



ECTU Central Office WPD ECTU_WPD_W2: Granting Blinded or Unblinded User Access to a Study Database

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

Document Revision History		
Version No	Date	Summary of Revisions
1.0	21 st Oct 2015	Initial creation/new document
2.0	10 th June 2016	Version 1 incorrectly named. Name changed as per naming convention in ECTU_SOP_OP_01 Change to number format of sections and subsections.
3.0	20 th November 2017	Minor changes to formatting and numbering throughout. Text added to section 2.5 clarifying that treatment allocation variables access should be denied.
4.0	13 th March 2019	Updated alongside ECTU_SOP_IT_14. Document moved to new template. Minor changes throughout document due to implementation of ECTU_SOP_ST_07



1. INTRODUCTION

This Working Practice Document (WPD) describes the procedure for granting blinded or unblinded access to the trial databases and should be used in conjunction with ECTU Central Office SOP ECTU_IT_14 Granting blinded or non-blinded access to the trial databases.

2. INSTRUCTIONS and GUIDANCE

- 2.2 A change request should be completed by the IT team recording the access request. The change request should include the information from the access request. The change request should also include the requesters' name, role and the date requested.
- 2.3 The UUN of the requesters should be added to the database users.
- 2.4 If the UUN is not available to add then the user does not have access to the database server. Contact IS to grant permission to the server for the user. Include the UUN and the database server name in the IS request.
- 2.5 Deny access to any participant identifiable data, unless there are specific reasons to allow access to this data.
- 2.6 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
- 2.7 Add the UUNs to the db_datareader role.
- 2.8 The access request will be documented using the Database Access Record Template. The signed copy of the document will be retained in the IT Management File.
- 2.9 Once the IT Programmer has created the 'Blinded Statistician' or 'Unblinded Statistician' user access, an email will be sent to the user confirming the access and any exemptions.

3. RELEVANT DOCUMENTS AND REFERENCES

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

ECT Unit/SOPs/Finalised SOP and WPD/IT/SOP/Current PDF version for use

Database Access Record Template

ECT Unit/SOPs/Finalised SOP and WPD/IT/Supporting Documents and Templates

ECTU Change Management:

<https://dcnapp4.dcn.ed.ac.uk/ECTUChangeRequests/login.aspx>

IS Self Service Portal: <https://ed.unidesk.ac.uk/tas/public/>

IS Helpline Email : IS.Helpline@ed.ac.uk