

FDP Virtual Spring Meeting January 11-14, 2021

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Quick meeting summary

The FDP conducted its Winter 2021 conference virtually from Monday, January 11, 2021 through Thursday, January 14, 2021. The following document provides a quick review of the sessions and topics, along with links to slides and video of the presentations. This meeting summary is not intended to replace the larger meetings notes documents, but rather is meant to serve as a reminder of what was covered in each session, with links to the meeting materials.

Prior to the kick-off of this meeting, two webinars were held to welcome Phase VII new members and provide some background on the FDP and how members can get involved.

- Monday, November 30, 2020 Slides & Recording
- Friday, January 8, 2021 Slides & Recording

Monday, January 11, 2021, 11:00am-12:30pm EST Plenary – Dr. Chris Austin, National Center for Advancing Translational Sciences – Dr. Chris Austin, Director of the National Center for Advancing Translational Sciences (NCATS), part of the National Institutes of Health, opened the January 2021 FDP Meeting with this session focusing on how NCATS pivoted its focus and activities in response to COVID-19. After a survey of the current state of knowledge about COVID-19, including increased risk for specific populations and those with underlying medical conditions, Dr. Austin described NCATS' collaboration-based approach to the pandemic. Highlights included:

- the OpenData Portal, launched in May 2020 to share drug discovery data and experiments
- the <u>ACTIV</u> (Accelerating COVID-19 Therapeutic Interventions and Vaccines) public-private partnership, which used NCATS' site to advise on small animal models being used for COVID-19 testing
- the mobile app <u>CURE ID</u>, created in collaboration with the FDA, and used to capture clinician experiences in real time with various drugs to share efficacy
- the NIH COVID-19 "Serosurvey" NCATS initiated in collaboration with NIAID, NIBIB, NCI, and CTSA Program hubs at the University of Alabama and the University of Pittsburgh, with over 10,000 participants
- the National COVID Cohort Collaborative (N3C), a compendium of EHR data on 2.5 million patients from organizations within the CTSA Program and IDEA CTR created to capture data on the characteristics, course, medication effects, and long-term sequelae of COVID-19 with population representation of race/ethnicity, age, and comorbidities and housed in a secure enclave built, administered, and maintained by NCATS and available to the entire research community for research projects

Hurdles overcome during the last year included those related to policy, privacy, data security, data agreements, and access to data, all of which raises the question of how to respond similarly to any other, or every other, disease. The session closed with a summary of lessons learned, most notably that it is possible to move from fundamental discovery to therapeutics much more rapidly than

Video Slides historically thought, the reasons for this, and what steps can be taken to recreate these approaches in the future.

Monday, January 11, 2021, 1:00pm-3:00pm EST Plenary – Federal Agency Updates – Agency representatives from the United States Department of Agriculture, National Science Foundation, National Institutes of Health, National Aeronautics and Space Administration, Department of Homeland Security, Air Force Office of Scientific Research, Government-University-Industry Research Roundtable, Office of Naval Research, and Environmental Protection Agency, presented on news, updates, and changes within their respective agencies. A compilation of summaries of each agency update can be found here.

Video
USDA Slides
NSF Slides
NIH Slides
NASA Slides
DHS Slides
GUIRR Slides
ONR Slides
EPA Slides

Monday, January 11, 2021, 3:30pm-5:00pm EST Phase VII Kickoff and FDP Committee Reports – FDP Co-chairs Alex Albinak and Michele Masucci started off the session with introductions and an overview of the of FDP committee structure. This was followed by brief presentations from the co-chairs of the six programmatic committees, including the structure, membership, and goals of each committee, descriptions of subcommittees and working groups, updates on current and planned demonstrations and initiatives, and volunteer opportunities. Additionally, the newly formed Nominating Working Group will be issuing calls for volunteers, both for programmatic and operational committees as well as the Nominating Working Group itself. Those interested in participating in any committee, subcommittee, or working group are encouraged to watch the video and review the slides for whom to contact.

