



FEDERAL DEMONSTRATION PARTNERSHIP
Redefining the Government & University Research Partnership

Research Compliance Committee

FDP Meeting – January 2022

Presenters:

Melissa Korf (Co-Chair), Harvard Medical School;
Aubrey Schoenleben, University of Washington;
Sally Thompson-Iritani, University of Washington;
Amanda Humphrey, Northeastern University;
Keri Godin, Brown University;
Debra Murphy, Arizona State University;
John Baumann, Indiana University;
Chris Martin, Rutgers University;
Jen Welch, Brown University;
Lindsey Spangler, Duke University



Agenda

- Research Compliance Committee overview and planning for 2022
- Compliance Unit Standard Procedure (CUSP)
- IACUC MOU Working Group
- Human Subjects Subcommittee
- Data Stewardship Subcommittee
- Conflict of Interest (COI) Subcommittee
- Closing Remarks



Research Compliance Committee (RCC) Structure

Research Compliance Committee
Melissa Korf
Diane Dean

Animal Care and Use
Ara Tahmassian
Axel Wolff

Conflict of Interest
Amanda Humphrey
Lindsey Spangler
Diane Dean

Data Stewardship
Chris Martin
Jen Welch

Export Controls
Doug Backman
Vacant

Human Subjects
Deb Murphy
John Baumann



RCC Goals

The Research Compliance Committee reviews existing and new administrative requirements imposed by federal regulations and program officers related to research compliance with an emphasis on harmonization of requirements across federal agencies, reduction of redundancies, and identification of good practices. This includes but is not limited to human subjects protections, animal care and use, conflict of interest, export controls, and data stewardship.



ThoughtExchange



- As you participate in this session, consider the question:
 - What could the Research Compliance Committee (RCC) do to help reduce burden in research compliance that we are not already working on?
- Access the ThoughtExchange at
 - <https://tejoin.com/scroll/776301423>
- Follow the prompts to share your ideas with us and rank the impact of the thoughts shared by your colleagues.
- ThoughtExchange will remain open for an hour after the session ends.



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CUSP Project

Aubrey Schoenleben, University of Washington

Sally Thompson-Iritani, University of Washington

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Agenda



- Background
- Current Status & Updates
- Site Demo



CUSP Sharing Site



- Goal: Create an online repository where participating institutions can share standard procedures used in animal care protocols.
- A burden reducing initiative of the 21st Century Cures Act

**CUSP
SHARING
SITE**



Current Status



- Build and testing of Beta site completed May 2021
- Transition to more modern technology stack in progress!
- Dedicated development resource
- Testing of new site to begin this month; build completion anticipated Q1 2022.



Site Demonstration



Other Updates

- WG is developing the necessary infrastructure to support the site once live:
 - Developed user participation agreement
 - Creating user help documents, FAQs and videos
 - Developing survey to collect feedback from users
 - Outlining process for reviewing bug fixes and enhancement requests
 - Drafting roll out plan





Resources

- CUSP Working Group Webpage
 - <http://thefdp.org/default/committees/research-compliance/iacuc/compliance-unit-standard-procedure-cusp/>
- CUSP Helpdesk
 - cusp@thefdp.org



Questions & Discussion

- All feedback, comments, questions - please email culp@thefdp.org

Volunteers Needed!

Email culp@thefdp.org





CUSP Contact Info

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- Sally Thompson-Iritani
 - University of Washington
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IACUC MOU Working Group

Keri Godin, Brown University

Amanda Humphrey, Northeastern University

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IACUC MOU Working Group

- Co-chairs:
 - Keri Godin, Brown University
 - Amanda Humphrey, Northeastern University
 - Ara Tahmassian, Harvard University
 - Axel Wolff, OLAW
- Goal: to reduce administrative burden through the creation of an IACUC MOU sample for FDP member institutions when collaborating on projects involving the use of vertebrate animals



Background

Both the Office of Laboratory Animal Welfare (OLAW) and the AAALAC International (formerly known as Association for Assessment and Accreditation of Laboratory Animal Care International) use the National Academy of Sciences' *Guide for the Care and Use of Laboratory Animals*, 8th Edition (*Guide*).

NIH OLAW has incorporated the *Guide* by reference.



Guide for the Care and Use of Laboratory Animals, 8th Edition

It contains guidance on inter-institutional collaborations, specifically,

- *“Interinstitutional collaboration has the potential to create ambiguities about responsibility for animal care and use. In cases of such collaboration involving animal use (beyond animal transport), the participating institutions should have a formal written understanding (e.g., a contract, memorandum of understanding, or agreement) that addresses the responsibility for offsite animal care and use, animal ownership, and IACUC review and oversight (AAALAC 2003). In addition, IACUCs from the participating institutions may choose to review protocols for the work being conducted.” (Page 15, 2011)*



IACUC MOU Working Group

- Started project in 2020 after outreach and community discussion
 - Two deliverables: MOU Sample & guidance document
- Put initial draft out for FDP community feedback and comment in April 2021
- Community input was very helpful and each comment was thoughtfully considered
- Documents have been updated in response to community input and are now with FDP leadership for review



IACUC MOU Working Group

- Anticipated rollout in February 2022
 - Announcement will go out on the FDP list serv
- Working on communication and rollout plan
 - FDP webinar to train users and answer questions
 - Engagement with other professional societies (e.g., 3I's) and distribution via regional list servs, IACUC Network (via Yammer), and other channels with relevant audience



FEDERAL DEMONSTRATION PARTNERSHIP
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Human Subjects Subcommittee

John R. Baumann, Indiana University

Debra Murphy, Arizona State University

FDP Meeting – January 2022



Human Subjects Subcommittee Agenda

Opening Remarks

Introductions

Role of the Subcommittee

Focus areas for the Coming Year



Human Subjects Subcommittee

Opening Remarks

Welcome

Subcommittee Co-Chairs:

John R. Baumann, Ph.D.

