A Sample Animal Care and Use Universal Protocol Form

Question Number	Regulatory Requirement	Protocol Section	Question
-	Needed for protocol management	Administrative Information Note: this information is needed for administrative purposes)	Protocol Title:
-	May be needed for review management	Administrative Information	Submission Type: New, Renewal, or Amendment
1	Needed for protocol management	Administrative Information	Principal Investigator (PI) Information Section
1a		Administrative Information	PI Name (Last, First):
1b		Administrative Information	Current Position (e.g., Faculty Member, Research Scientist):
1c		Administrative Information	Department or School:
1d		Administrative Information	Primary Lab Location (Building, Room #):
1e		Administrative Information	Cell Phone Number (for emergency contact):
1f		Administrative Information	Email:
2		Administrative Information	Personnel and personnel training information

2a	Guide, page 16: All personnel are adequately educated, trained, and/or qualified in basic principles of laboratory animal science. Need the AWAR and the PHS Policy citations	Administrative Information	According to Federal Regulations, all personnel must be qualified to perform those animal activities described in this protocol prior to working independently. By checking "Yes" to this statement you provide written assurance and documentation that all personnel listed on this protocol will complete all of the required training and be under the close supervision of and trained by qualified and experienced individuals before they are permitted to conduct any of the animal activities listed on this protocol independently. [] Yes [] No, Explain, <text box=""></text>
2b	Protocol management	Administrative Information	List those individuals that will be conducting animal activities under this protocol. The information gathered is the individuals' names, role on the protocol, and email address.
3	Protocol management	Administrative Information	Project Funding
3a		Administrative Information	Is this project or components of it externally (e.g., NIH or DoD) funded? [] Yes [] No
3b	Protocol management. This will ensure the Administrator knows who will be funding the project.	Administrative Information	If the project is externally funded, please check all that apply. Chooses include: the National Institutes of Health, the National Science Foundation, Department of Defense and an option to list any others.

3c	The Terms and Consitions of an NIH Grant (Need Citation), for example, require institutions to validate proposed animal activities have been approved by the IACUC before initiation. The PHS Policy requries the same (Need Citation). By checking "yes" to this assurance statement, the PI is ensuring a protocol grant congruecncy need not be conducted by the institution.	Administrative Information	Funding Agencies require all animal activities listed in the grant to be reviewed and approved by the IACUC prior to spending any of the associated funded on animal activities. Please check yes to provide assurance that proceeds from the grant(s) intended to support animal activities will only be spent after those activities are approved by an IACUC. [] Yes [] No, please explain <text box=""></text>
4	Serves as Metrics data and can help with assigning DMR's based on their experience (PHS, Guide, AWAR citations needed)	Administrative Information	Project Classification: Please check the box(es) that best describes your proposed activities. The choices include: Breeding Colony, Euthanasia only for a source of tissue, Instruction (e.g., teaching, training, demonstration), Specialized Services (e.g., Diagnostic, Imaging, and Transgenic Cores), Wildlife/Field Research, and other (open text box for the PI to list).
5	Compliance Management	Administrative Information	Animal Use Locations
5a	The IACUC is required to inspect the animal housing and support facilities at least sem-annually (Guide, PHS and AWAR citations needed)	Administrative Information	Please check "Yes" to provide assurance that all animal activities (i.e., housing and procedures) will occur in the institution's central animal facilities (e.g., areas managed by the Attending Veterinarian rather than the PI). [] Yes [] No, Explain

5b	The IACUC is required to inspect the animal housing and support facilities at least sem-annually (Guide, PHS and AWAR citations needed). This information will ensure the Administrator is able to identify new locations that require inspections as they are added to new procools.	Administrative Information	Please provide the following information about locations where animal activities will occur outside the central facilities and the activities to be conducted. The information collected includes: the building and room number, the species to be used, and the activities (e.g., behavior studies, euthanasia, housing, non-survival surgery, survival surgery, substance administration, use of hazardous materials, specialized equipment, other) to be performed
1	This information is needed to ensure the IACUC can perform its review of proposed animal activities.	needed for the IACUC to review and	Please provide the following information for the animals that will be used in the activities proposed under this protocol (complete for each species). The information collected includes: the species and the source of the animals.
2	The US Government Policies, AWAR, PHS Policy and the Guide requires scientists to select the appropriate animal model for the research they plan to conducte. The citations are needed. This assurance places faith that the PI has methodically selected a specific anima model based on the research they plan to perform.	IACUC Information	Please describe the rationale for involving animals in your research design. Describe specific language that describes how the animal model selected was chosen because, for example, its physiology is the most appropriate to achieve the project goals. For example, a swine model may be selected since its physiology is the closest to that of a human and it would provide the best transitional information. In addition, that the model selected is the lowest on the phylogenetic scale that can be used to satisfy the project goals (e.g., rabbits were not selected if the activities can be successfully conducted in mice since mice are less sentient). Text Box

3	The AVMA Euthanasia Guidelines (need link) specifically specify the types of acceptable euthanasia per species. By the PI checking "yes" they are assuring that they validated the method of euthanasia they selected conforms with the AVMA Guidelines	IACUC Information	Euthanasia and/or Final Disposition of the animals to be used (<i>Check all that apply</i>) Note: The American Veterinary Medical Association (AVMA) Guidelines define the humane methods of euthanasia that may be used to euthanize animals. Federal regulations (e.g., PHS Policy) require that the AVMA Panel recommendations be followed and any deviation from the guidelines require IACUC review and approval. Please check yes to provide assurance that all methods of euthanasia listed in this protocol are in accordance with the current American Veterinary Medical Association Panel on Euthanasia recommendations. [] Yes [] No, please explain <text box=""></text>
3 (choice 1)	For protocol management, it ensures the IACUC knows the final disposition of each animal, and also identifies for the administrator when an animal is eligible for transfer or adoption, for example.	IACUC Information	Qualified animals may, for example, be transferred to another IACUC approved protocol or adopted (if eligible) following institutional policies.
3 (choice 2)	For protocol management, it ensures the IACUC knows the final disposition of each animal, and also identifies for the administrator when an animal is eligible for transfer or adoption, for example.	IACUC Information	Wild animals being used will be released back to the wild
3 (choice 3)	For protocol management, it ensures the IACUC knows the final disposition of each animal, and also identifies for the administrator when an animal is eligible for transfer or adoption, for example.	IACUC Information	Some animals will be involved a terminal procedure that will be later described

