

Compliance Unit Standard Procedure (CUSP) Project

Aubrey Schoenleben and Sally Thompson-Iritani
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PRIM&R's

2018 IACUC Conference

March 19-21 • Columbus, OH

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Disclosure: Aubrey Schoenleben, Sally Thompson-Iritani

I have no relevant personal/professional/financial relationship(s) with respect to this educational activity.

Speaker Introductions



Aubrey Schoenleben, PhD, CPIA

Scientific Reviewer, Office of Animal Welfare
University of Washington



Sally Thompson-Iritani, DVM, PhD, CPIA

Director, Office of Animal Welfare
Associate Director, Washington National Primate Research Center
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



Image Source: parade.com

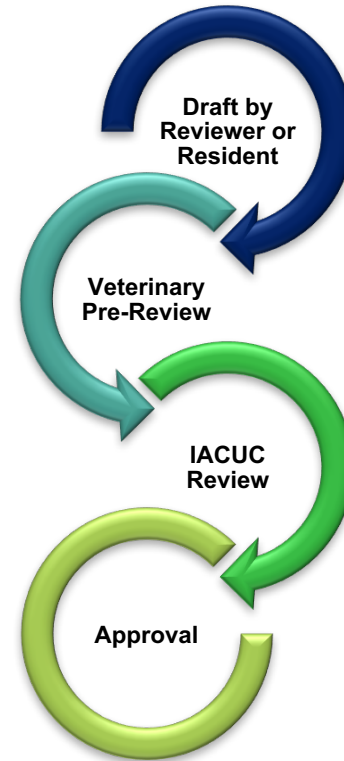
Prioritize

- 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...





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Redefining the Government & University Research Partnership

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"The University community has a crucial role to play in support of the President's goals for stimulating innovation and competitiveness in science and technology and developing the next generation of scientists and engineers. The Federal Demonstration Partnership provides a valuable forum through which Federal science and technology agencies can work creatively with University partners to reduce administrative burdens while advancing scientific discoveries and increasing transparency and accountability." ~ **Dr. John Holdren, Director, Office of Science and Technology Policy**

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

Announcements

2018 Faculty Workload Survey

Preparation for the 2018 Faculty Workload Survey has begun. You can read more about it [here](#).

Congressional Hearing on Academic Research Regulatory Relief: A review

Vision

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



**CUSP
SHARING
SITE**

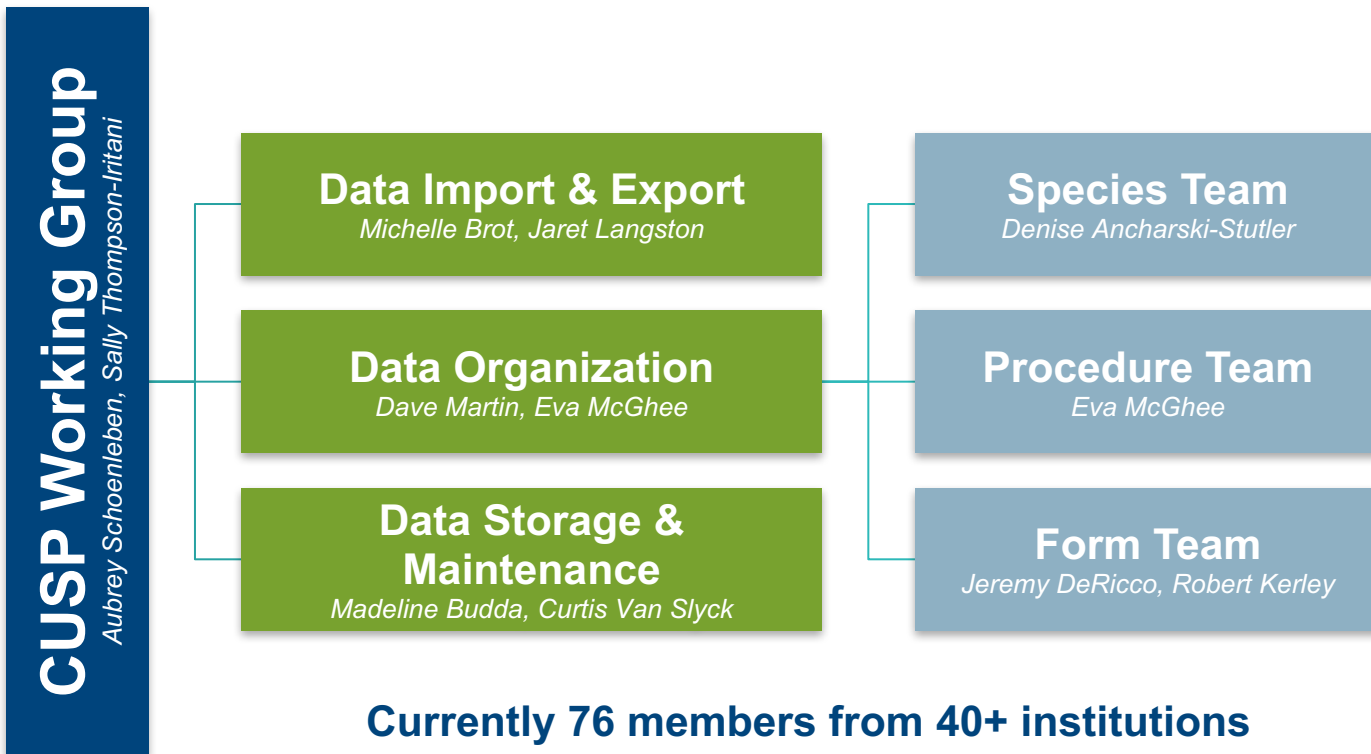
CUSP = Compliance Unit Standard Procedure

