Compliance Unit Standard Procedure (CUSP) Project

Aubrey Schoenleben and Sally Thompson-Iritani
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Speaker Introductions

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Director, Office of Animal Welfare
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University of Washington
Learning Objectives

1. Review an in-depth analysis of the CUSP project, including its uses and structure.
2. Examine how data will be organized, and how to import and export data.
3. Discuss the responsibilities of participants using the system.
4. Share information on the current status, future timelines, and what attendees should watch for moving forward.
Background

- Protocol preparation and review extremely time and effort intensive.
- A lot of back and forth clarifications during review
- Inconsistent review/comments
Institution grappled with the efforts to develop standard templates for common procedures

- List of Standard Templates
- Coded in an excel sheet
- Assigned it to people
- Nothing happened 😞
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**
Sharing…
The Federal Demonstration Partnership is a cooperative initiative among 10 federal agencies and 154 institutional recipients of federal funds for Phase VI. Our Chair and Vice-Chair are Richard Seligman from the California Institute of Technology and Dr. Michele Masucci from Temple University. The FDP is a program convened by the Government-University-Industry Research Roundtable of the National Academies. Its purpose is to reduce the administrative burdens associated with research grants and contracts. The interaction between FDP’s 450 or so university and federal representatives takes place in FDP’s 3 annual meetings and, more extensively, in the many collaborative working groups and task forces that meet often by conference calls in order to develop specific work.
Vision

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

CUSP = Compliance Unit Standard Procedure
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.
Currently 76 members from 40+ institutions
Currently 76 members from 40+ institutions
Data Import & Export

**Low Tech**
- Manual
- CSV (Excel)

**High Tech**
- JSON
- API

VS

Image Source: www.flrunning.com
Currently 76 members from 40+ institutions
Parent/Child Model

- Parent Procedure
  - Variation #1
  - Variation #2
  - Variation #3
## Parent/Child Model

### 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 a procedure for isofluorane anesthesia in mice, but your institution's procedure for isofluorane anesthesia in mice uses different steps, dosages, timing, and/or other details</td>
<td>Your institution has a procedure for isofluorane anesthesia in rats and the system does not already have any procedure for isofluorane 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 rats and the system does not already have any procedure for isofluorane 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 BrdU administration in mice and the system does not already have any procedure for BrdU procedure in mice</td>
</tr>
</tbody>
</table>
Data Organization

- Procedures will be characterized by various attributes, such as species or procedure type.
- Granular organization → Pick Lists
Data Organization

Procedures will be characterized by various attributes, such as species or procedure type. Granular organization →
Working Group

Currently 76 members from 40+ institutions
Site Access & User Roles

- **Administrator**
  - Full Access

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

- **Community Member**
  - Read Only Access
<table>
<thead>
<tr>
<th>Site Guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Participating Institution Expectations</strong></td>
</tr>
<tr>
<td>Opportunity and expectation to contribute</td>
</tr>
<tr>
<td>Maintain contributions as updates occur</td>
</tr>
<tr>
<td>Review and approve at local IACUC prior to use.</td>
</tr>
<tr>
<td><strong>Regulatory Agencies</strong></td>
</tr>
<tr>
<td>The specific content of a procedure will not be reviewed, approved, or endorsed by the regulatory agencies.</td>
</tr>
<tr>
<td>Regulatory agencies are participants in the monthly calls and contribute ideas.</td>
</tr>
<tr>
<td><strong>Accrediting Agencies</strong></td>
</tr>
<tr>
<td>Membership and representation on the working group encouraged.</td>
</tr>
<tr>
<td>AAALAC sees potential for future global sharing opportunities</td>
</tr>
</tbody>
</table>
CUSP Sharing Site
Timeline

Working Group Formed

March 2017

Pilot Project Approved

October 2017

Site Design & Function

In progress!

Initial Site Development

Pilot

Impact on Burden
Request for Information (RFI): Animal Care and Use in Research

Notice Number: NOT-OD-18-152

Key Dates
Release Date: March 14, 2018

Related Announcements
None

Issued by
National Institutes of Health (NIH)

Purpose
Through this Request for Information (RFI), the Office of Laboratory Animal Welfare (OLAW) in the Office of Extramural Research (OER), National Institutes of Health (NIH) is seeking information to improve the coordination of regulations and policies with respect to research with laboratory animals as required by the 21st Century Cures Act, Section 2034(d).

Background
The RFI is a coordinated effort of the Director of the National Institutes of Health in collaboration with the Secretary of Agriculture and the Commissioner of Food and Drugs to reduce administrative burden on investigators while maintaining the integrity and credibility of research findings and protection of research animals.
Questions?

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

Want to help?
Email Aubrey Schoenleben (aubreys@uw.edu) or Sally Thompson-Iritani (sti2@uw.edu)
Questions!

- How helpful would this kind of tool be at your institution? Why or why not?

- What features would be desirable? Not desirable?