3 (choice 4)	For protocol management, it ensures the IACUC knows the final disposition of each animal, and also identifies for the administrator when an animal is eligible for transfer or adoption, for example.	IACUC Information	For adult mice or rats, they will be euthanized by gas (i.e., carbon dioxide or isoflurane) inhalation or exsanguinations under anesthesia followed by one of the listed secondary physical methods (i.e., decapitation, bilateral pneumothorax, removal of a vital organ, cervical dislocation) of euthanasia
3 (choice 5)	For protocol management, it ensures the IACUC knows the final disposition of each animal, and also identifies for the administrator when an animal is eligible for transfer or adoption, for example.	IACUC Information	A physical method (e.g., cervical dislocation or decapitation) will be used. The information collected includes: the specific method and the species upon which it will be used.
3 (choice 6)	For protocol management, it ensures the IACUC knows the final disposition of each animal, and also identifies for the administrator when an animal is eligible for transfer or adoption, for example.	IACUC Information	Lethal Injection with or without tissue collection. The information collected includes: the agent, the dose and the species upon which it will be used.
3 (choice 7)	For protocol management, it ensures the IACUC knows the final disposition of each animal, and also identifies for the administrator when an animal is eligible for transfer or adoption, for example.	IACUC Information	Other (for wildlife studies, include the type of euthanasia that will be used should animals be unexpectedly injured during a procedure). The information collected includes: the method and the species.
4		IACUC Information	Agent Administration

4 a	Procedures are in place for review, approval, and suspension of animal activities (PHS Policy, IV.B.) Procedures are in place for review and approval of significant changes to approved activities (PHS Policy, IV.B.) AWARs - 2.31(d)(1)(iv)c)	IACUC Information	Other than anesthetics and analgesics, will substances (including but not limited to, for example, biologics, sedatives, tranquilizers, neuromuscular blocking agents (may not be used without anesthesia), antibiotics, supplemental fluids, experimental compounds, or test articles) be administered, either directly or as a food/water additive, to animals? [] Yes <complete table="" the="">[] No. The information collected in the table includes: the purpose, route, dose and frequency of the administration. It also identifies whether the agent is hazardous to humans.</complete>
4b	Procedures are in place for review, approval, and suspension of animal activities (PHS Policy, IV.B.) Procedures are in place for review and approval of significant changes to approved activities (PHS Policy, IV.B.)	IACUC Information	Substances (e.g., infectious agents, clinical specimens, and toxic chemicals) that are potentially hazardous to humans are regulated through, for example, the Institutional Biosafety Committee (IBC), and/or the institution's Office of Environmental Health and Safety (EHS). Please check yes, to attest that your use of the hazards listed in the table above has been cleared by the either the IBC, EHS or equivalent. [] Yes, [] No, explain If checked No, that a clearance has not been secured, the PI must identify the substance and the reason a clearance wasn't secured.

4c	Pharma Grade required - need citations from OLAW. The Guide and AWAR	IACUC Information	Federal regulations state that substances (e.g., anesthetics, analgesia, chemicals, biologics, and other substances) administered to animals as part of a research, teaching, or testing survival or non-survival activity must be pharmaceutical grade when available. The FDA provides a list* of currently available pharmaceutical agents. Please check yes to provide assurance that, when available, all substances administered to animals under this protocol will be pharmaceutical grade. [] Yes [] No, complete the table below *(http://www.accessdata.fda.gov/scripts/cder/drugsatfda). The information gathered in the table includes: whether a pharmaceutical grade is available, why it cannot be used, and how the suitability and purity, for example, will be assured.
5		IACUC Information	Related to the use of vertebrate animals: briefly describe the objective(s) and a general description of this project in language that can be easily understood by a nonscientific member of the IACUC.
6		IACUC Information	Please check "yes" to provide assurance that the scope of the proposed animal activities will not unnecessarily duplicate previously conducted activities, and either be used to identify potential medical advancements that improve the health and wellbeing of humans and/or animals, used as a resource in educational endeavors, or used to advancement human knowledge for the good of society. [] Yes [] No, Explain <text box=""></text>

7	IACUC	Please check "Yes" to provide assurance that as the PI you have considered the feasibly of using non-animal models (e.g., cell culture, isolated organ preparations, computer simulations, etc.) to achieve your research goals. In addition, your acknowledgment confirms that using living animals is essential to evaluate the hypothesis and determine the overall impact of the animal activities on a complete biological system. [] Yes [] No, Explain <test box=""></test>
8	IACUC	information Experimental Design
8a		Please provide a clear and concise, sequential description of the procedures involving the use of animals in a manner that is easily understood by lay members of the IACUC. This description should allow the IACUC to understand the experimental course of an animal from its entry into the experiment through the endpoint of the study. Note: Please do not provide the specific details (e.g., drug doses, routes of injection, and steps in a surgical procedure) of the animal procedures you will conduct since those details will be provided as part of subsequent questions.
8b	IACUC	The number of animals used for each experiment should be the minimum required to achieve the scientific aim(s) and produce, when possible, statistically valid results. Please check "Yes" to provide assurance that the number of animals used in this experiment is minimum needed to produce valid results. [] Yes[] No, Explain

8c	IACUC Info	Estimate the minimum and maximum number of animals that will be needed for this project to achieve valid results. The information gathered is the species of animal, the minimum and the maximum of each species that will be needed to meet the research focus.
9	IACUC Info	rmation Animal Housing
9a	IACUC Info	The living conditions that are appropriate for the species and contribute to the welfare and comfort of that species have been standardized in the Federal regulations. These conditions include, for example, maintaining appropriate light cycles and environmental conditions; providing ongoing access to enrichment devices; changing cages on a regular basis; and using standard size cages. Please check yes to confirm that animals under this study should be maintained according to the federally defined standards. [] Yes [] No, describe and justify the needed changes
9b	IACUC Info	Federal regulations require animals to be housed in compatible groups, which contributes to the welfare and comfort of the animals. Please check yes to confirm that animals under this study can be maintained in compatible groups according to the federally defined standards. (Note: single housing of animals due to fighting, veterinary treatment or post-op recovery, attrition, or separation of breeders does not need to be indicated here). [] Yes [] No, describe and justify why animals must be singly housed
	IACUC Info	rmation Animal Procedures