Benefits

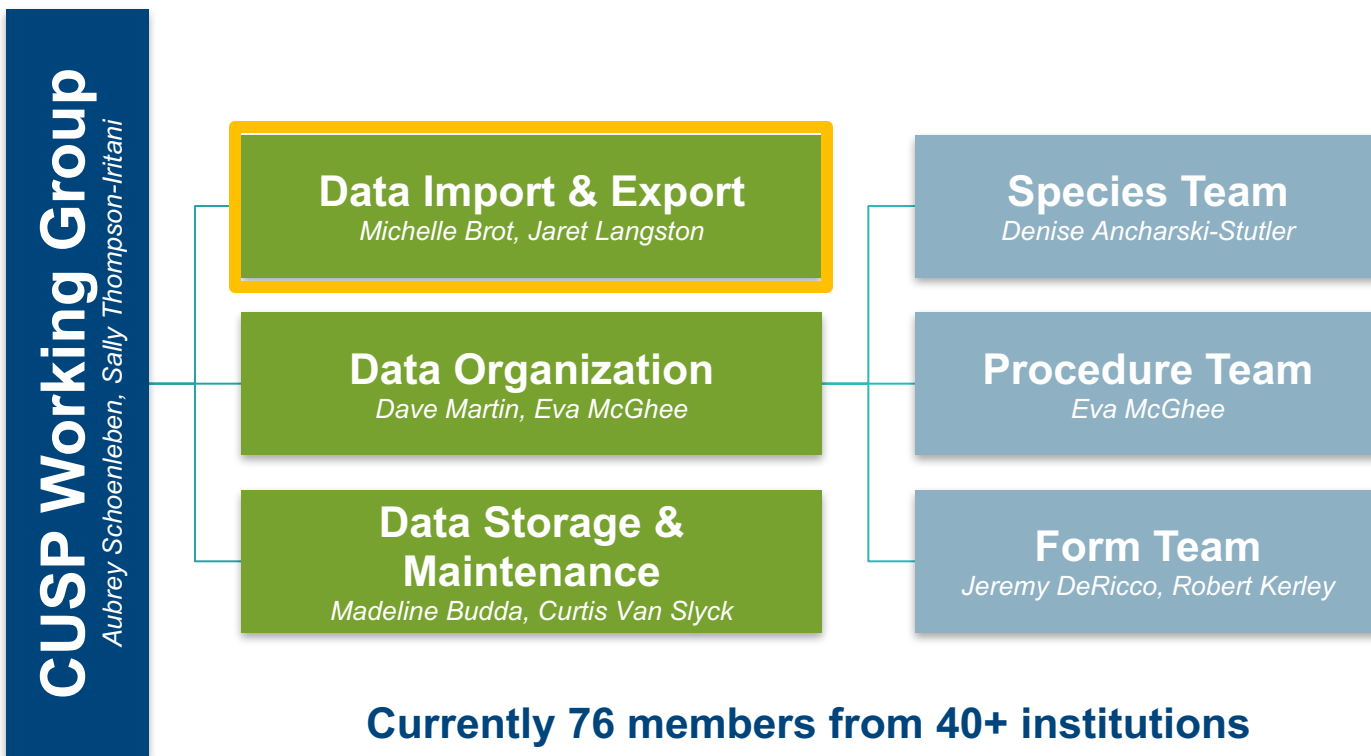
- ✓ Reduced administrative burden for researchers, IACUCs and IACUC staff.
- ✓ Support development of high quality animal care protocols.
- ✓ Provide consistency within and across institutions.
- ✓ Support knowledge sharing within the animal welfare compliance community.



