FEDERAL DEMONSTRATION PARTNERSHIP
Redefining the Government & University Research Partnership

Universal Protocol Template (UPT) Update

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Animal Subjects Subcommittee– September 24, 2020

Session Discussion Points

1. Project Summary
2. The overall goal of the UPT
3. Community Input
4. Status Update
5. Next Steps
6. Estimated Timeline
7. Protocol Outline
8. Administrative Information
9. Experimental Activities
10. Specific Procedures
11. Q/A

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Project Summary

1. How was the UPT initiative started
2. A community Resource
3. The Potential Benefits of an UPT
4. A Partnership: FDP, IAA, USDA, OLAW, DoD and VA

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What's the objectives of the UPT?

1. 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.

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UPT Use will not be Required

Disclaimer:

- Once the UPT is finalized and made available through the OLAW and IAA website, it can be used as a resource by any interested party.

- The use of the template will not be mandated by OLAW or the USDA.

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IACUC Community Input on the UPT

It's been a team effort!

1. Discussions on the UPT started around 10 years ago at Best Practice Meetings, which formalized during 2017-18 meetings.

2. Continued input from community members including academia, industry, VA, DoD, OLAW and the USDA through FDP.

FDP Working Group

FDP Universal Protocol Template (UPT) Comm			
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Last	First		
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Banks	Ron	University of Oklahoma Health Sciences Center	Ron-Ba
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Clarke	Carol	USDA	carol.l.cl
Cole	Lori	University of Tennessee, Knoxville	lcole
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Gibbens	Bob	USDA	robert.m.g
Glowacz	Susan	Indiana University, Bloomington	sglowac
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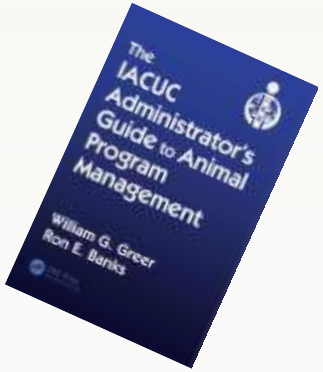

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Status Update

What Progress has been made?

1. **A draft template was developed through IAA;**
2. **The UPT was divided into sections;**
3. **Section were provided to subcommittee members for comments; and**
4. **The initial draft was updated to included subcommittee members' ideas.**

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Next Steps

1. The complete and updated draft will be provided in its entirety to FDP subcommittee members.

2. A Zoom meeting(s) will be established for round table discussions by the subcommittee.

3. Once the subcommittee has finalized the UPT user testing will begin
   a. Researchers
   b. Veterinarians,
   c. IACUC Administrators, and
   d. IACUC members