10	IACUC Information	Animal Procedures (Check all that apply) NOTE: According to the Federal Regulations, it is your responsibility to minimize the discomfort, distress, and pain that may be associated with any animal use activities proposed in this protocol. Please check yes to provide assurance that measures, not limited to anesthetics, analgesics, and sedatives, will be taken to avoid or minimize the discomfort, distress, and pain to the animals. [] Yes [] No, please explain
Check Box	IACUC Information	Survival surgery (i.e., the animal will recover) will be performed
1	IACUC Information	Please provide a descriptive name (e.g., laparotomy or abdominal) of the specific survival surgical procedure that will be performed.
2	IACUC Information	Briefly describe the surgery that will be conducted. Note: details regarding anesthesia, analgesia, surgical preparation, and post operative monitoring will be provided in subsequent questions.
3	IACUC Information	Survival surgery must be performed using aseptic technique. Aseptic technique is a series of practices and procedures that help to prevent contamination from pathogens. Aseptic technique is often influenced by the species of interest and include, for example, patient preparation (pre-emptive actions: fur removal, surface cleaning, etc.), surgeon preparation (protective clothing, PPE, skin disinfection, cover) and surgical location (room, table, surface disinfection). Consequently, please check yes to provide assurance that the following process will be followed to ensure aseptic technique is used.

		*The instruments and/or medical devices will be sterilized (e.g., autoclaved) prior to each surgery. The surgical area will be decontaminated using appropriate disinfecting practices. The surgeon will wear, at minimum, a mask, a surgical cap/bonnet, sterile gloves, and a clean scrub top, disposable gown, or lab coat.
		*Mammals, the surgical site will be prepped by removing the hair followed by at least three alternating scrubs with a disinfectant (e.g., betadine, chlorhexidine) and rinse (e.g., ethanol, warmed saline, sterile water) to remove remaining visible debris.
		*Birds, the feathers located within the surgical site will be removed followed by at least three alternating scrubs with a disinfectant (e.g., chlorhexidine) and rinse (e.g., ethanol, warmed saline, sterile water) to remove remaining visible debris.
		*For amphibians, reptiles and fish, the incision site will be prepared with a single wipe using, for example, sterile saline, dilute povidone iodine, or chlorhexidine immediately before surgery.
		*Please check yes to provide assurance the described aseptic procedures will be followed consistent with the species of interest. [] Yes[] No, explain
4	IACUC Information	Patient support before, during and after surgery is critical to animal welfare and necessary to minimize discomfort, pain and/or distress associated with the surgical procedure. Please provide the following information.

4a	IACUC Information	Anesthetics and Analgesics must be used to manage and control pain <u>during</u> and after surgical procedures. Please check yes to provide assurance that both will be used as part of this procedure. [] Yes [] No, please explain
4b	IACUC Information	List the anesthetic(s) and analgesic(s) that will be used for this procedure through the completion of <i>post-operative care</i> . Information (i.e., Substance, Species, analgesia/anesthetic, Dose, how applied and the frequency of the application) is collected in a table.
5	IACUC Information	Each animal must be monitored until it completely recovers from the surgery, please check yes to provide assurance that the following post operative monitoring procedure will be occur. The response to this question will be depend on the type of animal used. As assurance "Yes", but be selected, or a justification otherwise).
	IACUC Information	*Mammals (rodent): Post operatively each animal will be visibly observed at least every 15 minutes until the animal can hold itself upright. Each animal may be individually housed until it completely recovers from the surgery. Each animal will be monitored daily during the post-op recovery period (i.e., a minimum of 7 days), or until the sutures, staples or clips are removed. [] Yes [] No, please explain

IACUC Information	*Mammals (non-rodent): Post operatively each animal will be visibly observed continuously until the endotracheal tube is removed (if applicable), and then every 15 minutes until the animal can hold itself upright. Each animal will be monitored daily during the recovery period (7-14 days) and/or until the sutures, staples, or clips are removed. [] Yes [] No, please explain
IACUC Information	*Birds: Post operatively each bird will be visibly observed at least every 15 minutes until it can hold itself upright. Each may be individually housed until it completely recovers from the surgery. Each will be monitored daily during the post-op recovery period (i.e., a minimum of 7 days), or until the sutures, staples or clips are removed. [] Yes [] No, please explain
IACUC Information	* Amphibians and reptiles: Animals will be visibly observed every 15 minutes during recovery from anesthesia until they resume normal swimming and ambulation. Animals will be monitored at least once per day during the post-op recovery period, which is typically 10 to 14 days. If applicable, the sutures will be removed within 14 days post-surgery. [] Yes [] No, please explain
IACUC Information	*Fish: they will be visibly observed every 15 minutes during recovery from anesthesia until they swim normally. Each fish will be monitored for 24 hours post-surgery and then daily health checks performed. If applicable, the sutures will be removed within 14 days post-surgery. [] Yes [] No, please explain

Check Box	IACUC Information	Non-survival surgery (i.e., the animal will recover) will be performed
1	IACUC Information	How long will it take to complete the procedure?
2	IACUC Information	Please provide a descriptive name (e.g., laparotomy or abdominal) of the specific survival surgical procedure that will be performed.
3	IACUC Information	Briefly describe the surgery that will be conducted. Note: details regarding anesthesia, analgesia, surgical preparation, and post operative monitoring will be provided in subsequent questions.
4	IACUC Information	Performing non-survival surgery using aseptic technique is a recommended practice. Aseptic technique is a series of practices and procedures that help to prevent contamination from pathogens. Aseptic technique is often influenced by the species of interest and include, for example, patient preparation (preemptive actions: fur removal, surface cleaning, etc.), surgeon preparation (protective clothing, PPE, skin disinfection, cover) and surgical location (room, table, surface disinfection).
	IACUC Information	*The instruments and/or medical devices will be sterilized (e.g., autoclaved) prior to each surgery. The surgical area will be decontaminated using appropriate disinfecting practices. The surgeon will wear, at minimum, a mask, a surgical cap/bonnet, sterile gloves, and a clean scrub top, disposable gown, or lab coat.

