This note explains how to use the RGT Quality event form.

A quality event is any deviation from an intended or expected process within the study. These can be divided into two groups:

- Breaches of, or non-compliance with, the protocol, or associated principles of GCP – some of which may be serious. For instance, failure of a pharmaceutical product to be delivered to a participant on time.
- 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. For example, the misspelling of the participant's name on the consent form, the change to a member of the study team's name following marriage, a minor printing error on some pharmaceutical packaging.

The former category of event requires a breach report to the sponsor, and further onward reporting if the breach is classified as serious. The latter category of event requires a note to file, which should be logged in the Master File, preferably filed in the relevant section and referred to from a Note to File log.

From **07/03/2025** studies sponsored by the University of Bristol are expected to use the RGT Quality event form to record *all* quality events, unless a different process has been specifically agreed with the Research Governance team. The form is therefore the starting point for all quality events, and all quality events should be assessed and recorded using it.

The form requires the user to input responses to various questions. Depending on the nature of these responses, the form will provide further instructions.

- If the event is, or may be, a data breach, the form will instruct the user to contact the Information Governance team – in addition to other considerations.
- If the event is, or may be, a breach of the protocol or associated principles of GCP, the form will load a Breach Report template which must then be populated and sent in Excel format without macros (.xlsx) to the Sponsor for review within the timeline specified in the form.
- If the event is not a breach of the protocol or the principles of GCP, but some other deviation from intended or expected study processes, the form will load a Note to File template which must then be populated, exported to PDF and logged in the Study Master File. These should be made available to the Sponsor using the process agreed at study setup.

Occasionally, further reporting or action may be needed. For instance, management of a serious breach may require urgent safety measures (including a modification to the protocol); or notification of other parties. In these circumstances the Research Governance team will work with the study team to establish the necessary action.

Where the form requires sign-off (for instance, for Breach Reports), sending of the completed form from an institutional email constitutes a signature.

More in-depth detail on the Research Governance process for quality events can be found in **RG SOP 8 – Quality events**. More technical information about the form, including macro permissions, can be found in the FAQs tab within the spreadsheet. In the event of any questions about quality events, the quality event form or process, please contact the Research Governance Team.

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Change history

New version date	Summary of changes
28/04/2026	Terminology updated from 'amendment' to 'modification' to align with the UK Clinical Trial Regulations amendment.