

# Advancing Community Engagement by Using a Universal Protocol Template (UPT)

Webinar

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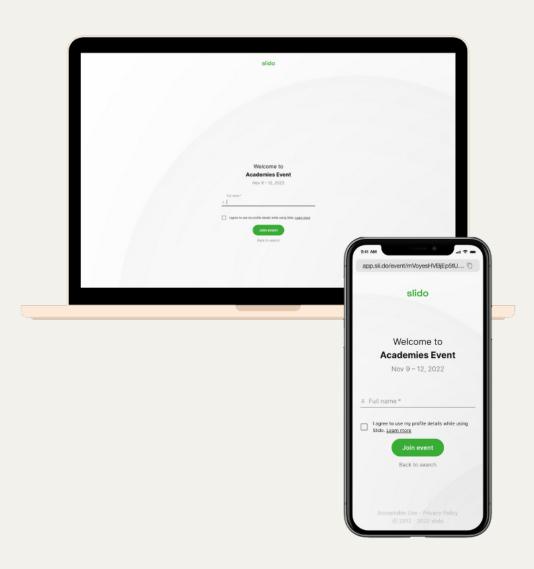
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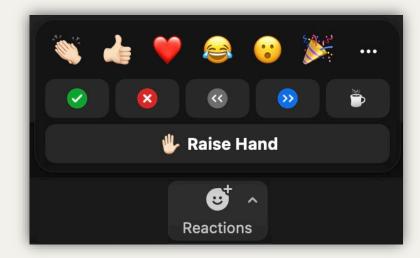
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Sciences Engineering Medicine

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We marshal knowledge and expertise across disciplines to study complex and sometimes contentious issues, reach consensus based on the evidence, and identify the best path forward.

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This webinar is hosted by The Roundtable on Science and Welfare of Animals in Research, and the Roundtable is supported by:

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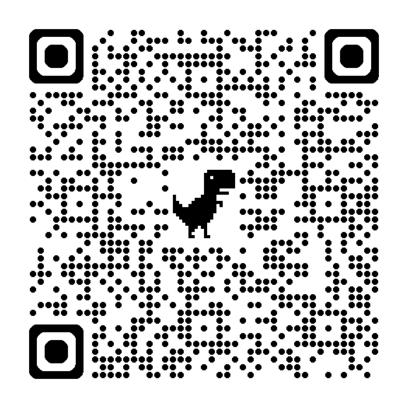
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Compliance Unit Standard Procedures

FDP member institutions are invited to join.

Email cusphelpdesk@thefdp.org.

Not sure if you're an FDP Member? Check here >

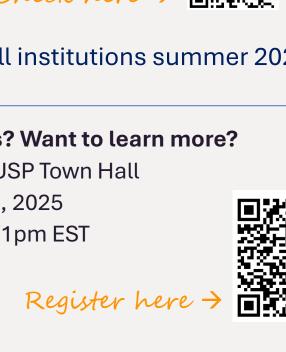


Open to all institutions summer 2025.

**Questions? Want to learn more?** 

Join the CUSP Town Hall February 6, 2025 10am PST/1pm EST







## Introductions

 Ron Banks, IACUC Administrators Association Faculty and Consultant

2. **Bill Greer**, IACUC Administrators Association Faculty and the University of Michigan

# Today's Goals

- 1. Disclaimers
- 2. The Researcher
- 3. A Historical Review
- 4. "A Tale of Two Protocol Forms"
- 5. The UPT
- 6. What's included and why



## **Disclaimers**

1. I understand that I'll likely never convince you to change your institution's form, and that's okay. My goal is simply to show you that the UPT can meet all regulatory requirements while maintaining compliance. At its core, a service unit like the IACUC should focus on serving researchers, allowing them to concentrate on conducting their research without unnecessary administrative burdens.

2. To truly appreciate this idea, I encourage you to think beyond the limitations of your current processes. Instead of focusing on why this approach might not work at your institution, consider how it *could* work to enhance efficiency, reduce complexity, and better align with the mission of supporting research."



## Disclaimer

The UPT is not formally endorsed by any organization, including the IACUC Administrators Association, the Department of Defense (DoD), the Department of Veterans Affairs (VA), the Office of Laboratory Animal Welfare (OLAW), or the United States Department of Agriculture (USDA). Instead, it is a product of the IACUC administrative community, developed through collaborative efforts and discussions during IACUC Administrators Best Practice Meetings, Federal Demonstration Partnership Subcommittee Meetings, and working group meetings that regularly involved representatives from OLAW, the VA, and the USDA.



## Final Disclaimer

The UPT, although developed with the idea of universal use, serves as a sample IACUC protocol form and represents a consensus-driven resource designed to meet the minimum regulatory requirements of both the AWARs and the PHS Policy. While not mandated or endorsed, the use of the UPT—such as by Great Eastern University—has been assessed to align with regulatory standards, ensuring compliance during reviews by those involved in its development.