	IACUC Information	*Mammals, the surgical site will be prepped by removing the hair followed by at least three alternating scrubs with a disinfectant (e.g., betadine, chlorhexidine) and rinse (e.g., ethanol, warmed saline, sterile water) to remove remaining visible debris.
	IACUC Information	*Birds, the feathers located within the surgical site will be removed followed by at least three alternating scrubs with a disinfectant (e.g., chlorhexidine) and rinse (e.g., ethanol, warmed saline, sterile water) to remove remaining visible debris.
	IACUC Information	*For amphibians, reptiles and fish, the incision site will be prepared with a single wipe using, for example, sterile saline, dilute povidone iodine, or chlorhexidine immediately before surgery.
	IACUC Information	*Please check yes to provide assurance the described aseptic procedures will be followed consistent with the species of interest. [] Yes [] No, explain
5	IACUC Information	Patient support before, during and after surgery is critical to animal welfare and necessary to minimize discomfort, pain and/or distress associated with the surgical procedure. Please provide the following information.
5a	IACUC Information	Anesthetics and Analgesics must be used to manage and control pain <u>during</u> and after surgical procedures. Please check yes to provide assurance that both will be used as part of this procedure. [] Yes [] No, please explain

5b	IACUC Info	List the anesthetic(s) and analgesic(s) that will be used for this procedure through the completion of <i>post-operative care</i> . Information (i.e., Substance, Species, analgesia/anesthetic, Dose, how applied and the frequency of the application) is collected in a table.
Check Box	IACUC Info	Multiple survival surgeries will be performed on the same animal and on different days <u>under separate</u> <u>anesthesia episodes</u>
1	IACUC Info	Please list the survival surgeries each animal will experience in the table below. In the table, the PI will list the species of anima, and the surgeries previously named in the order they will occur.
2	IACUC Info	Multiple surgeries conducted on the same animal are acceptable only if they are essential to the research rmation project and scientifically justified. Provide scientific justification for performing multiple surgeries on a single animal.
Check Box	IACUC Info	Food Manipulation in the form of restriction or regulation (food manipulation for clinical reasons such as pre-surgical fasting need not be included in the protocol)
1	IACUC Info	Define the proposed food manipulation in the table. The information to be collected includes; Species, Length of time (Hrs.) for a single occurrence, Minimum period of time between manipulations, and the reason for restricting food).

2	IACUC Information	Please check yes to provide assurance that animals will be closely monitored to ensure the food manipulation will not negatively impact animal welfare. Consequently, body weights will be recorded at least weekly and/or more often for animals under extreme restrictions. [] Yes [] No, please explain
3	IACUC Information	Food manipulations may negatively impact animal welfare. Consequently, the consideration of potential adverse consequences, and the identification of criteria for the removal (i.e., the humane endpoints) of an animal from the study is necessary. Removal from the study could either be euthanasia, the return to normal feeding, or another appropriate intervention. Do you expect the food restriction to negatively impact animal welfare? [] Yes, complete the table below [] No The table will be used to identify the endpoints that will be used to remove an animal from the study. The species, criteria used to remove an animal, and confirmation that animals will be euthanized according to this protocol will be gathered in the table.
4	IACUC Information	Food deprivation for periods exceeding 24 hours can result in prolonged distress for the animals. Will any animals be deprived of food for more than 24 hours [] Yes, complete the table below [] No

Check Box	IACUC Information	Fluid Manipulation in the form of restriction or regulation (fluid manipulation for clinical reasons such as pre-surgical fasting need not be included in the protocol)
1	IACUC Information	Define the proposed fluid manipulation in the table. The information to be collected includes; Species, Length of time (Hrs.) for a single occurrence, Minimum period of time between manipulations, and the reason for restricting fluid).
2	IACUC Information	Please check yes to provide assurance that animals will be closely monitored to ensure the fluid manipulation will not negatively impact animal welfare. Consequently, body weights will be recorded at least weekly and/or more often for animals under extreme restrictions. [] Yes [] No, please explain

3	IACUC Information	Fluid manipulations may negatively impact animal welfare. Consequently, the consideration of potential adverse consequences, and the identification of criteria for the removal (i.e., the humane endpoints) of an animal from the study is necessary. Removal from the study could either be euthanasia, the return to normal watering, or another appropriate intervention. Do you expect the fluid restriction to negatively impact animal welfare? [] Yes, complete the table below [] No The table will be used to identify the endpoints that will be used to remove an animal from the study. The species, criteria used to remove an animal, and confirmation that animals will be euthanized according to this protocol will be gathered in the table.
4	IACUC Information	Fluid deprivation for periods exceeding 24 hours can result in prolonged distress for the animals. Will any animals be deprived of fluid for more than 24 hours [] Yes, complete the table below [] No
Check Box	IACUC Information	Samples will be collected from research animals
Check Box	IACUC Information	Samples will be collected from the animal only after euthanasia.
Check Box	IACUC Information	A non-invasive technique is used to collect, for example, saliva, fecal, urine, hair, etc. samples that will be used for any reason included, e.g., genotyping.

Check Box	IACUC Information	Blood samples will be collected (Check all that apply)
1	IACUC Information	Please check, yes, to provide assurance that a maximum of 1% of body weight in blood (i.e., 1 ml of blood per 100 grams of body weight) will be collected in a 14-day (or less) period. [] yes, [] no, explain
2	IACUC Information	For mice or rats, please check, yes, to provide assurance that the route of blood collection will be lateral, tail and/or saphenous vein, and/or by tail incision, and/or submandibular [] yes, [] no, define and explain the alternate method and why it is necessary
3	IACUC Information	Please define and describe how blood will be collected (other than mice or rats)
Check Box	IACUC Information	Tissue biopsies will be collected (Check all that apply)
Check Box	IACUC Information	Biopsies will be collected to genotype animals.
1	IACUC Information	If you are using mice and rats, please check yes to confirm that a tail biopsy up to 5mm in length will be collected from a mouse or rat that is less than 21 days of age, or an ear punch for animals exceeding 21 days of age. [] yes, [] no, explain
2	IACUC Information	If you are using fish, please check yes to confirm that a sample of the caudal fin. [] yes, [] no, explain
3	IACUC Information	If using any other species, please indicate the type of tissue to be collected, how it will be collected, and reason for using this method.

