Demonstration Project Proposal: Compliance Unit Standard Procedure (CUSP) Sharing Site

Project Goal

The goal of this demonstration project is to create an online repository where participating institutions can share standard procedures to be used in animal care protocols with the broader animal welfare compliance community.

Background and Objectives

One of the most frequent complaints about Institutional Animal Care and Use Committees (IACUCs) protocols is the lack of available standard templates or procedures for animal research. This assertion is supported by several recent national workload surveys that have identified animal research regulations as one of the top sources of administrative burden.[1-7] In particular, these reports cite the preparation, revision, and review of animal research protocols as a primary contributor, with one third of investigators describing the protocol review process as unnecessarily complex and time consuming.[1] Identifying a mechanism to reduce the time and effort needed to create and review protocols would ease this burden for both researchers and IACUCs. To address this need, we propose to develop an online database that allows institutions to share common procedures used in animal care protocols.

Advantages: Development of a database to share standard procedures will:

- Reduce administrative burden for investigators, IACUCs, and IACUC staff by decreasing the time and effort involved in protocol preparation, revision, and review.
- Support the development of high-quality animal care protocols.
- Provide consistency of procedures and ease of replication across institutions.
- Support knowledge sharing within the animal welfare compliance community.

Disadvantages & Potential Challenges: Development of a database to share standard procedures may have the following disadvantages or challenges:

- Participation will initially be limited to FDP members.
- Volume of data for users to sort through may be overwhelming or cumbersome.
- Long-term system maintenance and support may be a challenge.
- Keeping participants and the animal welfare community engaged may be challenging.

Sharing Site: Functional Requirements & Description

General descriptions of desired site design and function are provided below. A detailed spec sheet outlining system requirements will be generated upon approval for site development.

Data Import & Export: A survey of working group members was performed and it was revealed that ~33% of respondents do not use an electronic protocol management system. Thus, to accommodate the widest variety of users, data import and data export will be supported via high tech and low tech options (JSON, CSV). The quality of data entered in to the system will be ensured by establishing a standard format with required fields for all procedures, and implementation of data quality rules.

Data Organization: Entries in to the database will follow a standard format and naming convention. Where possible, a pre-defined list of selections will be provided for fields within the web form (e.g., species, procedure type). Users will be able to search the database for entries of interest, and have the capability to filter and sort search results. Each entry in the database will be annotated with a unique ID, submission date, IACUC approval date, expiration

date (3 years after submission date), originating institution, number of downloads, and additional institutions that have implemented that procedure. Entries within the system will be organized in a "parent-child" structure, with the first instance of a given procedure acting as the "parent," and subsequent modifications or variants of that procedure being nested under the parent as "child" procedures.

Data Storage & Maintenance: Data (up to 250 GB) will be stored by an off-site web hosting service provided by FDP. The cost for hosting and data storage will be covered by the monthly fee FDP already pays their hosting provider. The existing security measures (secured and authenticated logins) offered by the web host are sufficient for the needs of this project. Contributing institutions will be able to update or delete their entries in the system. Data within the system will have a 3-year lifespan. When a given entry reaches its 3-year anniversary, an auto-generated email will be sent to the contributing institution requesting that the entry be updated. If the entry is not updated within 6 months, it will automatically be deleted from the system. Additionally, users would have the ability to "flag" entries with outdated information or which they believe need to be updated (e.g., if a new guidance is released).

Significance to FDP

This project will directly support the FDP's mission to streamline the administration of federally sponsored research. Development of a standard procedure database will help to reduce the time and effort involved in the preparation, revision, and review of animal care protocols, reducing the administrative workload for researchers, IACUC members, and IACUC staff.

Responsible Group

This project was initially proposed at the January 2017 FDP meeting as part of the Animal Subjects Subcommittee. A working group has since been formed to support the project. The working group currently consists of approximately 60 members across 40 different institutions, with representatives from academia, government, and industry. The working group meets monthly, with smaller task groups (teams) often meeting more frequently to address open questions within a given topic area.

