SOP 003_06

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| Title | Database locking, unlocking, and archiving |
| SOP Code | SOP 003_06 |
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# Site Approval/Authorization to Adopt

| **Name and Title of Local Personnel (Type or print)** | **Signature** | **Date dd/Mon/yyyy** |
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| **Dr. Munira Sultana**<br>Office of Research, Erie Shores Health Care |  | 23/06/2023 |
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**1.0 PURPOSE**

This Standard Operating Procedure (SOP) describes the procedures for locking, unlocking, and archiving a study database.

**2.0 SCOPE**

This SOP is applicable to all clinical or research studies undertaken at the site (Erie Shores Health Care), and to those research and Data Management personnel responsible for data management, unless otherwise stated in the study contract or Data Management Plan.

**3.0 RESPONSIBILITIES**

The Sponsor-Investigator or Qualified Investigator (QI)/Investigator, and Data Manager are responsible for ensuring that the database lock and archiving processes meet all of the applicable regulatory, International Conference on Harmonisation (ICH) Good Clinical Practice (GCP), Sponsor and local requirements.

Any or all parts of this procedure may be delegated to appropriately trained study team members, but remain the ultimate responsibility of the Sponsor, Sponsor-Investigator and/or Qualified Investigator (QI)/Investigator.

**4.0 DEFINITIONS**

**Database Lock:** Action taken to prevent further changes to a clinical trial database. NOTE: Locking of a database is done after review, query resolution, and a determination has been made that the database is ready for analysis.

**Database Unlock:** When write-access is granted to a designated individual(s) in order to allow a modification(s) to the data. The modification(s) is approved prior to unlocking the database.

**Quality Assurance:** All those planned and systematic actions that are established to ensure that the trial is performed and the data are generated, documented (recorded), and reported in compliance with good clinical practice (GCP) and the applicable regulatory requirement(s).

**Quality Control (QC):** The operational techniques and activities undertaken within the quality assurance system to verify that the requirements for quality of the trial related activities have been fulfilled.

**Study Database Manual:** The repository of information concerning the study data base.

See also, “CDISC Clinical Research Glossary, Version 8.0” and “N2 Glossary of Terms”.

**5.0 PROCEDURE**

**5.1 General**

5.1.1. Refer to the study Data Management Plan for details on all required tasks regarding database lock, unlock and archiving. These details may include specific QC procedures

**5.2. Database Lock**

5.2.1. The database lock process includes all of the following activities, but is not limited to the following:

- Ensure that the Sponsor, Sponsor-Investigator or QI/ Investigator (if applicable) is notified that the database will be locked and obtain approvals as necessary.
- Ensure that all data are received or are accounted for.
- Ensure that all external data are loaded into the study database, reviewed and reconciled appropriately.
- Ensure that all data have been quality checked appropriately.
- Ensure that all appropriate data validation and review procedures are complete.
- Ensure that there are no new discrepancies and all queries have been received, resolved and QC in the database.
- Ensure that all medical coding is complete and the final coding terms are reviewed for accuracy and consistency.
- Ensure that all SAEs are reconciled appropriately.
- Ensure that all protocol deviations/violations are identified, reviewed, QC and approved.
- Ensure that study database manual is up-to-date and final.
- Remove all user write-access to the database and lock the database.
- Unblind the study database if necessary.

5.2.2. Obtain approval/sign off for database lock as required.

**5.3. Database Unlock**

5.3.1. Ensure that any post database lock errors are investigated, documented, and analyzed for potential impact. The database may have to be unlocked if:

- The error affects a table or listing, in the statistical analysis plan.
- The error changes or has major impact on a narrative (summary of findings).
- The error involves a major change to a primary safety or efficacy parameter(s).

5.3.2. Ensure that appropriate authorizations are obtained prior to database unlock.

5.3.3. Obtain access to the database, unlock the database if necessary, and make the correction(s) and QC any changes. Ensure unlock and relock times and dates are documented.

5.3.4. Relock the database and remove all user write-access.

**5.4. Database Archiving**

5.4.1 The database must be archived to meet local, national, and international requirements. This may entail storing of the software version, including any software patches and updates used in the software version and all hardware components to resurrect the database in its original state. Refer to your site archiving plan.

5.4.2 Export the metadata, clinical data, codelists, coding dictionaries, audit trails, edit check documentation, discrepancy management documentation, and queries to long-term storage media in an open format (such as CSV files, XML, SAS Transport files, or PDF). Ensure the media are labeled appropriately, including archive date and how long the media must be maintained. Ensure test data in any test databases are also archived.

5.4.3 Record the hardware and software used for the study, including the specific version(s). This may be recorded in the study database manual or Data Management Plan.

5.4.4 Record the user history, including the user listings, all access rights or levels and any changes and the associated authorization dates.

5.4.5 Remove all necessary database access except for an Administrator account that controls all user accounts and accessibility to the database.

5.4.6 Ensure that the archived database and documentation are kept in a secure environment and that adequate backup copies have been performed.

5.4.7 The media storage device used to archive the database must be replicated to ensure that there is a working, backup copy in the event the original is damaged or unobtainable.

5.4.8 Establish a test schedule with regular timeframe intervals, such as every five years, to test that the archived database is retrievable and will load and run.

**6.0 REFERENCES**

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