Check Box	IACUC Information	Biopsies, for reasons other than genotyping, will be collected. Please complete the table below. Collected in the table includes the species, type of biopsy (e.g., skin, type of organ), and the reason for the sample collection.
Check Box	IACUC Information	Is the collection of the biopsy expected to cause more than momentary pain or distress? Yes, No A table will be completed by the PI if the response is yes and the following information will be collected, species, how many animals, pain relieving drugs, dose and frequency of the application (e.g., every 12 hrs.)
Check Box	IACUC Information	Behavior Studies will be conducted
1	IACUC Information	Please check "Yes" to provide assurance that when behavior studies are performed the animals will be observed (in person or via live video feed) throughout the entire procedure and that they cannot escape the behavior apparatus. [] yes, [] no, explain
2	IACUC Information	Will any of the behavior studies to be performed under this protocol result in more than momentary pain or distress for the animals? [] yes, complete the questions below [] no The table asks the PI to name the species undergoing the tests, the name of the behavior test and a brief description of the behavior study.

2a	IACUC Information	Animals experiencing more that momentary pain or distress as a result of a behavior study should receive appropriate medications (e.g., sedatives) to mitigate the negative effects of the study. Please complete the table below which includes the total animals, Test name, whether pain releiving medications will be provided, drug of choice and dose, a scientific justification when pain meds are not provided.
2b	IACUC Information	Behavior studies resulting in more than momentary pain or distress may negatively impact animal welfare. Consequently, the identification of criteria for the removal (i.e., the humane endpoints) of an animal from the study is necessary. Removal from the study could either be euthanasia, stop the behavior study, or another appropriate intervention.
Check Box	IACUC Information	Breeding
1	IACUC Information	Investigators should establish breeding colonies based on need and employ carefully designed breeding strategies and accurate genotype assessments to reduce the number of animals used and minimize the generation of unneeded animals. Please check "Yes" to provide assurance that the unnecessary breeding of animals will not occur. [] yes, [] no, explain

2	IACUC Information	For mice and rats, please check "Yes" to provide assurance that standard cage densities (e.g., two adult mice and one litter in a standard cage) will not be exceeded and that animals will be weaned no later than 21 days after birth. [] yes, [] no, explain
Check Box	IACUC Information	Tumor induction and growth
1	IACUC Information	How will tumors be induced? (Check all that apply) Chemically or drug induced, Spontaneous/phenotype, Injection or implantation of cells or tissues, Other
2	IACUC Information	Humane experimental endpoints (Check all that apply)
Check Box	IACUC Information	Mice, Visible Tumors: The animal will be euthanized if the diameter of a tumor exceeds 2cm, or if the tumor ulcerates greater than ½ its surface area, or the tumor develops in an area that impairs normal movement/physiologic behavior.
Check Box	IACUC Information	Rat, Visible Tumors: The animal will be euthanized if the diameter of a tumor exceeds 4cm, or if the tumor ulcerates greater than ½ its surface area, or the tumor develops in an area that impairs normal movement/physiologic behavior.
Check Box	IACUC Information	Other species, Visible Tumors: please describe the criteria that will be followed to determine when the animal will be euthanized.
Check Box	IACUC Information	All species, Non-Visible Tumors: please describe the criteria that will be followed to determine when the animal will be euthanized

Check Box	IACUC Information	Other procedures (e.g., Animal identification processes, Trauma, Wound or Burn, Induction of Paralysis), complete the series of questions below for each additional procedure.
Table Response	IACUC Information	Procedure
Table Response	IACUC Information	Species
Table Response	IACUC Information	Briefly describe the procedure
1	IACUC Information	Will this procedure cause more than momentary pain or distress to the animal [] Yes, complete the table (Q2) below, [] No
2	IACUC Information	Please check yes to provide assurance that analgesia (both pre-emptive and post-operative) will be used for this procedure. [] Yes, complete the table below [] No, please explain in the table below. The table gathers the relevant information regarding the use of pain releiving drugs (e.g., Analgesia, Pre-emptive/Post-precedure/other, dose, and how many days post the procedure.

IACUC Information

Experimental and Humane Endpoints

Check Box	IACUC Information	Humane and Experimental Endpoints Will any of the procedures listed in this protocol result in more than momentary pain or distress for the animals? [] yes, complete the tables below [] no The experimental endpoint of a study occurs when the scientific aims and objectives of the project has been reached. The humane endpoint is the point at which pain or distress in an experimental animal is prevented, terminated, or relieved. In some cases, the experimental and humane endpoints must be closely linked to achieve the project goal while minimizing the pain and distress an animal endures. Developing the project endpoints should be done in consultation with a veterinarian. Consequently, the identification of criteria for the removal (i.e., the humane endpoints) of an animal from the study is necessary. Removal from the study could either be euthanasia, stop the behavior study, or another appropriate intervention.
Table Response	IACUC Information	Procedure
Table Response	IACUC Information	Species
Table Response	IACUC Information	Experimental Endpoints
Table Response	IACUC Information	Adverse consequences, and the criteria that will be used to remove an animal from the study.

Table Response	IACUC Information	Indicate, yes, confirming the final disposition section of this protocol will be applied when removing an animal from the study. (If no, explain)
Check Box	IACUC Information	Field Studies
1	IACUC Information	Briefly describe the activities and procedures that will be conducted in the field or on the wild species, and whether the proposed procedures are expected to influence (e.g., be invasive or change their behavior) the activity of the animals.
2	IACUC Information	Please check "Yes" to provide assurance that all required local, state, or federal permits will be acquired prior to the initiation of the animal activities, and that all wildlife regulations will be followed. [] Yes [] No, please explain
3	IACUC Information	If not already previously identified and described, please identify, and describe the procedures that will be performed in the table below. The template gathers the procedure name, species and a description of the procedure.
4	IACUC Information	Please check yes, to provide assurance that no wild animals will be housed as part of this study for periods exceeding 12 hours. [] Yes [] No, complete the table below The table gathers, the species, the maximum number of days the animals will be housed and assurance that the housing records are being maintained appropriately

Formal search for alternatives to Painful and Distressful, which is only applicable to USDA Covered Species (e.g., all mammals except for

According to the Animal Welfare Act Regulations, any procedure that will cause more than slight or momentary pain or distress (Categories D and I available that would reduce or eliminate the pain and/or distress associated with the procedure. A literature search should consider the following quest reduce the level of pain or distress (a less invasive technique or establishing humane endpoints); (2) are non-animal models available; and (3) con invertebrates?

