Helpful Hints for Completing the NCI-Frederick Animal Study Proposal Form

The goal of the NCI-Frederick Animal Care and Use Committee [ACUC] is to promote the well-being of your animals and to ensure that our investigators obtain reliable scientific data for their research endeavors. The ACUC has developed these helpful hints in an effort to assist investigators with the Animal Study Proposal [ASP] submission process. Before you get started writing your ASP, the ACUC strongly encourages you to consider the following to ensure timely review and processing of your study:

- ✓ Take a look at the NCI-Frederick Animal Care and Use Committee website for assistance and reference materials
- ✓ Discuss the project with the facility manager and technical staff to ensure that the resources are available to support your study
- ✓ Be sure to download the most current version of the NCI-Frederick Animal Study Proposal Form
- ✓ Discuss the project with the LAM veterinary staff regarding the use of anesthetics and analgesics, proposed surgical procedures, preoperative and postoperative care, and/or necessary training that may be required for your study
- ✓ Review the current ACUC Guidelines to ensure you incorporate applicable refinements and recommendations into the text of your proposal submission
- ✓ If you are interested in using imaging technology in conjunction with your study, please discuss the project with the Director of the NCI-Frederick Small Animal Imaging Program [kalenj@mail.nih.gov] in advance of proposal submission
- ✓ Please send your proposal submission [hard copy signature pages can be submitted by interoffice mail under separate cover] by e-mail to stahlam@mail.nih.gov. Please be sure to include any appendices, tables, references with your submission.
- ✓ If you have any questions or concerns, feel free to contact the ACUC Office [301-846-7544 or stahlam@mail.nih.gov] for guidance and assistance

SECTION A – ADMINISTRATIVE DATA

- Please be sure to complete all blanks in Section A
- Ensure that you list all individuals working on your study [including LASP and dedicated technicians]
- List all of the procedures they will be performing [to include tail clipping, injections, blood collections, surgical/experimental procedures, euthanasia, etc.].
- List their relevant experience [# of years] for the procedures that they will perform under this study
- Please be sure that all individuals listed have taken one of the following courses: [1] The Animal Care and Use Introductory Online Training course or [2] NIH Office of Animal Care and Use Training Course.

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SECTION B – ANIMAL REQUIREMENTS

- Please be sure to complete all blanks in Section B
- For multi-species proposals, please be sure to provide a breakdown of the animal numbers by species for each year
- Please be sure to check your math
- Please be sure that the total number of animals requested under Section B, matches those outlined in Sections D, E, and G [as applicable]

SECTION B1 – INSTITUTIONAL BIOSAFETY COMMITTEE

- This section was designed to ensure appropriate coverage by the Institutional Biosafety Committee [IBC] for studies proposing the use of transgenic/knock-out animal models, Recombinant DNA, transfected cell lines, human or other primate tissues or cell lines, or potentially infectious materials
- Your ASP is not permitted to be released for approval until the necessary IBC registration documents have been secured. Therefore, if you are proposing work that involves any of these materials, please contact the IBC Office [301-846-7299] in advance to ensure that you are in compliance with safety requirements and to alleviate potential delays in your ASP approval.
- Please refer to the Institutional Biosafety Committee web page for additional guidance.

SECTION C – STUDY OBJECTIVES

- Describe the objectives of your research activities
- Describe the important benefits and/or outcomes that you expect as a result of performing this research project
- For support service studies, provide an overview of the service and for whom the services will be performed
- Use lay language … this section should be easily understood by the average high school student
- Define all abbreviations and acronyms

SECTION D – RATIONALE FOR ANIMAL USE

- Explain why a non-animal model [i.e., in vitro, chemical technique, computer simulation, etc.] cannot be used to fulfill your research objectives
- Explain why a less sentient animal species cannot be used for this study
- Explain why the animal model/strain selected is being used for this study [i.e., unique characteristics, etc.]
- Provide a mathematical calculation to justify the number of animals requested in Section B [tables and charts are highly recommended to outline the procedures and the associated numbers]. Please be sure that this number matches those outlined in Sections E and G [as applicable].
- For breeding studies, please be sure to include the number of breeders, the breeding scheme used, the number of offspring expected [% of correct genotype as applicable], etc.
- Refer to the LASP Animal Numbers for Research Calculator for assistance with calculating the number of animals required for your breeding study
- As an alternative to in-house Monoclonal Antibody Production, please check out the Developmental Studies Hybridoma Bank website. This site was established under the auspices of the National

Institute of Child Health and Human Development to supply investigators with monoclonal antibodies at cost.

