Standard Language and Terminology for ASPs

For use in ASPs depending upon relevance and applicability to the specific experiments.

Study Objectives (for use in **Section C)**
Please write this Section, or a portion thereof, in non-technical language that can be understood by our community/non-medical representative on the ACUC.

Example from an approved protocols:

In the United States, approximately half of all patients diagnosed with cancer will require radiation treatment. While radiation therapy can control the growth of some types of human cancers, often normal tissues within the radiation treatment field can be damaged resulting in inflammation or dysfunction. Radiation-induced mucositis, or inflammation and loss of the lining of an organ, causes both functional consequences and in some instances can lead to the need for feeding tubes or hospitalization. Various organs of the body have differing sensitivities to radiation-induced mucositis, but the esophagus, mouth, bowel and rectal mucositis are among the frequently observed clinically. There is a definite need to identify agents that can prevent this inflammation and mucositis to allow chemotherapy and radiation to be given with less side effects.

Hepatocellular carcinoma (HCC) is one of the most frequent neoplasms worldwide, with over four hundred thousand new cases and almost as many deaths each year. Hepatocarcinogenesis in humans, like most non-hereditary cancers, is a slow process. The emergence of HCC occurs following the appearance of a series of preneoplastic liver lesions and coincides with accumulation of irreversible alterations in a number of genes and chromosomes. Although much is known about both the cellular changes that lead to HCC and the etiological agents responsible for the majority of HCC, the molecular pathogenesis of HCC, in particular the sequence of genetic alterations that drive the development of liver neoplasm, is not understood.

Statistical terminology (for use in **Section D**)

Language from the Guide: Justification of the species and number of animals requested and whenever possible, the number of animals requested should be justified statistically.

Example from ARAC suggested language:

The total number of animals described in this section is the minimum number of animals required to test the hypotheses of this ASP and may be based on scientific experience, professional judgment, the relevant literature, and, where appropriate, statistical analysis.

Suggested examples:

Numbers of animals in each group are determined based upon previous studies conducted by this laboratory (cite references), which allow for statistically valid comparisons.

Numbers of animals in each group are determined based upon previous studies conducted by this laboratory (cite references), which account for the variability around the point estimates and allow for statistically valid comparisons.

Numbers of animals in each group are determined based upon previous studies conducted by this laboratory (cite references), which allow determination of statistically significant differences ($p < .05$).

Examples from an approved NCI protocol:

To test toxicity of oral tempol, we will include 8 mice per dose level as this is the minimum number of mice that will allow us to determine reproducibility and maximum tolerated dose of oral tempol.

We will use 10 animals per treatment group with the combination of radiation and to obtain the appropriate level of statistical significance for the radioprotection assays (combined tempol and radiation).

Language and Terminology for Humane Endpoints (for use in **Section E**)

Examples:

Any animal experiencing rapid weight loss, debilitating diarrhea, rough hair coat, hunched posture, labored breathing, lethargy, persistent recumbence, jaundice, anemia, significantly abnormal neurological signs, bleeding from any orifice, self-induced trauma, impaired mobility, or has difficulty obtaining food or water will be euthanized.

Animals will be euthanized at the time of tumor observation and/or measurement if it is expected that the tumor size will be at 20 mm, in any dimension, at the time of the next scheduled tumor measurement. Animals with a tumor that is necrotic, has cutaneous ulceration or multiple tumors that weigh in total more than 10% of the animal's body weight will be euthanized.

Exceptions to these endpoints may be reviewed on a case-by-case basis.

Example of multiple tumors weighing more than 10% of body weight:
A 20g mouse has 3 tumors, each with an average diameter of 1cm each. The estimated total weight of these tumors is 1x1x1 = 3g, which is over 10% of its body weight.