CUSP: An Option to Address Administrative Burden at the Institutional Level

Madeline Buddha, Jaret Langston & Aubrey Schoenleben
April 2, 2019
Hello!

Madeline Budda, DVM, MS, DACLAM  
Director, Office of Animal Welfare Assurance  
University of Oklahoma Health Sciences Center

Jaret Langston, MSEng  
Manager, Applications Architect - Enterprise  
University of Alabama at Birmingham

Aubrey Schoenleben, PhD, CPIA  
Scientific Reviewer, Office of Animal Welfare  
University of Washington
Content Copyright

All content included in this session is the property of the presenter(s), and is protected by United States and international copyright laws. Certain materials are used by permission of their respective owners. The course content may not be reproduced, transmitted, or shared in any way without the prior written permission of the presenter(s).

Access to this presentation should not be construed as a license or right under any copyright, patent, trademark or other proprietary interest of PRIM&R or third parties.
I have no relevant personal/professional/financial relationship(s) with respect to this educational activity
Learning Objectives

1. Provide an overview of the CUSP project and the responsibilities of participants using the system.

2. Demonstrate how participants can utilize the system through the use of a model.

3. Share the current status of the project and future timelines.
Background

• Transition to electronic protocol management system **motivated** development of standard procedures.

• Development and approval of standard procedures – **OAW staff, veterinarians and the IACUC**.

• Current library includes
  • 897 standard substances
  • **656 standard procedures**
It’s Not Just Us…

- Animals research regulations identified as a top source of administrative burden.
- Protocol review process “unnecessarily complex and time consuming.”
- Identifying a mechanism to reduce the time and effort needed to create and review protocols would reduce this burden for researchers and IACUCs.

Goal of the CUSP Project

Develop an online venue where participating institutions can share standard procedures used in animal care protocols.

CUSP = Compliance Unit Standard Procedure
Partnered with Federal Demonstration Partnership
Benefits

- Reduced administrative burden for researchers, IACUCs and IACUC staff.
- Support development of high quality animal care protocols.
- Provide consistency within and across institutions.
- Support knowledge sharing within the animal welfare compliance community.
Site Guidelines

- Participating institutions have the opportunity and expectation to contribute.
- Each institution is expected to maintain their contributions as updates occur.
- Each procedure must be reviewed and approved by the individual institution’s IACUC prior to use.
- The specific content of procedures will not be reviewed, approved, or endorsed by the FDP or regulatory agencies.
CUSP Working Group

Aubrey Schoenleben, Sally Thompson-Hirani

Data Import & Export
Michelle Brot, Jaret Langston

Data Organization
Scott Bury, Eva McGhee

Data Storage & Maintenance
Madeline Budda, Curtis Van Slyck

Species Team
Denise Ancharski-Stutler

Procedure Team
Eva McGhee

Form Team
Jeremy DeRicco, Robert Kerley

Currently 89 members from 50 institutions
FDP Compliance Unit Standard Protocol (CUSP)

CUSP is an online repository where participating institutions can share standard procedures used in animal care protocols with the broader animal welfare compliance community. This resource will support the development of high quality animal protocols, while reducing burden for researchers, IACUCs and IACUC support staff.

User Name: [input field]
Password: [input field]

Login

Forgot User Name?  
Forgot Password?  
New User? Request Account

Contact Info
FDP@nas.edu
500 Fith St, NW
Room 1401A
Washington, DC 20001

© Dev 2019
Site Access & User Roles

- **Administrator**
  - Full Access

- **Institutional Representative**
  - Read & Edit Access

- **Community Member**
  - Read Only Access
Procedure Type Categories

- Antibody Production
- Behavioral Testing
- Blood or Sample Collection
- Capture and Trapping
- Diet Modification
- Euthanasia
- Identification and Genotyping
- Imaging and Irradiation
- Induction of Illness
- Substance Administration
- Surgery
- Other
Example: Buprenorphine Analgesia

**ID:** 123  
**Procedure Name:** Buprenorphine Analgesia  
**Procedure Type:** Substance Administration  
**Species:** Mouse  
**Contributing Institution:** University of Washington  
**Date Submitted:** 10/10/2017  
**Date Last Modified:** 3/22/2018

**PROCEDURE DESCRIPTION**
Buprenorphine (0.05 mg/kg) will be diluted with sterile saline or water to the appropriate concentration and then injected subcutaneously (SC). Total injection volume will not exceed 10 uL/g of body weight. A single dose of buprenorphine will be administered to deliver up to 12 hours of analgesia.

If signs of pain are noted despite buprenorphine administration, or following this period, Veterinary Services will be consulted.

