St. Mary's College of Maryland
Institutional Animal Care and Use Committee (IACUC)
Instructions for Submission of Materials

1. SUBMISSION FORMAT

Your protocol submission to the IACUC will have two parts: the Animal Research Form (ARF), and a written section consisting of mandatory attachments. Both parts of the protocol can be found following these instructions. Please submit your protocol as a single electronic file, containing both the ARF and the attachments, to djtobiansky@smcm.edu. Save this file with a unique new name, and **delete the first two pages of instructions before submitting**. On both the ARF and the attachments, address each item independently, without reliance on information covered under other items or in other IACUC submissions. All attachments should be typed. Copied materials from grant applications are not acceptable.

2. HELPFUL INFORMATION

A. Submission Deadlines and Expiration

IACUC protocols are accepted on a rolling basis but are only reviewed by the committee the week following submission/review deadlines (https://www.smcm.edu/iacuc/schedule/). The committee will make every effort to respond to a new submission within 10 working days. Protocols remain valid for 3 years from the date of approval. Active protocols need to submit a yearly update (IACUC Protocol Update & End of Year Form) to the chair at djtobiansky@smcm.edu. Once you have completed your research protocol, please submit an IACUC Protocol Update & End of Year Form to the chair at djtobiansky@smcm.edu in order to terminate your IACUC protocol.

B. IACUC Coordinator

The IACUC Coordinator (Dr. Daniel Tobiansky) can assist with questions concerning submission & status of your protocol. She can be reached by phone at (240) 895-2001 or by email at djtobiansky@smcm.edu, and is located in Room 232 Schaefer Hall.

C. Justification of Animal Numbers

The USDA has noted that "A proposal to conduct an animal activity must provide a rationale for the appropriateness of the number of animals used." The USDA inspector has informed us that a statistical justification can be used when appropriate for this "rationale".

The experimental groups and number of animals/group should be clearly explained in the text, or using a diagram or chart. This is intended to make it clear how all animals are being utilized and to account for the number of all animals to be used throughout the study.

D. Category of Pain

Categories used:

A. Animals experiencing no pain or distress (e.g., breeding, behavior studies).

B. Animals experiencing little to negligible pain or distress or use of pain-relieving drugs (e.g., euthanize & harvest, antibody production) or Animals experiencing pain or distress but are receiving the appropriate anesthetic, analgesia or tranquilizing drugs for their relief (e.g., surgeries, dietary manipulations, tumor production, trauma, etc.).

C. Animals experiencing pain or distress that normally require pain-relieving drugs but cannot receive these drugs because of adverse effects to the procedures, results or interpretations of the experiments. THIS CATEGORY MUST BE WELL-JUSTIFIED AND DOCUMENTED IN THE NARRATIVE.

E. Database Literature Search <u>(Must Be Two Separate Databases)</u>

(This section is on the last page of the ARF.)

In order to comply with USDA regulations (Sect. 2.31(d)ii and 2.32[5] of the Animal Welfare Act), you must show that you have consulted Databases concerning the following three specific issues: (1) considering alternatives to procedures that may cause more than momentary or slight pain or distress to the animals; (2) considering alternatives to the use of live animals in your research; and (3) to prevent unintended and unnecessary duplication of research involving animals.

The following is an example of the information needed on the ARF of a search with Databases used, keywords and strategies for a proposal involving the study of the functional anatomy & number of visual centers contained within the visual cortex. Anatomical tracers & electrophysiological data will be used to map these centers in macaque monkeys.

DATE OF SEARCH: <u>March 1, 2000</u>

DATABASES:MEDLINE_<u>X</u>__;AGRICOLA_<u>X</u>__;EMBASE_<u>X</u>_;PSYCHINFO___;OTHER_____

STRATEGY OR KEYWORDS:_<u>VISUAL CORTEX; PRIMATE; VERTEBRATE ANIMALS; MAPPING/ANATOMY; ELECTROPHYSIOLOGY; ALTERNATIVES; IN VITRO OR CULTURE; MODEL OR SIMULATION</u>.

