

University of Southern Maine Office of Research Integrity and Outreach

Animal Study Proposal - USM and UMF Faculty and Staff, And Biodiversity Research Institute

<<Today's Month>> <<Today's Day>>

Instructions:

De Novo Review: The Institutional Animal Care and Use Committee (IACUC) is required under federal law to perform a complete re-review of the entire protocol every three years.

Please use the De Novo Submission Form (5/2025)

https://docs.google.com/forms/d/e/1FAIpQLSe5t_gHcsNScUxH5HADiN4m1ZnIhO_D-TB80RVA1s-C431ECA/viewform?usp=dialoa

Please contact the Research Integrity Administrator at 207-780-4517 or usmorio@maine.edu with auestions.

Required trainings can be found at: http://usm.maine.edu/orio/iacuc-training

Since this is a long form, you may download the sample form in pdf as a guide to answering auestions:

http://usm.maine.edu/sites/default/files/orio/IACUC_Form_Submissions_template.pdf

This form has also been given edit privileges. You may save your work at certain intervals and receive an email with a return link, or you may copy the link in the address bar above. Be aware the ORIO office receives the same email. We will consider your final submission when the "I agree" is checked at the end.

Project Information

- 1. Project Title:
- 2. Funding Source: Agency, Grant #, Account # (if known):
- 3. Duration: include start and end date:

<u>Personnel Training and Experience Information</u>

(Note: Indicate role of involved personnel as either Principal (PI), or Secondary (SI) Investigators, or technicians/assistants (T). Indicate each individual's years of experience with animals described herein (e.g., 6 yrs/snakes, 4 yrs/sharks).

- 4. Principal Investigator (PI):
- 5. Pl Organization:
- 6. PI Department (USM Only):
- 7. Pl Address:

- 8. Pl Phone:
- 9. PI Email:
- 10. Pl Degree:
- 11. PI Years of experience/species:
- 12. PI Date of Mandatory IACUC CITI Training: CITI Wildlife Research, or Lab: Working with IACUC: Investigators, Staff and Students
- 13. PI Date and Type of additional project-specific training: email proof of completion to: usmorio@maine.edu
- 14. PI First Aid Training date and description (USM Only)

If personnel are outside of a 3-4 minute radius of a clinic, infirmary, or medical treatment facility, then first aid training is required for at least one person on the crew.

- 15. PI Date of UMS Academy Basic Safety Training (USM Only): email to: usmorio@maine.edu
- 16. PI Date of Occupational Health Survey Completion (USM Only): email to: usmorio@maine.edu

Continue1:

Add another person

Go to next section: Characteristics of Animals and Pain Category of Research Save and Quit

Personnel 1/Faculty Adviser, if applicable

- 17. Personnel Name:
- 18. Role in research:
- 19. Organization:
- 20. Department (USM Only):
- 21. Email:
- 22. Degree:
- 23. Years of experience/species:
- 24. Date of Mandatory IACUC CITI Training: CITI Wildlife Research, or Lab: Working with IACUC: Investigators, Staff and Students
- 25. Date and Type of additional project-specific training: email proof of completion to: usmorio@maine.edu
- 26. First Aid Training date and description (USM Only)
- 27. Date of UMS Academy Basic Safety Training (USM Only): email to: usmorio@maine.edu
- 28. Date of Occupational Health Survey Completion (USM Only): email to: usmorio@maine.edu

Continue2:

Add another person

Go to next section: Characteristics of Animals and Pain Category of Research Save and Quit

Personnel 2

- 29. Personnel Name:
- 30. Role in research:
- 31. Organization:
- 32. Department (**USM Only**):
- 33. Email:
- 34. Degree:

- 35. Years of experience/species:
- 36. Date of Mandatory IACUC CITI Training: CITI Wildlife Research, or Lab: Working with IACUC: Investigators, Staff and Students
- 37. Date and Type of additional project-specific training: email proof of completion to: <u>usmorio@maine.edu</u>
- 38. First Aid Training date and description (USM Only)
- 39. Date of UMS Academy Basic Safety Training (USM Only): email to: usmorio@maine.edu
- 40. Date of Occupational Health Survey Completion (USM Only): email to: usmorio@maine.edu

Continue3:

Add another person

Go to next section: Characteristics of Animals and Pain Category of Research Save and Quit

Personnel 3

- 41. Personnel Name:
- 42. Role in research:
- 43. Organization:
- 44. Department (USM Only):
- 45. Email:
- 46. Dearee:
- 47. Years of experience/species:
- 48. Date of Mandatory IACUC CITI Training: CITI Wildlife Research, or Lab: Working with IACUC: Investigators, Staff and Students
- 49. Date and Type of additional project-specific training: email proof of completion to: usmorio@maine.edu
- 50. First Aid Training date and description (USM Only)
- 51. Date of UMS Academy Basic Safety Training (USM Only): email to: usmorio@maine.edu
- 52. Date of Occupational Health Survey Completion (USM Only): email to: usmorio@maine.edu

