

New York University School of Medicine  
Institutional Animal Care and Use Committee (IACUC)  
Laboratory Animal Protocol Form - IACUC FORM (Rev. 8/98)

**VERSION FOR USERS OF WORD PROCESSORS OTHER THAN MICROSOFT WORD**

**INSTRUCTIONS FOR USE:**

1. THIS FILE IS IN RICH TEXT FORMAT. IT MAY BE OPENED USING ANY WORD-PROCESSOR WITH A FILTER FOR THIS FORMAT.
2. WHEN THE DOCUMENT IS OPENED, USE THE SAVE AS FUNCTION, AND NAME THE DOCUMENT. YOU MAY THEN BEGIN RESPONDING TO THE QUESTIONS.
3. PLEASE INSURE THAT ALL ANSWERS ARE IN **BOLD FACE** or **ITALICS** SO THAT THEY ARE EASILY DISTINGUISHABLE FROM THE QUESTIONS.
4. WHEN PRESENTED WITH A LIST OF CHOICES, EITHER TYPE A BOLD FACE "X" NEXT TO THE APPLICABLE CHOICE, OR DELETE ALL NON-APPLICABLE CHOICES FROM THE LIST, AND RENDER THE CORRECT CHOICE IN BOLD FACE.
5. RESPOND TO ALL QUESTIONS PRECEDED BY AN ASTERISK. ANY QUESTION NOT PRECEDED BY AN ASTERISK MAY BE ANSWERED "N/A" IF IT IS NOT APPLICABLE TO THE RESEARCH.
6. RESPOND TO THE QUESTIONS IN SECTIONS I AND II.
7. COMPLETE THE REMAINDER OF THE FORM FOR ONE SPECIES. THE RESPONSE TO EACH QUESTION SHOULD ADDRESS THE SAME SINGLE SPECIES.
8. IF MULTIPLE SPECIES ARE INVOLVED, SKIP SECTIONS I AND II, AND COMPLETE THE REMAINDER OF THE FORM FOR THE NEXT SPECIES TO BE USED. REPEAT STEPS 5. AND 6. FOR EACH SPECIES INVOLVED.
9. YOU MUST RETAIN A COPY OF THE COMPLETED ANIMAL FORMS IN YOUR FILES. YOU MAY BE ASKED TO PRODUCE THIS FORM DURING INSPECTION OF YOUR RESEARCH AREA.
10. **WHEN SUBMITTING THE FORM FOR REVIEW, PLEASE INCLUDE ONE COPY AND THE ORIGINAL.**

**PROTOCOLS AND GRANT APPLICATIONS - WHAT IS THE RELATIONSHIP?**

An investigator may submit multiple grant applications that apply to the same use of animals. In such cases it is acceptable for the investigator to list ALL of the granting agencies that apply on this form. If an investigator has already submitted this form, and indicated sponsorship by "NIH", the form may be made applicable to "ACS" by adding that sponsor to Part I and resubmitting that single page of the form to the IACUC Office with a cover memorandum indicating that the submission is for the addition of a new sponsoring agency.

**RENEWAL PROJECTS: This form should be used to submit protocol renewals if the protocol has undergone modification or if the protocol has been renewed twice using the short renewal form. All other protocols may be renewed using the IACUC "Renewal Reminder and Submission Form." This Form will be sent to you approximately 45 days before the end of the current approval period.**

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Part I - GENERAL INFORMATION

**PRINCIPAL INVESTIGATOR'S ASSURANCE**

I agree to abide by the NYUMC policy on the care and use of laboratory animals. I understand that experiments involving animals are not to be conducted unless approved by the Institutional Animal Care and Use Committee (IACUC). I will not work with a species or procedure, including euthanasia, with which I and those members of my research staff involved in this project are not experienced, without first seeking the advice and instruction of a veterinarian from the Division of Laboratory Animal Resources, and will further consult the Division of Laboratory Animal Resources as circumstances require. To the best of my knowledge, the proposed research does not unnecessarily duplicate previous research with respect to

