plan via reported trends.

5.6. Documentation, oversight and learning

5.6.1. All breaches, whether classified as minor breaches or serious breaches must be recorded in the T/SMF.

5.6.2. Lessons learned from breaches will be used to inform researcher training and updates to related SOPs.

6. Related documents

N/A

7. References

UK Policy Framework for Health and Social Care Research

Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025

UK Medical Device Regulations 2002

International Council for Harmonisation Guideline for Good Clinical Practice E6(R3)

University of Sussex Research Ethics Policy

Code of Practice for Research

MHRA Protocol Deviation Tracker

8. Appendices

Appendix A: Deviation Report to Sponsor

VERSION HISTORY

Version number	Effective date	Reason for update
1.0	12-Oct-2026	Original version

APPENDIX A. Deviation Report to Sponsor

The form starting on the following page must be used to record Protocol and GCP deviations and breaches to the sponsor (researchsponsorship@sussex.ac.uk). A suspected serious breach must be reported within **one (1) working day** of becoming aware of it.

Delete pages 1-7 of this document before completing the form.

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DEVIATION REPORT TO SPONSOR

SECTION 1: STUDY DETAILS	
Study title:	Click or tap here to enter text.
Chief Investigator:	Click or tap here to enter text.
Local Principal Investigator:	Click or tap here to enter text.
Sponsor reference number:	Click or tap here to enter text.
IRAS number:	Click or tap here to enter text.
Protocol version and date:	Click or tap here to enter text.
REC reference:	Click or tap here to enter text.

SECTION 2: REPORT INFORMATION	
Report compiled by (name and position on the research team):	Click or tap here to enter text.
Date report form completed:	Click or tap to enter a date.
Date reported to sponsor:	Click or tap to enter a date.
CI signature:	

SECTION 3: DEVIATION DETAILS	
Event date:	Click or tap to enter a date.
Deviation from GCP?	Choose an item.
Deviation from the protocol?	Choose an item.
Deviation number:	Click or tap here to enter text.
Participant identifier(s):	Click or tap here to enter text.

Please provide a brief description of the deviation, including the reason it occurred:	Click or tap here to enter text.
Please provide a brief description of any urgent safety measures or corrective actions taken and any preventative actions to avoid recurrence:	Click or tap here to enter text.

SECTION 4: DEVIATION CLASSIFICATION	
To what extent does, or could, this deviation affect the safety or the physical or mental integrity of research participants? Please explain your reasoning:	Click or tap here to enter text.
To what extent does, or could, this deviation affect the reliability, robustness or scientific value of the data generated? Please explain your reasoning:	Click or tap here to enter text.
CI (or, where relevant PI) classification of deviation:	Choose an item.
Date classification confirmed by sponsor:	Click or tap to enter a date.
Name of sponsor representative confirming classification:	Click or tap here to enter text.

SECTION 4: EXTERNAL REPORTING	
NON-CTIMPS	
Date REC notified of serious breach:	Click or tap to enter a date.
CTIMPs	
Date REC notified of **serious** breach:	
Date MHRA notified of **serious** breach:	Click or tap to enter a date.
IMDs	
Date REC notified of **serious** breach:	Click or tap to enter a date.
Date MHRA notified of **any** breach:	Click or tap to enter a date.