Specific		
Painful		
Procedure		
Affected		Total affected
Species		Total affected
Years		
covered by		Date of Search
the search		
Sources of		
the		
literature		
search (at		
least two		
sources)		
Key words		
and search		
terms		

Summary of your search that confirms no	
acceptable alternatives were found	

Comments

Simple title provided by the PI. Note on occasion the grant agency (e.g., NSF) requires the protocol title to be the same as the grant title.

Submission type identified by the PI

Each user will need to identify who is eligible to be a PI (e.g., a policy).

This can be expanded by the user and used to validate consistency with an institution's policy on "Who is eligible to be a PI"

This is a demographic that can be used by the institution to determine, for example, which of its administrative units are the primary user.

This is the physical location of the PI's laboratory that the IACUC can use when physical visits are necessary.

This number can be used for contacting the PI in the event of an emergency.

The email address can be used by administration as a form of identification, and electronic communications

This statement can be revised by the user. This is an assurance statement that by checking "YES" the PI provides a confirmation. The premise is that the institution will have required trainings that perhaps an IACUC administrator validates the completion by each individual listed as personnel on the protocol. In addition, specialized training on specific procedures may be performed by the PI (or skilled technicians) before any one works independently. For regulatory purposes, the checking of this statement is considered the training documentation.

This is the minimum information needed to ensure IACUC Administration can identify the individual (e.g., email address) and relative demographics. Each user may supplement this as it wishes. The animal activities each will perform was intentionally omitted since the PI is confirming their staff will be appropriately trained before performing animal activities.

This a demographic that may be needed by IACUC Administration depending on the user. It will allow administration to ensure requirements (e.g., amendments to DoD funded protocols, and compliance letters to OLAW) implemented by external funding agencies are satisfied. Each user may supplement or omit this as it wishes.

This demographic can be enhanced by the user to meet the institution's expectations. Those identified were selected due to specific regulatory requirements, and the need for IACUC Administration to have a convenient process for knowing when external reporting is required.

This statement can be revised by the user. This is an assurance statement that by checking "YES" the PI provides a confirmation. The premise is that the PI is not going to perform any activities or spend any external funding on any animal activities until they have been reviewed and approved by the IACUC. For regulatory purposes, the checking of this statement ensures protocol and grant congruency. Each institution will need to decide if additional confirmation will be required.

This is a demographic that can be used by administration to classify the focus of each protocol. For users deciding to use an electronic system to implement this template, this question can be used to identify specific questions relative to the classification the PI selected. This question can be enhanced by the user based on the institutions research portfolio for example.

The purpose of this question is to ensure IACUC Administration can identify when a PI is housing or working with animals outside of a know location, for example their laboratory. At many institutions IACUC Administration maintains a list of locations where animal activities are performed to ensure semi-annual inspections occur. At some sites, this list is simply areas within the vivarium that are managed, for example, by the Attending Veterinarian (AV). This question can be enhanced to satisfy the needs of the user.

This is a demographic that may be needed when preparing, for example, the program description for an AAALAC site visit, or determining how many IACUC members (e.g., two when USDA covered species are used) need to inspect the area. This can also be enhanced based on the user's needs.

This question identifies each species that will be used under for animal activities listed and approved on the protocol. It identifies the source of the animals. This information allows IACUC Administration to confirm all animals are being acquired form the user's approved vendors (e.g., based on a policy). It helps to ensure biosecurity (e.g., mice from a pet store are not brought into the vivarium).

This statement can be revised by the user. This is an assurance statement that by checking "YES" the PI provides a confirmation. It simply summarizes in standard language something the PI has written over the years. The premise is that the PI has selected the appropriate animal model to perform the proposed research. The PI, almost always, uses a specific animal model based on their research needs. The IACUC is always able to challenge this selection should it believe a different choice should have been made.

This question will provide PIs a series of check boxes that can be used to identify the final disposition of the animals. It includes some standard language that can be used by the PI in the form of a check box depending on the species of interest. This question can be revised based on the needs of the user.

A "yes" check to this choice allows IACUC Administration to, for example, implement internal adoption policies or ensure regulatory expectations are satisfied such as confirmation multiple survival surgeries are not performed on the same animals unless the research focus is the same.

A "yes" check to this choice allows IACUC Administration and the IACUC to ensure when animals are released back into the environment that extraneous factors (e.g., aggressiveness of a species) does not create welfare concerns.

A "yes" check prompts the IACUC to review and understand the terminal procedure that will be identified and described later in the protocol.

A "yes" check indicates mice or rats will be euthanized following a procedure that's been standardized across the IACUC Administrative Community. This statement also relies on the fact that all staff listed on the protocol are trained to use both CO2 and Isoflurane. It also relies on the fact that all staff have been trained to perform an appropriate secondary method of euthanasia. The user can enhance the question based on its needs.

A check "yes" indicates a physical method will be used to euthanize the (some of the) animals listed on the protocol. *The IACUC is always free to challenge the choice by the PI*.

A check "yes" indicates lethal injection will be used to euthanize the (some of the) animals listed on the protocol. *The IACUC is always free to challenge the choice by the PI*.

A check "yes" indicates a procedure other than one specifically listed in the protocol will be used to euthanize the (some of the) animals listed on the protocol. *The IACUC is always free to challenge the choice by the PI*.

This information gathered in this section provides the IACUC members the relevant information needed to review and approve the use of agents as part of animal activities. It also identifies whether the agents are hazardous, which allows IACUC Administration to ensure safety precautions associated with each hazard have been addressed by, for example, the IBC or Environmental Health and Safety for example. This too can be enhanced based on the needs of the user.

This statement can be revised by the user. This is an assurance statement that by checking "YES" the PI provides a confirmation. The premise is that the PI has attained clearance from the IBC, EHS or equivalent to use the identified hazardous substances. This also provides the necessary information for the IACUC Administrator to confirm. For regulatory purposes, the checking of this statement ensures a safety review occurs as required.