Participants

Primary Institutional Sponsors (Teams Leads): Charles Drew University (Eva McGhee), Emory University (David Martin), Harvard University (Curtis Van Slyck), University of Alabama Birmingham (Jaret Langston), University of Oklahoma Health Sciences Center (Madeline Budda), and University of Washington (Michelle Brot, Sally Thompson-Iritani, Aubrey Schoenleben)

Please refer to the Appendix for a complete list of members.

Federal Partner: National Institutes of Health/Office of Laboratory Animal Welfare (OLAW)

Participants: The initial phase of this demonstration project will be limited to working group members (see Evaluation Plan). If this initial phase of development is successful, participation will be extended to include all FDP members.

Participant Expectations: Expectations for site users will be outlined in a User Guidance document that will be made available on the site. Participating institutions will be expected to designate a representative as their submitting author. All submissions to the CUSP Sharing Site would flow through the designated representative. The designated representative will be responsible for reviewing procedures for completeness, ensuring that procedures meet user guidance requirements (e.g., procedures must be reviewed and approved by the contributing institution's IACUC prior to posting), and entering information in to the database. Each institution will be expected to maintain their contributions as updates occur.

Evaluation Plan

The first step in accomplishing our goal is to develop a functional database where data can be easily imported, searched, and exported. Site development efforts will be shared between David Wright (user interface [UI] development) and Jaret Langston (application programming interface [API] development). The initial evaluation plan for this project will serve to validate the database itself, to ensure that it is secure, and that the integrity of the data is being maintained. This will be organized in to three phases, with each phase evaluating a different aspect of the site: (1) site structure, (2) data import, and (3) data export. Participation in this stage will be limited to working group members. Pre-defined test cases will be used to structure the testing in each phase. Progress during each phase will be reported at monthly working group meetings and at FDP meetings, as appropriate. A written report will also be submitted to the Executive Committee at the completion of each phase.

Phase 1 - Site Structure: The first phase will focus on site structure. The site will be loaded with a limited number of standard procedures from the NIH Animal Research Advisory Committee and/or from working group members' existing procedure libraries. Site function will be evaluated by validating data mapping between the user interface and the underlying database tables, assessing integrity of search/sort/filter features, and ensuring automated system notifications and system maintenance are functioning as intended (e.g., a procedure that has reached its 3-year lifespan).

Phase 2 - Data Import: The second phase will focus on ease of data entry in to the system, and will test the ability of existing data to be updated, modified, or deleted. Working group members from a limited number of institutions will be asked to enter standard procedures from their existing procedure libraries in to the database using either a high tech or low tech method (JSON, CSV). This will allow us to assess the integrity of the data quality rules, evaluate the flexibility of the web form (i.e., is the web form able to accommodate a wide variety of procedure formats from different institutions, are the required fields appropriate and capturing desired information), and the ability of the database to perform when used in conjunction with different web browsers. Additionally, Phase 2 pilot participants will be asked to update and delete database entries to test the integrity of the system under these circumstances.

Phase 3 - Data Export: The third phase will focus on data export. Working group members from a limited number of institutions will be asked to perform a search of the database, select entries of interest, and then export those entries using either a high tech or low tech (JSON, CSV) method. This will allow us to evaluate the integrity of data exported from the system, and the relative ease with which data can be accessed using these methods.

If this initial stage of development is successful, we will expand our evaluation plan to determine if use of standard procedures from the sharing site reduces administrative burden. These later stages of evaluation will be divided into multiple phases, with early phases being restricted to members of the working group, and later phases extending to the larger FDP community.

Budget Request

No budget is being requested at this time. The only anticipated cost for the project is for hosting and data storage, which is included in the monthly fee FDP already pays their hosting provider.

Early Termination Plan

The demonstration project will be terminated early if any one of the following conditions are met: (1) FDP does not endorse the project, (2) loss of interest from general FDP membership/lack of participation, (3) insurmountable technical challenges.