4. The final UPT will be made available to the community.

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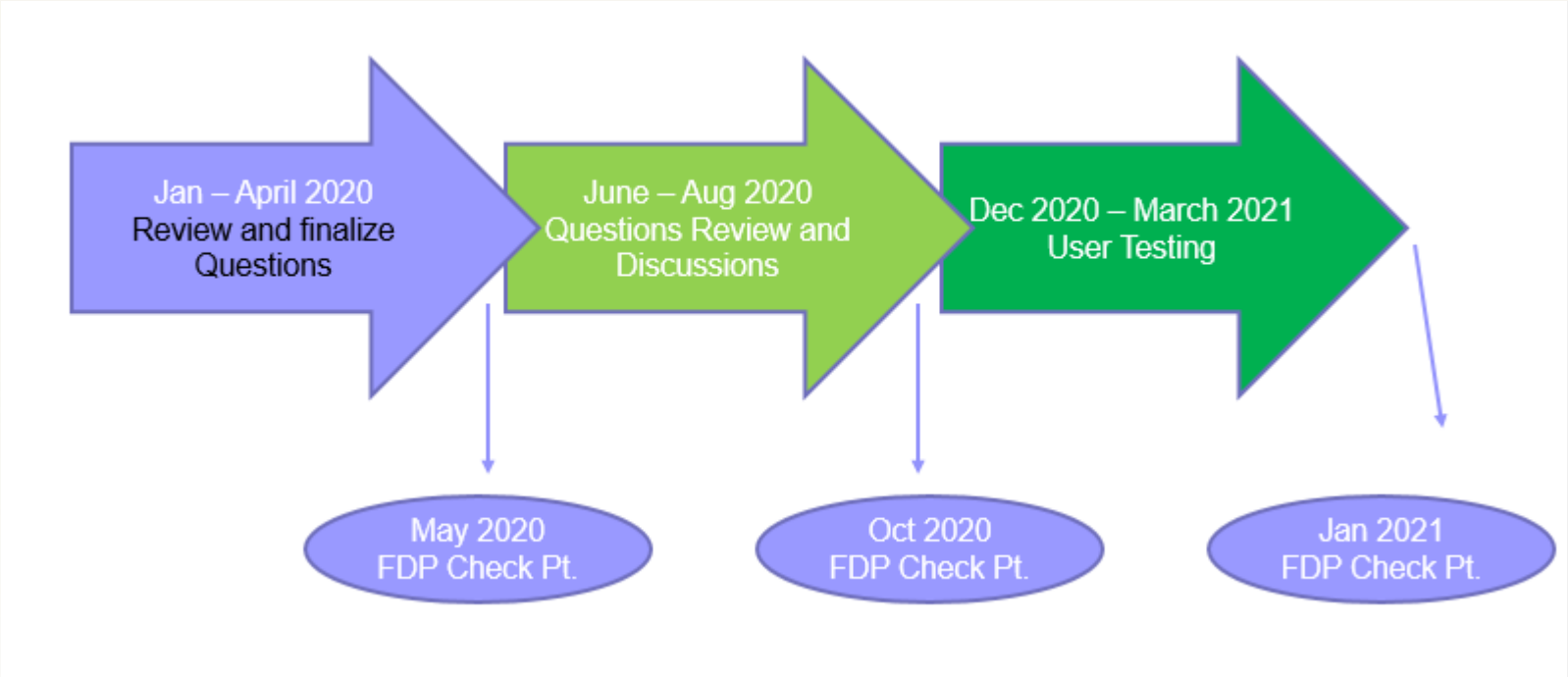
Estimated Timeline



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UPT Outline

Sections:

1. Administrative Information
2. Species information and justification for animal use
3. General Animal Activities Description (previously know as the experimental design)
4. Procedures
5. Departures & Justifications
6. Hazardous Materials Use
7. Acknowledgements

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Administrative Questions (1/2)

Section 1

Administrative Information

1. Project Title:
2. PI Name (First, Last):
3. Status (Faculty):
4. Department:
5. Primary Laboratory Location
6. Cell Phone Number:
7. Email:

Section 2

Project Funding Source(s)

1. Please check "Yes" to provide assurance that adequate funds are available for the procurement and care of the animals associated with this protocol for the project duration.

   [ ] Yes [ ] No

2. Please provide below the following information for each source of funding that will be used to support this project.

   a. Source of the funding (e.g., NIH or Internal):

   b. Reference Number (e.g., grant number):

   c. Period of Support (e.g., when does the grant start and when does it end):

   d. Granting agencies require institutions to verify that proposed animal activities are approved by an IACUC prior to funds being received by the institution. Please check "Yes" to provide assurance that the animal activities supported by these funds are describe in an IACUC protocol(s). [ ] Yes [ ] No

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Administrative Questions (2/2)

Section 7

Activity locations and the movement of animals between locations

1. Please check "Yes" to provide assurance that all animal activities (i.e., housing and procedures) will occur in the central facilities (i.e., areas directly managed by the Attending Veterinarian).

   [ ] Yes, continue to Q2 [ ] No, please provide the following information

   Please provide the following information about locations where animal activities will occur outside the central facilities.

   a. Building <Text Box>
   b. Room Number <Text Box>

   Please check all animal activities that will occur in this location

   ☐ Behavior studies

   ☐ Euthanasia

   ☐ Housing (i.e., Animals are maintained greater than 12 consecutive hours)

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Administrative Questions

Section 8

1: ***Protocol Participant's Occupational Health and Safety Program (OHSP):*** I understand it is my responsibility to insure that protocol participants associated with this protocol are enrolled in an appropriate OHSP / Medical Surveillance Program.

☐ No
☐ Yes

2: ***Training:*** I understand it is my responsibility to insure that protocol participants have competed required training prior to executing the procedures so described on this protocol.

☐ No
☐ Yes

3: ***Compliance***: I understand it is my responsibility to insure that protocol participants are aware of reporting options for perceived non-compliance and are aware of the potential outcomes of engaging in unapproved activities.

