

# CUSP SHARING SITE & UNIVERSAL PROTOCOL FORM

Working Group Meeting  
May 20, 2019



OFFICE OF ANIMAL WELFARE

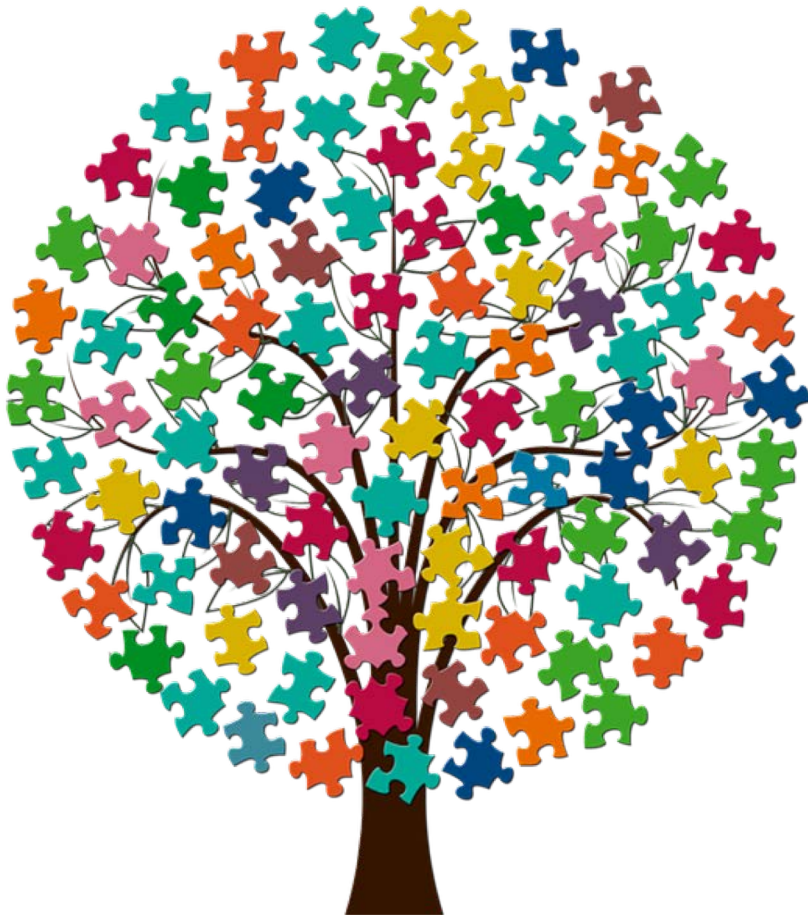
*Research Support Services*

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**Agenda:**

- 35 people attended in person, ~10 people attended online.
- CUSP Team Updates
- CUSP Development Update
- CUSP Goals for June Meeting
- Universal Protocol Form Discussion

## Procedure Team Update



Goal: Complete all procedure build outs for Beta Testing phase (~ late July)

### Procedure Types Completed:

- Diet Modification
- Identification & Genotyping
- Imaging & Irradiation

### Procedure Types In Progress:

- Behavioral Testing
- Capture & Trapping

### Procedures Types To Go:

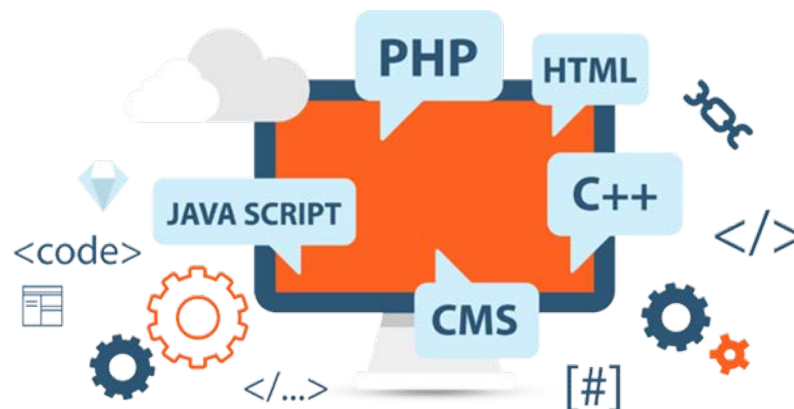
- Antibody Production
- Induction of Illness
- Substance Administration
- Surgery

## Procedure Team Update

- Team meets weekly; utilizing own expertise and that of their home institutions.
- Started by categorizing remaining procedure types as easy, medium, hard
- For difficult procedure types, focused on stimulus or modality (e.g., irradiation = modality).
  - Used general/broad categories, and then tested those against procedures in that category from their home institutions.
  - Easy: Ab production, identification/genotyping
  - Medium: Capture, Diet Mod, Imaging/Irradiation
  - Hard: Behavior, Illness, Substance Admin, Surgery, Other
- Recognize there is no perfect way to organize procedure types, but striving to maintain logical and easily accessible structure throughout (consistency across all categories).
- On track to be complete by the end of July.
- If other working group members would like to provide feedback – now is the time! Can provide feedback via Trello.