This information is gathered to ensure the IACUC is aware when non-pharmaceutical reagents will be used in animal activities even though pharmaceutical grades exist. The IACUC members can use this to assess the use of non-pharma agents and the appropriateness.

This question will be used to gather a brief summary of the project focus. It will not include any project details since they are described later in the form.

This statement can be revised by the user. This is an assurance statement that by checking "YES" the PI provides a confirmation. It simply summarizes in standard language information the PI has provided in text over the years. The premise is that the PI is not duplicating previously conducted research, and that the results of the project will improve the overall wellbeing of society and/or animals. The IACUC is always able to challenge this selection should it believe the research isn't achieving the expectations.

This statement can be revised by the user. This is an assurance statement that by checking "YES" the PI provides a confirmation. It simply summarizes in standard language information the PI has provided in text over the years. The premise is that the PI is conducting the research using animals because a non-animal model (e.g., cell culture or a computer simulation) cannot be used. The IACUC is always able to challenge this selection should it believe the research isn't achieving the expectations.

The IACUC should understand what each research animal will endure thought-out the course of the study. For example, "Cohort 1" will be received from a commercial, it will undergo blood draws, major survival surgery "xyz", major survival surgery "abc", It will be followed got ten weeks, euthanized and tissues will be collected. "Cohort 2"animals will undergo blood collection, followed by gavage, then undergo major survival surgery "xyz" followed for 3 weeks then euthanized and tissues will be collected. This information tells us there are two groups of animals with one group undergoing multiple survival surgery and the other gavage with only a single surgery.

This statement can be revised by the user. This is an assurance statement that by checking "YES" the PI provides a confirmation. The premise is the PI will use the minimum number of animals they need to complete the focus of the proposed research. In addition, the research data will be statistically valid. The IACUC is always free to challenge this selection should it believe the research isn't achieving the expectations.

This statement is intended to be an estimate of the animals the PI will use. It should be a logical assumption, and *the IACUC is free to challenge it at any time*.

This statement can be revised by the user. This is an assurance statement that by checking "YES" the PI provides a confirmation. The premise is that through this statement the PI agrees that the animals can be housed in accordance with the applicable federal regulations.

This statement can be revised by the user. This is an assurance statement that by checking "YES" the PI provides a confirmation. The premise is that through this statement the PI agrees that the animals can be housed in compatible groups and not singly housed unless absolutely necessary.

This section introduces the activities to be performed on the animals listed on this protocol. This statement can be revised by the user. This is an assurance statement that by checking "YES" the PI provides a confirmation. The premise is that the PI understands pain-relieving medications will be used anytime animal activities cause pain, or distress.

Checking this box signifies the PI will be performing survival surgery.

The PI will identify the surgical procedure with a specific name so that it can be referenced in other sections (e.g., the sequential description section) of the protocol form.

The PI will briefly describe how the surgery will be conducted in this question.

This question allows PIs to confirm that aseptic procedures will be followed while the surgical procedure is being conducted. Traditional aseptic technics have been defines by species and can be followed by the PI. However, should the PI decide an alternative technique be followed, they can specifically describe the procedure.

Prescribe procedures for preparing surgical devices.
The appropriate practices for performing aseptic surgical procedures in mammals.
The appropriate practices for performing aseptic procedures in birds.
The appropriate practices for performing aseptic procedures in amphibians, reptiles and fish.
This statement can be revised by the user. This is an assurance statement that by checking "YES" the PI provides a confirmation. The premise is that through this statement the PI agrees that the surgical procedure will be performed while adhering to the above applicable statements.
For the PI's information.

The medications that will be used to perform the surgery will be listed in a table as part of each surgery discussion to ensure clarity. The medications that will be used as part of post-operative care will be listed in a table as part of each surgery discussion to ensure clarity. This statement can be revised by the user. This is an assurance statement that by checking "YES" the PI provides a confirmation. The premise is that through this statement the PI agrees that all animals undergoing survival surgery will be monitored for the defined periods post-surgery. The appropriate practices for monitoring rodents post-surgery.

The appropriate practices for monitoring mammals (non-rodents) post-surgery.
The appropriate practices for monitoring birds post-surgery.
The appropriate practices for monitoring amphibians and reptiles post-surgery.
The appropriate practices for monitoring fish post-surgery.

Checking this box signifies the PI will be performing non-survival surgery. The idea is for the IACUC to understand how long an animal may be on a surgical table form initiation to "euthanasia". In extreme cases, antibiotics may be needed. The PI will identify the surgical procedure with a specific name so that it can be referenced in other sections (e.g., the sequential description section) of the protocol form. The PI will briefly describe how the surgery will be conducted in this question. This question allows PIs to confirm that aseptic procedures will be followed while the surgical procedure is being conducted. Traditional aseptic technics have been defines by species and can be followed by the PI. However, should the PI decide an alternative technique be followed, they can specifically describe the procedure. Prescribe procedures for preparing surgical devices.

The appropriate practices for performing aseptic surgical procedures in mammals. The appropriate practices for performing aseptic procedures in birds. The appropriate practices for performing aseptic procedures in amphibians, reptiles and fish. This statement can be revised by the user. This is an assurance statement that by checking "YES" the PI provides a confirmation. The premise is that through this statement the PI agrees that the surgical procedure will be performed while adhering to the above applicable statements. For the PI's information. The medications that will be used to perform the surgery will be listed in a table as part of each surgery discussion to ensure clarity.

The medications that will be used as part of post-operative care will be listed in a table as part of each surgery discussion to ensure clarity.

Checking this box signifies the PI will be performing multiple survival surgeries on a single animal.

This information will allow each IACUC member to assess the need for multiple survival surgeries on the same animal.

The PI will need to scientifically justify the reason for performing multiple survival surgeries in this question.

The PI will select this procedure when they plan to withhold or restrict an animals food as part of the research. It is intended to exclude clinical reasons such as pre-surgical fasting.

The PI will provide in table format the information needed by the IACUC to understand whether the restrictions could pose a welfare risk.

