

# Guidelines for Completing the NIH Intramural Research Program Animal Study Proposal Form

The [Animal Welfare Act Regulations](#) (AWARs) and the [Public Health Service Policy on Humane Care and Use of Laboratory Animals](#) (PHS Policy) require review and approval of an Animal Study Proposal (ASP) by the Institute/Center (IC) Animal Care and Use Committee (ACUC) prior to the initiation of any research activity involving vertebrate animals. All regulatory and guidance documents referred to in these instructions are provided on the NIH [Office of Animal Care and Use](#) website under the [ARAC Guidelines](#), [NIH Policies](#), or [Regulations & Standards](#) subpages.

## **General Instructions**

The goal of this guideline is to help an investigator prepare an ASP that can be approved by the IC ACUC in a single round of review. The most common mistake made by investigators that leads to delay of ASP approval is the inclusion of more detail in the ASP than is required by the regulations or requested on the form. The excess detail invites questions from ACUC members which require an investigator's time to clarify and additional ACUC time to review and approve. To avoid this problem, the best advice is to seek the guidance of a senior investigator who is familiar with animal research and the ACUC, an ACUC member, and/or the IC Animal Program Director (APD) for help during the preparation of the ASP. There are many opportunities for pre-review during the development stages that ensure that the ASP submitted to the ACUC is in near final form. A well-written ASP will facilitate an efficient review and approval process allowing a timely initiation of the research activity. Additionally, some IC ACUCs invite investigators to attend the ACUC meeting to address questions, which can be helpful in streamlining the review and approval process.

Important contacts for ASP development and pre-review:

- [IC DOHS Safety and Health Specialist](#) (301-496-2960)
- IC Animal Program Director or other IC Veterinarian
- [IC ACUC Coordinator](#)

## **Section A: Administrative Data**

**Principal Investigator (PI):** A scientist designated by the Laboratory/Branch Chief or the IC Director or Scientific Director as responsible for conducting an animal study in compliance with the *Guide*, the PHS Policy, and the AWRs, and who certifies acceptance of this responsibility by signing the Animal Study Proposal. Each ASP can have only one PI. Other investigators can be listed as Key Personnel.

**Type of Submission:** Indicate whether it is an initial (new) submission, renewal (every three years) submission, or modification (such as a change in PI or other significant change) of an existing ASP. If this is not an initial submission, also enter the number of the related ASP.

Key Personnel: List all personnel who will be conducting procedures involving live animals under this ASP. All personnel listed in this section will need to undergo NIH, IC, and facility training and be enrolled in the Animal Exposure Program (AEP) or an equivalent occupational health program. Investigators not handling or conducting procedures on live animals should not be listed here.

### **Section B: Animal Requirements**

Species, Age/Weight/Size, Sex, Stock or Strain: Provide specific information regarding these characteristics for the requested animals.

Source: List all animal vendors. Rodents are generally ordered from approved vendors through the Division of Veterinary Resources (DVR) [Centralized Animal Procurement System](#) (CAPS). If rodents or rodent products are obtained from a source other than the DVR list of approved sources, an [Online Rodent Import Application](#) is required. Contact the IC APD for any questions regarding animal procurement.

Holding Location(s): Provide the proposed housing location(s) (building and room number). If it is necessary to hold animals outside of a core animal facility for more than 12 hours, this must be indicated in the ASP. Additionally, if there is a need to hold animals outside of a core animal facility for more than 24 hours, a satellite facility must be established and approved by the IC ACUC. Contact the IC APD and/or IC ACUC Coordinator for assistance with non-standard housing requests.

Animal Procedure Location(s): Provide the proposed location(s) (building and room number) for all laboratory or special animal activity spaces that will be used for live animal procedures to include surgeries, other in-vivo procedures (e.g., physiological or behavioral tests, injections, imaging, etc.), euthanasia, and tissue harvesting.

Number of Animals: Provide the total number of animals estimated and justified in Section E3 for each of the three years of the ASP. If multiple species are used, provide the numbers separately for each species. If the study is a renewal, account for any existing animals to be carried over from the previous ASP.

