ECTU Central Office SOP ECTU_OP_15: Data Access Request Management

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Document Revision History		
Version No.	Effective Date	Summary of Revisions
1.0	17 April 2019	Initial creation
2.0	11 Oct 2021	Minor formatting updates at scheduled review, minor changes to processes.
3.0	10 Jan 2024	Changes to processes to include Portfolio Management Meeting, changes to the Type A and B forms, appeals process.
4.0	28 Oct 2026	Changes to processes replace the Portfolio Management with the Data Sharing Committee. SOP Title change. Data Access Requests forms, Type A and B merged into a single form OPF02

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

		New OP-F05 Data Access Assessment Form created

1.0 PURPOSE

This Standard Operating Procedure (SOP) describes the process to be used when a data access request is submitted. This SOP also describes the review procedure for applications received.

2.0 SCOPE

This SOP applies to any request from any source for access to any ECTU study data, both during the active phase of the study and post-analysis.

This SOP does not apply if the activity is already fully specified in the study protocol, data management plan or collaboration agreement. Examples include where a formal data sharing agreement is already in place, or where access to data is required by a study statistician or health economist for Data Monitoring Committee reporting or final analysis.

3.0 RESPONSIBILITIES

The Data Sharing Administrator (or designee) is responsible for coordinating and administering this process, as outlined in the procedures below. The Data Sharing Committee is responsible for reviewing and making decisions on data access applications in accordance with this SOP.

The Data Sharing Administrator can be contacted via the Data Sharing inbox at ECTUdatashare@ed.ac.uk, and has primary responsibility for monitoring this inbox, and dealing with its administration (for example, arranging for others to access it).

4.0 PROCEDURE

4.1 Definitions

Study Data: Study data within the remit of a data access request are defined as the data tables from an ECTU managed database, or any data tables derived from them, (for example, as part of the main statistical analysis of an ECTU study), where ECTU is the data controller.

Data Controller: As per the Information Commissioner's Office (ICO) "The natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data"

Active phase of the study: When the study is in any of the following stages:

- Currently actively recruiting participants.
- Closed to recruitment, with participants still in follow-up.

- Closed to recruitment, with follow-up completed, but the database has not yet been locked.
- Closed to recruitment, with follow-up completed, and the database locked, but the main statistical analysis has not yet been conducted and/or published.

Post-analysis phase of the study: When the study is closed to recruitment, follow-up has been completed, the database has been locked, and the statistical analysis has been executed.

4.2 Application Process

The following application process should be used for any study request regardless of the level of ECTU involvement (for example, fully managed, database only, statistics only etc.). It may not be appropriate for ECTU to sanction the release of study data in certain circumstances, but it is important to ensure oversight of all requests is maintained.

4.2.1 All requests for study data will be made in writing via email to the Data Sharing inbox in the first instance.

4.2.2 If the study is in its active phase and has an ECTU Trial Manager, they should be kept informed of the data access process.

4.2.3 Once received, the request will be initially assessed by the Data Sharing Administrator to verify whether ECTU holds the requested data. If ECTU is unable to sanction the request, it will be referred back to the requester.

4.2.4 If the data request is potentially feasible, the OP-F02 Data Access Application Form will be sent to the requester, advising them to complete and return it to the Data Sharing inbox, along with copies of the requesters' and associated researchers' curriculum vitae(s).

4.3 Application Review Process

When a completed data access request is received, the Data Sharing Administrator creates a record in the Data Sharing Request tracker, which is maintained in DataStore - \ECT Unit\1. ECTU FILING SYSTEM - AMENDED 2010\ECTU Data Sharing. All associated documentation generated, received or completed during the execution of this SOP is saved in DataStore.

4.3.1 Once the completed OP-F02 Data Access Application Form has been received, the Data Sharing Administrator will update the tracker, and add the application to the agenda for the next appropriate Data Sharing Committee meeting, allowing sufficient time for the application to be reviewed and considered in advance of the meeting.

4.3.2 Before the Data Sharing Committee meeting, the Data Sharing Administrator will ensure that the Data Sharing Committee members have access to the relevant paperwork and information, either by sharing documentation, or by ensuring that someone attending that meeting has checked the paperwork and can speak to its contents.