## Introducing Great Eastern University

Everything happens there!!





A fictitious institution, it doesn't exist and nope I've never been there, but it is PHS Assured, Registered with the USDA and it's even AAALAC Accredited.

## The Researcher

Researchers are the ACUP primary stakeholders. Without researchers:

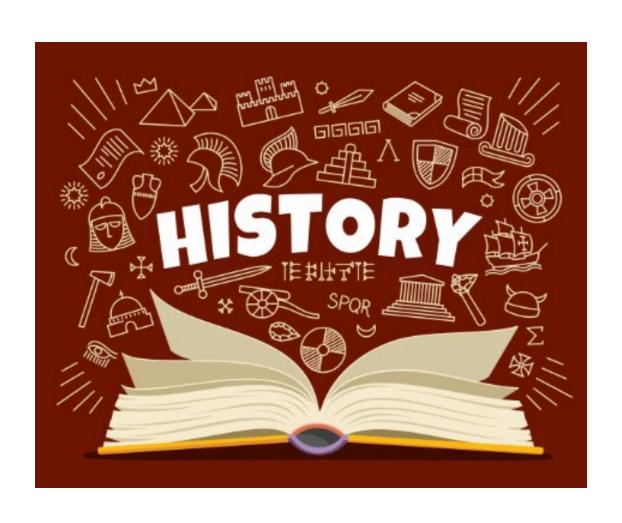
- 1. No protocols requiring compliance oversight.
- 2. No animals requiring veterinary care.
- 3. No need to ensure adherence to laws governing animal use.

These points highlight that the roles of compliance staff, veterinarians, and institutional administrators exist to support the research enterprise. Without researchers, these roles—and the ACUP itself—would not be necessary. Therefore, successful and efficient programs fostering a culture where researchers are fully engaged in program expectations and trusted collaborators in achieving shared goals.



By embracing this culture, we empower researchers to work alongside ACUP staff to operate a goal-oriented program that prioritizes animal welfare and wellbeing, while also facilitating impactful research. This research advances knowledge and contributes to the wellbeing of both humans and animals, underscoring the vital partnership between researchers and program stakeholders.

# A Historical Prospective



## It started with a thought!

1. Regulatory burden; not a barrier to innovation. Compliance and simplicity coexist seamlessly.

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4. Researchers focus on tl together they achieve a

5. It's a dream—but one



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# It started with a thought!

- 1. Regulatory burden; not a barrier to innovation. Compliance and simplicity coexist seamlessly.
- 2. A clear, concise, and intuitive protocol form. Easy to fill out, straightforward to review, and contains only the information needed for the IACUC to fulfill its duties.
- 3. The form has no regulatory gaps or compliance failures. The entire community (including researchers and regulators) is confident the document is effective and efficient and meets the requirements.
- 4. Researchers focus on their science, administrators focus on facilitating ethical oversight, and together they achieve a balance where compliance is achieved, and progress thrives.
- 5. It's a dream—but one that can be made a reality, starting with a single, simple form.

# What are the benefits to be gained?

### Several core values in adopting a common protocol template form.

- 1. Ensures regulatory compliance and provides confidence that only the required information is collected. This consistency reassures both institutions and regulators that the form aligns with ethical and legal expectations.
- 2. A common form fosters collaboration between institutions. When organizations collaborate, they and their IACUCs know that they are using the same streamlined form for the protocol review and approval processes.
- 3. Using a standard form streamlines IACUC review by focusing solely on essential information, reducing regulatory burden and avoiding unnecessary requests for extraneous details.
- 4. It's a balance model that meets regulatory requirements and minimizes administrative fatigue.
- 5. It reflects the IACUC community's commitment to supporting both research and ethical oversight in the most efficient and effective way possible.





# Quick Introduction of the IAA and IACUC Administrators Best Practice Meetings

We are in our 25<sup>th</sup> year!!

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We asserve in the soversight. Our roles as challenges several, but we have a common thread – humane care and compassionate use of animals in an appropriate regulatory environment!

2. To get the miside scoop' on new ideas at the Best Practice meetings.

2. To have access to previous Best Practice





Questions? E-mail IAA.



AA The IACUC Administrators

About IAA

Join IAA

Meetings

Resources

Contact



Network with other administrators. Share successful procedures and practices. Keep current on changes in laws, regulations and policies, and other professional standards.

#### Who We Are

We are a society of professionals who serve in the trenches of animal care & use oversight. Our roles are many and our challenges several, but we have a common thread – humane care and compassionate use of animals in an appropriate regulatory environment!