### **Section C: Transportation**

For ASPs involving animal transportation, include the destination and consult with the IC APD about acceptable routes and caging requirements. To ensure the security and safety of the animals and humans involved, requirements for proper transportation of animals are described in the following guidance documents:

- ARAC [Guidelines for NIH Rodent Transportation](#)
- ARAC [Guidelines for NIH Non-Rodent Transportation](#)
- [Research Animal Transport for the NIH Clinical Center](#)

### **Section D: Study Objectives**

Include a brief (e.g., 300-word) non-scientific summary of the research objectives. The summary should explain why the work is important and how the results of the study might benefit humans

and/or animals. Abbreviations, technical terms, and scientific jargon should be minimized. The section should be easily understood by the nonscientist and nonaffiliated members of the ACUC. If the ASP is a renewal, also provide a summary of the work completed in the past three years.

### **Section E: Rationale for Animal Use**

- 1) **Animal Model:** Explain why an animal model is necessary for this study as opposed to cell cultures, computer simulations, or other non-animal models.

Examples:

- *This study depends on complex behavioral activities that require a functioning animal with a highly developed nervous system with multiple cell types and a complex multicellular architecture. Cell culture systems are usually composed of a single type of cell that have no multicellular arrangements and can be used to model nervous system function.*
- *The investigation of the effects of anterior hypothalamic lesions on immune responses can only be performed on living organisms with both a well-developed and intact nervous system and an immune system.*
- *Living animal cells are necessary to study the translation of exogenous mRNAs. Oocytes have been used very successfully for these types of studies and are superior to extracts of cultured cells.*

- 2) **Appropriateness of Species:** Describe why the selected species is essential for the proposed study as opposed to a lower order vertebrate or an invertebrate. If multiple species are listed, a justification is required for each.

Example:

- *This research will examine the genetics of mammary tumors. Zebrafish strains with mutations in some of the genes of interest have been identified but cannot be used for the study of mammary tumors. In addition, few human or mouse mammary tumors can be grown in tissue culture, making the mouse the ideal organism for generating primary mammary tumors.*

- 3) **Estimated Number of Animals:** Provide an estimate of the minimum number of animals required to accomplish the research goals. An outline, a table, or a flow chart for each strain listed can be very helpful in presenting this information. Whenever possible, the number of animals and experimental group sizes should be statistically justified. For new experimental paradigms or pilot studies, a flow chart or table may be sufficient. If rodents are to be used for breeding, the following categories can be used in justifying and estimating animal numbers:

- an estimate of the numbers of progeny intended for experimental use,
- an estimate of the progeny expected,

- the numbers used for breeding (including founders and initial mates),
- the numbers of progeny needed for continuation of the experimental line, and
- the numbers that will be euthanized due to undesirable genotype.

Please note that offspring are counted at first cage change or manipulation, whichever comes first.

If the study represents a new animal model, drug or procedure, a statistical analysis may not be appropriate. If the study is a continuation of ongoing work (3-year renewal) or parallels current or previous experiments where the magnitude of the effects and the degree of variance is known, then a short summary of statistical principles that were applied to arrive at the group size(s) may be appropriate.

When the use of animals is for the harvesting of normal tissues, organs or fluids for *in vitro* use or *in vivo* transfer, briefly cite expected usage levels to provide the quantity of tissues or fluids needed for the study. If no prior experience is available, state an anticipated tissue/fluid harvest per animal with a description of the process.

Examples:

- *We estimate that we need to request 200 animals for this study because we will be using five (5) animals per group and examining the effects of five (5) compounds (including vehicle), at four (4) doses of drug per compound, with two (2) replications (to assure reproducibility), per determination. Past experience and review of referenced publications (specify) have shown that a group size of 5 provides reasonable assurance of statistical power for this type of study, however if our initial experiments justify a larger or smaller sample size, we will amend our ASP. The total numbers requested will be:  $5 \times 5 \times 4 \times 2 = 200$ .*
- *In our experience, 10 rats are required to generate enough cells for one experiment. Since we plan to conduct one experiment per week, we need 520 rats per year. This number of animals will enable us to test 10 drugs at the desired dosage.*
- *We estimate that 100 homozygous mutant animals will be needed to obtain valid results. These animals will be divided into three groups of 15 receiving different doses of the drug, along with 5 untreated controls and parallel groups of wild type animals given the same dosages in two experiments. From our initial founder animals (~3) we will obtain ~10 heterozygous animals along with 10 wild type animals we will use as controls. We will cross heterozygotes to generate ~50 litters of 8 animals each, which should contain 100 homozygous animals if they are born in the expected ratio. [If we find that this breeding scheme does not generate the required number of animals, we will submit an amendment describing the new breeding scheme.] Estimated number of animals: 3 founders + 3 wild type mates (6) to generate 20 F1 progeny, including 10 heterozygotes for breeding. These will be mated and expanded to generate 400 mice of which we estimate that ~100 will be homozygous mutants for our studies. The*

remainder will be used as controls or for continued breeding or euthanized. Total:  $6+20+400 = 426$ .

