Research and Enterprise

Standard Operating Procedure
Research Governance

Title:	**Preparation, Completion, Signing and Correcting Case Report Forms**		
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Revision Log

Previous Version number	Date of Review/Modification	Reason for Review/Modification	New Version Number

1. Purpose

This Standard Operating Procedure (SOP) is to describe the procedure for completing, signing and correcting Case Report Forms (CRFs).

Case Report Forms are used in clinical research to collect data from each research participant. It is vital that they are legible, accurate, complete and prepared in a timely fashion. A CRF acts as a reminder to all investigators of the protocol that is being followed.

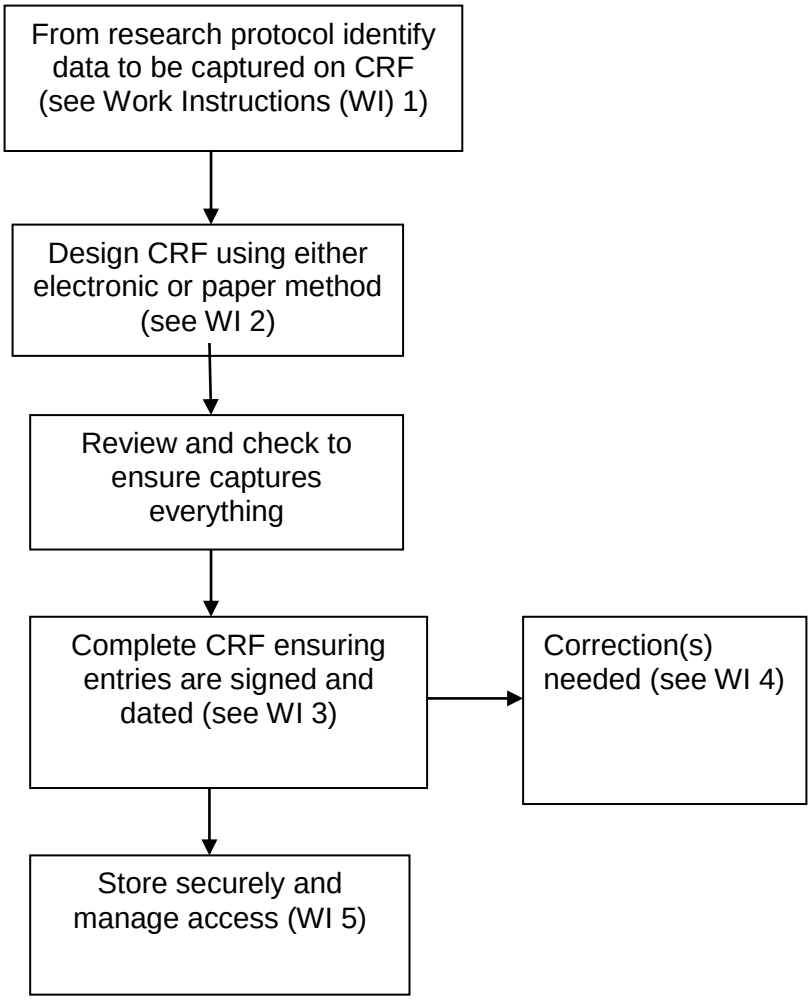
They can be paper based or electronic and form a critical record of the research and are subject to examination.

2. Scope

This SOP applies to all studies where the University is acting in the capacity of Sponsor, or Co-Sponsor. It applies to all members of University staff; both academic and support staff as defined by Statute 1, including honorary staff and students.

The University does not sole sponsor CTIMPs and therefore, the Lead Sponsor's requirements and approval of CRFs should always be met.

3. Procedure



4. References

International Conference on Harmonisation (ICH) Harmonisation Tripartite Guideline: Guideline for Good Clinical Practice EB (R1).