Working Group



Working Group



Data Import & Export

Low Tech
Manual
CSV (Excel)

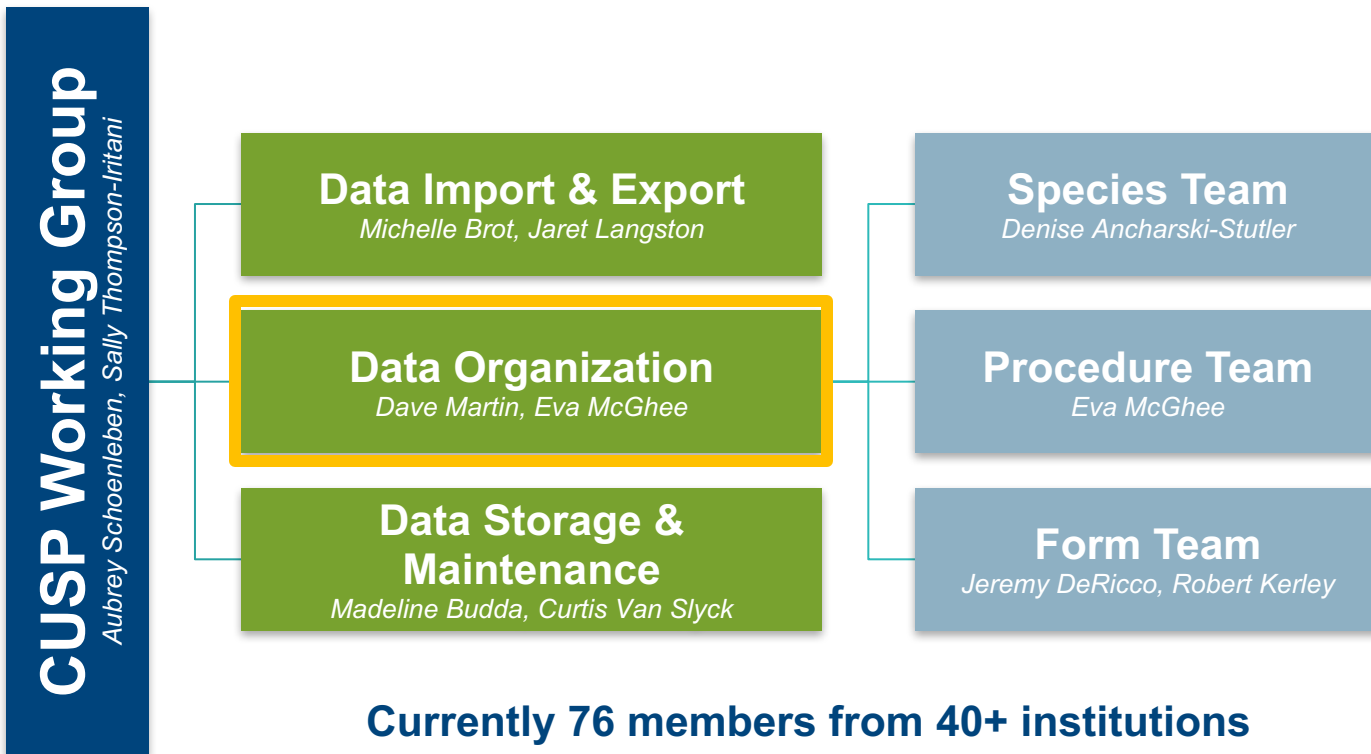


VS

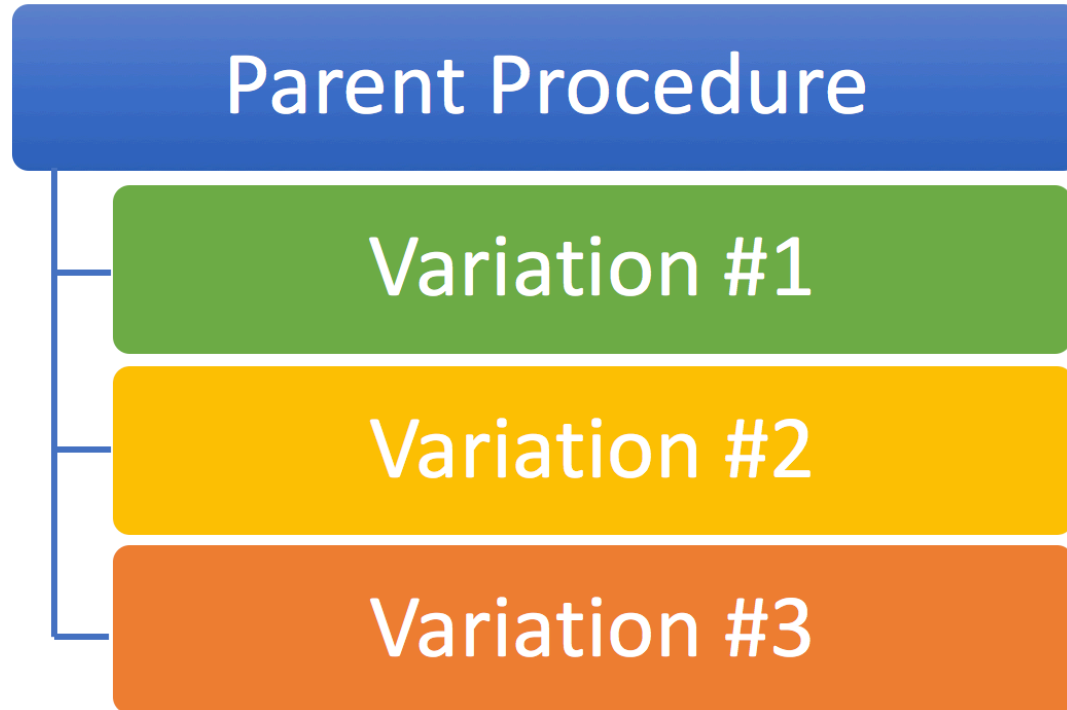


High Tech
JSON
API

Working Group



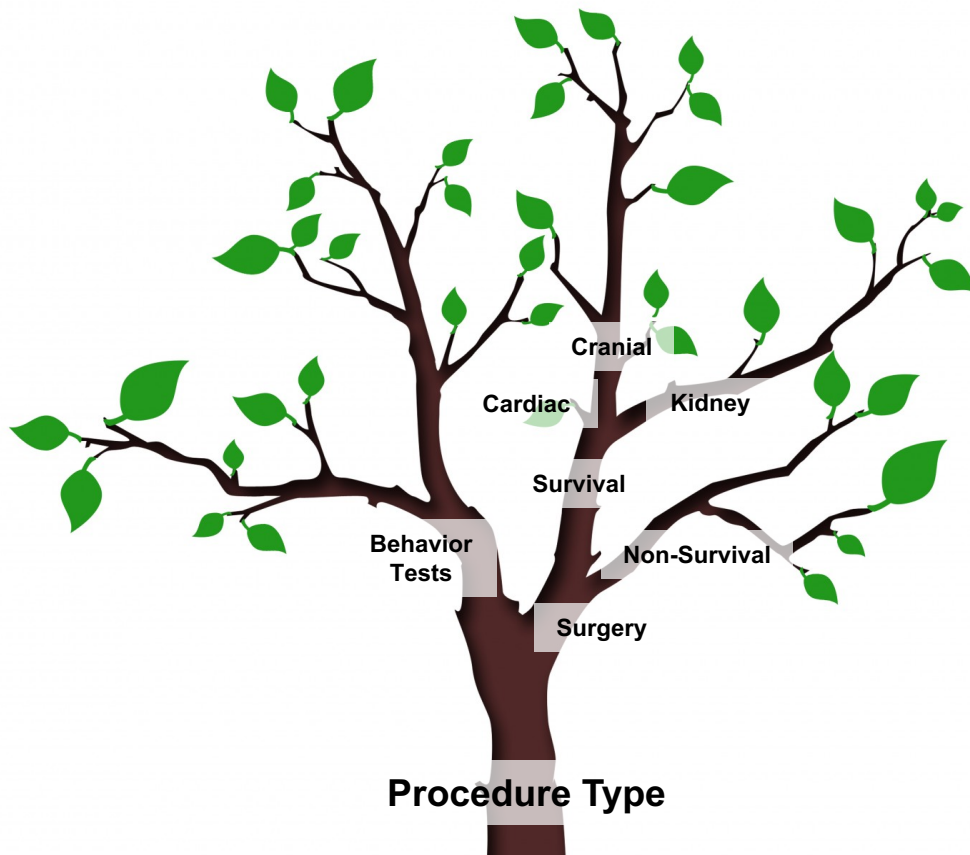
Parent/Child Model



Parent/Child Model

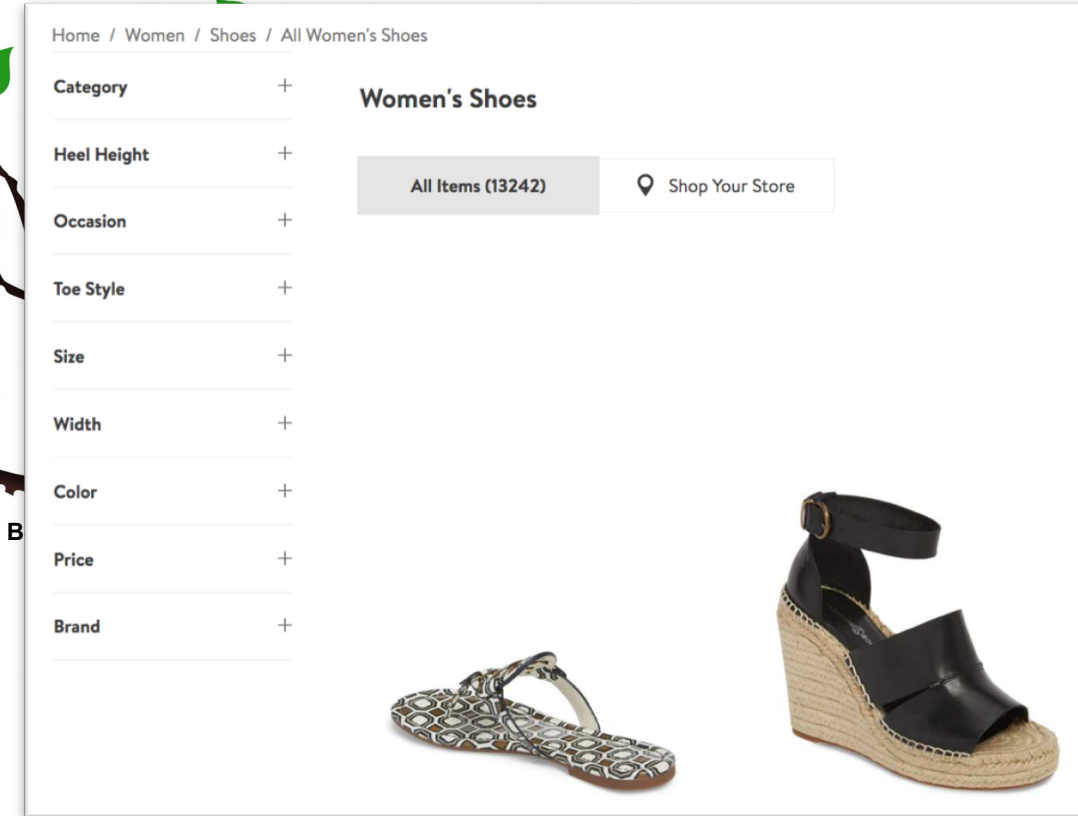
Example of when to Create a Variation (Child) Procedure or a New Procedure	
Create a Variation Procedure	Create a New Procedure
<p>Same procedure, same species, different steps/dosages/timing/other info</p> <p>The system has an procedure for isoflurane anesthesia in mice, but your institution's procedure for isoflurane anesthesia in mice uses different steps, dosages, timing, and/or other details</p>	<p>Same procedure, different species</p> <p>Your institution has a procedure for isoflurane anesthesia in rats and the system does not already have any procedure for isoflurane anesthesia in rats</p> <p>Same species, different procedure</p> <p>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</p>
<p>Same procedure, same species, different steps/dosages/timing/other info</p> <p>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</p>	<p>Same procedure, different species</p> <p>Your institution has a procedure for ovariectomy surgery in rats and the system does not already have any procedure for isoflurane anesthesia in rats</p> <p>Same species, different procedure</p> <p>Your institution has a procedure for an osmotic pump surgery in mice and the system does not already have any procedure for isoflurane anesthesia in rats</p>
<p>Same procedure, same species, different steps/dosages/timing/other info</p> <p>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</p>	<p>Same procedure, different species</p> <p>Your institution has a procedure for BrdU administration in mice and the system does not already have any procedure for BrdU procedure in mice</p> <p>Same species, different procedure</p> <p>Your institution has a procedure for administering LPS in rabbits and the system does not already have any procedure for administering LPS in rabbits</p>