IACUC PROTOCOL FORM

the use of laboratory animals. I will comply with all requests for data as may be required by governmental and institutional guidelines. I will permit emergency veterinary care to animals showing evidence of pain or illness. I will advise and seek the approval of the Institutional Animal Care and Use Committee on all changes in the project, which involve laboratory animals. I will abide by NYUMC policy on occupational health. The information provided on this form reasonably summarizes the nature and extent of the proposed involvement of laboratory animals. I HAVE RECEIVED A COPY OF THE NYUMC HANDBOOK FOR INVESTIGATOR'S WORKING WITH LABORATORY ANIMALS, AND HAVE USED THE GUIDE AS A RESOURCE IN THE DESIGN OF THIS PROJECT. I understand that failure to consult with the Guide may result in this protocol form being completed incorrectly, and a subsequent delay of approval.

Signature of Principal Investigator (with date)----->:

Type Name of Principal Investigator (with date)--->:

Signature of Department Head (with date) ----->:

Type Name of Department Head (with date)----->:

Are you applying for, or receiving funds for the proposed experiments, from external sources that require peer review?

YES  NO

If YES, identify the funding agency(ies) by name and I.D. # in the space(s) provided below (e.g., NHLBI, HL12345)

1. \*Title(s) of Project(s):

2. \*Name of Principal Investigator and Faculty Position:

3. \*Principal Investigator's Full Interoffice Mail Address, including Department:

4. \*Principal Investigator's Telephone Extension and FAX number:

5. Principal Investigator's E-Mail address:

6. \*Describe the research goals of the project in **LAY TERMS understandable to a non-scientist or the lay members of the IACUC**. Describe the scientific aims of the project, address the relevance of the work with animals to the human condition if appropriate, and the need to use animals in the research.

IACUC PROTOCOL FORM

7. \*Does this project involve animal work that will be conducted at a collaborating institution?

YES  NO

8. \*If YES to question 7, a copy of the protocol submitted to the Animal Care and Use Committee at the collaborating institution, and a copy of the approval granted for that protocol, must be attached. CHECK YES if this information is attached. CHECK NO and provide an explanation in the space provided if this information will be submitted when it is received from the collaborating institution. Note that the protocol may not be approved in the absence of this information.

YES  NO

Explanation:

9. \*List the Personnel involved in the project, including name and degree, faculty position, department, and the % of their total effort which will be dedicated to this project (such as: John Smith, Ph.D., Assistant Professor, Department of Medicine, 25%). Provide this information for all individuals working on the project.

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PART II - Information for Renewal Protocols. Only those renewal protocols that have undergone significant modification from the prior submission or those that have been renewed twice using the short form should be submitted using this form. For such protocols, the entire form must be completed, and all questions in this section must be answered. All other protocols may be renewed using the DLAR "Renewal Reminder and Submission Form" that will be sent to you approximately 90 days before the project end date. Skip to section III if this is a new project.

1. Provide the animal use protocol # assigned to this protocol:

2. Provide the most recent date of IACUC approval:

3. Describe the changes in the design or conduct of the animal experiments.

4. Has there been unanticipated morbidity, mortality, or other complications occurred during the conduct of the study over the prior 12 month period?

YES  NO

5. If YES to question 4., describe the circumstances and the species and number of animals involved.

6. If this protocol is a renewal, please provide information on the PROGRESS made-to-date towards fulfilling the specific aims of the protocol as described in the original submission to IACUC. The progress report should also reflect the procedures performed and outcome with the animals requested over the course of the study.

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IACUC PROTOCOL FORM

**PLEASE COMPLETE PARTS III-VII SEPARATELY FOR EACH SPECIES INVOLVED.**

Part III - HOUSING, HUSBANDRY, AND RATIONALE FOR USE - THIS SECTION MUST BE COMPLETED ONCE FOR EACH SPECIES OF ANIMALS INVOLVED. EACH ANSWER SHOULD APPLY TO ONLY ONE SPECIES.

