



A Universal Protocol Template (UPT): An FDP Update Sept 2021



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
 1. Several meetings thus far ...
 2. Still Working to overcome ...
 1. COVID
 2. Life
 3. Surprises

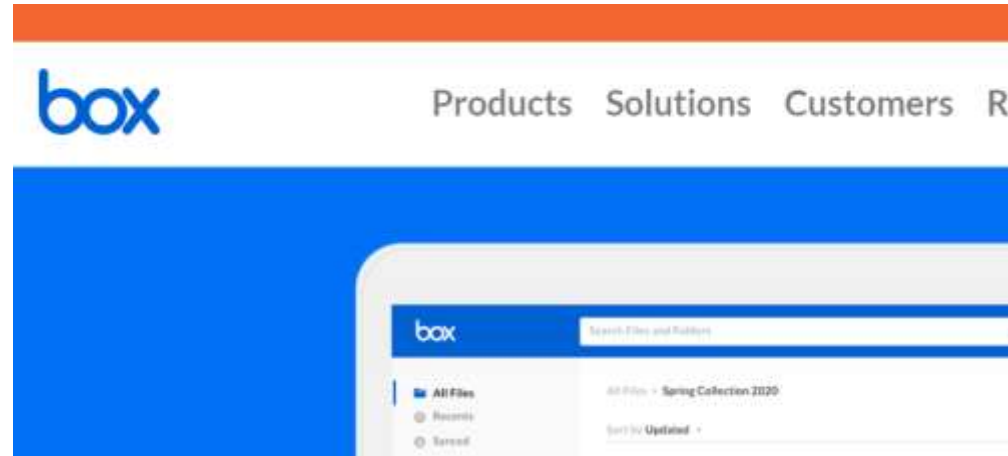


FDP Working Group



| FDP Universal Protocol Template (UPT) Committee | | | |
|---|------------------|--|----------------------------|
| Name | | Instituion | email |
| Last | First | | |
| Armstrong | Erica | Vanderbilt University | erica.r.armstrong@vumc.org |
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| Fitzhugh | Dawn | DoD | |
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Communication Tools



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



Goal: Build a Universal Protocol Template

STANDARDS:

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 (maximize check boxes); and
4. 'User' friendly (& regulatory compliant)!



Title: Experimental DESIGN

Date: Friday, 07 July 2017

Within on _____ the researcher will usually manipulate the _____ and study its influence on the _____. The manipulation of the IV is usually established through different _____. Experimental design relates to the _____ and _____ of participants and their _____ to certain conditions of the IV.

Three ways of arranging participants into conditions:

1. Repeated Measures: allocation experiment IV
2. Independent groups: counterbalancing IV conditions
3. Matched pairs: randomization

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 by 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



Ancillary Information

(Distinguishing IACUC reviewer needs FROM Program management needs)

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... (some regulatory, some institutional)

Research Objectives and Animal Use

(Distinguishing IACUC reviewer needs FROM Program management needs)

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. 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. Justify why this species was selected for this proposed study.

Procedures (1/2)

(Maximize check boxes / reference to SOP / short answer)

□ **Blood Collection** <as an example>

1. Check if applicable:

- 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. Identify the route of blood collection

- Lateral tail and/or saphenous vein, facial vein, tail incision.
Note: This is for mouse or rat; other parameters would apply for other species
- Cardiac or Orbital: Identify reference or describe procedure: **<Text Box>**
- Other, please describe (**Only appears if the species is mouse or rat**) **<Text Box>**
- Describe how blood will be collected **<Text Box>**

Note: Always appears if the species is other than mice or rats.

Procedures (2/2)

(Maximize check boxes / reference to SOP / short answer)

Euthanasia:

1. Identify the method(s) that will be used (check all that apply)

- 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. **Note: Only appears if mouse or rat.**
- Lethal injection with or without subsequent tissue harvest
 - SOP I will follow is: _____
 - If not approved SOP, then:
 - Provide the substance that will be used <Text Box>
 - Provide the dosage / methodology 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

(Capture Regulatory Issues)

- Temperatures for some/all animals will be maintained outside of the standard range for scientific reasons**
 - No
 - Yes: If yes, then answer below:
 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

(Capture Regulatory Issues)

