Title: Data management for clinical trials

1. Scope

1.1 This SOP applies to any individual involved in research project sponsored, or co-sponsored, by University of Aberdeen (UoA) and/or NHS Grampian (NHSG) and describes the procedure for data collection, data management and security for data held in databases used in clinical trials.

1.2 In addition to the principles of GCP and the appropriate UoA and NHSG policies, research data shall be collected, recorded and managed in accordance with, the Data Protection Act 1998.

1.3 This SOP may also be used by staff from other NHS areas, or organisations, with prior agreement.

2. Responsibilities

Sponsor 
Ensure investigators have control of, and continuous access to, data reported to the Sponsor.

Chief Investigator (CI) 
Acting on behalf of Sponsor, may delegate data management.

3. Procedure

3.1 Data Management System

- The study protocol, or other study document, shall clearly specify the data to be collected using Case Report Forms (CRF) and/or stored electronically, and which data elements are to be retained upon archiving.

- There shall be a unique identifying ID for each participant. The code or file linking participants’ names with their IDs (Subject Identification Log) shall be kept secure and separate from the data used for trial analysis.

- The computerised system shall safeguard study blinding where this exists. Blinding shall not be broken through the day-to-day use of the computerised system. Any data which may inadvertently break the blind (eg specific laboratory test data) must be inaccessible to the study team. The system shall provide protection against unintentional unblinding but support, where appropriate, any unblinding procedures described in the study protocol.
• Identifiable data shall not be retained for longer than is necessary to meet the requirements described in the study protocol and to meet requirements set by the grant-awarding body, Research Ethics Committee (REC) and regulatory authorities. For the latter, this is at least five years after the conclusion of the trial and for the sponsor (UoA/NHSG) the requirement is 25 years (see SOP-QA-32 – Archiving). Deleting data may require the physical destruction of digital media.
• Any changes or updates to the system must be documented as part of a change control process and the relevant parts of the system revalidated.
• The trial team shall be trained in completion of the CRF (paper or electronic) prior to recruitment of the first participant.

3.2 Data security

• Electronic data shall only be stored on devices that that are backed-up securely and timely.
• Data used for trial analysis shall be anonymised. Data used for trial management shall use the minimum number of personal identifiers necessary for study conduct and to ensure patient safety.
• Personal data shall not be stored or transmitted on removable media or laptops without encryption. Datasets shall be encrypted prior to transmission, or transfer (eg on CD), using an industry-standard encryption mechanism (eg AES-128), or transferred securely using the NHS net email system.
• All machines used to enter or access trial data shall have appropriate security software installed.
• Access to the data shall be limited to authorised personnel and each user of the system shall have an individual account.
• A record shall be kept in the TMF of authorised users and their access levels that apply.
• The study database shall have an audit trail for any changes made to electronic data after initial entry. This shall include the original value together with the date of the change and who made that change. If possible a brief explanation of why the change was made should also be recorded.
• At the end of a trial, data shall be locked to prevent further additions or changes to the data using the data management system’s file-locking facility, if such a facility exists, otherwise a snapshot of the data should be taken for analysis and access to the data denied to anyone except the Data Manager or statistician.

3.3 Electronic Data capture

Data capture and entry shall be undertaken by suitably trained personnel.

• Electronic data capture systems shall reflect the layout and design of data capture documents.
• Electronic systems shall include data validation, range checks and consistency checks, where agreed with the trial team, to ensure good data quality.
• Actual (rather than scheduled) dates/times of events or data collection points shall be recorded.
• If necessary, data entry checking shall be considered for critical data.
• Data queries or data anomalies shall be handled following trial specific guidelines.
3.4 Paper Case Report Forms

- 🔴 Paper CRFs shall be version controlled, paginated, with effective date on each page.
- 🔴 Participant ID shall be documented on every page.
- 🔴 The study ID and name shall be clearly stated.
- 🔴 △ No identifiable information shall be on the CRF.
- 🔴 Paper CRFs shall set out all the data to be collected or procedure to be carried out, on each participant at each visit.
- 🔴 △ No information shall be collected that cannot be justified by the protocol or standard safety procedures.
- 🔴 Paper CRFs shall be completed in permanent ink.
- △ Any error or alteration shall be crossed through once, initialled and dated, leaving the original value visible (see SOP-QA-27 – Good Documentation Practice).
- 🔴 All required fields shall be completed. If a procedure is not carried out, then this shall be indicated.
- 🔴 To enable consistence, CRFs shall indicate which unit of measurement is to be used.
- The use of free-hand text shall be discouraged.

3.5 Raising Data Queries

All data queries should be raised as soon after data collection as is practicable. These may include missing, inconsistent or implausible data. All data queries shall be resolved prior to data lock. Data provided for analysis shall always remain verifiable against source data.

3.6 Data analysis

The data shall be presented in a form appropriate for the particular needs of the trial.

3.7 There must be a quality check of data prior to interim and final analyses. Quality checks shall include checking for outliers, missing data, date checks and any inconsistencies. A study monitoring plan shall describe any data entry checking process to be used (eg single data entry and verification or double data entry) an acceptable data entry error limit and action to be taken if the error rate exceeds this limit.

3.8 △ When data are to be exported for statistical analysis, the dataset must be fully anonymised.

3.9 △ Any files containing sensitive data must be encrypted and password protected before transfer. Passwords shall be communicated to the recipient separately.

3.10 Data protection

△ All person-identifiable data must be treated in an appropriate, confidential manner.

3.11 △ Paper or computer records shall be accessible to the minimum number of people needed to ensure the smooth delivery of the trial. All of these staff shall be made aware of their responsibility to maintain confidentiality by the CI.
3.12 ⚠ Personal information shall not be sent by email; encrypted files should be used, unless via the secure NHS net email system.

3.13 ⚠ Personal data shall not be transmitted in a way that could cause loss of data or allow interception by unauthorised parties.

4. Abbreviations and definitions

GCP       Good Clinical Practice

5. Related documentation and references

SOP-QA-12  Case Report Forms
SOP-QA-18  Randomisation and blinding for controlled trials
SOP-QA-27  Good documentation practice
SOP-QA-32  Archiving