

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

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Authorship and Approval			
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1.0	06 Apr 2022	Initial Creation

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1. INTRODUCTION

This WPD applies to ACCORD sponsored studies, where protocol deviation and violation reporting has been delegated to ECTU in the co-sponsorship agreement.

This Working Practice Document (WPD) provides guidance on the process of requesting and recording protocol deviation 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.

2.1 Deviation log request procedure

- 2.1.1 Protocol deviation logs from each study site should be sent to the Sponsor quarterly, 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 in a timely manner 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), 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 should be sent, thereafter if no response the issue should be escalated to ACCORD on a quarterly basis.

2.2 Deviation Reporting

- 2.2.2 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 SOP.
- 2.2.3 The Deviation Request Tracker (TM-T16) should be completed, 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.
- 2.2.4 All deviation logs, any communications regarding sponsor review or the resolution of corrective/preventative actions from ACCORD should be filed in the TMF.

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2.3 RECEIVING VIOLATION REPORTS

- 2.3.1 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 SOP.
- 2.3.2 All violation reports, evidence of sponsor review and any communications regarding the resolution of corrective/preventative actions from ACCORD should be filed in the TMF.

2.4 DEVIATIONS AND VIOLATIONS IDENTIFIED BY NON-SITE STAFF

- 2.4.1 Deviations and violations at sites may be identified by non-site staff (e.g. ECTU staff or ACCORD).
- 2.4.2 In these cases, the study monitor, TM (or designee) will request that the site complete a deviation log following the ACCORD SOP CR010 and the TM will record these within the "Deviations Requested" tab of the Deviation Request Tracker.

2.5 TRIAL DEVIATIONS AND VIOLATIONS RECORDED AT ACCORD

ACCORD will hold details of all deviations and violations. On a yearly basis these data need to be requested from ACCORD (in the form of a line listing) and reconciled with the data held within the trial TMF to ensure accuracy. Documentation of reconciliation should be filed in the TMF. The line listing should be used to document reconciliation (e.g. adding additional column and inserting 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 SOP CR010 Management of Protocol and GCP Deviations and Violations
- ACCORD CR010-T01 Protocol Deviation Log
- CR010-F01 Protocol GCP Violation Reporting Form
- TM-T15 Deviation site training slide
- TM-T16 Deviation Request Tracker

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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,

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