REDCap Study Database Validation Plan

**<<Study Name/Acronym>>**

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| **Authorship and Document History** | | | |
| **Date** | **Author Name and Designation** | **Version No** | **Summary of Revisions** |
|  |  | 1.0 | * Initial Creation * Study-specific version set at 1.0 |

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| **Approval** | | | |
| **Name and Project Role** | **Version No** | **Date Approved** | **Signature** |
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*All text in italic green is for guidance purposes only and should be deleted from the final version. This template is for guidance only and should be altered as appropriate.*

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| 1. **Purpose of Document** |
| The ECTU Data Management Team have created a study database for the **STUDY NAME/ACRONYM** trial on the ECTU-licensed REDCap platform in accordance with the protocol and associated specification documents provided for this purpose.  This document describes the procedure for validating this database prior to final release for use by research staff to enter live data for the trial. This plan will be updated for each database release throughout the life-cycle of the trial.  This Validation Plan is for **<<Database Release No>>** of the database. |

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| 1. **Validation Procedure** |
| REDCap is a secure web platform for building and managing databases. The platform consists of generic built-in functionality to which additional functions and data collection instruments can be added for bespoke data collection. The Data Manager/Assistant Data Manager (delete as appropriate) has implemented a series of core database functions and data collection instruments (features) for the study which must be validated in a training setting (Training database) before proceeding to final release (Live database).  Validation is completed by entering dummy data in the selected data collection instruments built within the Training database to check the behaviour of each field or function added within that instrument is correct. The core database functionality is also validated using dummy data to check the described behaviour.  This will be completed by the designated Validator. The Validator ***cannot*** be the Data Manager/Assistant Data Manager (delete as appropriate) who built the database.  For this database release, the Validator will be ***specify who this will be, e.g. Trial Manager or designee.***  The Data Manager/Assistant Data Manager (delete as appropriate) will provide the Validator with a Validation Document for each feature included on the training database.  This will describe each feature including field description, field attributes and expected functionality and will include an option to ‘Pass’ or ‘Fail’ each field based on the descriptions provided.  The Validator will complete the document and specify a ‘Pass’ or ‘Fail’ for each field. If any field is listed as a ‘Fail’ the Data Manager/Assistant Data Manager (delete as appropriate) will be informed of the failure. Once the correction has been implemented, the feature will be revalidated  In order for a feature to pass validation, all fields or functions listed on the Validation Document must be listed as a ‘Pass’. The Validation document will be signed by the Validator and the Data Manager/Assistant Data Manager once the feature has passed.  **The Training database cannot be released to a Live database until all features have passed validation.**  All features will be validated for the initial release of the database. For subsequent releases, only the features that have been altered will be validated again.  A list of the features to be validated for this release is included in section 4. |

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| 1. **Retention of Documents** |
| The Data Manager/Assistant Data Manager (delete as appropriate) is responsible for the creation, maintenance and retention of the study-specific Validation Plan and all study-specific Validation Documents.  These will be retained electronically in ***specify drive location.*** Paper copies will be retained in a study-specific database document folder within the secure storage in the ECTU Trial Office. |

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| 1. **List of Features** | | |
| **Feature No** | **Feature Name** | **Version No** |
| *e.g. 001* | *e.g. Visit Date* | *e.g. 1.0* |
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| **Template Revision History** | | | |
| **Version No** | **Effective Date** | **Revised By (Name and Designation)** | **Summary of Revisions** |
| 1.0 | 20-June-2024 | Lynsey Milne (Data Manager) | * Initial creation * Template version set at 1.0 |