- *ENU at the dose we have proposed causes mutations in approximately 1 locus out of 1000 loci. Therefore, 1 in every 1000 gametes from a mutagenized male might be expected to carry a mutation in a gene of interest. Based on the frequency of mutations, the following number of animals per year is anticipated:*
  - *60 BALB/c males (G0) to be mutagenized in 3 sets of 20. Based on previous experience, we expect that 6/20 mutagenized males will regain fertility after ENU treatment. The fertile males will be mated to 3 C57BL/6J females each to generate 3 litters averaging 8 pups per litter. 6 males x 2 females (one female is used twice) x 8 pups/litter x 3 litters = 192 G1 x 3 ENU treatments/year = 571 G1 progeny, 50% male and 50% female. ~288 G1 females will be discarded. ~250 G1 males will be crossed to 3 C57BL/6 females = 750 litters at 8 pups/litter = 6,000 pups to be screened for dominant mutations. Sperm and tissues from all G1 males will be cryopreserved and archived for sequencing and later mutation retrieval. 60 treated males + 36 C57BL/6 females + 576 G1 progeny = 672 mice. 250 G1 matings generates 6000 mice for screening. Total Mice = 6672*

- 4) Justification for Use of Only One Sex: If applicable, justify why the study uses only animals of the same sex in all experimental groups.

#### **Section F: Experimental Design and Animal Procedures**

Provide a clear description of the experimental design and animal procedures. The description should allow the IC ACUC to understand the experimental course of an animal from its entry into the experiment to the endpoint of the study. The use of flow charts and tables for more complicated experimental paradigms is often an effective way to present this information.

- 1) Injections, Inoculations or Instillations: List all substances administered (other than anesthesia/analgesia) with the requested information (name, dose, volume, concentration, route, diluent, schedule, grade, etc.). The use of non-pharmaceutical grade compounds should be described in accordance with the ARAC [Guidelines for the Use of Non-Pharmaceutical Grade Compounds in Laboratory Animals](#).
- 2) Blood Withdrawals: Indicate collection site, frequency, and volume collected. Please refer to the ARAC [Guidelines for Blood Collection in Mice and Rats](#) for more information.
- 3) Non-Survival Surgical Procedures: Include details on any non-survival surgical procedures. Provide details of survival surgical procedures (both major and minor) in Section G.
- 4) Radiation/Hazardous Agents: Describe any hazardous agents used in Section K; include anticipated effects on animals and safety concerns for personnel encountering the animals in Section M.

- 5) Methods of Restraint: All restraint, other than that used for routine procedures, should be described. If prolonged restraint is required, describe: 1) the purpose of the restraint and its duration, 2) where appropriate, the adaptation training and schedule if compatible with the research objectives of the restraint, 3) frequency of monitoring while in the restraint device, 4) criteria for removal from the device and/or the study if adaptation is not achieved, and 5) consideration of alternatives. Note that alternative restraint methods might include chemical restraint, which should be listed in Section I.
- 6) Animal Identification Methods: Describe any methods used to identify animals (i.e., ear tags, tattoos, etc.).
- 7) Other Procedures:

**Behavior Tests**: Describe how each test is conducted, how the test is necessary to meet the aims of the study, whether the test is conducted once or multiple times within the same session, the interval between tests or sessions, whether the test or session will be grouped or conducted in parallel with other tests which may involve pain and/or distress, and the test endpoints. If the behavior test involves pain and/or distress, also describe: the nature and magnitude of the stimulus invoking the pain and/or distress and its control, how much the pain and/or distress the test will cause the animal to experience, measures implemented to mitigate or end the pain and/or distress, and the length of time the animal will be subjected to the painful and/or distressful portion of the test.

Please refer to the [ARAC Guidelines](#) for information on other animal procedures.

