MEDICAL COLLEGE OF WISCONSIN CANCER CENTER

Cancer Center Clinical Trials Office

STANDARD OPERATING PROCEDURE CANCER CENTER CTO RESEARCH LABORATORY PROCESSES	
SOP#: 6.2.7	**Original Approval Date: 7/11/18**
Version#: 3.0	**Current revision Date: 3/13/25**

1.0 PURPOSE/BACKGROUND

Correlative laboratory samples are an extremely important part of successfully conducting clinical trials. The CCCTO is committed to maintaining the integrity of all research samples obtained. The purpose of this Standard Operating Procedure (SOP) is to describe the standards for laboratory processing, storage, shipping, and receiving of research lab samples and supplies.

2.0 SCOPE

This SOP affects any clinical trials managed by the CCCTO that involve research laboratory samples.

3.0 RESPONSIBILITY

Individuals impacted by this SOP may include:

- Study Staff
- CCCTO Lab Staff
- Study sponsors and their designees
- Others as required

4.0 DEFINITIONS

Refer to Glossary of Common Terms and Definitions

Additional definitions:

Sample(s): Specimens obtained for research purposes, such as blood, urine, saliva, stool, bone marrow, and tissue.

CCCTO Lab Staff: Any study staff member delegated to work with Research Samples as their primary responsibility, or other study staff that may assist with these duties as assigned.

5.0 ROLES AND PROCEDURES

5.1 Laboratory supplies and kits will be received by the lab staff and stored in designated CCCTO laboratory space. This space may be inspected by study sponsors upon request.

5.2 Samples are processed, stored, and shipped according to the study protocol and/or lab manual. Deviations from this process will be noted in the study chart and filed according to IRB policy.

5.3 Specimens are labeled with a non-smearing permanent marker and fields are labeled according to study provided labels. If labels are not provided, tubes are labeled with

criteria that is listed in the protocol. This information may include but is not limited to the following items: study name, subject ID, collection date and time, timepoint, and sample type.

5.4 For the safety of the staff, patients, and the samples, any samples requiring transport are transported through hallways in a shatterproof, sealed container.

5.5 Daily temperature logs of ambient, refrigerator, -20°C, and -80°C freezer storage are maintained by the Lab Staff and documentation is available upon request. Logs for the current month are electronically saved upon the month's completion. The -80°C freezer is alarmed, as well as on backup emergency power. The supervisor of the CCCTO Lab receives the alarm notifications It is also on a backup monitoring system (24/7), which notifies CCCTO Clinical Research Laboratory Coordinator of temperature excursions. The refrigerator/-20°C freezer is also on backup emergency power.

5.6 Freezer maintenance is completed monthly by Lab Staff. Maintenance includes removal of ice buildup, cleaning grates and filters, keeping units clean. Freezers are not calibrated. Documentation of maintenance is located on the daily temperature logs.

5.7 Min/Max Temperatures: Refrigerator: 4°C (+/- 3°C), -20°C (+/- 10°C), -80°C (min -60°C, no max)

5.8 Centrifuges are calibrated yearly. Calibration is conducted by Froedtert Healthcare Technology Management. CCCTO Lab Staff keeps records electronically and are available upon request.

5.9 The Lab Staff maintains a database documenting all samples processed. It is preferred that Lab Staff not duplicate documentation whenever possible, for example, completing forms that contain information already collected in the CCCTO's online laboratory database or that would be included in sponsor-provided requisitions.

5.10 If a sponsor requires processing-specific documentation (for instance, exact processing times for procedures such as spinning, aliquoting, and freezing) these fields should be included on the corresponding requisition forms.

5.11 Monitors requesting access to view physical frozen samples will be allowed a brief visual of samples. Close inspection/handling/inventorying of frozen samples jeopardizes the integrity of the samples through a potential freeze/thaw cycle and will not be permitted. The CCCTO greatly values the integrity of research samples; therefore, inventory of samples will be completed when samples are shipped by the Lab Staff and received by the receiving lab. The Lab Staff will provide inventory information from the CCCTO online laboratory database to sponsors upon request.

5.12 The CCCTO is not a long-term laboratory storage facility due to space constraints. It is requested that samples be shipped as often as possible due to these limitations. If the CCCTO lab space is in jeopardy, sponsors will be contacted to discuss a plan for shipment in the near future.

5.13 Laboratory kit destruction will take place when any of the following occur:

- The kits have expired
- The study has closed to accrual and study kits are no longer needed
- The study has permanently closed
- Kits have been updated and the current kits are obsolete

Due to the large number of studies managed by the CCCTO Lab, documentation is not maintained for kits destroyed; however, a general Note to File can be provided upon request.

5.14 A representative from the CCCTO Lab will attend the lab portion of SIVs and PSVs as invited. Upon delivery of the lab manual, all Lab Staff will review appropriate documents and notes from SIVs to comply with applicable training.

5.15 All subsequent updates to lab documents are reviewed by CCCTO Lab Staff upon receipt. Documentation of training is electronically saved and available upon request.

6.0 REFERENCES

None

7.0 APPENDICES

None

Authorized by:

Signed Electronically by:
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21-Mar-2025 @ 01:16 PM CDT
Reason: Approval

CCCTO Administrative Director

Revision dates:
7/11/18, v1.0
3/16/20, v2.0
3/13/25, v3.0

Review dates:
7/11/18, 3/16/20, 11/5/21, 3/13/25