Continue4:

Add another person

Go to next section: Characteristics of Animals and Pain Category of Research Save and Quit

Personnel 4

- 53. Personnel Name:
- 54. Role in research:
- 55. Organization:
- 56. Department (**USM Only**):
- 57. Email:
- 58. Degree:
- 59. Years of experience/species:
- 60. Date of Mandatory IACUC CITI Training: CITI Wildlife Research, or Lab: Working with IACUC: Investigators, Staff and Students
- 61. Date and Type of additional project-specific training: email proof of completion to: usmorio@maine.edu
- 62. First Aid Training date and description (USM Only)
- 63. Date of UMS Academy Basic Safety Training (USM Only): email to: usmorio@maine.edu

64. Date of Occupational Health Survey Completion (USM Only): email to: usmorio@maine.edu Continue5:

Add another person

Go to next section: Characteristics of Animals and Pain Category of Research Save and Quit

Personnel 5

- 65. Personnel Name:
- 66. Role in research:
- 67. Organization:
- 68. Department (**USM Only**):
- 69. Email:
- 70. Degree:
- 71. Years of experience/species:
- 72. Date of Mandatory IACUC CITI Training: CITI Wildlife Research, or Lab: Working with IACUC: Investigators, Staff and Students
- 73. Date and Type of additional project-specific training: email proof of completion to: usmorio@maine.edu
- 74. First Aid Training date and description (USM Only)
- 75. Date of UMS Academy Basic Safety Training (USM Only): email to: usmorio@maine.edu
- 76. Date of Occupational Health Survey Completion (USM Only): email to: usmorio@maine.edu

Continue6:

Add another person

Go to next section: Characteristics of Animals and Pain Category of Research Save and Quit

Personnel 6

- 77. Personnel Name:
- 78. Role in research:
- 79. Organization:
- 80. Department (**USM Only**):
- 81. Email:
- 82. Degree:
- 83. Years of experience/species:
- 84. Date of Mandatory IACUC CITI Training: CITI Wildlife Research, or Lab: Working with IACUC: Investigators, Staff and Students
- 85. Date and Type of additional project-specific training: email proof of completion to: <u>usmorio@maine.edu</u>
- 86. First Aid Training date and description (USM Only)
- 87. Date of UMS Academy Basic Safety Training (USM Only): email to: usmorio@maine.edu
- 88. Date of Occupational Health Survey Completion (USM Only): email to: usmorio@maine.edu

Characteristics of Animals and Pain Category of Research

List and describe the animals to be studied. Indicate the anticipated number of animals to be used in each Pain Category of Research and the total number of animals involved during the

3-year approval period of this protocol. Indicate whether Pain Category B: Breeding or Holding Colony Protocols. <u>Pain Category C</u>: No more than momentary or slight pain or distress and no use of pain-relieving drugs, or no pain or distress. For example: euthanized for tissues; just observed under normal conditions; positive reward projects; routine procedures; injections; and blood sampling. Pain Category D: Pain or distress appropriately relieved with anesthetics, analgesics, and/or tranquilizer drugs or other methods for relieving pain or distress. Pain Category E: Pain or distress or potential pain or distress that is not relieved with anesthetics, analgesics and/or tranquilizer drugs or other methods for relieving pain or distress.

Note: The IACUC recognizes that field studies often involve many species, some of which may be unanticipated or even unknown to science before the onset of the study. The IACUC recognizes that it is not always possible to predict at the initiation of field studies the number of animals to be encountered, the species to be encountered, or the effects of research procedures on each species. The IACUC recognizes that pain perception by many species of vertebrate animals may not be uniform over the various portions of their bodies, and that broad extrapolation of pain perception across taxonomic lines may not be appropriate.

