Office of Clinical Research | School of Medicine & Health Sciences
THE GEORGE WASHINGTON UNIVERSITY

Procedure Name: Case Report Form Query Resolution Procedure	**Number:** SOP 5 v3.0
Subject: Clinical Research	**Effective Date:** July 01, 2004
Linked Policy: Clinical Research Operations & Compliance Policy	**Revised Date:** June 08, 2023

PURPOSE:

To establish the GW Medical Faculty Associates ("MFA") procedure for completing and correcting Case Report Forms ("CRF") and resolving CRF Queries/Edits.

SCOPE:

This standard operating procedure ("SOP") applies to all research team members responsible for developing, completing and correcting CRFs and resolving CRF queries/edits associated with a clinical research study conducted at GWU MFA. The term CRFs is used in this SOP to refer to paper CRFs or electronic CRFs (eCRFs), unless otherwise specified.

RESPONSIBILITY:

This SOP sets forth responsibilities of research team members involved with completing and correcting CRFs and resolving CRF queries/edits. The Principal Investigator ("PI") retains CFR responsibility unless the investigator has specifically delegated this duty to another research team member and the delegation is documented on a study specific Delegation of Authority Log.

PROCEDURES:

Prior to starting a study, ensure that there is an adequate supply of paper CRFs or that access has been granted to the electronic CRF system for the appropriate research team members. CRFs are the data collection tools used for collecting and documenting clinical trial data that is obtained during a subject visit. CRFs are the source of truth and the first place of documenting research related information such as vitals, assessments, AEs or summary of a visit. The CRF is what monitors will look at to review information on a patient visit. If you will be using Epic as your source of study visit documentation, please ensure that that all study related procedures are documented in the Epic encounter and noted in the subject file.

<u>Case Report Form (CRF) Completion</u>

1. Complete CRFs immediately following the completion of a subject study visit.

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a. If information is not immediately available to complete a CRF, e.g., awaiting lab reports, the information should be completed as soon as the information is received.
b. Complete the associated encounter notes in Epic, as applicable.
c. Sponsor timelines as outlined in the contract or data entry guidelines should be followed for the length of time from study visit to data entered into eCRF data entry system.

2. Complete CRFs as follows:

    a. Capture study visit data on the Source Documentation. Source Documentation will also include the patient encounter associated with the patient visit in Epic;
    b. Copy Source Documentation data to the CRFs; and
    c. Record all documentation in black ballpoint pen. Complete all fields in the CRFs according to sponsor specifications, e.g., NA – not applicable; ND – not done; UNK – unknown.

3. Ensure that all entries are accurate, legible and verifiable with the source data/documents.
4. Paper CRFs: Correct errors by striking through the error with a single line, dating and initialing the strike through, and making the correction. Do not obliterate the original entry. White-out or correction tape is prohibited.
5. If the study requires data entry into eCRFs:

    a. Ensure that the data are entered into the eCRF according to the sponsor's specifications;
    b. Enter data into the eCRF promptly after collecting the source documentation information; and
    c. Follow strict adherence to access and password protected practices/policies.

<u>Preparing for Monitoring Visits</u>

1. Complete CRFs prior to any monitor visits.
2. Thoroughly review the CRFs to make sure that all pages have been completed and no information is missing.
3. Following the monitoring visit, review any discrepancies noted on the data clarification form provided by the sponsor or on the monitoring report or visit follow up letter.
4. Correct any errors to the CRFs that were noted during the monitoring visit.

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CRF Query Resolution

1. Resolve sponsor identified CRF queries/edits within five working days (unless otherwise required by the Sponsor); Sponsor timelines as outlined in the contract or data entry guidelines should be followed for query resolution.
2. Return resolved CRF queries to the Sponsor or monitor, as applicable; and
3. Place resolved paper CFR queries/edits in the corresponding CRF notebook unless otherwise specified by the Sponsor.

Review and Revision

This procedure shall be reviewed every 2 years. This procedure may be reviewed more frequently if it does not reflect current operations.

REFERENCES:

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21 CFR Part 11	Circumstances in which IRB review is required.
21 CFR 312.50	Exemptions from IRB requirement.
21 CFR 312.56	IND safety regulations and monitors.
21 CFR 312.60	Selecting investigators and monitors.
21 CFR 312.62	Emergency research under 50.24 of this chapter.
21 CFR 312.64	Assurance of IRB review.
21 CFR 312.68	General responsibilities of sponsors.
21 CFR 812.40	FDA and IRB approval.

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21 CFR 812.46	Emergency research under 50.24 of this chapter.
21 CFR 812.100	Specific responsibilities of investigators.
21 CFR 812.140	Records.
21 CFR 812.150	Reports.
MFA SOPs	SOP 6- Source Documentation SOP 10- Monitoring Visits
ICH E6 (R2)	Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice E6 (R2)