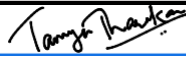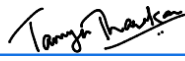# ECTU Central Office SOP ECTU_QA_03: Management of Deviations and Data Security Incidents within ECTU

Version No:	1.0
Issue Date:	21 Mar 2025
Effective Date:	04 Apr 2025

Authorship and Approval			
Name and Designation	Author/Reviewer /Approval/ Authorisation	Date	Signature
Tanya Tharakan QA Manager	Author	21-Mar-2025	Tanya Tharakan (Mar 21, 2025 13:11 GMT)
Lynne McGillivray ECTU Business and Quality Assurance Administrator	Reviewer	21-Mar-2025	
Joyce Thomson Chief Operating Officer	Approver	21-Mar-2025	Joyce Thomson (Mar 21, 2025 12:53 GMT)
Tanya Tharakan QA Manager	QA Authorisation	21-Mar-2025	Tanya Tharakan (Mar 21, 2025 13:11 GMT)

Document Revision History		
Version No.	Effective Date	Summary of Revisions
1.0	04 Apr 2025	Initial creation

The user of this document is responsible for ensuring it is the current version.

1.0   PURPOSE

A deviation management system is used to identify, record, investigate and correct incidences that may result in non-compliance. Reporting deviations is an essential part of a good quality management system to ensure that clinical research studies are conducted, documented and data generated in compliance with the protocol, Good Clinical Practice and all applicable regulatory requirements.

The purpose of this SOP is to define the process and the responsibility for generating, handling and investigating deviations; taking action to mitigate risks associated with them and for initiating and completing corrective and preventative action in ECTU.

2.0   SCOPE

This SOP is applicable to all staff members employed within Edinburgh Clinical Trials Unit. (ECTU)

3.0   RESPONSIBILITIES

All staff members within ECTU are expected to follow the guidelines detailed in this SOP when reporting an occurrence that could result in a deviation. The QA Manager is responsible for completing the relevant sections of the Deviation Log.

4.0   PROCEDURE

Definitions: A deviation is an unexpected occurrence, or departure from a planned process, or a non-conformance which can be against an SOP, WPD or policy or an independent event.

Deviations relating to the protocol: Any change, divergence, or departure from the study design, procedures defined in the protocol or GCP that does not significantly affect a subjects' rights, safety, or well-being, or study outcomes. For such deviations the ACCORD process in CR010 Management of Protocol Deviations and Violations must be followed. (See section 4.1.2 and 5)

4.1   Any member of staff within ECTU can log a deviation using the online form Deviation Log Microsoft Forms link. Staff are expected to report deviations as soon as they become aware. The various sections of the form are detailed below.

   4.1.1   **Deviation from an ECTU SOP**: Any event or incident which is a deviation from an ECTU SOP, WPD or Policy.

   4.1.2   **Deviation from an ACCORD SOP**: Any event or incident which is a deviation from an ACCORD SOP, WPD or Policy, and outwith the remit of the ACCORD Deviation Log reporting. This can be applicable to sponsors other than ACCORD.

   4.1.3   **Data Security Incident**: Events/ incidents relating to data breaches, data security incidents etc. Additionally, these entries will be included in the Data Security Incident Log for resolving along with ECTU IG.

4.1.4 **Observation:** If the user would like to report any activities within the unit, but is not of a critical nature.

4.1.5 **Near Misses:** These types of events can be either study related or incidents that are related to internal ECTU processes.

4.1.6 **None of the above/ other**: Any event or incident which does not fall under any of the above categories, or if the user is unsure of the category. (See section 4.4.4)

4.2 The staff member is expected to provide as much detail of the incident as possible, providing dates in the format (DD MMM YYYY) where applicable, and detailing actions where these have taken place. Providing more details will help to complete the report accurately and in a timely manner.

4.3 Should the incident require urgent attention; the staff member must log the deviation and bring it to the attention of their line manager and the QA Manager via email.

4.4 Processing the Deviation Log

4.4.1 The QA Manager and Chief Operating Officer will have access to the log.

4.4.2 The QA Manager will maintain the Deviation Log, assess and complete the root cause and corrective and preventative actions (where applicable) for all records and will be reviewed monthly. This will take place in discussion with the Chief Operating Officer, and escalated to the Director when required. Relevant documents related to the assessment and root cause analysis will be saved on the shared drive in the QA folder.

4.4.3 The online Deviation Log form will automatically define the deviation numbering system and will assist the QA Manager in tracking the actions to completion. Since user access is restricted to ECTU staff by the QA Manager, the log will also record the name and email address along with a time stamp.