SECTION E – DESCRIPTION OF EXPERIMENTAL DESIGN AND ANIMAL PROCEDURES

You are only permitted to conduct procedures on live animals that have been approved by the NCI-Frederick ACUC in advance. Conducting procedures that have not been listed in an approved ASP form* can result in the suspension of your animal activities. Section E is where you will describe all the procedures that live animals will undergo in your study. This includes, but is not limited to the following:

- Breeding details [scheme, breeder endpoints, endpoints for offspring not required for studies, genotyping, compliance with SOP 3.021]
- Blood withdrawals [volume, site, frequency, max number a single animals will undergo]
- Injections/Treatments [substance, volume, route, dose based on body weight as applicable]
- Tailclipping [anesthesia is required for re-tailclips]
- Sample collections
- Monitoring frequency for health issues [daily]
- Tumors [location, observation, palpation/measurement frequency, maximum burden]
- Endpoints [experimental and humane]
- Diets [manufacturer sheets should be provided]
- Body Weights [indicate frequency]
- Anesthesia [details to be provided in Section H]
- Imaging [a SAIP imaging request form will be required prior to approval]
- Radiation
- Surgical Procedures [details to be provided in Section F]
- Restraint method
- Resultant effects
- Potential adverse effects [please provide clinical descriptions for the veterinary and technical staff]
- Deleterious phenotypes
- Euthanasia [details to be provided in Section I]
- Maximum period of time a single animal remains under the study
- Please check the applicable ACUC Guidelines that will be followed in conjunction with your study
- Please check the applicable methods of identification that will be used
- If animal numbers have been outlined in this section, please ensure that they match those proposed in Sections B, D, and G

* If during the course of your study, you and/or your technical staff determine that changes, refinements, additions, etc., are required … you MUST submit a modification to the NCI-Frederick ACUC and receive approval before proceeding. Modifications include, but are not limited to changes in personnel, strains to be used, diets, injection volumes, route of injections, doses of agents, blood collections, changes/additions of procedures specific to the study, facility location, increase in the number of animals to be used, method of euthanasia, etc.

SECTION F – CONDUCTING SURGICAL PROCEDURES

- Surgical preparation
- Sterilization/Aseptic techniques
- Anesthetics used [agent, volume, dose, route]

- Incision details [size, location]
- Procedure details/approach
- Wound closure [and removal]
- Analgesics used [agent, volume, dose based on body weight as applicable, route]
- Post-operative care [individual responsible, special housing, maintaining body temperature]
- Personnel experience
- Location where surgery will be performed
- Please contact the LAM veterinary staff in advance [301-846-5195] if you are proposing to conduct major survival surgery

SECTION G – PAIN, DISTRESS, GENERALIZED DISCOMFORT

- Any animal receiving an anesthetic or analgesic must be listed under Category 2 [unless used for restraint purposes only]
- If you conduct a study for which animals are placed in Category 3, you are required to perform a literature search to demonstrate that you have considered alternatives to procedures that may cause more than momentary pain, distress, or generalized discomfort
- The literature search statement must include the database[s] searched [at least two], the date of the search, the period covered, and the keywords that were used
- For Category 3, you must also include scientific justification for performing the proposed procedure and a description of your considerations to alternative procedures and why they cannot be utilized in this study
- Please ensure that the total number of animals outlined in this section match those proposed in Sections B, D, and E [as applicable]

SECTION H – ANESTHESIA, ANALGESIA, TRANQUILIZATION

- Agents used
- Volume
- Route
- Dose [based on body weight as applicable]
- Frequency

