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# SOP 860 Clinical Data Management System: DATA REQUEST

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| **For Use in:** | Research |
| **By:** | All staff |
| **For:** | All staff involved in the conduct of research |
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This Standard Operating Procedure (SOP) is available on the Research & Development pages on the NNUH website

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# SOP 860 Clinical Data Management System: DATA REQUEST

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## 2. Definitions of Terms Used / Glossary

| | |
|---|---|
| CDMS | Clinical Data Management System |
| CI | Chief Investigator |
| CTU | Clinical Trials Unit |
| DMB | Database Manager |
| DBP | Database Programmer |
| GCP | Good Clinical Practice |
| ICH | International Conference for Harmonisation |
| NNUH | Norfolk and Norwich University Hospital |
| PI | Principal Investigator |
| R&D | Research and Development |
| SM | Study Manager |
| SOP | Standard Operating Procedure |
| UEA | University of East Anglia |

## 3. Objectives

The process ensures that datasets for analysis are controlled and known to come from a stable database.

## 4. Scope

This SOP applies to all research managed by Norwich CTU however the principles contained in this SOP shall be followed for all other trials.

## 5. Purpose

This SOP describes the standard procedures for access to datasets from locked study databases associated with Clinical Trials and Clinical Data Management Systems, including the provision of read-only direct access so that statisticians and others may build their own datasets.

## 6. Rules

**Responsibilities**

- Study Manager (SM) - for trial specific documents
- Database Manager (DBM) - for database/systems

## 7. Provision of Data or Access to Data

- Study Team members requiring data should complete a Data Request form, based on an agreed template, giving details of their requirement, refer to **SOP 825 Clinical Data Management Systems – VALIDATION.**

- Data may be provided by one of 2 methods

- Every effort must be made to send data by encrypted email.
- If an encrypted email cannot be sent or received, the data must be extracted into a file (spreadsheet) and sent to the requester.
- Data sent in a spreadsheet **must** be encrypted and the password communicated separately and by another means, not by email.

- On receipt of a Data Request form, the DBP will produce the dataset in the requested format (or set up direct access as required) and make it available to the requester.
- The dataset must be in a file whose name includes the study name, status, the requester's initials and the date, and must be stored in the Data Management team study folder.

- It must be ensured that provision of the dataset does not result in unblinding of blinded study team members, either directly by disclosing the randomization arm or indirectly by including data that otherwise identifies a participant's randomisation.
- Provision of unblinded data requires approval of a study team member with delegated authority from the Sponsor.

## 8. References and Related Documents

| References | |
|---|---|
| **SOP No.** | **SOP Title** |
| SOP 825 | Clinical Data Management System - VALIDATION |

## 9. Approval

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## 10. Training Implication

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| **Training Implication** | No |
| **Actions required** | • n/a |