4.4.4 If the type of event was incorrectly classified, the QA Manager will correct it and record the same in the log, noting the reason for change.

4.4.5 All entries with be reviewed by QA and treated on an individual basis. This may include escalation to the Chief Operating Officer, Director and/ or the Sponsor.

4.4.6 Where applicable this will be discussed at the weekly Operations meeting or the regular QA meeting.

4.5 Processing Data Security Incidents

4.5.1 Once an incident has been identified it should be reported to QA either via the deviation log or by emailing the QA Manager on qa.ectu@ed.ac.uk.

4.5.2 Data security incidents reported via the deviation log will be further analysed in the Data Security Incident log.

The user of this document is responsible for ensuring it is the current version.

ECTU Central Office SOP Template v3.0   **Page 3 of 4**

4.5.3   Once received, the QA Manager will analyse the situation and provide information on any necessary actions that need to be undertaken.

4.5.4   The QA Manager will inform ECTU IG if they are not already included in the email. The ECTU IG staff member will offer advice or suggest further actions where applicable.

4.5.5   It is the responsibility of either ECTU IG or QA to enter the incident in the Data Security Incident Log.

4.5.6   The QA Manager will add the incident to the subsequent weekly Operations Meeting agenda, for the awareness of ECTU Management, and process any feedback received.

4.5.7   The QA Manager or ECTU IG will have oversight of the log and feedback to management on any trends that have been observed, and to discuss remedial actions.

4.5.8   The data security incident log will be password secured, with access provided to the QA Manager, Digitally Enabled Clinical Trials Team/ ECTU IG and the Chief Operating Officer.

5.0   RELEVANT DOCUMENTS AND REFERENCES

ACCORD WEBSITE

- CR010 Management of Protocol and GCP Deviations and Violations

Others

- Deviation Log Online Microsoft Teams Form
- Deviation Management Guidelines & Tools - UKCRF
- Data Security Incident Log – On the shared drive (ECT Unit\DSPT - Data Security and Protection Toolkit\Data Security Incident Log)

The user of this document is responsible for ensuring it is the current version.

ECTU_SOP_QA_03 Management of Deviations and Data Security Incidents within ECTU v1.0

Final Audit Report   2025-03-21

Created:	2025-03-21 (Greenwich Mean Time)
By:	Tanya Tharakan (tanya.tharakan@ed.ac.uk)
Status:	Signed
Transaction ID:	CBJCHBCAABAAANXaeZWRs0f4xrhebO8u3cHD0uCzPbqJ

"ECTU_SOP_QA_03 Management of Deviations and Data Security Incidents within ECTU v1.0" History

📄 Document created by Tanya Tharakan (tanya.tharakan@ed.ac.uk)
2025-03-21 - 12:05:33 GMT- IP address: 192.41.114.230

✉️ Document emailed to Tanya Tharakan (tanya.tharakan@ed.ac.uk) for signature
2025-03-21 - 12:08:39 GMT

✉️ Document emailed to Lynne McGillivray (lynne.mcgillivray@ed.ac.uk) for signature
2025-03-21 - 12:08:39 GMT

✉️ Document emailed to Joyce Thomson (joyce.thomson@ed.ac.uk) for signature
2025-03-21 - 12:08:39 GMT

📄 Email viewed by Lynne McGillivray (lynne.mcgillivray@ed.ac.uk)
2025-03-21 - 12:08:55 GMT- IP address: 48.209.223.21

📄 Email viewed by Joyce Thomson (joyce.thomson@ed.ac.uk)
2025-03-21 - 12:08:57 GMT- IP address: 13.74.250.110

✍️ Document e-signed by Joyce Thomson (joyce.thomson@ed.ac.uk)
Signature Date: 2025-03-21 - 12:53:10 GMT - Time Source: server- IP address: 5.64.191.62

✍️ Document e-signed by Lynne McGillivray (lynne.mcgillivray@ed.ac.uk)
Signature Date: 2025-03-21 - 12:57:56 GMT - Time Source: server- IP address: 77.97.244.198

✍️ Document e-signed by Tanya Tharakan (tanya.tharakan@ed.ac.uk)
Signing Link is created by Tanya Tharakan (tanya.tharakan@ed.ac.uk)
Signature Date: 2025-03-21 - 13:11:48 GMT - Time Source: server- IP address: 192.41.114.230

✅ Agreement completed.
2025-03-21 - 13:11:48 GMT