ECTU Central Office SOP_ECTU_DM_14: Study Closure and Data Availability for PIs

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Document Revision History		
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1.0	20 Jun 2025	Initial creation

1.0 PURPOSE

To establish a standardized process for ensuring that site data is made available to principal investigators (PIs) in compliance with regulatory requirements.

2.0 SCOPE

This SOP applies to all studies where Edinburgh Clinical Trials Unit is responsible for data management and programming activities at the time of database lock and encompasses the finalisation of trial activities, documentation, data availability, and communication with PIs.

3.0 RESPONSIBILITIES

The Data Manager or Senior Software Developer or designee is responsible for the tasks detailed in this SOP.

The Trial Manager or designee is responsible for informing the PIs when the data is available for download.

The Principal Investigators (PIs) or designee are responsible for downloading the data at the site.

4.0 PROCEDURE

Definitions:

Study Closure: The formal process of completing a study, including site closure, final reporting, and data sharing.

Site Data: Data collected from individual study sites, which may include, but not limited to case report forms (CRFs), adverse event reports, and monitoring visit reports.

4.1 The site data should be made available for download to the PIs at the point of database lock and before study closure. This is the timepoint at which the dataset becomes static. There is scope to provide the dataset to the PI before database lock however any study specific arrangements will be agreed with the Sponsor and documented at the study risk assessment.

4.2 The site-specific datasets should be organised, including de-identified patient information. This will be finalised with the trial statistician or designee before database lock.

4.3 The Data Manager or Senior Software Developer will provide access for the PI for REDCap and bespoke databases respectively.

4.4 The PI will be notified by the Trial Manager, or designee, that the data is ready for download, and advise the PI that the data must not be shared externally once downloaded. The data will be available for 12 months from Database Lock. Access will be revoked at the end of this 12-month period. Note: The end of the 12-month period can go beyond the study closure period and grant end date.

4.5 If the database is unlocked and data is changed, the Data Manager or Senior Software Developer will provide an updated dataset for download from the database, and the Trial Manager, or designee, will email the PIs of the respective sites informing them that a new version is available for download. The timelines are the same as detailed in 4.4

4.6 PIs are expected to acknowledge receipt of the email notification and confirm that the dataset has been downloaded by either mailing the trial inbox (if the inbox is active at the time) or the Trial Manager, or designee. Ahead of archiving, the emails will be saved in the TMF.

4.7 It is the PI or designee's responsibility to ensure that the data is downloaded within the given time frame, filed at site prior to ISF archiving, and stored for duration of the archiving period in compliance with local procedure.

4.8 A record of dataset download (user and time stamp) is available within the database audit trail. The Trial Manager, or designee, will notify the Sponsor if any of the PIs have not confirmed data download.

5.0 RELEVANT DOCUMENTS AND REFERENCES

ECTU Website

- ECTU_SOP_TM_14: End of Trial Notification and Close Out
- ECTU_SOP_OP_20: Requests to Lock and Unlock a Study Database

ECTU_SOP_DM_14 Study Closure and Data Availability for PIs v1.0

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