## Development Update

- Currently working on –
  - Development of entity relationship diagrams (ERD) and underlying database structure.
  - Mocking up screens in CMS (only a few left to go!)
    - Walked through several of the screen mock-ups during session.
- Tying the user interface and underlying databases together



## Alpha Testing Plan

- **Goal:** This phase of testing will focus on the user's interaction with the system (data entry and look up).
- **Approach:** Agile-type approach, with one week iterations. Trello will be used to track work and test results.
- **Tester Training Session:**
  - May 21<sup>st</sup> at 12pm, Executive Room
- **Testing Schedule:**
  - June 3-7: Deploy Iteration #1 to test environment; load with dummy data
  - June 10-14: Iteration #1 Testing
  - June 24-18: Iteration #2 Testing
  - July 8-12: Iteration #3 Testing
  - July 29: Final Go/No Go Decision





## **Goals for June Meeting**

- Aubrey/UW: Complete test case development; prep Trello board; load site with dummy data.
- Dev Team: Complete development for iterations #1 and #2.
- Alpha Testers: Attend tester training session; participate in first rounds of testing.
- Procedure Team: Continue with procedure build out.



## **Proposed Agenda Topics for June:**

- Email Aubrey ([aubreys@uw.edu](mailto:aubreys@uw.edu)) if you'd like to add a topic to the agenda.
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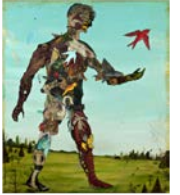
**Tester Training:**  
**May 21<sup>st</sup> @ 12-2pm**  
**Executive Room**

**Next Meeting:**  
**June 28<sup>th</sup> @ 11am PST**





*IACUC Administrator Association*



# A Universal Protocol Template



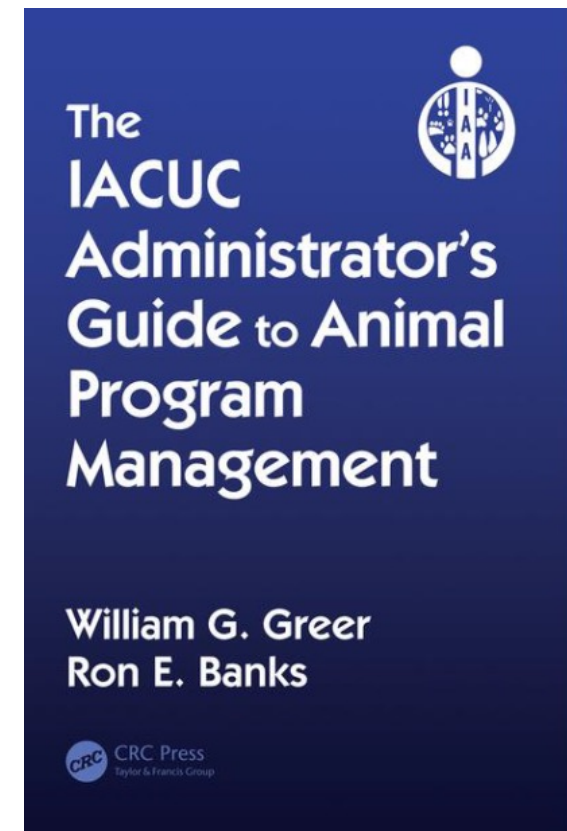
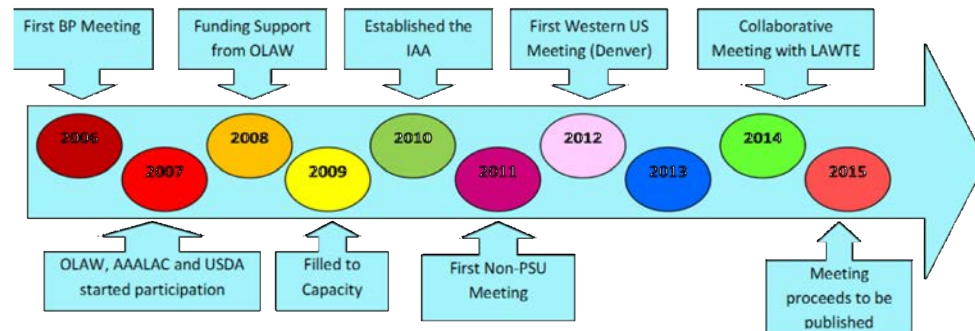


