A Guide to Use of Approved SOPs

What version of the SOP am I approved to use?

Requirement:

All SOPs used in animal research and teaching must be approved by the LTU AEC prior to use. SOPs will be approved for a 3-year period. SOPs nearing their expiry date may be renewed following review by the AEC before the expiry date passes.

Code references:

- The AEC must approve only those projects that are ethically acceptable and conform to the requirements of the Code (s2.3.2(i)).
- The AEC may also approve SOPs (s2.2.33) and new SOPs must not be used until approved by the AEC and may be included with an application for consideration by the AEC (s2.2.34)
- If an approved SOP is not reviewed by the AEC within three years of its approval, approval for the SOP lapses, and the SOP cannot be used (s2.2.35).
- The AEC may decide that an application to commence a project or activity, or amend an approved project or activity, is approved with or without conditions, deferred subject to modification, or not approved (s2.3.9 (i)). Investigators must conduct all aspects of a project in accordance with the conditions and requirements of the AEC approval and any subsequent amendments approved by the AEC (s2.4.13).

SOP version control and use practice:

When an application for a new project is approved, currently approved SOP versions would become part of that project, where SOPs were referenced.

However, SOPs can be revised (and approved with a different expiry date) or renewed and re-approved (with a different expiry date) at any time. Changes that are made to SOPs can be administrative or technical and some will have animal welfare impacts. Indeed, changes to SOPs may be because of animal welfare concerns e.g., aligning with updated international standards or contemporary veterinary practice. This has led to some confusion as to which version of the SOP would apply.

Throughout the approval period of an AEC-approved project, it may be the case that SOPs linked to that project will expire and updated versions approved.

Where SOPs have been revised, the AEC will add a condition of approval to relevant approved projects that new SOP versions are in place and must be followed.

For this to occur, PRIME can identify projects for which a particular SOP applies

- Notification through PRIME to PIs that an SOP linked to their project has been updated.
- Note LARTF training will be in accordance with the latest version of an SOP.

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- The AEC will advise Principal Investigators that such a condition will be imposed and offer opportunity to apply for an amendment that retains reference to older versions of the SOP in exceptional circumstances where appropriate for research continuity.

This is consistent with the Code's requirement for the AEC to only approve projects that are ethically acceptable and conform to the requirements of the Code (s2.3.2 (i)); to conduct follow-up review of approved projects and activities and allow the continuation of approval only for those projects and activities that are ethically acceptable and conform to the requirements of the Code (s2.3.2 (iii)).