INSTRUCTIONS to fill out the IACUC Animal Use Protocol Form

SECTION I. INVESTIGATOR AND PROTOCOL:	
Section I.A.	Provide Principal Investigator (PI) information and emergency contact info.
Section I.B.	Indicate project title and funding source. If funding did not come from a grant, then indicate "Departmental Funds" (e.g. Startup Funds)
Section I.C.	List any Protocol Operating Procedures (POPs), Animal Care and Use Standard Operating Procedures (SOPs), or IBC applications included as part of the proposed study application. Deviations from the procedure(s) described in an existing POP or SOP should be described under NOTES section below the table. Please contact the IACUC Coordinator and POP owner if you want to propose changes to any POP or SOP itself. Copies of the POP and SOP may be obtained through IACUC Coordinator.
Section I.D.	Use the check box to indicate the type of application.
Section I.E.	Using no more than 300 words, briefly describe the manner in which animals will be used. It is important that this section be written such that a lay person will understand purpose of the experiments you propose. The following questions may be used to help guide the completion of this section. Please consider answering these questions in the following order: "The goals of the research are to…" "We plan to use (species) by (describe procedure(s)." "This will further our knowledge of (insert area of study)" OR "This will benefit humans by…"
Section I.F.	List any non-NYU Shanghai collaborators participating on this project.
Section I.G.	The Principal Investigator (PI) must assure that ALL individuals working with animals will be appropriately trained or otherwise qualified. It is the responsibility of the PI to train or arrange for training for all personnel working with animals on this study. Describe the animal research education, technical and animal experience directly related to the species being employed that qualifies each person to perform the listed responsibilities
SECTION II. ANIMAL USE: EACH SPECIES REQUIRES A SEPARATE APPLICATION	
Section II.A	Indicate animal species/strains/sex/age range to be used on study
Section II.B	Specify whether genetically manipulated or mutant animals will be used and whether special husbandry care needs other than what was

	described in SOP NYUSH-HUS-4 (Animal Husbandry Procedures) will be required.
Section II.C	Provide brief justification of why this animal model is used.
Section II.D	Indicate the number of animals being requested over the 3 year period, with breakdown of estimation of annual animal requirement.
Section II.E	Provide scientific reasoning used to determine the number of animals requested. In the event you are proposing a parametric or non-parametric statistical analysis of your data, a power analysis is required. Report the assumptions of the analysis (change or mean difference, variability, and alpha and beta levels). Use best estimates for variability. If your study is so unique that there is no basis for estimating variability, propose a small pilot study to obtain the necessary estimates and then request the required number of additional animals to complete the full study. If your study is complex or consists of multiple groups, accompany the rationale with a table showing the groups and the number of animals in each. Pending support with relevant citations for the type(s) of study, it is acceptable practice for PI to justify sample size by listing high profile papers in high tier journals using the proposed study size to achieve highly comparable goals. If a statistical analysis is not to be performed, then provide a narrative describing how the sample size was determined. For example, if your study requires the collection of tissue or measurements of cells, describe the number of cells or weight of tissue necessary and the approximate yield per animal. Please be thorough in responding to this question. Stating that "the number of animals was selected to achieve statistical significant" is an inappropriate and unacceptable response, as are references to **undocumented** "standards" or "requirements." The smallest number of animals required by the study must be used.
Section II.F	Indicate whether animals will be used in classroom demonstrations.
Section II.G.	Indicate whether animals will be transported out of the vivarium, and if so, by what method and route, as well as how animal safety will be accomplished.
Section II.H	Indicate whether animals will be transported off campus on public roads or out of Shanghai.
Section II.G.	Indicate source of the animals needed. Contact the Attending Veterinarian for information regarding approved animal vendors of NYU

	Shanghai, and animals will be ordered through Research Institute designated individuals.
SECTION III. ALLEVIATION OF PAIN AND DISTRESS	
Section III.A	Check the appropriate box indicating USDA pain category for the proposed animal study. **USDA Category B** is for production breeding or holding colony protocols only and do not apply to animals at NYU Shanghai; therefore not an option. **USDA Category C** is for studies that will not involve more than minimal or momentary pain or distress to animals, and therefore, no anesthetic, analgesic, or tranquilizer is needed. Examples of procedures that generally do not require anesthesia include administration of fluid and electrolyte therapy, immunization, oral medications, blood collection (except intracardiac and periorbital), gastric gavage, and euthanasia for tissue collection. **USDA Category D** is for studies that involves pain or discomfort but anesthetic, analgesic, or tranquilizing drugs are to be used to prevent pain or discomfort. Examples of procedures involving pain which require anesthesia include: acute electrophysiologic procedures, surgery (including biopsy), or intracardiac and periorbital blood collections. USDA Category E is for studies that include procedures in which more than slight or momentary pain is NOT treated with anesthetics and/or analgesics. Examples include but are not limited to the following: • Stimuli, including shock reinforcement, which produce unavoidable or inescapable persistent discomfort or pain • Any agent which induces excessive inflammation or necrosis without analgesia Tumor growth causing skin ulceration and/or impaired ability to eat, drink and ambulate normally. **If USDA Pain Category E box** is selected, provide scientific justification why the use of anesthetics, analgesics, or tranquilizers cannot be used, and what non-pharmaceutical methods to minimize pain and distress will be used. DO YOU WANT TO SAY A BIT MORE ABOUT CAT E STUDIES BEING KEPT TO A MINIMUM OR HAVING A HIGH BAR?
Section III.B.	The Animal Welfare Act requires a literature search for alternative procedures to EACH procedure causing more than momentary pain and/or distress. Alleviation of pain during surgical procedures by administration of anesthetics and analgesics does not eliminate the need to address alternatives to the procedure. The use of the term “alternatives” should not be used in the search strategy. For help with