SECTION I – METHOD OF EUTHANASIA OR DISPOSITION

- Please be sure to utilize the appropriate method [species and/or age specific]
- If using CO2, please indicate the source [gas cylinder, in-house line, etc.]
- Please refer to the ACUC Guidelines for Euthanasia of Rodents
- If using cervical dislocation in mice, please provide scientific justification, indicate the individual performing the procedure and their experience
- If PHL services may be utilized, list additional known methods of euthanasia that may be performed by PHL staff [i.e., terminal perfusion under anesthesia]

SECTION J – HAZARDS

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- This section was designed to inform the animal facility staff of potential hazards associated with your research study
- Complete Sections I and II as they relate to human health hazards
- Attach all Material Safety Data Sheets, Recombinant DNA Documents, and/or Human Pathogen Registration Documents

SECTION K – BIOLOGICAL MATERIALS AND ANIMAL PRODUCTS

- List all materials that are to be used in your study [tumors, cell lines, matrigel, collegenase, rodent derived antibodies, natural cytokines, any other unpurified or nature materials/rodent by products]
- Include copies of all MAP/RAP Test Results
- Test results that are greater than 10 years old for lines that have not been used recently, must be submitted for re-testing
- All human tumor cell lines must undergo human pathogen testing unless special housing arrangements have been made through the animal facility manager. Please contact the ACUC Office [301-846-7544] in advance if you obtained your human tumor cell line from the DCTD repository. If DCTD conducted human pathogen testing, the ACUC Office will obtain a copy of the results on your behalf.

- If using synthetic materials, please provide the manufacturer sheet that indicates that no murine products were involved in the making of the material and/or the purification process
- Indicate if lines have been manipulated in any way [i.e., transfected] … this may prompt additional testing requirements.

SECTION L – TRANSPORTATION

- Verify that all transportation will be in accordance with approved policies and procedures
- List all locations [Building and Room] where live animals will be transported
- Provide details on the procedures to be performed at that location [i.e., tissue collection]
- State the time point and method of euthanasia [i.e., within 6 hours by CO2]
- If transporting to Bethesda, please provide the NCI-Bethesda proposal that covers the work
- List the individual responsible for care in the new location
- If applicable, refer to the ACUC Policy on Transportation of Newborns

SECTION M – SPECIAL CONCERNS AND ENVIRONMENTAL ENRICHMENT

List all of the special requirements of your study, this includes [but is not limited to]:

- *Special caging*
- *Special diets*
- *Treated water or feed*
- *Fasting*
- *Exceptions to ACUC Guidelines*
- *Biohazard waste disposal*

For environmental enrichment, please check the appropriate boxes for singly housed and group housed animals.

SECTION N – INVESTIGATOR CERTIFICATIONS

This section is where the investigator certifies the following:

- All individuals listed under Section A have taken one of the following courses: [1] The Animal Care and Use Introductory Online Training course or [2] NIH Office of Animal Care and Use Training Course
- All individuals under Section A are adequately trained to perform the procedures proposed in the study
- The proposed work is NOT duplicative
- That you have reviewed the literature to confirm that there are no alternatives to procedures that may cause pain and/or distress to the animals
- That staff are enrolled in the appropriate occupational health and safety surveillance programs
- That if changes are required to your study, that a modification memorandum is submitted in advance to the ACUC for review and approval
- That animals used in your study are in compliance with the Technology Transfer Branch requirements

SECTION O - ANIMAL AUTHORIZATION DISPOSITION

- Complete this form in its entirety
- List all adverse clinical symptoms and/or signs that the tech and vet staff should be aware of in relation to your study
- Please provide at least two contact names with their cell/home/pager numbers
- Please specify what you would like to have done with the animal prior to or after euthanasia [i.e., bleeding, collect specific tissues, necropsy, refrigerate, etc.]

SECTION P – LAB/BRANCH CHIEF CONCURRENCE

- The Principal Investigator is not permitted to sign this section
- The PI lab/branch chief or division director MUST sign this section

ELECTRONIC COPIES OF THE ASP SHOULD BE SENT TO STAHLAM@MAIL.NIH.GOV
HARD COPIES OF THE APPLICABLE SIGNATURE PAGES CAN BE SENT BY MAIL UNDER SEPARATE COVER
THE ACUC HAS IMPLEMENTED PROPOSAL SUBMISSION DEADLINES
IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT THE ACUC OFFICE AT 301-846-7544