Slides Video

Slides

Video

Tuesday, January 12, 2021, 11:00am-12:30pm EST Foreign Influence Management – Enhancing the Security and Integrity of America's Research Enterprise - Pamela Webb (University of Minnesota) and Jim Luther (Duke University) led this session that featured a diverse group of copresenters who shared their perspectives on the ever-evolving issue of foreign influence management. The session began with an overview of recent developments in this space, most notably the JCORE Report and resulting actions, the disclosure requirements in NDAA Section 223, the MITRE Report and its principal findings, and the GAO Report. Most recently, the FDP Foreign Influence Working Group (FIWG) coordinated a listening session with officials from NIH and NSF concerning the challenges faced by institutions of higher education in gathering, integrating, and reporting on foreign influence disclosure information; the session was entitled "Connecting the Dots" - Foreign Interference and Associated Risks to the Integrity of Research". Building on this, FIWG distilled the various issues into a set of "white paper" topics to guide the discussion relating to foreign influence management. These topics include institutional and cultural challenges in managing and reporting on researchers' outside activities; management of financial conflict of interest data; the complexity and breadth of issues and connecting all of the dots; pitting the institution against individual faculty; technical barriers; the faculty perspective; and accountability of institutions and Pls. The co-presenters considered the issues and challenges relating to each topic, as well as recommendations to explore next steps, and members are strongly encouraged to watch the video to benefit from the productive discussion that followed.

> Slides Video

Tuesday, January 12, 2021, 1;00pm-2:30pm EST **Subawards Subcommittee** – The session began with a new member orientation to the subcommittee; its purpose and duties; and its products and structure. An update was given on the Subaward Delays survey, including next steps, which will consist of framing the results in terms of "what is preventing incredible productivity in our research enterprise?" The goal of this project is to complete the qualitative analysis and present recommendations at the May 2021 meeting. Updates to the templates were then presented, including the changes to amendment templates, as well as to the cost-reimbursement and fixed-amount templates to accommodate

the recent UG changes. Laura Register was given a virtual ovation for her efforts over the years in programming the PDF files for the templates. While she will continue to assist with the programming, she has moved to a new position that will reduce her participation in the Subawards Subcommittee working groups. A Subaward Subcommittee webinar was announced for January 27 to help familiarize new members (and new staff) with the templates, the guidance, and the tools available. Guidance document updates include new User Guides that walk users through each section of the templates with descriptions of the purpose of each item. The User Guide for the amendment templates has been posted, while the guides for the cost-reimbursement and fixed-amount templates are forthcoming. Updated FAQs v.8 will be released by the time of the webinar for comment. There was a discussion on the frequency of invoicing for subawards, from both the PTE and subrecipient viewpoints, followed, and this topic will be pursued by the Subcommittee in the future, possibly in coordination with other groups. Finally, Amanda Hamaker announced that she would be stepping down as a co-chair of this Subcommittee; she described the role of the co-chairs and indicated that anyone interested in volunteering should reach out to the co-chairs at subawards@thefdp.org.

Tuesday, January 12, 2021, 3:00pm-4:00pm EST Compliance Unit Standard Procedure/Universal Protocol Template – A short history of the UPT and updates were provided by Ron Banks (University of Oklahoma Health Sciences) and Bill Greer (University of Michigan). The objective was to provide a user-friendly template tailored to common species which included only information essential to IACUC review. A draft template from the IACUC Administrators Association (IAA) was formatted into logical sections and provided to committee members for comment. The template was revised in December and will now be tested by user volunteers. Michelle Brot (University of Washington) provided an update on the CUSP project, an online resource for institutions to share common animal care procedures. The site is in beta testing in Q1 2021 with 6-8 institutions, expanding in Q2 to 15-20 institutions, with a planned go-live date of Q3 2021. The help desk is now live and receiving/handling emails (cusp@thefdp.org).

CUSP Slides
UTP Slides
Video

Tuesday, January 12, 2021, 4:30pm-6:00pm EST Faculty Forum - FDP Co-chair and Faculty Chair Michele Masucci (Temple University) and Faculty Committee Vice-chair Robert Nobles (Emory University) led this session that served both as an introduction to the role that faculty play in the FDP, and as an overview of past, current, and potential future faculty-relevant FDP initiatives. After a brief explanation of the Faculty Steering Committee and its function within the organization, the most recent Faculty Workload Survey and the Phase VII strategic goals were discussed from the faculty perspective. Major initiatives for faculty participation currently underway include the Faculty Workload Survey; development of FDP evaluation metrics, scholarly FDP publications; FACT (the Faculty Administrator Collaboration Team); crosscutting engagement across all FDP committees, subcommittees, and working groups; faculty-relevant demonstrations; convenings; and engagement with federal representatives. Session attendees were then split out into breakout rooms to discuss these initiatives, specifically the background, informational needs, and potential action items relating to each initiative. After the breakout discussions, the full group reconvened, with each group reporting on its topic and what consistent themes emerged from their discussion.

