ECTU Central Office SOP ECTU_DM_12: User Access Management on the REDCap System

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Authorship and Approval			
Name and Designation	Author/Reviewer /Approval/ Authorisation	Date	Signature
Lynsey Milne, Data Manager	Author	31-Oct-2024	*Lynsey Milne* Lynsey Milne (Oct 31, 2024 10:58 GMT)
Ruth Armstrong, Data Manager	Reviewer	31-Oct-2024	*R. Arms* Ruth Armstrong (Oct 31, 2024 11:00 GMT)
Tony Wackett, Data Management and Programming Architect	Approver	31-Oct-2024	*Tony Wackett* Tony Wackett (Oct 31, 2024 10:29 GMT)
Tanya Tharakan, QA Manager	QA Authorisation	31-Oct-2024	*Tanya Tharakan* Tanya Tharakan (Oct 31, 2024 11:11 GMT)

Document Revision History		
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1.0	18 Nov 2024	Initial creation

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1.0   PURPOSE

This Standard Operating Procedure (SOP) describes the procedure for managing user access requests for the REDCap system and any study databases built within the platform.

2.0   SCOPE

This SOP applies to all members of the ECTU Data Management team with REDCap Administrator access rights.

This SOP applies to Trial Managers or appropriate study designee who oversee study database access.

3.0   RESPONSIBILITIES

The ECTU Data Management team are responsible for granting and removing access to the REDCap system. This can only be done by those with appropriate REDCap Administrator access.

The ECTU Data Management team may also be responsible, where appropriate, for granting access to study databases.

The Trial Manager or appropriate study designee is responsible for requesting REDCap system and study database access (if appropriate) from the ECTU Data Management Team for individual users as required.

The Trial Manager or appropriate study designee may be responsible for granting study database access if this has been delegated to the Trial Office user role (or similar user role) as part of the study management.

4.0 PROCEDURE

Definitions

'REDCap system' and related references refers to the version of REDCap licensed to ECTU with web address of https://redcap.clinicaltrials.ed.ac.uk/ and not to any other version licensed within the University of Edinburgh or another external institution.

4.1   Granting access to the REDCap system

4.1.1   Before access to a study database can be given, users must be granted access to the REDCap system which hosts the database.

4.1.2   User access to the REDCap system can only be granted by designated REDCap Administrators within the ECTU Data Management team.

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4.1.3 The Trial Manager or appropriate study designee should request user access via email to redcap.ectu@ed.ac.uk. The request should include the name and email address of the user.

4.1.4 User access should only be granted using a professional email address. It is not recommended that personal email addresses are used.

4.1.5 On receipt of the request, the ECTU Data Management team will create the user profile on the REDCap system.

4.1.6 Once created, the user will be notified of their access via direct email from the REDCap system. The email will advise the username and contain a link to log-in and set a password. This email is only accessible via the designated email address provided for the User Profile.

4.1.7 The ECTU Data Management team will reply to the Trial Manager or appropriate study designee who made the request, advising that REDCap access has been granted. The username may also be provided to the requester if study database access is delegated to the Trial Office or similar role.

4.1.8 The ECTU Data Management Team will retain all request emails in a designated study folder within the REDCap inbox.

4.1.9 The access granted at this point is to the **REDCap system only.** REDCap system access does not allow a user to access any study databases or functions. Further access to a study database is granted separately via the study database itself. (Section 4.3)

4.2 Resetting a Password for a REDCap User Profile

4.2.1 A password can only be reset by REDCap Administrators in the ECTU Data Management team. This function cannot be delegated to a user role on the database as the password is set for the system as a whole rather than per study database.

4.2.2 A password reset can be requested via email to redcap.ectu@ed.ac.uk with the username/email address.

4.2.3 Once reset, the user will receive notification via direct email from the REDCap system. The email will contain a link to log-in to the system and set a new password. This email is only accessible via the designated email address provided for the User Profile.

4.3 Granting access to a REDCap study database

4.3.1 Study database access can be granted by REDCap Administrators in the ECTU Data Management team or can be delegated to an appropriate user role on the study database. User roles are defined as part of the initial specification and database build.

4.3.2 How study database access will be granted will be agreed with the Trial Manager or appropriate study designee and the database developer during the initial database build. The developer will ensure that an appropriate role (most commonly the Trial

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Office role) is granted User Rights access. The User Access procedure will be detailed in the Data Management Plan (DMP) for the study.