Animal 1

89. Common Name:

90. Taxa or Species:

91. Age, Sex, Weight:

92. Pain Category B#:

93. Pain Category C#:

94. Pain Category D#:

95. Pain Category E#:

96. Total # anticipated:

Continue7:

Add Another Animal

Go to next section: Justification for the Use of Animals

Save and Quit

Animal 2

97. Common Name 2:

98. Taxa or Species 2:

99. Age, Sex, Weight 2:

100. Pain Category B # 2:

101. Pain Category C # 2:

102. Pain Category D # 2:

103. Pain Category E # 2:

104. Total # anticipated 2:

Continue8:

Add Another Animal

Go to next section: Justification for the Use of Animals

Save and Quit

Animal 3

- 105. Common Name 3:
- 106. Taxa or Species 3:
- 107. Age, Sex, Weight 3:
- 108. Pain Category C # 3:
- 109. Pain Category C # 3:
- 110. Pain Category D # 3:
- Pain Category E # 3: 111.
- 112. Total # anticipated 3:

Continue9:

Add Another Animal

Go to next section: Justification for the Use of Animals

Save and Quit

Animal 4

- 113. Common Name 4:
- 114. Taxa or Species 4:
- 115. Age, Sex, Weight 4:
- 116. Pain Category B # 4:
- 117. Pain Category C # 4:
- 118. Pain Category D # 4:
- 119. Pain Category E # 4:
- 120. Total # anticipated 4:

Continue 10:

Add Another Animal

Go to next section: Justification for the Use of Animals

Save and Quit

- 121. Common Name 5:
- 122. Taxa or Species 5:
- 123. Age, Sex, Weight 5:
- 124. Pain Category B # 5:
- 125. Pain Category C # 5:
- 126. Pain Category D # 5:
- 127. Pain Category E # 5:
- 128. Total # anticipated 5:

Justification for the Use of Animals

Briefly state in lay terms the purpose and scope of work:

- 129. Research hypothesis or teaching objectives:
- 130. Briefly describe why the requested animals are the subject of study, or are well suited to answer the research questions posed:

- 131. Procedures (general sequence of events) animals will be involved:
- 132. Please justify the number of animals to be used (from Characteristics of Animals and Pain Category of Research):
- 133. Briefly describe the rationale, prior experience, statistical analysis, or other methods used to understand the population status of the taxa or species to be studied, and used to determine the anticipated total number of animals that will be encountered or involved during the 3-year approval period of this protocol. The total number of animals requested above must be justified here. (Note: The IACUC recognizes that it is not always possible to accurately predict at the initiation of field studies the number of animals to be encountered. The minimum number of animals necessary for accomplishing the goals of the study should be used.):

Save and Quit? Yes/No

<u>Literary Search</u>

A search for alternatives and alternative methods, including a search of at least two relevant databases indicated below, covering the indicated years (at least the last 10 yrs.), and using the indicated search term(s), demonstrates that suitable alternatives to these procedures, and to aspects of these procedures which may cause pain or discomfort to animals, or to this animal use are not available or applicable. The methods described will be used and continuously refined so as to reduce animal discomfort and use.

Conduct will be in accordance with the Guideline of the American Society of Mammalogists for the Use of Wild Mammals in Research, the Guidelines for Use of Fishes in Research, the Guidelines for Use of Live Amphibians and Reptiles in Field and Laboratory Research, the Guidelines to the Use of Wild Birds in Research, Drug Enforcement Administration (DEA) regulations, Institutional Animal Care and Use Committee (IACUC) Principles & Procedures, Public Health Service (PHS) policy, Animal Welfare Association (AWA) Guide, and Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) guidelines.

The described animal use does not duplicate previous or existing studies. This description is complete and accurate. Implementing changes to this description requires prior written IACUC approval. Complete animal procedural/surgical/testing records will be maintained. Personnel are certified as adequately trained and experienced, and have complied with IACUC occupational health & safety policies.

- 134. Identify ≥ 2 Databases:
- 135. Years:
- 136. Search Terms:
- Date of Literature Search: 137.

Research Protocol

Describe below the anticipated location(s) where the study will be performed. If this protocol is to be conducted at another academic institution, or a zoological garden, aquarium, or oceanarium, please name that institution and attach a letter with official letterhead from that institution that indicates that they are anticipating the presence of this research protocol, and whether they have an assurance on file with the Policy on Humane Care and Use of Laboratory Animals (PHS). (Note: The IACUC recognizes that it is not always possible to predict at the initiation of field studies all potential observation or collection opportunities.)

- 138. Study Location:
- 139. Will this study only consist of the direct, unobtrusive observation of free-ranging animals under natural conditions, and not require that animals be contacted, captured or restrained at any time?