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Wednesday, January 13, 2021, 11:00am-12:30pm EST Contracts & Data Stewardship Subcommittees – The session included a discussion of current activities and next steps across contract and data stewardship topics. The workgroup will be updating the Troublesome Clauses database to version 2.0. The workgroup is also working to develop a survey that will be used to gather information on federal contract negotiation issues/delays; COGR will use this information, in conjunction with their own survey, to bring forward and discuss issues with DoD representatives (February meeting planned). An overview and update was provided on DoD's progress with both the

Slides Video Cybersecurity Maturity Model Certification and the SPRS 'self-assessment' registration, including polling of participants on how CMMC and SPRS are impacting institutions. An update on the pending CUI FAR clause was given; the estimated comment period is March to May 2021. The workgroup presented on the Final NIH Policy for Data Management and Sharing Policy, issued October 2020 with an effective date of January 25, 2023. Suggestions on how FDP can contribute to reducing burden around this new policy were explored/discussed.

Wednesday, January 13, 2021, 1:00pm-2:30pm EST Finance, Audit, and Costing Policy Committee – Co-chairs: Michelle Bulls (NIH) and Jim Luther (Duke University). NIH Updates: The Notice of Award cover page update for DHHS was implemented in October 2020. The Single Portal PMS/FFR portal is complete, and FFRs are now submitted through the payment management system. The implementation of new Other Support requirements has been postponed to March. The issuance of the 2020 update to the NIH grants policy statement has been postponed a bit. Phase 2 for the FFR elimination is expected sometime in this fiscal year; FCTR will no longer be required.

Open Government: The goal of this subcommittee is to provide a forum to track, analyze and, streamline the impact of data driven initiatives stemming from various federal government directives. The subcommittee presentation began with an update to the LoC survey. The survey assessed 5 payment systems with input from 63 respondents. Next steps will be to continue user engagement and enhancements, OMB approval, and a live pilot. There will be a session on FIT (Financial Innovation and Transformation) at the spring FDP meeting.

Treasury Offset: The Treasury Offset Program (TOP) is intended to collect the debts owed to the federal government by withholding money from a federal payment to the debtor. It can be difficult for entities to determine the source of delinquent debt. Recommendations included having TOP send a letter to the Receivables office of the Grantee, and that agencies should have one office that has the information pertaining to all invoices sent to TOP. There will be a follow-up initiative to address this item.

Data Storage Costs and Coordination with Data Stewardship Subcommittee: NIH issued a final policy for data management and sharing, including related allowable costs. Concerns about overhead, costs after the project period, data curation, and preservation were noted.

FFR Migration – The FFR expenditure report is due before the next transaction report, leading to the disbursement data and payment management report being out of date. A working group is planned to facilitate interaction with PMS and agencies to understand some of the problems.

Pennies, small credits, and FFR migration – Changes in small dollar amounts after the FFR is filed can be problematic, and HHS is looking into whole dollar requirements.

Wednesday, January 13, 2021, 3:00pm-4:00pm EST Research Compliance Committee: Phase VII Road Map Planning – Melissa Korf (Harvard Medical School) is the new co-chair of the Research Compliance Committee (RCC) replacing outgoing RCC co-chair Alex Albinak. A brief history of the RCC and its goals were discussed. The committee works to reduce unnecessary burdens without comprising needed compliance. Current RCC subcommittees include Animal Care and Use, Conflict of Interest, Data Stewardship, Export Controls, and Human Subjects. Many of the subcommittees have vacancies and are seeking co-chairs. Highlights on research compliance areas from the 2018 Faculty Workload Survey were presented, along with results on the priority level (low, medium, high) for change. Conflict of Interest had the highest prevalence of the compliance requirements. IACUC/Animal Subjects, Clinical Trials, and IRB/Human Subjects had the highest substantial workload and also the highest priority for change. Specific areas to look into further were

Slides Video

Slides Video identified for IACUC and IRB. Data Management was covered in the Research Administration section of the 2018 Faculty Survey, with lower results for substantial workload and priority level for change than other Research Administration areas. Data Management may become more of an issue for faculty and institutions with the new NIH Data Management and Sharing Policy. Safety/Security was a separate section in the 2018 Faculty Survey, and the results indicated increases in substantial workload for Biosafety, Controlled Substances/Narcotics and Chemical Safety since the 2012 Faculty Survey. Export Controls, Recombinant DNA, Controlled Substances/Narcotics and Biosafety all had a high priority for change. RCC is considering the establishment of a Biosafety Subcommittee to complement the other subcommittees. Suggestions were made to invite AALAC and PRIM&R to future FDP RCC sessions. The session ended with Melissa asking that members share ideas on their priorities and pain points with her, and to contact her if interested in one of the vacant cochair positions (see final slide for contact information).