DATE PARAMETERS OF SEARCH: <u>1975 to Present</u>

<u>Please note that Medline, Medline Complete, and PubMed use the same database and should not be considered as two separate searches.</u>

The SMCM library has access to several Databases; see a reference librarian or the IACUC coordinator if you are not sure how to access them.

ST. MARY'S COLLEGE OF MARYLAND
INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)
ANIMAL RESEARCH FORM (ARF)

Principal Investigator (PI): _____Degree: _____
Address: _____ Dept: _____ Phone: _____
E-mail: _____Emergency Contact: _____ Phone: _____
Project Title:_____
_____

Co-Investigators:			Technicians:		
Name	Dept	Phone	Name	Dept	Phone
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____

I. RESEARCH CATEGORIES

Major Categories of Research Use: Please check as applicable. All "checked" responses must be completely addressed in the NARRATIVE attachment.

A.___ Euthanize and Harvest Tissue (detail method of euthanasia)
B.___ Immunization/Antibody Production (include antigen, adjuvant use, route of immunization, method of obtaining blood as well as volume & frequency)
C.___ Physiologic Measurements (provide detailed descriptions)
D.___ Dietary Manipulations (food or water restriction, special diets, details on parameters, monitoring & justification, etc.)
E.___ Pharmacology/Toxicology (materials used, dose, route of administration, frequency, duration, endpoint, etc.)
F.___ Investigational Drug (provide company drug information sheets and/or list of possible side effects to animals, etc.)
G.___ Behavioral Studies (provide detailed description)
H.___ Trauma (provide a detailed description)
I.___ Oncology/Tumor Transplantation (provide information on origin, passage, adventitious pathogen testing [MAP], biohazard potential, endpoint, etc.)
J.___ Sampling (tissue/substance, amount, frequency, method, etc.)
K.___ Dosing (agent, dose, route of administration, frequency, duration, etc.)
L.___ Breeding Colony (justify need)
M.___ Biohazardous /Infectious Agents (describe the nature of hazard and personnel safety precautions)
N.___ Chronic or Prolonged Restraint (provide justification for restraint, a description of the device & restraint duration)
O.___ Surgery
___ Survival Surgery
___ Non-Survival Surgery
___ Multiple Major Survival Surgery: species_____(Same animal surviving two or more surgeries) Provide adequate justification for need.
P.___ Specialized Housing/Husbandry
Q.___ Teaching

II. CATEGORY OF PAIN

DEFINITIONS of each category are given on page 1 of the instruction sheets.

A. _____ B. _____ C. _____

III. FUNDING SOURCE

CURRENT OR ANTICIPATED
_____PHS (NIH)
_____NSF
_____State of Maryland
_____Departmental/Internal Funds

_____Other External Funds (specify)_____

IV. ANIMAL USAGE

Species/Strain	Weight/Age	Sex	(# PER YEAR) YR 1	YR 2	YR3	Max Daily Census

IF ADDITIONAL SPECIES/STRAINS ARE BEING REQUESTED, INCLUDE ON AN ADDITIONAL PAGE

V. BIOHAZARD INFORMATION

Please indicate the general biohazard being used in vivo:

Infectious Agents_____ Radioactive Substances_____ Toxic Chemicals/ Chemical Carcinogens_____ Recombinant DNA _____

Others (specify) _____

Name of Agent _____

Please provide: A) ABL level (1, 2, or 3) of infectious agents_____

B) Concentration _____

C) Route of administration _____

D) Duration of exposure _____

E) Room location where agent is administered _____

F) Location of animal housing post exposure _____

G) Length of time animals will be kept following exposure _____

H) Method of animal disposal _____

VI. SURGERY

Survival Surgery *

A. Procedure _____

B. Anesthesia_____

C. Building & Room Number where surgery will take place _____

D. Person(s) performing survival surgery _____

E. Post-Operative Care (e.g., supportive fluids, analgesics, antibiotics. other drugs & frequency of observation)

_____

F. Person(s) providing & recording post-operative care _____

*Describe in detail the surgery, aseptic procedures & post-operative care in the NARRATIVE section.

