

WORKING GROUP: COMPLIANCE UNIT STANDARD PROCEDURE (CUSP) SHARING SITE

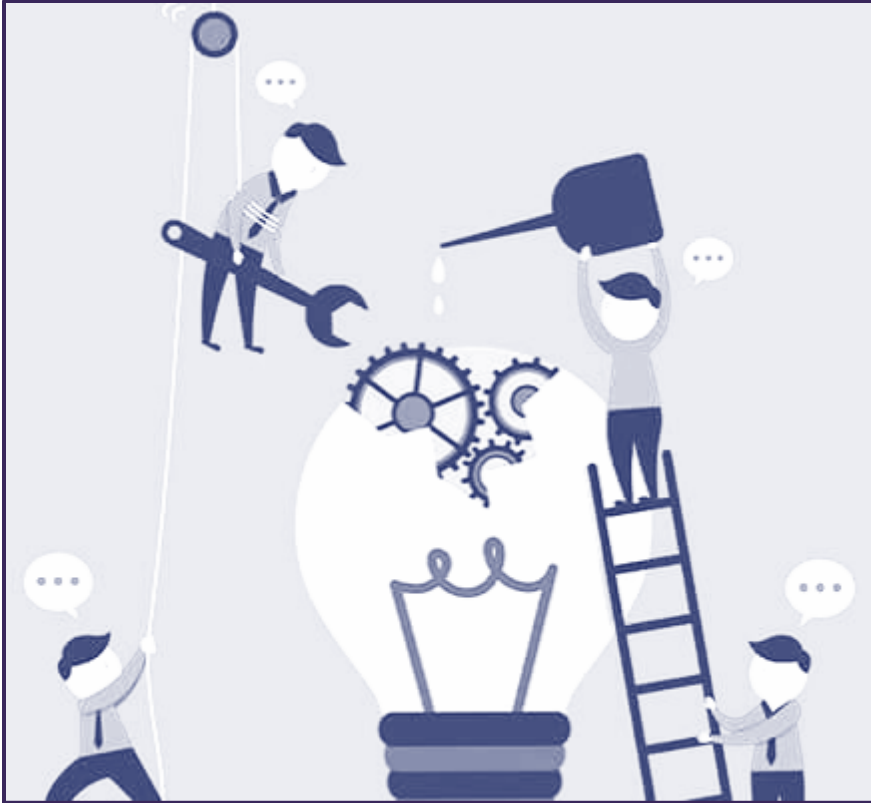
Working Group Meeting
January 24, 2019



Agenda:

- ~25 individuals attended in person, 18 online
- Team Updates
- Discussion Topics
- Goals for February Meeting
- Update on 21st Century Cures Act

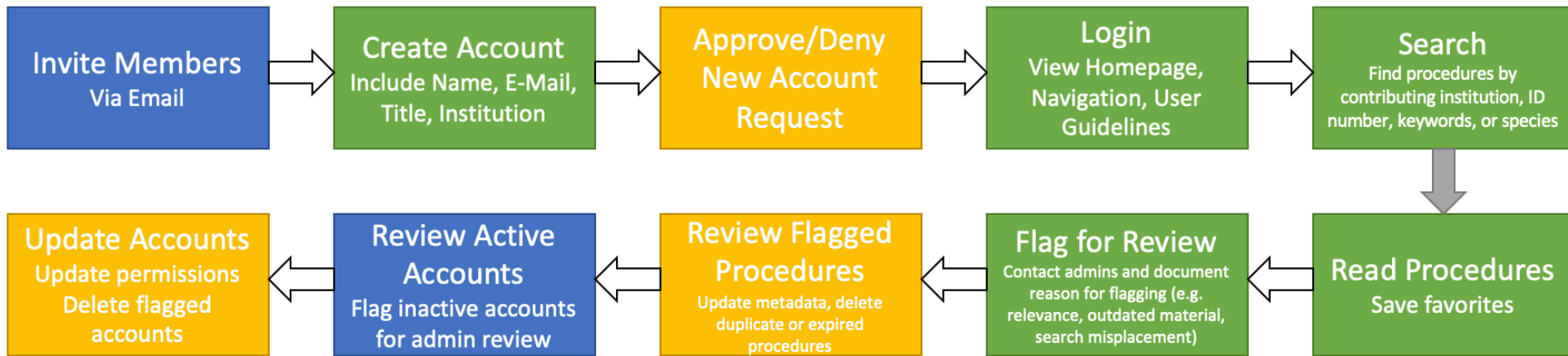




Team Updates

1. **Data Storage & Maintenance**
 2. **Data Organization**
 3. **Species**
 4. **Data Import & Export**
-