#### Why Join IAA?

- To network with other IACUC Administrators who are dealing with issues similar to yours.
- 2. To get the 'inside scoop' on new ideas at the Best Practice meetings.
- 2. To have access to previous Best Practice

#### Our Next Meeting...





## What is the IACUC Administrators Association?

- It serves as a "professional home" for IACUC Administrators
- Overall, IAA ensures well-rounded professional development opportunities for individuals at various stages of their careers in IACUC administration, equipping them with the expertise needed to effectively navigate the complexities of the field. It facilitates opportunities for administrators to network and communicate, discuss programmatic issues, and to discover, develop and implement successful plans/best practices.
- It serves as a hub for knowledge exchange and networking. Faculty focus on understanding applicable regulations, maintaining compliant animal care and use programs, and developing effective and efficient practices for program management.





# IAA's first attempt at an UPT; No Never! (2006-7ish)

#### Upon first consideration:

- 1. The IACUC administrative community explored the idea of developing a UPT that would be used across institutions, simplifying processes and fostering consistency.
- 2. Institutions were deeply attached to their own forms. They were convinced that their unique research needs required equally unique protocols.
- 3. This reluctance to look beyond their forms led the concept to fade, disappearing quietly with the sunset.
- 4. As the community evolved and embraced a stronger spirit of collaboration, the idea of a UPT began to rise.
- 5. Strengthened by a shared vision and a renewed focus on reducing administrative burden, the community found itself ready to reimagine what was once deemed impossible, **but an unconscious bias remained**.



## Reconsiderations...

- 1. All animal using institutions follow the same federal regulations, but the protocol forms used can differ significantly.
- 2. A common misconception is that these differences are necessary because institutions have unique research portfolios—such as food and fiber studies or biomedical studies.
- 3. The information required in a protocol is consistent across institutions because the regulations dictate the same core elements. For example:
  - a. All must include a justification for the number of animals used (per the Animal Welfare Act and PHS Policy),
  - b. A description of procedures to minimize pain and distress, and
  - c. Personnel qualifications and training (outlined in USDA regulations and OLAW guidance).
- 4. Regardless of research focus, these foundational details are universal, demonstrating that protocol forms could be more standardized without compromising compliance.

## The push that was needed

## Statement on the Evolution of Federal Research Regulations

- 1. The debate over the balance between effective oversight and over-regulation in research compliance has spanned multiple presidential administrations.
- 2. President Obama acknowledged growing concerns from the research community that the landscape of compliance was overly burdensome.
- 3. In response, the **21st Century Cures Act** was signed into law in December 2016. This legislation aimed to accelerate medical innovation by reducing administrative barriers while maintaining ethical and regulatory standards.

## Continued momentum

- 1. President Trump implemented the Cures Act, but he also introduced a bold policy requiring federal agencies to eliminate two regulations for every new one enacted.
- 2. This "two-for-one" rule prioritized deregulation and aimed to regulatory requirements.
- This effort was designed to reduce administrative fatigue for researchers and compliance administrators, promoting efficiency while maintaining accountability.

## м

## All Aboard

### Federal Interest with a little "Cures Act" arm twist...

- 1. The UPT initiative gained momentum caught attention of key federal agencies, including the USDA, and OLAW.
- 2. These agencies saw that the UPT had the potential to minimize redundancy in submissions, improve clarity for researchers, and enhance oversight across institutions.
- 3. With the Cures Act, aiming to reduce administrative burden, emerging as a driving force. Federal agencies express interest in collaborating.
- 4. A partnership with Federal Demonstration Partnership (FDP) was formalized, and a dedicated subcommittee was formed to formalize the UPT.



## **Development Through Collaboration**

- 1. Through the FDP subcommittee the form was reanalyzed by IACUC administrators, researchers, federal representatives, and compliance experts. The desired goal was to further formalize the UPT.
- 2. The team approached the process systematically. It was broken into core sections such as project justification, animal care details, and personnel qualifications.
- 3. Some adjustments were made with an emphasis on clarity, usability, and flexibility.
- 4. Development was hindered by the *unconscious bias* that everyone on the development committee "still" believed their protocol form was the "one and only".



## UPT attention lessened...

- 1. President Biden shifted focus from aggressive deregulation and concentrated on other priorities, resulting in a diminished emphasis on the Cures Act.
- 2. FDP subcommittee members were unable to agree on an acceptable outcome and they insisted additional information was required. Finalizing the UPT was left to IAA.
- 3. Although the project did have federal involvement under the 21<sup>st</sup> Cures Act initiative without that pressure requirement federal agencies chose to withdraw from further development. They too have shifted the responsibility of finalizing the UPT to IAA.
- 4. Note: The federal 21st CCA committee has not had a change in mission or responsibility to carry out the initial congressional mandate under Section 2034(2) of the Act. Although there may be less pressure on development of the UPT, the original directive to the federal partners is still in place and active.

# Trump is back on the political stage ...

1. The conversation of reducing regulatory burden is once again center stage. Trump is proposing that for every new regulation at least ten must be eliminated.