	your literature search or additional databases contact the Animal Welfare Information Center at awic@nal.usda.gov or http://www.nal.usda.gov/awic/databases/database.htm. A literature search should be done for each painful procedure.
Section III.C	All survival and non-survival surgeries must be performed following NYU Shanghai SOPs and guidelines. See NYUSH-VET-4 and NYUSH-VET-5 for requirements. Provide description of surgical procedures and location where surgeries will be performed.
Section III.D.	Describe the use of anesthetic drugs **if** you or personnel from your lab will be responsible for pre-surgical and intra-operative care. Common pharmaceutical products and dosages can be found in ACUP SOP NYUSH-VET-6.
Section III.E	Indicate method(s) used to monitor the depth of anesthesia during surgery.
Section III.F.	Indicate if paralytic drugs will be used. The use of paralytic drugs is generally discouraged. However, if there is a scientific need to use such product(s), provide information on concurrent general anesthetic and methods by which the PI will verify absence of pain.
Section III.G	Describe post-surgical care in more detail.
Section III.H.	Description of post-operative care, including analgesia use.
Section III.I.	Indicate the location where **intra-operative veterinary medical records** will be kept in case of request for review from regulatory agencies, IACUC, or Attending Veterinarian.
SECTION IV. ANIMAL HOUSING AND NUTRITION	
Section IV.A.	All animals must be housed within IACUC approved animal facilities, except under special circumstances. Primates and other USDA covered species must be returned to the animal facility no longer than 12 hours after leaving the animal facility for use in laboratories or other specialized areas, unless an alternative is specifically authorized. Rodents (mice and rats) not covered by the USDA must be returned no longer than 24 hours after leaving the animal room areas unless an alternative is specifically authorized. All animals must be provided with adequate food and water, environmental enrichment, and when appropriate to the species, social housing with compatible animals. Exceptions to specific aspects of the program involving housing, feeding, provision of water, and

	environmental enrichment and social housing, **must** be listed and justified based on experimental requirements. Indicate where animals will be housed.
Section IV.B.	Indicate whether animals will be housed outside the vivarium for more than 12 hours. If so, provide scientific justification.
Section IV.C.	Indicate any special housing or caging required and provide details to ensure research objectives can be met. As example, IVC/EVC for immunocompromised or virus/antibody free rodents; animals receiving hazardous chemicals or infectious agents; animals of unknown health status. Indicate if the animal's environmental conditions will require modification which deviates from the Guide recommended practice. Please discuss any special requirement with Laboratory Animal Resources staff.
Section IV.D.	Specify if there are any special feeding or watering requirements for animals on study. Indicate if any compounds will be added to feed or water, and whether special handling procedures are required. Indicate if any side effects are expected.
Section IV.E.	Indicate whether controlled food and/or water access will be used as part of experimental manipulation, and how animal body weight and/or hydration status will be monitored.
Section IV.F.	Indicate whether there will be exceptions to the enrichment program (e.g. provision of social interaction with conspecifics, offering of toys, food treats).
Section IV.G.	Indicate whether single housing of social species is required as part of experimental manipulation. This does not include the need to single house for health reasons (e.g. veterinary prescribed).
SECTION V. HAZARDOUS MATERIALS USED IN ANIMALS & RISK ASSESSMENT:	
Section V.A.	Indicate if any hazardous materials will be used during all phases of the animal experiment. Hazardous materials include: radioisotopes (note: special facility and license requirement needed); potentially infectious materials (microorganisms, recombinant DNA/viral vectors, any primate or human cell lines including tumor cells), and hazardous chemicals and toxins (chemicals used during post-sacrifice procedures, antineoplastic compounds, halogenated anesthetics, fixatives/preservatives, etc.). Please contact NYU Shanghai Environmental Health and Safety Officer (Joshua.qiao@nyu.edu) to ensure proper risk assessment had been conducted and all necessary precautions and training have taken place.

