

ECTU Central Office SOP ECTU DM 15: In Study Data Reports, Exports, Sharing and Transfers

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Document Revision History		
Version No.	Effective Date	Summary of Revisions
1.0	28 Oct 2025	Initial creation

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1.0 PURPOSE

This Standard Operating Procedure (SOP) describes ECTU's process for requesting, generating, reviewing, and sharing data files extracted from ECTU clinical trial databases that are necessary to achieve the studies' objective(s), while ensuring compliance with data protection regulations, Good Clinical Practice (GCP), the trial protocol and associated studies documentation.

2.0 SCOPE

This SOP applies to all members of the ECTU Data Management & Programming team where any of these tasks have been delegated to the team to complete.

This SOP applies to all ECTU Statisticians, Trial Management and the Data Sharing Committee members for the relevant tasks detailed in this SOP.

3.0 RESPONSIBILITIES

Data Management team coordinate all data export requests, ensures compliance, checks accuracy, and manages secure transfer.

Software Developers/Programmers are responsible for coordinating with the Data Managers, generating reports/exports for bespoke databases based on data management requests on bespoke databases. For REDCap databases, the Data Manager or Assistant Data Manager responsible for the database build will facilitate the export process by generating the appropriate report for download directly from the platform.

The trial statistician is responsible for reviewing protocolled exports at study end (post database lock) as detailed in the Statistical Analysis Plan (SAP).

4.0 PROCEDURE

4.1 Definitions

Export: Any transfer of data from the case report form (CRF) in the database into another format (e.g., CSV, PDF, DOC).

Exception: The reference to data exports in this SOP excludes reports that are required for routine data management tasks as well as any reports that are specified at the beginning of the trial. Irrespective of this, consideration must always be given to personal data.

Data Sharing: Transferring exported data/report beyond the original requester.

In study data sharing activity: Data sharing or transfer necessary to achieve the aims of the study should ideally be documented a priori in for example: the study protocol, the data management plan, and/or the statistical analysis plan.

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4.2 Requesting an In-study reporting, sharing, export or transfer

4.2.1. All requests must be submitted in writing to the DM team.

4.2.2. The Data Manager will assess whether the report is specific and proportionate. The Data Manager will also ensure that the data is accurate with only the required fields included, making certain that withdrawn participants have been excluded where applicable. Consideration must be given to whether the export contains personal data.

4.2.3 If there are unusual requests or in case of uncertainty, these must be escalated to the Data Management and Programming Architect or Trial Statistician

4.3 Data Handling Requirements

4.3.1 Data files prepared for reporting, sharing, export or transfer containing personal data must be downloaded/ stored on Datastore (personal drive) and encrypted before transfer

4.3.2 Exports containing personal data must be deleted from all device locations after it's intended use.

4.4 Types of Data files prepared for reporting, sharing, export or transfer

There are different considerations based on when the request comes during the lifespan of the trial. Follow the steps in the flowchart and find appropriate actions. (Figure 1)