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- 3. The resear deregulati research is

The opportunity for the IACUC Administrative Community is still "Alive and Well"

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# Trump is back on the political stage ...

- 1. The conversation of reducing regulatory burden is once again center stage. Trump is proposing that for every new regulation at least **ten** must be eliminated.
- 2. This announcement sparks both anticipation and uncertainty. While the potential for reducing administrative burden is significant, the challenge lies in ensuring that ethical standards and compliance frameworks remain robust amidst sweeping changes.
- 3. The research community is bracing for what could be a transformative period of deregulation under Trump's leadership, with the potential to profoundly reshape how research is conducted and governed in the United States.

## What does the UPT look like?



# Let's talk about the UPT

- 1. Standardized to collect the information needed to review and approve animal use activities.
- 2. Designed to align with federal regulations ensuring compliance while minimizing complexity.
- 3. Streamline the submission and review process by including only the minimum information necessary:
  - a. Project justification and objectives.
  - b. Description of procedures and methods to minimize animal pain and distress.
  - c. Animal species, numbers, and rationale for their use.
- 4. Designed for use across diverse research institutions.
- 5. Promotes consistency, reduces administrative burden, and facilitates collaboration.
- 6. A common and thorough framework that ensures IACUCs operate "on the same page," enhancing both efficiency and regulatory confidence.



- 1. It was the best of protocols; it was the worst of protocols.
- 2. Two contrasting approaches to IACUC protocol forms emerged, each driven by a shared goal: to uphold the ethical and regulatory standards of animal research.
- 3. Yet, their paths diverged dramatically in how they sought to achieve this balance.

# The first: A Fortress of Over-Regulation

- 1. The first form was towering with detail, built with the unwavering belief that more is always better. Every possible question was asked, and every conceivable scenario was accounted for, ensuring compliance beyond a reasonable doubt.
- 2. Researchers faced a time-consuming process, navigating numerous pages to answer questions that seemed redundant or irrelevant.
- 3. Administrators valued the thorough review, researchers were frustrated by time spent on compliance instead of science.
- 4. The IACUCs over-emphasis provided reassurance, addressing every risk and contingency. However, it came at a cost: researcher fatigue, strained relationships with stakeholders, and a system that, while safeguarding against criticism, hindered progress and collaboration.



## The second: The Goldilocks Protocol?

- 1. The second form embraced a different philosophy—the Goldilocks Theory. It was "just right," containing only the essential regulatory information needed to ensure a thorough review without unnecessary complexity.
- 2. The form was streamlined, focusing on clarity and efficiency. It asked what was required by federal regulations and what was necessary for the IACUC to assess animal activities.
- 3. Researchers valued the streamlined process, which let them focus more on their work while upholding compliance. The IACUC, with a more focused and efficient review, strengthened engagement with researchers and enhanced oversight.
- 4. This balance created an environment of trust and collaboration. The form wasn't a barrier but a bridge—a tool that facilitated research while ensuring the ethical treatment of animals.



# A Tale of Reflection

- 1. The forms represent more than just contrasting approaches—they symbolize a fundamental debate in research compliance. Is it better to overregulate and ensure absolute certainty at the cost of efficiency and goodwill? Or to aim for balance, acknowledging that regulatory compliance doesn't have to be burdensome to be effective?
- 2. In the end, the tale of these two IACUC protocols serves as a reminder: the ideal lies not in extremes but in finding a middle ground where ethics, compliance, and research progress coexist. It challenges us to ask, "What is just right for us?" and to have the courage to embrace that answer.

# For example,

#### The Goal:

- 1. Determine whether the procedure impacts animal welfare.
- 2. If so, has the impact been addressed.

# Ways to satisfy the goal:

- 1. Include significant detail in the protocol and use it to decide.
- 2. Ask the PI to provide confirmation.

which it would be pointed collected.



# Overregulate?

Describe the process of blood collection in mice. What route of collection will be used. Provide the volume to be collected and the frequency at which it would be collected.

# The Goldilocks Theory?

Please check yes to provide assurance that the amount of blood collected will not exceed 10% of the animal's body weight over a two-week period.

# IAA starting point

Home » Resources » Sample Documents for Implementation of the PHS Pol
» Animal Study Proposal

**OLAW** 

Based

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Supple by mar As a further disclaimer note that the use of the OLAW sample animal study proposal is not required and is provided for the convenience of the IACUCs at Assured institutions. Sections may be added, deleted, or modified to meet the needs of the individual programs. This seems like an applicable statement for the UPT as well.

posal mal study

used

Resource: (https://olaw.nih.gov/resources/documents/animal-study-prop.htm)



Home » Resources » Sample Documents for Implementation of the PHS Pol » Animal Study Proposal

# OLAW Protocol Sample Template Animal Study Proposal

Based on a form used by the intramural NIH investigators



- Introduction
- View the animal study proposal
- Download the sample animal study proposal
- Supplemented with information gathered from templates used by many different other institutions

Resource: (https://olaw.nih.gov/resources/documents/animal-study-prop.htm)



# What should the UPT look like?

- Must be inclusive, but tailored to species most commonly used (i.e., mice and rats);
- 2. Only include information needed by the IACUC to conduct the review;
- 3. Provide as much information as possible to the PI (use check boxes); and
- 4. Keep it user friendly for all.



