Standard Operating Procedure: Case Report Forms

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Document History:

<table>
<thead>
<tr>
<th>Version No.</th>
<th>Description of Changes</th>
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<tbody>
<tr>
<td>1</td>
<td>New Document</td>
<td>17-6-11</td>
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<tr>
<td>2</td>
<td>Changes to 6.1 and 6.3.3</td>
<td>7-5-12</td>
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<td>3</td>
<td>Change of title to reflect the content (from 'Recording or managing study data on Case Report Forms'). Added statement that Sponsor will not approve the use of CRFs as source documents without previous consultation and valid reason at 6.1. SOP reworded to delete duplication and enhance advice.</td>
<td>1-4-15</td>
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This SOP will be reviewed at least every 3 years from initial and subsequent issue dates.

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PURPOSE / INTRODUCTION

1.1 This SOP describes the correct procedure for designing, completing, signing and correcting both paper based and electronic CRFs.

2 SCOPE

2.1 This SOP applies to all clinical trials Sponsored or Co-Sponsored by the University of Aberdeen (UoA) and / or NHS Grampian (NHSG). UoA-NHSG SOPs may also be used by staff from other NHS areas, or organisations, with prior agreement.

3 ASSOCIATED DOCUMENTS

UoA-NHSG-SOP-008 - Establishing and Maintaining a Trial Master File.
UoA-NHSG-SOP-009 - Establishing and Maintaining a Site File.
UoA-NHSG-SOP-011 - Managing Substantial and Non-substantial Amendments.
UoA-NHSG-SOP-016 - Establishing and Maintaining a Training Record.
UoA-NHSG-SOP-021 - Archiving data from interventional research projects involving human participants.
UoA-NHSG-SOP-047 - Good documentation practice.

4 REFERENCES


- UK Medicines for Human Use (Clinical Trials) Regulations 2004
- Health Research Authority website www.hra.nhs.uk
  It is assumed that by referencing the principle regulations, all subsequent amendments made to the principle regulations are included in this citation.

4.1 Abbreviations:

CI  Chief Investigator
CRF  Case Report Form
GCP  Good Clinical Practice
NHSG  NHS Grampian
PI  Principal Investigator
UoA  University of Aberdeen

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5 RESPONSIBILITIES

The CI is responsible for the design of CRFs to comply with GCP and protocol. It is the responsibility of a designated member of staff to ensure there is an adequate supply of CRFs at the research site to conduct the study.

6 PROCEDURE

6.1 General
- Clinical research data shall be collected using case report forms.
- CRFs shall not be accepted as source documents without prior consultation and approval of sponsor.
- CRFs shall be designed to collect only the information required to meet the aims of the study and to ensure the eligibility and safety of the participant.
- CRFs must be version controlled and dated.
- All versions of the CRF must be filed in the TMF.
- All CRFs shall be completed in accordance with GCP.
- There must be clear evidence that the CI or statistician has seen and approved the document to be used.
- CRFs will be stored in a secure location when the trial is active.
- CRFs will be archived as required by Sponsor (UoA-NHSG-SOP-021 ‘Archiving data from interventional research projects involving human participants’).
- CRFs shall be available for monitoring by Sponsor and/or legislative authorities.
- CRFs shall at all times match with source data. Any discrepancies should be clearly noted and the reason explained.

6.2 CRF Design
- CRF design shall be dependant of the data to be collected.
- The CRF shall be consistent with the protocol.
- The Inclusion/Exclusion criterion shall be clear and unambiguous.
- The data fields shall be clear, logical and user friendly.
- Consideration should be given to CRF layout in relation to database entry.
- Space for free text is discouraged unless a specific requirement of the protocol.
- For variables where the actual value is captured, the number of boxes provided shall be adequate and if appropriate, reflect the number of decimal places.
- Laboratory numbers shall be entered without conversion from printed reports. If conversions are necessary e.g. multi centre sites where units of measurement differ, space should be made available on the CRF for the original figure, the conversion factor, and the converted result.
- Each CRF page shall include study ID (i.e. acronym).
- Each CRF page shall include version number, date of version and page number.
- Each CRF page shall include the participant Identification Code number.
- Each CRF should include participant demographics but ensure no identifiable information must be used.
- Each CRF should require the confirmation of the date of Informed Consent.

6.3 The data to be collected could include, but not be limited to:
- Participant unique ID number.
- Date of birth and age at consent.
- Demographic as per protocol requirements.

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• Medical history.
• Primary and secondary outcomes.
• Dosing and compliance.
• Randomisation.
• Adverse Event Form.
• Concomitant medications.
• Withdrawal form.
• End of treatment form.
• The date of Informed Consent shall be clearly indicated.
• Participant eligibility shall be clearly indicated.

6.4 Recording of Data:

Data should be complete, without omissions.
CRFs should be completed only by those delegated the task to do so.

• CRFs shall be completed as soon as possible after each participant assessment.
• Any missing data shall have an explanation in source documents.
• Entries should be accurate, legible and verifiable against source data (i.e. medical notes or other agreed documentation).
• Values outside normal, or expected reference ranges, shall have a comment (e.g. the significance) noted in the source data.
• Corrections to entries shall be made as follows:
  - Cross out the incorrect entry with a single line so that the incorrect entry is still readable. Never use correction fluid or obliterate entries made on the CRF,
  - Enter the correct data,
  - Date and initial the change, and give an explanation of the correction.
(see UoA-NHSG-SOP-047 ‘Good documentation practice’).
• The CRF must be signed, where indicated, by the CI or delegate to assert that the CRF entries are complete and accurate.
• Data queries shall be addressed quickly and an audit trail exist to detail outcome.

6.5 Training in CRF completion

• The CRF design shall be reviewed and approved by the CI or delegate before use in the trial.
• Study staff shall receive training on the completion of CRFs to ensure that data is collected in a consistent manner.
• Clear instructions shall be given at all participating sites.
• CRF training shall be documented in a training log and/or study meeting minutes.

6.6 Electronic CRF Completion (eCRF)

6.6.1 eCRFs shall be completed using a computer and information downloaded, as agreed in the protocol, or a web-based application may be used to access the eCRF.
6.6.2 An audit trail of all entries and data amendments must be captured.

6.6.3 Electronic data should then be archived when the study has finished according to sponsor archiving procedures. (UoA-NHSG-SOP-021 – ‘Archiving data from interventional research projects involving human participants’).