Wednesday, January 13, 2021, 4:30pm-6:00pm EST **eRA** – **SciENcv Adoption** – Please refer to the slide deck and video recording for full presentation. For technical or IT system-related questions regarding the SciENcv formats, please contact the NSF Help Desk at fastlane@nsf.gov or at 1800-673-6188 (7:00 AM - 9:00 PM ET; Monday - Friday except federal holidays). Please direct questions related to policies to the NSF Policy Office at policy@nsf.gov.

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Thursday, January 14, 2021, 1:00pm-2:30pm EST Faculty Administrator Collaboration Team (FACT) - This session, led by Steven Post and Suzanne Alstadt (both from University of Arkansas for Medical Sciences), shared the results of a recent Thought Exchange related to the "natural experiment" that has resulted from COVID-19 circumstances. The presentation focused on how institutional responses to the pandemic positively or negatively impacted collaboration between faculty and administrators. Results of the Thought Exchange were grouped into three major themes: communication/relationships, flexibility/adaptability, and resources/infrastructure. FACT found that there were many positive impacts, including increased options for faculty and administrators to communicate and more flexibility to work in different environments. Participants voiced negative impacts on maintaining work-life balance, system and technology challenges in the shift to remote work, and increased demand for staffing support while staffing/resource budgets were cut. The ensuing dialogue prompted a number of follow-on inquiries by the panel and participants; for example, evaluating the sustainability of process improvements beyond the pandemic, accommodating technology and staffing needs, and how best to guery and communicate with the broader FDP community.

Thursday, January 14, 2021, 3:00pm-4:00pm EST

eRA – GSA Update on SAM and EUI – SAM.gov is progressing toward becoming the fully-integrated funding site for the federal agencies. Already, five systems have been integrated into SAM and decommissioned as stand-alone systems, including CFDA (now ALN). The next system to be integrated and then decommissioned as a stand-alone will FSRS, but no target date has yet been indicated. In March 2021, beta.SAM.gov will be refreshed to give users one month to familiarize themselves with the new look of the system, which will then go live on April 26, 2021, at SAM.gov. On February 9, 2021, an "industry day" will be held as a virtual meeting to explore the new system. Alpha testers are encouraged to email newsamtesting@sam.gov to sign up. A walkthrough was then conducted of the new SAM system.

Universal Entity Identification will be implemented by April 2022. An audience question was asked about subrecipients who need to obtain a UEI, which requires SAM registration, although this is not currently required for subrecipients to receive federal subawards. The presenters clarified that an abbreviated registration would

Slides Video be made available so that subrecipients are not required to complete the full registration.

Thursday, January 14, 2021, 4:30pm-6:00pm EST

Plenary - Research Trends and Outlook for 2021 - The closing session of the January 2021 meeting was a panel discussion with a focus on the state of research and higher education, both in light of the ongoing pandemic and the imminent changes in federal leadership. FDP Co-chairs Alex Albinak and Michele Masucci guided the conversation with panelists Toby Smith of the American Association of Universities, Debbie Altenburg of the Association of Public and Land-Grant Universities, Joanne Carney of the Amercian Association for the Advancement of Science, and Jennifer Poulakidas of the University of California, Los Angeles, with each sharing the perspective of their organizations. Topics of discussion included initial responses to COVID-19, lessons learned from those responses and what to expect in the year ahead, impacts on graduate education and international students in particular, and what changes can be expected from the incoming administration in terms of policies that impact research and investment in science and education. There were also a number of audience questions that sparked discussion on issues such as how to apply the hybrid model to post-COVID meetings and educational settings, restarting investigator labs, immigration policy, and other areas impacting research and higher education.

Thursday, January 14, 2021, 6:00pm EST

FDP Meeting Adjourned

Video