-	Date: Friday, 07 July 2017
and study its infli is usually established th design relates to the participants and their _	_the researcher will usually manipulate the uence on the The manipulation of the IN rough different Experimental of to certain conditions of the IV.
Repeated Measures     Independent groups     Matched pairs	allocation experiment DV  categorisation IV conditions  organisation

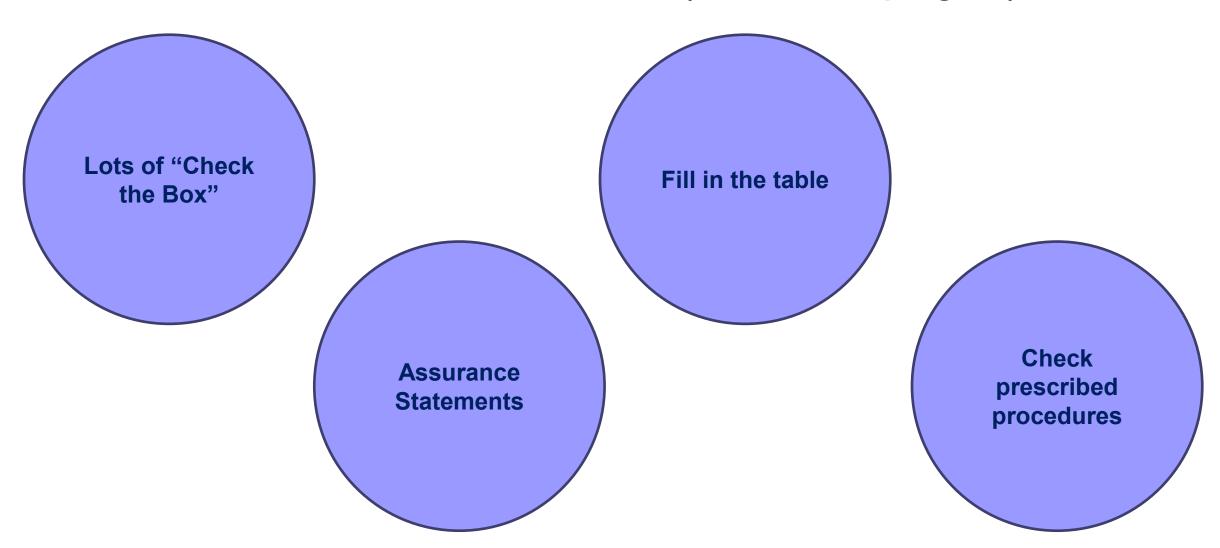
# A Template for Rodents and One for Others!



Rodents play an invaluable role in biomedical research. Approximately 95 percent of all laboratory animals are mice and rats. Reducing reliance on higher-order species, rodents have become the animal model of choice for biomedical researchers because their physiology and genetic make-up closely resembles that of people. Despite certain differences between people and rodents, the similarities are strong enough to give researchers an enormously powerful and versatile mammalian system in which to investigate human disease.

The sequencing of rodent genomes has enabled researchers to recreate human diseases in rodents through genetic engineering. Researchers "knock in" or "knock out" disease-related traits in mice and rats, and new technology allows researchers to directly edit the DNA of the rodents<sup>[1]</sup>. Research with genetically modified mice and rats has led to significant new treatments, cures and therapies and continues to revolutionize science and medicine.

# UPT - The Word Format (about 20 pages)



#### A Sample Animal Care and Use Universal Protocol Form (UPT)

Note: Assigned by the administrator or an IT system

IACUC Protocol Number	Submission Date	Final Approval Date

#### **Administrative Information**

Protoc	ol Title:		
Please	check all that apply:		
	New Submission Three Year de novo review		
	Protocol Amendment		Dagaganahan
1. Pri	ncipal Investigator Information		Researcher emographics
a.	PI Name (Last, First):		
b.	Current Position (e.g., Faculty Member, Research Scientist):		
c.	Department or School:		
d.	Primary Laboratory Location: Building: Room No.:		
e.	Cell Phone Number (for emergency contact):	1	

### PI Notice

Please be aware that 11 gives false infor

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We must have the "trust the PI philosophy" but remind them that their protocol is a contract between them, the IACUC and the Institution.