## Objectives

1. IACUC Administrators Association
2. IAA's progress on developing a Universal Protocol Template
3. Why a Universal Protocol Template
4. Discuss the idea of the 80/20 Rule
5. Practices to use in a universal template



# IACUC Administrators Association (IAA)





# IAA Projects



1. Establisheded a venue for the IACUC Administrative Community to regularly meet to discuss common challenges
2. Publisheded common practices used to manage ACUP
3. Workeded on FAQs with OLAW on the VVC process
4. Incorporate MOU language into OHSP subcontracts
5. Develop a common resource for disaster plan development
6. Develop a tool kit for reviewing and overseeing wildlife studies
7. Develop an IACUC universal protocol template





## Where did IAA start?

### OLAW Protocol Sample Template

- Based on a form used by the intramural NIH investigators
- Supplemented with information gathered from templates used by many different other institutions

Resource: (<https://olaw.nih.gov/resources/documents/animal-study-prop.htm>)

Home » Resources » Sample Documents for Implementation of the PHS Pol  
» Animal Study Proposal

#### Animal Study Proposal



- [Introduction](#)
- [View the animal study proposal](#)
- [Download the sample animal study proposal](#)

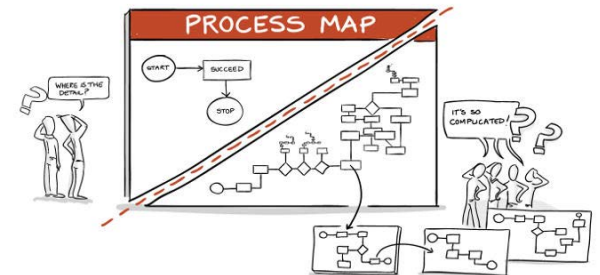
## Current Status

1. Revised the current OLAW resource template
2. Community weigh-in and review
  - a. Compliance Staff (Best Practice and Beyond the Basics Meetings)
  - b. Veterinary Staff
  - c. Members of the scientific community (i.e., scientists)
3. Next Step
  - a. FDP opportunity to provide thoughts
  - b. Additional discussions between compliance, regulators and scientists



# The process

1. Define the criteria that would qualify - requesting information from the PI through the protocol template
2. Review/consider the questions currently in the template
  - a. Information is necessary to review the proposed animal activities
  - b. Information related to compliance, but not necessarily the activities
  - c. Is the information managed another portion of the program (e.g., Vet Care)
3. Consider the wording of each question





## Concepts Considered

1. Building in Standardized Procedures “with a check box”?
2. Using Assurance Statements?
3. Using ACUP/Vet standing policies rather than the protocol?
4. Looking for other ideas?

The idea is the Universal Template will

1. Take advantage of processes and procedures that have already been standardized – i.e., **Enable the 80/20 rule!**
2. Ensure only information that's needed by the IACUC to review animal activities is gathered
3. Help to minimize the PIs regulatory burden







# A Template for Rodents and One for Others!

80/20 rule



Rodents play an invaluable role in biomedical research. Approximately 95 percent of all laboratory animals are mice and rats. Reducing reliance on higher-order species, rodents have become the animal model of choice for biomedical researchers because their physiology and genetic make-up closely resembles that of people. Despite certain differences between people and rodents, the similarities are strong enough to give researchers an enormously powerful and versatile mammalian system in which to investigate human disease.

The sequencing of rodent genomes has enabled researchers to recreate human diseases in rodents through genetic engineering. Researchers “knock in” or “knock out” disease-related traits in mice and rats, and new technology allows researchers to directly edit the DNA of the rodents<sup>[1]</sup>. Research with genetically modified mice and rats has led to significant new treatments, cures and therapies and continues to revolutionize science and medicine.

## Check the Box – “Build in Standardized Procedures”

- ☐ 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.
- ☐ Up to 1% of body weight in blood (i.e., 1 ml of blood per 100 grams of body weight) may be collected from mice or rats in 14 days or less using either the lateral tail and/or saphenous vein, and/or by tail incision.
- ☐ A tail biopsy up to 5mm in length will be collected from a mouse or rat that is less than 21 days of age for genotyping.