1. \*Indicate species and strain(s) described in following sections:

2. If this project is limited to antibody production by an outside vendor, provide the name of the vendor in the space below and **STOP HERE**.

3. \*Choose one to indicate the facility where the animals will be housed.

- BCAF (the Berg Central Animal Facility)
- SCAF (the Skirball Central Animal Facility)
- SMCAF (the Smilow Central Animal Facility)
- DCAF (the Dental School Animal Facility)
- PCAF (the Medical and Molecular Parasitology Central Animal Facility)
- DEMSAF (the Department of Environmental Medicine Animal Facility)

Other (If the use of animals will NOT be performed at NYU Medical Center, but will be conducted at a collaborating institution, indicate the institution, and provide a copy of the IACUC approved protocol from that institution covering those animals, as well as a copy of the approval notification, and **STOP HERE**).

4. \*Choose one to indicate the source of the animals to be used.

- Commercial vendor
- In-house Breeding
- Transfer from Another Institution (Required Description including name of institution):

4.A. If animals will be bred in house, provide a justification. Appropriate justification would be the need to perpetuate a genetically manipulated rodent strain or the maintenance of strains not available commercially. Please describe breeding scheme to be used, method of genotyping and age at which mice are genotyped in Part IV Question 2.

5. \*Choose one to indicate whether or not Transgenic/Knockout mice will be used.

YES  NO

IACUC PROTOCOL FORM

5A. If YES to question 5, indicate whether or not the animals will be produced by the Skirball Transgenic ES Cell Chimera Facility (STgESCF).

YES  NO

*Please note that if transgenic mice will be produced by the STgESCF, the number of animals needed for production, as well as a description of transgenic mouse production procedures should NOT be included in this protocol. The STgESCF maintains an umbrella protocol for this activity.*

6. \*Choose one to indicate whether or not animals will be housed outside of an approved NYU Medical Center animal facility for a period in excess of 12 hours.

YES  NO

6.A. If YES to question 6, provide the location where the housing will take place.

7. \*Will live animals be taken from the facility to the investigator's laboratory?

YES  NO

7.A. If YES to question 7, provide the building and room number of the laboratory.

8. \*Will the animals require a special diet?

YES  NO

8A. If YES to question 8, describe the special diet.

9. \*Non-Duplicative Research Assurance. Choose the choice below that best applies.

- The proposed research has not been conducted before
- Previously performed experiments similar to those in this protocol were inconclusive
- Although similar to previous experiments, these experiments extend our knowledge
- None of the above (requires specific justification below).

10. \*Do any of the proposed procedures involving animals require that the animals endure more than minimal or slight pain or distress? Respond YES or NO. **Note that relief of pain by anesthesia does not mean that pain is not involved, and if the use of an anesthetic will be employed, the correct response is YES.** The correct response is YES for projects involving surgery, and/or restraint. For sacrifice for tissue harvest, and routine injections, the correct response is NO.

YES  NO

IACUC PROTOCOL FORM

10A. If YES to question 10, indicate at least two sources searched to determine that there are no alternatives to each of the specific proposed procedures that may cause more than minimal pain or distress.

- MEDLINE
- ANIMAL WELFARE INFORMATION CENTER
- BIOLOGICAL ABSTRACTS
- OTHER. Requires a narrative description in the space below.

11. Provide the KEYWORDS used to perform the literature search described in question 10.A. above. Please include keywords animal alternatives and models in your literature search.

12. Provide the date the literature search described in question 10.A. above was performed.

13. Provide the period covered (dates/years) by the literature search described in question 10.A. above.

14. \*Provide a rationale for the need to use animals in this research. Address why in vitro, or computer models may not be used instead of live animals.

15. \*Provide a rationale for how this species of animals was selected as the appropriate model for this research. Address why a "lower" species may not be used.