Yes, skip to permits No, go to Capture and Restraint Save and Quit

- 140. Are animals euthanized immediately at the moment of capture? Yes/No
- If yes, does the method of euthanasia immediately upon capture, and means of assuring death following euthanasia comply with all applicable regulations including but not limited to the Animal Welfare Act and the Guide?
- 142. If yes, describe the method of euthanasia used for each taxa or species. If a chemical agent will be used, indicate the dose and route of administration. If tissues are to be collected post mortem, list the tissues to be collected.
- 143. If no, indicate why a deviation is necessary.
- 144. Describe the euthanasia methods to be used in the event it is needed.
- 145. Briefly describe the technique(s) of wild animal capture, and the method(s) and duration of animal restraint that will be used. If drug-induced immobilization will be used, indicate the dose and route of administration. (Note: Techniques that have minimal impact on the animal, require the shortest period of time to accomplish, reduce hazards to research personnel, and are environmentally benevolent should be used whenever possible.)
- 146. Briefly describe the methods to be used that will assist in avoiding or alleviating the potential for animal distress, pain, or discomfort. If drug-induced sedation, analgesia, or anesthesia will be used, list the drugs, and the dose and route of administration.
- 147. Will the captured animals ever be transported from the study locations/habitats? Yes/No
- 148. If yes, describe how animals will be transported, with specific details on the methods, containment and care that will be utilized.

- 149. Animal housing or holding location:
- 150. Locations where manipulation will be conducted:
- 151. All equipment needed:
- 152. How animals will be cared for during the holding/housing:
- 153. What is the time frame for which they will remain in holding?
- 154. Will scheduled substances controlled by the Drug Enforcement Administration be used in the protocol? Yes/No
- 155. If yes, list the controlled substances to be used.
- 156. Are Controlled substances kept in an appropriately secure location?
- 157. Are Controlled substance use routinely logged?
- After capture, will animals need to be identified or marked in some manner? Yes/No 158.
- 159. If yes, briefly describe the marking technique that will be used, the nature and duration of restraint required during marking, the amount of tissue affected by the technique, and whether the method of marking will cause animals momentary or prolonged distress. (Note: If drug-induced sedation, analgesia, or anesthesia will be used during the marking of animals, list the drugs, and the dose and route of administration.)
- 160. After marking, is it anticipated that animals will be at greater than normal risk of infection, predation, or survival, or have reduced reproductive fitness? Yes/No
- If yes, justify below why this marking technique must be used, and why other techniques that have less impact on the animal may conflict with the purposes of this research activity:

Save and Quit: Yes/No

A link to APPENDICES will be available at the end of Permits. Take note of which APPENDICES you need to fill out.

Are specimens (e.g., tissues, blood, lymph, body fluids, etc.) collected from the captured animals prior to their release?

Yes (fill out Appendix A, "Specimen Collection, Ante Mortem") No

163. Are test substances, other than those used for marking, or for sedation, analgesia, or anesthesia administered to the captured animals prior to their release?

Yes (Fill out Appendix B, "Test Substances") No

- 164. Does this animal use end with the release of the animals (with no planned recapture) at the site of capture within twenty-four hours of their restraint, without impairment of their ability to survive, while environmental conditions are conducive to their survival, and while their release is not likely to spread pathogens? Yes/No
- 165. Does this animal use end after the same marked animals are recaptured again one or more times, with or without the collection of tissue specimens, or the administration of test substances, using methods identical to those described above, with their release at the original site of capture within twelve hours of each episode of restraint, without impairment of their ability to survive, while environmental conditions are conducive to their survival, and while their release is not likely to spread pathogens? Yes/No
- 166. If yes, indicate below the anticipated number of times that the same wild animal will need to be re-captured, the time interval between each re-capture, and whether tissue specimens will be collected, or test substances will be administered during each episode of restraint:

A link to APPENDICES will be available at the end of Permits. Take note of which APPENDICES you need to fill out.

- 167. Will animals be confined or restricted to an enclosure in their natural setting for longer than 12 hours, or transported to, and housed within an enclosure? Yes/No
- 1 Will surgery be performed on animals as part of this protocol? Yes (Fill out Appendix D, "Surgery") No
- 169. Will animals be subject to experimental procedures other than those described above (e.g., behavioral manipulations, noxious stimuli, or forced exercise)? Yes (Fill out Appendix E, "Other Experimental Procedures") No
- 170. Will animals be involved in Pain Category C research activities where more than momentary or slight painful or stressful outcomes are anticipated or possible, which cannot, or will not be alleviated by the administration of appropriate anesthetics and/or analgesics? Yes/No
- 171. If yes, describe the methods and/or clinical criteria that will be used to ensure timely intervention and removal of the animals from the study in advance of the anticipated discomfort, or why avoidance or alleviation of animal pain or discomfort adversely affects the protocol. The earliest possible clinical end point, which will contribute to the resolution of the hypothesis, must be identified and utilized. (Note: The IACUC recognizes that pain perception by many species of vertebrate animals may not be uniform over the various portions of their bodies, and that broad extrapolation of pain perception across taxonomic lines may not be appropriate.)