☐ No
☐ Yes

3: ***Veterinary Support:*** I understand it is my responsibility to insure that protocol participants are aware that the institution's veterinary staff are here to assist and support my research; I will encourage protocol participants to communicate with the veterinary staff whenever animal issues are observed.

☐ No
☐ Yes

4: ***Amendments:*** I understand it is my responsibility to insure that only IACUC-approved procedures will be performed. If a new or different procedure or method is desired, then I will submit an Amendment to the IACUC for approval prior to engaging in the new procedure or method.

☐ No
☐ Yes

7.5: ***Annual Reports:*** I understand it is my responsibility to insure that protocol annual reports are filed with the IACUC by the 12th month (anniversary month) of the protocol's approval date.

☐ No
☐ Yes

7.6: ***DeNovo Review:*** I understand it is my responsibility to insure that if I desire to continue animal work past 36 months, I will submit a new and updated protocol around month 34 to allow sufficient time for IACUC review and approval prior to reaching the mandated termination date of 36 months protocol life.

☐ No
☐ Yes

7.7: ***Veterinary Authority:*** I understand that the institution's veterinarians have the authority to treat, medicate, or euthanize animals on this study, in accordance with good veterinary practice. I understand that when possible, the veterinary staff will consult with me regarding the condition of the animal(s) prior to providing therapy or causing euthanasia.

☐ No
☐ Yes

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Animal Information

Section 4

Animal Subjects Information (to be completed for each species used under this protocol)

Please provide the following information for the animals that will be used in the activities proposed under this protocol. If multiple species, the information will need to be provided for each species.

1. Species (Could be a drop down box for e-forms):

2. Source(s)

   - ☐ Another approved protocol
   - ☐ Captured Wildlife
   - ☐ Commercial Vendor (Animal Resource Program Approved Vendor)
   - ☐ Other <Text Box>

3. Explain why this species was selected to conduct the activities describe in this protocol.

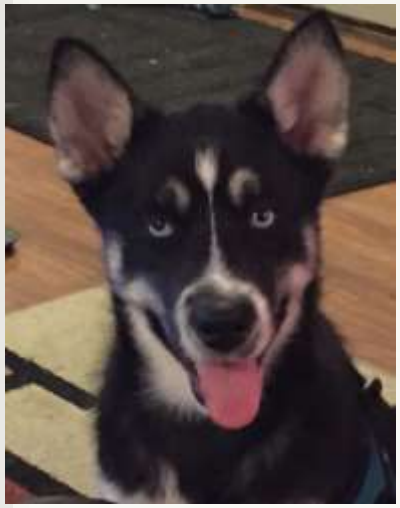
   ○ <Text Box>

4. Please check "Yes" to provide assurance that the species selected is the lowest on the phylogenetic scale that can be used to satisfy the study requirements (e.g., rabbits were not selected if the activities can be successfully conducted in mice).

   [ ] Yes [ ] No, please provide your rationale <Text Box>

5. Please indicate the final disposition of the animals (Check all that apply).

   - ☐ The animal will be euthanatized according to the process described in this protocol
   - ☐ The animal will be transferred to another approved protocol
   - ☐ The animal will be release back to the wild
   - ☐ Other (please describe) <Text Box>



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Justification for Animal Use

2. Briefly provide the goal(s) and a general description of this project in language that can easily be understood by a layperson. **Note: The specific and related details (e.g., drug doses, routes of injection, and steps in a surgical procedure) of the associated procedures will be provided in later questions.** <Text Box>

3. Please describe the importance of this project as it relates to human or animal health, the advancement of knowledge, or the good of society. <Text Box>

4. Explain your rationale for animal use, and indicate why you cannot use non-animal models (e.g., cell or tissue culture, isolated organ preparations, computer simulations, etc.). <Text Box>

5. ~~Please check "Yes" to provide assurance that the animal activities conducted under this protocol do not unnecessarily duplicate previously conducted activities.~~

