Quality Control Document:

Deviation Management

# Purpose

Where deviations (planned or otherwise) arise, robust and documented processes must be in place. This is to enable the impact of the deviation to be assessed, and the appropriate actions executed, within the set timeframe.

This document provides a tool that can be used to detail a deviation-management process. For laboratories performing analyses that contribute to the endpoints of clinical trials of an investigation medicinal product (CTIMPs), refer to the procedures described in the Reportable Issues SOP (UoB-CRL-SOP-005).

# Instructions

1. Remove this first instruction page.
2. Update the trial/study ID in the header.
3. Update the footer, retaining the document reference information relating to this quality control document (QCD).

## Defining a process for deviation reporting

1. Document the procedure for reporting, reviewing, investigating and escalating (where appropriate) a deviation. See the Deviation Form (UoB-DSB-QCD-002) document for a deviation form template.
2. Identify who will be initiating the reporting process (e.g. any member of staff who finds a deviation) and state what reporting mechanism must be used.
3. Identify the person responsible for reviewing the initial deviation report.
4. Identify who/where the deviation should be reported to. Consider giving guidance on scenarios where this should be:

* the sponsor (or their representative)
* the chief investigator and/or
* a staff member at the co-ordinating centre.

1. Identify an appropriate staff member/job role to carry out an investigation. They will carry out a root-cause analysis to identify the factors that contributed to the deviation (if applicable).
2. Identify an appropriate staff member/job role to document corrective and preventative actions in a CAPA plan, and assign actions/tasks to the people who will be responsible for completing them.
3. Identify an appropriate staff member/job role to review and approve the CAPA plan.
4. File this written procedure in the relevant study/trial master file (S/TMF) and investigator site file (ISF)/laboratory master file (LMF) as applicable.

# Related documents

* UoB-CRL-SOP-005 Reportable Issues
* UoB-DSB-QCD-002 Deviation Form
* UoB-DSB-SOP-001 Deviations and Serious Breach Reporting

Note the UoB QMS documents can be found on the [CRCT website](https://www.birmingham.ac.uk/research/activity/mds/mds-rkto/governance/index.aspx). Internal work instructions can be obtained from the CRCT ([crct@contacts.bham.ac.uk](mailto:crct@contacts.bham.ac.uk)) and/or from the RGT ([researchgovernance@contacts.bham.ac.uk](mailto:researchgovernance@contacts.bham.ac.uk)).

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| Deviation reporting procedure Provide details on who reports deviations, how deviations are reported (e.g. email/case report forms (CRFs)/deviation form), who reviews initial deviation reports, who deviations should be reported to (contact details provided below) and where to file evidence of the deviation. See also the Deviations and Serious Breach Reporting SOP (UoB-DSB-SOP-001). | | |
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| Staff member(s) to review deviation | | |
| Name | Role | Contact details |
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| Staff member(s) to perform root cause analysis (where appropriate) | | |
| Name | Role | Contact details |
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| Staff member(s) to identify corrective actions and preventative actions (CAPA) plans (where appropriate) | | |
| Name | Role | Contact details |
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| Staff member(s) to approve corrective actions and preventative actions (CAPA) plans (where appropriate) | | |
| Name | Role | Contact details |
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