REDCap Study Database Validation Document

Database Core Functionality

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

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| **Feature Details** | | |
| **Feature No** | **Feature Name** | **Database Release No** |
| N/A | Database Core Functionality |  |

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

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| 1. **Procedure** |
| This document is used to validate the core functionality included in the database. Separate Validation Documents are provided for the instruments included for data collection.  For each item listed in the Validation Checklist, please indicate whether the item is a ‘Pass’ or a ‘Fail’. Once completed in full, complete the Validation Confirmation section. Validator and Data Management Sign-Off will be completed when all items have passed. |

Text in green is for guidance only and should be removed from the study-specific document.

The following sections are common to most study databases built on REDCap. Sections can be altered, removed or additional sections added as required depending on the functions used.

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| 1. **Study Arms - Validation Checklist (for completion by designated validator)** | | | | |
| **Description** | **Attributes** | **Pass** | **Fail** | **If ‘Fail’ please provide details** |
| *The study includes xxx Arm(s)* | *The Arm(s) are named:* |  |  |  |
| Include any further functionality as applicable to study Arms (e.g. Arm 2 is only applicable to X Site) |  |  |  |  |

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| 1. **Event Grid - Validation Checklist (for completion by designated validator)** | | | | |
| **Description** | **Attributes** | **Pass** | **Fail** | **If ‘Fail’ please provide details** |
| The Event Grid is displayed for each individual record added in each Arm | Once ‘Add a New Record’ is selected the Event Grid automatically appears |  |  |  |
| The Event Grid includes and displays separate Events with appropriate data collection instruments included in them | The Event Grid includes the following Events and data collection instruments:  List all Events that should appear. For each Event, list all data collection instruments that should appear within that Event |  |  |  |
| Clicking on any orb for any data collection instrument allows you to access the instrument itself | When clicked, the orb for each data collection instrument displays the correct instrument.  This does not apply to the following instruments where Form Display Logic is implemented (see section 4 for description):  List any data collection instrument that includes Form Display Logic. |  |  |  |

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| 1. **Form Display Logic - Validation Checklist (for completion by designated validator)** | | | | |
| **Form Display Logic allows an instrument to remain inaccessible until the set logic is met. This means that although the orb will be visible, clicking on it will not display the instrument itself unless the correct logic has met.** | | | | |
| **Instrument** | **Accessibility Logic** | **Pass** | **Fail** | **If ‘Fail’ please provide details** |
| Name of data collection instrument where Form Display Logic is included (as specified in section 3) | Detail the logic required for this instrument to be accessible |  |  |  |

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| **5. Status Alerts - Validation Checklist (for completion by designated validator)** | | | | |
| **Status Alerts will appear on each data collection instrument according to the current status of the participant. The default status for any participant is ‘Active’. This may be changed using the Change of Status instruments on the database** | | | | |
| **Description** | **Attributes** | **Pass** | **Fail** | **If ‘Fail’ please provide details** |
| Current Participant Status: Active | Descriptive  Field appears if detail logic required for this field to be displayed |  |  |  |
| Participant died on [include logic for date of death to be displayed] | Descriptive  Field appears if detail logic required for this field to be displayed |  |  |  |
| This participant was withdrawn from trial treatment on [include logic for date of change of status]. Please refer to the Change of Status page for details.  Data collection and follow up may continue, but the participant should not have received any trial-specific treatment after this date.  Text for withdrawal from IMP may differ depending on the study requirements | Descriptive  Field appears if detail logic required for this field to be displayed |  |  |  |
| This participant withdrew consent for data collection on [include logic for date of change of status]. Please refer to the Change of Status page for details.  Data collected before that date may be entered if applicable, but please ensure that no data collected after that date is entered.  Text for withdrawal from all aspects of the trials may differ depending on study requirements | Descriptive  Field appears if detail logic required for this field to be displayed |  |  |  |

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| **5. Surveys - Validation Checklist (for completion by designated validator)** | | | |
| **Where a survey link is sent to the participant (via text or email) for completion, logic is implemented to ensure these are sent correctly** | | | |
| **Description** | **Pass** | **Fail** | **If ‘Fail’ please provide details** |
| The following questionnaires are included in the survey queue:  List the questionnaires that are required for completion in the survey. |  |  |  |
| The following fields must be completed for the survey invitation to be automatically triggered:  State which fields require completion for the email/text link to be sent to the participant |  |  |  |
| Surveys are scheduled to be automatically issued once the fields above are completed at the following timepoints:  State the timepoints when the survey invitation will be triggered and the completion window set for each |  |  |  |
| If the survey has not been completed within xx days, a reminder will be sent.  State the reminder frequency as required. This may be different for each different timepoint. |  |  |  |
| The survey invitation will be sent from  State the email address that the link will be sent from |  |  |  |
| The following approved text will be included on the survey invitation:  State approved text provided for the invitation |  |  |  |
| The survey invitation will not be sent under the following circumstances:  State the stop logic implemented for the survey |  |  |  |
| At each timepoint, state first questionnaire in survey list will be completed first. Submitting the data automatically directs participants to the next questionnaire on the survey queue |  |  |  |
| Surveys can be completed by direct entry onto REDCap (not via a survey invitation) if required |  |  |  |

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| 1. **Validation Confirmation (for completion by designated validator)** | |
|  | Please tick as applicable |
| All fields and functionality within the instrument as specified in the Validation Checklist have passed. Validation is complete |  |
| One or more fields failed the validation as specified in the Validation Checklist. Correction and re-validation is required |  |
| Validation has failed for another reason (specify below). Correction and re-validation is required |  |
| Failure Details: | |

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| 1. **Validator Sign-Off (for completion by designated validator)** | | |
| **Validator Name and Designation** | **Signature** | **Date** |
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| 1. **Data Management Sign-Off** | | |
| **Data Manager/Assistant Data Manager Name** | **Signature** | **Date** |
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<<<<<<<<For template control only. Remove this page from study specific version>>>>>>>

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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 |