**Standard Operating Procedure**

**SOP title CHAIN Site Checklist**

**Version 1.0**

**Date issued 07-07-2021**

**Next Review 07-07-2022**

1. **Purpose**

The following describes the procedure which will guide sites in preparation for a starting trial.

1. **Scope**

This procedure is applicable to all site data managers.

1. **Abbreviations/Definitions**

* File **–** An electronic document that can be shared.
* eCRF – Electronic case report form
* pCRF – manual (usually paper based) case report form

1. **PERSONNEL/ROLE(S)**

Site Data Team – Responsible in executing this procedure during site visits.

Central Data Team– Custodian of this procedure.

1. **Procedure**
2. The site data manager should ensure that the said items in the checklist are available before the study starts.
3. Actual Checklist- Ensure the following areas have been checked
   1. Electronic devices for data collection if working. These includes computers, GPS devices, internet availability e.t.c.
   2. Data collection workflow – in consultation with clinical & lab team
   3. Data entry workflow
   4. Data Security arrangements – verify all active system accounts are valid with authorised users.
   5. Data Responsibilities.
   6. Query resolution plan
   7. Dashboard reports & OrangeScrum adoption at site – including conducting a training for all users at the site.
4. In case you note that something is not provided kindly contact Central Data Team for advice.
5. **References**
6. **Document history**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Version 1 | Author | Approved by | Dated | SOP No: |
| 1.0 | Amos Fondo |  |  |  |
|  |  |  |  |  |

1. **Site training record**

All sites are required to maintain a master copy of this SOP that documents the site staff that have been trained on this SOP.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Document History** | | | | |
| **Version No.** | **Trained staff initials** | **Signature of trained staff** | **Date** | **Trainer’s Initials** |
| **1.01** | **KDT** | **Example row** | **1st July 2021** | **DM** |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

