

## STANDARD OPERATING PROCEDURE FOR 3T MRI SOPs: Preparing, Maintaining and Training

<b>SOP Number:</b> 3T MRI 100.03	
<b>Version Number &amp; Date:</b> 3 <sup>rd</sup> version; 01 Feb 2009	<b>Effective Date:</b> 1 Feb 2009
<b>Superseded Version Number &amp; Date (if applicable):</b> 100.02 02 Oct 2007	<b>Review Date:</b> 1 Feb 2010

Revision Chronology:		
Version Number	Effective Date	Reason for Change
100.01	19 May 2006	Initial Version
100.02	02 Oct 2007	Review
100.03	01 Feb 2009	Revision

Director Signature: \_\_\_\_\_ / /

**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 3, 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> <li>• The number of pages in this SOP</li> </ul>
<ul style="list-style-type: none"> <li>• 3T MRI Facility Director</li> <li>• 3T MRI 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>• Procedures</li> </ul> <p>Maintain a Table of Contents by number and title of the SOPs</p>
<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>
<p>3T MRI Facility Manager/Technologist</p>	<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>	At least annually, review all SOPs. If revisions are required, follow the procedure described above. If no changes are required, document and file appropriately.
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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>	Provide training to all members of the research team within 1 month of a new or revised SOP becoming effective.
<ul style="list-style-type: none"> <li>• 3T MRI Facility Manager/Technologist</li> </ul>	Ensure that each employee documents the date of training and the SOPs reviewed (using Attachment A, Training Compliance Form).
<ul style="list-style-type: none"> <li>• 3T MRI Facility Manager/Technologist</li> </ul>	Ensure that each new employee reviews all applicable SOPs prior to undertaking any responsibilities at this site for which the SOPs apply. Ensure that each new employee documents the date of review (or training, if appropriate) and the relevant SOPs (using Attachment A, Training Compliance Form).
<ul style="list-style-type: none"> <li>• 3T MRI Facility Manager/Technologist</li> </ul>	Maintain a record of SOP training and review for all employees at this site.

**D. Standard Operating Procedure Log**

SOP type (code)	SOP #	Title	Date
General Administration	100.03	SOP on SOPs: Preparing, Maintaining and Training	01 Feb 09
	105.03	3T MRI Facility Approval	01 Feb 09
	110.03	3T MRI Facility Visitor Approval	01 Feb 09
	115.03	New Protocols and Ethics	01 Feb 09
	120.03	System Billing Guide and Standard Rates	01 Feb 09
	Safety and Emergency	200.03	General Safety Procedures
205.03		Emergency Code Blue Procedure	01 Feb 09
210.03		Emergency Fire Procedure	01 Feb 09
215.03		Emergency Quench Procedure	01 Feb 09
220.03		Safety and Operator Training	01 Feb 09
225.03		Incidental Pathological Findings	01 Feb 09



**E. Training Compliance Form**

Form for \_\_\_\_\_ (Employee Name)

When you initial that you have reviewed an SOP, you are acknowledging that you have read and understood the SOP, and that you agree to comply with the procedures laid out in it.

<b>SOP #</b>	<b>Standard Operating Procedure Title</b>	<b>Initials</b>	<b>Date Reviewed</b>
100.03	SOP on SOP's		
105.03	3T MRI Facility Approval Procedure		
110.03	3T MRI Facility Visitor Approval Procedure		
115.03	New Protocols and Ethics Procedures		
120.03	System Billing Guide and Standard Rates		
200.03	General Safety Procedures		
205.03	Emergency Code Blue Procedure		
210.03	Emergency Fire Procedure		
215.03	Emergency Quench Procedure		
220.03	Safety and Operator Training		
225.03	Incidental Pathological Findings		
230.03	Sedation During MRI Scanning		
300.03	3T MRI System Start-up and Restart		
305.03	3T MRI System Shutdown		
310.03	MRI Equipment Handling and Procedures		
315.03	Gradient Insert Coil Installation and Removal		
320.03	Daily Quality Assurance		
325.03	Data Handling		
330.01	Connecting Non-Commercial Coils to the 3T GE MR750		
335.01	Research PSD Loading and Backup on the 3T GE MR750		
400.03	Decontamination		