Account Lifecycle



Key

Community Member

- Create, **Review**, and **Edit Personal Account**
- Login
- Read Procedures
- Search, **Filter**, and **Sort** Procedures
- **Bookmark Favorites**
- **Export Procedures**
- Flag Procedures for Admin Review

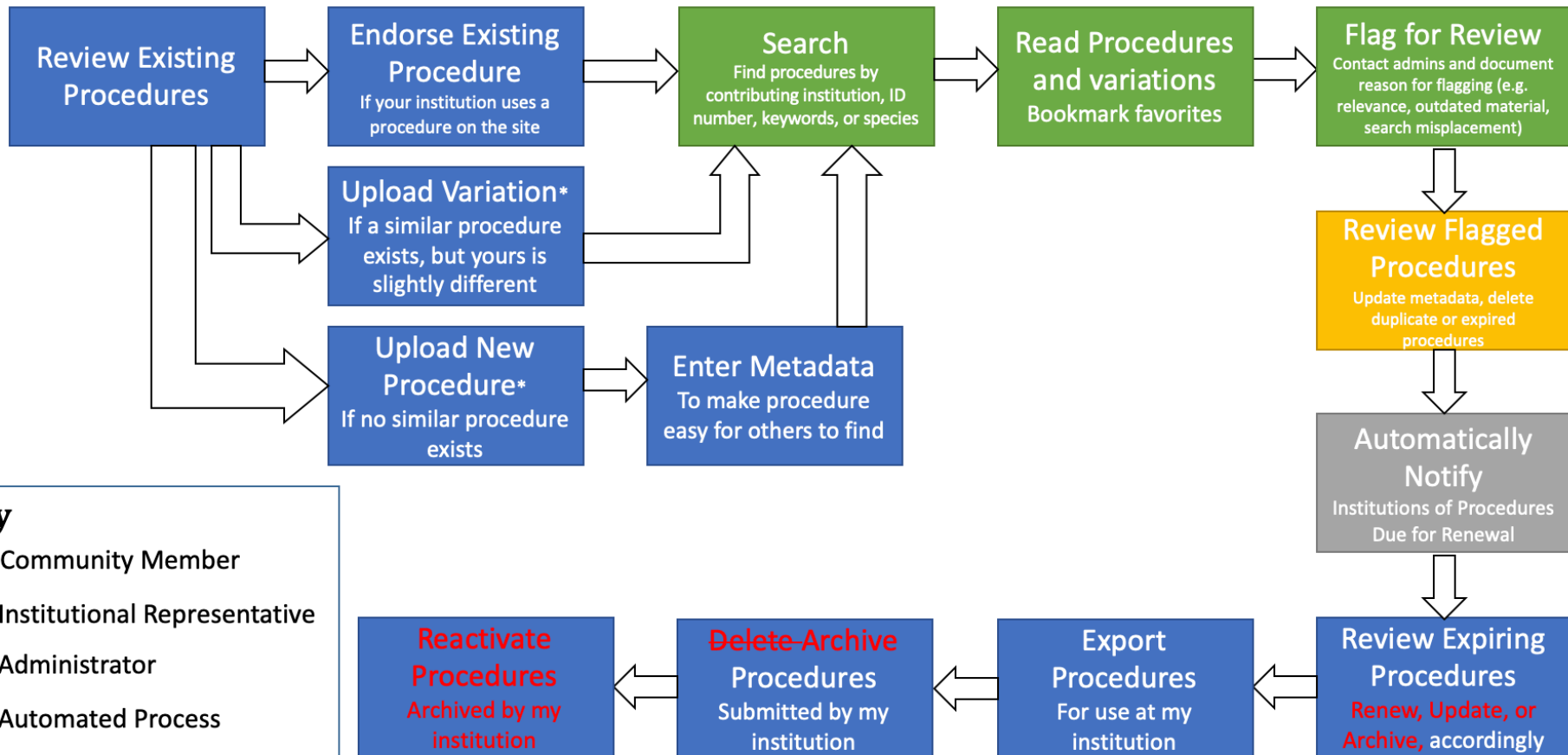
Institutional Representative

- Review community accounts within Institution
- **Review procedures submitted by institution**
- **Submit New Procedures**
- **Endorse Procedures from Other Institutions**
- **Edit, Renew, Archive, and Reactivate Procedures from My Institution**
- **Submit System Queries and Generate Reports**

