






## 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			
Name and Designation	Author/Reviewer/Approval/Authorisation	Date	Signature
Lynsey Milne, Data Manager	Author	17-Jul-2024	 <a href="#">Lynsey Milne (Jul 17, 2024 07:27 GMT+1)</a>
Ruth Armstrong, Data Manager	Reviewer	17-Jul-2024	 <a href="#">Ruth Armstrong (Jul 17, 2024 09:16 GMT+1)</a>
Joyce Thomson, Chief Operating Officer	Approver	17-Jul-2024	 <a href="#">Joyce Thomson (Jul 17, 2024 08:11 GMT+1)</a>
Tanya Tharakan, QA Manager	QA Authorisation	17-Jul-2024	 <a href="#">Tanya Tharakan (Jul 17, 2024 09:39 GMT+1)</a>

Document Revision History		
Version No.	Effective Date	Summary of Revisions
1.0	14 Aug 2024	<ul style="list-style-type: none"><li>Initial Creation/New document</li></ul>

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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 is 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.

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- 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

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

**ECTU DM&P Project Change Requests (Live)** PID 338

**Record Status Dashboard (all records)**

Displayed below is a table listing all existing records/responses and their status for every data collection instrument (and if longitudinal, for every event). You may click any of the colored buttons in the table to open a new tab/window in your browser to view that record on that particular data collection instrument. Please note that if your form-level user privileges are restricted for certain data collection instruments, you will only be able to view those instruments, and if you belong to a Data Access Group, you will only be able to view records that belong to your group.

**Legend for status icons:**

- Incomplete  Incomplete (no data saved) ?
- Unverified  Partial Survey Response
- Complete  Completed Survey Response

Dashboard displayed: [Default dashboard] Create custom dashboard

Displaying record Page 4 of 4: "301" through "324" of **324** records 100 records per page

+ Add new record

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

**ECTU DM&P Project Change Requests (Live)** PID 338

**Record Home Page**

+ **Record "325" is a new Record ID.** To create the record and begin entering data for it, click any gray status icon below.

The grid below displays the form-by-form progress of data entered for the currently selected record. You may click on the colored status icons to access that form/event.

**Legend for status icons:**

- Incomplete  Incomplete (no data saved) ?
- Unverified  Partial Survey Response
- Complete  Completed Survey Response

NEW Record ID 325

Data Collection Instrument	Status
Change Request	<input type="radio"/>

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

<b>Record ID</b>	325
Date Request Logged	<input type="text" value="2023-09-04 15:33:46"/>
Request Logged By	<input type="text" value="lynseymilne"/>
<b>Project Name</b> <small>* must provide value</small>	<input type="text"/>
<p>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.</p> <p>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&amp;P Team will contact you to discuss further.</p>	
<b>Requested Change(s)</b> <small>* must provide value</small>	<input type="text"/> <span style="float: right;">Expand</span>
<b>Upload Supporting Documentation</b>	<input type="text"/> <a href="#">Upload file</a>
<b>Date Update Required</b> <small>* must provide value</small>	<input type="text"/> <input type="button" value="Today"/> D-M-Y <small>Please provide the desired deadline date for the changes. Please note the date entered here is not guaranteed. The DM&amp;P Team will confirm estimated timelines following receipt of this change request.</small>
<b>Comments</b>	<input type="text"/> <span style="float: right;">Expand</span>
<p>Thank you for contacting the Data Management &amp; Programming Team. A member of the DM&amp;P Team will be in contact with you within 3 business days.</p> <p>If you have an urgent request, please contact Kenton D'Mellow, DM&amp;P Team Lead: kenton.d@mellow@ed.ac.uk</p>	
<b>Form Status</b>	
<b>Complete?</b>	<input type="text" value="Incomplete"/>
<b>Lock this instrument?</b> <small>If locked, no user will be able to modify this instrument for this record until someone with Instrument Level Lock/Unlock privileges unlocks it.</small>	<input type="checkbox"/> <input checked="" type="checkbox"/> <b>Lock</b>
<div style="text-align: right;"><input type="button" value="Save &amp; Exit Form"/> <input type="button" value="Save &amp; Go To Next Form"/></div>	

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# 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
Transaction ID:	CBJCHBCAABAASnICTDa9-u0V6IKXuqElypRhrpMZwfYy

## "ECTU REDCAP\_03, 04, 06 and W2" History

-  Document created by Tanya Tharakan (tanya.tharakan@ed.ac.uk)  
2024-07-16 - 17:41:06 GMT+1- IP address: 192.41.114.230
-  Document emailed to Lynsey Milne (Lynsey.Milne@ed.ac.uk) for signature  
2024-07-16 - 17:50:03 GMT+1
-  Document emailed to Ruth Armstrong (Ruth.Armstrong@ed.ac.uk) for signature  
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-  Document emailed to Joyce Thomson (joyce.thomson@ed.ac.uk) for signature  
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-  Email viewed by Lynsey Milne (Lynsey.Milne@ed.ac.uk)  
2024-07-17 - 07:27:25 GMT+1- IP address: 104.47.11.254
-  Document e-signed by Lynsey Milne (Lynsey.Milne@ed.ac.uk)  
Signature Date: 2024-07-17 - 07:27:58 GMT+1 - Time Source: server- IP address: 192.41.114.230
-  Email viewed by Joyce Thomson (joyce.thomson@ed.ac.uk)  
2024-07-17 - 08:08:11 GMT+1- IP address: 104.47.11.62
-  Document e-signed by Joyce Thomson (joyce.thomson@ed.ac.uk)  
Signature Date: 2024-07-17 - 08:11:33 GMT+1 - Time Source: server- IP address: 94.14.215.249
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2024-07-17 - 09:07:36 GMT+1- IP address: 104.47.11.126
-  Document e-signed by Ruth Armstrong (Ruth.Armstrong@ed.ac.uk)  
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Document e-signed by Tanya Tharakan (tanya.tharakan@ed.ac.uk)

Signature Date: 2024-07-17 - 09:39:36 GMT+1 - Time Source: server- IP address: 192.41.114.230



Agreement completed.

2024-07-17 - 09:39:36 GMT+1

