



# IACUC Policy 16: Standard & Laboratory Operating Procedures

**Policy Intent: The intent of this policy is to describe the use, development and classification of Repeatable Animal Related Operating Procedures at TTU.**

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## 1. Purpose

- a. The term standard operating procedure, or SOP, is used in a variety of different contexts, including healthcare, aviation, engineering, education, industry, and military. In clinical research, the International Conference on Harmonisation (ICH) defines SOPs as "detailed, written instructions to achieve uniformity of the performance of a specific function". SOPs get usually applied in pharmaceutical processing and for related clinical studies. Here the focus is always set on repeated application of unchanged processes and procedures and its documentation, hence supporting the segregation of origins, causes and effects. The main difference between an SOP and a policy are details. An effective SOP communicates who will perform the task, what materials are necessary, where the task will take place, when the task shall be performed, and how the person will execute the task.
- b. They should serve as a framework for organizational policy – to provide direction and structure
  - Written documentation of best practices
  - Tells what, how, when, why, and who
  - Provides a foundation for:
    - research task descriptions,
    - research training
    - corrective actions, and
    - protocol performance review

## 2. Definitions

For the purposes of this policy, the following definitions should be applied to the writing and approval of animal related operating procedures.

- a. Standard Operating Procedures (SOP's): A written, detailed set of instructions, which apply to specific processes that can be employed by a broad range of Investigators from a variety of research interests and focus. These shall be freely available through digital sources including the IACUC website.
- b. Laboratory Operating Procedures (LOP's): A written, detailed set of instructions, which apply to specific processes that individual Investigators consistently use within their specific area of research and or laboratory.



### **3. IACUC Policy**

- a. It is the policy of the IACUC that whenever appropriate, IACUC approved SOP's should be utilized in approved research and teaching protocols.
- b. SOP's will be reviewed and approved by the IACUC at their regularly scheduled meetings as necessary, and will be reviewed/amended to reflect current best practices on a regular schedule constituting a 3 year cycle, or as needed when new or superior practices are identified.
- c. LOP's will be reviewed for consistency with current animal welfare standards as described by the animal welfare act and PHS policy guidelines and will be reviewed/amended to reflect current best practices on a regular schedule constituting a 3 year cycle, or as needed when new or superior practices are identified.

### **4. Elements**

- a. The details in an SOP *standardize* the process and provide step-by-step how-to instructions that enable *anyone* to perform tasks in a consistent manner. The SOP document serves as an instructional resource that allows researchers to act without asking for directions, reassurance, or guidance. The step-by-step written procedure can also help decrease the need to repeatedly provide details in Animal Use Protocols, because expectations are documented and their actions can be measured against the SOP. Communicating procedures that anyone in the research field can follow with consistent results will ensure your investigations continually provide high quality repeatable results.
- b. The elements essential to well-reasoned and functioning SOP's and LOP's should include, but may not be limited to the following:
  - Rationale for the SOP or LOP
  - Detailed, step by step description of procedures – based on best practice/standards
  - Who will perform the task,
  - What materials are necessary,
  - Where the task will take place,
  - When the task shall be performed,
  - How individuals will execute the task,
  - Monitoring actions,
  - Impact on animals and welfare, and
  - Date of last review or revision date