

FDP Meeting May 10-12, 2017

The Federal Demonstration Partnership (FDP) is a cooperative initiative among 10 federal agencies and 155 institutional recipients of federal funds. Its purpose is to reduce the administrative burdens associated with research grants and contracts with the goal of improving the productivity of research without compromising its stewardship. The FDP is a program convened by the Government-University-Industry Research Roundtable of the National Academies. The interaction between FDP's 450 or so university and federal representatives takes place in FDP's 3 annual meetings and, more extensively, in the many collaborative working groups and task forces that meet often by conference calls in order to develop specific work products. It does not develop or recommend policy. UM was a founding institution. Each phase is 6 years; the FDP is currently in Phase VI. For more information about the FDP, go to <http://sites.nationalacademies.org/pga/fdp/index.htm>.

As the faculty representative, I will post a synopsis of the FDP meeting discussions of interest to the faculty, and welcome your suggestions and input to bring back to the group. Please feel free to contact me directly: jsagen@miami.edu.

Agency updates:

GUIRR (Government-University-Industry Research Roundtable, convening body of the National Academies of Sciences, Engineering, and Medicine; Susan Sloan, Director): GUIRR holds several interesting meetings and webinars a year; a description of these and access can be found at: www.nas.edu/guirr. Their recent meeting focused on examining the mistrust of science, trends in public opinion, and ways to improve this. A recent Pew study found that public trust in science is high and remains stable, despite politics, religion, and gender differences. The only scientific trust issue that appeared to be rooted in politics was climate change. Even presentation of factual evidence does not necessarily change public opinion. There will be a report coming out from this meeting. The next GUIRR meeting topic (July) will be "Beyond patents" and take up topics related to private investment in science. There are also monthly webinars.

Air Force (AFRL, AFOSR): BAAs are now open until suspended (rather than previous one year expiration). The Young Investigator Program (YIP) is expanding eligibility for 2010 PhDs (previously they were limited to 5 yrs post-PhD). All AFOSR applications must be submitted via grants.gov. Pre-award costs can be requested but human/animal use approvals must be obtained prior to funds being released. Annual and final reports go to gizmo (if not, they will be considered delinquent). Timely billing is important for everyone as spending rate determines the future availability of AFOSR dollars that will be allocated.

ONR: Debbie Rafi has been promoted to the Director position. The ONR biennial Technology Expo will be July 20-21 (June 1 submission deadline for presentations). Go to navalengineers.org. ONR interim RPPRs are due June 15.

NSF (Jean Feldman): The annual PAPPG update was opened for public comment in spring 2017, will be released in October 2017 and effective January 2018. Changes are highlighted in yellow. NSF is planning a complete move to Alexandria this coming August through October. The data center will be moving July 1-4. All systems will be offline during that time and deadlines will be impacted. Be sure to check with NSF for changed deadlines. Proposal submission modernization: To reduce administrative burden, NSF will take advantage of grants.gov capabilities (instead of fastlane). They are targeting a live demo for the next FDP meeting.

NIH: Legislation has passed to fund NIH through fall for \$34.7 B exclusive of Cures Act (about \$3B higher than FY16 budget). Salary caps for Executive II level were increased from \$185,000 to \$187,000. Grants can be rebudgeted to accommodate this. The 21st Century Cures Act contained several mandates for reducing administrative burden and streamlining processes including sub-recipient monitoring, FCOI, financial expenditure reporting, documentation of personnel expenses, animal care and use in research, and establishment of a Research Policy Board. These are being implemented. As of March 2, prior approval requests for no-cost extensions and changes in PD/PI can now be done in eRA commons. NRSA Postdoc stipends: can request supplemental funds to honor these increases in stipends for postdocs with 0-2 years of experience. Note that these requests must be submitted by June 30, 2017. Reporting preprints and other interim research products: As of May

2017, NIH will now allow these to be cited in the biosketch and other sections. The purpose is to encourage dissemination and rigor of science.

Grants.gov: They are now implementing Workspace (similar to googledocs). It is a shared online environment to work collaboratively to complete and submit applications. Advantages include the ability to work on an application concurrently, can re-use and copy prior Workspace forms, it will give you immediate notice of any errors, and the complete application form is done using online webforms. The previous Legacy pdf application will be retired on December 31, 2017 (no longer downloadable). You can still continue to submit them until March 31, 2018 if they have already been downloaded. As of Jun 2017, Workspace owners can allow applicants from other institutions to be added; they can allow those access to some but not all forms if they wish (e.g. budgets can stay locked to keep salaries confidential). There will also be a Workspace progress bar added. As of October 2017, more enhancements will be made, particularly the ability to preview attachments (pdf form). The registration process is being streamlined. There will be tutorials available through the website.