## Human Endpoints?

- ❑ Visible Tumors: A mouse will be euthanized if the diameter of a tumor exceeds 2cm, or if the tumor ulcerates greater than  $\frac{1}{2}$  its surface area, or the tumor develops in an area that impairs normal movement/physiologic behavior.
- ❑ Visible Tumors: A rat will be euthanized if the diameter of a tumor exceeds 4cm, or if the tumor ulcerates greater than  $\frac{1}{2}$  its surface area, or the tumor develops in an area that impairs normal movement/physiologic behavior.
- ❑ Neurodegenerative diseases??





## How about survival surgery?

Anything Standardized? Maybe surgery prep...

Aseptic technique means to use a series of practices and procedures that help to prevent contamination from pathogens. Survival surgery must be performed using aseptic technique. Consequently, please check yes to provide assurance that the following process will be followed to ensure aseptic technique is used.

The instruments and/or medical devices will be sterilized (e.g., autoclaved) prior to each surgery. The surgical area/table will be decontaminated using an appropriate disinfectant. The surgeon will wear, at minimum, a mask, a surgical cap/bonnet, sterile gloves, and a clean scrub top, disposable gown, or lab coat. The surgical site will be prepared by removing the hair followed by at least three alternating scrubs of disinfectant (e.g., betadine, chlorhexidine) and rinse (e.g., ethanol, warmed saline, sterile water) ensuring to remove any remaining visible debris.

☐ Yes

☐ No, please explain <Text Box>



## Minimize discomfort, pain...



Steps must be taken to avoid or minimize discomfort, pain and distress associated with the surgical procedure. Please respond to the following information.

1. Please check yes to provide assurance that sterile ophthalmic ointment will be applied to each eye.

**☐ Yes    ☐ No, please explain <Text Box>**

2. Please check yes to provide assurance that thermoregulatory support will be provided, and the animal will be continuously monitored while under anesthesia.

**☐ Yes    ☐ No, please explain <Text Box>**

## Anesthetic and Analgesia Use (1/3)

1. Please select the anesthesia that will be used for this surgery. Check all that apply
  - ☐ Isoflurane (4-5% induction and 1-2% for maintenance) – **inhalant**
  - ☐ Ketamine (80-120 mg/kg) + Xylazine (5-10 mg/kg) – **IP injection**
  - ☐ Pentobarbital (Nembutal) (40-60 mg/kg) – **IP injection**
  - ☐ Other, please provide the anesthetic, dose and **method of application**



## Anesthetic and Analgesia Use (2/3)

1. Please select the analgesia that will be used for this surgery  
Check all that apply

- ☐ Buprenorphine (.05 -.1 mg/kg ) every 6-12 hours – SC or IP injection
- ☐ Carprofen (5 mg/kg) every 24 hours – IP injection
- ☐ Ketoprofen (2 - 5 mg/kg) every 12-24 hours – SC
- ☐ Other, please provide the anesthetic, dose and method of application

2. Please check yes to provide assurance that the selected analgesia will be provided through the post operative recovery period (i.e., until the surgical sutures or clamps are removed).

☐ Yes      ☐ No, please explain <Text Box>

## Anesthetic and Analgesia Use (3/3)



### Maybe these?

3. Please check yes to provide assurance that the selected analgesia will also be preemptively provided (i.e., immediately before the surgery is conducted). **Yes, No, text box**
4. Please check yes to provide assurance that post operative surgery records will be maintained that document daily observations and the administration of analgesia.  
**[ ] Yes [ ] No, please explain <Text Box>**



# Confirmations through Assurance Statements

1. How are assurance statements used and why are they used?
2. What's the threshold for and the associated risk when using an assurance statement



## OK or not, What's the risk?



1. Granting agencies require institutions to verify that proposed animal activities are approved by an IACUC prior to funds being received by the institution. Please check “**Yes**” to provide assurance that all of the animal activities proposed in the grant application are describe in an IACUC protocol(s).
2. Please check “Yes” to provide assurance that animals will be transported according to the specifications of veterinary or husbandry staff (i.e., a vet care policy), and that personal vehicles will not be used to transport animals.

## Community Asks'

1. Consider developing a template that highlights the questions needed for the IACUC to conduct its review;
2. Includes other questions that have been traditionally asked, but provide guidance statements that helps the community understand why asking the question isn't necessary; and
3. Provides sample responses to each question to help the community understand the minimum amount of information that should be provided for each question.



# Other Ideas?