ECTU Central Office WPD_TM_W4: Requesting and Recording Protocol Deviation Logs and Protocol Violations in ACCORD Sponsored Studies

Version No:	2.0
Issue Date:	27 May 2024
Effective Date:	10 Jun 2024

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Document Revision History		
Version No.	Effective Date	Summary of Revisions
1.0	06 Apr 2022	Initial Creation
2.0	10 Jun 2024	Addition of Recording and Reporting deviations in Medical Device studies. Medical device (CIMD) deviation log template added to section 3. Grammatical corrections and clarifications added throughout.

1. INTRODUCTION

This WPD applies to ACCORD sponsored studies, where protocol and GCP deviation and violation reporting have been delegated to ECTU in the Co-sponsorship agreement or ACCORD GS003-T04 Trial Support Responsibilities Record.

This Working Practice Document (WPD) provides guidance on the process of requesting and recording protocol deviations and violations to comply with ACCORD SOP CR010 Management of Protocol and GCP Deviations and Violations.

2. INSTRUCTIONS and GUIDANCE

Protocol deviation and violation training slides (provided by ACCORD) are available for use when training sites. They require customisation before use but provide clear guidance on reporting deviations and violations by sites. All departures from the approved protocol or from Good Clinical Practice (GCP) must be identified and recorded as a deviation or violation. Definitions and examples are described in ACCORD SOP CR010.

2.1 Deviation log request procedure

2.1.1 Protocol/ GCP deviation logs from each study site open to recruitment should be sent to the Sponsor quarterly from the site, unless a different timeframe is detailed in the study protocol.

2.1.2 The Trial Manager (TM) (or designate) should contact each site research team at the end of each quarter (or timeframe agreed) requesting protocol deviation logs or confirmation that no deviations have occurred.

2.1.3 The deviation logs and/or confirmation that no deviations have occurred should be submitted via email to ACCORD (QA@accord.scot), and the relevant ECTU trial email should be copied in. A template email is available for use and is provided in Appendix A.

2.1.4 If sites do not respond, at least two reminders, a few weeks apart, should be sent, thereafter if no response the issue should be escalated to ACCORD on a quarterly basis.

2.2 Recording and Reporting Deviations (CTIMP and non-CTIMP studies)

2.2.1. All deviation report emails (including reports of no deviations) received from sites should be checked to ensure ACCORD (QA@accord.scot) are copied in, if not the report should be forwarded to them within the timeframe specified within the ACCORD SOP.

2.2.2 The Deviation Request Tracker (TM-T16) should be updated, maintained within the trial specific electronic file structure on the ECTU shared drive and then archived within the Trial Master File at the end of the trial.

2.2.3 All deviation logs, any communications regarding sponsor review or the resolution of corrective/preventative actions from ACCORD should be filed in section 5.4 of the TMF

2.3 Recording and Reporting Deviations: Medical Device Studies

2.3.1 For Clinical Investigations of a Medical Device (CIMD), the PI or designee, will record the deviation using the MHRA Deviation Log template (unless otherwise agreed with the Sponsor) and email ACCORD, copying in the trial inbox. Refer to section 2.1.2 and 2.1.4

2.3.2 All deviation report emails (including reports of no deviations) received from sites should be checked to ensure ACCORD (QA@accord.scot) are copied in, if not the report should be forwarded to them within the timeframe specified within the ACCORD SOP CR010

2.3.3 The deviation report should also be reported to the MHRA (info@mhra.gov.uk). This is usually the responsibility of the site or ECTU and will be detailed in the protocol and/or risk assessment.

2.3.4 The Deviation Request Tracker (TM-T16) should be updated, maintained within the trial specific electronic file structure on the ECTU shared drive and then archived within the Trial Master File at the end of the trial.

2.3.5 All deviation logs, any communications regarding sponsor review or the resolution of corrective/preventative actions from ACCORD should be filed in section 5.4 of the TMF.

2.4 RECEIVING VIOLATION REPORTS

2.4.1 On receipt of a violation report from the site the TM (or designee) will forward the report to QA@accord.scot (if not already sent by the site) within the timeframe specified within the ACCORD SOP CR010.

2.4.2 All violation reports, evidence of sponsor review and any communications regarding the resolution of corrective/preventative actions from ACCORD should be filed in section 5.3 of the TMF.

2.5 DEVIATIONS AND VIOLATIONS IDENTIFIED BY NON-SITE STAFF

2.5.1 Deviations and violations at sites may be identified by non-site staff (for example, ECTU staff or ACCORD).

2.5.2 In these cases, the study monitor, TM (or designee) will request that the site complete a deviation log or violation report following ACCORD SOP CR010. The TM will record any deviation requests within the “Deviations Requested” tab of the TM-T16 Deviation Request Tracker.