Data Organization



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

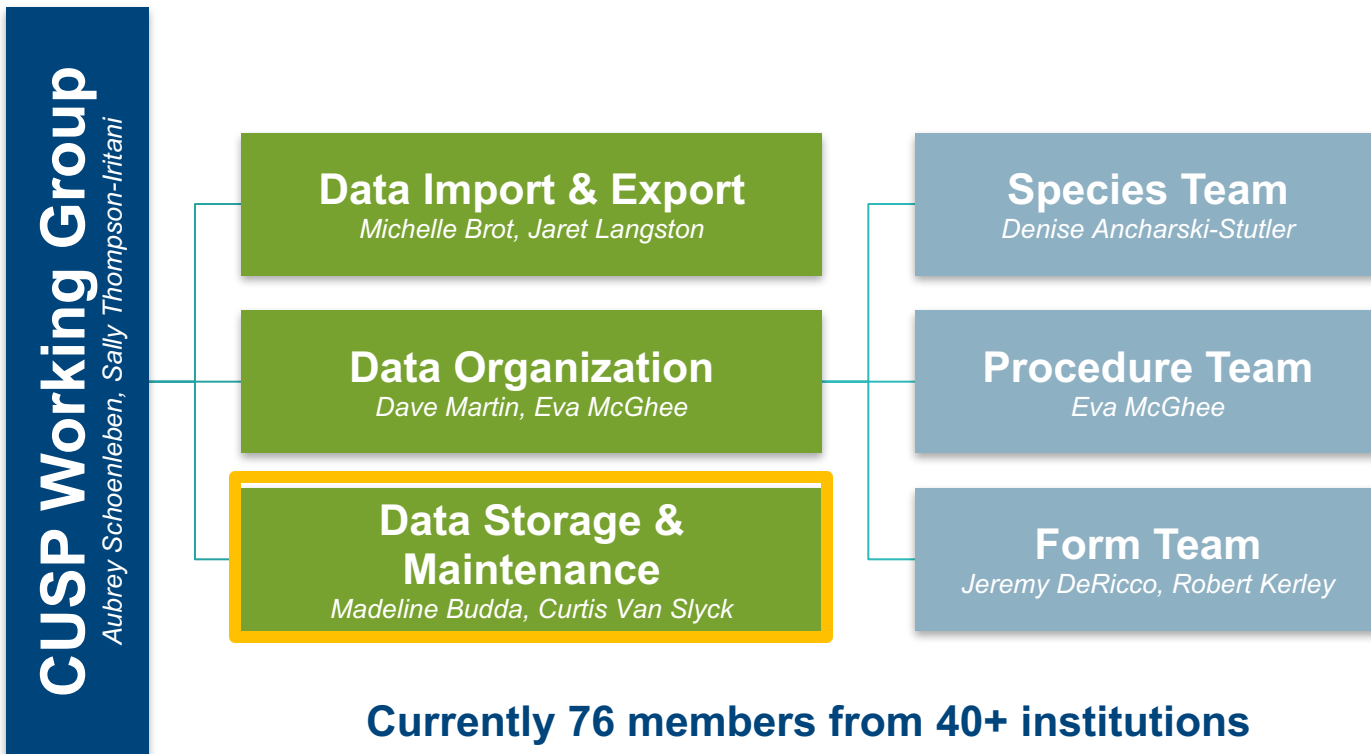
Data Organization