**Appendix**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **CHAIN STUDY - SITE DATA MANAGEMENT REVIEW CHECKLIST** | | | | |
| **Equipment & Materials** | | | | |
| **No.** | **Item** | **Description** | **Status** | **Comments** |
| 1 | Paper CRFs Storage | Ensure there is a Mechanism for storing CRFs and source documents. Are there Lockable Cabinet infrastructure? Also, to note is if the site has a paper CRF movement control procedure and tracking log. | Done | - All CRFs will be printed and kept in central place in lockable cabinets.  - Study clinicians responsible for all CRFs.  - Site has implemented a CRF delivery log. |
| 2 | Study ID Allocation Cards and labels | Ensure they are available. Is there an SOP for Study ID allocation? | Done | - Clinicians responsibility.  - An SOP is in place.  - Generate a checklist for the IDs to track assignment. |
| 3 | Computers | For data entry, analysis, communication. General specification: should be atleast core i3, 4GB RAM, 2 duol core processer of at least 1.8Ghz and at least 50GB HDD. Installed with web browsers and an internet connection. Review to check if the number of computers present can manage the workload and data entry staff requirements of the site. | Done | * A total of 3 data team members * With 3 computers |
| 4 | Internet Connection | Stable internet. Recommended 3MBPS speed but anything above 1.5mbps is good. Do some speed test experiments with tools like: http://www.speedtest.net/ to record performance metrics. Also record page load times of both ALEA and KIDMS at the site. | Done | * Everything is okay |
| 5 | Patient Folders | For storing CRFs & other files for each patient. Review the numbering system of the site. How they allocate CRFs and check if Lab CRFs are included in the final patient folders sent to archives. | Done | - Lab storage of samples – to get CRFs back for filing within 24hrs. |
| 5 | Printing | For printing CRFs and other study documents. Review the printing procedures of the site including how they print their barcodes. | Done |  |
| ALEA Requirements | | | | |
| 6 | UAT server |  |  |  |
| 6.1 | Data Access Group | Check that all users can access the UAT ALEA and KIDMS instances and that they know the purpose for this. | Done |  |
| 6.2 | eCRF translations | Document any translation needs needed. | - |  |
| 6.3 | Training | Has training been conducted. Is everyone able to access and test the system. | Done |  |
| 6.5 | Help Documentation | User guides available | Done |  |
| 7 | Production Server |  |  |  |
| 7.1 | System Access | Data Access Groups created, and user accounts added. Table based authentication configured. | Done |  |
| 7.2 | Language Support | Same as 7.2 but for production server | Done |  |
| 7.3 | eCRF translations | Same as 7.3 but for production server | - |  |
| KIDMS Requirements | | | | |
| 8 | UAT Server |  |  |  |
| 8.1 | AD Accounts | Do users have enough rights to access the system and accomplish their work | Done | * We have 2 lab techs in Malawi. They can change passwords through self service |
| 8.2 | NDA for KIDMS access signed | Forms signed and sent to Kemri. Review that all users assigned to access the system have a non-disclosure agreement signed and sent to Kemri-Wellcome Trust IT department. | Done |  |
| 8.3 | Training & Test sessions conducted | Training on KIDMS Labs sample collection and processing conducted | Done | - More practice to be done in RSS (registering participants and sample collection) |
| 8.4 | Help Documentation | User guides available in local language. | Done | - |
| 9 | Production Server |  |  |  |
| 9.1 | System Access | User can access and accomplish their work | Done |  |
| Data Collection & Generation | | | | |
| 10 | Training on Data entry | Each site user must be trained on the EDC system prior to being granted permission to work in the production version of the EDC system | Done |  |
| 11 | Data collection and entry SOP and related documentation | Have we prepared enough documentation on data collection and entry processes | Done |  |
| 12 | Data Entry Approach | Specify what data will be entered where. What is the paper control system? What is the approach when doing validation, verification, and correcting data | In Progress | * Site has old versions of SOPs. * Amos to send updated versions as soon as possible. |
| 13 | Data Entry Completion Guidelines | Describe any documents or in-system resources that will be developed to help users during the data-entry process. Describe where these resources may be found (i.e., network drive location, URL, or functional area within the EDC, etc. | Done |  |
| 14 | Data Completions Guidelines | Confirm that the completion guidelines are properly associated with each form/field. | Done |  |
| Data Quality & Standards | | | | |
| 15 | Quality Control Procedures | Describe the quality control (QC) processes to be employed. Such procedures may include built-in procedures of the EDC system such as automated checks to ensure manually entered subject numbers conform to study-defined site/subject # format rules and real-time data value edit checks as referenced above. More-manual checks may include strategies such as developing Stata or R code to ensure the right number of entries is present for a given data domain and errors are picked faster | In Progress | - Inline form validations are done.  - Dashboard queries need to be written for external checks.  - |
| 16 | High Availability of System | What measures are in place to ensure continuity incase of system outages. |  |  |
| Data Security & Confidentiality | | | | |
| 17 | Data Security | Detail the procedures and methods to be used to ensure data security. Examples include employing individual user accounts with role-based data management and access privileges, website security technologies, database access security, server physical plant security features, and backup or restore processes that constitute the EDC system’s disaster-mitigation plan. |  |  |
| 18 | Signed NDA for the study, KIDMS access e.t.c. | Non-Disclosure Agreements signed to safeguard staff from leaking information or systems to external parties. |  |  |
| 19 | Role assignment | Review system. Confirm using list of role functionality, have testers assigned to each role, and ensure that they are only able to do/see what they are entitled to per their assigned role. |  |  |
| 20 | Data Security Standards | Identify formal information standards with which the study is or will be compliant. Are there any conflicts with current procedures in implementing these standards |  |  |
| 21 | Main Risks to Data Security | Summarise the main risks to the confidentiality and security of information related to human participants*,* the level of risk and how these risks will be managed. Cover the main processes or facilities for storage and processing of personal data, data access, with controls put in place and any auditing of user compliance with consent and security conditions. |  |  |
| 22 | The study team’s exclusive use of the data | What are the timescale/dependencies for when data will be accessible to others outside of your team? Do we have such a policy? |  |  |
| Responsibilities | | | | |
| 23 | General Data Management Responsibilities |  |  |  |
| 23.1 | How many staff will be working on data entry/management | Are they aware of their duties. |  |  |
| 23.2 | Paper CRFs responsibilities | Paper control process flow custodian |  |  |
| 23.3 | Quality checking & assurance | Quality control process custodian |  |  |
| 23.4 | Data Security responsibilities | Data Security custodian |  |  |
| Relevant institutional, departmental or study policies | | | | |
| 24 | Data Management Policy & Procedures | Does the institution have this policy/procedure? |  |  |
| 25 | Data Security Policy |  |  |  |
| 26 | Data Sharing Policy |  |  |  |
| 27 | Institutional Information Policy (IT Policy) |  |  |  |
| 28 | Study Specific Policies |  |  |  |
| 29 | Other |  |  |  |
| 30 | Other |  |  |  |