Research Governance Standard Operating Procedure 8 – Quality events

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v110	23/04/2026	Emily Avent	Links to internal documents updated; typos corrected; reference to UK clinical trials regulations updated	v1.1	Rachel Davies	28/04/2026

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1. Glossary

Terminology is explained in the Research Governance Glossary, the most recent version of which can be found **on the Research Governance webpages.**

2. Background

A *quality event* is any occurrence where an intended or expected study process or standard has not been met. For the purposes of this SOP, these occurrences can be divided into two groups. First, breaches of, or non-compliance with, the protocol, or associated principles of GCP. Second, other events which do not, by themselves, violate any requirements of the protocol, or of GCP, but nevertheless threaten to impair the quality of research, or diverge from expected standards. All quality events require assessment by the study team. Those events which are, or may be, in the former category, i.e. *Breaches*, further require assessment by the Sponsor, and possibly the REC or regulator. This is to ensure they have not resulted in actual or possible compromise of participant safety or study quality and, where they have, to find appropriate remedy.

This SOP therefore covers the management of quality events; their recording, reporting to the RGT, assessment and onward reporting. It discusses both notes to file, and breach reports. It explains moreover how to manage a *serious breach*, a breach of:

> "the conditions and principles of good clinical practice in connection with that [study or] the protocol relating to that [study that was] likely to effect to a significant degree – (a) the safety or physical or mental integrity of the participants of the [study]; or (b) the scientific value of the [study]" The **Medicines for Human Use (Clinical Trials) Regulations 2004**, as amended by the **Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025**.

Note, a breach still qualifies as *serious* if it did not actually have a significant effect in the sense above, but was likely to do so at the time of the event's occurrence.

Though this definition is drawn from the **UK Clinical Trials Regulations**, it applies for all health and social-care research and should not be interpreted overly narrowly. A breach that risked or caused harm to participants, researchers or others might still require classification as serious, and therefore the corresponding onward reporting.

This SOP helps to ensure that the RGT satisfies its requirements as Sponsor representative to remain compliant with the principles of **UK Policy Framework for Health and Social Care Research**, the principles of GCP and the **UK Clinical Trials Regulations.**

3. Scope

This SOP only applies to studies involving human participants, their data, or their tissue, which are Sponsored by the University. Quality events within studies that are not Sponsored by the University (but are, for instance, hosted by us) are the responsibility of that study's Sponsor, and should be managed in line with that Sponsor's established procedures. Breaches which occur in studies that fall under the auspices of a University REC are managed by the **REIM** in line with the Process for Considering Ethical Breaches in Taught Research**.** Breaches of requirements which do not directly pertain to human participant research, for instance human resources or contractual requirements, are also not in scope.

4. Responsibilities

This SOP describes how the **members of the RGT** should triage an initial report of a quality event; how the **RGT member** it is assigned to should assess and manage the quality event and associated documentation; how that **RGT member** should report the quality event onwards where applicable, with the support of the **HoRG** as necessary.

5. Procedure

5.1 During study setup

The responsible **RGT member** should confirm to the study team that quality events are to be recorded using the RGT Quality Event form, and that completion and communication of the form should be their starting point for management of the Quality Event, rather than an email alone. They should provide the team with both the form template and the corresponding guidance note. Access to notes to file during the course of the study should be agreed with RGT at this point. The appropriate process will depend upon a number of factors, primarily; the risk associated with the study, and the scale of the study (and therefore the anticipated quantity of notes to file). Typical models are:

- All notes to file are shared with RGT as they are generated. (This would only be expected for very high risk, very small studies.)
- Notes to file are stored in a manner that can be accessed by RGT - such as an eTMF which is wholly or partially accessible by RGT staff - and a list of events is shared on a pre-agreed routine basis.
- Notes to file are collated and shared with RGT on a pre-agreed routine basis. (This would only be expected for very low risk studies.)

