



STANDARD OPERATING PROCEDURE FOR REPORTING AND MANAGEMENT OF DEVIATIONS AND BREACHES IN NON-CTIMP RESEARCH

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1. PURPOSE

This Standard Operating Procedure (SOP) describes how breaches in NHS Tayside (NHST) and/or University of Dundee (UoD) sponsored non-CTIMP (Clinical Trial of Investigational Medicinal Product) research are identified, assessed, managed and, where required, reported by the Sponsor.

2. SCOPE

Applies to all NHST/UoD sponsored non-CTIMP studies.

It applies to studies that are not regulated as CTIMPs under the UK Clinical Trials Regulations.

3. RESPONSIBILITIES

Chief Investigator (CI):

- report significant breaches promptly, protect participants, notify Research Ethics Committee (REC)/funder where required.

Principal Investigator (PI) :

- notify CI immediately of any potential serious breach.

Sponsor:

- assess potential serious breaches.
- determine whether they constitute a serious breach.
- oversee Corrective Action and Preventative Action (CAPA).
- determine external reporting and maintain Sponsor records.

4. PROCEDURE

4.1 Definitions

Deviation: A deviation is when the study does not follow the approved protocol or study procedures. A deviation is not automatically a breach. A deviation is what happened and may be a breach following the outcome of an assessment. Most deviations can be managed locally by the study team (under the CI's responsibility).

Uncontrolled when printed. Please visit the [TASC website](#) for the latest version of this SOP.

Breach: A breach is when the study does not follow the approved protocol, the conditions of approval, Sponsor requirements, or other requirements that apply to the study.

Non-Serious Breach: A breach that does not need to be reported to the Sponsor as a potential serious breach.

Potential Serious Breach: A deviation or breach that may be serious and must be reported to the Sponsor for assessment.

Serious Breach: A breach that, following Sponsor assessment, is determined to have resulted in, or to have the potential to result in:

- significant harm to participants
- significant compromise of participant rights
- significant compromise to the scientific integrity of the research
- non-compliance with the conditions of ethical approval.

4.2 Local Management of Deviations and Non-serious Breaches

Deviations and non-serious breaches should be managed locally under the responsibility of the CI.

The CI or delegate must:

- record the deviation or breach in the study Breach and Deviation Log (Doc Ref 134).
- record the assessment and, for a non-serious breach, the reason it has been classified as non-serious.
- put any necessary CAPAs in place.
- review for repeated or wider problems.
- verify that any actions have been effective before closing the deviation or breach.

A deviation or non-serious breach must be reported to the Sponsor if it may be serious, is repeated, suggests a wider problem, or there is uncertainty about its classification.

4.3 Reporting a Potential Serious Breach

Potential serious breaches must be reported to the Sponsor without delay using the Sponsor Serious Breach Reporting and CAPA Form (Doc Ref 135).

Any immediate action needed to protect participants or research integrity should be taken without waiting for the Sponsor's assessment.

4.4 Sponsor Assessment

The Sponsor will assess the information and determine whether the matter is:

- not a breach
- a non-serious breach

- a serious breach.

The Sponsor will also determine any immediate actions, further investigation or CAPA required.

4.5 Sponsor Review and Management

Where appropriate, the Sponsor may convene a Sponsor Breach Review Group (SBRG) to review the breach, agree CAPA, determine whether external reporting is required and oversee the actions to completion.

4.6 External Reporting

The Sponsor will determine whether notification is required to the REC, Health Research Authority (HRA), funder, collaborating organisations, Data Protection Officer or other approving bodies.

Reporting will be undertaken where required by the conditions of favourable opinion, approval conditions, Sponsor agreements or applicable legislation.

Non-CTIMPs are not subject to the statutory MHRA serious breach reporting requirements under the UK Clinical Trials Regulations.

4.7 CAPA and Closure of Sponsor-managed Breaches

CAPA must address the root cause, corrective and preventive actions, responsibilities and timelines.

The Sponsor must verify that the actions have been completed and are effective before closing a Sponsor-managed breach.

The assessment, actions, supporting evidence and closure decision must be documented in the Trial Master File.

4.8 Data Protection

As defined by UK General Data Protection Regulation (GDPR). All suspected or confirmed personal data breaches must be reported to the Sponsor immediately. A personal data breach may also constitute a protocol breach or serious breach and should be considered separately.

5. ABBREVIATIONS & DEFINITIONS

CAPA	Corrective Action/Preventative Action
CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
GDPR	General Data Protection Regulation
HRA	Health Research Authority
MHRA	Medicines and Healthcare Products Regulatory Agency
NHST	NHS Tayside
PI	Principal Investigator

REC Research Ethics Committee
SBRG Serious Breach Review Group
SOP Standard Operating Procedure
TASC Tayside Medical Science Centre
UoD University of Dundee

6. ASSOCIATED DOCUMENTS & REFERENCES

Doc Ref 134: Breach and Deviation Log

Doc Ref 135: Serious Breach Reporting and CAPA form

7. DOCUMENT HISTORY

Version Number:	Reviewed By (job title):	Effective Date:	Details of editions made:
1	Patricia Burns	20/10/2026	New SOP. Developed following separation of CTIMP and non-CTIMP breach management procedures. New Doc Refs 134 & 135 are associated with this SOP.

8. APPROVALS

Approved By (job title)	Date
Dr Valerie Godfrey (TASC Quality Assurance Manager) on behalf of TASC Clinical Research Guidelines Committee	15 Oct 2026
Dr Steve McSwiggan, Senior R&D Manager NHS Tayside	15 Oct 2026