



A Universal Protocol Template (UPT)



Session Goals

1. Summarize the project status
2. Identify the FDP working group
3. Define the product (UPT)
4. Discuss communication tools and processes
5. Discuss and refine the UPT “Action Plan”
6. Define a completion timeline



Project Status Update

1. IAA developed a draft protocol template (2017- 2018)
2. Formalized a project with FDP (May, October, 2019)
3. Established an FDP Working Group



FDP Working Group



FDP Universal Protocol Template (UPT) Committee			
Name		Instituion	email
Last	First		
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Did we miss anyone?

Send me an email with your contact information:

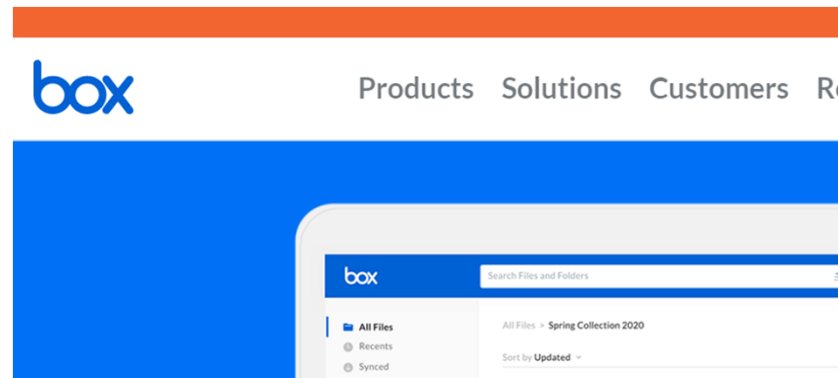
Bill Greer

Assistant Vice President for Research

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Communication Tools



1. Email
2. Conference Calls (when necessary)
3. FDB Meetings for updates and status checks



What should the UPT look like?

1. Tailored to rodent users;
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.



Action Plan (1/2)

1. Think about every question

- a. Is the question clearly written from a PI's prospective
- b. Is the information necessary to review the proposed animal activities
- c. Is the information related to compliance, but not necessarily the activities
- d. Is the information managed another portion of the program (e.g., Vet Care)

2. Break the UPT into sections

- a. Research Objectives and Animal Use
- b. **Ancillary Information**
- c. Procedures
- d. Departures
- e. Hazardous Materials Use





Research Objectives and Animal Use

1. 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.**
2. Please describe the importance of this project as it relates to human or animal health, the advancement of knowledge, or the good of society.
3. 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.).
4. Explain why this species was selected to conduct the activities describe in this protocol.



Ancillary Information

1. Administrative Information
2. Project Funding
3. Animal Activity Type (e.g., Research, Teaching, Breeding)
4. Animal Subjects information (e.g., species, source, final disposition)
5. Experimental Design
 1. Clear and sequential description of what will happen to each animal
 2. Estimated animal use (i.e., numbers)
 3. Painful procedures and refinement
6. Locations where animal procedures will be conducted
7. Assurance statements...



Procedures (1/2)

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*)
- Other, please describe (*Only appears if the species is mouse or rat*) <Text Box>
- Please define and describe how blood will be collected (**Always appears if the species is other than mice or rats**) <Text Box>

Procedures (2/2)

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
 1. Please provide the substance that will be used <Text Box>
 2. Please provide the dosage that will be used <Text Box>
- Physical Method (check all that apply):
 - Decapitation with or without anesthesia
 - Decapitation of rodent pups that are under 10 days of age
 - Cervical dislocation under anesthesia
 - Conscious cervical dislocation (without anesthesia), please justify <Text Box>
- Other, please describe and justify <Text Box>



Departures/Procedures 1/2

- Temperatures for some/all animals will be maintained outside of the standard range for scientific reasons
 1. Please indicate the temperature range(s) at which the animals will be maintained <Text Box>
 2. Please approximate the duration and frequency for when ambient temperatures must be maintained outside of the standard range <Text Box>
 3. Please indicate why it is necessary to maintain temperatures outside of the standard ranges <Text Box>