- ❑ **Non-standard enclosures and housing conditions will be required for some/all animals.** Check the box(es) that describes 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

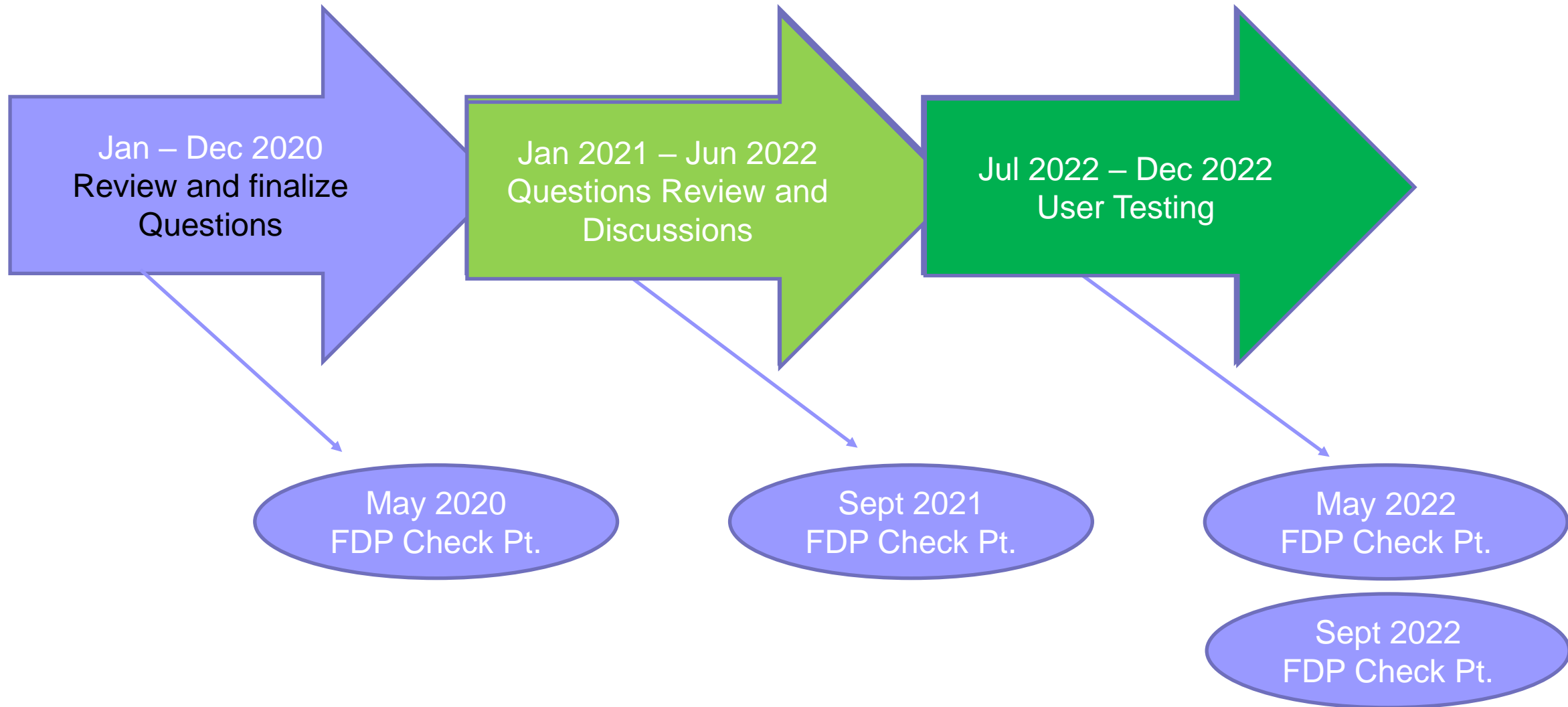
1. **What will animals be given (e.g., orally, injected, cutaneous application) or exposed to?**
 1. Chemical/toxins – provide the class [<Text Box>](#)
 - Biologic (e.g., Bacteria, Virus, Prion, Fungi) provide the specific strain [<Text Box>](#)
 - Physical (e.g., isotope, lasers, X-Rays) – provide the type [Text Box>](#)

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



LET'S TALK

Email contacts:

Bill Greer

Assistant Vice President for Research

University of Michigan

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Ron Banks

Professor, Department of Pathology

Director Division of Comparative Medicine

University of Oklahoma Health Sciences Center

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CUSP PROJECT UPDATE

AUBREY SCHOENLEBEN, UNIVERSITY OF WASHINGTON

SEPTEMBER 23, 2021



PROJECT GOAL



- Goal: Create an online repository where participating institutions can share standard procedures used in animal care protocols.
- A burden reducing initiative of the 21st Century Cures Act

STEERING COMMITTEE & WORKING GROUP

Education & Outreach

Michelle Brot & Scott Bury

Help Desk

Elaine Kim & April Ripka

Federal Partners

OLAW: Axel Wolff, Neera Gopee

USDA: Carol Clarke

VA: Alice Huang, Marissa Wolfe

Quality Control

Eva McGhee & Cyndi Rosenblatt

Technical Systems

Mark Hnath

- 62 participating institutions
- >100 individuals who have contributed to the project

Volunteers Needed!

Email culp@thefdp.org



Overall Project Direction & Oversight: *Aubrey Schoenleben & Sally Thompson-Iritani*

CURRENT STATUS



- Build and testing of Beta site completed May 2021
- Transition to more modern technology stack in progress!
- Dedicated development resource
- Testing of new site to begin October 2021

TRANSITION TO MODERN TECHNOLOGY STACK

Who?

Mark Nijland

What?

*Transition from
ColdFusion to
PHP/JavaScript*

Why?

*Long term
maintenance;
FDP Internal
Systems vision*

When?

*Completion
anticipated
December 2021*

How?

*AGILE approach;
automated and
user testing*

Home



Welcome!

CUSP is a knowledge sharing service through which Federal Demonstration Partnership (FDP) member institutions share standard procedures used in animal care protocols. Users can search for procedures of interest then filter and sort the results. Institutions can add new procedures, then edit, version, archive, delete existing procedures, and download selected procedures.

Disclaimer

The FDP and federal regulatory agencies are not responsible for, and have not reviewed or approved, the contents of this service.



User Documentation & FAQ

Proident proident posuier consequat totam ridiculus! Magna cunit, pellentesque tempora, quasi a blandis cursus consectetur penatibus illi urna, massa? Facilis.

[Explore the documentation →](#)



Troubleshooting Guide

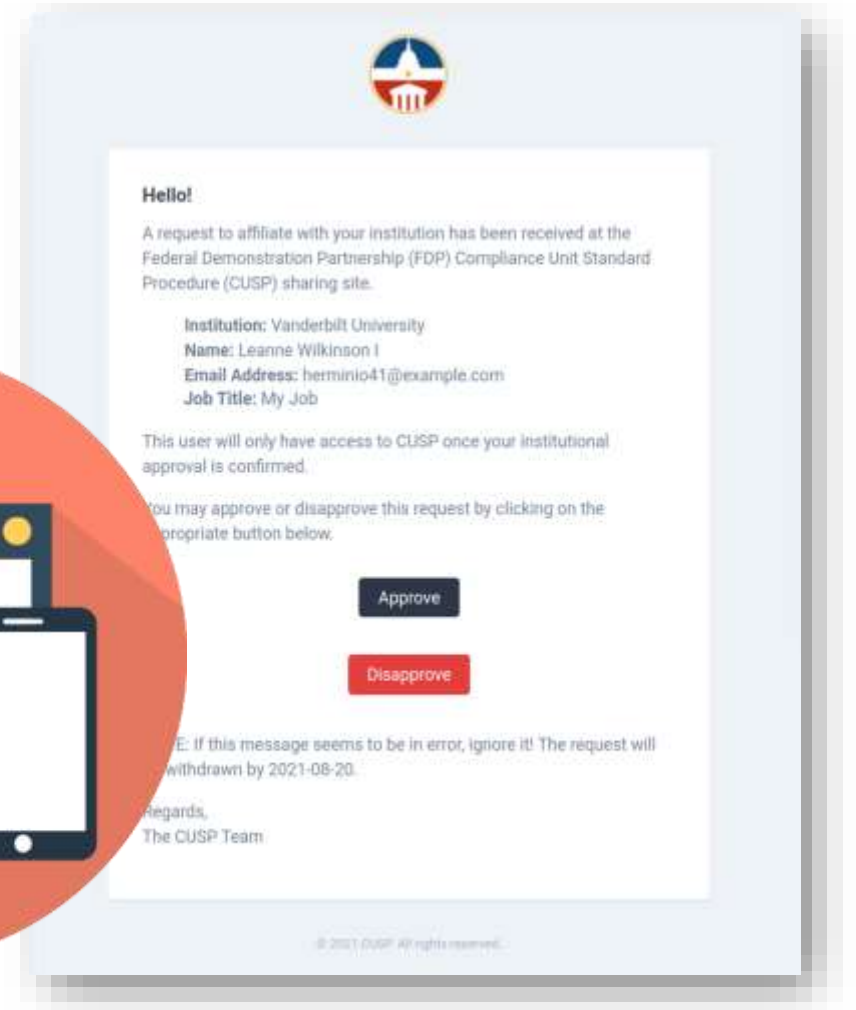
Interdum corrupti. Et deserunt inure aliquam sociis metellae fermentum at bibendum leo-quis cupidatat accusantium, mattis nullis serum, fermentum accusamus.