**KEYWORDS**
Opioid, Buprenex

**SUBSTANCE TYPE**
Analgesic
Example: Euthanasia

**PROCEDURE DESCRIPTION**

Put fish in a beaker in system water, and add 4% buffered tricaine (stored in the fridge) until body and gill movements stop (approx. 10 mL tricaine/150 mL system water). Wait 5 minutes to make sure all fish are dead. Collect fish in a fish net and put the carcasses in designated bucket in the freezer. Dispose the tricaine water mix in designated bottle. Death will be confirmed by absence of opercular movement for 5-10 minutes as stated in the zebrafish book.

Make tricaine (MS-222) solution for euthanizing fish by combining the following in a glass bottle with a screw cap: 4 g tricaine powder, 98 mL DD water. Adjust to pH 7 with sodium bicarbonate or Tris pH 9. Cover the bottle with foil and store in fridge.

Always prepare tricaine in a fume hood and wear PPE (goggles, lab coat and gloves).

**KEYWORDS**

Danio

**SUBSTANCE TYPE**

Chemical Agent
Example: Blood Collection

ID: 326
Procedures Name: Blood Collection, Peripheral Vein (Unsedated)
Procedure Type: Blood or Sample Collection
Species: Macaque
Contributing Institution: Institution Not Identified
Date Submitted: 7/30/2018
Date Last Modified: 12/1/2018

PROCEDURE DESCRIPTION

The animal must be acclimated to an appropriate restraint device, such as a procedure cage or tabletop restraint device (TTRD). Acclimation takes place over the course of several days to weeks, during which time animals are allowed to access the restraint device and are given treats and verbal reinforcement to encourage the animal to enter and sit calmly in the restraint device. Once animals consistently enter the restraint device, they will be gradually acclimated to physical restraint by engaging the restraint mechanism repeatedly (over different sessions) until the animal is fully restrained in the device. Treats and verbal reinforcement will be used to encourage the animal to tolerate the restraint. Once restraint is tolerated, manipulation for research procedures can begin. Use of the restraint device will be aborted if an animal is clearly distressed by the prospect of restraint (e.g. refusal to enter the TTRD or procedure cage, or constant motion preventing appropriate positioning for restraint). A successfully acclimated animal will, in general, enter the restraint device with minimal encouragement and will allow manipulation for study procedures. Duration of restraint will be less than 5 minutes. If the blood draw is unsuccessful or if the animal has to be released from restraint because 5 minutes has elapsed, a maximum of three attempts at blood collection per day are permissible. If multiple collections are scheduled in a single day, a maximum of two attempts per time point are permissible.

While the animal is in the restraint device, blood is collected from the femoral, saphenous, or cephalic vein via percutaneous venipuncture. Pressure is applied at the site after the procedure to prevent bleeding. Animals are never left unattended and are always monitored when they are in the restraint device. Timing as described in experiment. Volume will not exceed 10 ml/kg within two weeks (14 days).

KEYWORDS
Cephalic, Femoral, Saphenous

SUBSTANCE TYPE
N/A
How Can My Institution Use CUSP?
Use Cases

- **Something for Everyone**
  - IACUC
  - Veterinarians
  - Researchers
  - Institutional administrators

- **Reduction of administrative burden**
  - One place to find and share procedures
  - Focus on methodology
  - Procedures can be incorporated directly into protocols
  - Best practices
What’s the current status of CUSP?
CUSP Project Timeline

- **Working Group Formed**: March 2017
- **Pilot Project Approved**: October 2017
- **Site Design & Function**: February 2019 (In progress!)
- **Initial Site Development**: 
- **Pilot**: Fall 2019
- **Impact on Burden**
Strategy for Development Phase

<table>
<thead>
<tr>
<th>Phase</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alpha</td>
<td>• System construction&lt;br&gt;• Initial testing of system&lt;br&gt;• Identify major bugs, usability issues or feature gaps&lt;br&gt;• Tech team + 2-3 institutions</td>
</tr>
<tr>
<td>Beta</td>
<td>• Second phase of testing&lt;br&gt;• Simulates how system will be used in real life&lt;br&gt;• Identify bugs and other technical issues&lt;br&gt;• 6-8 institutions</td>
</tr>
<tr>
<td>Pilot</td>
<td>• Last phase before release&lt;br&gt;• Identify bugs and other technical issues&lt;br&gt;• Evaluate qualitative aspects (e.g., how user friendly is the system)&lt;br&gt;• 15-20 institutions</td>
</tr>
</tbody>
</table>
Questions?

Want to chat further?
Email Aubrey Schoenleben (aubreys@uw.edu) or Sally Thompson-Iritani (sti2@uw.edu)
Thank you!