- 8) Potentially Painful or Distressful Effects: If animals are expected to experience pain or distress without alleviation with an appropriate anesthetic, analgesic, or tranquilizer, a description of the procedure(s) producing pain and/or distress, and a scientific justification explaining why pain and/or distress cannot be relieved must be provided in this section. Please refer to the [ARAC Guidelines for Pain and Distress in Laboratory Animals: Responsibilities, Recognition, and Intervention](#) for more information.
- 9) Endpoint Criteria: Provide an experimental endpoint such as a timeline or clinical condition (e.g., a 1 cm tumor) that will signal the study endpoint. In studies where adverse outcomes or complications might be expected, humane alternative endpoints should also be described. A humane endpoint is the earliest scientifically justified point at which pain or distress in an experimental animal can be prevented, terminated, or relieved, while meeting the scientific aims and objectives of the study. Such endpoints are preferable to death or moribundity since they minimize pain and distress. The effective implementation of endpoints requires properly trained and qualified individuals to perform both general and study-specific observations on research animals at appropriate time points. The assessment criteria and required response must be clearly defined within the ASP, and the use of study-specific animal assessment records should be considered. For all studies, death as an experimental

endpoint should be minimized and must be scientifically justified. Please refer to the ARAC [Guidelines for Endpoints in Animal Study Proposals](#) for further details on setting appropriate endpoints.

### **Section G: Survival Surgery**

All survival surgery, major and minor, is to be described in this section. Non-survival surgery is to be described in Section F. Consultation with the IC APD or other IC Veterinarian is recommended for all ASPs involving surgical procedures.

- 1) Surgical Procedures and Aseptic Methods: Sterile instruments and aseptic technique are required for ALL species (e.g., rodents, rabbits, dogs, etc.). Describe surgical preparations including pre-operative medications and/or hair clipping and skin disinfection procedures. Describe intraoperative support procedures for the animal, i.e., methods for maintaining body temperature, and methods for assessing depth of anesthesia (e.g., heart rate, respiration rate, etc.). Describe methods of instrument sterilization for the initial surgery and (for rodents) between surgeries, i.e., cold sterilant, hot beads, etc.
- 2) Surgeon's Qualifications: Provide the names of all individuals performing animal surgery and describe their qualifications to perform the specific procedures listed in terms of related training and experience.
- 3) Location: Specify the building and room number where survival surgeries will be performed.
- 4) Post-Operative Care: Describe supportive therapy that is required (e.g., supplemental heat source, I.V. fluids, etc.). In addition, describe longer term post-operative care needs such as analgesia, suture/staple removal, catheter flushing, etc., that accompanies the surgical procedure(s).
- 5) Prior Surgery/Multiple Survival Surgeries: Indicate whether animals have experienced survival surgery prior to this study and whether more than one survival surgery is planned for a single animal. If more than one operative procedure is to be performed on a single animal, the need for multiple procedures usually constitutes related components of a single experimental paradigm which must be justified in this section.

Please refer to the ARAC [Guidelines for Survival Rodent Surgery](#) for more information.

### **Section H: Pain and Distress Column**

The USDA/NIH requires all animals used in research be assigned to one of three categories of pain and/or distress:

- Column C: Minimal, transient, or no pain or distress. Examples of these procedures include: blood collection, fluid administration, gastric gavage, and use of sedation for restraint purposes.
- Column D: Pain or distress relieved by anesthesia, analgesia, sedatives, or tranquilizers.

Examples of such procedures include: surgery (survival and non-survival), implantation of devices, and intra-cardiac blood collection.

- Column E: Unrelieved pain or distress. Examples of procedures and models often categorized as Column E include: electroshock that induces seizure activity, sepsis, heart failure, and chronic inflammation. In addition to such procedures, studies that use moribundity or mortality (death) as an endpoint must also classify these animals in Category E.

Note: Animal numbers listed in Sections B, E3, and H should match.

For animals in Columns D or E, a literature search of at least two different databases must be performed to identify any alternative procedures that are less painful. This requirement can be met by searching databases such as MEDLINE, AGRICOLA or ALTWEB. The written narrative of the database search should contain the databases searched, the date of the search, the years covered by the search, and the keywords and/or search strategy used. The results of the search should be summarized. The [NIH library staff](#) can provide information on appropriate key words and databases to use depending on the area of research.