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yes,

#### PI Notice

Please be aware that there are potential civil and criminal penalties involved if someone gives <u>false information</u> to obtain monetary support from for example the National Institutes of Health. I hereby affirm that the information I have provided in this document is accurate and true to the best of my knowledge and belief. Please check yes, to provide confirmation.

[] Yes [] No, Explain, < Text Box>

### **Assurance Statements**



### Personnel – **Assurance Statement**



- a. 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 outprovide written assurance and documentation that all personnel listed on this protocol will complete all 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>
- List those individuals that will be conducting animal activities under this protocol.

Name (Last, First)

Role (e.g., Admin contact, lab manager, Post doc, research assistant, student):

Unique identifier (i.e., email, employee number)

3.	Pro	oject Funding Source(s)	
		Is this project or components of it externa	Protocol and Grant Congruency
	b.	If the project is externally funded by, plea	The IACUC doesn't need this information to conduct its review.
		☐ National Institutes of Health (NIH)	Some have a process through Sponsored
		☐ National Science Foundation (NSF)	Programs
		☐ Department of Defense (DoD)	
		☐ Other, please list.	
	c.		



#### 3. Project Funding Source(s)

- a. Is this project or components of it externally (e.g., NIH or DoD) funded? [] Yes [] No
- If the project is externally funded by, please check all that apply.
  - □ National Institutes of Health (NIH)
  - National Science Foundation (NSF)
  - ☐ Department of Defense (DoD)
  - Other, please list.

c. 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, Explain



Inspections need to occur...

#### Animal Use Locations



The IACUC doesn't need this information to conduct its review,

but the administrators do to ensure they're inspected...

that all animal activities (i.e., housing and central animal facilities (e.g., areas managed by PI).

out locations where animal activities will tivities that will be performed.

Building, Room Number	Species	Activities to be performed (e.g., behavior studies, euthanasia, housing, non-survival surgery, survival surgery, substance administration, use of hazardous materials, specialized equipment, other)





Inspections need to occur...



#### Animal Use Locations

a. 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

b. Please provide the following information about locations where animal activities will occur outside the central facilities and the activities that will be performed.

Building, Room Number	Species	Activities to be performed (e.g., behavior studies, euthanasia, housing, non-survival surgery, survival surgery, substance administration, use of hazardous materials, specialized equipment, other)



# **Objective And Rationale for Using Animals**



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, please explain

• IACUC Members: this question should always be answered yes.







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



### Reminder and an Assurance

Animal Procedures (Check all that apply)

NOTE: According to the Federal Regulations, it is your responsibility to midistress, and pain that may be associated with any animal use activities propose. Please check yes to provide assurance that measures, not limited to anesthetics, a sedatives, will be taken to avoid or minimize the discomfort, distress, and pain to the

[] Yes [] No, please explain.

Also Training, and an "I understand".



### Reminder and an Assurance

10. 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.

# **Objective And Rationale for Using Animals**



 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.

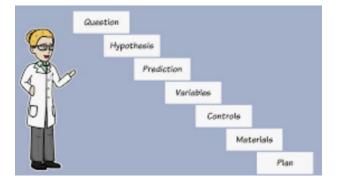
This question need not include anything more than the goal and a general description of the project.



# **Experimental Design**

a. Please provide a clear and concise, sequential description of the procedures involving the use of animals in a manner that is easily understood by a nonscientific member 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.





### Minimum Number of Animals

b. 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 the minimum needed to produce valid results. [] Yes[] No, Explain

# **Experimental Design**

Estimate the minimum and maximum number of animals that will be needed for this
project to achieve valid results.

Species	Minimal needed to achieve valid results	Maximum Need





# **Animal Information**

- 1. What will happen to the animals after the activities are completed (Check all that apply).
  - The animals will be euthanatized according to the process described in this protocol
  - ☐ The animals will be transferred to another approved protocol
  - ☐ The animals will be made available for adoption
  - Other (please describe)



# **Animal Housing**

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 cages of the appropriate size. 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

Note: Through this question, the PI confirms that the standard housing conditions should be used for all the research animals involved in the activities.

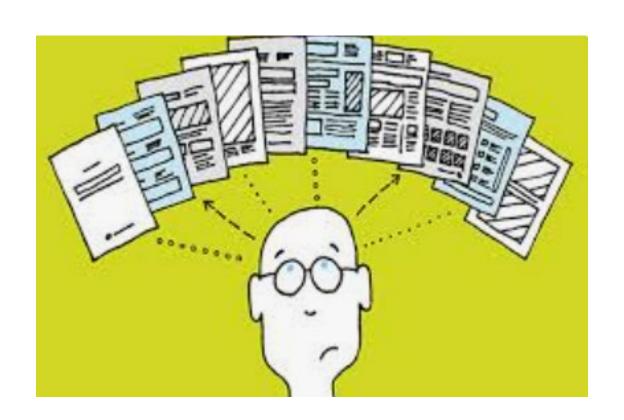
IACUC members: If someone checks "No" they should provide a research or medical reason for departing from the defined standards.



