

# ECTU Central Office WPD ECTU\_REDCap\_W2: Requesting a Change to a Study Database

Version No:	1.0
Issue Date:	17 Jul 2024
Effective Date:	14 Aug 2024

Authorship and Approval						
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Document Revision History				
Version No.	Effective Date	Summary of Revisions		
1.0	14 Aug 2024	Initial Creation/New document		



Version No Effective Date ECTU\_REDCap\_W2

Value 1.0

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1. INTRODUCTION

This WPD provides instruction on how to request a change to be implemented on a live study database. This procedure is applicable to all study databases built on the REDCap platform by the ECTU Data Management Team and bespoke databases built by the ECTU Programming Team.

#### 2. INSTRUCTIONS and GUIDANCE

- 2.1 Changes to a live study database must be logged on the ECTU DM&P Project Change Requests database held on the REDCap platform.
- 2.2 Access to the database will be given by REDCap Administrators to the Trial Manager or appropriate study designee who will be responsible for making the requests. Access will be provided under the 'Project Managers' user role.
- **2.3** The 'Project Managers' user role is limited to adding a record and completing or amending the 'Change Request' page.
- 2.4 To make a new request, the user will add a new record (via the Record Status Dashboard) and complete the 'Change Request' form by clicking the grey orb. See Appendix 1 for details.
- 2.5 The request will be logged under the 'Project Name' in the drop-down list. If the study is not listed, this should be logged under 'Other'. The Data Management team will review and update the system every six months to include new studies or remove closed studies.
- 2.6 Provide details of the change(s) required in the 'Requested Change(s)' section. Supporting documents can be added to the request to give further information if necessary.
- 2.7 Provide a date the update is required by. This is the deadline date for the change to be implemented on the training database to be ready for review and possible validation. NOTE: This is not the date that the change will be implemented on the live database. Requested dates cannot be guaranteed by the Data Management and Programming Team and should be discussed with the developer if urgent.
- **2.8** Change the form status to 'Complete' and save the record.
- 2.9 Saving the record will automatically send an email notification to the designated database developer for the study in the Data Management Team (for REDCap databases) or Programming Team (for Bespoke databases). The ECTU Data Management and Programming Team Leads and the Chief Operating Officer will also receive a notification of the request.
- 2.10 If the study in unallocated to a specific developer or the request is logged under 'Other', the email notification will be automatically sent to the ECTU Programming Team Lead for further action.



Version No 1.0

Effective Date 14 Aug 2024

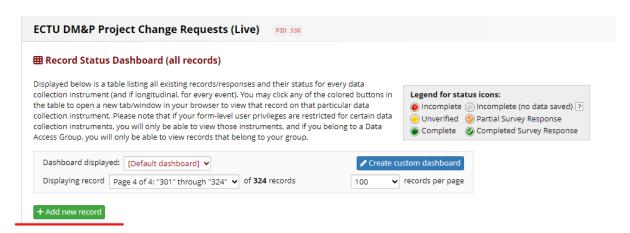
- 2.11 The 'Requested Change(s) section can be amended if required, however, this will not trigger a new notification to the database developer. Should you wish to amend or add to an existing request, it is recommended that the developer is informed separately via email.
- 2.12 On receipt of the notification, the database developer will complete the acceptance section of the 'DM&P Management' form on the ECTU DM&P Project Change Requests database for the request. This form is not visible to those with 'Project Managers' user role.
- **2.13** The database developer will assign one of the following statuses to the request:
  - **Accepted** the request is accepted by the developer and will be implemented on the training database for testing and validation
  - Deferred the request has been provisionally accepted by the developer but has been put on temporary hold in agreement with the requester. The request will then be further reviewed and at a later date
  - **Rejected** the request has been rejected by the developer after discussion with the requester. This may occur if the change request is not feasible or is no longer required.
  - **Complete** the request has been validated and is now implemented on the live database
- **2.14** The database developer will liaise with the requester and other relevant designees to ensure the change is implemented as required.

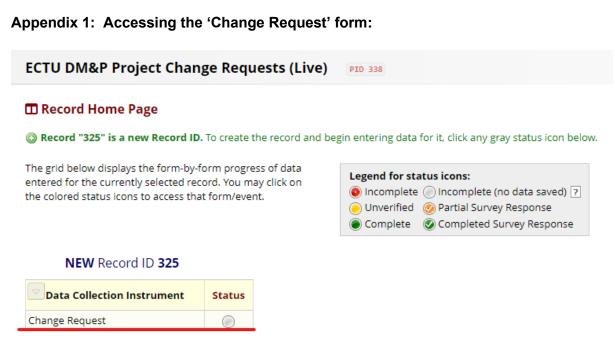
#### 3. RELEVANT DOCUMENTS AND REFERENCES



Version No Effective Date 1.0 L4 Aug 2024

### Appendix 1: Add a 'Change Request':







Version No 1.0 Effective Date 14 Aug 2024

## Appendix 1: Completing the 'Change Request' form:

Record ID		325				
Date Request Logged		2023-09-04 15:33:46				
Request Logged By		lynseymilne				
Project Name						
* must provide value	9					
Please list all changes in the 'Requested Changes' field below. If multiple changes are required, please detail in Word or Excel and upload in the 'Upload Supporting Documentation' field.						
Only one file may be uploaded per record. If you have multiple documents detailing the changes required, e.g. updated pCRFs, please note this in the 'Requested Changes' field. A member of the DM&P Team will contact you to discuss further.						
Requested Change(s)  * must provide value	P					
		Expand				
		Exporta-				
Upload Supporting Documentation	9	<b>1</b> <u>Upload file</u>				
		Today D-M-Y				
Date Update Required  * must provide value	<i>-</i>	Please provide the desired deadline date for the changes. Please note the date entered here is not guaranteed. The DM&P Team will confirm estimated timelines following receipt of this change request.				
Comments	P					
		Everand				
		Expand				
Thank you for contacting the Data Management & Programming Team. A member of the DM&P Team will be in contact with you within 3 business days.						
If you have an urgent request, please contact Kenton D'M kenton.d'mellow@ed.ac.uk�	ello	w, DM&P Team Lead:				
Form Status						
Complete?	9	Incomplete 🗸				
Lock this instrument?						
If locked, no user will be able to modify this instrument for this record until someone with Instrument Level Lock/Unlock privileges unlocks it.		□ 🛅 Lock				
		Save & Exit Form Save & Go To Next Form				

The user of this document is responsible for ensuring it is the current version.

# ECTU REDCAP\_03, 04, 06 and W2

Final Audit Report 2024-07-17

Created: 2024-07-16 (British Summer Time)

By: Tanya Tharakan (tanya.tharakan@ed.ac.uk)

Status: Signed

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