2.6 TRIAL DEVIATIONS AND VIOLATIONS RECORDED AT ACCORD

ACCORD will hold details of all deviations and violations reported. On a yearly basis the data, in the form of a line listing, should be requested by the Trial Manager or designee from ACCORD (QA@accord.scot) and reconciled with the data held within the trial TMF to ensure accuracy. Documentation of reconciliation should be filed in sections 5.3/5.4 of the TMF. The line listing should be used to document reconciliation (for example, adding an additional column and inserting a tick to indicate correct entries) and the date reconciliation performed. Any anomalies should be raised with ACCORD and resolved.

3. RELEVANT DOCUMENTS AND REFERENCES

ACCORD SOPs

- ACCORD SOP CR010 Management of Protocol and GCP Deviations and Violations
- ACCORD CR010-T01 Protocol Deviation Log
- ACCORD CR010-F01 Protocol GCP Violation Reporting Form
- ACCORD GS003-T04 Trial Support Responsibilities Record.

ECTU Shared Drive

- TM-T15 Deviation Site Training Slides
- TM-T16 Deviation Request Tracker

Others

- MHRA Protocol Deviation Tracker

APPENDIX A

Template Email

Subject: [Trial Name] – Deviation Log Reminder [Year] [Quarter]

Body:
Dear all,
This is a reminder that deviation logs for the [Trial Name] trial between [Time Period] are due for submission to the Sponsor.

If not already done so, please send your deviation log for this quarter to QA@accord.scot and copy in [Trial Email].

If your site has had no deviations for this quarter please send an email confirming this to QA@accord.scot and copy in [Trial email]

If you need any advice on this process, please get in touch with us.

Best wishes,

ECTU_WPD_TM_W4 Requesting and Recording Protocol Deviation Logs and Protocol Violations in ACCORD Sponsored Studies. v2.0

Final Audit Report 2024-05-27

Created:	2024-05-23 (British Summer Time)
By:	Tanya Tharakan (tanya.tharakan@ed.ac.uk)
Status:	Signed
Transaction ID:	CBJCHBCAABAA61a1efEu634r6ZPtoURELlim8Vqg4H9U

"ECTU_WPD_TM_W4 Requesting and Recording Protocol Deviation Logs and Protocol Violations in ACCORD Sponsored Studies. v2.0" History

Document created by Tanya Tharakan (tanya.tharakan@ed.ac.uk)
2024-05-23 - 14:40:04 GMT+1- IP address: 192.41.114.230

Document emailed to Phillip Rayson (Phillip.Rayson@ed.ac.uk) for signature
2024-05-23 - 14:48:04 GMT+1

Document emailed to Julia Boyd (Julia.Boyd@ed.ac.uk) for signature
2024-05-23 - 14:48:04 GMT+1

Document emailed to Gina Cranswick (gina.cranswick@ed.ac.uk) for signature
2024-05-23 - 14:48:04 GMT+1

Document emailed to Tanya Tharakan (tanya.tharakan@ed.ac.uk) for signature
2024-05-23 - 14:48:04 GMT+1

Email viewed by Phillip Rayson (Phillip.Rayson@ed.ac.uk)
2024-05-23 - 15:30:17 GMT+1- IP address: 104.47.11.254

Document e-signed by Phillip Rayson (Phillip.Rayson@ed.ac.uk)
Signature Date: 2024-05-23 - 15:30:29 GMT+1 - Time Source: server- IP address: 46.69.87.227

Email viewed by Julia Boyd (Julia.Boyd@ed.ac.uk)
2024-05-23 - 15:53:10 GMT+1- IP address: 104.47.11.254

Document e-signed by Julia Boyd (Julia.Boyd@ed.ac.uk)

Signature Date: 2024-05-23 - 15:53:19 GMT+1 - Time Source: server- IP address: 192.41.114.229

Email viewed by Tanya Tharakan (tanya.tharakan@ed.ac.uk)

2024-05-27 - 08:45:42 GMT+1- IP address: 192.41.114.230

Email viewed by Gina Cranswick (gina.cranswick@ed.ac.uk)

2024-05-27 - 10:21:50 GMT+1- IP address: 104.47.11.254

Document e-signed by Gina Cranswick (gina.cranswick@ed.ac.uk)

Signature Date: 2024-05-27 - 10:22:00 GMT+1 - Time Source: server- IP address: 5.181.59.56

Document e-signed by Tanya Tharakan (tanya.tharakan@ed.ac.uk)

Signature Date: 2024-05-27 - 12:43:46 GMT+1 - Time Source: server- IP address: 192.41.114.230

Agreement completed.

2024-05-27 - 12:43:46 GMT+1