- 172. Do the consequences of these procedures introduce the possibility of earlier animal death (excluding death from euthanasia) as an endpoint to this protocol (e.g., survival analysis)? Yes/No
- 173. If yes, explain why an earlier endpoint is not possible.
- 174. Are animals euthanized at the completion of this study? (Refer to IACUC Principles & Procedures XXIII.35.) Yes/No
- 175. Indicate the final disposition of the involved animals:
- 176. If yes, does the method of euthanasia and means of assuring death following euthanasia comply with the AVMA Guidelines for the Euthanasia of Animals? Yes/No
- 177. If yes, describe the method of euthanasia used for each species. If a chemical agent will be used, indicate dose and route of administration.
- 178. If no, indicate why a deviation is necessary.

Save and Quit: Yes/No

Permits

The IACUC recognizes that state and federal wildlife agencies review applications for permits for their scientific merit and their potential impact on native populations, and issue permits that authorize the taking of specified numbers of individuals, the taxa and methods allowed, the period of study, and often other restrictions designed to minimize the likelihood that an investigation will have deleterious effects.

USM hereby informs all researchers that IACUC Approval does not replace any or all necessary permit issuing, and further informs researchers that animal research is NOT to begin until any and all necessary permits have been obtained by the researcher from the appropriate Federal and/or State agencies, entities, etc. USM holds no responsibility or liability in researchers performing work without the appropriate permits.

- 179. Do you have knowledge of all regulations pertaining to the animals under study, including whether they are considered endangered or threatened, and will obtain all applicable permits before initiating the study (such as Maine Dept. of Inland Fisheries and Wildlife Scientific Collection Permit)? Yes/No
- 180. If no, explain within the space below:

Permit 1

- 181. Permit Required 1:
- 182. Permitting Agency 1:
- 183. Which species or circumstances require the permit?1:
- 184. Under whose name is the permit held? 1:
- 185. Date that permit was obtained? 1:

Continue:

Add another permit

Appendix A: Specimen Collection, Ante Mortem

Appendix B: Test Substances

Appendix D: Surgery

Appendix E: Other experimental procedure

Principal Investigator Certifications and Agreement, submit protocol

Save and Quit

Permit 2

186. Permit Required 2:

187. Permitting Agency 2:

188. Which species or circumstances require the permit? 2:

189. Under whose name is the permit held? 2:

190. Date that permit was obtained? 2:

Continue:

Add another permit

Appendix A: Specimen Collection, Ante Mortem

Appendix B: Test Substances

Appendix D: Surgery

Appendix E: Other experimental procedure

Principal Investigator Certifications and Agreement, submit protocol

Save and Quit

Permit 3

191. Permit Required 3:

192. Permitting Agency 3:

193. Which species or circumstances require the permit? 3:

194. Under whose name is the permit held? 3:

195. Date that permit was obtained? 3:

Continue:

Add another permit

Appendix A: Specimen Collection, Ante Mortem

Appendix B: Test Substances

Appendix D: Surgery

Appendix E: Other experimental procedure

Principal Investigator Certifications and Agreement, submit protocol

Save and Quit

Permit 4

196. Permit Required 4:

197. Permitting Agency 4:

198. Which species or circumstances require the permit? 4:

- 199. Under whose name is the permit held? 4:
- 200. Date that permit was obtained? 4:

APPENDIX A: SPECIMEN COLLECTION, ANTE MORTEM

Complete ONLY if specimens (tissues, blood, lymph, body fluids, etc) are being collected.

- 201. Within the space provided, list the tissues or specimens (e.g., blood, spleen, liver, lymph node, body fluid) that will be collected ante mortem from animal(s), and indicate the amount of tissue to be collected, the frequency of collection, and the method that will be used to collect the tissue sample (e.g., needle aspiration, punch biopsy, or surgical excision).
- 202. Will the procedure used in collecting tissues cause more than momentary pain or discomfort? (Note: Invasive procedures that are performed while animals are anesthetized which open the integument, enter a body cavity, orifice, or hollow visceral organ are considered to cause more than momentary, slight pain or distress, respond "Yes" below; non-invasive procedures such as needle aspiration, respond "No" below). Yes/No
- 203. If yes, describe how anesthesia will be induced and maintained, including the dose and route of agents used, whether post-operative/procedural analgesics will be used, their dose and frequency of administration, and a description of the post-procedural methods of minimizing and/or alleviating pain and discomfort.
- 204. If no, describe the method of restraint, and whether tranquilizers, sedatives, or anesthetics will be used, and their dose and route.

