

<b>SOP Number:</b>	<b>100.13</b>	
<b>Title:</b>	<b>Standard Operating Procedure on SOP's</b>	
<b>Version Number</b>	<b>Effective Date</b>	<b>Changes</b>
100.13	15 August 2023	Reviewed

Directors Signature: \_\_\_\_\_  \_\_\_\_\_ Date: 2023/SEP/01

## 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 SOPs or revising previously issued SOPs

<ul style="list-style-type: none"> <li>• 3T MRI Facility Director</li> <li>• 3T MRI 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>• 3T MRI Facility Director</li> <li>• 3T MRI 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 by number and title of the SOPs</li> </ul>
<ul style="list-style-type: none"> <li>• 3T MRI Facility Director</li> <li>• 3T MRI Facility Manager/Technologist</li> </ul>	<p>Review draft SOP to ensure accuracy and completeness.</p>
<ul style="list-style-type: none"> <li>• 3T MRI Facility Director</li> </ul>	<p>Approve, sign, and date each new SOP after it is finalized.</p>
<ul style="list-style-type: none"> <li>• 3T MRI Facility Manager/Technologist</li> </ul>	<p>Distribute the new SOP to all team members. Collect the superseded SOP if appropriate. Maintain a distribution list.</p>
<ul style="list-style-type: none"> <li>• 3T MRI Facility Manager/Technologist</li> </ul>	<p>Maintain an archive of all previous versions of SOPs to be available in the event of an audit.</p>

**b. Procedure for reviewing SOPs**

<ul style="list-style-type: none"> <li>• 3T MRI Facility Director</li> <li>• 3T MRI Facility Manager/Technologist</li> </ul>	<p>At least annually, review all SOPs. If revisions are required follow the procedure described above.</p> <p>If no changes are required, document and file appropriately.</p>
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**c. Procedure for providing training on implementing SOPs**

<ul style="list-style-type: none"> <li>• 3T MRI Facility Manager/Technologist</li> </ul>	<p>Provide training to all MR personnel within 1 month of a new or revised SOP becoming effective.</p>
<ul style="list-style-type: none"> <li>• 3T MRI Facility Manager/Technologist</li> </ul>	<p>Ensure that all new MR personnel document the date of training and the SOPs reviewed (see Appendix 1: <u>SOP Compliance Form</u>).</p>
<ul style="list-style-type: none"> <li>• 3T MRI Facility Manager/Technologist</li> </ul>	<p>Ensure that all new MR personnel review all applicable SOPs prior to undertaking any responsibilities at this facility for which the SOPs apply.</p> <p>Ensure that all new MR personnel of the research team documents the date of review (or training, if appropriate) and the relevant SOPs (See Appendix 1: <u>SOP Compliance Form</u>).</p>
<ul style="list-style-type: none"> <li>• 3T MRI Facility Manager/Technologist</li> </ul>	<p>Ensure that all MR personnel attend a safety review session each year to review all SOP's, including revisions, and newly implemented SOP's. (See Appendix 2: <u>Safety Review Checklist</u>)</p> <p>Ensure that each member of the research team documents the date of review (or training, if appropriate) at the time of their annual MRI safety review session.</p>
<ul style="list-style-type: none"> <li>• 3T MRI Facility Manager/Technologist</li> </ul>	<p>Maintain a record of SOP training and annual review for all members of the research team at this site.</p>

## d. 3T MRI Standard Operating Procedure Log

SOP type (code)	SOP #	Title	Date
<b>General Administration</b>	100.13	SOP on SOP's	15AUG2023
	105.10	Facility Access Approval Procedure	15AUG2023
	110.12	Facility Visitor Approval Procedure	15AUG2023
	115.12	New Protocols and Ethics Procedures	17AUG2023
	120.12	System Billing and Standard Rates	17AUG2023
	125.10	Privacy and Confidentiality	15AUG2023
<b>Safety and Emergency Procedures</b>	200.12	General MRI Safety	15AUG2023
	205.11	Emergency Code Blue Procedure	15AUG2023
	210.12	Emergency Fire Procedure	15AUG2023
	215.12	Emergency Quench Procedure	17AUG2023
	220.12	Safety and Operator Training Procedure	17AUG2023
	225.12	Incidental Pathological Findings	17AUG2023
	230.12	Research Subjects Requiring Oral Sedation	17AUG2023
<b>Equipment</b>	300.12	System Start-up, Restart, and Shutdown Procedure	17AUG2023
	310.12	Equipment Handling Procedure	17AUG2023
	315.10	Insert Gradient Coil Installation and Removal	17AUG2023
	325.10	Data Handling and Storage Procedure	17AUG2023
	335.08	Goodbye Scan	17AUG2023
	340.08	PSD Loading and Backup	18AUG2023
<b>Room Use</b>	400.12	MRI Decontamination and Waste Disposal Procedure	18AUG2023
	401.03	Minimizing Risk - COVID-19	18AUG2023