4.3.3 Where the ECTU Data Management team is responsible for granting study database access, the request should be made via email to redcap.ectu@ed.ac.uk. Study database access can be requested at the same time as REDCap system access as specified in section 4.1 above.

4.3.4 The request email should include the following:

- User Name
- User Email Address
- Study Name
- Database Access Required (e.g. study database, screening log database, training version or live version)
- DAG (Site) Allocation (from those available on the study databases)
- User Role Required (from those available on study databases)

4.3.5 Study database access requests will only be accepted from the Trial Manager or appropriate study designee. .

4.3.6 The ECTU Data Management team will reply to the Trial Manager or appropriate study designee who made the request, advising that study database access has been granted as requested. If the user has been copied into the request email, they may be included in the confirmation reply as well.

4.3.7 The ECTU Data Management team will retain all request emails in a designated study folder within the REDCap inbox.

4.3.8 Where study database access has been delegated via a user role on the database, access can be granted by any individual within that role as required (as per ECTU_DM_W3: Managing Us er Profiles on the REDCap System in 4.2.6) using the username that was provided when REDCap system access was granted (as per 4.1.8). The individual granting database access will also be responsible for informing users of their database access as appropriate.

4.4   User Access Review and Removal of User Access from Study Databases

4.4.1 The ECTU Data Management team is responsible for completing a user review for all REDCap study databases.

4.4.2 The review is initiated automatically on the REDCap system every six months. A list of all users on all versions of the study databases is sent to the Trial Manager or appropriate study designee for review. This is sent to a designated email address (usually generic trial email if available) from redcap.ectu@ed.ac.uk.

4.4.3 The Trial Manager or appropriate study designee will advise by email of any user access that can be removed.   The ECTU Data Management team will arrange for access to be removed as specified.

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4.4.4 The User Access Review is conducted by the ECTU Data Management team to ensure study database access for users is accurate and appropriate, however, database access should be removed as soon as it as practical to do so and not just as part of the review process.

4.4.5 It is recommended that the Trial Manager or appropriate study designee ensure that site staff regularly inform the Trial Office of staff changes so that database access can be removed as soon as possible.

4.4.6 Study database access can be removed at any point on an ad-hoc basis as is necessary by email request to the ECTU Data Management team specifying the following:

- User Name
- Study Name
- Database Access to be Removed (e.g. study database, screening log database, training version or live version)

4.4.7 Where study database access has been delegated via a user role on the database, access can be removed by any individual within that role as required.

4.4.8 Removal of study database access does not remove user access to the REDCap system as a whole. Whilst the user is removed from the study databases and cannot access any data within them, they will still be able to log-in to REDCap using their username and password.

4.4.9 Users can be removed from the REDCap system entirely by the REDCap Administrators in the ECTU Data Management team if required (for example, if a user leaves an organisation), however, REDCap system access can be left intact with no associated study access so that it can be used again where necessary (for example, if a user moves to a different study hosted on our REDCap system).

4.4.10 The ECTU Data Management team will retain all user access review and removal request emails in a designated study folder within the REDCap inbox.

4.5 Suspension of REDCap User Access

4.5.1 In certain cases it may be appropriate to suspend user access rather than remove it entirely (e.g. if a user is on an extended leave period but is expected to return). User profiles can only be suspended and unsuspended by REDCap Administrators in the ECTU Data Management Team.

4.5.2 Suspending user access means the user will be unable to log-in to the REDCap system (and therefore be unable to access any assigned study databases) until their user profile has been unsuspended.

4.5.3 Before using the suspension option, consideration should be given to the impact on the user and the study. It may not be appropriate to suspend access if the user works on multiple studies but suspension is only required in relation to one. Use of this option

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should be discussed with the Trial Manager or appropriate study designee and the REDCap Administrators before implementing.

4.6   Further User Management Guidance

4.6.1   Further guidance on the procedures detailed in section 4.1-4.5 above is described in ECTU_WPD_DM_W3 Managing User Profiles for REDCap Study Databases.

5.0   RELEVANT DOCUMENTS AND REFERENCES

ECTU Website:

- ECTU_WPD_DM_W3 Managing User Profiles on the REDCap System

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ECTU_SOP_DM_12 and WPD_DM_W3

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