

FDP Virtual Spring Meeting September 20-23, 2021

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Quick meeting summary

The FDP conducted its Fall 2021 conference virtually from Monday, September 20, 2021, through Thursday, September 23, 2021. The following document provides a quick review of the sessions and topics, along with links to slides and video of the presentations.

Monday, September 20, 2021, 11:00am-12:30pm EDT Plenary – NIH-Wide Strategic Plan for Fiscal years 2021-2025 –

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Representatives from the NIH Division of Program Coordination, Planning, and Strategic Initiatives presented on how the strategic plan is developed pursuant to mission and goals, framework, and measuring progress. The 21st Century Cures Act maps out Congress's expectations for the plan, including a requirement that strategic plans be developed at least every six years, and that institute/center plans address NIH-wide goals and use a common template. The current plan. developed over a two-year period, communicates the NIH mission, how it will achieve its priorities, and benchmarks to the last plan. The three main objectives discussed in the presentation were Advancing Biomedical and Behavioral Sciences; Developing, Maintaining, and Renewing Scientific Research Capacity; and Exemplifying and Promoting the Highest Level of Scientific Integrity, Public Accountability, and Social Responsibility in the Conduct of Science, with representative highlighted content including: BRAIN initiative, Universal Flu Vaccine, HEAL Initiative, Native American Research Internship Program (NARI), the transformative high resolution cryo-EM program, new PubMed Central, antiharassment, and the public/private partnership of ACTIV (accelerating Covid-19 therapeutic interventions and vaccines). The strategic plan reflects priority setting at NIH and takes both a "top down" (priorities) and "bottom up" (investigator initiated) approach that encompasses all 27 institutes and centers, 24 of which are grant-making. Measuring progress is also a factor, and NIH has been actively implementing the Evidence Act to modernize its data management practices, evidence-building functions, and statistical efficiency to inform policy decisions. The final section of the presentation focused on initiatives to better capture and communicate the value of NIH's investments and the impact of NIH's work, with examples ranging from NIH's impact on cost savings, commercial activity, and business startups, to data points such as numbers people treated or saved as a result of NIH activities.

Monday, September 20, 2021, 1:00pm-3:00pm EDT Plenary – Federal Agency Updates – Agency representatives from the National Science Foundation, National Institutes of Health, National Aeronautics and Space Administration, Air Force Office of Scientific Research, Department of Homeland Security, Department of Agriculture, Government-University-Industry Research Roundtable, Environmental Protection Agency, and Department of Education presented on news, updates, and changes within their respective agencies. A compilation of summaries of each agency update can be found here.

Video
NSF Slides
NIH Slides
NASA Slides
AFOSR Slides
DHS Slides
USDA Slides
GUIRR Slides
EPA Slides
Dept. of Ed. Slides

Monday, September 20, 2021, 3:30pm-5:00pm EDT FDP Phase VII Strategic Plan Initiatives – FDP co-chairs Alex Albinak and Michele Masucci introduced this session, which was intended to provide an overview of the FDP's goals and objectives for Phase VII and a summary of activities and accomplishments to date. There were updates on FDP meetings, and a new working group to reimagine meetings going forward, as well as on the FDP budget, followed by presentations from chairs of the working groups for evaluation, federal engagement, and volunteer engagement and nominating, and by the communications and eRA committees. The session concluded with a review of the CUSP (Compliance Unit Standard Procedure) project, which served as an example of FDP's definition of a "demonstration." Members are encouraged to review the slides and video for more detailed information on these working groups and committees, and those interested in volunteering with the FDP will find numerous opportunities to participate.

Tuesday, September 21, 2021, 11:00am-12:30pm EDT **National Science Foundation Proposal Modernization Update** – Members are encouraged to review the slides and view the video of the presentation for full details on the session. Answers to questions asked in the chat window are also available **here**.

Video Slides

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Slides

Tuesday, September 21, 2021, 1:00pm-2:30pm EDT Subawards Subcommittee - The Subawards session started with some friendly reminders about the subaward templates: 1) The templates were created to make the process more efficient and less burdensome, so institutions using them should not make changes (unless the FDP moniker is removed). Any additional terms and conditions should be specific and reasonable. If the additional terms are the result of a risk assessment, keep in mind 2 CFR 200.208, which requires that those terms be specific to the determined risk, and that they be removed once the conditions are satisfied. 2) If you do get a subaward that has been changed, you should contact the Subawards Subcommittee (Subawards@thefdp.org), who will contact the institution and help negotiate the changes. The Subcommittee will continue to monitor trends in subawards negotiations and reinforce the consensus that supports the templates' efficacy. Further discussion included questions and concerns about the templates and the negotiation process with additional/changed terms, as well as adding terms stemming from specific state laws (it was noted that FAQ # 52 allows for adding state law requirements that are otherwise unavoidable). Additional guidance may be forthcoming on this topic. FFATA reporting has gained a higher profile, and an update on the subcommittee's work on this, including a future survey about the "user experience," was provided, with a goal of discussing the survey results with OMB. An operational-level listening session was scheduled for October to discuss subaward invoicing issues; a leadership-level listening session will follow in November. Both sessions are being coordinated with the Finance, Audit, and Costing group. Other topics presented included the telecom prohibitions contained in 2 CFR 200.216, a call for volunteers for a new subaward monitoring tools working group, Adobe Sign, and Universal Entity Identifiers (UEI).