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Part IV - BASIC PROCEDURES - THIS SECTION OF THE FORM MUST BE COMPLETED ONCE FOR EACH SPECIES TO BE USED. THE RESPONSE TO EACH QUESTION SHOULD APPLY TO ONLY ONE SPECIES.

1. \*Indicate the total number of animals to be used over the course of the study or the three year approval period, whichever is shorter. Provide a detailed justification for the number of animals requested by relating the number of those animals to specific experiments. Describe the experimental and control groups, if appropriate. Use a Power Analysis to justify animal numbers requested.

2. \*Describe in detail the procedures involving laboratory animals. THE RESPONSE TO THIS QUESTION SHOULD PROVIDE A CLEAR PICTURE OF THE PROCEDURES TO BE PERFORMED. DO NOT provide details of antibody production, physical restraint, food or water deprivation, or surgery, in response to this question.

IACUC PROTOCOL FORM

3. IN-HOUSE POLYCLONAL ANTIBODY PRODUCTION – Complete this section ONLY if animals will be housed in NYUMC animal facilities. Select the choice that corresponds to the adjuvant used for the initial immunization

- Complete Freund's Adjuvant
- Incomplete Freund's Adjuvant
- RIBI
- OTHER (must be specified)

3.A. Indicate the total volume of the antigen/adjuvant mixture that will be used for immunization. The recommended adjuvant mixture for Complete Freund's Adjuvant is 1 CFA: 1 antigen.

3.B. Provide the volume administered per site, the number of sites, and the route of administration. For rabbits, 0.1 ml per site subcutaneously (SC), or 0.05 ml intradermally (ID) is recommended so as to minimize pain and distress to the animal. Injections to the neck and rump area should be avoided, and footpad injection is expressly forbidden. IF CFA IS USED, PLEASE COMPLETE QUESTION 6, INDICATING THE ANALGESIC TO BE ADMINISTERED IF THE USE OF CFA RESULTS IN PAINFUL INFLAMMATION.

3.C. Describe the immunization schedule and the adjuvant used for the BOOSTER injections. Complete Freund's Adjuvant may not be used for booster injections.

3.D. Provide the volume of blood withdrawn. Volume should not exceed 7.5 ml/kg body weight.

3.E. Provide the interval between bleeds. Interval should be no less than every two weeks.

4. IN-HOUSE MONOCLONAL ANTIBODY PRODUCTION - Indicate whether or not hybridomas will be produced.

YES  NO

4.A. Select the choice that corresponds to the adjuvant used for the initial immunization

- Complete Freund's Adjuvant
- Incomplete Freund's Adjuvant
- RIBI
- OTHER (must be specified)

IACUC PROTOCOL FORM

4.B. Indicate the total volume of the antigen/adjuvant mixture and the route of injection.

4.C. Describe the immunization schedule and the adjuvant used for the BOOSTER injections. Complete Freund's Adjuvant may not be used for booster injections

4.D. Indicate whether or not hybridoma cells will be injected into the animals for ascites production. APPLICANT SHOULD REVIEW AND UNDERSTAND THE NYUMC "RECOMMENDATIONS FOR MONOCLONAL ANTIBODY PRODUCTION" BEFORE ANSWERING QUESTIONS 4D – 4G.

YES  NO

4.E. Provide a compelling justification for producing monoclonal antibodies by the ascites method rather than one of the various in vitro methods.

4.F. If YES to 4.D., indicate the method used to prime the animal. In priming prior to injection of hybridomas, 0.1 ml has been shown to be an adequate dose of pristane. In no case should more than 0.2 ml of pristane be injected.

4.G. If YES to question 4.D., state how often the animals will be observed, and provide the name(s) of individual(s) who will observe the animals and perform the single post mortem tap to harvest the ascites fluid. Daily observation for abdominal distension and poor general condition (rough hair coat, dyspnea, and lack of mobility) should be performed.

5. Indicate whether or not this protocol requires ANESTHETICS for procedures OTHER THAN ascitic fluid collection, euthanasia, or survival surgery. IF THE ONLY USE OF ANESTHETICS IS IN CONNECTION WITH SURGERY, CHOOSE "NO."

