**<<Study Name/Acronym>>**Database Validation Plan

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| **Authorship and Document History** | | | |
| **Date** | **Author Name and Designation** | **Version No** | **Summary of Revisions** |
| *DD/ MMM/ YYYY* | *Name, Designation* | *X.X* | * *Initial Creation* * *Study-specific version set at 1.0* |

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| **Approval** | | | |
| **Name and Project Role** | **Version No** | **Date Approved** | **Signature** |
| Software Developer |  |  |  |
| Validator |  |  |  |
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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 Software Developer has created a study database and eCRF for the **STUDY NAME/ACRONYM** trial in accordance with the protocol and associated specification documents provided for this purpose.  This document describes the procedure for validating this database/eCRF 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** |
| The Software Developer (CDMA) has implemented a web-based data management tool for the study. This consists of a series of electronic case report forms (eCRFs), referred to here as features, to enable data collection and management, 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 features built within the Training database to check the behaviour of each field and functionality contained within that feature is correct.  This will be completed by the designated Validator. The Validator ***cannot*** be the software developer who built the database.  For this database release, the Validator will be <<***specify who this will be, e.g., Trial Manager or designee>>.***    The software developer will provide the Validator with a Training and description document and a Validation document for each feature included on the training database eCRF. Features that do not have an associated eCRF, for example, randomisation algorithm, automated mailing, would not have a Training and description document.  The Training and description document describes how to use the feature and contains a complete set of screenshots and step-by-step instructions.  The Validation Document contains a list of the items of the feature that require validation. This will include the behaviour of the feature and confirmation of the dataset. It describes the validation rules and queries applied to individual dataset fields and will include an option to ‘Pass’ or ‘Fail’ each item 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 Software developer 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 functionality listed on the Validation Document must be listed as a ‘Pass’. The Validation document will be signed by the Validator 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 Software developer is responsible for the creation, maintenance and retention of the study-specific Validation Plan and all study-specific Validation Documents.  These will be retained either electronically, or aspaper copies in a study-specific database document folder within the secure storage in the ECTU Trial Office as appropriate. |

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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 |  | Garry Milne (Senior software developer) | * Initial creation * Template version set at 1.0 |