ECTU Central Office SOP ECTU_IT_14: Management of Blinded and Unblinded Access User Roles

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Authorship and Approval			
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Document Revision History		
Version No.	Effective Date	Summary of Revisions
1.0	21 Oct 2015	Initial creation/New document
2.0	10 Jun 2016	Name change to WPD in relevant documents to comply with ECTU_OP_01. Change to numbering in section 3
3.0	20 Nov 2017	Minor alterations to formatting and numbering throughout. Additional text added to section 3.5 regarding treatment allocation variables
4.0	13 Mar 2019	Document moved to new template. Section 3.2 added. Document updated substantially to reflect ECTU_SOP_ST_07. Change of title.
5.0	07 Jun 2024	Moved to new version of template (v3.0). ECTU_WPD_W2: Granting Blinded or Unblinded User Access to a Study Database has been merged with this SOP

6.0	11 Nov 2026	Minor updates made throughout section 4.0 to reflect current processes. QMS template updated to v4.0

1.0 PURPOSE

This Standard Operating Procedure (SOP) describes the process for developing and granting blinded or non- blinded access to bespoke trial databases developed and maintained by ECTU.

2.0 SCOPE

This SOP applies to all Software Developers who are responsible for granting access to bespoke ECTU trial databases.

3.0 RESPONSIBILITIES

The Software Developer is responsible for implementing the tasks set out in this SOP.

4.0 PROCEDURE

4.1 Developing Blinded and Unblinded User Access Roles

4.1.1 The Trial Statistician or designee is responsible for defining the access requirements for an Unblinded access role. For Trial Statisticians within ECTU, this procedure is outlined in ECTU_SOP_ST_07 Defining Data Access Requirements for Blinded and Unblinded Statisticians.

4.2 Blinded and Unblinded User Access Requests

4.2.1 A request for access to the database should be made to the Software Developer, via email as referenced in ECTU_SOP_ST_07 Defining Data Access Requirements for Blinded and Unblinded Statisticians

4.2.2 The Software Developer will review the access request**.** Careful consideration should be given to providing access to participant identifiable data (specifically name and address details, care providers name and address details and identifiers for other systems – CHI, NHS number). Access to these should only be given if there is a specific need (such as linking part postcodes to deprivation scores), which should be stated in the email request. Access should be given to the minimum number of fields possible.

4.2.3 If the access request is accepted, then the UUN of the requesters should be granted access to the database.

4.2.4 If the UUN is not available (e.g for a new statistician) to add then the user does not have access to the database server. If necessary, contact IS to grant permission to the server for the user. Include the UUN and the database server name in the IS request.

4.2.5 Add the UUN to the Unblinded Statistician or Blinded Statistician user role as created for the study database. The criteria for these user roles will have already been agreed with the Trial Statistician or designee.

4.2.6 Add the UUNs to the db_datareader role.

4.27 The access request will be documented using the IT001 Database Access Record Log. The updated document will be retained within the TMF, Section 9 (Full service) or Section 3 (Partial service studies).

4.2.8 Once the Software Developer has created the 'Blinded Statistician' or 'Unblinded Statistician' user access, an email will be sent to the requester, and the trial inbox confirming the access and any exemptions.

5.0 RELEVANT DOCUMENTS AND REFERENCES

ECTU Website

- ECTU_SOP_ST_07 Defining Data Access Requirements for Blinded and Unblinded Statisticians
- IT001 Database Access Record Log Template

ECTU_SOP_IT_07, IT_14 and IT001

Final Audit Report 2026-10-13

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