Administrator

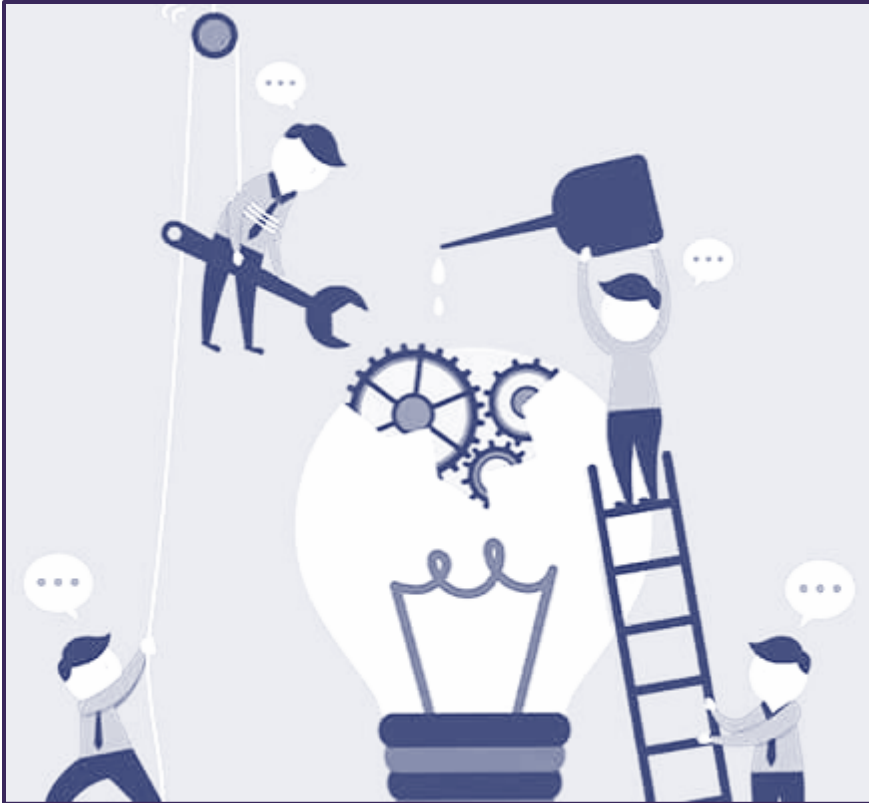
- Review Accounts
- Update User Permissions
- Edit or Deactivate Flagged or Inactive Users
- **Edit, Renew, Archive, and Reactivate Procedures**
- **Review and Delete Flagged Procedures**

Procedure Lifecycle



Data Storage & Maintenance Team: Discussion

- Team updated business process maps for account and procedure lifestyle based on group decisions/discussions over past few months.
 - Edits are shown in red.
 - No further suggestions/discussions.
-



Team Updates

1. Data Storage & Maintenance
 2. Data Organization
 3. Species
 4. Data Import & Export – No Update
-



Final 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

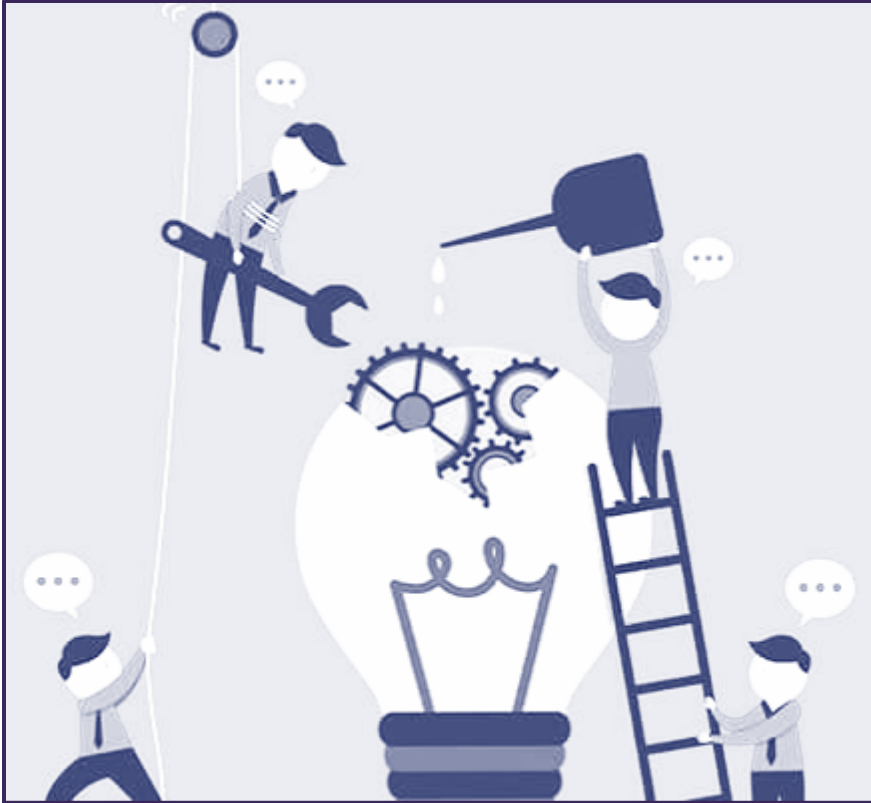
Developing a standard naming convention for procedures was identified as a requirement by the working group early in the project.