Departures/Procedures 2/2

- ❑ Non-standard enclosures and housing conditions will be required for some/all animals. Please check the box(es) that best describes your non-standard housing conditions.
 - ❑ Wire-bottom cages
 - ❑ Housing without bedding
 - ❑ Enclosures with square footage that's less than the regulatory standards
 - ❑ Other, please describe <Text Box>
- 1. Please approximate the duration and frequency during which animals must be maintained in non-standard enclosures/housing conditions for each of the conditions selected <Text Box>
- 2. Please indicate why it is necessary to use non-standard enclosures/housing conditions <Text Box>



Hazardous Materials Use

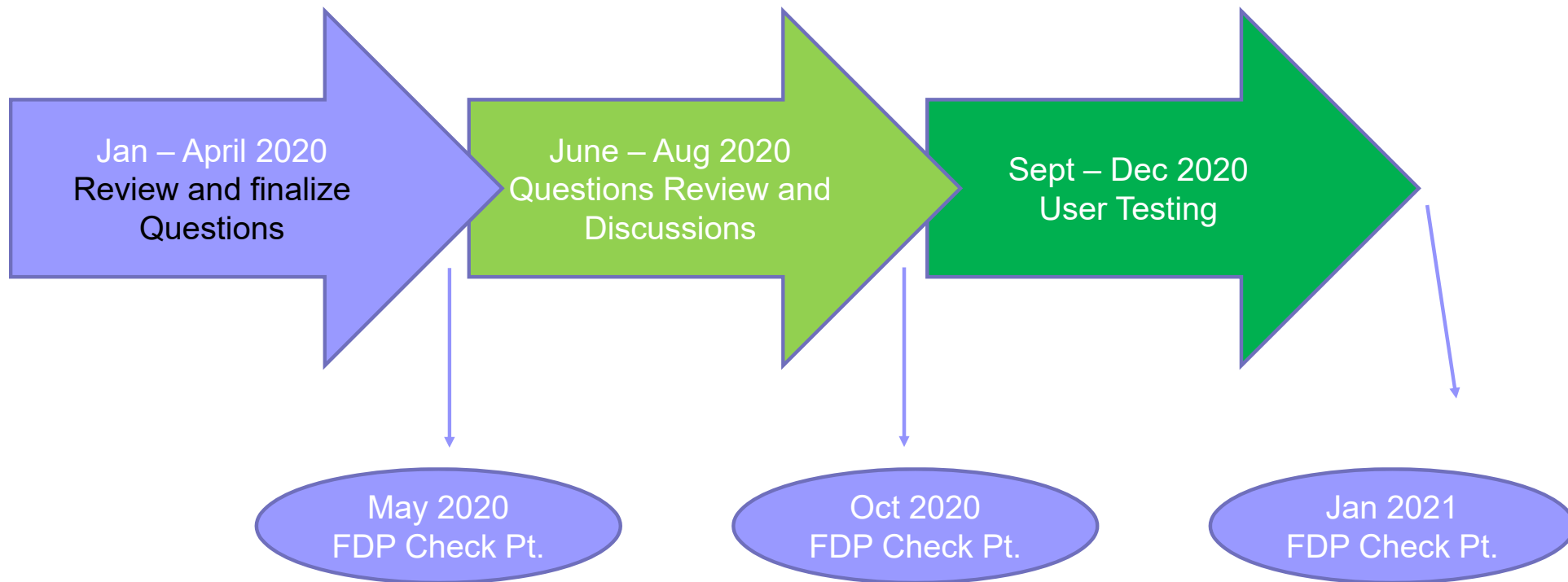
1. What will animals be given (e.g., orally, injected, cutaneous application) or exposed to?
 - a. Chemical/toxins – provide the class
 - b. Biologic (e.g., Bacteria, Virus, Prion, Fungi) provide the specific strain
 - c. Physical (e.g., isotope, lasers, X-Rays) – provide the type

Action Plan (2/2)

1. Think about every question
2. Break the UPT into sections
3. Question Reviews
 - a. Regulatory – OLAW and the USDA
 - b. VA and DoD
 - c. Principal Investigator
 - d. IACUC Member
4. Final Document User Testing
 1. PIs,
 2. IACUC Members
 3. Compliance Directors and Veterinarians



Timeline



Questions/Thoughts

To Do's:

1. Make sure I have your contact information (email, phone); and
2. Check with your institution to ensure they support "Box";



LET'S TALK