





ECTU Central Office SOP ECTU_ST_07: Defining Data Access Requirements for Blinded and Unblinded Statisticians

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| Version No: | 4.0 |
| Issue Date: | 05 Jun 2024 |
| Effective Date: | 26 Jun 2024 |

| Authorship and Approval | | | |
|--|---|-------------|---|
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| Steff Lewis, Statistics Team Lead | Approver | 04-Jun-2024 |  |
| Tanya Tharakan QA Manager | QA Authorisation | 05-Jun-2024 |  <small>Tanya Tharakan (Jun 5, 2024 09:44 GMT+1)</small> |

| Document Revision History | | |
|---------------------------|---------------------------|---|
| Version No. | Effective Date | Summary of Revisions |
| 1.0 | 13 th Mar 2019 | Initial creation/New Document |
| 2.0 | 25 Mar 2021 | Execution of Periodic review and section 3.2 updated to clarify procedure |
| 3.0 | 05 Nov 2021 | Change in section 2. Scope to incorporate the REDCap application. Minor changes in sections 3.2.1 and 3.2.2 to clarify that static minimisation/stratification variables should not be used for statistical reporting. |
| 4.0 | 26 Jun 2024 | Moved to new Template. New section added regarding access to ECTU study related shared file areas. Minor formatting changes. |

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1.0 PURPOSE

This Standard Operating Procedure (SOP) describes the procedure for defining which data tables and shared file areas in a study can be accessed by Blinded and Unblinded Statisticians.

2.0 SCOPE

This SOP applies to all trials (regardless of randomisation status) with statistical support provided through ECTU that require the use of Blinded or Unblinded access for their execution, and it applies to all statisticians who require Blinded or Unblinded access to ECTU built databases and shared file areas until this type of access is required or applicable (for example, at the end of a study).

3.0 RESPONSIBILITIES

The Trial Statistician (or designee), Trial Data Manager/ Software Developer (or designee) are responsible for the implementation of this SOP.

4.0 PROCEDURE

4.1 Access to data tables in a study database

4.1.1 Access to data tables which will be used for the statistical analysis are strictly controlled by the data management and programming staff responsible for the database build.

4.1.2 Statisticians can be granted blinded or unblinded access to these tables:

- Blinded access limits access to any data tables that would not break the blind and reveal the study treatment allocations.
- Unblinded access allows access to all data tables (excluding participant identifiable data).

4.1.4 The Trial Statistician or designee will be responsible for identifying which data tables within the study database should be included as part of the blinded access at the database design process. The data tables containing the following information should be excluded as they may break the blind if fully accessible:

- Treatment Allocation Variables.
- Treatment Names lookup table – knowing that the treatment is A or B (rather than the allocation) may break the blind.
- Other Tables identifying types of treatments received or containing any data related to treatment delivery (for example, appointment schedules for receiving a treatment).

4.1.5 The Trial Statistician or designee will discuss the requirements with the Trial Data Manager/ Software Developer who will develop a blinded statistician user access role based on these requirements. The Trial Statistician will also indicate who will be the unblinded statistician. This should be confirmed in writing (for example, via email) from the Trial Statistician or designee once agreed.

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4.2 Access to minimisation/stratification variables in a study database

4.2.1 When randomisation occurs, the variable values used in the minimisation and/or stratification algorithm (if applicable) are stored in a table in the database, in order to leave a record of what was used to generate the allocated treatment, these are the static minimisation/stratification variables.

4.2.2 The information used for creating the static minimisation/stratification variables is likely to appear in other data tables within the database. However, while the information in the minimisation/stratification variables is static, there is a possibility that the same information in another database table could be updated (for example, as a result of a data query). Any difference between the values stored in the static minimisation/stratification variables and these other data tables could have an adverse effect on the subsequent analysis. Therefore, the static minimisation/stratification variables should not be used for statistical reporting (refer to ECTU WPD ECTU_ST_W5: Statistical Analysis and Reporting). Access to the static minimisation/stratification variables for the Trial Statistician or designee is provided only for checking purposes.

4.3 Requesting Blinded or Unblinded Access to a study database

4.3.1 If access is required, a request must be sent via email to the Trial Data Manager/ Software Developer, the Trial Statistician and the Trial inbox (or equivalent) with the following information:

- The project name and related database.
- Whether this is blinded or unblinded access, and any other specification.
- The name and University of Edinburgh UUNs of the users to receive access.
- Reason for access.

4.3.2 The Trial Statistician (or designee) will review the access request and approve or decline as required.

4.3.3 The requester will be notified by email once access has been granted or if the access request has been declined.

4.4 Revoking of access

4.4.1 The Trial Statistician will identify the personnel whose access needs to be revoked and email the Trial Data Manager/ Software Developer and the Trial inbox (or equivalent) with the following information:

- The project name and related database.
- Whether this is blinded or unblinded access.
- The name and University of Edinburgh UUNs of the users to receive access.
- Reason for revoked access.