	Additional restrictions and guidelines following ECNU policy and Shanghai regulations may apply. To answer question in the IACUC protocol, please provide information on storage conditions, containment procedures, and list any specific safety precaution requirements when handling animals and animal waste.
Section V.B.	By checking the box and signing, PI confirms disclosure of all potentially hazardous materials and chemicals for use on animals and in lab to NYU Shanghai EHS and provide assurance to IACUC that proper risk assessment had been conducted to ensure personnel safety.
SECTION VI. EXPERIMENTAL PROCEDURES	
Section VI.A.	Indicate whether experimental procedure section had been reviewed by a veterinary reviewer. Protocol review by a Veterinarian is required by the Animal Welfare Act. This includes previously published procedures, as all institutions must assure compliance with current veterinary practice. Review by the veterinarian prior to IACUC review will facilitate the approval process.
Section VI.B.	Indicate whether physical or chemical forms of restraint will be used.
Section VI.C.	Investigators or their designee(s) are expected to monitor experimental animals at least once daily (including weekends and holidays). Describe monitoring procedures and schedule for monitoring experimental animals.
Section VI.D.	Indicate the desired plan of action in case of animal illness (e.g., initiate treatment, call investigator prior to initiating treatment, euthanize, etc.).
Section VI.E.	Indicate if any drugs (pharmaceutical or experimental), reagents, or other materials (including cells) be administered to animals.
Section VI.F.	The USDA requires that pharmaceutical-grade medications be used when available. Are any drugs being proposed for use in this application non-pharmaceutical-grade medication (e.g. drugs available either over-the-counter or by prescription for clinical use in humans or animals)? Refer to NYUSH-POL-5 on guidelines related to the use of non-pharmaceutical grade products in animal research.
Section VI.G.	Indicate whether any biospecimen (e.g. blood, urine, bile, cerebrospinal or ascites fluids) will be collected while the animal is alive.
SECTION VII. EXPERIMENTAL ENDPOINT CRITERIA and EUTHANASIA: This section provide the details surrounding endpoints for each animal involved in this study. These endpoints involve both the proposed endpoint and unexpected adverse events. Also included should be the final disposition of the animal(s) (whether a terminal	

procedure under anesthesia, euthanasia, a return to their normal housing, or other). It is an ethical imperative to relieve pain and suffering in animals in a timely fashion whether these events occur. This section should include the methods used to meet that imperative.	
Section VII.A.	Indicate the study time points or clinical signs expected which to serve as study endpoints.
Section VII.B.	Indicate the humane endpoints used to determine when euthanasia is to be performed, before scheduled or expected study endpoint is to take place. When a study involves the administration of tumor cells, biologics, infectious agents, radiation or toxic chemicals which are expected to cause significant symptomatology or are potentially lethal, you must list the criteria to be used to determine when euthanasia is to be performed (e.g. tumor size, percentage body weight gain or loss, inability to eat or drink, behavioral abnormalities, clinical signs, or signs of toxicity). Please consult IACUC Policy NYUSH-POL-4 on Humane Endpoints for common indicators of clinical signs used as humane study endpoints.
Section VII.C.	Indicate how verification of death after euthanasia is performed.
Section VII.D.	Indicate method of euthanasia to be used. Proposed methods should be an approved method described in the 2013 Edition of AVMA's Guidelines for the Euthanasia of Animals. Physical methods of euthanasia such as cervical dislocation or decapitation is not to be used unless justified by scientific necessity, and technical proficiency must be demonstrated prior to use of the technique. In lieu of demonstrated technical competency, animals must be anesthetized. For decapitation, equipment must be serviced regularly, blades must be sharp ad personnel properly trained. List the anesthetic agents to be used during euthanasia. Physical form of euthanasia without anesthesia, please provide scientific justification.

SECTION VIII. EXPERIMENTAL DESIGN AND ANIMAL PROCEDURES:

Provide a chronologic flow chart in the form of a pictorial diagram which details the experimental course *each* animal will follow from its entry into the study to its experimental endpoint. A brief narrative of the experimental flow should accompany the diagram. Identically treated animals should be designated as quantified groups. All groups, number of animals per group and all procedures should be included and chronologically clear to follow while demonstrating the complete experimental design. The diagram should include the POPs and SOPs from section I.C with their titles, when appropriate. Do not include detailed descriptions of in-vitro activities after animal euthanasia. Use additional sheets if necessary.

SECTION IX. INVESTIGATOR'S ASSURANCE STATEMENT:

PI will assure the IACUC that all animal work being conducted at NYU Shanghai will be in compliance with applicable US and Chinese regulations and guidelines, and institutional policies.

NYU 上海 SHANGHAI 纽约大学

INSTRUCTIONS to fill out the IACUC AMENDMENT Form

Section I.	Provide Principal Investigator (PI) and approved protocol information.
Section II.	Indicate whether the requested change to an approved protocol is a significant or minor change, and check all applicable change type(s)
Section III.	Provide protocol amendment details
Section III.A.	Please provide a brief summary of the goals of the original approved protocol and how the proposed modification is related to those goals. If this amendment is solely for the purpose of changing staff or their responsibilities, please indicate that below and include their title, animal-related responsibilities, who they will be trained by, if applicable, and when that training will be completed. (If any of the above are non-applicable, please indicate with 'N/A')
Section III.B.	Please provide the materials and methods of this modification to the original approved protocol to include additional experimental and control groups,
Section III.C.	Please indicate the sections of the protocol form that would have been amended, the corresponding page numbers and the newly inserted text:
Section IV.	Investigator's Assurance Statement