



UNIVERSITY of
TASMANIA

Division of Research

Instructions for creating and submitting Standard Operating Protocols for Ethics Committee endorsement

Introduction.

Standard Operating Procedures (SOP) are documents which describe a preferred method for performing a task.

SOPs can be used to describe how a certain procedure or task involving animal or human research or teaching participants is performed.

SOPs can be submitted to the relevant UTAS Ethics Committee for endorsement. Once endorsed, the SOP can be referred to in any subsequent applications in lieu of restating the procedure in full within the body of the application.

Drafting SOPs.

Format:

If SOPs are to be submitted for ethics committee endorsement, they must be created using the approved Word templates provided.

The template header and footer may be changed to one that reflects the department, school, division, or institute creating the SOP. [UTAS brand guidelines](#) must be followed.

Additional sections may be added to the template.

Only text within the editable fields may be changed but additional lines may be added to tables and additional images added to the diagrams section.

For detailed instructions on the type and style of content required in each section, see *Detail and Style of SOP contents*, below.

Content:

A general rule of thumb for drafting SOPs is to ensure the level and clarity of detail is such that a person with no previous experience of the technique would have a reasonable chance of performing the task correctly solely by following the SOP.

If other SOPs are relevant to the described task, those SOPs should be referred to in the new SOP by their full name and SOP reference number (if appropriate).

Versioning SOPs

Each SOP should be given a number expressed in the form 'x.x'.

Numbering drafts prior to approval: 0.1, 0.2, 0.3 etc.

Numbering finalised version prior to endorsement: 1.0

Numbering revised versions:

1.1, 1.2, 1.3 etc for **minor** revisions, **or** draft revisions prior to finalising version 2.0

2.0, 3.0 etc for **major** revisions.

Ethics Committee endorsement

SOPs can be submitted for ethics committee endorsement either on their own or as part of an application.

Submit SOPs in Word format.

Ensure the versioning box on the last page is completed.

Versions should be stated to one decimal place e.g., 1.0, 2.1 etc. See Versioning SOPs, above.

The ethics committee will review submitted SOPs during their usual meetings and may request amendments to the document prior to endorsement.

Once endorsed, the Ethics Committee Executive Officer will complete the approval details at the end of the document and assign an SOP reference number and approval expiry date. Approval expiry dates are 3 years for AEC approved SOPs and X years for HREC approved SOPs from the date of approval but may be shortened or extended at the discretion of the Committee.

If SOPs are to be used in lieu of a detailed description of a procedure/s in the main body of the application they must remain current for the life of the project (see Revising SOPs, below).

Revising SOPs.

SOPs may be revised at any time and resubmitted for Committee endorsement.

SOPs must be revised and submitted prior to the endorsement expiry date. **You will not receive a reminder from the Ethics Committee prior to expiry**, therefore it is your responsibility to ensure all SOPs you intend to use as part of an approved ethics application are revised prior to expiry. If you are using an SOP created by another author, you can either contact them and ask that they revise and resubmit the SOP for endorsement or you can ask for their permission to revise and resubmit.

The revising author's name must be entered in the Author field.

Upon endorsement, the Ethics Committee Executive Officer will update the approval expiry date. The SOP reference number remains unchanged.

Sharing approved SOPs.

The Ethics Committees reserve the right to store and share endorsed SOPs in full via the University of Tasmania staff intranet on the Ethics Committee SharePoint page. The Committee will decide whether an SOP should be made available on the AEC SharePoint page, with the author's permission.

If the author of an SOP **does not** want the SOP made available on the Staff Intranet the "No" option must be ticked in the versioning box. If the author's permission to share is not given, only the SOP number, title, author's name and dates of endorsement and expiry will be listed on the Ethics Committee SharePoint page.

Approved SOPs must not be shared, other than by the Ethics Committee and via the staff intranet, without the author's prior approval.

Detail and style of SOP contents by section

Title:

This should be a short description of what the procedure is and the species it is used on.

Example: Humane killing of mice and rats using pentobarbital.

Purpose:

Similar to the title, but more detail can be provided here including the relevance to your research.

Special requirements:

Use bullet points to describe conditions that must be met before performing the procedure, and other limitations or rules that apply to the procedure.

Example:

- *A successful Veterinary Service Competency Assessment is required prior to performing this procedure unsupervised.*
- *Animals under 10 days old must not be killed using this method.*
- *Ketamine must only be obtained and used under a valid S8 Directive and all ketamine use must be recorded in a S8 register.*

Safety requirements:

Use bullet points to list human safety requirements for the described procedure.

Example: This procedure must be performed in a well-ventilated space.

Materials:

Use bullet points to list all the materials and equipment required to perform the described procedure.

Method:

Use a numbered list to detail sequentially all the steps that must be taken to successfully perform the procedure. Take care not to assume prior or special knowledge.

If ancillary procedures e.g., donning of PPE; preparation of solutions or dose materials or completion of paperwork are or can be covered by a separate SOP, refer to that SOP by its number and title at the appropriate point in the description of the method.

Disposal:

Describe how any surplus or used animal parts or fluids should be disposed of.

Diagrams:

Number and describe each diagram, image or figure. Ensure diagrams, images and figures are referred to accurately in the method section.

Animal welfare consideration:

Using bullet points, detail the animal welfare consideration, impacts or effects.

Example:

- *Exposure to CO₂ is distressing to rodents by causing both dyspnoea due to reduced atmospheric oxygen and pain due to formation of carbonic acid on moist tissues exposed to CO₂*
- *Behaviours indicative of distress during this procedure include increased locomotion, rearing and jumping, defecation and urination.*

Glossary

Provide a lay description for any scientific or technical terms used in the SOP