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

Version No:	
	4.0
Effective Date:	
	13th March 2019

Authorship and Approval			
Name and Designation	Author/Reviewer/ Approval	Date	Signature
Lynsey Milne, Assistant Data Manager	v4.0 Author	24th October 2018	Signature on file
Steff Lewis, ECTU Stats Team Leader	v4.0 Reviewer	27th February 2019	Signature on file
Allan Walker, Data and IT Systems Manager	v4.0 Approval	27th February 2019	Signature on file

Document Revision History		
Version No	Date	Summary of Revisions
1.0	21st Oct 2015	Initial creation/New document
2.0	10th June 2016	Name change to WPD in relevant documents to comply with ECTU_OP_01. Change to numbering in section 3
3.0	20th November 2017	Minor alterations to formatting and numbering throughout. Additional text added to section 3.5 regarding treatment allocation variables
4.0	13th March 2019	Document moved to new template. Section 3.2 added. Document updated substantially to reflect ECTU_SOP_ST_07. Change of title.

1. 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. SCOPE

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

3. PROCEDURE

3.1 Developing Blinded and Unblinded User Access Roles

3.1.1 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 Central Office SOP ECTU_ST_07 Defining Data Access Requirements for Blinded and Unblinded Statisticians.

3.2 Blinded and Unblinded User Access Requests

3.2.1 A request for access to the database should be made to the IT Programmer via email with the following information:
- The project name and related database.
- Whether this is blinded or un-blinded access.
- The name and University of Edinburgh UUNs of the users to receive access.
- Reason for access.

3.2.3 The IT team 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 no.). Access to these should only be given if there is a specific need (such as linking part postcodes to deprivation scores), and access should be given to minimum number of fields possible.

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

4. RELEVANT DOCUMENTS AND REFERENCES

ECTU Central Office SOP ECTU_ST_07 Defining Data Access Requirements for Blinded and Unblinded Statisticians
ECT Unit/SOPs/Finalised SOP and WPD/ST/SOP/Current PDF version for use

ECTU Central Office WPD ECTU_IT_W2 Granting Blinded or Unblinded Access to a Trial Database
ECT Unit/SOPs/Finalised SOP and WPD/IT/WPD/Current PDF version for use