Goal: Re-assess this requirement to determine if it is still needed.

- Working on a guidance document for how to name procedures.
- Sent out a survey to get feedback from group.

Data Organization Team: Discussion

- Over the past month, team sent out some draft guidance re: naming conventions for procedures, asked for feedback from group.
- Decided that naming conventions will be offered as guidance; not strictly required/enforced.
 - Will add this to the general User Guidance document
- Discussion re: if the common name should be used or formal Greek/Latin terminology. Common name might be easier for users when searching for procedures.
- Decided that both could be used – in the name of the procedure and through the use of keywords.

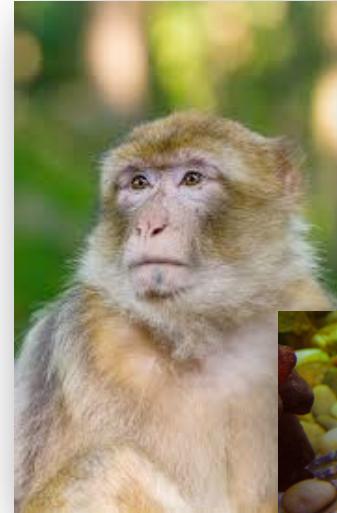


Team Updates

1. Data Storage & Maintenance
 2. Data Organization
 3. Species
 4. Data Import & Export
-

Defining Aliases for Top 10 Species

- Goal: Identify other common names or misspellings for each species.
- Allows us to “teach” the system to correct these to the species defined in the pick list.
 - Ex: "mus" or "mice" would be aliases for "mouse"



Top 10 Species: Focus for Pilot

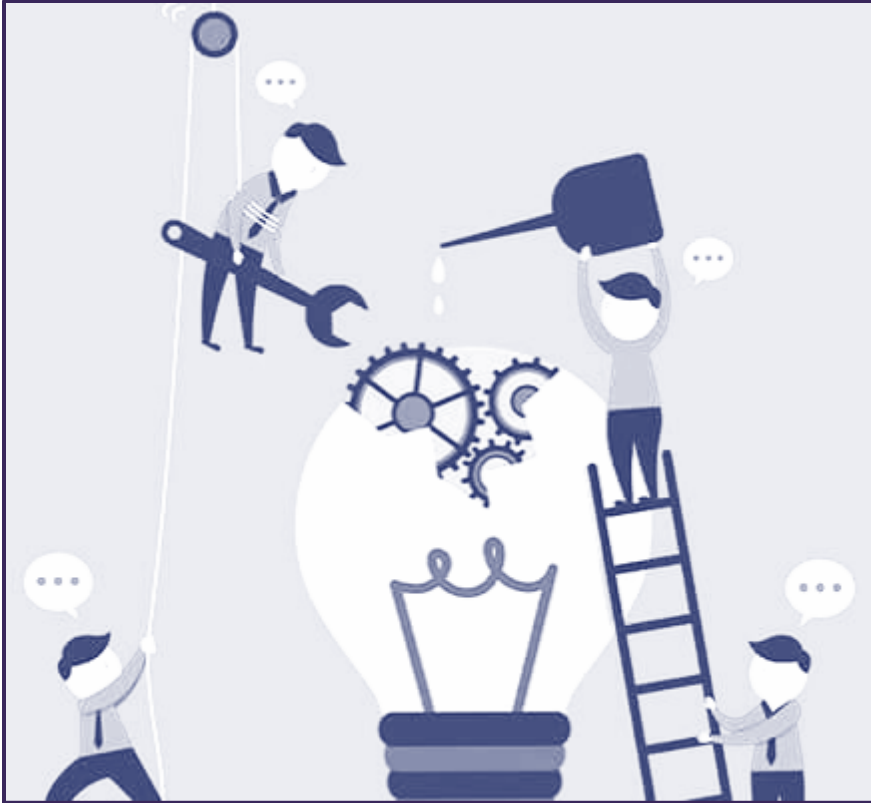
Zebrafish	Macaque
Pig	Sheep
Rat	Frog
Mouse	Guinea Pig
Rabbit	Dog



