**SOP 38c Associated Document 1: Database Validation Form**

*This document is for use in research studies that are not regulated by the Medicines and Healthcare products Regulatory Agency (MHRA). Please refer to* [*Standard Operating Procedure (SOP) 38b*](http://www.jrmo.org.uk/performing-research/standard-operating-procedures-sops/sop-38b/) *for the requirements associated with databases for regulated research.*

# Database specifications, validation, and operation

| **No.** | **Database information** | **Provide all appropriate details and how requirements are met** |
| --- | --- | --- |
|  | Describe the intended use of the database and justification for choice |  |
|  | What company developed the database software? |  |
|  | What are the requirements of a database for this study? Consider what conditional formatting will be used (e.g. Only permit values between 16-99 in “Age” field). |  |
|  | What SOP’s, manuals, or guidance documents are available for this data processing system? |  |
|  | Is any installation documentation from the manufacturer or developer available? |  |
|  | Will the system interact with any other software (e.g. data imported from external sources, or exported to other software)? If so, describe how these systems will interact and be tested. |  |
|  | Where will the database be hosted? If it will not be hosted on Barts Health NHS Trust or Queen Mary University of London ICT servers, please justify the reasons. |  |
|  | Will a data management plan be put in place? If not, please justify why one is not needed. |  |
|  | If blinding is required, how will this be maintained? |  |
|  | How will users be trained in using the database? |  |
|  | How will data queries be managed? |  |
|  | How will an audit trail be maintained? It should be possible to trace when any changes are made to the data, who made them, and when. |  |
|  | Is a maintenance plan / schedule in place? |  |
|  | Is there technical customer support available? |  |
|  | How will access to the data processing system be managed? Who will be responsible for managing access? |  |
|  | How will version changes to the database be managed? |  |
|  | How will the data processing system be backed-up? |  |
|  | What security measures will be in place to secure the database and data? |  |
|  | How will the database be locked when all data input and cleaning is completed? |  |
|  | How will data be exported from the database for analysis? How will it be sent to the statistician? |  |
|  | How will the database and data be archived at the end of the study? |  |

# Software risk assessment

*Please use the table below to determine what level of User Acceptance Testing (UAT) will be required for your database. Determine whether you will be using a custom or off-the-shelf system, and whether you will be generating high or low impact data, to select one of the four options below.*

|  | **Bespoke / custom configuration**  e.g. database software programmed specifically for study; MS Access database developed for study. | **Off-the shelf package**  e.g. MS Excel spreadsheet with simple formatting (no Visual Basic alterations). |
| --- | --- | --- |
| **High Impact Data**  Data which could:   * be submitted to a regulatory body. * scrutinized by an external body (e.g. National Institute of Health and Care Excellence (NICE)). * published in a high impact journal. * change clinical practice. | UAT required:   * All fields and features. | UAT required:   * Informed Consent fields * Eligibility fields * Treatment data fields * Safety data fields * Primary and secondary endpoint fields * Security arrangements (e.g. password protection) |
| **Low Impact Data**  Does not meet the definition of high impact data. | UAT required:   * Informed Consent fields * Eligibility fields * Treatment data fields * Safety data fields * Primary and secondary endpoint fields * All security measures | UAT required:   * Primary and secondary endpoint fields only. * Security arrangements (e.g. password protection) |

# Specification

*Use these sections to prepare a specification for your database. As a minimum, define the fields and features required by your risk assessment above.*

# 3a. Required features

*Define the features that will be required for your database. Common features are listed below. Remove the features that are not required for your database and add any extra requirements that you have.*

|  |  |  |  |
| --- | --- | --- | --- |
| Data Entry | Manual Data Queries | Automatic Data Queries | Report Generation |
| Audit Trail | Document Hosting | Randomisation | Unblinding |
| Role-based access | Password protection | Data encryption | Safety reporting |
|  |  |  |  |

