



Research Compliance

- Co-chairs: Alexandra Albinak, JHU; Cheryl Kit, NIH
- Subcommittees
 - Data Stewardship
 - Human Subjects
 - Animal Care and Use
 - Conflict of Interest
 - Export Control
- Working Groups
 - DTUA
 - SMART/IRB
 - Wizard
 - Lab Safety
 - CUSP



Data Stewardship

- Melissa Korf, HMS; Rick Ikeda, NIH
 - Data Management Costs
 - In collaboration with Financial/Audit/Costing
 - Public Access
 - Data Transfer and Use Agreements (DTUA)



DTUA Template Working Group

- Working group co-chairs:
 - Melissa Korf, HMS and Jill Frankenfield, UM
- Work Completed To-Date:
 - Template components for use in sharing de-identified data about human subjects and a Limited Data Set published to website (May 2017)
 - Glossary, Guidance Chart, and Tool for Classifying Human Subjects Data published to website (July 2017)
 - Attachments for use in sharing Personally Identifiable Information (Common Rule Only, HIPAA, and FERPA) distributed to Contracts and Data Stewardship listservs for feedback due 1/31/2018 (December 2017)



DTUA Next Steps

- **Work in Progress:**
 - Discuss feedback on PII attachments to develop final versions for publication on the website
 - Plan a formal pilot of the DTUA templates
 - Explore other avenues to encourage adoption
- **Pending Work Items:**
 - Implement pilot and disseminate results
 - Develop additional guidance documents to address feedback/questions received
 - Collaborate with Subawards to develop data transfer and use language for use in subaward agreements



Human Subjects Subcommittee

- Jane McCutcheon, NYU; Debra Murphy, ASU
- Completed Projects
 - Exempt wizard demonstration
- Ongoing projects
 - SMART/IRB Task Force
 - Working group co-chairs – Lynette Arias, UW; Alexandra Albinak, JHU
 - Exempt Wizard 2.0 and pilot



FDP & SMART IRB Partnership Taskforce

- Utilize broad FDP membership for input & advocacy
- Assist SMART IRB with broad adoption and support through FDP member involvement
- Provide feedback on Reliance Agreement and HSC documents, tools and resources
- Discuss use cases and specifics of implementation
- Maintain open dialogue for bidirectional opportunities



Exempt Wizard

- Working Group co-chairs:
 - Jane McCutcheon, NYU and Sandra Schneider, USF
- Progress Report
 - Finishing up the final report for the wizard demonstration (Sandy Schneider)
 - Demonstration for Wizard 2.0 (Jane McCutcheon)
 - Template is complete
 - Subgroup for remaining issues
 - Language from new regulations
 - Presentation to OHRP (Sandy Schneider & Jane McCutcheon)