Dog	Frog	Guinea Pig	Macaque	Mouse
canis canine dogs puppy	frogs tadpole Xenopus	Cavia cavy guinea pigs	Cyno Cynomologus macaques non-human primate NHP Rhesus Pig tail	mice Mus Musculus
Pig	Rat	Rabbit	Sheep	Zebrafish
hog piglet pigs Sus swine	rats Rattus	bunny Lagomorph Lagomorpha New Zealand White Oryctolagus rabbits	lamb ovies sheeps	Danio larva zebrafishes

Species Team: Discussion

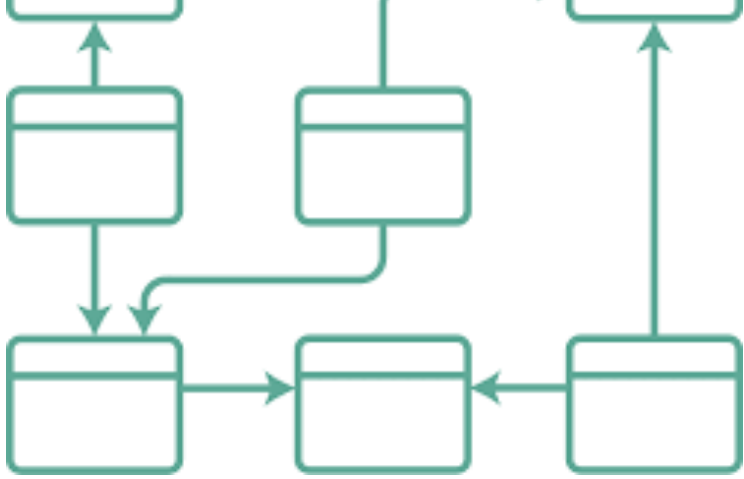
- Discussion was brief; group generally in agreement with suggestions.
 - Need to be cautious with more ambiguous terms like “larvae” as this can apply to multiple species, particularly as the database grows over time.
 - Will post list to Trello as well in case there are other thoughts/suggestions over the next month.
-



Team Updates

1. Data Storage & Maintenance
 2. Data Organization
 3. Species
 4. Data Import & Export
-

Goal: Build a model of the CUSP database in Microsoft Access

- This exercise will help determine underlying data architecture and work out the necessary logic for search and filter features.
 - This logic will then be used to develop the code within the CMS.
 - Demo of model/pick list architecture
- 
- ```
graph TD; T1[Table 1] --> T2[Table 2]; T1 --> T3[Table 3]; T2 --> T4[Table 4]; T3 --> T4; T4 --> T5[Table 5]; T5 --> T6[Table 6]; T6 --> T7[Table 7];
```
- The diagram illustrates a model/pick list architecture with seven tables represented as rectangles. The relationships are as follows: Table 1 (top left) has arrows pointing to Table 2 (middle left) and Table 3 (middle right). Table 2 has an arrow pointing to Table 4 (bottom left). Table 3 has an arrow pointing to Table 4. Table 4 has an arrow pointing to Table 5 (bottom middle). Table 5 has an arrow pointing to Table 6 (bottom right). Table 6 has an arrow pointing to Table 7 (top right). Table 7 has an arrow pointing back to Table 1, completing a cycle.
- *Group liked the pick list structure that was presented.*
  - *After reviewing site requirements document, JL feels that we no longer need to build a full prototype in Access; okay to move straight to developing in CMS. Will touch base with DW to confirm he's okay with this plan.*

## Discussion Topic: Automated Notifications

Question: Is a notification to the institutional representative(s) needed when a procedure expires and is automatically archived?

