

SOP Number :	100.02
Title :	SOP on SOPs

Revision Chronology			
Version Number	Effective Date	Review Date	Reason for Change
100.01	August 3, 2021	January 21, 2022	Initial Version
100.02	January 24, 2022	January 10, 2023	Facility Name Change

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 Director Signature

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 Date

## 1. Scope

This SOP applies to the written procedures followed by this research team as it conducts all studies.

## 2. Procedures

### a. Procedure for Preparing New or Revising Previously Issued SOPs

<ul style="list-style-type: none"> <li>• CentRI Facility Director</li> <li>• CentRI Facility Manager/Technologist</li> <li>• Investigators</li> <li>• Support Staff</li> </ul>	<p>Based on the regulations and guidelines listed in Section C, write a new SOP or revise a previously issued SOP that describes the new or revised procedures.</p> <p>Each SOP includes the following information on the first page:</p> <ul style="list-style-type: none"> <li>• The title</li> <li>• The number for that SOP</li> <li>• The date of the current version</li> <li>• The date of the previous version (for revisions)</li> <li>• A log of all previous versions of that SOP</li> </ul>
<ul style="list-style-type: none"> <li>• CentRI Facility Director</li> <li>• CentRI Facility Manager/Technologist</li> <li>• Investigators</li> <li>• Support Staff</li> </ul>	<p>Draft the SOP using the following format:</p> <ul style="list-style-type: none"> <li>• Introduction and Purpose</li> <li>• Scope</li> <li>• Applicable Regulations and Guidelines</li> <li>• References to Other Applicable SOPs</li> <li>• Attachments</li> <li>• Responsibility</li> <li>• Definitions</li> <li>• Process Overview</li> <li>• Procedure</li> <li>• Maintain a Table of Contents of the SOPs</li> </ul>
<ul style="list-style-type: none"> <li>• CentRI Facility Director</li> <li>• CentRI Facility Manager/Technologist</li> </ul>	<ul style="list-style-type: none"> <li>• Review draft SOP to ensure accuracy and completeness.</li> </ul>
<ul style="list-style-type: none"> <li>• CentRI Facility Director</li> </ul>	<ul style="list-style-type: none"> <li>• Approve, sign, and date each new SOP after it is finalized.</li> </ul>
<ul style="list-style-type: none"> <li>• CentRI Facility Manager/Technologist</li> </ul>	<ul style="list-style-type: none"> <li>• Distribute the new SOP to all team members.</li> <li>• Collect the superseded SOP if appropriate.</li> <li>• Maintain a distribution list.</li> </ul>
<ul style="list-style-type: none"> <li>• CentRI Facility Manager/Technologist</li> </ul>	<ul style="list-style-type: none"> <li>• Maintain an archive of all previous versions of SOPs to be available in the event of an audit.</li> </ul>

### b. Procedure for Reviewing SOPs

<ul style="list-style-type: none"> <li>• CentRI Facility Directors</li> <li>• CentRI Facility Manager/Technologist</li> </ul>	<ul style="list-style-type: none"> <li>• At least annually, review all SOPs. If revisions are required, follow the procedure described above.</li> <li>• If no changes are required, document and file appropriately.</li> </ul>
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**c. Procedure for Providing Training on Implementing SOPs**

<ul style="list-style-type: none"> <li>• CentTRI Facility Manager/Technologist</li> </ul>	<ul style="list-style-type: none"> <li>• Ensure that all new CentTRI personnel document the date of training and the SOPs reviewed (see Appendix 1: SOP Compliance Form).</li> </ul>
<ul style="list-style-type: none"> <li>• CentTRI Facility Manager/Technologist</li> </ul>	<ul style="list-style-type: none"> <li>• Ensure that all new CentTRI personnel review all applicable SOPs prior to undertaking any responsibilities at this facility for which the SOPs apply.</li> <li>• Ensure that all new CentTRI personnel of the research team documents the date of review (or training, if appropriate) and the relevant SOPs (See Appendix 1: SOP Compliance Form).</li> </ul>
<ul style="list-style-type: none"> <li>• CentTRI Facility Manager/Technologist</li> </ul>	<ul style="list-style-type: none"> <li>• Ensure that all CentTRI personnel attend a safety review session each year to review all SOP's, including revisions, and newly implemented SOP's. (See Appendix 2: Safety Review Checklist).</li> <li>• Ensure that each member of the research team documents the date of review (or training, if appropriate) at the time of their annual CentTRI safety review session.</li> </ul>
<ul style="list-style-type: none"> <li>• CentTRI Facility Manager/Technologist</li> </ul>	<ul style="list-style-type: none"> <li>• Maintain a record of SOP training and annual review for all members of the research team at this site.</li> </ul>

d. CentRI Standard Operating Procedure Log

SOP type (code)	SOP #	Title	Date
<b>General Administration</b>	100.02	SOP on SOPs	24JAN2022
	105.02	Facility Access Approval Procedure	24JAN2022
	110.02	Facility Visitor Approval Procedure	24JAN2022
	115.02	New Protocols and Ethics Procedures	24JAN2022
	120.03	System Billing and Standard Rates	05MAY2022
	125.02	Privacy and Confidentiality	24JAN2022
<b>Safety and Emergency Procedures</b>	200.03	General X-ray Safety	07JUN2022
	205.02	Emergency Code Blue Procedure	24JAN2022
	210.03	Emergency Fire Procedure	11AUG2022
	215.03	Safety and Operator Training Procedure	07JUN2022
	220.02	Incidental Pathological Findings	24JAN2022
	225.02	Animal Handling and Safety	24JAN2022
<b>Equipment</b>	300.04	Equipment Handling Procedure	15AUG2022
	305.03	Radiographic Data Handling and Storage	08OCT2022
	310.02	CT Suite Start-up, Restart, and Shutdown	24JAN2022
	315.02	Angiography Suite Start-up, Restart, and Shutdown	24JAN2022
	320.03	RSA Suite Start-up, Restart, and Shutdown	11JUL2022
	325.02	Weight-bearing CT Suite Start-up, Restart, and Shutdown	24JAN2022
	330.01	Digital Tomosynthesis Suite Start-up, Restart, and Shutdown	07JUN2022
<b>Room Use</b>	400.03	Decontamination and Waste Disposal Procedure	11AUG2022
	405.03	Minimizing Risk - COVID-19	05MAY2022
	410.02	Biosafety Level 2	24JAN2022
<b>IV Contrast</b>	500.02	Contrast Injections	24JAN2022
	505.02	Contrast Documentation	24JAN2022
	510.02	Contrast Reactions	24JAN2022
	515.02	Interstitial Injections	24JAN2022
	520.02	Contrast Usage in Breastfeeding Patients	24JAN2022
	525.02	Contrast Injections in At Risk Patients	24JAN2022
	530.02	Contrast Infection Control	24JAN2022