

CAMRIS SOP #000

Drafting, Approval, and Review of CAMRIS Standard Operating Procedures (SOPs)

Responsible Committee: Executive	Effective From: April 2, 2024	Last Approved: March 14, 2024	Next Review March 14, 2025	Next Approval: April 30, 2025
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1. Purpose

This standard operating procedure (SOP) describes the process for drafting, approving, and reviewing a SOP within the Center for Advanced Magnetic Resonance Imaging and Spectroscopy (CAMRIS). For the purposes of CAMRIS, SOPs are considered externally facing guidance documents that describe CAMRIS' processes and procedures. CAMRIS SOPs incorporate but do not override applicable standards, policies, and processes from the University of Pennsylvania and the Perelman School of Medicine. In addition, CAMRIS facilities within the University of Pennsylvania Health System follow the relevant policies of the Hospital of the University of Pennsylvania and the Department of Radiology.

Internal CAMRIS processes are documented separately, and do not use the SOP process.

2. Scope

This procedure applies to all SOPs developed by CAMRIS.

3. Instructions and Procedures

3.1. Formatting

The current CAMRIS SOP template is filed in the CAMRIS Sharepoint space. All CAMRIS committees, when generating an SOP for review and distribution, are to use this template.

3.2. Responsibility

Each SOP is drafted by a specific CAMRIS committee (with input from other committees or outside groups), which is called the *responsible committee* and denoted at the top of the SOP template. The choice of responsible committee also defines the first digit of the SOP#, as follows:

Committee:	SOP#s
Executive	000-099
Administration, Scheduling, and Billing	100-199
Technical Operations	200-299
Safety	300-399

3.3. Drafting New SOPs

Issues, concerns, or ideas for policy are brought from CAMRIS staff and/or the user community to the attention of the appropriate CAMRIS committee. The committee reviews and evaluates the information at its regular meetings, to decide if an SOP is needed.

If a new policy is appropriate, the committee will create a draft SOP, becoming the responsible committee for the SOP. When the draft policy is complete, they will vote (either during their regular meetings, or via email) to submit the draft policy for public comment.

3.4. Public Comment on new SOPs

Draft policies that are available for public comment will be posted on the CAMRIS website, along with contact information to submit comments. Notification of the new draft policy will be posted to the CAMRIS Slack #general channel to ensure that the community is aware. In addition, efforts should be made to notify relevant user groups and others impacted by the SOP directly so they have an opportunity to comment. The public comment period for all new policies is a minimum of 2 weeks from the date it is posted and will be noted with the draft policy when it is posted.

All members of the Penn community can provide comments. These are to be collected and saved along with the draft policy, so that they are available for future review. At the end of the comment period, the responsible committee must review these comments and consider whether any modifications to the draft policy are appropriate based on the feedback. The responsible committee is not required to respond to each public comment but should use their expertise and judgement to integrate comments where appropriate.

Once the responsible committee is satisfied that they have appropriately addressed any issues raised in public comment, they will vote (either during their regular meetings, or via email) to submit the draft policy for executive committee approval.

3.5. Approving New SOPs

The Executive Committee reviews new SOPs received from the responsible committees and votes to either adopt the new SOP or return it to the responsible committee for amendments. A vote to adopt to an SOP will also specify the Effective From and Next Approval dates, which are denoted on the SOP template. The Next Review date should be two months before the Next Approval date unless the Executive Committee has reason to specify it as something sooner.

Newly adopted SOPs are posted on the CAMRIS website to be accessible to the public. Relevant user groups and others impacted by the SOP should be notified as quickly as possible of the new SOP, including its intent, its effective date, and who to contact with questions.

3.6. Reviewing SOPs

Each SOPs will be reviewed by the responsible committee before the Next Review date. Responsible committees should draft an updated version of the SOP, reflecting changes in the environment and lessons learned from application of the SOP since last review, ensuring the SOP continues to address its goals. If the SOP is no longer needed, the responsible committee can choose to recommend it be terminated (see section 3.8)

The updated SOP will be approved by the responsible committee before the Next Review date. The SOP is then posted for public comment (see section 3.4), and then sent to the Executive Committee, who will then vote to approve it before the Next Approval date (see section 3.5).

In cases where the approval of a reviewed SOP is not possible before the Next Approval date, the

active SOP version continues to be in effect.

Copies of all previous version of the SOP will be kept on file with CAMRIS administration in accordance with University Policy 2132, Record Retention.

3.7. Modifying SOPs Between Reviews

SOPs should be updated by their responsible committee before their Next Review date whenever deemed necessary by the Executive or the responsible committee. The process for modifying SOPs is the same as that for Reviewing SOPs in section 3.6.

3.8. Urgent SOP Modifications

Urgent modifications to SOPs can be made as-needed and skipping the drafting and public comment processes in sections 3.4 and 3.5, under direct approval by the Executive committee.

3.9. Terminating and Archiving SOPs

SOPs that are no longer needed will be terminated. The responsible committee will vote to recommend termination of an SOP, which will then be approved by a vote of the Executive. The SOP# of terminated SOPs will not be re-used, and copies of the terminated SOP and all previous versions will be kept on file with CAMRIS administration in accordance with University Policy 2132, Record Retention

4. Update History

Date:	Description of Revision
April 26, 2023	Initial version
Nov 22, 2023	Removed role of review committee and replaced with public comment process. Added rules for Urgent SOP Modifications
March 14, 2024	Annual review conducted, no updates