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Note: The audit trail in the REDCap databases, an automatic process, is the main source of information regarding access. For bespoke systems, the Software Developer will keep a record of access as per SOP_ ECTU_IT_14 Management of Blinded and Unblinded User Access Roles. This is complemented by the information copied to the Trial inbox (or equivalent).

4.4 Creating and Requesting Unblinded Access to a study area

4.4.1 The Trial Statistician or designee will create an 'unblinded' folder at the start of the study, in the stats section of the electronic study folder set up on the ECTU shared drive as per ECTU_WPD_W6: Preparing, maintaining and reviewing the Trial Master File and Investigator Site Files.

4.4.2 Before anything is stored in the 'unblinded' folder, an email should be sent to the ECTU statistics team leads (copy Trial inbox (or equivalent)), who will then coordinate with IS support to restrict and control access to the folder using their "Group Maintenance Manager" in their service delivery dashboard (or equivalent).

4.4.3 Once an unblinded statistician is appointed to the trial, the Trial Statistician or designee will request the ECTU statistics team leads to grant access to the 'unblinded' folder for the unblinded statistician. If another statistician needs access to the unblinded area (e.g., for validation purposes), the Trial Statistician or designee will similarly request the ECTU statistics team leads to provide access. When an individual's involvement has ceased, the Trial Statistician or designee will request the ECTU statistics team leads to revoke access to the 'unblinded' folder. In all instances, the ECTU statistics team leads will document when individuals are added or removed from access in the "ECTU Statistics team projects" document on the "ECTU Statos" MS Teams.

4.4.4 When the study database has been locked, the final statistical report finalised and the trial results made public, restricted access to the unblinded folder is no longer necessary. The Trial Statistician or designee can request the ECTU statistics team leads to remove all access restrictions on the 'unblinded' folder.

5.0 RELEVANT DOCUMENTS AND REFERENCES

[On ECTU Website](#)

- ECTU_SOP_IT_14 Management of Blinded and Unblinded User Access Roles
- ECTU_WPD_IT_W2 Granting Blinded or Unblinded Access to a Study Database
- ECTU_WPD_ST_W5 Statistical Analysis and Reporting
- ECTU_WPD_TM_W6: Preparing, maintaining and reviewing the Trial Master File and Investigator Site Files

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Final Audit Report

2024-06-05

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| Created: | 2024-06-04 (British Summer Time) |
| By: | Tanya Tharakan (tanya.tharakan@ed.ac.uk) |
| Status: | Signed |
| Transaction ID: | CBJCHBCAABAA4uRjqG0rr2lmiP6F71C67AmxCCzWus4_ |

"SOP_ST_07 Defining Data Access Requirements for Blinded and Unblinded Statisticians v4.0" History


-  Document created by Tanya Tharakan (tanya.tharakan@ed.ac.uk)
2024-06-04 - 17:03:10 GMT+1- IP address: 192.41.114.230
-  Document emailed to Aryelly Rodriguez Carbonell (Aryelly.Rodriguez@ed.ac.uk) for signature
2024-06-04 - 17:06:15 GMT+1
-  Document emailed to Kenton D'Mellow (Kenton.D'Mellow@ed.ac.uk) for signature
2024-06-04 - 17:06:15 GMT+1
-  Document emailed to Steff Lewis (Steff.Lewis@ed.ac.uk) for signature
2024-06-04 - 17:06:15 GMT+1
-  Document emailed to Tanya Tharakan (tanya.tharakan@ed.ac.uk) for signature
2024-06-04 - 17:06:15 GMT+1
-  Email viewed by Aryelly Rodriguez Carbonell (Aryelly.Rodriguez@ed.ac.uk)
2024-06-04 - 17:06:53 GMT+1- IP address: 40.94.94.126
-  Document e-signed by Aryelly Rodriguez Carbonell (Aryelly.Rodriguez@ed.ac.uk)
Signature Date: 2024-06-04 - 17:10:01 GMT+1 - Time Source: server- IP address: 192.41.114.227
-  Email viewed by Steff Lewis (Steff.Lewis@ed.ac.uk)
2024-06-04 - 17:15:53 GMT+1- IP address: 104.47.11.62
-  Document e-signed by Steff Lewis (Steff.Lewis@ed.ac.uk)
Signature Date: 2024-06-04 - 17:16:23 GMT+1 - Time Source: server- IP address: 185.104.136.49

 Email viewed by Kenton D'Mellow (Kenton.D'Mellow@ed.ac.uk)

2024-06-04 - 23:21:29 GMT+1- IP address: 90.243.33.120

 Document e-signed by Kenton D'Mellow (Kenton.D'Mellow@ed.ac.uk)

Signature Date: 2024-06-05 - 08:34:46 GMT+1 - Time Source: server- IP address: 90.243.33.120

 Document e-signed by Tanya Tharakan (tanya.tharakan@ed.ac.uk)

Signature Date: 2024-06-05 - 09:44:07 GMT+1 - Time Source: server- IP address: 192.41.114.230

 Agreement completed.

2024-06-05 - 09:44:07 GMT+1