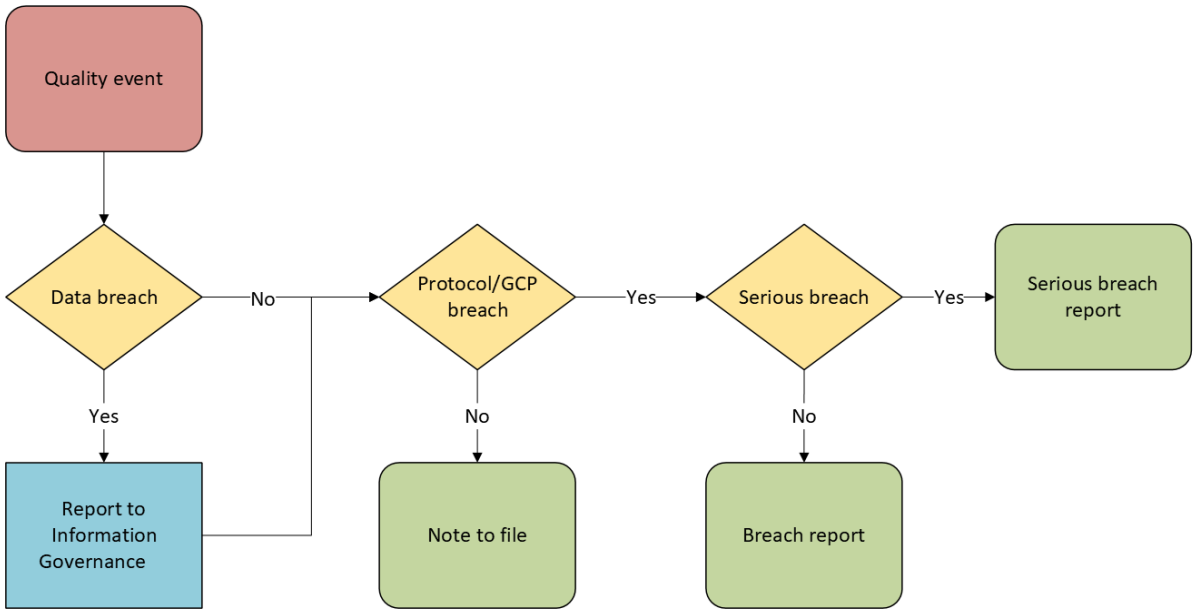
Conversely, in all cases, **all** breaches must be reported to the Sponsor within 24 hours of the study team becoming aware of this.

The **RGT member** reviewing the study documentation should ensure that the management of quality events described therein is consistent with the below, or where different, that the **RGT member** is satisfied this difference is justified. The **RGT member** does not need to insist on use of the exact wording below.

5.2 When a quality event is identified

This flowchart describes the assessment needed when a quality event is identified, and the associated onward reporting requirements. This flowchart is to be used by the **RGT member** handling the quality event to determine what reports need to be made by conclusion of the event's management. The Quality Event Form follows this same logic.

In practice, the handling of the event may be more fluid than the process laid out in the flowchart. Members of the study team may initially determine whether a note to file is required rather than a breach report, or directly contact Information Governance in the event of a data breach; the 'Serious breach report' terminus is actually prefigured by the completion of the Breach report section of the RGT Quality event form, and assessment by the Sponsor, as explained in sections 5.4 and 5.5; and so on. The flowchart does not seek to override this practice; rather, it ensures that the **RGT member** can check the correct endpoint for the quality event has been found, even if the route by which that is reached is not exactly as depicted below.



In managing the event, the **RGT member** should use the RGT Quality event form, in collaboration with the study team. The form provides a series of questions to assist the user in completing the correct reports, whether a note to file, breach report, or serious breach report, in line with the flowchart above.

5.3 Data breach

A *personal* data breach is defined as "a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, personal data transmitted, stored or otherwise processed" **UK GDPR**. Data breaches more generally may include loss of (non-identifying) study data, or any other kind of data mismanagement.

The Research Governance Team cannot handle data breaches directly, but can at least expedite their management, by referring them to the Information Governance team at data-protection@bristol.ac.uk if the study team have not already done so. Both **RGT members** and the study team should err on the side of caution with data breaches; if it is possible, but not certain, that a quality event qualifies as one, the **RGT member** handling the event should refer it to Information Governance for their assessment.

5.4 Breach of protocol or principles of GCP

Where the quality event is a breach of protocol or the principles of GCP, it should be reported to the study team as soon as possible. The study team should report the breach to the sponsor within not more than 24 hours of their becoming aware of it. This report should use the RGT Quality event form, and provide as much information as is available at point of submission. The Chief Investigator should not sign the form until it has been reviewed by an **RGT member**, in case of required amendments.

