



Compliance Unit Standard Procedure (CUSP) Project

Point of Contact	Aubrey Schoenleben, University of Washington; Sally Thompson-Iritani, University of Washi
Activities/Progress to Date	The goal of this working group is to develop an online resource for sharing standard procedures used in animal care protocols. See below and session slides for progress to date.
Agenda/Discussion Points	
Pending Decisions	<ul style="list-style-type: none">- Build out picklists for two procedure types (Euthanasia, Blood/Tissue Collection).- Define a process for how procedures will be 'renewed' within the system.- Develop the procedure entry form.- Determine if single sign on (SSO) is a viable option to access the site.
Participation	This session was attended by approximately 40 individuals, either in person or via web conference.
Key Risks/Issues	See Key Decisions Pending above.
Meeting Summary	<p>Two new documents for the working group were introduced – the Key Decision Log and the Site Scope and Spec Sheet. The Key Decision Log outlines project decisions and the rationale behind each decision. The Site Scope and Spec Sheet defines the scope for the first phase of the project and details the different requirements and characteristics of the CUSP site. This document will be used to support the development phase of the project.</p> <p>The working group is exploring whether use of single sign on (SSO) authentication is a viable option for the site. Initial evaluation revealed that 77% of FDP member institutions are members of InCommon Federation, an SSO solution that serves a broad range of education and research institutions. The group is currently evaluating what other SSO options might be available to leverage for the remaining 23% of FDP member institutions. It was recommended that we reach out to the eRA committee, as they have already done some work in this area.</p> <p>The group also reviewed and provided feedback on the initial wireframes for webpages that users with the roles of Designated Institutional Representative and Administrator will interact with. The pages reviewed include My Procedures, My Accounts, and Reports.</p> <p>The federal sponsor for this project provided an update on the Request for Information (RFI) that was issued in March 2018 in response to the 21st Century Cures Act. The purpose of this RFI is to seek input from the wider scientific community and public on potential measure that may be taken to reduce regulatory burden.</p> <p>A subset of working group members also met for an in-depth discussion on species and procedure types, and how to build the related pick lists. The picklists for the species was finalized, and the build out of picklists for two procedure types was started.</p>



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Volunteer Opportunities

Please contact Aubrey (aubreys@uw.edu) or Sally (sti2@uw.edu) if you are interested in joining this working group. The working group meets monthly.



Subawards Subcommittee

Point of Contact

Amanda Hamaker, Amanda Humphrey, Stephanie Scott

Activities/Progress to Date

Guidance Group - Two documents were produced since the last meeting. 1) Guidance document to share with internal institutional stakeholders (legal counsel, etc - those who may require added language to the templates). The document has background on FDP and the purpose of the templates, checklist of considerations prior to requesting language changes/additions, and process for making requests. 2) New form for requesting changes to the templates.

Fixed Priced Subawards, Prior Approval, and Clinical Trials - Recap of the issue discussed in the January 2018 /September 2017 meetings. Draft language has been developed for requesting prior approval. Discussion over what is a Clinical trial - sub versus vendor, etc. Discussion of the Simplified acquisition threshold (SAT). Increased from \$150K to \$250K when the micro-purchase threshold increased. The group engaged with COGR Research Compliance & Administration (RCA) Committee. They met with NIH OPERA on 2/21/18 to present burdens and possible alternatives. The group with RCA provided draft language for GPS based on language found in DoD General Research Terms & Conditions. This is drafted and ready to be sent to NIH. If you are currently still having issues, Jennifer McAllister is still collecting information. She can also provide you with more information. Recommendation is to get OPERA involved in the meantime if you are dealing with one of these issues. Discussions from attendees show that there are lots of issues surrounding this topic.

Agenda/Discussion Points

Pending Decisions

Research Integrity - Recap of the issue discussed at the January 2018 meeting. After last meeting, we gathered more information. A Research Integrity Officer meeting had a discussion wanting to know if institutions were ensuring subrecipients had applicable policies/assurances in place. Discussed the use of adding language specific to foreign/high risk template and/or adding something to the FDP Clearinghouse. Completed a survey to see how membership wanted to handle this issue. Suggested outcomes include: add language to foreign template; develop a welcome packet for foreign intuitions; explore FDP EC options; no language added to the FDP subaward templates; add guidance explaining choices. Also, engage RIO community for feedback. Poll of the audience is strong agreement with this plan.

Certificates of Confidentiality - Recap of the issue discussed at the January 2018 and prior meetings. Sent out with the Research Integrity survey to gauge membership preference of whether or not to include language in the subaward templates and which of the two provided language options were preferred. Very mixed results and no clear concurrence from the survey. Very strong opinions on all options. Intuition types did not correlate to



the responses. Suggested outcomes: No clear suggestions. We have decided to post both versions of the language on the FDP Website and allow institutions to test over the next few months. Institutions should evaluate which work best for them, which get the least pushback, etc. We will ask for feedback at some point in late 2018 via another survey. These responses will help to determine what may get incorporated into the templates. The majority of attendees found this to be a reasonable approach.