Go to:

Appendix B: Test Substances

Appendix D: Surgery

Appendix E: Other experimental procedure

Principal Investigator Certifications and Agreement, submit protocol

Save and Quit

APPENDIX B: TEST SUBSTANCES

Complete ONLY if using substances, other than those used for marking, or for sedation, analgesia, or anesthesia administered to the captured animals prior to to release.

- 1. Complete the table below. Name the test substance(s) that will be administered to animals.
- 2. Very briefly indicate the purpose of substance administration in the relation to the hypothesis, and the expected effect to the animal(s). If none, so state.
- 3. Indicate if there a possibility that any of the test substance(s) could cause more than momentary or slight pain, discomfort, or distress to the animals, either immediately following substance administration, or as a consequence long after administering the test substance(s). (Note: Log entries describing health concerns or complications that develop as a consequence of substance administration to non-rodent mammals, and their treatment and resolution, or

when animals are euthanized must be kept by the PI in the animal facility on forms provided by Comparative Medicine.)

4. Indicate if any of the test substances are included in any of the classes A through G, and considered a regulated or potentially hazardous material to research or animal care personnel.

Indicate the CLASS of each substance as either an: (A) infectious agent, (B) primary explant, uncharacterized human blood, lymph or tissue specimen, (C) recombinant DNA, (D) radioisotope, (E) carcinogen, (F) hazardous or toxic chemical, (G) biological toxin, (H) Cell line, (I) Adjuvant, (J) Antigenic Substance, (K) Pharmacologic Agent, or (L) Other class of substance by using the appropriate capital letter. Indicate to which species each substance will be administered. Indicate the dose (e.g., µg/gm bwt), volume per administration, route (e.g., i.v., i.p., s.c.), and interval (e.g., 1x, daily, eod, every 3rd day), and duration of administrations (e.g., 5 wks).

Substance 1

- 205. Substance:
- 206. Class (above):
- 207. Species (administered to):
- Dose/Volume/Route (3.0mg/kg bw / 0.1ml / i.p.): 208.
- 209. Interval (1x, eod ev 3rd day):
- 210. Duration:
- 211. Purpose and Expected Effect of Substance Administration to the Animal:
- 212. If there a possibility that this test substance could cause more than momentary or slight pain, discomfort, or distress to the animals, either immediately following substance administration, or as a consequence long after administering the test substance(s), describe the consequences of administration that have a potential to cause animal discomfort, pain, or distress, and how discomfort, pain or distress will be anticipated, minimized or alleviated (e.g., nude mice administered tumor cells will be humanely euthanized if induced tumors become > 1.0 cm in diameter, or if tumors ulcerate, or if tumors interfere with posture, locomotion or feeding). If discomfort, pain, or distress will not be alleviated, then justify how treatments interfere with the procedures or the interpretation of results.
- 213. If this test substance is Class A-G and considered a regulated or potentially hazardous material to research or animal care personnel, describe procedures to ensure these substances and/or animals to which these substances have been administered will be handled safely (e.g., BSL-2, USF Chemical Hygiene Plan, Universal Precautions, etc.):

Go to:

Add another substance Appendix D: Surgery

Appendix E: Other experimental procedure

Principal Investigator Certifications and Agreement, submit protocol

Save and Quit

Substance 2

- 214. Substance 2:
- Class (above) 2: 215.
- 216. Species (administered to) 2:

- 217. Dose/Volume/Route (3.0mg/kg bw / 0.1ml / i.p.) 2:
- 218. Interval (1x, eod, ev 3rd day) 2:
- 219. Duration 2:
- 220. Purpose and Expected Effect of Substance Administration to the Animal 2:
- 221. If there a possibility that this test substance could cause more than momentary or slight pain, discomfort, or distress to the animals, either immediately following substance administration, or as a consequence long after administering the test substance(s), describe the consequences of administration that have a potential to cause animal discomfort, pain, or distress, and how discomfort, pain or distress will be anticipated, minimized or alleviated (e.g., nude mice administered tumor cells will be humanely euthanized if induced tumors become >1.0 cm in diameter, or if tumors ulcerate, or if tumors interfere with posture, locomotion or feeding). If discomfort, pain, or distress will not be alleviated, then justify how treatments interfere with the procedures or the interpretation of results. 2:
- If this test substance is Class A-G and considered a regulated or potentially hazardous material to research or animal care personnel, describe procedures to ensure these substances and/or animals to which these substances have been administered will be handled safely (e.g., BSL-2, USF Chemical Hygiene Plan, Universal Precautions, etc.) 2:

Go to:

Add another substance Appendix D: Surgery Appendix E: Other experimental procedure Principal Investigator Certifications and Agreement, submit protocol Save and Quit

