REDCap Study Database Release Specification

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

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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 recording the specification of the database prior to final release. It also records the approval process for the Trial Manager or designee, Trial Statistician or designee and Trial Sponsor (where applicable) |

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| 1. **Study Details** | |
| **Chief Investigator** |  |
| **Sponsor** |  |
| **Trial Manager** |  |
| **Data Manager/Assistant Data Manager (REDCap Developer)** |  |
| **Study Type** | CTIMP  Other Regulated Trial  non-CTIMP |
| **LIVE Database Name** |  |

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| 1. **Core Database Functionality at Release** | |
| **Identifier Method** | Sequential Numbering allocated by REDCap  Custom Identifier allocated by User |
| **Arms** | Single Arm  Multi-Arm Specify number of Arms:  N/A |
| **Randomisation** | Yes  No |
| **If Yes, please specify** | Randomisation using API token  Randomisation using REDCap Randomisation Module |
| **Surveys or Reminders via Email** | Yes  No |
| **Surveys or Reminders via Text** | Yes  No |
| **If Yes, please specify Text System used** | Text Anywhere using API token  TWILIO using REDCap Telephony Service (currently not applicable) |
| **Additional Specification Information** | All documentation relating to the specification is available from the Data Management team |

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| 1. **Release and Approval Details** | |
| **Protocol Version/Date at time of Release** |  |
| **Type of Release** | Initial Release  Subsequent Release due to a Database Update – Release No <<specify no>> |
| **Release Description** | *Standard Text if Initial Release:*  Initial Release of new study database.  Full details of the validated database instruments and functionality at initial release can be found in the Validation Plan and Validation Document associated with this release. These are available from the ECTU Data Manager and on the ECTU shared drive:  *Include drive pathway*  *Standard Text if Subsequent Release*  *Give brief description of why the database was updated, who requested the updated and include the Change Request Id if applicable*  *e.g. Database update after protocol amendment as requested by Trial Manager. This implements the Change Request Id 100.*  Full details of the changes made to the database instruments and functionality for this release can be found in the Validation Plan and Validation Documents associated with this release. These are available on the ECTU Database Release Documents database. |
| **Date Validation Complete** | DD-MMM-YYYY  All validation documents have been approved and signed as of this date. Please see individual documents for date each validation was completed. |
| **Date of Trial Manager (or designee) Release Approval** | DD-MMM-YYYY |
| **Date of Trial Statistician (or designee) Release Approval** | DD-MMM-YYYY |
| **Date of Trial Monitor Release Approval** | DD-MMM-YYYY  Not applicable |
| **Date of Trial Sponsor Release Approval** | DD-MMM-YYYY  Not applicable |

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| 1. **Live System Release** | |
| **System Version** |  |
| **Date Production (Live) Database Release** | DD-MMM-YYYY |
| **Released By (Name and Designation)** |  |
| **Release Notification Sent To** | *List Name and Designation of all personnel notified of release* |
| **Date Notification Email Sent** | DD-MMM-YYYY |

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| 1. **Approval (For completion by the DM/ADM completing the Live database release)** | |
| **Signature** |  |
| **Date** | DD-MMM-YYYY |

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| **Template Revision History** | | | |
| **Version No** | **Effective Date** | **Revised By (Name and Designation)** | **Summary of Revisions** |
| 1.0 | 03-July-2024 | Lynsey Milne (Data Manager) | * Initial creation * Template version set at 1.0 |