### *Current Notifications:*

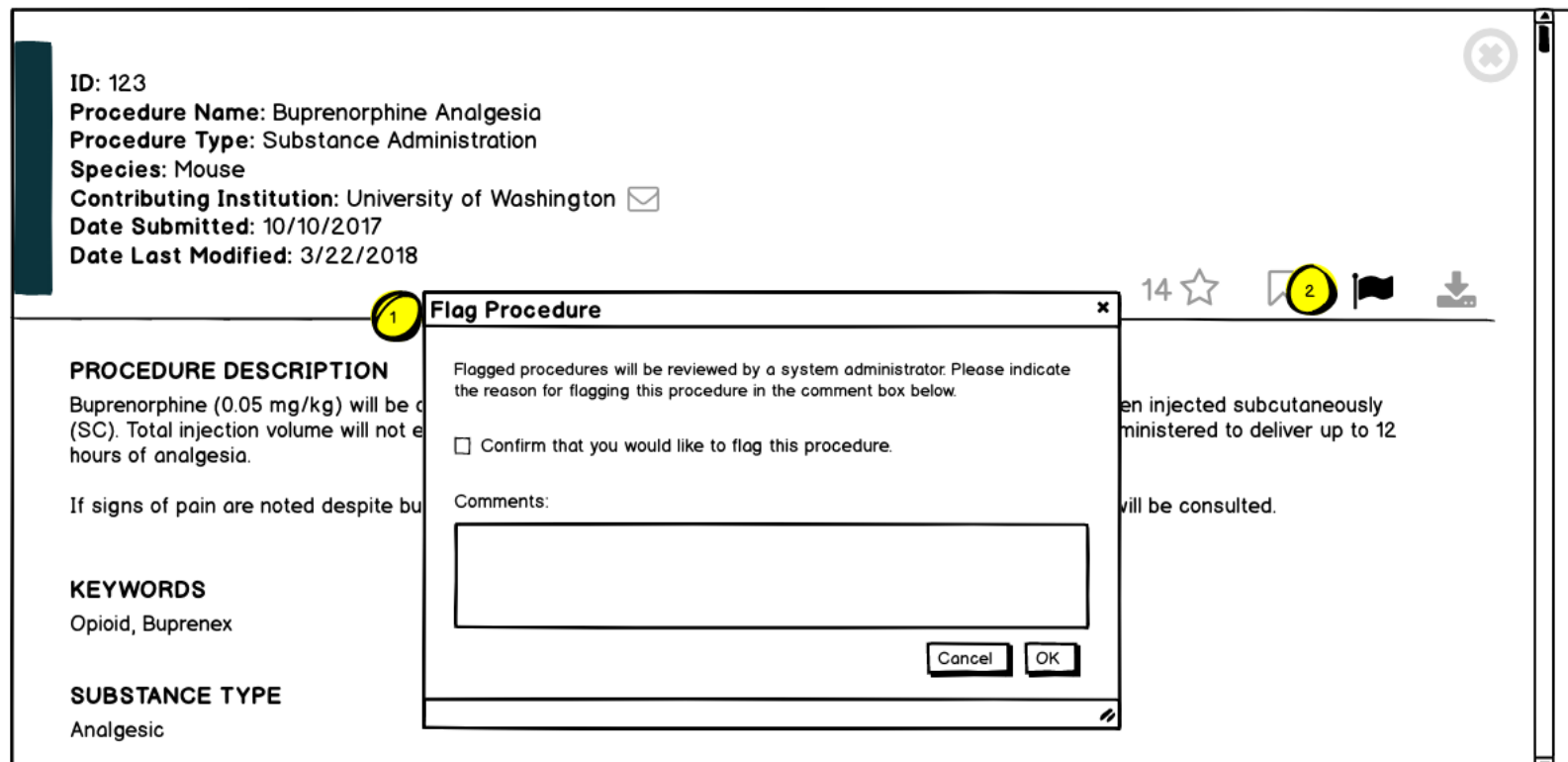
|                                                                               |                                                                                                                                                                                                               |
|-------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Community Members will receive an email when...</b>                        | <ul style="list-style-type: none"><li>• Their request for a new account has been approved.</li><li>• Their request for a new account has been denied.</li><li>• Their account has been inactivated.</li></ul> |
| <b>Designated Institutional Representatives will receive an email when...</b> | <ul style="list-style-type: none"><li>• A user from their home institution requests a new account.</li><li>• A procedure approaches its expiration date (3 years from date of submission).</li></ul>          |
| <b>Administrators will receive an email when...</b>                           | <ul style="list-style-type: none"><li>• A user from an unapproved (new) institution requests a new account.</li><li>• When a procedure has been flagged for review.</li></ul>                                 |




➤ *Yes this would be helpful!*

## Discussion Topic: Flagged Procedures

Question: Once a procedure has been flagged, what do we want the review process to look like? What actions can the site administrator take?