Substance 3

- Substance 3: 223.
- 224. Class (above) 3:
- 225. Species (administered to) 3:
- 226. Dose/Volume/Route (3.0mg/kg bw / 0.1ml / i.p.) 3:
- 227. Interval (1x, eod, ev 3rd day) 3:
- 228. Duration 3:
- 229. Purpose and Expected Effect of Substance Administration to the Animal 3:
- 230. If there a possibility that this test substance could cause more than momentary or slight pain, discomfort, or distress to the animals, either immediately following substance administration, or as a consequence long after administering the test substance(s), describe the consequences of administration that have a potential to cause animal discomfort, pain, or distress, and how discomfort, pain or distress will be anticipated, minimized or alleviated (e.g., nude mice administered tumor cells will be humanely euthanized if induced tumors become >1.0 cm in diameter, or if tumors ulcerate, or if tumors interfere with posture, locomotion or feeding). If discomfort, pain, or distress will not be alleviated, then justify how treatments interfere with the procedures or the interpretation of results. 3:
- If this test substance is Class A-G and considered a regulated or potentially hazardous material to research or animal care personnel, describe procedures to ensure these substances and/or animals to which these substances have been administered will be handled safely (e.g., BSL-2, USF Chemical Hygiene Plan, Universal Precautions, etc.) 3:

Go to:

Add another substance

Appendix D: Surgery

Appendix E: Other experimental procedure

Principal Investigator Certifications and Agreement, submit protocol

Save and Quit

Substance 4

- 232. Substance 4:
- 233. Class (above) 4:
- 234. Species (administered to) 4:
- 235. Dose/Volume/Route (3.0mg/kg bw / 0.1ml / i.p.) 4:
- 236. Interval (1x, eod, ev 3rd day) 4:
- 237. Duration 4:
- 238. Purpose and Expected Effect of Substance Administration to the Animal 4:
- 239. If there a possibility that this test substance could cause more than momentary or slight pain, discomfort, or distress to the animals, either immediately following substance administration, or as a consequence long after administering the test substance(s), describe the consequences of administration that have a potential to cause animal discomfort, pain, or distress, and how discomfort, pain or distress will be anticipated, minimized or alleviated (e.g., nude mice administered tumor cells will be humanely euthanized if induced tumors become > 1.0 cm in diameter, or if tumors ulcerate, or if tumors interfere with posture, locomotion or feeding). If discomfort, pain, or distress will not be alleviated, then justify how treatments interfere with the procedures or the interpretation of results. 4:
- If this test substance is Class A-G and considered a regulated or potentially hazardous material to research or animal care personnel, describe procedures to ensure these substances and/or animals to which these substances have been administered will be handled safely (e.g., BSL-2, USF Chemical Hygiene Plan, Universal Precautions, etc.) 4:

Go to:

Add another substance Appendix D: Surgery

Appendix E: Other experimental procedure

Principal Investigator Certifications and Agreement, submit protocol

Save and Quit

Substance 5

- 241. Substance 5:
- 242. Class (above) 5:
- 243. Species (administered to) 5:
- 244. Dose/Volume/Route (3.0mg/kg bw / 0.1ml / i.p.) 5:
- 245. Interval (1x, eod, ev 3rd day) 5:
- 246. Duration 5:
- 247. Purpose and Expected Effect of Substance Administration to the Animal 5:

- 248. If there a possibility that this test substance could cause more than momentary or slight pain, discomfort, or distress to the animals, either immediately following substance administration, or as a consequence long after administering the test substance(s), describe the consequences of administration that have a potential to cause animal discomfort, pain, or distress, and how discomfort, pain or distress will be anticipated, minimized or alleviated (e.g., nude mice administered tumor cells will be humanely euthanized if induced tumors become >1.0 cm in diameter, or if tumors ulcerate, or if tumors interfere with posture, locomotion or feeding). If discomfort, pain, or distress will not be alleviated, then justify how treatments interfere with the procedures or the interpretation of results. 5:
- 249. If this test substance is Class A-G and considered a regulated or potentially hazardous material to research or animal care personnel, describe procedures to ensure these substances and/or animals to which these substances have been administered will be handled safely (e.g., BSL-2, USF Chemical Hygiene Plan, Universal Precautions, etc.) 5:

Go to

APPENDIX D: SURGERY

Appendix E: Other experimental procedure

Principal Investigator Certifications and Agreement, submit protocol

Save and Quit

APPENDIX D: SURGERY

Complete ONLY if performing surgery on animals as part of this protocol.