Subaward Templates Updates - Working on potential modifications to the code to stabilize the code. Asked the attendees if we should go ahead and post the updated templates with the code changes for bug fixes since this is an off-cycle update. Request to verify all links on attachment 2 to research terms and conditions are updated.

Participation

Open Questions at the end -

1. Discussion over DocuSign - one institution using Echosign (sp?), another using DocuSign with no issues, still seeing pushback from state agencies/others who want hard signed blue ink, multiple copies, etc.
2. What if we want a new template - combining a couple of templates for a new scenario - should we use the change request form? Bigger requests like this should probably involve some pre-discussion with the co-chairs.
3. Single audit entities - Who has stopped sending out single audit certifications or not? Most comments indicated they are pushing back when they get a certification to complete. May be helpful to have a push back template language. Pamela will send out the UG language on the listserv.

Key Risks/Issues

Upcoming activities:

Guidance Group - Finalize Change Request Form & Guidance Doc; New FAQs to include - Clarify Term 'Effective Date' for Mods (how and when it is used), Certificates of Confidentiality - language options, Research Integrity, sIRB - how it was incorporated into the templates, Revise FAQ7 - formatting change requests, New FAQs on template change requests, New FAQ on when it is appropriate for PTEs to request back-up of invoices, and the Carryover Doc - Total Amount of Federal Funds Obligated to Date (TAFOD).

Foreign Subaward Guidance/FAQs - new group. Foreign subawards may require different terms. As a result, guidance/FAQs will be created to help membership with these subawards.

Subcontract Working Group - finalizing the updated sample.

Looking ahead: September meeting - Closeout, Back up for invoices, Foreign / high risk subrecipient informational packet, Collaboration agreement for federal entities

Meeting Summary

The session covered the following:

- Research Integrity - review of the survey results; action plan moving forward with audience approval
- Certificates of Confidentiality - review of the survey results; action plan moving forward



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with audience approval

- Subaward Templates Update - Discussion of the need for off-cycle bug-fix release to stabilize code in Adobe templates
- Fixed Price/Clinical Trial Update - Update on progress since the January meeting. Joint COGR/FDP representative meeting with NIH OPERA. Draft language to be sent to NIH.
- Guidance Document Update/New Proposal Form - Shared information about the new change request form and related guidance doc for University stakeholders.
- Foreign Guidance Update - Discussion over need to develop guidance and FAQs.

Volunteer Opportunities

Guidance Document Group is looking for more volunteers to work on new and revised FAQs. Contact Stephanie Scott; new workgroup to be formed, led by Julie Renkas, to focus on guidance when issuing subawards to foreign entities.



Emerging Research Institutions (ERI)

Point of Contact	Susan Anderson
Activities/Progress to Date	In a continuing effort to support engagement by ERI members in FDP activities, a session at the May meeting was dedicated to an opportunity to have focused discussion with a Federal partner (NIH). Additional activities include recent administration of a survey to ERI Administrative Representatives; the survey is intended to identify areas in which ERI members would like to place attention. Survey results will be analyzed and discussed at a future meeting.
Agenda/Discussion Points	
Pending Decisions	Survey results will guide future project choices and meeting session topics/guests.
Participation	In addition to the 5 representatives from NIH (Megan Columbus, Division of Communication and Outreach and NIH Program Manager for Electronic Submission of Grant Applications in the Office of Extramural Research, who led the discussion on behalf of NIH; along with Sheri Cummins, NIH Office of Extramural Research Communications and Scarlett Gibb, eRA Customer Relationship Manager; and Sam Ashe, Director, Division of Grants Policy, Stefanie Harris, Grants Policy Analyst, Division of Grants Policy), Federal representatives from NSF and USDA attended. Among the non-Federal institutions, representatives from 10 ERI and 7 non-ERI members participated. Of note was interest in the session among non-ERI members, many of whom desired information to help them collaborate with ERI members.
Key Risks/Issues	There was robust discussion of several items of interest to attendees and to NIH staff. NIH representatives took away several ideas, concerns, or suggestions that resulted from the discussion. Participants also left with a number of suggestions and resources to help them navigate NIH programs and systems.
Meeting Summary	Challenges and risks: what makes ERIs unique? Limited support staff (e.g., JIT IRB turnaround challenging); limited experience with NIH (e.g., vocabulary; when/where to send JIT responses; appropriate programs). Concerns: competitiveness for some mechanisms; unsure who to talk to at NIH; how to get involved in peer review process (suggestion: NIH's Early Career Reviewer program); equity re: clinical trials definition/policies (e.g., AREA--CTs not allowed; small behavior studies no longer permitted re: CT issue); clean up of costs in PMS. How can NIH help? Single matrix of compliance requirements; provide systematic way to extract application data to avoid need to rekey; provide a resource with timelines for critical actions; indication in Commons if application will not be funded; best practice guidance for institutional policies; guidance for PIs on getting started with NIH. Additional resources noted: RePORT system; AREA mechanism; K12; SCORE program; RCMI



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program; Diversity Program Consortium including BUILD initiative and NRMNetwork.