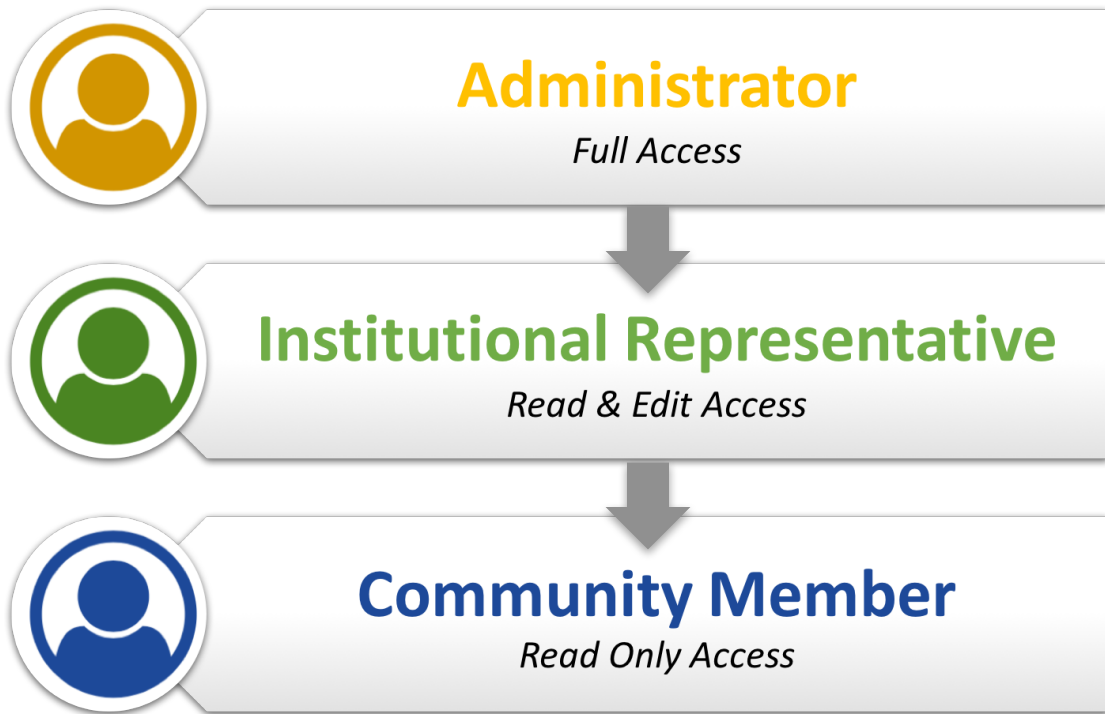
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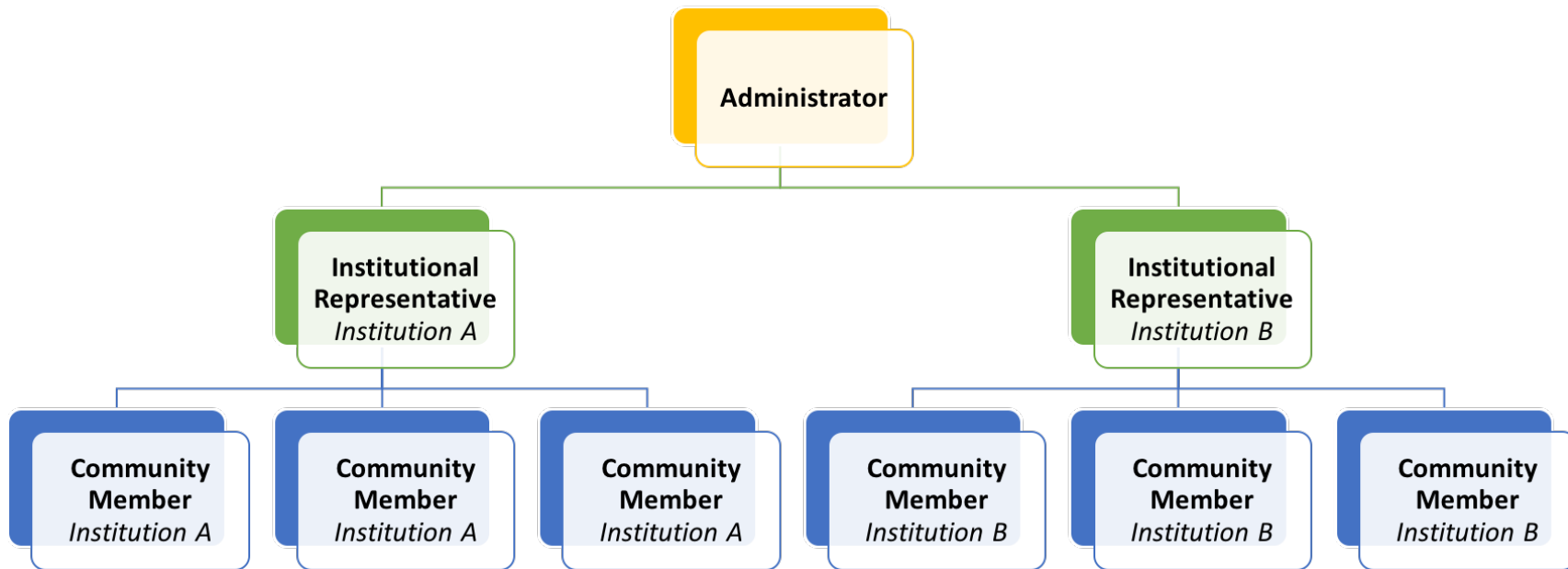
Working Group



