MEDICAL COLLEGE OF WISCONSIN CANCER CENTER

Cancer Center Clinical Trials Office

STANDARD OPERATING PROCEDURE INVESTIGATOR REVIEW OF SUBJECT LABORATORY REPORTS	
SOP#: 6.4.2	**Original Approval Date: 7/21/17**
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1.0 PURPOSE/BACKGROUND

Investigator oversight is essential in the proper conduct of any clinical trial. Some sponsors have historically requested that investigators provide a wet-ink sign-off on laboratory results originating from the patient electronic medical record, indicating clinical significance of values. This has put undue burden on study staff and investigators, as this is duplicative effort since it is standard practice for the investigators to review a subject's labs in the electronic medical record prior to treatment. Often it is not possible for study staff to obtain a physical signature on printed labs prior to treatment, so signatures may have been obtained days or weeks later. The Cancer Center Clinical Trial Office (CCCTO) does not feel this practice improves patient safety and does not add value to the clinical trial process. Signing off on pages of labs that took place in the past is a hindrance to study investigators and takes away time from performing other meaningful safety-related tasks. Lab results generated from a central lab will continue to be reviewed and signed by investigators if required by the sponsor.

2.0 SCOPE

This SOP applies to all studies managed by the MCW Cancer Center Clinical Trials Office that involve patient laboratory results.

3.0 RESPONSIBILITY

Principal Investigators
Sub-Investigators
Regulatory Staff
Other members of the study staff, as necessary

4.0 DEFINITIONS

Refer to Glossary of Common Terms and Definitions

5.0 ROLES AND PROCEDURES

5.1 Study staff will not obtain investigator signatures on laboratory results originating from the electronic medical record. As a standard practice, patient laboratory results are reviewed by the study coordinator and the subject's clinical team prior to treatment. These values are evaluated with the protocol to check for any necessary dose modifications, sponsor reporting, or other necessary clinical actions.

5.2 All laboratory results requiring action (e.g., dose modification and/or other intervention such as supportive medication administration, supplementation, physical therapy, diet change, fluid administration, transfusions, additional testing, etc.) will be considered "clinically significant". If no action is taken based on an out-of-range lab value, it will be considered "not clinically significant." All abnormal labs and adverse events will be captured and monitored in the source documents as required by the protocol (e.g. the electronic medical record, central laboratory reports), however only abnormal labs deemed "clinically significant" will be tracked as collected data and reported in case report forms, unless otherwise specified in the study protocol.

5.3 Treatment decisions will be based on local lab results. An investigator will only use central labs to determine treatment decisions if local labs results are unavailable or if required by the protocol.

5.4 Laboratory reports originating from a central lab will be reviewed and signed by the investigator, if required by the sponsor.

6.0 REFERENCES

None

7.0 APPENDICES

None

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

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