The screenshot displays a web application interface for animal welfare procedures. On the left, a sidebar contains a dark teal vertical bar. The main content area shows details for a procedure with ID 123, named 'Buprenorphine Analgesia', of type 'Substance Administration' for a 'Mouse' species, submitted by the 'University of Washington' on 10/10/2017, and last modified on 3/22/2018. Below this, the 'PROCEDURE DESCRIPTION' section begins with 'Buprenorphine (0.05 mg/kg) will be...' and '(SC). Total injection volume will not e... hours of analgesia.' The 'KEYWORDS' section lists 'Opioid, Buprenex'. The 'SUBSTANCE TYPE' is 'Analgesic'. A 'Flag Procedure' dialog box is open in the center, featuring a yellow circle with the number '1' next to its title bar. The dialog contains the text: 'Flagged procedures will be reviewed by a system administrator. Please indicate the reason for flagging this procedure in the comment box below.' It includes a checkbox labeled 'Confirm that you would like to flag this procedure.' and a 'Comments:' section with a text input area. At the bottom of the dialog are 'Cancel' and 'OK' buttons. In the background, to the right of the dialog, there are icons for a star, a flag with a yellow circle containing the number '2', and a download icon. The number '14' is visible near the star icon.

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...  
(SC). Total injection volume will not e...  
hours of analgesia.

If signs of pain are noted despite bu...

**KEYWORDS**  
Opioid, Buprenex

**SUBSTANCE TYPE**  
Analgesic

**Flag Procedure**

Flagged procedures will be reviewed by a system administrator. Please indicate the reason for flagging this procedure in the comment box below.

☐ Confirm that you would like to flag this procedure.

Comments:

Cancel OK

14 ☆ 2 🚩 ⬇

en injected subcutaneously  
ministered to deliver up to 12

will be consulted.

## Flagging Procedures: Discussion

- Quite a bit of discussion re: how the follow up process for flagging a procedure will work. Ran out of time, so will re-visit topic in February.
- Questions on table:
  - Will a “flag” remain permanently with a response visible to visitors?
  - Governance structure for site admins reviewing flagged procedures? Should >1 site admin discuss? Include institution in conversation?
  - How do we track what happens to flagged procedures? JL suggested its possible to track all actions (e.g., from initial flag → resolution)

## **Goals for February Meeting**

- Aubrey/UW: Meet with Jaret & David to discuss site spec document; have EC review 'About' page and email content.
- All WG Members: Review and provide feedback on wireframes and aliases on Trello.

In February, I would like to start planning for the initial build and alpha phase of testing. Please start to think about what we'll need to do to prepare.



## **Proposed Agenda Topics for February:**

- Continue flagging procedures discussion.
  - Email Aubrey ([aubreys@uw.edu](mailto:aubreys@uw.edu)) if you'd like to add a topic to the agenda.
-



# 21<sup>st</sup> Century Cures Act - Update

*All comments on draft report must  
be submitted by February 20, 2019*

*See additional slides at the end.*





**Next Meeting:**  
**February 22, 2019**  
**11am-12pm PST**

**Upcoming Events:**

- PRIM&R IACUC 2019 conference – CUSP Session B07 (April 2 at 3:30pm)



# 21st Century Cures Act



Patricia Brown, VMD, MS, DACLAM  
Director, Office of Laboratory Animal Welfare, NIH

FDP – January 2019



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Office of Laboratory Animal Welfare

# 21<sup>st</sup> Century Cures Act

## What is it?

- Bipartisan legislation signed in December, 2016
- Intended to accelerate research and drug approval, address the opioid epidemic and mental illness
- Mandates federal efforts to reduce administrative burden for researchers
- Section 2034(d) assigns NIH as lead agency in cooperation with USDA and FDA to focus on animal care and use in research



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# What Does it Ask?

## SEC. 2034. REDUCING ADMINISTRATIVE BURDEN FOR RESEARCHERS.

(d) Animal Care And Use In Research.—Not later than 2 years after the date of enactment of this Act, the Director of the NIH, in collaboration with the Secretary of Agriculture and the FDA Commissioner, shall complete a **review of applicable regulations and policies** for the care and use of laboratory animals...



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# What Does it Ask, cont.

...and make revisions, as appropriate, to

- **reduce administrative burden on investigators**
- **while maintaining the integrity and credibility of research findings**
- **and protection of research animals.**

In carrying out this effort, the NIH Director shall seek the input of experts, as appropriate.