Site Access & User Roles



Site Access & User Roles



Site Guidelines

Participating Institution Expectations

Opportunity and expectation to contribute

Maintain contributions as updates occur

Review and approve at local IACUC prior to use.

Regulatory Agencies

The specific content of a procedure will not be reviewed, approved, or endorsed by the regulatory agencies.



Regulatory agencies are participants in the monthly calls and contribute ideas.

Accrediting Agencies




Membership and representation on the working group encouraged.

AAALAC sees potential for future global sharing opportunities

CUSP Sharing Site


A Web Page

https://



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Download Selected Procedures 

Pick List One

- ☐ Item 1
- ☒ Item 2
- ☒ Item 3
- ☐ Item 4
- ☐ Item 5

Pick List Two +

Pick List Three +

Pick List Four +

ID	Procedure Name	Species	Procedure Type	Contributing Institution	Select
123	Buprenorphine Analgesia (24 hours) 14 ☆ 📄	Mouse	Substance Administration	University of Washington	<input type="checkbox"/>
456	Intracranial Injection 32 ☆ 📄	Mouse	Survival Surgery	Emory University	<input checked="" type="checkbox"/>
789	Administration of AAV 0 ☆ 📄	Rat	Substance Administration	Institution Not Identified	<input type="checkbox"/>
234	CO2 Euthanasia 10 ★ 📄	Mouse	Euthanasia	University of Washington	<input checked="" type="checkbox"/>
012	CO2 Euthanasia 25 ★ 📄	Rat	Euthanasia	Michigan State University	<input checked="" type="checkbox"/>
345	Tricaine Overdose 11 ☆ 📄	Zebrafish	Euthanasia	Penn State University	<input checked="" type="checkbox"/>

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MEDICINE AND RESEARCH

CUSP Sharing Site

A Web Page
https://

Jane Doe
Log Out

Home About My Procedures Help

search
Download Selected Procedures

Pick List One

- ☐ Item 1
- ☒ Item 2
- ☒ Item 3
- ☐ Item 4
- ☐ Item 5

ID	Procedure Name	Species	Procedure Type	Contributing Institution	Select
123	Buprenorphine Analgesia (24 hours)			University of Washington	<input type="checkbox"/>
456	Intracranial Injection			University of Washington	<input checked="" type="checkbox"/>
789	Administration of AAV			University of Washington	<input type="checkbox"/>
234	CO2 Euthanasia			University of Washington	<input checked="" type="checkbox"/>
012	CO2 Euthanasia			University of Washington	<input checked="" type="checkbox"/>
345	Tricaine Overdose			University of Washington	<input checked="" type="checkbox"/>

NAME: Buprenorphine Analgesia
PROCEDURE TYPE: Substance Administration
SPECIES: Mouse
DATE: 10/10/2017
CONTRIBUTING INSTITUTION: University of Washington

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

Analgesia, opioid, Buprenex

Pick List Two +
Pick List Three +
Pick List Four +

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Timeline



Request for Information: Reduce Administrative Burden in Animal Use

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)



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Questions!

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