USDA: ezFedGrants is being implemented, the goal is to have all of their agencies/programs using this system by 2022. It interfaces with Treasury's ASAP and grants.gov. USDA includes 17 grant-making agencies with 253 CFDA programs, budget about \$125B. (e.g. AMS, APHIS, NIFA, NRCS, FAS, FNS, OAO).

FDP Pilot updates:

IRB Wizard pilot: This study has been 3 years in the making. The purpose was to demonstrate whether an automated system can be used for reviewing minimal risk human research by comparing outcomes to see if they are the same as institutional IRB decisions. They needed to develop language acceptable to regulatory agencies, be sufficient for IRB to track, ways to bump back if not research friendly etc. The first results have now been analyzed based on 542 cases from 10 institutions. Results are good, showing 40% with perfect agreement between the Wizard and IRB determination that studies are exempt. Another 30% were referred back to the IRB. About 20% had definition issues for the use of the terms "research" and "human subject", which are not always clear-cut, so these need to be ironed out. Also problematic are the small number of cases where the Wizard indicated exempt status but IRB ruled not exempt (about 5% of cases. (there were another 5% with opposite outcomes). This may be due to expected disagreement that might be found between different IRB panels, but the causes of disagreement will be evaluated in more detail in the coming months.

Expanded Clearinghouse subrecipient monitoring pilot: 127 profiles have been uploaded in 2 cohorts (F&A rates, audits, etc.). The pilot found that 6,784 admin hours were saved by using the profile. The pilot has just gone live with the profile system. They are now starting cohort 3 and encouraging all the rest of the FDP institutions to join: Fdpclearinghouse.org. The next cohort will go live in July.

Faculty/Administrative Partnerships for Successful Research Operations: The purpose of the session was to open an ongoing dialog between faculty and administrators regarding efforts to eliminate administrative burden within their own institutions, and to develop "home-grown" solutions. Representative faculty/administrator teams served as the panel from a large-size university (University of Washington), mid-size (Michigan Tech University), and small (College of Charleston) for examples and comparisons in organization and workflow. University of Washington gets \$1.3 B sponsored research (5052 grants), has 44,000 students and a medical center. They have a Faculty Council on Research and a Research Advisory Board in place. There is a Pre-award office and a Post-award office, as well as others (animal welfare, tech transfer, environmental safety, etc.). All departments have their own sponsored programs administrative staff too. Michigan Tech has 402 faculty (most are non-tenure track), gets \$51.M awards, about 7200 students. They are STEM intensive with a charge to be industry responsive. They describe more personal interactions with their sponsored programs administrators, knowing them on a name basis and often interacting with them as neighbors outside of the workplace. The College of Charleston also does not typically have departmental administrators. They have a split organizational structure between Academic affairs and Business Affairs. They hold PI Briefings when new grants are awarded, discussing the roles, responsibilities, etc. They report good working relationships. It is a public institution with 111 grants, most <\$1M, about \$6.3 M federal, \$3.9M non-federal. There are 11,000 students, most are undergraduate, some masters, no PhD students. There are no faculty research committees or research advisory councils and faculty have heavy courseloads. They made the point that they hear from their administrators: "How can I help you"

rather than “No you can’t do that”. This may be in contrast to large universities who have so many grants that its staff has to specialize, resulting in faculty feeling like they are on an assembly line. Also, this can result in special circumstances that no one is equipped to handle, and some of these challenges need to involve 3-4 different offices and difficulties guiding faculty to the right people/offices to go for special questions or circumstances. There is often misunderstanding or misimpression of each other’s goals – with administrators complaining that faculty have no understanding of the grant process and faculty complaining that administrators don’t understand why faculty want to write grants! Should it be as a concierge service or partnership? These topics and joint conversations will continue in the next FDP meetings. Slides from this interesting panel session can be viewed here: http://sites.nationalacademies.org/cs/groups/pgasite/documents/webpage/pga_179249.pdf.

“How FASEB is Working on Funding, Regulatory, and Policy Issues” A forum on perspectives on research from FASEB was presented by Jennifer Zeitzer, Director of Legislative Relations, FASEB. Link to slides: http://sites.nationalacademies.org/cs/groups/pgasite/documents/webpage/pga_179213.pdf

With the new administration, key science positions are still open (OSTP, Presidential Science Advisor). Neomi Rao (Professor, Scalia School of Law, former Associate Councilor with Bush administration) has been nominated in April to head OIRA. The current landscape has created tension between Congress and Administration over policy (but noted that this is nothing new!): over ACA repeal and replace, entitlement reform, “Costs” of tax reform (deficit neutral), foreign policy, immigration, and spending; recognizing the separation of powers (role of the judiciary, passing legislation vs governing by executive order); focus on limiting size/scope of government (hiring freeze imposed in Jan, relaxed somewhat in April by OMB memo to agencies to overhaul operations, improve efficiency, and cut costs).

