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

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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

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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) Comm

Name		Institution	
Last	First		
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Clarke	Carol	USDA	carol.l.cl
Cole	Lori	University of Tennessee, Knoxville	lcole
Fitzhugh	Dawn	DoD	Dawn.c.fitz
Gibbens	Bob	USDA	robert.m.g
Glowacz	Susan	Indiana University, Bloomington	sglowac
Greer	Bill	University of Michigan	wggree
Hauser	Melinda	University of Tennessee, Knoxville	mhau
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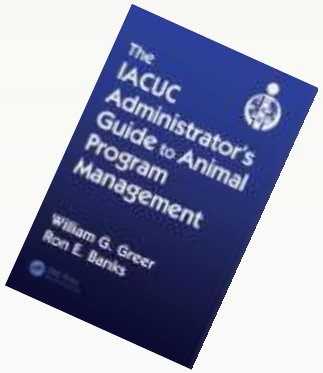
Kane	John	Academic Sinica, Taiwan	mbkung@c
Maglia	Anne	UMass Lowell	anne_m
Mitchell	Andrea (Andi)	Texas A&M University	mitche



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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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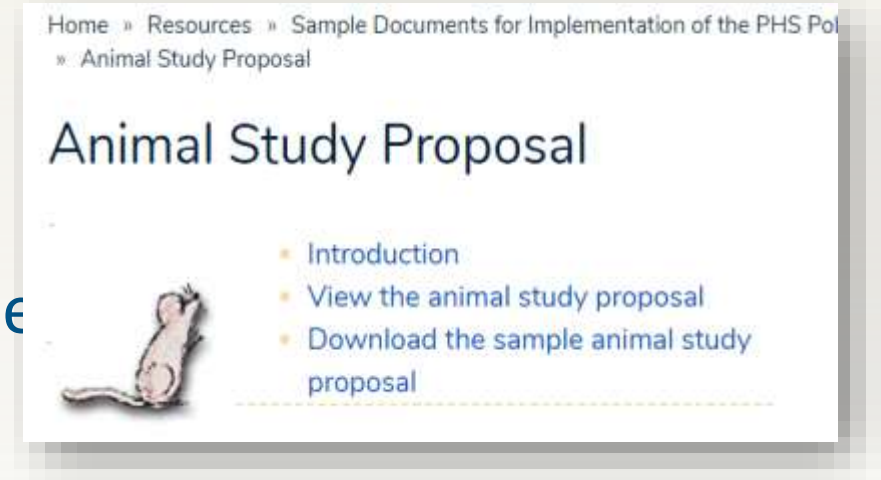
As a reminder, the Starting Point

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)

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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.

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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 is 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

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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. 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.

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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.

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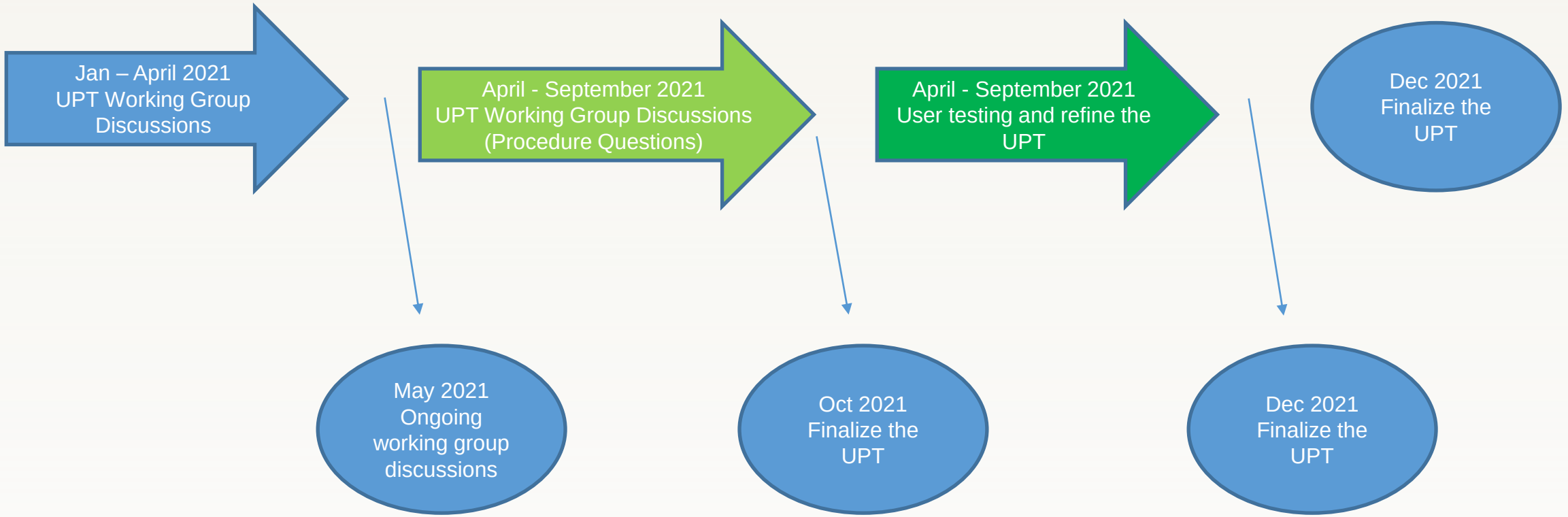
Estimated Timeline



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Questions/Thoughts

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