

## **ACUC Guidance on Creating a New Animal Use Protocol vs. Adding a New Species Procedure**

### **Outline:**

1. Purpose
2. When to Create a New Protocol
3. When to Add a New Project to an Existing Protocol
4. Appendices:
  - A. How Protocol Sections are Organized
  - B. How Species Procedures are Organized

**Purpose:** The purpose of this document is to provide guidance for PIs who have an existing, approved animal use protocol and have a new project that needs to be covered in an ACUC protocol. Is a new protocol warranted or can the new information be added to an existing protocol in a new Species Procedure, or into an existing Species Procedure?

### **When to Create a New Protocol:**

1. If your new project is not reasonably covered by the goals or aims given in your existing abstract, then a new protocol is probably warranted.
2. Funding from the DoD may require a separate animal use protocol for each project/grant. The PI should consult the Program Officer of the agency to see if the new work requires a new protocol.
3. A separate protocol should be created for VA funding as they require annual IACUC review.
4. USDA regulated species should also be separated into a new protocol since those species require annual review while other species are reviewed triennially.

**When to Add a New Project to an Existing Protocol:** If new, proposed experiments fall under the abstract of an existing protocol, then either:

- 1) Add a new Species Procedure to the existing protocol if it fits within the scope of the abstract.
- 2) Add the new work to an existing Species Procedure in that protocol, but only if it fits within the scope of that Species Procedure. This option is uncommon, as most new projects would require a new Species Procedure, if not a new protocol.

All procedures on an individual animal should be listed within one Species Procedure and include a clear, concise, sequential description of procedures from acquisition to euthanasia and disposition of the animal.

## **Appendices:**

**A. Protocol Sections:** An animal use protocol is organized into two parts:

**Part I:** The Protocol Summary contains general information about the PI and Contact Person; the funding that covers the project; the Protocol ID (Education, Research or Pilot Study); the Abstract – written in lay terms and contains a concise statement of the research goal; Animal Use Justification; the 3 Rs of Replacement, Reduction and Refinement; Storage of Controlled Substances and other general information.

**Part II:** Different proposed experiments that would lead to the goal in the abstract are organized within separate Species Procedures. Procedures for an individual animal are to be included within one Species Procedure. These procedures are written by following the questions in the protocol. All animal handlers that have been assigned to work on the experiments described are added to each Species Procedure accordingly and provided with corresponding animal handler responsibilities.

## **B. Species Procedure Organization:**

Species Procedures should be organized to describe the different experiments that occur to the same animal. Different animal species can be included in one protocol as long as they both share the same goal. In most cases, it is suggested that a breeding colony, that produces all the progeny to be used within the protocol, be added as one separate Species Procedure. Only breeders, replacement breeders and unused animals are to be counted in the breeding colony and categorized into USDA categories B or C, depending on whether genotyping is required. The offspring from the breeding colony would only be counted in the experiments of the subsequent Species Procedures where they are used experimentally. Another example is the description of donor and recipient mice for bone marrow transplants and T-cell reconstitution which should be added to one Species Procedure if the overarching study focuses on heart disease. If procedures are oriented on a specific technique then the technique should be described clearly once and then referred to in subsequent procedures as needed.