

ECTU Central Office SOP_IT_13: Making a Database Inaccessible at the End of Study

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Document Revision History		
Version No.	Effective Date	Summary of Revisions
1.0	14 Mar 2012	Initial creation/New document
2.0	10 Jun 2016	SOP Review – alteration to section 3.2. Change of title of WPD in relevant documents to comply with ECTU_OP_01
3.0	15 May 2024	Document moved to template v3. SOP title has been changed from 'Database Archiving' and integrated with ECTU_WPD_IT_W1 Database Archiving. Significant wording changes to section 4. Minor numbering and format changes throughout the document.
4.0	21 Oct 2026	Updated section 1.0 and added sections 4.1 and 4.6. QMS SOP template updated to v5.0

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1.0 PURPOSE

This Standard Operating Procedure (SOP) provides guidance on making a bespoke database that has been developed by ECTU inaccessible at the end of the project, in preparation for archive.

2.0 SCOPE

This SOP applies to all University of Edinburgh staff employed within ECTU who are responsible for developing and maintaining a bespoke database.

3.0 RESPONSIBILITIES

The Software Developer or designee is responsible for setting up the user database permissions.

4.0 PROCEDURE

Databases will be made inaccessible when the project has been completed and the database is no longer in use, at the point where digital archive of the trial is being considered.

- 4.1 The Software Developer receives a request from the Trial Manager or, Chief Investigator, Data Management and Programming Team Lead or designee informing them that project has concluded the database should be made inaccessible to everyone in the trial team. The email request will be saved as a PDF in the TMF Section 3 (Partial service studies) or 9 (Full service studies).
- 4.2 The Software Developer reviews each user's permissions on the database resources.
- 4.3 Add all individual users that do not require access, to the "denydatareader" and "denydatawriter" groups on the database. Note: The accounts should be left in the database. The IT accounts should be left as Database Owner (DBO).
- 4.4 Set the database to read-only by sending a request to information services. Requests can be made through email: IS.Helpline@ed.ac.uk or through self-service: <https://ishelpline.ed.ac.uk/>.
- 4.5 The email confirmation is sent to the requestor informing them that the database is no longer accessible.
- 4.6 The relevant sponsor SOPs must be followed. For ACCORD sponsored studies, see section 5.0

5.0 RELEVANT DOCUMENTS AND REFERENCES

[ACCORD SOP](#)

- GS005 Archiving Essential Study Documentation
- CR009 Study Closure and Archiving

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ECTU_SOP_IT_13 Making a Database Inaccessible at the End of Study v4.0

Final Audit Report

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