# 3b. Forms and Fields

*Define the forms and fields required in your database using the table below. As a minimum, define the fields that require UAT as described by your above risk assessment. Add more rows as necessary. Examples for two forms have been provided:*

|  |  |  |
| --- | --- | --- |
| **Form** | **Field Name** | **Formatting** |
| *Screening Visit* | *Visit Date* | *DD/MM/YYYY format* |
|  | *Heart Rate* | *Number only. Range 0-200* |
|  | *Medical History* | *Free Text* |
|  | *Pregnancy Test* | *“+” or “–“ only.* |
| *Treatment Visit 3* | *Visit Date* | *DD/MM/YYYY format.* |
|  | *Treatment administered* | *XX:XX format.* |
|  | *Dose administered (mg)* | *Numbers only.* |
|  | *Route* | *Free text* |
|  |  |  |
|  |  |  |

# 3c. User Access Rights

*Please explain below what access rights different study team members will have to the database, whether they can enter and modify data or have read-only access. The roles described below are suggestions only and will not be applicable to all studies. Please indicate the roles you anticipate using for your database to regulate access rights to the data and amend the permissions (e.g. read-only access) to be appropriate for the roles for your study.*

*Examples of possible roles and their associated permissions are given in appendix 1.*

| **Role** | **Database permissions** | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Enter / edit data from all sites**  (Read and write, Read only, No) | **Enter / edit site specific data**  (Read and write, Read only, No) | **Identifiable data**  (Read and write, Read only, No) | **Unblinded data**  (Read and write, Read only, No) | **Open / close data queries**  (Yes or No) | **Respond to data queries**  (Yes or No) | **Sign off CRFs**  (Yes or No) | **Sign off SAEs / SUSARs**  (Yes or No) | **Other**  (please define role and permission levels) |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |

# User Acceptance Testing (UAT) plan

*Please complete according to the Risk Assessment above. To be completed before the database is deployed.*

| **Field** | **Test** | **Expected result** | **Actual result** | **Comments / any changes required** | **Pass / Fail?** | **Test Date** |
| --- | --- | --- | --- | --- | --- | --- |
| *Example:*  *Height\_(m)* | *Enter “172”* | *Error message: “Please enter height in meters”* | *Allows 172* | *Change validation rule to prevent entering height in cm.* | *Fail* | *01/07/2019* |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

**UAT completed by**

|  |  |  |
| --- | --- | --- |
| **Print name** | **Signature** | **Date** |
|  |  |  |

# Database “Go Live”

As Chief Investigator (CI) of this study, I confirm that the database has been set up according to the database specification and study protocol. All required UAT has been completed. Data entry may now commence.

|  |  |  |
| --- | --- | --- |
| **Print name** | **Signature** | **Date** |
|  |  |  |

# Version Control Log

*Please complete the date the first version of the database is deployed for use and data input. Update this section whenever a change is made to the database after its initial deployment.*

|  |  |  |  |
| --- | --- | --- | --- |
| **Database section changed** | **Reason for change** | **New version number** | **Date of deployment** |
| N/A | N/A | 1.0.0 |  |
| *Example: Conditional formatting for field “Age” changed from “16-99” to “16-70”* | *Inclusion criterion changed from participants aged 16-70 (from 16-99) as part of substantial amendment 7 (protocol changed from v6.0 to v7.0)* | *2.0.0* | *15th July 2019* |
|  |  |  |  |

# Appendix 1

Examples of possible access roles for a study database and their associated permissions.

| **Role** | **Database permissions** | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Enter / edit data from all sites | Enter / edit site specific data | Identifiable data | Unblinded data | Open / close data queries | Respond to data queries | Sign off Case Report Forms (CRF) | Sign off Serious Adverse Events (SAE) / Suspected Unexpected Serious Adverse Reaction (SUSAR) |
| CI | Read only | No | No | No | Yes | No | No | Yes |
| Study Manager / Coordinator | Read only | Read only | No | No | Yes | Yes | No | No |
| Site user | No | Read and write | Read and write | No | No | Yes | No | No |
| Principal Investigator (PI) | No | Read and write | Read and write | No | No | Yes | Yes | Yes |
| Monitors / auditors / inspectors | Read only | Read only | Read only | Read only | No | No | No | No |
| Laboratory users | Read and write | Read and write | No | Read and write | No | Yes | No | No |
| Blinded assessors | Read and write | Read and write | No | No | No | Yes | No | No |
| Statistician | Read only | Read only | No | Read only | Yes | No | No | No |