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# 21<sup>st</sup> Century Cures Act - Details

The Director of NIH shall —

- 1) identify ways to ensure such regulations and policies are not inconsistent, overlapping, or unnecessarily duplicative, **including with respect to inspection and review requirements by Federal agencies and accrediting associations;**



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# 21<sup>st</sup> Century Cures Act - Details

The Director of the National Institutes of Health shall —

- 2) **take steps to eliminate or reduce identified inconsistencies**, overlap, or duplication among such regulations and policies; and



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# 21<sup>st</sup> Century Cures Act - Details

The Director of the National Institutes of Health shall —

**3) take other actions**, as appropriate, to **improve the coordination of regulations and policies** with respect to research with laboratory animals.



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# Working Group Actions

- Convened in February 2017
- Meets quarterly or as needed
- Held listening sessions in 2018
- Released Request for Information (RFI) for public comment in March 2018
- Analyzed over 19,000 responses
- Released draft report in December 2018 with 75 day public comment period



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# Working Group Activities

- Reviewed reports, communications and surveys published from 2013-2018 that addressed investigator burden
- Held listening sessions and Q&A sessions with multiple stakeholders
- Analyzed suggested approaches from the RFI in development of draft report recommendations



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# Documents reviewed

- Reforming Animal Research Regulations, FASEB, COGR, AAMC, NABR, 2017
- Optimizing the Nation's Investment in Academic Research, NAS, 2016
- Reducing Investigators' Administrative Workload for Federally Funded Research, NSF, 2014
- 2012 Faculty Workload Survey Research Report, FDP, 2014
- Findings of the FASEB Survey on Administrative Burden, FASEB, 2013



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# Documents reviewed

- Revising the Requirements for Prompt Reporting under PHS Policy IV.F.3, 2017, NABR
- Animal Welfare Regulations Must Not Be Compromised to Comply with the Goals of the 21st Century Cures Act, 2018, HSUS and HSLF
- Rebuttal to Federation of American Societies for Experimental Biology's Reforming Animal Research Regulations, 2018, People for the Ethical Treatment of Animals.



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# Recommended Steps to Reduce Burden

## *Inspections*

NIH and USDA will develop guidance to address flexibilities in how and by whom IACUC inspections are conducted. This includes:

- inspection of study areas if animals are in their natural environment and the area is prohibitive to easy access
- AAALAC site visits may be counted as one of the IACUC semiannual inspections



# Recommended Steps to Reduce Burden

## *Protocol Review*

- Enhance resources to streamline protocol review by use of DMR for low-risk activities and three-year de novo reviews
- Outline what is exempt from IACUC review
- Update guidance on non-pharmaceutical grade compounds
- Change Section 2.31(d)(5) to remove the requirement that IACUCs conduct continuing reviews not less than annually



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# Recommended Steps to Reduce Burden

## *Reporting*

- Annual reporting to both agencies on same reporting schedule through shared portal
- Support the use of AAALAC program description elements in the OLAW Assurance
- Review and refine reporting requirements for reportable situations to OLAW
- Regulatory change to eliminate need to renew USDA registration every 3 years



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- # **Actions to Improve Coordination**
- ## ***Guidance on Federal Standards***
- NIH provide a minimum of 60 day comment period for significant policy guidance
  - NIH will review its disclaimer concerning current guidance and alternative approaches
  - USDA will make any revised and future policies available for public comment
  - USDA will add a statement in its policy manual that policies are clarifications of the AWA and Animal Welfare Regulations



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# Actions to Improve Coordination

## ***Agency Coordination***

- NIH and USDA will engage the Department of Defense and the Department of Veterans Affairs about harmonization to reduce administrative burden on investigators who receive support for research with animals from multiple federal agencies.



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# Actions to Improve Coordination

## *Training and Resources*

- Support industry-led training and resources to assist institutions in reducing administrative burden on investigators
- Support the efforts of the IAA to create a repository of IACUC best practices
- Support the efforts of the FDP to create CUSP as a repository for standard procedures used for research with animals



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# Actions to Improve Coordination

## ***Training and Resources (continued)***

- NIH will simplify its sample animal study protocol form and pilot the revised protocol form through FDP
- NIH plans to consider other new website resources in coordination with USDA



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# In Summary

In the coming years, NIH, USDA, and FDA intend to make progress on the steps and actions described in this report and will identify additional areas to protect animal welfare while reducing unnecessary administrative burden on researchers.



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# Contacts - 21<sup>st</sup> Century Cures Act

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- ListServ or RSS feed:  
subscribe through OLAW  
webpage for current  
announcements, notices,  
policy interpretations.