Non-Survival Surgery

A. Procedure _____Species _____

B. Anesthesia _____

C. Method of Euthanasia _____

D. Building & Room Number where surgery will take place _____

E. Person(s) performing non-survival surgery_____

VII. METHOD OF ANIMAL DISPOSITION

Please indicate how animals will be disposed of at the conclusion of the experiment. This section should typically describe the method of euthanasia. Adoption of experimental animals as pets will be approved only under limited circumstances.

SPECIES	AGENT	DOSE	ROUTE/METHOD

VIII. LOCATIONS OF ANIMAL USAGE

Please list all locations where Animal Procedures will be performed.

Building and Room #	TYPE OF PROCEDURE(s)
1. _____	_____
2. _____	_____
3. _____	_____
4. _____	_____

IX. DATABASE LITERATURE SEARCH

Identify the services (computer databases, literature searches, etc.) that were used to obtain information on alternatives to painful procedures, use of live animals and prevention of unnecessary duplication of research.

Please check below the databases searched and your search strategy or key words. A MINIMUM OF TWO SEPARATE DATABASES MUST BE USED. Please do not submit the actual search results (however, they should be available upon request). (Refer to instructions for examples.)

DATE OF SEARCH:_____

DATABASES: MEDLINE/PubMed_____; AGRICOLA_____; EMBASE_____; PSYCHINFO_____;OTHER_____

STRATEGY OR KEY WORDS:_____

_____

DATE PARAMETERS OF SEARCH: _____

AREAS OF RESPONSIBILITY

The Principal Investigator is responsible for all aspects of the research protocol including post-operative monitoring and care, research related complications, and humane treatment by investigative personnel, as well as supervising laboratory animal care, including animal procurement, husbandry, disease control and prevention, humane treatment and adequate veterinary care under the supervision of a doctor of veterinary medicine.

PRINCIPAL INVESTIGATOR'S ACKNOWLEDGMENT OF RESPONSIBILITY

I certify that the activities described in this protocol do not unnecessarily duplicate previous experiments.

I certify the above protocol will be conducted in compliance with the Federal, State, and local policies and regulations. I also acknowledge full responsibility for knowledge of and compliance with all applicable standards governing radioactive or biohazardous materials involved in my project. I understand that compliance with these policies is a prerequisite for purchasing and housing animals, and for the use of animals in research and teaching at St. Mary's College of Maryland.

_____ _____

Signature of PI Date

_____

Printed Name of PI

_____ _____

Signature of IACUC Coordinator Date Approved

NOTE Electronic submissions to the IACUC coordinator are strongly preferred. All information must be submitted, completely, as requested on the St. Mary's College of Maryland IACUC Animal Research Form. Insufficient information may delay the review process. The IACUC reserves the right to request additional information or to table protocols that do not meet the basic submission requirements.

MANDATORY ATTACHMENTS

Title of Project
Name(s) of Principal Investigator and Co-Investigators (if any)
Academic Department(s) and Affiliation(s)

A. Summary of Study.
Please write two paragraphs: (1) a paragraph explaining your project and its importance, in lay terms (non-technical language) suitable for a broad audience; and (2) a scientific abstract of your project and its importance, including relevant citations. The scientific abstract should clearly indicate how the project is supported and justified by the existing scientific literature.

B. Justification for the use of animals and species.
Provide rationale for using animals and for appropriateness of the species selected. In particular, give reasons as to why non-animal methods (e.g., computer simulations, *in vitro* testing) cannot be employed.

C. Justification of number of animals.
How was the number of animals determined? A diagrammatic flow chart is often helpful to illustrate groups and manipulations used.

D. Narrative.
This should be the longest section of your protocol. Explain the experimental design and provide a complete description of all animal procedures. The experimental course for all animals should be clearly presented from start to finish, including plans for the disposition of animals at the end of the experiment (euthanasia, use of animals in another experiment, or adoption [approved only in limited circumstances]). Include all research categories checked on page 1 of the ARF.

E. Qualification, experience, or training.
Name, title, and qualification, experience and/or training of <u>each</u> person (including PI) as it pertains to the current project, the specific species and the procedures to be used. The PI must be a current SMCM faculty member.

F. References.
A list of sources cited in the protocol.