Please refer to the following ARAC guidance documents for more information and examples:

- [Guidelines for Preparing USDA Annual Reports and Assigning USDA Reporting Columns](#)
- [Guidelines for Pain and Distress in Laboratory Animals: Responsibilities, Recognition, and Intervention](#)

### **Section I: Anesthesia, Analgesia, Tranquilization**

Include the following details on any anesthesia, analgesia, or tranquilization used in the ASP: name of drug, dose, route of administration, and frequency of administration. The type and dose must be appropriate for both the species being used and the type of pain or distress being prevented/relieved. Doses and routes of administration should be clearly appropriate and effective, i.e., commonly accepted or formulary doses. If agents are to be given as needed, a brief description of the indications for administration should be provided, e.g., "at the first indication of discomfort as evidenced by lethargy, anorexia, hunched posture, eye squinting, or vocalization".

The compounds used must be pharmaceutical grade or justified in accordance with the ARAC [Guidelines for the Use of Non-Pharmaceutical Grade Compounds in Laboratory Animals](#).

Consultation with the IC APD or other IC Veterinarian is recommended for ASPs involving anesthesia, analgesia, or tranquilization.

### **Section J: Method of Euthanasia**

Indicate the method(s) of euthanasia that will be used. If chemical agents are used, also include the dose and route of administration.



Please refer to the following guidance documents for more information:

- ARAC [Guidelines for Euthanasia of Rodents Using Carbon Dioxide](#)
- ARAC [Guidelines for Use of Zebrafish in the NIH Intramural Research Program](#)
- [AVMA Guidelines for the Euthanasia of Animals: 2020 Edition](#)

Methods which are not consistent with the recommendations in the *AVMA Guidelines for the Euthanasia of Animals: 2020 Edition*, must also be scientifically justified.

Animal carcasses that have NOT been contaminated with hazardous agents are to be disposed of as Medical Pathological Waste (MPW) in accordance with NIH Office of Research Facilities Development and Operations, [Division of Environmental Protection waste management guidelines](#). Please consult with the IC ACUC Coordinator or IC APD for IC-specific procedures. Disposal of contaminated carcasses should be described in Section K.

### **Section K: Hazardous Agents**

Your ACUC Chairperson or Coordinator can refer you to your ACUC assigned DOHS Health and Safety Specialist for assistance in describing the use of Hazardous Agents in animal research. Contacting the DOHS Health and Safety Specialist early in the ASP development phase is imperative as the use of hazardous agents requires the signature of the Safety representative(s) before an ASP can be approved. The description of the agents on the form defines the biosafety level for the ASP. The disposal of carcasses contaminated with Hazardous Agents should be described here as well.

Ionizing/non-ionizing Radiation: Identify radioactive isotopes and other ionizing radiation sources used *in vivo*. A Division of Radiation Safety (DRS) Health Physicist signature is required. Contact DRS at: 301-496-5774 for additional information.

Biological Agents with Pathogenic Potential: List all human pathogens and other pathogens of concern; human blood, body fluids, or tissues; biological toxins; and the blood, tissues, or body fluids of old-world non-human primate (NHP) species. A Pathogen Registration Document (PRD) must be [filed with the DOHS](#) for the use of these biological agents. Identify the PRD number.

Recombinant DNA: Identify any nonexempt Recombinant DNA used *in vivo* e.g. constructs used for development of transgenic or knock-out animal models. A recombinant [DNA registration document](#) (RD) must be filed with and approved by the [NIH Institutional Biosafety Committee](#) prior to initiation of the study; unless the recombinant rDNA qualifies for registration simultaneous with initiation, e.g. ABSL-1 constructs. Verify rDNA requirements with the NIH IBC or refer to the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.

Hazardous Chemicals or Drugs: List any hazardous chemicals or drugs (carcinogens, mutagens, formaldehyde, inhalant anesthetics, etc.). All known carcinogen, mutagens, teratogens, other hazardous chemicals, and potentially hazardous novel compounds are listed in Section K or

Hazardous Materials Section within the ASP by the IC Safety Specialist with safety language to communicate how to prepare, administer, and dispose of the chemical hazards. The specialist may use various resources such as Safety Data Sheets (SDSs) and consultation with other specialists to determine if a chemical is hazardous.

**NOTE:** All PIs working with human pathogens and other pathogens of concern; human blood, body fluids, or tissues; biological toxins; and the blood, tissues, or body fluids of old-world non-human primate (NHP) species, must submit a registration document to the NIH Biosafety Officer for subsequent review by the NIH Institutional Biosafety Committee (IBC). Investigators handling *tissues or body fluids* from Old-World nonhuman primate (NHP) species (i.e., Rhesus, Pigtails, and Cynomolgus Macaques, Baboons, African Green Monkeys, etc.) outside of an *ACUC-approved NHP animal research facility*, are required to register their work and experimental use of these materials with the NIH IBC via a [Pathogen Registration Document \(PRD\)](#). Further details are provided in [PM 3044-2 Protection of NIH Personnel Who Work With Nonhuman Primates](#).