Where the form is sent to research-governance@bristol.ac.uk, the **RGC** should ensure that the report has reached the **member of the RGT responsible for the study**. The **RGT member** should now review the RGT Quality event form to ensure it contains:

- Comprehensive and clear information throughout.

- Descriptions of *who* did *what*, *when, why* and *how*, with references to job roles, or names as initials only.
- Chronologically ordered information.
- An assessment of whether the cause is isolated or systematic.
- Information about corrective and preventative measures that have been put in place.

The **RGT member** should assess whether the information in the form is accurate, and whether the preventative measures described are appropriate.

When satisfied that all necessary information has been provided by the study team, the **RGT member** should complete the Sponsor Assessment section of the RGT Quality event form. This includes an assessment of whether the breach is *serious,* viz., a breach of:

> "the conditions and principles of GCP in connection with that [study or] the protocol relating to that [study that is] likely to effect to a significant degree – (a) the safety or physical or mental integrity of the subjects of the [study]; or (b) the scientific value of the [study]" (**UK Clinical Trial Regulations)**

In making their assessment, the **RGT member** should be mindful of previous breaches within the study. A breach may not be serious in itself, but commonalities with other breaches (for instance, the same process being repeatedly affected, or the same member of staff being responsible) might suggest an underlying issue that is, in fact, serious.

Sponsor assessment can be completed by the **RGT member** once the event has been resolved – if applicable, all information about the event has been gathered and confirmed, and clear Corrective and Preventative Actions agreed. At this point, both the **RGT member** and the CI should sign the form (sending of, or agreement to, the form via institutional email address constitutes a signature). A version of the signed form should then be filed in the case on F2, and in the study master file.

If the breach has been assessed as serious, the **RGT member** should refer to the procedure in section 5.5 of this SOP.

5.5 Serious breach of protocol or GCP

Serious breaches require onward reporting by the Sponsor. The **RGT member**, **HoRG** and CI should collaborate to ensure appropriate reporting has taken place, using the below table as a guide.

	CTIMP	**CIMD**	**Non-CTIMP/CIMD**
Report to:	MHRA, REC	MHRA, REC	REC
Using:	MHRA Serious Breach Form (prepared in first instance by **RHTM for CTIMPs)**	MHRA protocol deviation tracker Excel template, to info@mhra.gov.uk	RGT Quality event form
Within:	Seven calendar days of Sponsor being made aware of breach, even if information is incomplete.	As soon as the Sponsor is made aware.	Seven calendar days of Sponsor being made aware of breach, even if information is incomplete.

	Follow-up information should be provided when available, in line with the MHRA's **Guidance for the Notification of Serious Breaches of GCP or the Trial Protocol.**		Follow-up information should be provided as requested by the REC.

Occasionally, further reporting or action may be needed. For instance, management of the serious breach may require urgent safety measures (including a modification to the protocol); or notification of other parties, such as the CTU or the IMP manufacturer. In these circumstances the **RGT member** should consult with the CI and **HoRG**, and refer to the study protocol, the principles of GCP, and the MHRA's **Guidance for the Notification of Serious Breaches of GCP or the Trial Protocol**.

5.6 Note to file

Some quality events fail to constitute a breach of the protocol or the principles of GCP, but still threaten to impair the quality of the study, by falling short of an intended or expected process associated with the study.

These quality events should result in the completion of a *note to file*, which explains the occurrence and its remedy, and is added to the study master file so that the study can be reconstructed if needed. The note to file should be written up by the study team, using the RGT Quality event form.

The study team should file the RGT Quality event form containing the Note to File in line with agreed study practices. The forms should be made available to the Sponsor as agreed at setup, as described above.

6. Related documents

Internal documents

RGT Quality event form

UoB RGT Quality event form – Guidance note

External documents

UK Clinical Trials Regulations

UK Policy Framework for Health and Social Care Research

ICH GCP E6 (R3)

MHRA Notification of Serious Breach of Good Clinical Practice or Trial Protocol

MHRA Guidance for the Notification of Serious Breaches of GCP or the Trial Protocol (Version 6, 08.07.20)

MHRA protocol deviation tracker Excel template