[Start troubleshooting →](#)

LET'S GET STARTED

NEW FEATURES & FUNCTIONALITY

- Mobile friendly design
- New account request workflow – more secure, easier for users to change institutional affiliation
- Ability to approve/deny account requests via email
- QC role
- User agreement





THANK YOU!





Home



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User Documentation & FAQ

Proident provident pulvinar consequat totam ridiculus! Magna cum, pellentesque tempora, quasi a blanditiis cursus consectetur penatibus illo urna, massa? Facilisis.

[Explore the documentation →](#)



Troubleshooting Guide

Interdum corrupti. Et deserunt irure eligendi sociis molestiae fermentum at bibendum leo quae cupidatat accusantium, mattis mollis eanum, fermentum accusamus.

[Start troubleshooting →](#)

LET'S GET STARTED



Procedures



Search

Terms

Procedure Type

Species

| PROCEDURE NAME | TYPE | SPECIES | ACTIONS |
|--|-------------------------------|--------------------|---------|
| Cognitive testing in juvenile monkeys using CANTAB | Behavioral Testing | Marmoset | |
| Euthanasia of rodent fetuses and neonates | Euthanasia | Rodentia (Rodents) | |
| Irradiation for immuno-oncology studies | Induction of Illness | Mouse | |
| Model of Parkinson's Disease | Induction of Illness | Macaque | |
| Ocular blood sampling | Blood and Sample Collection | Mouse | |
| Operant chamber testing and addiction | Behavioral Testing | Rat | |
| Preparation and induction of anesthesia in pigs | Surgery | Pig | |
| Pre-weaning tail snip | Identification and Genotyping | Mouse | |
| Protein restriction during pregnancy | Diet Modification | Hamster | |
| Skinner Box conditioning | Behavioral Testing | Pigeon | |

Showing 1 to 10 of 11 results

< 1 2 >



Representative Tasks - Procedures

Vanderbilt University

Procedures

0 FLAGGED

0 ENDORSED

3 ACTIVE

0 EXPIRING

0 INACTIVE

Search

Terms

Search procedures...

Procedure Type

Species

PROCEDURE NAME

TYPE

SPECIES

ACTIONS

Model of Parkinson's Disease

Induction of Illness

Macaque



Operant chamber testing and addiction

Behavioral Testing

Rat



Protein restriction during pregnancy

Diet Modification

Hamster



[Home](#)[Procedures](#)[Representative](#)[Site](#)[System](#)[About](#)

Representative Tasks - Users

University of Washington

My Users

6 ACTIVE **0** EXPIRING **0** INACTIVE **0** CONTACTS

Search

User

| NAME ^v | EMAIL / USERNAME | LAST LOGIN | ACTION |
|------------------------------|------------------|------------|--------|
| Aubrey Schoenleben | aubreys@uw.edu | -- | |
| Community User | uw_user@cusptest | -- | |
| Institutional Representative | uw_rep@cusptest | -- | |
| Lynette Arias | ariasl@uw.edu | -- | |
| Sally Thompson-Iritani | sti2@uw.edu | -- | |
| Site Admin | uw_site@cusptest | -- | |