MEDICAL COLLEGE OF WISCONSIN CANCER CENTER **Cancer Center Clinical Trials Office**

STANDARD OPERATING PROCEDURE **EXTERNAL AUDITS**	
SOP#: 6.5.3	**Original Approval Date: 1/20/14**
Version#: 7.0	**Revision Dates: 3/17/25**

1.0 PURPOSE/BACKGROUND

Auditing is essential to ensure research conducted at the Medical College of Wisconsin (MCW) Cancer Center is of the highest quality and meets MCW and regulatory agency standards. This SOP provides information about External Audits and how to prepare for audits conducted by departments or organizations outside of the Medical College of Wisconsin Cancer Center Clinical Trials Office (CCCTO), such as the Food and Drug Administration (FDA), the National Cancer Institute (NCI), study sponsors or their designees, Medical College of Wisconsin Office of Research QI/QA Department, and Froedtert & Medical College of Wisconsin Compliance Offices. Audits can be at random or for cause.

2.0 SCOPE

The scope of this SOP covers all CCCTO managed protocols that are being audited by any agency or organization outside the CCCTO.

3.0 RESPONSIBILITY

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

- Study Staff
- Investigational Drug Service (IDS)
- CCCTO Budget Staff
- CCCTO Quality Assurance Staff
- Sponsor Investigator, Study sponsor, and their designees
- Medical College of Wisconsin Office of Research QI/QA department
- Froedtert & Medical College of Wisconsin Compliance Offices
- Institutional Review Board overseeing the clinical trial

4.0 DEFINITIONS

Refer to Glossary of Common Terms and Definitions.

External Audit: A formal inspection of study records by any agency outside of the CCCTO to ensure the accuracy and validity of the collected data, to guarantee adherence to a protocol, to ensure that any published results are reliable, and to make certain that human subjects are protected.

5.0 ROLES AND PROCEDURES

Scheduling

5.1. **FDA Inspections**

The Federal Food, Drug, and Cosmetic Act permits the FDA to inspect any establishment in which investigational products are held at reasonable time intervals. Sponsors, Monitors, and Investigators of any clinical trial may be audited. The FDA may arrange for the inspection by contacting the institution to make an appointment, however the FDA is not required to provide advanced notice of an inspection.

5.2 **NCI Audits**

The NCI will conduct audits on a predetermined schedule according to their own SOPs. All institutions that are participating in NCI-sponsored protocols, which includes the NCTN (National Clinical Trial Network), are equally subject to an audit during any one year.

5.3 **Sponsor Audits**

A study sponsor or their designee may conduct a formal inspection of study records (i.e. regulatory files, drug accountability records, and medical/research charts) on an as-needed basis to ensure the accuracy of the collected data, to assess adherence to the protocol and federal regulations, and to assure that any published results are reliable. This differs from a routine monitoring visit. Sponsors are required to provide adequate advanced notice of an audit.

5.4 **Medical College of Wisconsin Office of Research QI/QA Department and Froedtert & Medical College of Wisconsin Compliance Office**

The MCW Office of Research and MCW Compliance Office may conduct audits of studies per their internal SOPs.

Notification

5.5 Once the study staff is notified of an external audit, the CCCTO Administrative Director, Investigational Drug Pharmacy, IRB, CCCTO Quality Assurance Staff, and any other applicable study staff members must be notified as soon as possible so that preparation efforts can be coordinated. (Notify IRB when applicable – FDA, NCI, and Sponsor/designee audits only.) Note: industry sponsors require that they are notified immediately upon knowledge of an FDA audit.

Preparation

5.6 As deemed appropriate by the Research Manager, pertinent study files should be pre-reviewed by a member of the study staff or the CCCTO's Quality Assurance Staff to ensure the files are complete and accurate to the study staff's knowledge.

5.7. Once a date has been scheduled for an audit, the study coordinator should ensure that an appropriate room is reserved for the auditors if being conducted in person. The room must be in an area that is secure and should be equipped with wireless internet access. Access to a copier, a fax machine, and a telephone should be available upon request. If the audit will be conducted remotely, platforms for meetings, tours, and data sharing should be established with the auditors

(Zoom, WebEx, BOX, Florence, etc.).

During the Audit

5.8 Auditors will be greeted by a staff member designated by the CCCTO and credentials should be verified at this time. This may be the Administrative Director, a Research Manager, the Education/Quality Assurance staff, or another CCCTO staff member, as assigned.

5.9 No food/meals will be provided to the auditors; however they will be directed to an area where food may be purchased.

5.10 The auditors will be provided with contact information for any applicable staff that may need to be accessed during the audit.

Audit Conclusion Meeting

5.11 A meeting at the audit's conclusion will be conducted per the auditors' discretion and may include the following staff as appropriate: The Principal Investigator, CCCTO Administrative Director, Research Manager(s), Regulatory, Education/QA, a representative from the IRB, Investigational Pharmacy staff, and study staff.

Follow up

5.12 Follow up to the audit will be conducted in accordance with the auditors' requests and/or SOPs.

5.13 Corrective and Preventive Action plans should be reviewed by the audited study's Research Manager, the CCCTO's Education & QA Staff, and CTO Leadership prior to finalization and must be reviewed and approved by the MCW Office of Research prior to being returned to the auditors.

6.0 REFERENCES

MCW Corporate Compliance Policy: *External Audit, Inspection, and Program Review of Research Activity Managment*.

7.0 APPENDICES

None

Authorized by: Signed Electronically by:
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Reason: Approval
CCCTO Administrative Director

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