Volunteer Opportunities

- NIH maintains a Commons Working Group listserv and holds meetings (associated with FDP but generally after). This group helps NIH ensure they design NIH eRA systems with the end user in mind and helps them identify opportunities to improve efficiencies for organizations. Megan Columbus can add you to the list; email her at Megan.columbus@nih.gov.
- NIH's Office of Extramural Research is responsible for the resources about NIH grants processes and policies at grants.nih.gov. Please email megan.columbus@nih.gov or oer@od.nih.gov with suggestions or questions.



FDP Expanded Clearinghouse

Point of Contact

Lynette Arias, Pamela Webb

Activities/Progress to Date

- The Pilot has moved into an initiative and includes a Steering Committee.
- Publications/Communications: Final Pilot Report, Press Release, NCURA Article, NCURA regional meetings with more requests for publicity coming
- Almost all FDP members have joined the Expanded Clearinghouse - 200 profiles total to-date!
- Sample pushback language has been updated and is available on the website.
- Website has been updated
- oPilot information is being archived
- Instructional videos are available for the Expanded Clearinghouse with a few more coming
- Significant codebase updates, though users will not see any changes, in order to improve maintainability and sustainability
- Data Export feature extensively reviewed but will not be offered
- oDuplicates API functionality
- oReduces references to website, increases risk of old/bad data
- oEnhanced search tools will be coming to the website in the future
- API will go live this month
- o3 tokens have been issued to Beta testers
- oAccess may be requested through the Data Access tab on a published profile
- Financial Questionnaire
- oCurrent list on FDP website is exhaustive and is being consolidated
- oProgress to-date
- ?Goal to create a document that is widely usable
- ?Creating a survey to be sent to Pass through Entities to get a better understanding of interest and challenges

Agenda/Discussion Points

Pending Decisions

- Mandatory for all FDP members? At this point it is moot, but is something to consider in future phase.
- Inviting non-FDP organizations to join.
- More Federal Involvement? We'd like to start conversations with SAM.gov and the Federal Audit Clearinghouse.
- Financial Questionnaire added to Clearinghouse?
- FCOI Clearinghouse to be added as well?
- Who should own the system/data?
- What data fields are irrelevant or not being utilized by the institutions?

Participation

Approximately 100 attendees, actively participating in user group type discussions.

Key Risks/Issues

Should we allow non-FDP organizations to join? A significant amount of thought must go



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into ensuring the integrity of the data, among other things.

Meeting Summary

The session covered the following:

- Recent press releases and other communications and marketing of the Clearinghouse,
- Reviewed parameters for updating profiles and identify key areas currently causing confusion or delays
- Provided status of all FDP members who have become Participating Organizations
- System updates including: status of Automated Programming Interface (API); data dictionary; possible data export; SAM.gov mapping; and other enhancements
- Future planning including: status of adding additional members, financial questionnaire pilot, partnering with federal agencies on what we have learned

Volunteer Opportunities

Participate in Financial Questionnaire pilot. Please email Sara Clough sarac@austin.utexas.edu or Lesley Schmidt Sindberg schm1421@umn.edu



Faculty Administrator Collaboration Team (FACT)

Point of Contact	Mark Haselkorn/Dave Reed
Activities/Progress to Date	<ul style="list-style-type: none"> •Developed a charter •Executive Committee endorsement •Initiated website •Established Communication and Marketing Subgroup •Expanded membership •Initiated two pilot projects to better understand the Faculty & Administrator collaboration <ul style="list-style-type: none"> oQuantitative assessment of research administration with the FACT partner institutions oQualitative assessment of research administration with the FACT partner institutions
Agenda/Discussion Points	
Pending Decisions	Finalize quantitative metrics and gather qualitative interviews at nine participating institutions.
Participation	Open to pairs of faculty/administrator. Contact Mark Haselkorn/Dave Reed
Key Risks/Issues	Still gathering preliminary data. No obstacles to report to date.
Meeting Summary	<p>See FACT webpage, http://sites.nationalacademies.org/PGA/fdp/PGA_184146</p> <p>For detailed sessions notes</p>
Volunteer Opportunities	<ul style="list-style-type: none"> •Understand diversity of existing structures and strategies for Faculty-Administration research collaborations •Identify best practices and opportunities for improvement of institutional structures and strategies for Faculty-Administration research collaborations •Gain understanding of institutional definitions of research enterprise success •Establish conditions for, and examples of, Faculty-Administration collaboration successes •Establish examples of frequent challenges to Faculty-Administration collaboration