   ~~[ ] Yes [ ] No, please provide your rationale <Text Box>~~

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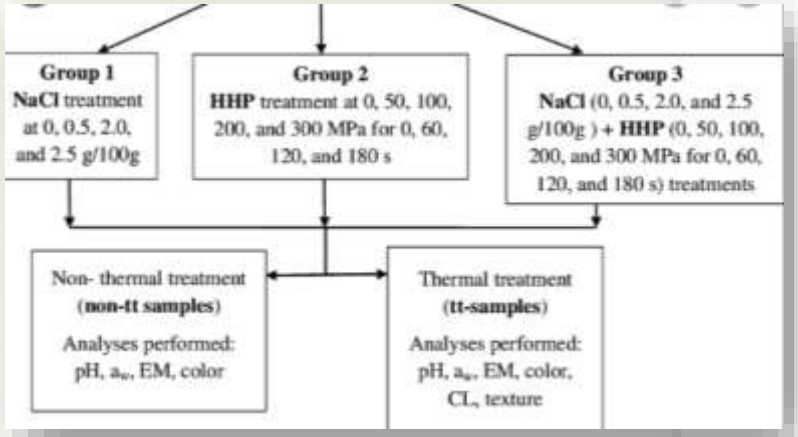
General Animal Activities
i.e., Experimental Design



Section 5

Experimental Design

1. The goals of this protocol are achieved through animal activities. Comparisons are typically made by using numerous cohorts of animals with each having a different variable.

   a. Experiment Title or Number (i.e., the comparison to be made): <Text Box>

   b. Species: <Text Box>

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

   d. Please indicate the estimated total number of animals needed for this protocol

   e. The number of animals used for each experiment should be the minimum required to achieve the scientific aim(s) and produce statistically valid results. Please check "Yes" to provide assurance that the number of animals used in this experiment is minimum needed to produce statistically valid results.

      [ ] Yes [ ] No, please provide your rationale <Text Box>

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Procedure Questions

1. Blood Collection
2. Euthanasia
3. Behavior Studies
4. Etc.

☐ **Euthanasia**

Please identify the method(s) that will be used (check all that apply)

☐ ***(Only appears if the species is mice or rats)*** 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

☐ Lethal injection with or without subsequent tissue harvest

☐ **Blood Collection**

1. Please check all that apply

   ☐ Up to 1% of body weight in blood (i.e., 1 ml of blood per 100 grams of body weight) may be collected in 14 days or less.

   ☐ Other, please describe <Text Box>

2. Please identify the route of blood collection

   ☐ The lateral tail and/or saphenous vein, and/or by tail incision ***(Only appears if the species is mouse or rat)***

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How about survival surgery?

Aseptic technique means to use a series of practices and procedures that help to prevent contamination from pathogens. Survival surgery must be performed using aseptic technique. 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/table will be decontaminated using an appropriate disinfectant. The surgeon will wear, at minimum, a mask, a surgical cap/bonnet, sterile gloves, and a clean scrub top, disposable gown, or lab coat. The surgical site will be prepared by removing the hair followed by at least three alternating scrubs of disinfectant (e.g., betadine, chlorhexidine) and rinse (e.g., ethanol, warmed saline, sterile water) ensuring to remove any remaining visible debris.

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

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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>

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Anesthetic and Analgesia Use

1. Please select the anesthesia that will be used for this surgery. Check all that apply

- ❑ Isoflurane (4-5% induction and 1-2% for maintenance) – inhalant
- ❑ Ketamine (80-120 mg/kg) + Xylazine (5-10 mg/kg) – IP injection
- ❑ Pentobarbital (Nembutal) (40-60 mg/kg) – IP injection
- ❑ Other, please provide the anesthetic, dose and method of application

Anesthetic and Analgesia Use

1. Please select the analgesia that will be used for this surgery Check all that apply

   - ❑ Buprenorphine (.05 -.1 mg/kg) every 6-12 hours – SC or IP injection
   - ❑ Carprofen (5 mg/kg) every 24 hours – IP injection
   - ❑ Ketoprofen (2 - 5 mg/kg) every 12-24 hours – SC
   - ❑ Other, please provide the anesthetic, dose and method of application

2. Please check yes to provide assurance that the selected analgesia will be provided through the post operative recovery period (i.e., until the surgical sutures or clamps are removed).

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

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Hazard Agents

1. It is not the IACUC's role to assess hazardous agent use, but the role of the IBC or other safety group on campus.
2. The IACUC question could list the agents being proposed and then the safety person (or if a pre-defined list is used by the IACUC Admin), could select those protocols requiring a deeper safety review and provide the necessary safety specific questions for the safety committee to review.

Questions/Thoughts

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