5. Appendices

Work Instructions 1 - Contents of CRF from protocol
Work Instructions 2 – Design CRF
Work Instructions 3 – Completion of CRF
Work Instructions 4 – Correcting CRF
Work Instructions 5 – Storage and Access

Work Instructions 1 – Contents of CRF from protocol

1. CRF's are designed according to the protocol, therefore each one will be different. The following provides guidance as to what should be contained as these are common to research studies:
    - Demographic information – DOB, Gender, Date of Visit(s) etc
    - Inclusion/Exclusion Criteria – use tick boxes to demonstrate compliance with each criterion.
    - Screening undertaken – medical examination, vital signs, laboratory and other tests to demonstrate compliance with inclusion criteria, medication.
    - Visit(s) to capture activity undertaken at each visits
    - Early termination/withdrawal of participant that captures date of termination/withdrawal and the reasons for same.
    - End of study page to include date of completion.
2. The CI should collaborate with the statistician when developing the CRF and ensure that all those involved in the research study have a clear understanding of the contents of the CRF, before it is signed off.
3. The number of pages in the CRF will be dependent upon the nature of the study. Pages which include laboratory results should have the units of measurement pre-printed alongside each entry.

Work Instructions 2 – Design CRF

1. Each page of the CRF should have the following information included as a header:
    - Name of study or study number;
    - Patient Code Number;
    - Patient Initials;
    - Date in the format of dd/mm/yyyy to capture the clinical visit/information.
2. Each page of the CRF should have the following information as a footer:
    - Signature of the delegated individual completing the page;
    - Signature of the CI with responsibility of signing off the entry;
    - If the CRF extends over a number of pages indicate on each the number of the page in conjunction with the length of the document i.e. page 1 of 3, page 2 of 3, page 3 of 3.
3. Design the CRF with a logical layout that is consistent with protocol and participants visits to study.
4. To facilitate data collection and subsequent analysis provide choices for each question, collect raw data rather than calculated data.
5. Ensure CRF is reviewed and approved by CI, the statistician (if required for the study), and the Sponsor.

Work Instructions 3 – Completion of CRF

1. Provide clear instruction as to how CRF is to be answered and completed i.e. answers circled, underlined, redundant responses deleted or boxes ticked. Note - a ticked box provides less confusion.
2. Ensure CRFs are completed as soon as possible after each visit.
3. Entries should be:
    - In English;
    - Legible;
    - In permanent ink, preferably black ballpoint pen;
    - Verifiable.
    - The confidentiality of the research participant must be maintained at all times. The research participant must only be identified in the CRF using a trial number or code.

Only where the protocol specifies that CRFs are source documents and that the patient name can be collected, should names appear. In addition, informed consent must be obtained to retain patient identifiable information on University premises as outlined in SOP-RGEI-004.

- Data should be complete with no fields left blank. If data are unavailable it is necessary to write 'not applicable', 'missing', 'not known' or 'test not done' on the CRF.
- Likewise, do not create additional fields. Only provide the information that is asked for.
- All CRF data derived from source documents must be accurately transcribed, in particular, when copying out results, such as laboratory results. Any discrepancies with source data should be explained and the significance noted in the CRF and the source document.
- Unless otherwise agreed, laboratory values should be entered without conversion from printed reports. If conversions are required, in the case of multicentre studies where units of measurements may differ, space should be made in the CRF for the original figure, the conversion factor and the converted result. This facilitates the checking of calculations by trial monitors and regulatory authorities.

4. When all entries and corrections are deemed to be complete, the CRF must be signed by the CI (or designee) to assert that they believe it to be complete and correct.
5. Before any monitoring visit, the relevant members of the research team should ensure that all CRFs are as up to date as possible.

Work Instructions 4 – Correcting CRF

1. Corrections should be made by crossing through the incorrect entry with a single line so that the original entry is still readable.
2. Do not use correction fluid, completely obliterate the entries or overwrite an entry.
3. The correct data should then be entered, the correction dated and initialled and if necessary an explanation given of the correction.

Work Instructions 5 – Storage and Access

1. CRFs should be stored in secure storage cabinets and a secure location during the course of the study.
2. They must be archived when the study has finished.
3. The Standard Operating Procedure for the setting up, maintaining and archiving of trial master file(s)/site master file(s) QUB-RGEI-xxx should be complied with. Therefore, CRFs should be retained with the Study Master File and centrally archived.
4. Access to CRFs should be restricted to the Investigators, study monitors and Regulatory Authorities.