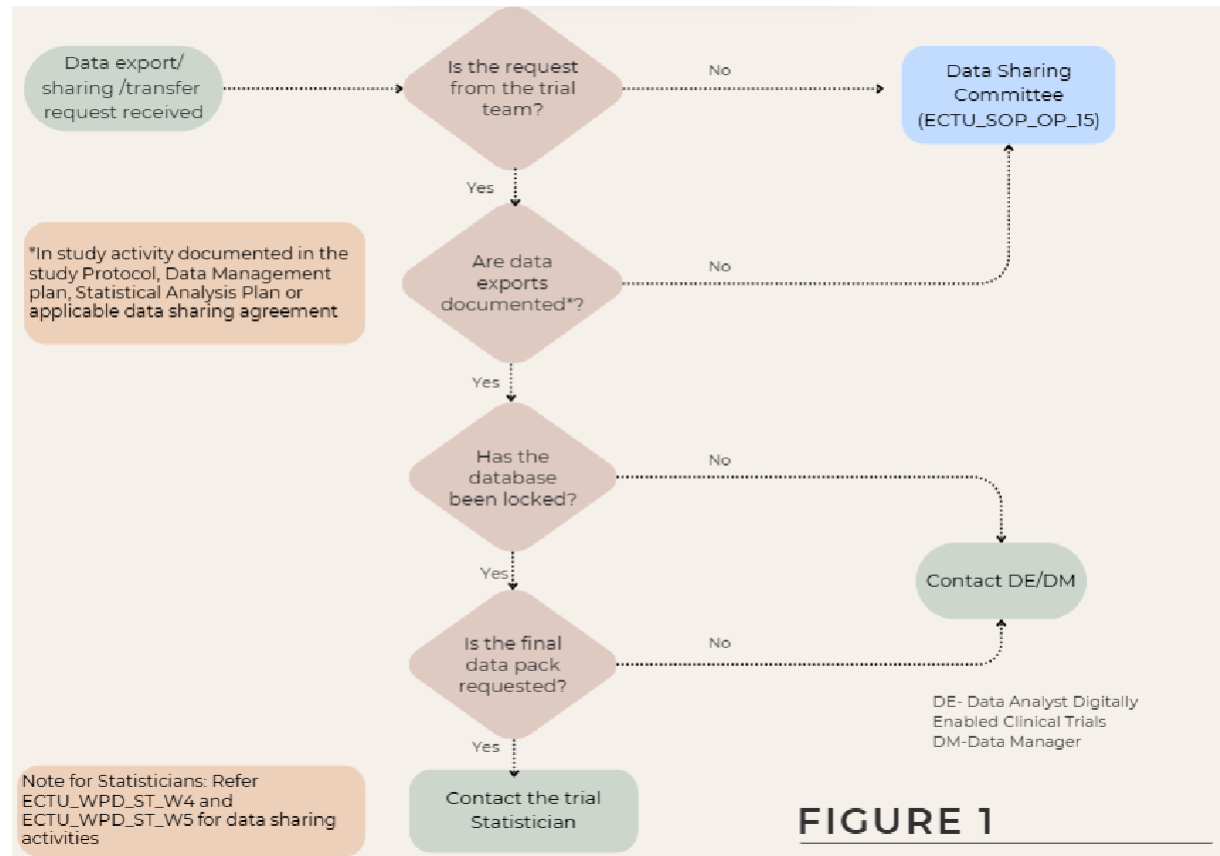


FIGURE 1

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4.5 Data file (s) for Export Generation and Review

- 4.5.1. The request for the data export must be emailed to the Data Manager on DM.ect@ed.ac.uk
- 4.5.2 The data manager arranges report generation (by the Software Developers if required).
- 4.5.3. The report is checked for accuracy, completeness, and compliance by the Data Manager
- 4.5.4. The report is then reviewed by the appropriate authority (Data Management, Statisticians, or Data Sharing Committee as applicable).
- 4.5.5. The data export is securely transferred to requester. If the report contains personal data, it should be saved on Datastore and exported securely via DataSync or by other reliable methods.
- 4.5.6 For external data export requests (For e.g. labs, data providers etc), the review will be completed by a member of the DE team by referring to Appendix 1.

Exception: Routine reports that are agreed at the time of designing the database do not follow the above steps. Authorised users are provided access to download reports directly from the database.

4.6 Documentation

- 4.6.1 The Data Managers will save email requests in the relevant folder of the DM inbox
- 4.6.2 For those trials involving external data sharing requests, the DE team member with save email evidence of requests and approvals must be saved as a PDF file and stored in the Trial Master File (TMF)
- 4.6.3 Where the Data Sharing Committee is involved, ECTU_SOP_OP_15 Data Access Request and Application Management will be followed. (See Figure 1)

5.0 RELEVANT DOCUMENTS AND REFERENCES

[ECTU Website:](#)

- ECTU_SOP_OP_15: Data Access Request and Application Management

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APPENDIX 1

This list is not exhaustive and serves as a guidance to safeguard against any missed steps.
It can be amended as required for the project and depending on the data export request.

S. No	Item	Comments	Complete Y/N/NA
Ethical & Regulatory Approvals			
1	Formal communication received from the requestor (email)		
2	Export is permitted under the approved study protocol.		
3	Export is consistent with participant informed consent (data sharing clauses checked)		
4	Ethics committee approval covers the proposed transfer.		
5	Export complies with MHRA requirements (if CTIMP)		
Governance & Legal			
6	A valid Data Sharing Agreement (DSA) or Data Transfer Agreement (DTA) is in place, signed by both parties		
7	If data leaves the UK, an International Data Transfer Mechanism is in place (UK Addendum to SCCs, IDTA, or adequacy decision)		
8	Recipient organisation assessed as having equivalent data protection safeguards		
9	Export logged with the Data Protection Officer (DPO) / Caldicott Guardian		
10	Data Minimisation & Confidentiality (have participants who have withdrawn consent been excluded)		
11	Only the minimum dataset necessary for the stated purpose is included		
12	Direct identifiers removed (e.g., name, CHI/NHS number, DOB, address)		

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13	Data is pseudonymised or anonymised, unless identifiers are essential and justified		
14	Data minimisation rationale documented		
Security Controls			
15	Data will be transferred using an approved secure method (e.g., encrypted SFTP, Safe Haven)		
17	Dataset is encrypted at rest and in transit (AES-256 or equivalent)		
18	Access restricted to authorised named recipients		
19	Transfer will be audit logged (date, time, sender, recipient, dataset description)		
Review & Authorisation			
20	Dataset checked for accuracy, completeness, and correct pseudonymisation		
21	Request reviewed and approved by CI / Sponsor		
22	DPO / Information Governance lead (or appropriate designee) sign-off obtained		
23	Export recorded [enter appropriate location here and if applicable]		
Post-Transfer Oversight			
24	Receipt confirmed by recipient organisation		
25	Data retention & destruction policies agreed and documented, if applicable		
26	Periodic compliance monitoring in place (if ongoing transfer)		

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Final Audit Report

2025-10-13

Created:	2025-10-10 (British Summer Time)
By:	Tanya Tharakan (tanya.tharakan@ed.ac.uk)
Status:	Signed
Transaction ID:	CBJCHBCAABAAJq0dXyiyAmPGMD-Bn0nb5X3oRXK_yHel

"ECTU_SOP_DM_15 In Study Date Reports, Exports, Sharing and Transfers v1.0" History

-  Document created by Tanya Tharakan (tanya.tharakan@ed.ac.uk)
2025-10-10 - 14:41:00 GMT+1- IP address: 185.241.227.251
-  Document emailed to Tony Wackett (Tony.Wackett@ed.ac.uk) for signature
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-  Document emailed to Lynsey Milne (Lynsey.Milne@ed.ac.uk) for signature
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2025-10-11 - 09:08:59 GMT+1- IP address: 104.47.11.62
-  Document e-signed by Aryelly Rodriguez (Aryelly.Rodriguez@ed.ac.uk)
Signature Date: 2025-10-11 - 09:14:07 GMT+1 - Time Source: server- IP address: 192.41.114.226
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 Agreement completed.

2025-10-13 - 09:23:22 GMT+1