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# Procedures



### Common Procedures





#### Check the Box – "Build in Standardized Procedures"

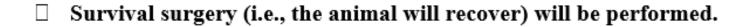
- Adult mice or rats will be euthanized by gas (i.e., carbon dioxide or isoflurane) inhalation followed by one of the listed secondary physical methods (i.e., decapitation, bilateral pneumothorax, removal of a vital organ, cervical dislocation) of euthanasia.
- □ Up to 1% of body weight in blood (i.e., 1 ml of blood per 100 grams of body weight) may be collected from mice or rats in 14 days or less using either the <u>lateral tail and/or saphenous vein</u>, and/or by tail incision.
- □ A tail biopsy up to 5mm in length will be collected from a mouse or rat that is less than 21 days of age for genotyping.

# Humane Endpoints?

- □ Visible Tumors: A mouse 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.
- □ Visible Tumors: A rat 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.



#### **Surgical Procedures**



 Please provide a descriptive name (e.g., laparotomy or abdominal) of the specific survival surgical procedure that will be performed.



 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. 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

Spell it out.

#### Surgery

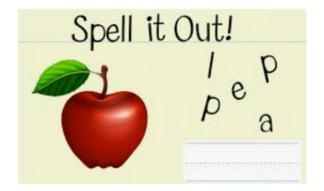
assurance that the following process will be followed to ensure aseptic technique is used.

- 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.

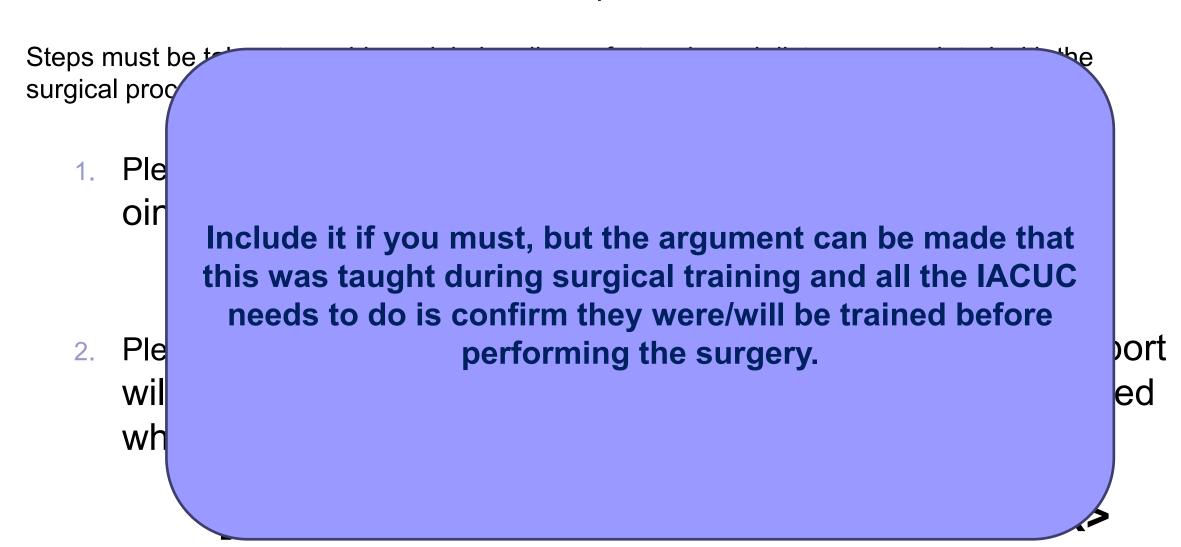
Please check yes to provide assurance the described aseptic procedures will be followed consistent with the species of interest. [] Yes [] No, explain.



No guessing or a chance to receive incomplete information



#### Minimize discomfort, pain...



#### Minimize discomfort, pain...

Steps must be taken to avoid or minimize discomfort, pain and distress associated with the surgical procedure. Please respond to the following information.

1. Please check yes to provide assurance that sterile ophthalmic ointment will be applied to each eye.

# [] Yes [] No, please explain <Text Box>

2. Please check yes to provide assurance that thermoregulatory support will be provided, and the animal will be continuously monitored while under anesthesia.

# [ ] Yes [ ] No, please explain <Text Box>

### **Post Surgical Support**

- 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.
  - a. Anesthetics and Analgesics must be used to manage and control pain during and after surgical procedures. Please check yes to provide assurance that both will be used as part of this procedure. [ ] Yes [ ] No, please explain.

 List the anesthetic(s) and analgesic(s) that will be used for this procedure through the completion of post-operative care.

Substance	Species	Anesthetic or Analgesic	Dose	Application: induction, maintenance, or post- operative	Frequency of application (e.g., every 12 hrs.)