YES  NO

5.A. If YES to question 5., provide the drug name, dose and route of administration, i.e. "pentobarbital 40 mg/kg body weight i.v." IF THE ONLY USE OF ANESTHETICS IS IN CONNECTION WITH SURGERY, LEAVE BLANK.

6. Indicate whether or not ANALGESICS will be used. IF THE ONLY USE OF ANALGESICS IS IN CONNECTION WITH SURVIVAL SURGERY, LEAVE BLANK.

YES  NO

6.A. If YES to question 6., provide the indications for use, drug name, dose, route, frequency of administration.

7. Indicate whether or not ANTIBIOTICS will be used. IF THE ONLY USE OF ANTIBIOTICS IS IN CONNECTION WITH SURVIVAL SURGERY, LEAVE BLANK.

IACUC PROTOCOL FORM

YES  NO

7.A. If YES to question 7., provide the drug name, dose, route and frequency of administration.

8. Indicate whether or not PARALYTICS will be used.

YES  NO

8.A. If YES to question 8., provide the drug name of the paralytic, the dose, route and frequency of administration.

8.B. If YES to question 8., indicate whether or not the animals will be anesthetized in conjunction with administration of the paralytic and be sure that the anesthetics use is described in response to questions 5., and 5.A.

YES  NO

8.C. If there is a scientific need for the use of a paralytic WITHOUT ANESTHESIA, provide a compelling JUSTIFICATION.

9. Check the appropriate box to indicate whether or not tumors, cells, or any other biological materials will be implanted or injected into the animals.

YES  NO

9.A. If YES to question 9. identify the source of the tumors, cells or other biological material.

9.B. If YES to question 9. describe the serologic screening, such as MAP testing, done to determine that the material is free of adventitial viruses.

10. \*Indicate whether or not IRRADIATION will be used.

YES  NO

10.A. If YES to question 10., indicate the building and room number of the facility.

10.B. If YES to question 10., indicate dose and frequency of radiation delivered.

10.C. If YES to question 10., indicate whether or not animals will subsequently be maintained on antibiotics and be sure that the drug name, dose, route and frequency of administration is provided.

IACUC PROTOCOL FORM

11. \*Identify the individual(s) responsible for monitoring animals on study, and indicate how often the animals are observed.

12. EUTHANASIA -

Indicate the method of euthanasia to be employed.

- Overdose of pentobarbital 120 mg/kg body weight i.p. for rodents
- Overdose of pentobarbital 120 mg/kg body weight i.v. for rabbits and larger animals
- CO2 narcosis
- Perfusion of anesthetized animal (see 12.A.)
- Exsanguination of anesthetized animal (see 12.A.)
- Cervical dislocation of anesthetized animal (see 12.A.)
- Decapitation of an anesthetized animal (see 12.A.)
- Cervical dislocation without prior anesthesia (see 12.B.)
- Decapitation without prior anesthesia (see 12.B.)
- Decapitation of neonatal mice or rats
- Other - Provide a detailed description of the method used to achieve euthanasia:

12.A. SKIP THIS QUESTION UNLESS REFERRED HERE BY QUESTION 12. State the anesthetic to be used, including drug name, dose, and route of administration, prior to perfusion, exsanguination or cervical dislocation.

12.B. SKIP THIS QUESTION UNLESS REFERRED HERE BY QUESTION 12. Provide a justification for withholding anesthesia if the animals will be euthanatized by cervical dislocation or decapitation.

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Part V - RESTRAINT AND DEPRIVATION

1. Indicate whether or not animals will be restrained BEYOND the brief restraint that may be required for procedures such as blood drawing. If NO, skip the remainder of this section.

YES  NO

2. If YES to question 1., state how long the animal will be restrained (i.e. 4 hours per session), and how often the animal will be restrained (i.e. one session every other day for the three week study duration).

