ECTU Central Office SOP ECTU_OP_15: Data Access Request and Application Management

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Authorship and Approval			
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Tanya Tharakan, QA Manager	QA Authorisation	15 Dec 2023	See retained email approval dated 15 Dec 2023

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.

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 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 or collaboration agreement (for example, a formal data sharing agreement is already in place as specified in the protocol or collaboration agreement, or access to data is required by a study statistician for DMC reporting or final analysis).

3.0 RESPONSIBILITIES

The Data Sharing Administrator (or designee) is responsible for this process, as outlined in the procedures below. The Data Sharing Administrator can be contacted by emailing ECTUdatashare@ed.ac.uk, and has primary responsibility for monitoring this mailbox, and dealing with its administration (for example, arranging for others to access it).

4.0 PROCEDURE

4.1 Definitions

4.1.1 Study Data

Study data within the remit of a data access request are defined as the data tables from the main ECTU database, or any data tables that are derived from them, for example, as part of the main statistical analysis.

4.1.2 Data Access Request Application Type A (Form OP-F02)

A Data Access Request Application Type A is made when the study is still in any of the following stages:

- Currently recruiting participants
- Closed to recruitment with participants in follow-up
- Study closed (all recruitment and follow-up completed) but main statistical analysis not yet complete

4.1.3 Data Access Request Application Type B (Form OP-F03)

A Data Access Request Application Type B is made when the study data required are from a completed study where the statistical analysis has been completed. If the study 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. This will be considered by the panel during the review process (see section 4.3.)

4.2 Application Process

The following application process should be used for any request for any study 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 ECTUdatashare@ed.ac.uk in the first instance.

4.2.2 If there is a current ECTU Trial Manager for the study, they should be kept informed.

4.2.3 Once received, the request will be reviewed by the Data Sharing Administrator and allocated to the appropriate review stream (Type A or B), or referred back to the requester if ECTU are unable to sanction the request.

4.2.4 If allocated to a review stream, the appropriate data request application form template will be sent to the requester, advising them to complete and return it to the ECTUdatashare@ed.ac.uk mailbox.

4.3 Application Review Process

When a data sharing request is received, a record is created at the first instance, and updated in the tracker by the Data Sharing Administrator.

4.3.1 Once the completed data request application form has been received, the Data Sharing Administrator will update the Data Sharing Request Tracker, and add an entry into the next Portfolio Management Meeting agenda to discuss the application for data.

4.3.2 Before the Portfolio Management meeting, the Data Sharing Administrator will ensure that Portfolio Management meeting attendees 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 historical study requests, and/or assess whether any study participants rejected consent to data sharing, the Data Sharing Administrator will request support via the Operations Team, if required. This information is made available at the subsequent Portfolio Management meeting, and noted in the Datasharing Request Tracker.

4.3.4 For active studies, if the Chief Investigator has asked to be contacted about data sharing requests, the Data Sharing Administrator will send the request. The Chief Investigator's feedback should be fed into the Portfolio Management meeting, if received

4.3.5 The Portfolio Management meeting attendees will consider the following:

- Permissions listed in Ethics/Patient Information Sheet Consent Form (PISCF), and any other restrictions on sharing.
- Stage of study, and if/when data will be available to share
- Risk of affecting study outcomes/data access embargo date

- Specification of the dataset to be shared – wherever possible, the minimum amount of data in the least identifiable format should be shared, but decisions should take into account the amount of work needed, sharable versions of the data that already exist, and methods of access available (for example, user access to a safe haven space).
- Risk of re-identification
- Requester evaluation (for example, competence, qualifications)
- Scientific merit of proposed data use
- Overlap with other study data projects
- View of the Chief Investigator
- Timescale (the data may be archived or hosted off-site)
- Costs
- Any commercial aspects

4.3.6 If necessary, further information may be sought and brought back to the Portfolio Management meeting before a final decision is made.

4.3.7 If the application is approved, the Portfolio Management meeting attendees will consider the method of access and whether any additional agreements or funding will be required prior to the access being granted. Depending on the request, it may be necessary to further consult with external colleagues (e.g., ERO, Contracts, Information Governance) at this stage and/or undergo a Data Sharing Impact Assessment (when we are working with another organisation, or are using the data for new and unexpected or more intrusive purposes). Data sharing outside the European Economic Area and their list of approved countries will be more complex and perhaps subject to higher levels of Information Governance scrutiny.

4.3.8 The Data Sharing Administrator will inform the requester of the decision in writing via email, and update the Datasharing Request Tracker.

4.4 Data Access Process

4.4.1 If approved and once any required contracts/ legal requirements are in place, the Data Sharing Administrator will liaise with relevant parties and the data pack will be sent to the requester using a suitably secure method, such as the University of Edinburgh DataSync service. Instructions on how to do this are available (see section 5.0 for details). The Data Sharing Administrator will oversee this process.

4.4.2 The data pack could contain the following items (the precise list will depend on items already sent or readily available to the requester, and necessity versus time and budget considerations):

- anonymised/de-identified dataset(s)
- a data dictionary
- relevant version(s) of the protocol
- relevant extracts of the relevant Statistical Analysis Plan
- ways in which shared data differs from the published data (e.g., where data have been removed relating to participants who did not consent to sharing data)
- blank case report forms (CRFs)

4.5 Appeals Process

The requester has the right to appeal against data sharing decisions. In the first instance, these will be considered by the Portfolio Management Meeting attendees, and if necessary, can be referred on to the study sponsor.

5.0 RELEVANT DOCUMENTS AND REFERENCES

- Data Access Request Application Form Type A (OP-F02)
- Data Access Application Form Type B (OP-F03)
- University of Edinburgh DataSync Service - https://www.ed.ac.uk/information-services/computing/desktop-personal/datasync