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
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<thead>
<tr>
<th>Name</th>
<th>Institution</th>
<th>Email</th>
</tr>
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<tr>
<td>Armstrong</td>
<td>Vanderbilt University</td>
<td><a href="mailto:erica.r.armstrong@vumc.org">erica.r.armstrong@vumc.org</a></td>
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<tr>
<td>Banks</td>
<td>University of Oklahoma Health</td>
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<tr>
<td>Brot</td>
<td>University of Washington</td>
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<td>Centola</td>
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<td>Clarke</td>
<td>USDA</td>
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<tr>
<td>Cole</td>
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<td>Fitzhugh</td>
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<td>USDA</td>
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<td>Greer</td>
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<td>Huang</td>
<td>VA</td>
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<td>Mitchell</td>
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<tr>
<td>Wolff</td>
<td>OLAW</td>
<td><a href="mailto:wolffa@od.nih.gov">wolffa@od.nih.gov</a></td>
</tr>
</tbody>
</table>
Communication Tools

1. Email
2. Conference Calls (when necessary)
3. FDB Meetings for updates and status checks
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 use of check boxes); and

4. ‘User’ friendly (& regulatory compliant)!
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)
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.
Blood Collection  

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  

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:  
   - Other, please describe  *(Only appears if the species is mouse or rat)*  
   - Describe how blood will be collected  

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

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

2. Please indicate why it is necessary to use non-standard enclosures/housing conditions
1. What will animals be given (e.g., orally, injected, cutaneous application) or exposed to?

1. Chemical/toxins – provide the class

- Biologic (e.g., Bacteria, Virus, Prion, Fungi) provide the specific strain

- Physical (e.g., isotope, lasers, X-Rays) – provide the type
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

Jan – Dec 2020
Review and finalize Questions

Jan 2021 – Jun 2022
Questions Review and Discussions

Jul 2022 – Dec 2022
User Testing

May 2020
FDP Check Pt.

Sept 2021
FDP Check Pt.

May 2022
FDP Check Pt.

Sept 2022
FDP Check Pt.
Questions/Thoughts
Email contacts:

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

Volunteers Needed!
Email cusp@thefdp.org
CURRENT STATUS

- Working Group Formed
- Project Proposal Approved: October 2017
- Site Design & Function: June 2019
- Site Development & Testing: In Progress!
- Pilot
- Impact on Burden

In Progress!

- 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
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

Troubleshooting Guide

Start troubleshooting →
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!
Welcome!

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User Documentation & FAQ

Proident provident pulvinar consequat totam ridiculus? Magna cum,哥伦布ensque utopia, quis a blanditiis cursus consectetur pensabils ida ura, massa? Faciliis.

Explore the documentation →

Troubleshooting Guide

Interdum corrupti. Et deorsum inure eligendi sociis molestiae fermentum at bibendum leo qui cupidaet accusantium, martis modis earum, fermentum accusamus.

Start troubleshooting →

LET'S GET STARTED
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<thead>
<tr>
<th>Procedure Name</th>
<th>Type</th>
<th>Species</th>
<th>Actions</th>
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<tbody>
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<td>Cognitive testing in juvenile monkeys using CANTAB</td>
<td>Behavioral Testing</td>
<td>Marmoset</td>
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<tr>
<td>Euthanasia of rodent fetuses and neonates</td>
<td>Euthanasia</td>
<td>Rodents (Rodents)</td>
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<td>Irradiation for immuno-oncology studies</td>
<td>Induction of illness</td>
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<td>Blood and Sample Collection</td>
<td>Mouse</td>
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<td>Opioid chamber testing and addiction</td>
<td>Behavioral Testing</td>
<td>Rat</td>
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<td>Surgery</td>
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Showing 1 to 10 of 11 results

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[Image 134x-20 to 815x508]
### My Users

- **ACTIVE**: 6
- **EXPIRING**: 0
- **INACTIVE**: 0
- **CONTACTS**: 0

### Search

#### User

Search names...

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<th>Name</th>
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<th>Action</th>
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<td><a href="mailto:aubrey@uw.edu">aubrey@uw.edu</a></td>
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<td>Lynette Akins</td>
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<tr>
<td>Sally Thompson-Weber</td>
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