Debra Murphy



Human Subjects Subcommittee Update

- Subcommittee Members –
 - Mariette Marsh – University of Arizona
 - Rachel Wenzl – University of Nebraska
 - Sarah Kiskaddon – Dana Farber/Harvard Cancer Center
 - Michelle Stickler – University of Texas - Austin



Human Subjects Subcommittee

- The Human Subjects Subcommittee is part of the programmatic umbrella of the Research Compliance Committee. The subcommittee is charged with reviewing existing and new administrative requirement for Human Subject Protection Programs. Our emphasis focuses on harmonization of requirements, reduction of redundancies and identifying best practices.



Human Subjects Subcommittee

- Discussion of plans for 2022
- Questions? Suggestions?



FEDERAL DEMONSTRATION PARTNERSHIP
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Data Stewardship Subcommittee

Chris Martin, Rutgers University

Jen Welch, Brown University

FDP Meeting – January, 2022



Working Group: Finance, Audit and Costing Committee

FDP Units:

Finance, Audit and Costing Committee

Data Stewardship Sub-Committee

Objective:

Evaluate the NIH Policy on Data Management and Sharing, including supplemental material, to develop costing guidance while maintaining the ethical sharing of data.

Deliverable:

Guidance on the budget and costing incurred by a proposal's Data Sharing and Management Plan



Working Group: Human Subjects Sub-Committee

FDP Units:

Human Subjects Sub-Committee

Data Stewardship Sub-Committee

Objective:

Investigate the reasonable expectations of participants and regulatory requirements of informed consents that promote the ethical conduct of research

Deliverable:

Identification of Best Practices, and

Creation of Guidance Document



Internal Group: Data Destruction

FDP Unit:

Data Stewardship Sub-Committee

Objective:

Explore the ethical, legal, regulatory, and commonly observed practices and considerations in the destruction of data.

Deliverable:

Report/Paper discussing the various considerations regarding data destruction and recommendations



DTUA Working Group Updates

- Diana Boeglin (U. Chicago) and Kris McNitt (Penn State) have been heading the DTUA Working Group since last year, along with a new group of 35 volunteers
- Version 2 of the DTUA FAQs was uploaded to the Data Stewardship website last year
- The Working Group has been focused on identifying areas of greatest need for the FDP membership, including an updated/expanded guidance document and refining the DTUA templates
- In response to participant needs, the Working Group finalized discussions on a new guidance flow chart for determining when a DTUA is required/recommended. This chart should be polished and disseminated soon.
- The Working Group just began work on its next topic – Developing guidance on non-human subjects determinations v. de-identified human subjects data



Future Goals, DTUA Working Group

- The Working Group wants to develop smart PDFs for the DTUA templates. If anyone has the skills for this and would like to assist, please reach out to DTUA@thefdp.org.
- The Working Group would like to develop a version 2.0 of the one-way DTUA, and has a two stage plan:
 - 1) After the language for the FDP Subaward template Attachment 7 (data sharing terms) is fully approved, the Working Group will examine whether further alignment between the Subaward template language and Attachment 2 of the DTUA is appropriate.
 - 2) A full review of the one-way DTUA to ensure the terms remain relevant and in line with evolving best practices



Plans for the FDP May 2022 Meeting

- The DTUA Working Group hopes to present the following at the May meeting:
 - A discussion around the distribution of the finalized guidance flow chart, “Determining when a DTUA is required or recommended for a research purpose.”
 - A preview of draft guidance on non-human subjects determinations v. de-identified human subjects data



Housekeeping Items

- If the Data Stewardship Subcommittee or its Working Groups are of interest to you, please register for the Data Stewardship List-Serv. We'll put out a call from there for new volunteers:
 - <https://thefdp.org/default/mailling-lists/>
- Currently, the Data Stewardship Subcommittee FDP website contains only information about the DTUA Working Group, but our goals for the website include a redesign that contains information about the larger Subcommittee, with subpages for each new working group.
 - <https://thefdp.org/default/committees/research-compliance/data-stewardship/>



FEDERAL DEMONSTRATION PARTNERSHIP
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Conflict of Interest (COI) Subcommittee

Amanda Humphrey, Northeastern University

Lindsey Spangler, Duke University

FDP Meeting – January 2022



COI Subcommittee

- Co-chairs:
 - Amanda Humphrey, Northeastern University
 - Lindsey Spangler, Duke University
- Committee:
 - Engaged new committee members through volunteer sign-up
 - Range of institutions and roles, including faculty and administration
 - First meeting next week



COI Subcommittee

- Current Scope: reduce administrative burden in Conflict of Interest (COI) related matters
 - Disclosures being worked by FIWG and we don't want to overlap and potentially create confusion
 - What is the most effective way to frame our committee?
 - What projects will provide the most benefit?
- Next Steps:
 - Define potential projects
 - Listening session with broader FDP community to hear more about which projects would have greatest impact



RCC Closing Remarks

- Preliminary ThoughtExchange results
- Best way to stay up-to-date on Research Compliance Committee activities and opportunities?
 - Sign-up for and post to our committee and subcommittee listservs!
 - <http://thefdp.org/default/mailing-lists/>
 - Current listservs:
 - Research Compliance Committee (FDP-Res-Comp-L)
 - Animal Care and Use Subcommittee (FDP-IACUC-L)
 - Data Stewardship (FDP-Data-L)
 - Additional subcommittee listservs coming soon!



Contact Info

Co-Chair Contact Info:

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Research Compliance Committee webpage:

<http://thefdp.org/default/committees/research-compliance/>