

Standard Operating Procedure

SOP Number: **02-18-5806**
Service: **Research**
Operating Section: **IACUC**
Unit: **LUC/HSD**
Title: **Determining Research Category**

Purpose:

To provide an outline of the research categories as determined by the IACUC. Investigators are required to categorize their research protocols utilizing these definitions in order to facilitate preparation of the USDA annual report. Committee members can change the research category if another category is deemed more appropriate during committee deliberations.

Procedure:

- 1) Investigators are provided with the following descriptions of the pain categories in the protocol forms. They will determine which category most appropriately fits their research. IACUC members will also review the criteria during the process of individual protocol review and determine whether the investigator has placed the protocol in the appropriate category.
 - a) Category A: Experiments involving either no living materials or use of plants, bacteria, protozoa, or invertebrate animal species. Biochemical, botanical, bacteriological, microbiological or invertebrate animal studies, tissue cultures, studies on tissues obtained from autopsy or from a slaughterhouse, studies on embryonated eggs. Invertebrate animals have nervous systems and respond to noxious stimuli, and therefore must also be treated humanely.
 - b) Category B: Experiments involving animals that will be bred or purchased for breeding, but not used for experiments. This includes breeders, young that cannot be used because of improper genotype or gender, and any other animals that will not have any research procedures performed on them or participate in research studies. If numbers cannot be determined exactly, estimate as closely as possible. (Note: if tail snips are necessary for genotyping, this category is not appropriate.)
 - c) Category C: Experiments involving animals that will undergo procedures that involve no or only very brief pain or distress, with no need for or use of pain relieving drugs. Examples include observational studies, most intravenous and parenteral injections of non-irritating agents, most blood collections from peripheral vessels, and the collection of cells and/or tissues from animals after euthanasia has been performed.
 - d) Category D: Experiments involving animals that will undergo procedures involving potential pain or distress that is relieved by appropriate anesthetics, sedatives, decapitation or analgesics. Examples include major and minor surgery performed under anesthesia (survival or non-survival), tissue or organ collections prior to euthanasia, painful procedures performed under anesthesia (such as retro-orbital blood collection in rodents), prolonged restraint accompanied by tranquilizers or sedatives, decapitation, and experiments involving infectious or other hazardous materials in animals that have provisions for immediate euthanasia if they become sick to effectively prevent pain and/or suffering. If an

endpoint is used that involves significant pain or distress, consideration should be given to putting animals into Category E.

- e) Category E: Experiments involving animals that will undergo procedures in which pain or stress is NOT relieved with the use of anesthetics, analgesics, tranquilizers, or by euthanasia. Examples include studies in which animals are allowed to die without intervention (i.e. LD₅₀ mortality as an end-point), studies that allow endpoints that are painful or stressful, addictive drug withdrawals without treatment, pain research, thermal injury, noxious stimulation.

Comments:

None.

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APPROVALS

Responsible Official Signature		Date	
QA Signature		Date	
Version #2	Effective Date	Supersedes #1	Original Date 6/7/04