REDCap Study Database Validation Document

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

|  |  |  |  |
| --- | --- | --- | --- |
|  | | | |
| **Feature Details** | | | |
| **Feature No** | **Feature Name** | **Version No** | **Database Release No** |
|  |  |  |  |

|  |  |  |
| --- | --- | --- |
| **Authorship and Document History** | | |
| **Date** | **Author Name and Designation** | **Summary of Revisions** |
|  |  |  |

|  |
| --- |
| 1. **Procedure** |
| 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. |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1. **Validation Checklist (for completion by designated validator)** | | | | |
| **Field Label/Description** | **Field Attributes** | **Pass** | **Fail** | **If ‘Fail’ please provide details** |
| *e.g. Visit Date* | *e.g. Text (DD/MM/YYYY)*  *Max: Today*  *Alert appears if date is in the future* |  | e.g. X | e.g. A future date is accepted without any alert |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **3. Data Quality Rule Validation (for completion by designated validator)** | | | | |
| **Data Quality Rule Validation is only applicable if the rule is set to execute in real-time and will trigger an alert at the point of data entry. If this is not applicable, please specify below** | | | | |
| **Data Quality Rule Text/Description** | **Trigger** | **Pass** | **Fail** | **If ‘Fail’ please provide details** |
| *e.g.’ Diastolic BP’is missing* | *e.g. ‘Diastolic BP’ field has not been completed when the Baseline Visit instrument is saved* |  | e.g. X | e.g. Field was not completed but no alert appeared |

|  |  |
| --- | --- |
| **4. 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: | |

|  |  |  |
| --- | --- | --- |
| **5. Validator Sign-Off (for completion by designated validator)** | | |
| **Validator Name and Designation** | **Signature** | **Date** |
|  |  |  |

|  |  |  |
| --- | --- | --- |
| **6. Data Management Sign-Off** | | |
| **Data Manager/Assistant Data Manager Name** | **Signature** | **Date** |
|  |  |  |

<<<<<<<<For template control only. Remove this page from study specific version>>>>>>>

|  |  |  |  |
| --- | --- | --- | --- |
| **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 |