



FEDERAL DEMONSTRATION PARTNERSHIP
Redefining the Government & University Research Partnership

Universal Protocol Template (UPT) Update

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Animal Subjects Subcommittee – May 24, 2021



Session Discussion Points

1. How did we determine an UPT is needed?
2. The general goals behind developing a UPT
3. Community Input and FDP Involvement
4. Status Update
5. Next Steps
6. Estimated Timeline
7. Q/A





What made us think an UPT would be useful?

1. Through IAA the idea was imagined based on ~8 years of conversations with IACUC Administrators during portions of BP meetings (*Concepts and Philosophies*)
2. The IAA Project formalized a project in 2016 and formalized partnerships (*Specific goals*)
3. IAA held dedicated sessions to gather info & develop an UPT(2017 – 2018)
4. FDP and IAA partnered to establish a project dedicated to developing an UPT





IACUC Community Input on the UPT

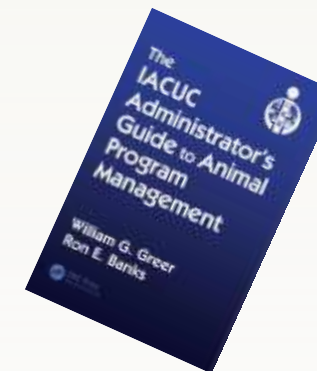
It's important to reiterate that it's been a long term team effort!

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) Commi			
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- # RESEARCH OBJECTIVES



A Template for Rodents and One for Others!

nabr National Association for Biomedical Research

Rodents play an invaluable role in biomedical research. Approximately 90 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 remove human disease 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. Research with genetically modified mice and rats has led to significant new treatments, cures and therapies and continues to revolutionize science and medicine.

RESEARCH DESIGN

Title: Experimental DESIGN

Date: Friday, 07 July 2017

When an _____, the researcher will usually manipulate the _____ and study its influence on the _____. The metaphor of the IV is usually established through different _____. Experimental design relates to the _____ of _____ and participants and their _____ to certain conditions of the IV. There are ways of arranging participants into conditions:

 1. Perceptual Measures
 2. Independent groups
 3. Matched pairs

Experimental IV Dependent DV Experimental DV Dependent DV Experimental DV Dependent DV



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.



As a reminder, the Starting Point

OLAW Protocol Sample Template

- Which was based on a form used by the intramural NIH investigators
- And then 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?

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.





Action Plan (1/3)

1. Requested information must be consistent with regulation and policy
2. Review/consider the question's primacy
 - a. Is the information necessary to robustly review the proposed animal activities?
 - b. Is the information related to compliance, but not necessarily the animal activities?
 - c. Is the information managed by another agency at the institution (e.g., Vet Care, OHSP)?





Action Plan (2/3)

3. Consider the wording of each question

- a. Keep it SIMPLE!
- b. Keep it straightforward (no guessing games)
- c. Is every question in the template clearly written from a PI's prospective
- d. Is the information needed by the IACUC to review the proposed animal activities
- e. And

4. Is it logically formatted (Break the UPT into logical sections)

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





Action Plan (3/3)

5. Question Reviews

- a. Regulatory – OLAW and the USDA
- b. VA and DoD
- c. Principal Investigator
- d. IACUC Member

6. Final Document User Testing

- a. Researchers
- b. Veterinarians,
- c. IACUC Administrators,
- d. IACUC members, and
- e. Compliance Directors





Status Update

What Progress has been made?

1. A draft template was developed through IAA;
2. The UPT was divided into sections;
3. Sections were provided to subcommittee members for comments; and
4. The comments were collated into a common document, and shared with the working group; and
5. Discussion group meetings have been established.



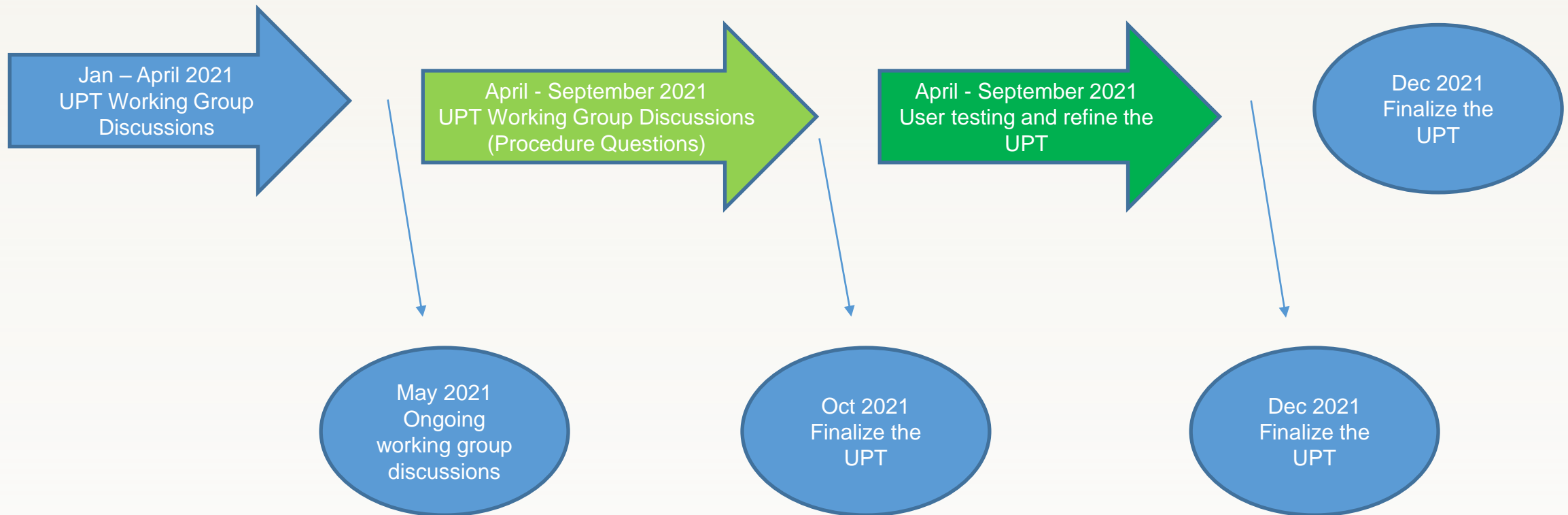
Next Steps

1. During Zoom meeting(s) the working draft of the UPT will be thoroughly analyzed, discussed and finalized
2. Once the UPT is finalized, it will go through user testing
 - a. Researchers
 - b. Veterinarians,
 - c. IACUC Administrators, and
 - d. IACUC members
3. The final UPT will be made available to the community.





Estimated Timeline





Questions/Thoughts