Tuesday, September 21, 2021, 3:00pm-4:00pm EDT Research Administration Committee – Exploring Proposal Development & Submission Possible Demonstrations – This session was led by Amanda Hamaker, Purdue University, Lisa Mosley, Yale University, Lori Schultz, University of Arizona, Stephanie Gray, University of Florida and Alice Young from Texas Tech University. This session included an overview of the initiatives that the Research Administration Committee has focused on, in partnership with the Faculty Committee, such as Proposal Initiative with the goal of reducing administrative burden. They discussed the Flexibility Matrix which highlights the types of items and when each sponsor handles it (JIT or time of proposal) and the launch of ThoughtExchange to capture input from the FDP membership. During this session results from the ThoughtExchange were shared and additional information will be forthcoming as the results are further analyzed.

Tuesday, September 21 2021, 4:30pm-6:00pm EDT Faculty Forum and Business Meeting – Faculty Committee Chair Michele Masucci (Temple University) and Vice-chair Robert Nobles (Emory University) facilitated the session. Representatives from the Federal Engagement Working Group—Co-Chairs Jim Luther (Duke University) and Maria Koszalka (National Science Foundation) and Project Manager Julie Thatcher (Institute for Systems Biology)—summarized their presentation from the previous day with a "faculty focus." Their aim was to spark conversation, particularly around the workgroup's Phase 1 Draft Recommendations to: 1) Create Federal liaisons; 2) Create pop-up listening groups; 3) Provide agency update templates and create agency webpages; 4) Consider different levels of Federal engagement; and 5) Continue to evaluate opportunities to seek meaningful engagement.

Video FEWG Slides Evaluation Slides

A discussion ensued with participants expressing a range of ideas, including that faculty liaisons to agencies should represent familiarity with a variety of funders and institutional needs; that these positions should be on a rotating basis, and that there should be faculty-administrator liaison pairs. The idea of pop-up listening groups was well received, and participants also expressed interest in being able to be more involved in the development stages of federal policies that affect research. Conversely, participants shared feedback related to the depth and breadth of some federal presentations at FDP meetings, and suggested that content be added with increased relevance to investigators and research faculty.

In the remaining time in the forum, Robert Nobles presented a "Deeper Dive on Evaluation", building on his presentation from the May 2021 FDP Faculty Forum. A brief discussion followed touching on topics such as the value of interactions among faculty from different institutions and publishing findings/accomplishments after each workload survey.

Wednesday, September 22 2021, 11:00am-12:30pm EDT **Agency Implementation of Unique Entity Identifier (UEI)** – Representatives from USDA, NIH, and NSF presented updates on their agencies' implementation of the transition from DUNS numbers to UEIs and registration in SAM.gov.

USDA will use UEIs to validate and identify recipients of financial assistance and contracts in SAM.gov, and the shift to UEIs is currently underway for new entities. One major challenge is transitioning to UEI implementation in all USDA systems, tools, and data collection forms, which include approximately 50 systems/interfaces. USDA is UEI-ready for FMMI (financial system), ezFedGrants, and Data Act reporting, with full UEI compliance expected by April 2022.

NIH issued a guide notice in August, 2021 (NOT-OD-21-170), which announced that starting in October 2021, NIH will be populating UEI data in institutional profiles with no need for entity action, and entities can expect to begin to see UEI data in the eRA Commons in January 2022. UEIs will be required for NIH applications submitted on or after January 25, 2022 as part of the transition to FORMS-G, although DUNS information will be maintained in NIH and eRA systems for historical reference. Both FORMS-F and FORMS-G will be active during application cycle III, so institutions should be aware of application due dates and follow the appropriate guidance. FORMS-G application guide will be posted on October 25, 2021, and FORMS-G test FOAs are now available. Updated NOA templates with updated UEI guidance will be released starting in October 2021.

