**Deviation Log Spot Checks**

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# Foreword

## The Academic & Clinical Central Office for Research & Development (ACCORD) is a joint office comprising clinical research management staff from NHS Lothian (NHSL) and the University of Edinburgh (UoE).

## The Quality Assurance (QA) Administrator, in consultation with the QA Manager and/or QA Coordinator and the Senior Clinical Trials Monitor(s), will conduct regular deviation log spot checks.

## The spot checks will reconcile the data captured in the QA protocol deviation assessment tracker with the deviation logs (CR010‑T01) retained in the Trial Master File (TMF)/Sponsor File.

## These spot checks will include confirming that trial locations have submitted protocol/GCP deviation logs in compliance with the study protocol and Standard Operation Procedure (SOP) CR010 (Management of Protocol and GCP Deviations and Violations.

## These checks will be conducted for studies that have undergone Combined Risk Assessment (SOP GS002) and are sponsored by the UoE and/or NHSL.

# Instructions

## **Deviation Log Reconciliation Spot Checks**

### At the start of each calendar month (+ 2 weeks), the QA Administrator will contact the Senior Clinical Trials Monitor(s) by e-mail to ask which study/studies (minimum of 1/maximum of 3) require a deviation log reconciliation check. All studies will be subject to a check, whilst still active.

### The QA Administrator will use Deviation Log Reconciliation form (CR010-WI01-F01) to document the reconciliation check, completing all sections of the form as the check progresses.

### Where there are deviation logs missing from the TMF/Sponsor file, the QA Administrator will record these on form CR010-WI01-F01 and inform the QA Coordinator.

### Where there are deviation logs missing from the ACCORD SharePoint, the QA Administrator will record these on form CR010-WI01-F01 and inform the QA Coordinator.

### The QA Administrator will locate the missing deviation log(s) (electronic or paper) on the ACCORD SharePoint, the QA mailbox, or the TMF/Sponsor file and ensure that the missing data (electronic or paper) is added to the ACCORD SharePoint or the TMF/Sponsor file.

### If required, the QA Administrator will seek support from the QA Coordinator or QA Manager to locate the missing logs.

### The QA Administrator will file the missing deviation logs in the TMF/Sponsor File and document this on the Deviation Log Reconciliation form (CR010‑WI01-F01).

### The QA Administrator will e-mail the Senior Clinical Trials Monitor(s) to confirm that the deviation log reconciliation is complete and will retain this e-mail communication in the QA folder on the ACCORD SharePoint (Quality Assurance/Deviations & Violations/Deviation Log Reconciliation/YYYY/MMMM).

### The QA Administrator will sign the completed form (CR010-WI01-F01) and file on the ACCORD SharePoint (Quality Assurance/Deviations & Violations/Deviation Log Reconciliation/YYYY/MMMM). The QA Administrator will also complete the Deviation Log Reconciliation Tracker on the ACCORD SharePoint to document which trial has been checked.

## **Deviation Reporting Spot Checks**

### At the start of each January (Q1), April (Q2), July (Q3) and October (Q4) (+ 6 weeks), the QA Administrator will contact the QA Manager & QA Coordinator by e-mail which studies/locations require a deviation log spot check. All studies will be subject to a check, whilst still active.

### A minimum of 1 study (all locations) up to a maximum of 4 studies (all locations) will be checked each quarter.

### The QA Administrator will use Deviation Reporting Spot Check form (CR010‑WI01-F02) to document the spot check, completing all sections of the form as the spot check progresses.

### For each location, the QA Administrator will check deviation reporting compliance over the previous 4 reporting periods i.e. 4 quarters.

### The QA Administrator will send the completed Deviation Reporting Spot Check form (CR010-WI01-F02) to the QA Coordinator and/or QA Manager for review.

### The QA Administrator will make any changes, recommended by the QA Coordinator and/or QA Manager, to the Deviation Reporting Spot Check form (CR010-WI01-F02), sign it, and send this to the Trial Manager, copying the CI and assigned Clinical Trials Monitor. The template e-mail in Appendix 1 will be used for this e-mail communication.

### The form will provide details on trial/location compliance and may recommend one of the following actions depending on the level of non-compliance;

* E-mail circular to all locations reminding of the requirement to report deviations quarterly to the trial Sponsors e.g. non-compliance across all locations <30%.
* Trial Manager and CI to agree course of action e.g. non-compliance across all locations >30%.
* Monitoring visit to location(s) e.g. at the discretion of the QA/Monitoring team depending on the level of location non-compliance at location(s) over 2 spot checks periods.

### The QA Administrator will complete the Deviation Reporting Spot Check Tracker on the ACCORD SharePoint to document which trial and which locations have been checked each quarter ((Quality Assurance/Deviations & Violations/ Deviation Reporting Spot Checks/Deviation Reporting Spot Check Tracker YYYY).

### The QA Administrator will retain the completed form (CR010-WI01-F02) and the e-mail communication with the trial team on the ACCORD SharePoint (Quality Assurance/Deviations & Violations/ Deviation Reporting Spot Checks/YYYY/Q1-4). A copy will also be printed and filed in the TMF/Sponsor File.

## **Deviation Reporting Non-Compliance Escalation**

### When a CI or Trial Manager contacts the ACCORD QA to escalate any issues around deviation reporting non-compliance for a specific trial location, perform a deviation reporting spot check for the location following section 2.2.

# References

* SOP CR010 Management of Protocol and GCP Deviations and Violations
* SOP GS002 Combines Risk Assessment
* CR010-WI01-F01 Deviation Log Reconciliation Form
* CR010-WI01-F02 Deviation Reporting Spot Check Form

# APPENDIX 1: E-Mail Template

To: [**Insert Trial Manager’s e-mail address**]

cc: [**Insert CI’s e-mail address, QA Manager, QA Coordinator, Assigned Clinical Trials Monitor**]

Subject: [**Insert Trial Name**] – Deviation Reporting Spot Check

Dear [**Insert Trial Manager’s name**]

The Sponsor’s Quality Assurance (QA) team has conducted a spot check of deviation reporting compliance for the [insert trial name] trial. This included reconciling data captured in the ACCORD QA protocol and GCP deviation assessment tracker, with deviation logs retained in the Sponsor File/TMF (delete as appropriate). The spot check report is attached, which includes the individual location compliance level e.g. whether the location has submitted quarterly deviation logs as stipulated in the protocol. Can you please review this report including the summary and the Sponsor’s recommendations (on Page 1) with regards to further action (where appropriate).

Should you require further support or advice, please contact your Clinical Trials Monitor (copied here) or contact QA@accord.scot.