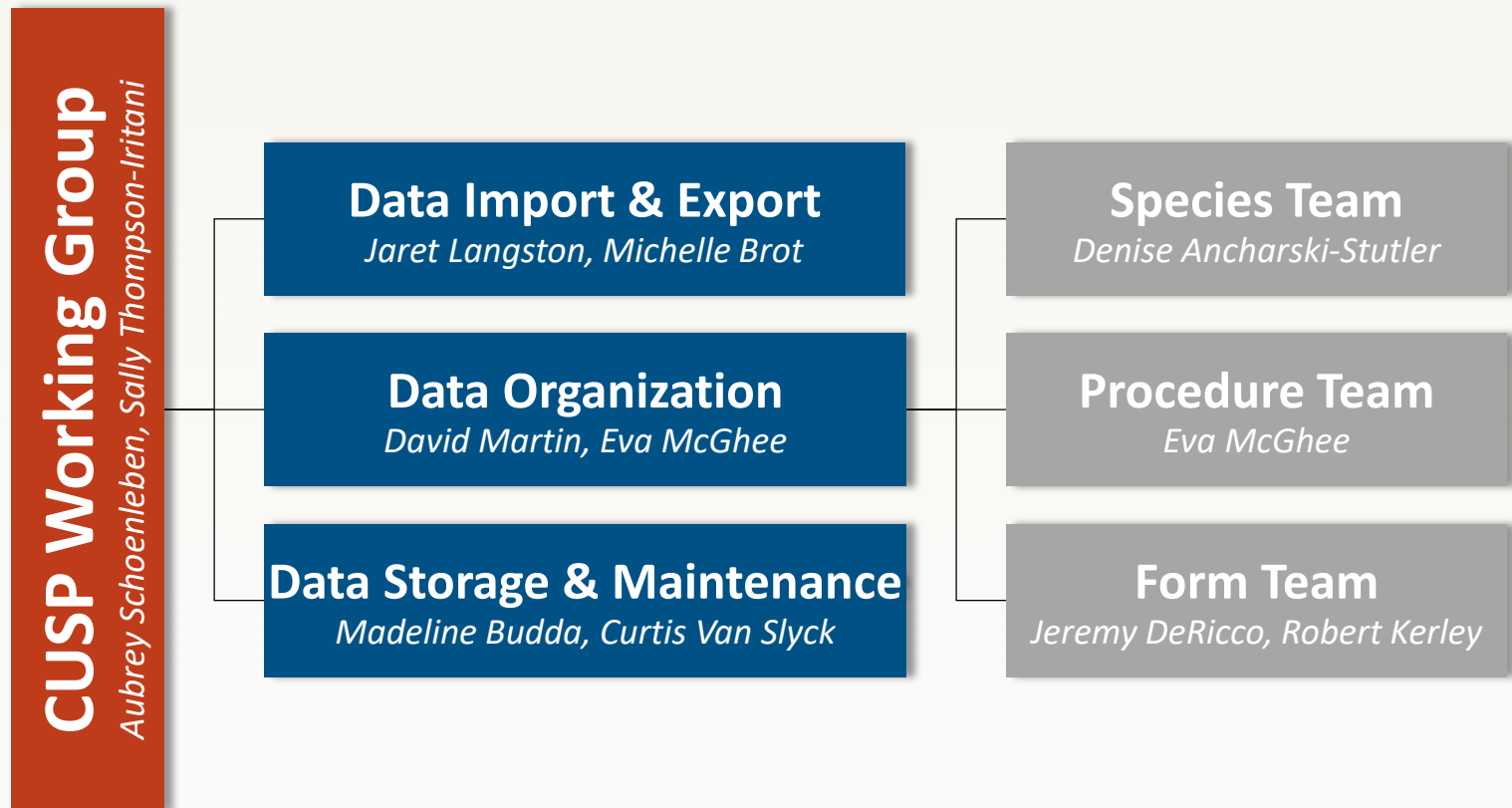
Animal Care

- Ara Tahmassian, Harvard; Axel Wolff, NIH
 - Animal Care and Use Subcommittee
 - 21st Century Cures Act Listening Session on Animal Research with NIH, USDA, and FDA
 - Compliance Unit Standard Procedure (CUSP)
 - Working group co-chairs - Aubrey Schoenleben, UW; Sally Thompson-Iritani, UW



CUSP Working Group

Goal: To create an online venue where participating institutions can share standard substances and procedures used in animal care protocols.





CUSP Working Group



March 2017



Pilot
Project
Approved

October 2017



Site Design
& Function

In progress!



Initial Site
Development



Pilot



Impact
on
Burden



Conflict of Interest

- Mary R. Lee, Stanford U; Melissa Petersen, UW; Diane Dean, NIH
 - Subrecipient COI Monitoring
 - 21st Century Cures Act – COI Regulations/requirements catalog
 - Survey results follow-up



Conflict of Interest

- 175 Responses (98 Complete)
 - Wide range of institution sizes
 - Number of annual financial disclosures ranging from 100 – 11,000
- Nearly two thirds of institutions are impacted by state laws on COI
- Most institutions have electronic COI systems:
 - 16.5% indicated no electronic system
 - Nearly half indicated a “home-grown” system
 - About one third have a purchased system



Export Controls

- Doug Bachman, UCF;
- Seeking federal co-chair!