MEDICAL COLLEGE OF WISCONSIN CANCER CENTER

Cancer Center Clinical Trials Office

STANDARD OPERATING PROCEDURE INTERNAL QUALITY ASSURANCE REVIEWS	
SOP#: 6.5.2	**Original Approval Date: 7/11/18**
Version#: 3.0	**Revision Dates: 3/17/25**

1.0 PURPOSE/BACKGROUND

This SOP describes the plan for Internal Quality Assurance Reviews (IQARs) in the Medical College of Wisconsin Cancer Center Clinical Trials Office (CCCTO) by the Quality Assurance (QA) staff. An important element of a quality program for research is proper oversight. IQARs evaluate the research studies to ensure that research conducted at the Medical College of Wisconsin (MCW) Cancer Center is of the highest quality and meets MCW and regulatory agency standards. The goals of IQARs are to identify areas of noncompliance or potential noncompliance and to provide education and suggestions for corrective action. Investigators should view the role of the IQAR as performing an essential function in maintaining a high state of research compliance.

2.0 SCOPE

This SOP applies to all IQARs conducted by the MCW CCCTO internal QA staff. This SOP applies to all personnel involved in the implementation and coordination of clinical trials involving human subjects in all disease teams within CCCTO.

3.0 RESPONSIBILITY

Individuals impacted by the new or updated SOP(s) may include:

- Study staff
- Quality Assurance staff
- Investigational Drug Pharmacy
- MCW Cancer Center Scientific Review Committee (SRC)
- MCW Cancer Center Data & Safety Monitoring Committee (DSMC)
- Other applicable staff involved in the conduct of the study

4.0 DEFINITIONS

Refer to Glossary of Common Terms and Definitions.

Internal Quality Assurance Review (IQAR): A formal review of study records by the MCW CCCTO Quality Assurance staff to ensure the accuracy of the study data, to evaluate reasonable adherence to a protocol and MCW Approved SOPs and guidelines, and to verify the protection of human subjects.

5.0 ROLES AND PROCEDURES

Scope of Reviews:
5.1 IQARs focus on four main categories: Investigational Initiated Trials (IIT), NCTN Trials, New Staff Reviews, and By Request. All reviews are categorized as routine or directed (for cause). Directed IQARs may be initiated per the request of the DSMC, IRB, Research Manager, or an Investigator.

a) Investigational Initiated Trials (IIT) Reviews
b) NCTN Reviews
c) New Staff Reviews
d) By Request

a.) Investigator Initiated Trials (IITs):
Prior to study start up, all new Investigator Initiated Trials (IITs) will be reviewed and assigned a risk level by the Cancer Center Scientific Review Committee and confirmed by the DSMC. QA oversight will be based on the risk level of the study, as outlined in the Cancer Center's Data and Safety Monitoring Plan.

b.) NCTN Trials:
NCTN trials are reviewed on a rotating basis to aid in preparation for scheduled NCTN audits.

c.) New Staff Reviews:
New study coordinators and regulatory staff have their work reviewed at approximately 6 months and 12 months after their employment start date. The goal of these reviews is to identify gaps in training and performance issues.

d.) By Request:
This category consists of routine or for cause reviews when requested by CTO or Cancer Center Leadership (e.g. study staff member performance issues).

5.4 During the IQAR, the QA staff may inspect all or a percentage of study records (e.g., completed CRFs, source documents, regulatory files, drug accountability records, medical records, OnCore, etc.). This will be at the discretion of the QA staff and will be done using a risk-based approach.

Scheduling & Notification
5.5 The QA staff will notify the following study staff of the upcoming IQAR at least 10 business days prior to the proposed IQAR date: Research Manager, Study Coordinator, Regulatory Manager, Regulatory Coordinator/Specialist, and Principal Investigator. This may be rescheduled to a later date or deferred at the discretion of the QA staff for significant conflicts. Requests to postpone an IIT review may not be granted if the DSMC review schedule does not allow adequate time to reschedule. Because QA reviews are done to assess compliance and offer early intervention when needed, deferrals of any scheduled reviews are discouraged.

5.6 The QA staff will conduct the IQAR in a timeframe considered sufficient to review appropriate study material, as determined by the QA staff. Logistics of review will be arranged between QA staff and Study Coordinator.

IQAR Summary Meeting

5.7 Summary Meetings will be conducted as needed at an agreed upon time among attendees. The following staff may be invited to the Summary Meeting at the discretion of the QA staff: Principal Investigator, applicable sub-investigators, CCCTO Administrative Director, Research Manager, Regulatory staff, applicable study coordinators, and investigational pharmacy. If the QA staff determines a meeting unnecessary, the findings will be communicated via email.

5.8 In the Summary Meeting, the QA staff will review the draft report from the IQAR and preliminary findings. The QA staff may also make recommendations for quality improvement, suggested protocol revisions, and education.

5.9 Following the Summary Meeting, the study staff will receive a draft of the preliminary report prior to the Summary Meeting to confirm that the draft report is accurate to the best of their knowledge.

Follow-up

5.10 A final report will be provided to the study team, the CTO Directors, and to the DSMC (IITs only) after completion of the IQAR. All findings, recommendations, and action items will be detailed in the final report.

5.11 A response to the final report should be provided to the QA staff within 30 days of receipt of the final report. The study staff may request an extension for significant conflicts.

5.12 A copy of the report and the responses will be filed with the CCCTO QA staff and uploaded to Oncore. A copy of the report will be provided to the Cancer Center Data Safety Monitoring Committee.

5.13 A follow-up IQAR or further external auditing may be recommended based on the IQAR findings (e.g., Clinical Translational Science Institute-CTSI, MCW Office of Research, etc.).

6.0 REFERENCES

Oversight of Clinical Investigation – A Risk-Based Approach to Monitoring, US Department of Health and Human Services, Food and Drug Administration, August 2013

7.0 APPENDICES

Medical College of Wisconsin Cancer Center Data and Safety Monitoring Plan, v. 12/15/2024

ICH-GCP (E6) Guidelines

FDA 21 CFR Part 312

Authorized by: Signed Electronically by:
Erin Lynch - eelynch@mcw.edu
21-Mar-2025 @ 01:17 PM CDT
Reason: Approval
CCCTO Administrative Director

Revision dates:
7/11/18, v1.0
3/16/20, v2.0
3/17/25, v3.0

Review dates:
7/11/18, 3/16/20, 3/17/25