### **Section L: Biological Material/Animal Products for Use in Animals**

Biological material and animal products such as cell lines, tissues, and tumors that are introduced into research animals can harbor animal pathogens (e.g., ectromelia, lymphocytic choriomeningitis, and mouse hepatitis) which can then infect NIH animal colonies. IC ACUC approval is required prior to introducing any rodent, rodent product, or biological material that originates from sources other than those approved by the Division of Veterinary Resources (DVR). Refer to [NIH Policy Manual 3043-1, Introduction of Rodents and Rodent Products](#) for additional information.

It is the PI's responsibility to ensure that the biologic materials used in their study will not endanger the health of the animals used in their study or other animals housed in the animal facility.

If applicable, provide a description of the materials or products to be used, the tests performed, and a certification that the materials or products can be used safely in the animal facility. Documentation of the testing should be submitted as an attachment. Contact the IC APD for more information about the required testing.

### **Section M: Special Concerns or Requirements**

List any items or procedures that may require special care or attention by either the PI or the animal facility during the study. Include procedures that may adversely affect the animals, how those effects will be detected, and the actions that will be taken to support the animals and to minimize pain or distress.

Information regarding animals that may require special care due to surgical alterations (e.g., splenectomy, adrenalectomy, etc.) or genetic manipulations (e.g., adverse phenotypes) should be recorded.

List any unusual requirements that the facility management may need to consider, including specialized housing, lighting, feed, water, or a need for other than routine veterinary care.

Justification for single housing and exceptions to standard environmental enrichment should also be included in this section.

#### **Section N: Principal Investigator Certifications**

All ASP forms must be signed by the PI. The signature of the PI in this section certifies the following:

- 1) That the PI has completed the NIH OACU course [Using Animal in Intramural Research: Guidelines for Principal Investigators](#) and will complete required refresher training triennially.
- 2) That the proposed research is not unnecessarily duplicative of previous research.
- 3) That all individuals working on the proposal who have animal contact are participating in the NIH Animal Exposure Program (or equivalent program, for contract personnel).
- 4) That the individuals listed in Section A are authorized to conduct procedures involving animals under this proposal, have completed the course [Using Animals in Intramural Research: Guidelines for Animal Users](#), will complete triennial refresher training as required, and have 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. That the PI is responsible for the professional conduct of all personnel listed in Section A.
- 5) That for all Column D and E procedures, the PI has reviewed the pertinent scientific literature and the sources and/or databases (2 or more) as noted in Section H and have found no valid alternative to any procedures described which may cause more than momentary pain or distress, whether it is relieved or not.
- 6) That the PI will obtain approval from the IC ACUC before initiating any changes to the study.

#### **Section O: Concurrences**

It is the responsibility of the PI to obtain the signature of the Laboratory/Branch Chief. ASPs originating from a Laboratory/Branch Chief require the concurring signature of the Scientific Director. This signature is a certification of review and approval based on scientific merit and sex as a biological variable.

The signatures of the DOHS Health and Safety Specialist, Facility Manger, Facility Veterinarian, Attending Veterinarian, etc., must also be obtained prior to ASP approval. Contact the IC ACUC Coordinator for IC-specific procedures for signature collection.

Signatures from the facility staff certify they have reviewed the ASP and have the infrastructure and veterinary care resources/information to support the ASP. Approval is not withheld or delayed for other reasons. If the facility staff have questions outside of the areas of infrastructure and veterinary care, those questions must be presented in writing to the IC ACUC Chair.

**Section P: Final Approval**

The IC ACUC Chairperson has authority for final approval of the ASP.

Please note: Once an ASP is approved, it is subject to release under the Freedom of Information Act (FOIA). NIH would withhold any information that is exempt from disclosure under the FOIA in consultation with the NIH FOIA office.

Revised and approved by ARAC as a *useful document*: 04/09/2003, 08/10/2005, 07/12/2006

Approved as an ARAC Guideline: 12/18/2007

Revised: 07/11/2012; 04/09/2014; 02/22/2017; 09/22/2021