IACUC PROTOCOL FORM

3. If YES to question 1., provide a detailed description of the restraint device. Provide a diagram or picture as an attachment, if possible.

4. If YES to question 1., describe the period of conditioning to the restraint device prior to commencing the study.

5. If YES to question 1., indicate whether or not the animal will be monitored for the development of lesions, contusions, decubital ulcers, dependent edema, and/or weight loss.

YES  NO

6. Identify the individual(s) responsible for the monitoring described in response to question 5.

7. Indicate whether or not animals will experience food or water (or other) deprivation/restriction.

YES  NO

7.A. If YES to question 7., indicate the purpose of the deprivation, and justify the need to employ deprivation/restriction.

7.B. If YES to question 7., state the duration of the deprivation, i.e. 16 hours.

7.C. If YES to question 7., state the frequency of the deprivation, i.e. three days a week for 4 weeks.

7.D. If YES to question 7., describe the stable deprived state (such as 80% of free feeding weight) of the animal, the regimen used to initially achieve that state, and the monitoring methods employed to assure that the desired state is not exceeded (such as measuring animals' weight daily).

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Part VI - SURGERY -

1. Provide the building and room number where surgery will be performed.

IACUC PROTOCOL FORM

2. Preoperative Period: Describe the procedure for fasting (if appropriate), and drug names, dosages and routes of administration of any drugs administered pre-operatively.

3. Provide a detailed description of the proposed surgical procedure.

4. Describe the monitoring and supportive care provided during surgery.

5. Provide the names and qualifications, AS THEY PERTAIN TO THE PROCEDURE DESCRIBED ABOVE, of the members of the surgical team.

6. Describe the ANESTHETICS to be used, indicating the drug name, dose and route of administration.

6.A. Indicate how anesthetic depth will be monitored by selecting as many of the choices below that apply

- |   |   |  |
|---|---|--|
| <input type="checkbox"/> Respiratory Rate | <input type="checkbox"/> Heart Rate         | <input type="checkbox"/> Corneal reflexes    |
| <input type="checkbox"/> Pedal reflexes   | <input type="checkbox"/> Palpebral reflexes | <input type="checkbox"/> Ear twitch response |
| <input type="checkbox"/> Blood pressure   | <input type="checkbox"/> EEG                |  |

7. Indicate whether or not ANALGESICS will be used.

YES  NO

7.A. If YES to question 7., provide the indications for use, the drug name, dose, route and frequency of administration.

8. Indicate whether or not ANTIBIOTICS will be used.

YES  NO

8.A. If YES to question 8., provide the drug name, dose, route and frequency of administration.

9. Post-operative period (SURVIVAL SURGERY ONLY): Identify the individual(s) responsible for monitoring, and providing care for the animals post-operatively.

IACUC PROTOCOL FORM

10. Describe the post-operative supportive care provided.

11. Indicate whether or not animals will undergo MULTIPLE survival surgical procedures.

YES  NO

11.A. If YES to question 11., provide a justification for the need to perform multiple survival surgical procedures on the same animal, and indicate the time between procedures.

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Part VII - HAZARDOUS MATERIALS – In vivo use of infectious agents, toxic/carcinogenic materials, radioisotopes, and recombinant DNA.

1. Indicate whether or not hazardous materials will be used.

YES  NO

2. List the hazardous materials to be used in or on LIVE animals.

3. Identify the individual responsible for handling the materials.

4. Describe in detail how the hazardous materials are used in the protocol, and how they are administered.

5. Describe any special housing required to insure safety of animal facility personnel, such as ventilated cabinets or hoods.

6. Describe how the hazardous material will be metabolized by the treated animal, and whether hazardous metabolites will be eliminated by respiration, oral secretions or urinary or fecal excretion.

7. Describe the procedures for decontamination of lab surfaces, equipment, animal cages, etc. and special requirements for disposal of contaminated materials including animal bedding and carcasses.

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Part VIII - LITERATURE CITED (Optional)

1. Provide bibliographic citations of literature referenced in the protocol being submitted.