Institutional Animal Care and Use Committee Guidance 105

TITLE: Alternatives Documentation

PURPOSE: To provide guidance on performing and documenting the alternatives literature search.

REVIEW/REVISIONS: The IACUC will review and revise this guidance as needed.

DATE OF LAST REVIEW: 09/11/2017

1. All protocols with a pain category of C or higher must include alternatives documentation.

2. Amendments to protocols that include new procedures or changes in species must include a newly conducted literature search and alternatives documentation.

3. Alternatives should be considered in the planning phase of the animal use proposal. When a proposal is modified during its performance, significant changes are subject to prior review by the IACUC, including the review of the implications of those changes concerning the availability of alternatives.

4. Information in the Alternatives Documentation section of the protocol or amendment form should include adequate information for the IACUC to assess that a reasonable and good faith effort was made to determine the availability of alternative models or methods. If the database search or other source identifies a bona fide alternative method (one that could be used to accomplish the goals of the animal use proposal), the written narrative should justify why this alternative was not used.

   The written narrative for federally-mandated animal testing (for example, testing product safety/efficacy/potency) needs only to include a citation of the appropriate government agency's regulation and guidance documents. Mandating agency guidelines should be consulted since they may provide alternatives (for example, refinements such as humane endpoints or replacements such as the Murine Local Lymph Node Assay) that are not included in the Code of Federal Regulations. If a mandating agency-accepted alternative is not used, the principal investigator should explain the reason in the written narrative.

5. Alternatives Documentation must include a written narrative description of the methods and sources used to consider alternatives to procedures that cause more than momentary or slight pain or distress to the animals.

6. When a database search is the primary means of meeting the Alternatives Documentation requirement, the narrative must, at a minimum, include:
   a. The names of the databases searched
   b. The date the search was performed
   c. The period covered by the search
   d. The key words and/or the search strategy used

7. Keywords that must be used in the Alternatives Documentation search include: Alternatives, pain, distress, euthanasia, reduction and refinement.

8. Examples of acceptable data bases include:
9. The following sites can help you develop strategies for searching for alternatives and can link you to data bases that will perform the searches:

b. IACUC: Searching for Alternatives to Painful Procedures Used on Research Animals: Alternatives searching home: http://guides.library.yale.edu/c.php?g=589364&p=4074027 Includes guide to creating an effective search: How to search, where to search, examples, etc. (Harvey Cushing/John Hay Whitney Medical Library, Yale)

JUSTIFICATION:

Animal Welfare Act (AWA) regulations require principal investigators to consider alternatives to procedures that may cause more than momentary or slight pain or distress to the animals and to provide a written narrative of the methods used and sources consulted to determine the availability of alternatives, including refinements, reductions, and replacements. The following is an excerpt from the Actual USDA Policy #12: Consideration of Alternatives to Painful/Distressful Procedures.

USDA Policy 12: “Alternatives or alternative methods are generally regarded as those that incorporate some aspect of replacement, reduction, or refinement of animal use in pursuit of the minimization of animal pain and distress consistent with the goals of the research. These include methods that use non-animal systems or less sentient animal species to partially or fully replace animals (for example, the use of an in vitro or insect model to replace a mammalian model), methods that reduce the number of animals to the minimum required to obtain scientifically valid data, and methods that refine animal use by lessening or eliminating pain or distress and, thereby, enhancing animal well-being. Potential alternatives that do not allow the attainment of the goals of the research are not, by definition, alternatives.”

“A fundamental goal of the AWA and the accompanying regulations is the minimization of animal pain and distress via the consideration of alternatives and alternative methods. Toward this end, the regulations state that any proposed animal activity, or significant changes to an ongoing animal activity, must include:

1. A rationale for involving animals, the appropriateness of the species, and the number of animals to be used;

2. A description of procedures or methods designed to assure that discomfort and pain to animals will be limited to that which is unavoidable in the conduct of scientifically valuable research, and that analgesic, anesthetic, and tranquilizing drugs will be used where indicated and appropriate to minimize discomfort and pain to animals;
3. A written narrative description of the methods and sources used to consider alternatives to procedures that may cause more than momentary or slight pain or distress to the animals; and

4. The written assurance that the activities do not unnecessarily duplicate previous experiments.”

“When a database search is the primary means of meeting this requirement, the narrative must, at a minimum, include: 1. the names of the databases searched; 2. the date the search was performed; 3. the period covered by the search; and 4. the key words and/or the search strategy used.”

“The Animal Welfare Information Center (AWIC) is an information service of the National Agricultural Library specifically established to provide information about alternatives. AWIC offers expertise in formulation of the search strategy and selection of key words and databases, access to unique databases, on- and off-site training of institute personnel in conducting effective alternatives.”