SOP number	**17.045**	Version	**4.0**
Title	**Case Report Form (CRF) Completion**		

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Released by Signature	Julie Brittenden Date

SOP category	17 NHS GG&C Clinical Research Facility – Clinical

Staff category

Staff Category	**R**	**A**	**C**	**I**
Nursing	X			
Administration	X			
Principal Investigator	X			
Clinical Research Fellow	X			
GCRF Manager		X		
GCRF Associate Director				X
Senior R&I Manager				X

1. Scope

This procedure applies to all staff working within Glasgow Clinical Research Facility (GCRF).

2. Purpose

This SOP will outline who is responsible for and the procedures to be followed when completing a Case Report Form (CRF) this includes paper and electronic.

The CRF is used in a study to collect study specific information.

3. Procedures

It is the responsibility of the Principal Investigator to delegate the task of completing the CRF and this must be documented on the Study Delegation of Duties Log. Only those individuals named on the log may enter data in a CRF.

CRFs should be completed in accordance with the study protocol. The study design will provide the visit schedule and when visits are due.

CRFs must be completed promptly and accurately, with attention to detail.

3.1. Paper CRF completion

- Use a black pen unless specified in the CRF to use a dark blue one.

- Ensure data entry is as complete as possible without omissions. If data are unavailable write, for example, 'unknown', 'missing' or 'test not done' or if available use the study CRF completion guidelines.

- Ensure all entries are accurate, legible and verifiable with the source data in the medical records or other agreed documentation.

- CRF entry may be used as source data as if stated in the protocol and Source Data Agreement. Where the CRF is used as source a copy should be retained at site.

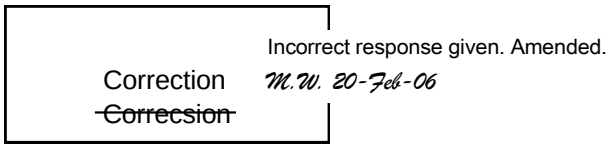
- Explain any discrepancies with source data and note the significance in the CRF and patients' medical notes.

- Laboratory values out with the reference range, or values showing significant variation from one assessment to the next should be highlighted and the significance noted in the CRF and patient notes.

- Never over-write an entry. Corrections should be made as follows:
    - Cross out the incorrect entry with a single line so that the incorrect entry is still readable. **Do not use** correction fluid or obliterate entries made on the CRF.

    - Enter the correct value using the completion conventions from the study CRF guideline.

    - Initial and date the correction, and give an explanation of it, using codes as applicable.



    - The procedure for the resolution of data queries should be agreed with the study sponsor and where possible, completed by site staff within the timeframe stipulated by the sponsor.

- In order to maintain confidentiality the patient must be identified by a study number and/or initials only on the CRF. The Subject Identification Log must be kept with details of patients in the study.

- The CRF must be signed by the Principal Investigator or designee where indicated to assert that they believe it to be complete and correct.

- CRFs should be kept in a secure location during the course of the study and should be archived when the study is finished according to GCTU archiving procedures.

3.2. Electronic CRF Completion

- eCRFs will be completed as described in the protocol and/or eCRF manual.

- An eCRF may be access through HTML webpage or an application to be downloaded by site team.

- Training will be provided for staff using eCRF by the sponsor and recorded in ISF and in individual staff training record.

- Data entered directly on to the eCRF may be considered source documentation if stated in the protocol and source data agreement.

- The procedure for the resolution of data queries should be agreed with the study sponsor and where possible, completed by site staff within the timeframe stipulated by the sponsor.

- The CRF must be signed electronically by the Principal Investigator or designee where indicated to assert that they believe it to be complete and correct.

- Sponsor should provide a complete copy to the site on completion of study. This may be on a disk, USB or other digital storage device. This should be in a readable format and archived with all other essential documents after study close-out.

4. Referenced documents

None

5. Related documents

- GUI 57.005B – GCRF Archiving Process

6. Document history

Version	Date	Description
Draft	09/10/07	Creation of SOP
1.0	22/11/07	Release of Version 1
1.1	19/05/08	Released to staff
1.2	30/09/09	Release of Version 2 – general update
2.0	15/07/16	Renumbering of SOP Update to SOP template v1.4 Change of approved and released by
3.0	26/08/2019	Update to include Administration in staff category, reference source data agreement, include sponsor responsibility to provide eCRF copies to site
4.0	23/06/2023	Update to SOP template v2.0 Addition of RACI matrix Change author Section 3.2 added