NSF anticipates overlapping use and display of DUNS and UEI between January and April 4, 2022, but will not accept DUNS numbers after January 2022. By the end of January 2022, institutions must update their legal business and physical addresses in SAM.gov, and Research.gov will use legal and business address data from SAM.gov to populate in systems and on generated forms such as the proposal cover page and RPPRs.

Wednesday, September 22, 2021, 1:00pm-2:30pm EDT Science and Security - Latest Developments in Managing Improper Foreign Influence – Members are encouraged to review the slides and view the video of the presentation for full details on the session.

Video Slides

Wednesday, September 22, 2021, 3:00pm-4:00pm EDT **Export Controls - Future Subcommittee Objectives and Direction** – This session was led by Doug Backman from University of Central Florida and Robert Gutierrez from Florida International University. This session included an overview of the subcommittee and discussed current export control issues. It focused on the High-Risk Entity Lists; Foreign Talent Programs; Export Classification Determination; Cybersecurity and CUI and Harmonizing Federal Regulations Across Agencies. The Co-chairs solicited membership suggestions on what topics this subcommittee should further concentrate on. They are also soliciting members to this subcommittee. Anyone interested should contact Doug or Robert.

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Wednesday, September 22, 2021, 4:30pm-6:00pm EDT

Update on Implementation of the NIH Data Management and Sharing Policy-Taunton Paine, Director of NIH Office of Science Policy's Scientific Data Sharing Policy Division, and Cindy Danielson, Health Science Policy Analyst in NIH's Office of Extramural Research, presented this session with updates on implementing the NIH Policy on Data Management and Sharing. The session began with a review of the evolution of NIH's data sharing expectations, policies, and requirements from the early 1980s to the present. A new policy for data management and sharing will take effect in January 2023, and will require the submission of a data management and sharing plan in all NIH applications as well as full awardee compliance with their NIH Institute/Center approved plan, with compliance to be used in decisions regarding future funding. Detailed information was provided on the scope of what data is to be shared, when it must be shared, and the duration for which it must be shared, as well as recommended elements to be included in data sharing and management plans. Other topics covered included what costs are allowable/not allowable to support activities under the new policy, next steps for implementation of the policy and commonly received questions, the development of resources for awardees such as clarifying how the policy may interact with other NIH-wide policies on data sharing and FAQs, and NIH's plans to ensure tribal sovereignty and tribal laws in implementing the new requirements. The session concluded with a group discussion on implementation of the new policy, ways in which the FDP community could contribute towards implementation, and strategies to reduce administrative burden. Questions can be directed to sciencepolicy@mail.nih.gov.

Useful links: OSP Data Management and Sharing Website;

NOT-OD-21-013 —Final NIH Policy for Data Management and Sharing;
NOT-OD-21-014 — Supplemental Information to the NIH Policy for Data
Management and Sharing: Elements of an NIH Data Management and Sharing
Plan;

NOT-OD-21-015 —Supplemental Information to the NIH Policy for Data Management and Sharing: Allowable Costs for Data Management and Sharing; NOT-OD-21-016 —Supplemental Information to the NIH Policy for Data Management and Sharing: Selecting a Repository for Data Resulting from NIH-Supported Research.

Thursday, September 23, 2021, 11:00am-12:30pm EDT CUSP & Universal Protocol Template Update – Ron Banks (The University of Oklahoma Health Sciences Center) opened the session with an overview of the Universal Protocol Template's (UPT) origin and work the group has completed to date. The UPT aims to streamline the IACUC application to be more user friendly while satisfying regulatory requirements. Numerous examples of protocol template questions were presented. Progress on the UPT has been somewhat hampered by the pandemic. The draft UPT is currently being thoroughly analyzed and discussed, with the goal of completing analysis by June 2022. Following this, user testing with researchers, veterinarians, IACUC administration, and IACUC members is anticipated July - December 2022, with a planned finalization and

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release in early 2023. Anyone interested in working on this project should contact Ron (ron-banks@ouhsc.edu) or Bill (wggreer@umich.edu).

Aubrey Schoenleben (University of Washington) provided an introduction to the Compliance Unit Standard Procedure (CUSP) project and the working group that supports the project. Funding from NIH/OLAW was recently secured to support a dedicated development resource to transition the beta version of the site to a more modern technology stack. This transition is currently underway and will better support long term maintenance of the site and align the project with FDP's internal systems goals for Phase VII. A brief demo of the new site was shared. The demo gave an overview of the home screen, procedure record details, and user dashboards. Completion of development and testing is anticipated by the end of year, with rollout to the FDP community in January 2022. The Help Desk, Quality Control, and Technical Systems teams within the working group are actively seeking volunteers. Anyone interested in participating should email cusp@thefdp.org.

