***Text in blue is for instruction only and should be deleted.***

***Text in black should be included if appropriate for the trial.***

**SOP Ref No *Insert trial title*\_SOP00**

**SOP title Database Lock**

**Version *Insert number* 0.0**

**Date issued *Insert date* DDMMMYYYY**

**Valid until *Insert date* DDMMMYYYY**

**Author(s) Name:**

**Signature:**

**Date:**

**Approved by Name:**

**Signature**

**Date**

**Modification history**

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| **Version No** | **Date** | **Author(s)** | **Date reissued to previous recipients** |
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**Purpose**

The purpose of this standard operating procedure (SOP) is to outline the procedures required to lock the ***insert trial title*** clinical trial database.

1. **Scope**

This SOP describes the activities which need to be carried out, prior to study closure and locking of the clinical trial database.

1. **Responsibility**

All ***insert trial title*** staff will be responsible for ensuring all study closure activities are completed prior to database lock.

1. **Database lock procedures**
2. All active study subjects must complete scheduled follow up and final visits.
3. All supporting clinical trial data - CRFs, laboratory reports, SAEs etc. must be entered onto the database and cleaned.
4. All data coding must be completed.
5. All SAEs must be reconciled.
6. All outstanding data queries or questions to the investigators or site personnel must be resolved and entered onto the database (according to the ***insert trial title SOP00 Data Entry and SOP00 Data Query***), prior to completing database lock.
7. Permission to lock the database will be agreed by Study Statistician, Data Manager and Clinical Project Manager and the ***insert trial*** title Database Lock Approval Form completed.
8. If identification of significant errors should occur after database lock but prior to final analysis and publication. The ***insert*** ***Study Statistician, Data Manager and Clinical Project Manager*** will meet to discuss and document the procedure which will be undertaken to allow for these changes. Copies of the original database and the corrected database will be archived.
9. If any further changes are made following publication from the original results, copies of the original database and the corrected database will be archived. Clear documentation of the archived databases with reference to the publication will be given.
10. **Associated documents**

***Insert trial title*** Database Lock Approval Form V0.0 DDMMYYYY