This statement can be revised by the user. This is an assurance statement that by checking "YES" the PI provides a confirmation. The premise is that as long as the animals are on food restrictions each will be monitored to include at a minimum body weights. This table will be used to define the endpoints for removing animals receiving restricted feed from the study. The IACUC can ensure this information was provided by the PI in consultation with the veterinarian, or the veterinarian can review this section during protocol review. This question will allow IACUC members to identify those animals that will undergo prolonged food deprivation (24 hours is a common practice, but can obviously be changed by each institution)

The PI will select this procedure when they plan to withhold or restrict an animals water as part of the research. It is intended to exclude clinical reasons such as pre-surgical fasting.

The PI will provide in table format the information needed by the IACUC to understand whether the restrictions could pose a welfare risk.

This statement can be revised by the user. This is an assurance statement that by checking "YES" the PI provides a confirmation. The premise is that as long as the animals are on fluid restrictions each will be monitored to include at a minimum body weights.

This table will be used to define the endpoints for removing animals receiving restricted fluid from the study. The IACUC can ensure this information was provided by the PI in consultation with the veterinarian, or the veterinarian can review this section during protocol review.

This question will allow IACUC members to identify those animals that will undergo prolonged fluid deprivation (24 hours is a common practice, but can obviously be changed by each institution)

The PI will select this box any time samples are being collected from animals.

As described, PIs will select this box when they are euthanizing animals and collecting samples.

As described, PIs will select this box when they collecting samples using non-invasive techniques.

As described, PIs will select this box when they are collecting blood from animals.

This question is intended to serve as a control to ensure the researchers understand the maximum volume of blood that can be collected from an animal in a two week period.

This question provides the research with the flexibility to use any of the specific methods of blood collection. The IACUC freely makes the assumption that only skilled researchers will be collection blood as per the training assurance provided earlier in the template.

This provides the researcher the flexibility to add any other method that may be used that wasn't previously defined.

As described, PIs will select this box when they are collecting tissue samples to satisfy any other research requirement.

As described, PIs will select this box when they are collecting tissues for genotyping.

Although a very common best practice, this can be modified by the institution depending on its tail biopsy procedure.

Although a very common best practice, this can be modified by the institution depending on its own policy for genotyping zebra fish, for example.

This provides the researcher the flexibility to add any other method that may be used that wasn't previously defined.

This provides the researcher the flexibility to add any other biopsy collections that will be used for reasons other than genotyping.

Through this information the PI provides assurance and the relevant details biopsy collections that may cause pain.

Any researcher performing behavior studies will select this box.

This statement can be revised by the user. This is an assurance statement that by checking "YES" the PI provides a confirmation. The premise is that a researcher will always be present to observe any animals undergoing behavior studies.

This question makes the assumption that a PI is aware if a proposed behavior study is going to cause more than momentary pain or distress. The only behavior studies that need to be specifically described by the PI are those intended to cause stress or distress.

This question helps the IACUC identify all behavior studies causing more that momentary pain and distress, and it encourages the PI to use pain relieving medications, or explain why they cannot be used.

The response to this question will ensure the IACUC and the PI agree on and identify conditions that would require removing an animal from the study (i.e., human endpoints).

Any researcher maintaining breeding animals will select this box.

This statement can be revised by the user. This is an assurance statement that by checking "YES" the PI provides a confirmation. The premise is that the researchers guarantee to manage their breeding animals and that breeding will only occur when research animals are absolutely necessay.

This statement can be revised by the user. This is an assurance statement that by checking "YES" the PI provides a confirmation. The premise is that the researchers guarantee to wean their animals in accordence with policy.

Any researcher working with tumor developing animals would select this box.

As described, PIs will identify how tumors are induced, for example, by phenotype or chemically induced.

Since tumors can result in the need for establishing humane endpoints, the researcher and the veterinarians can define the enpoints using this section

As described, Pis will identify the endpoints for visible tumors on mice.

As described, Pis will identify the endpoints for visible tumors on rats.

As described, Pis will identify the endpoints for visible tumors on all other species.

As described, Pis will identify the endpoints that will be observed for non-visible tumors on all species.

This sequence of questions is a catch-all for listing procedures not previously covered in the protocol template.

The PI will list the specific procedure (e.g., gavage).

The PI will list the species of animals on which it will be performed.

The PI should provide a description of how the procedure will be performed, for example, Gavage will be used to administer orally a therapeutic agent ABC to test animals. To perform gavage, the therapeutic will be loaded into a syringe, for example, a cannula or tube affixed to the syringe will be carefully placed into the esophagus of the animal and the substance will be carefully delivered directly into the animal's stomach.

This statement can be revised by the user. This is an assurance statement that by checking "No" the PI provides a confirmation. The premise is that the researchers guarantee the procedure is not painful when No is selected. The IACUC is always free to question.

This question helps the IACUC identify when a listed procedure causes more that momentary pain and distress, and it encourages the PI to use pain relieving medications, or explain why they cannot be used.

The researcher will liste each painful procedure (separately) The animals experiencing the activity The point at which an animal reaches the reasearch goal The define point at which an animal will be removed from the		
The researcher will liste each painful procedure (separately) The animals experiencing the activity The point at which an animal reaches the reasearch goal The define point at which an animal will be removed from the study	This section will be used to identify all procedures that cause more than momentary pain or distress.	
The point at which an animal reaches the reasearch goal The define point at which an animal will be removed from the	The researcher will liste each painful procedure (separately)	
The define point at which an animal will be removed from the	The animals experiencing the activity	
	The point at which an animal reaches the reasearch goal	

Confirmation that the final disposition of the affected animals will be consistent with this protocol.

Any researcher working with tumor developing animals would select this box.

The response to this question will allow the IACUC to decide whether the proposed activies are covered by the USDA.

This statement can be revised by the user. This is an assurance statement that by checking "Yes" the PI provides a confirmation. The premise is that the researchers agree that field activities will be initated only after the appropriate permints and permissions are acquired.

This information should have been previously provided, but in the event the PI jumped straight to Field Studies they will be able to provide the relevant information in this table.

This question is used by the IACUC to identify when and where wild species of animals may be housed as part of this study.

laboratory mice and rats and birds not bred for research)

E), requires a literature search to determine if other methodions: (1) could proposed painful procedures be refined/repuld the study be conducted on a less sentient species such a	laced to
Category D or E	