Estimate of Time Required to Accomplish Objectives

If we receive approval from the Executive Committee and general membership, we will work closely with the Executive Committee to develop a time frame for the initial development of the site. Once this initial development is complete, we anticipate that validation of the database will take approximately 12 weeks (4 weeks/phase).

References

1. National Science Board. 2015. Reducing Investigators' Administrative Workload for Federally Funded Research. Retrieved from: https://www.nsf.gov/pubs/2014/nsb1418/nsb1418.pdf
2. 21st Century Cures Act. January 2017. Retrieved from: https://www.congress.gov/114/bills/hr34/BILLS-114hr34enr.pdf
3. Federal Demonstration Partnership. 2012. Faculty Workload Survey Research Report. Retrieved from: http://sites.nationalacademies.org/cs/groups/pgasite/documents/webpage/pga_087667.pdf
4. National Research Council Institute for Laboratory Animal Research. 2011. Guide to the Care and Use of Animals Eighth Edition. Retrieved from: https://www.nap.edu/catalog/12910/guide-for-the-care-and-use-of-laboratory-animals-eighth
5. National Academy of Sciences. 2016. Optimizing the Nation's Investment in Academic Research: A New Regulatory Framework for the 21st Century. Retrieved from: https://www.nap.edu/catalog/21824/optimizing-the-nations-investment-in-academic-research-a-new-regulatory
6. NIH Initiative to Reduce Regulatory Burden. 1999. Retrieved from: https://archives.nih.gov/asites/grants/06-17-2015/archive/grants/policy/regulatoryburden/index.htm
7. Findings of the FASEB Survey on Administrative Burden. 2013. Retrieved from: www.faseb.org.

Appendix

A list of working group members as of August 31, 2017 is provided below. For the most up to date list, please visit the CUSP Working Group SharePoint site. Primary institutional sponsors/team leads are highlighted in **blue**.

Alex Albinak, Johns Hopkins University, FDP
Leanne Alworth, University of Georgia
Denise Ancharski-Stutler, CHOP
Gwen Anderson, Washington State University
Rob Anderson, University of Cincinnati
Christine Arnold, In Vivo Strategies
Julie Bakken, Institute for Systems Biology
Michelle Brot, University of Washington
Madeline Budda, University of Oklahoma HSC
Amy Chuang, Virginia Commonwealth University
Alli Czarnecki, Yale University
Jeremy DeRicco, Penn State University
Rebecca Dye, University of North Carolina, Chapel Hill
Jennifer Edge, University of Houston
Alan Ekstrand, University of California, Davis
Phyllis Erdman, Washington State University
Michele Fahey, Boston University
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Troy Hallman, Yale University
Damir Hamamdzic, Rutgers University
David Hamilton, University of Tennessee HSC
Ele Haynes, Georgia Southern University
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Margo Holland, USDA-NIFA
Jenny Iwamoto, University of Washington
Sarah Kaatz, Iowa State University
Jon Kaye, Cedars Sinai Medical Center
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Elaine Kim, Colorado State University
Julia Kissling, University of Texas, Arlington
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Sally Light, Michigan State University
David Martin, Emory University
Natalie Mays, New York University
Eva McGhee, Charles R. Drew University
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Glen Otto, University of Texas, Austin
Kerry Peluso, Emory University
Joanne Polzien, Michigan Tech University
April Ripka, Penn State University
Kerrey Roberto, University of Arkansas Medical Center
Kristin Rochford, University of Houston
Ajay Sagar, Cedars Sinai Medical Center
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Julie Sharp, SUNY, Downstate
Roger Sloboda, Dartmouth College
Lisa Snider, Purdue University
Mickey Stevenson, University of Texas, San Antonio
Laszlo Szabo, Rutgers University
Sally Thompson-Iritani, University of Washington
Debra Thurley, Penn State University
Thomas Todd, University of Houston
Curtis Van Slyck, Harvard University
Ashley Williams, Washington State University
Axel Wolff, OLAW (Advisory Role)
Nina Woodford, Washington State University
David Wright, FDP
John Yunger, Govenors State University
Lauren Zizza, Rutger University