Want to chat further? Email Aubrey Schoenleben (aubreys@uw.edu) or Sally Thompson-Iritani (sti2@uw.edu)
Data Organization: Parent/Child Model

**Parent Procedure**

**Variation #1**

**Variation #2**

**Variation #3**

### Example of when to Create a Variation (Child) Procedure or a New Procedure

<table>
<thead>
<tr>
<th>Create a Variation Procedure</th>
<th>Create a New Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Same procedure, same species, different steps/dosages/timing/other info</strong></td>
<td><strong>Same procedure, different species</strong></td>
</tr>
<tr>
<td>The system has an procedure for isoflurane anesthesia in mice, but your institution’s procedure for isoflurane anesthesia in mice uses different steps, dosages, timing, and/or other details</td>
<td>Your institution has a procedure for isoflurane anesthesia in rats and the system does not already have any procedure for isoflurane anesthesia in rats</td>
</tr>
<tr>
<td><strong>Same procedure, same species, different steps/dosages/timing/other info</strong></td>
<td><strong>Same species, different procedure</strong></td>
</tr>
<tr>
<td>The system has an procedure for ovariectomy surgery in mice, but your institution’s procedure for ovariectomy surgery in mice uses different steps, dosages, anesthetic/analgesic drugs, timing, and/or other details</td>
<td>Your institution has a procedure for Ketamine/Xylazine anesthesia in mice and the system does not already have a procedure for Ketamine/Xylazine anesthesia in mice</td>
</tr>
<tr>
<td><strong>Same procedure, same species, different steps/dosages/timing/other info</strong></td>
<td><strong>Same procedure, different species</strong></td>
</tr>
<tr>
<td>The system has a procedure for administering BrdU in rabbits via intraperitoneal injection, but your institution’s procedure for delivering BrdU in rabbits uses different steps, dosages, routes (e.g., in drinking water, or injected locally into the brain ventricles), timing, and/or other details</td>
<td>Your institution has a procedure for ovariectomy surgery in mice and the system does not already have any procedure for isoflurane anesthesia in rats</td>
</tr>
<tr>
<td><strong>Same species, different procedure</strong></td>
<td><strong>Same species, different procedure</strong></td>
</tr>
<tr>
<td>Your institution has a procedure for administering LPS in rabbits and the system does not already have any procedure for administering LPS in rabbits</td>
<td>Your institution has a procedure for administering LPS in rabbits and the system does not already have any procedure for administering LPS in rabbits</td>
</tr>
<tr>
<td>Substance Type</td>
<td>Subcategory</td>
</tr>
<tr>
<td>----------------------</td>
<td>--------------------------------------------------</td>
</tr>
<tr>
<td>Adjuvant</td>
<td>Carcinogen</td>
</tr>
<tr>
<td>Analgesic</td>
<td>Cell, Cell Line, or Tissue</td>
</tr>
<tr>
<td>Anesthetic</td>
<td>Chemical Agent</td>
</tr>
<tr>
<td>Antibiotic</td>
<td>Chemotherapeutic</td>
</tr>
<tr>
<td>Antibody</td>
<td>Cytokine</td>
</tr>
<tr>
<td>Antiemetic</td>
<td>DNA/RNA</td>
</tr>
<tr>
<td>Antifungal</td>
<td>Fungi</td>
</tr>
<tr>
<td>Antimicrobial</td>
<td>Hormonal Regulator</td>
</tr>
<tr>
<td>Antiparasitic</td>
<td>Immuno-suppressant</td>
</tr>
<tr>
<td>Antiviral</td>
<td>Infectious Agent</td>
</tr>
<tr>
<td>Bacteria</td>
<td>Nanoparticle</td>
</tr>
<tr>
<td>Biological Agent</td>
<td>Nutritional supplement</td>
</tr>
<tr>
<td>Blood or Body Fluids</td>
<td>Paralytic Agent</td>
</tr>
</tbody>
</table>
Data Import & Export

**Low Tech**
Manual
CSV (Excel)

**High Tech**
JSON
API

Image Source: www.flrunning.com
Site Access & User Roles

Administrator

Institutional Representative
Institution A

Community Member
Institution A

Community Member
Institution A

Community Member
Institution A

Community Member
Institution B

Community Member
Institution B

Community Member
Institution B
Single Sign On: Central Authentication Service (CAS)
Development Phase: Tentative Timeline

- **March**: Initial Build
- **April**: Alpha Testing
- **May**: Beta Testing
- **June** - **December**: Pilot Testing

Each testing phase will be ~2 months

**In progress!**

**Alpha Tester Training**
@ FDP Meeting (May 19-21)