4.3.3 For active phase studies, the Chief Investigator and Trial Statistician should be contacted about data access requests, the Data Sharing Administrator will send them the completed OP-F02 Data Access Application Form. The Chief Investigator and Trial Statistician's feedback should be fed into the Data Sharing Committee meeting, if received.

4.3.4 For post post-analysis studies, if the results have not yet been published, it may be appropriate to embargo any data access requests until post-publication to ensure the results are not undermined.

4.3.5 If necessary, further information may be sought and brought back to subsequent Data Sharing Committee meetings. The OP-F05 Data Access Assessment Form will then be revisited and updated considering the additional information. This process may be repeated, as necessary, until the Committee has sufficient information to reach a decision.

4.3.6 Once the Data Sharing Committee has reached a decision, the OP-F05 Data Access Assessment Form" will be finalised to document the Committee's assessment and decision. The applicant will then be notified of the outcome.

4.3.7 The Data Sharing Committee will inform the requester of the decision in writing via email, and the Data Sharing Administrator will update the tracker.

4.4 Approved applications

4.4.1 For approved applications, the Data Sharing Administrator will liaise with relevant parties to facilitate the delivery of the corresponding study data.

4.4.2 **Where the requester is from an external institution (i.e. outside the University of Edinburgh (UoE)), no data will be released until all required contracts, agreement and any other applicable legal requirements are fully in place.** It may therefore be necessary to consult with other UoE colleagues (e.g., the Edinburgh Research Office (ERO)) to initiate the preparation of a data sharing agreement or other relevant documentation. Data sharing outside the European Economic Area (EEA) and its list of approved countries, may be more complex and subject to higher levels of Information Governance scrutiny. Where applicable, this should be discussed with ERO during the drafting of the relevant contract or agreement.

4.4.3 For both internal and external requests, a Data Protection Impact Assessment (DPIA) may be required, where applicable (e.g. where the data is to be used for new and unexpected or more intrusive purposes). Relevant UoE colleagues, such as the Data Protection Officer (DPO), should be consulted as appropriate.

4.4.4 In some instances, most commonly for studies in the Post-analysis phase, the requested study data may be provided as a data pack, which was prepared alongside the final analysis by the study statistician(s) (as per ECTU_WPD_ST_W5). The contents of the data pack will be determined on a case-by-case basis and may include the items listed below:

- anonymised/de-identified dataset(s)

- a data dictionary
- relevant version(s) of the protocol
- applicable extracts of the relevant Statistical Analysis Plan
- blank case report forms (CRFs)
- ways in which the shared data differs from the data used for publication (e.g., where data have been removed relating to participants who did not consent to further sharing data)

The precise contents will depend on the nature of the request, the documentation and materials already provided or readily available to the requester, and what is considered necessary and proportionate, taking into account the time and resources required to prepare the data pack.

4.4.5 The requested study data (or data pack, where applicable) will be sent to the requester using a suitably secure method, such as the University of Edinburgh DataSync or DataVault services. Instructions on how to do this are available (see section 5.0 for details). The Data Sharing Administrator will oversee this process.

4.5 Declined applications

For declined applications, the Data Sharing Administrator will notify the requester of the decision and the reason(s) for the decline. The requester may appeal the decision in accordance with the appeal process outlined in this SOP.

4.6 Appeals Process

The requester has the right to appeal a data access decision. Any appeal should provide further clarification or new information relevant to the original decision. In the first instance, the appeal will be considered by the Data Sharing Committee and, if necessary, may be referred to the study sponsor for further consideration.

5.0 RELEVANT DOCUMENTS AND REFERENCES

ECTU Website

- OP-F02 Data Access Application Form
- OP-F05 Data Access Assessment Form
- ECTU_WPD_ST_W5 Statistical Analysis and Reporting

Others

- University of Edinburgh DataSync Service - https://www.ed.ac.uk/information-services/computing/desktop-personal/datasync
- DataVault - https://library.ed.ac.uk/research-support/research-data-service/after/datavault
- DPIA - Data protection impact assessments (DPIAs) | Data Protection | Data Protection

ECTU_SOP_OP_15 Data Access Request and Application Management v4.0 and associated documents

Final Audit Report 2026-09-28

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