- 250. Describe the pre-operative medications, including tranquilizers, sedatives, pre-anesthetics, and general anesthetics, and their dose and route.
- 251. Describe all pre-operative procedures, including whether food or water are withheld, (for what period of time), the shaving of hair, surgical scrub, draping, and placement of leads, probes, or catheters.
- Will paralyzing agents be used? Yes/No 252.
- 253. If yes, justify why it is necessary to use them.:
- 254. Describe the surgical procedures in chronological order, and in sufficient detail so that the IACUC will be able to determine what is being performed on the animal. (Note: Intra-operative monitoring, medications and support are to be described in the next question).
- 255. Describe the methods used for monitoring intra-operative anesthesia, and all intraoperative medications and/or support.
- 256. Will the animal(s) regain consciousness from anesthesia following surgery?
- 257. If no, stop here. This description is complete. Go to Principal Investigator Certifications and Agreement. Otherwise go to Appendix E.

Appendix E: Other experimental procedure

Principal Investigator Certifications and Agreement, submit protocol

- 258. If yes, indicate below where the surgery will be performed, whether in the field at the location(s) described in response to STUDY LOCATION (above), or on campus in a laboratory. If on campus, name the building and room number
- 259. Will aseptic techniques be used (as a minimum including working in an uncluttered area, the wearing of surgical gloves & mask, preparation of the surgical site with disinfectant, cleaning of instruments with a disinfectant, and appropriate wound closures)? Yes/No
- 260. If no, justify why not:
- 261. Animals recovering from general anesthesia must be monitored at least until they are sternal recumbent and capable of purposeful movement. Prior to that point, describe the interval and manner of immediate post-operative monitoring, and clinical reassessment. How frequently will the animals be evaluated, and in what manner will the animal(s) be monitored post-operatively?
- 262. Will more than one major surgical procedure be performed on a single animal? (Note: If a survival surgical procedure is followed by a non-survival surgical procedure, respond "No".): Yes/No
- 263. If yes, justify:
- 264. Describe post-operative patient care after the animals have been returned to long-term housing, including the administration of analgesics, medications, fluids, and any other support methods (dose, route and frequency of post-operative analgesics and medications must be described), and indicate that skin sutures or staples will be removed at approximately 10 - 14 days post-operatively.

Go to:

Appendix E: Other experimental procedure Principal Investigator Certifications and Agreement, submit protocol Save and Quit

APPENDIX E: OTHER EXPERIMENTAL PROCEDURES

Complete ONLY if animals are to be subject to experimental procedures other than e.g. behavioral manipulations, noxious stimuli, or forced exercise.

- 265. Describe other experimental procedure(s) that have not been described in detail above (e.g., behavioral manipulation, forced exercise, noxious stimuli, physical restraint) and the expected outcome.
- 266. How long will each procedure last?
- 267. Will the procedure(s) cause more than momentary, slight pain or discomfort to the animals?

- 268. If yes, describe the methods that will be used to minimize pain and discomfort.
- 269. Describe the methods for monitoring the condition of the animal during the procedure and during the post-procedural period, and whether a log of observations will be kept.

PRINCIPAL INVESTIGATOR CERTIFICATIONS AND AGREEMENT

270. Check all that apply:

- (1) I certify that I have determined that the research proposed herein is not unnecessarily duplicative of previously reported research.
- (2) I certify that the individuals listed as research personnel are authorized to conduct procedures involving animals under this proposal and have completed the institutionally required investigator training course, and received training in: the biology, handling, and care of this species; aseptic surgical methods and techniques (if necessary); the concept, availability, and use of research or testing methods that limit the use of animals or minimize distress; the proper use of anesthetics, analgesics, and tranquilizers (if necessary); and procedures for reporting animal welfare concerns.
- (3) I certify that I have reviewed the pertinent scientific literature and the sources and/or databases as noted above and have found no valid alternative to any procedures described herein which may cause more than momentary pain or distress, whether it is relieved or not.
- (4) I certify that I will obtain approval from the IACUC before initiating any changes in this study.
- (5) I certify that I will notify the IACUC regarding any unexpected study results that impact the animals. Any unanticipated pain or distress, morbidity or mortality will be reported to the attending veterinarian and the IACUC.
- (6) I certify that I am familiar with and will comply with all pertinent institutional, state, and federal laws and policies.
- (7) I certify that I understand and will abide by any and all Federal and/or State permit requirements as applicable for the research proposed, and understand that IACUC Approval for this research does not replace these requirements. I certify that I will not begin this research prior to the obtainment of any and all necessary permits.

271. By ch certificat	necking the box below, I, the Primary Investigator named above, agree tions.:	
I agre	ee	

How easy was it to use this Google Form?

1= Difficult 5=Easy

	1	2	3	4	5	
Difficult	\circ	\circ	\circ	\circ	\circ	Easy

Any comments about the use of this Google Form?

Long answer text