Bournemouth University

BU RDS SOP 022 V1

Title: Case Report Form Design	
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Approver: University Research Ethics Committee	

1.   Scope

This Standard Operating Procedure (SOP) outlines the requirements and good practices with regard to the design, development and completion of Case Report Forms (CRFs) for the purposes of data collection in clinical research studies, sponsored by Bournemouth University.

2.   Responsibilities

The *Clinical Governance Advisor (CGA)*, on behalf of the Sponsor, is responsible for supporting the Chief Investigator/Researcher with CRF design and approving versions for use. They are also responsible for providing/ensuring adequate training with regard to CRF completion and filing.

The *Chief Investigator (CI)/Researcher* is responsible for designing the CRF, or for delegating this duty to another individual, before consulting the Sponsor or appropriate contact on its suitability.

The *Principal Investigator (PI)* at the participating site has overall responsibility for the data collected on paper CRFs or entered into eCRFs, and is likewise responsible for ensuring that CRF data queries are resolved at site. The PI may delegate the duties of CRF completion and query resolution to their study team, but maintains overall responsibility for the data.

The *site research team* is responsible for ensuring that they complete CRFs in accordance with Good Clinical Practice (GCP) guidelines and that they trained in data entry and corrections.

3.   Procedure

3.1   CRFs are useful tools in collecting the data required as outlined in a given study protocol. They can be in paper form, electronic form, or both, and are used to record data that has been taken from original (source) documents such as medical records, scan reports etc. The CRF may sometimes be the first place data is recorded, then becoming the source, e.g. height and weight measurements done at the study visit.

CRF Content

3.2   The content of the study CRFs should conform to the data requirements that are outlined in the study protocol and should be accompanied by a CRF completion guidelines document, developed by the CI or delegated individual, in accordance with the protocol.

3.3   Each study visit (if more than one), should have its own page for the research team to complete, examples of suggested pages, depending on the protocol:

1. Screening visit;

2. Eligibility *(including a space for PI or Co-Investigator sign-off)*;

3. Confirmation of consent, medical history etc. *(including a space for PI or Co-Investigator sign-off)*;

4. Randomisation;

5. Treatment visit(s);

6. Drug accountability/treatment (*there should be space for recording dose administration, kit numbers, IMP compliance and amount of returned IMP*) ;

7. Follow-up visit(s);

8. Unscheduled visit(s);

9. Laboratory results *(including a space for PI or Co-Investigator sign-off)*;

10. Final study visit/study completion;

11. CRF sign-off page.

Within the CRF pack, there should also be a CRF page for protocol deviations/violations, in addition to (if applicable) safety reporting, and death.

Safety reporting CRFs should be reviewed and then signed off by the PI or Co-Investigator (i.e. a medically qualified Investigator), and filed within the patient CRF pack.

3.4   Personally identifiable information should be kept to a minimum, such as participant initials. The presence of the participant study I.D. number will ensure that CRFs are distinguishable. The name of the study should be at the top of each page.

3.5   <u>CRF Design</u>

- Each CRF should include a space for the member of staff completing the form, to sign and date once the required information has been used to populate the document.

- Dates should be collected as dd-mmm-yyyy, e.g. 01-OCT-2017;

- Time should be collected in 24 hour clock;

- There should be separate sections for the date and time of each intervention, investigation or assessment, e.g. when a whole blood sample was taken, when a quality of life questionnaire was completed, when the Investigational Medicinal Product (IMP) was administered, etc.;

If laboratory results are printed on paper from electronic sources, then they must be signed off by the site PI.

Completion of CRFs

3.6   CRF completion guidelines should be made available to research staff that have been delegated the duty of CRF completion. The guidelines should include the following sections:

- When to complete the CRF;
- How to complete the CRF;
- The correct units for any data that is required;
- List accepted abbreviations;
- How to correct data in the CRF;
- What to enter when no data is available;
- How/when the CRF should be sent to the sponsor, or researcher;
- Key reference ranges;
- Contacts for support in CRF completion;

3.7   CRFs, if held in paper form, should be kept separately to participants' identifiable records, held in their own folder, and the participant data should be pseudonymised in accordance with GDPR.

3.8   Paper CRFs must be version controlled, dated and paginated. At the top of each page there should be space for the participant I.D. and the data requested should be in accordance with the study protocol.

3.9   CRFs should only be completed and signed by the staff members delegated this duty on the delegation log. The documents should be completed legibly and indelibly, with no blank spaces, and errors crossed out with a single line, initialled and dated.

3.10   CRFs should be completed within the timelines stipulated in the study protocol/CRF completion guidelines.

3.11   Electronic systems should reflect the layout and design of paper-based documents. They should also include functions pertaining to data validations, range checks, and consistency checks, as well as the ability to store metadata, and make it available upon request.

Data Queries

3.12   Data queries should be raised when data is incomplete, does not match the source data, or requires clarification. These queries may be raised by remotely following on-site monitoring visits, or automatically should an eCRF system be used.

3.13   For a complete audit trail, corrections should be made on the existing paper form, and re-sent to the Sponsor/study management team. eCRF queries are answered with the electronic system, and so create an automatic audit trail.

Amendments to CRFs/Creating New Versions

3.14   Amendments to CRFs are usually considered as a non-substantial amendment and so require approval by the HRA[1]. Due to this classification, NHS REC and MHRA approval (if applicable) is not required.

3.15   Blank copies of CRFs should be filed in the ISF and Sponsor file, alongside superseded versions and the CRF completion guidelines. If held electronically then paper copies of these should be filed.

4.   Abbreviations and definitions

CGA	Clinical Governance Advisor
CI	Chief Investigator
(e)CRF	(Electronics) Case Report Form
GCP	Good Clinical Practice
GDPR	General Data Protection Regulations
HRA	Health Research Authority
IMP	Investigational Medicinal Product
MHRA	Medicines and Healthcare products Regulatory Agency
NHS REC	National Health Service Research Ethics Committee
PI	Principal Investigator

5.   Related documentation and references

BU RDS SOP 019 – Data Management for Clinical Research

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[1] Please note, as of June 2018, HRA approval is now HRA and Health and Care Research Wales (HCRW) approval