Thursday, September 23, 2021, 1:00pm-2:30pm EDT

Grants Quality Service Management Office (QSMO): Working to Improve the Recipient Experience with Federal Grants Management Systems - The Grants Quality Service Management Organization (QSMO), housed at the U.S. Department of Health and Human Services, was created as a result of the Presidential Management Agenda of the previous administration, and is tasked with reviewing the entire grants management lifecycle from all user perspectives with a goal of improving all users' experience. They aim to do this by easing burden and increasing efficiencies in the process, responding to user needs, and using data to strategically identify pathways to these goals. Representatives from the Grants QSMO stressed that they are not a policy-making office and don't intend to be a standards setting agency for grants management; rather, they are working to improve the grants ecosystem to empower and enable applicants, recipients, and federal awarding agencies to efficiently and effectively deliver on the grants mission. They presented the current system landscape, which is fragmented and customized to individual agencies, in many cases with aging technology. These characteristics make the varying systems more difficult to streamline among federal awarding agencies. The long-term goal is a "technology target state" that leverages a modular and interoperable design to deliver a seamless user experience. for all grant lifecycle activities across all funding agencies. In the meantime, the Grants QSMO is working to provide what 70% of survey respondents requested: a unified portal for accessing the various systems. Leveraging the use of Login.gov, a single sign-on solution, the Grants QSMO is developing the Recipient Seamless User Experience (RUX) portal to improve the overall user experience. A demonstration of a clickable prototype for this portal was provided, and this was followed by discussion on what improvements and/or additions would enhance the user experience. Generally, the biggest frustration among the FDP membership was user access and authentication across the many systems, and the best example of IT solutions currently available was Commons. A single portal was discussed as a great initial solution to these concerns. The presenters requested additional input to be sent to grantsQSMO@hhs.gov.

Thursday, September 23, 2021, 3:00pm-4:00pm EDT Finance, Costing, Audit Committee – Committee Co-chairs Michelle Bulls from the National Institutes of Health and Jim Luther, formally of Duke University, along with several other committee members, provided updates on Finance, Costing, and Audit Committee activities and initiatives. Highlights from NIH included the latest news on transitioning of FFRs into the Payment Management System, the process for requesting drawdowns outside the 120-day liquidation period, current audits by the NIH OIG and the GAO, efforts to improve turnaround times on the approval of financial reports, and guidance on how to handle credits and rebates that hit accounts after they have been closed. Updates were also presented on the DLT (Direct Ledger Technology) Working Group and its efforts to engage with federal partners to streamline the grant payments workflow process, and the TOP (Treasury Offset Program), with guidance for awardees in navigating the TOP

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process. The session concluded with a detailed discussion on data management and sharing from a finance and costing perspective, including results of a recent Thought Exchange on this topic, main areas of concern for institutions, and what can be done to help prepare institutions for upcoming changes to agency data management and sharing policies such as the NIH policy scheduled to take effect in January 2023.

Thursday, September 23, 2021, 4:30pm-6:00pm EDT Human Subject Subcommittee Update – Debra Murphy (Arizona State University) and John Bauman (Indiana University) led the update from the Human Subjects Subcommittee. A steering committee was recently formed to provide overall direction for the subcommittee. The subcommittee members are Mariette Marsh (University of Arizona), Rachel Wenzl (University of Nebraska), Sarah Kiskaddon (Dana Farber/Harvard Cancer Center) and Michelle Stickler (University of Texas – Austin. The focus of activities includes deployment of the IRB Wizard, as well as three new areas related to the Revised Common Rule: (1) exempt and limited IRB review; (2) single IRB; and (3) continuing review. Working groups will be formed around each of these topics to explore where efficiencies are needed. If you have questions or are interested in volunteering, email John Bauman (baumanj@iu.edu).

Debra Murphy provided an overview of the IRB Wizard project, its history, and the related pilot study. The goal of this project is to develop a researcher-friendly electronic tool that will assist in determining which human subjects studies any of the targeted categories eligible for exemption from IRB review. A demo of the IRB Wizard was provided, including an explanation of the branching logic used in the underlying survey. The Wizard is built in Qualtrics. Implementation by individual institutions is accomplished by downloading the Qualtrics file (i.e., it's not hosted on a shared platform). The Wizard also allows for a wide range of reporting. An institutional MOU describing appropriate use of the tool and related data will be required for implementation, and is currently being drafted. The subcommittee is also working on a deployment plan to make this tool available to the FDP community in the near future.

Thursday, September 23, 2021, 6:00pm EDT **FDP Meeting Adjourned**