### Surgery



- ☐ Multiple survival surgeries will be performed on the same animal and on different days under separate anesthesia episodes.
  - Please list the survival surgeries each animal will experience in the table below.

	Surgery #1	Surgery #2	Surgery #3
C	(Descriptive Name	(Descriptive Name	(Descriptive Name
Species	Previously Provided in	Previously Provided in	Previously Provided in
	the Description)	the Description)	the Description)

Multiple surgeries conducted on the same animal are acceptable only if they are
essential to the research project and scientifically justified. Provide scientific
justification for performing multiple surgeries on a single animal.

#### **Substance Administration**

a. Other than anesthetics and analgesics, will substances (including but not limited to, for example, biologics, sedatives, tranquilizers, neuromuscular blocking agents, antibiotics, supplemental fluids, experimental compounds, or test articles) be administered, either directly or as a food/water additive, to animals? [] Yes <complete the table> [] No

Agent:				
	Purpose for Administration	:		
	Route of administration (e.g., orally, dermal, IV injection)	Dosage (units and Volume)	Frequency	
	Is this agent hazardous to humans (Yes/No):	·		

b. 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 (FHS). 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.

Substance	Reason for lack of safety clearance



The Administrator can check with safety to verify, but it's not the IACUC's responsibility to assess the hazards.



# Other "spelled out" procedures

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)							
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)							
☐ Samples will be collected from research animals.							
		Samples will be collected from the animal only after euthanasia.					
		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.					
		Blood samples will be collected (Check all that apply)					
Beh	avio	r Studies will be conducted.					
Bre	edir	ıg					

#### Cannot catch everything.

Other procedures (e.g., Animal identification processes, Trauma, Wound or Burn, Induction of Paralysis), complete the series of questions below for each additional procedure.

In the table below, please provide the name of and a written technical description of those procedures <u>not</u> already described in the protocol above.

Gavage will be used to administer orally a therapeutic agent ABC to evaluate animals. To perform gavage, the therapeutic will be loaded into a syringe, for example, a cannula or tube affixed to the syringe  (Example)  Mice will be carefully placed into the esophagus of the animal and the substance will be carefully delivered directly into the animal's stomach.	Procedure one Name	Species	Briefly describe the procedure and how it will be performed
		Mice	evaluate 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

1. Will this procedure cause more than momentary pain or distress to the animal?

[ ] Yes, complete the table (Q2) below [ ] No, Add any additional procedures.

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# Excel Version with Regulatory References is also available

#### A Sample Animal Care and Use Universal Protocol Form

Question Number	Regulatory Requirement	Protocol Section	Question	Comments
-	Needed for protocol management	Administrative Information Note: this information is needed for administrative purposes)	Protocol Title:	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.
	May be needed for review management	Administrative Information	Submission Type: New, Renewal, or Amendment	Submission type identified by the PI
1	Needed for protocol management	Administrative Information	Principal Investigator (PI) Information Section	
1a		Administrative Information	PI Name (Last, First):	Each user will need to identify who is eligible to be a PI (e.g., a policy).
1b		Administrative Information	Current Position (e.g., Faculty Member, Research Scientist):	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"
1c		Administrative Information	Department or School:	This is a demographic that can be used by the institution to determine, for example, which of its administrative units are the primary user.
1d		Administrative Information	Primary Lab Location (Building, Room #):	This is the physical location of the PI's laboratory that the IACUC can use when physical visits are necessary.

# Excel

Question Number	Regulatory Requirement	Protocol Section	Question	Comments
2	AWAR = § 2.31(e)(2), pg 61;  PHS = U.S. Government Principle  III, pg 4;  Guide, "Protocol Review", pg 25)	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	The PI must provide a narrative that justifies the appropriate animal model to perform the proposed research is being used.

# Excel

Question Number	Regulatory Requirement	Protocol Section	Question	Comments
3	The AVMA Euthanasia Guidelines, https://www.avma.org/sites/default/files/2020-02/Guidelines-on-Euthanasia-2020.pdf By the PI checking "yes" they are assuring that they validated the method of euthanasia they selected conforms with the AVMA Guidelines. AWARs - 2.31(d)(1)(xi), 2.31(e)(5)	IACUC Information	Euthanasia and/or Final Disposition of the animals to be used (Check all that apply) 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>	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.

#### UPT Form and Resources Available on a National Academies Website

Because the UPT Form is aligned with the needs of the community of researchers that care for and use animals,

the UPT Form and other resources such as:

- Webinar recording
- Slides

are available on a website hosted by the National Academies Roundtable on Science and Welfare of Animals Involved in Research.

Use the QR Code to access the website, or the URL below: https://www.nationalacademies.org/event/44357\_01-2025\_advancing-community-engagement-by-using-a-universal-protocol-template-upt