FY2016 for NIH budget was increased about \$2B from Congress, funding more research grants, and increased another \$2B for FY2017. NSF saw a very small increase, most of it earmarked. Budget issues coming in September: Debt ceiling – the Federal debt limit was reached in March 2017, so Congress will have to reach an agreement on borrowing to prevent default on US debt obligations by fall. Fiscal conservatives may demand spending cuts as condition on agreeing to increase the debt ceiling.

The FY2018 budget is “a whole bunch of worries”. On March 16, a 60 page document was released that included a recommended \$5.6 B (18%) cut for NIH, eliminated Fogarty, and proposed reorganization of NIH (silent on NSF). It also recommended \$900 M cut to DOE, flat on agriculture research. More details of the President’s budget were expected May 22-23. Fights over spending priorities are expected, e.g. on spending for a wall on our southern border (delayed from 2017, expected in 2018 budget), funding for major infrastructure improvements, tax reforms/cuts, immigration enforcement/sanctuary cities. The outlook for 2018 suggests there will be a return of fiscal austerity: overall spending cap is \$6 B below 2017, sequestration will be “turned back on” (without even considering additional expenses of the wall and infrastructure financing), changing the cap will require a bipartisan agreement. In addition, there is pressure to increase defense spending – a priority for President Trump with growing support in Congress, and there is no commitment to equal increases for defense/non-defense programs as in the previous administration. Further, the appropriations process is behind schedule – delays in releasing the President’s budget until the full document comes out, so a continuing resolution in September would not be a surprise to anyone and there will probably not get to a budget agreement by Oct. 1. A continuing resolution could be the story for a year, but the budget would still need to stay within the cap, so there would still be some cuts in the NIH budget.

Re regulatory burden from the administration perspective: A January 20 memo issued a regulatory freeze allowing no new regulations can be sent to OFR without agency approval and pending regulations not published in the Federal Register must be withdrawn. Also issued a 1-for-2 executive order on January 30: for every new agency regulation released, 2 must be repealed. New regulations must have an incremental cost of zero. The use of the Congressional Review Act (CRA) allows Congress to repeal regulations with a simple majority (for regulations issued within 60 days of the previous administration). Agencies cannot re-issue repealed regulations. Using this, 13 rules are already eliminated as of May 5 (mostly EPA). The House CRA window has closed, Senate window will close this week. What happens post-CRA? The Administration can re-write regulations it does not like – but it is more time-consuming, and subject to court challenges. However, a pending regulatory reform bill, the Midnight Rules Relief Act (HR21) passed January 4 by a vote of 238-184, expands the CRA to allow multiple

regulations issued in the final year of an Administration to be repealed in a single vote. There is some good news re 21st Century Cures bill, which showed strong NIH support, is already in the implementation phase, which requires the HHS Secretary to reduce some regulatory burdens on research and create a Research Policy Board to address these issues.

FASEB recommends that the research community vigorously and collectively oppose the addition of unnecessary or duplicative regulations. Why engage in policy? Science impacts policy and policy impacts science; you are the best and sometimes only advocate for your interests, and members of Congress want to hear from their constituents. There is a strong bipartisan support in Congress for the research agencies: 206 House members signed a letter in March requesting \$36B for NIH in FY2018; 162 signed a letter requesting \$8B for NSF in 2018. Many members of Congress are not aware of how Federal research funding benefits their district/state, and voters are having a greater impact on members of Congress (e.g. town hall meetings). Make your research relatable, connect with your elected officials on social media, attend town hall meetings, invite them to visit your lab if possible, be sure to document visits with elected officials, in newsletters and social media (include photos). Submit letters and op-eds to your local paper with catchy headlines like “NIH cuts threaten local research” or “Bioscience research needs Federal help”. FASEB has online resources: e.g. how to be an advocate, medical breakthroughs, district by district breakdown of funding.

“Changing Demographics of the Scientific Workplace” Michael Lauer (Deputy Director for Extramural Research, NIH). [Link to slides:](http://sites.nationalacademies.org/cs/groups/pgasite/documents/webpage/pga_179214.pdf)

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A recent special issue in Nature (2016), “Young, talented, and FED-UP” addressed the extraordinary pressures on young scientists to publish, get funding, and obtain a permanent position, leaving little time to do actual research. Young scientists were asked what are their concerns: 1) Desperate pursuit of grants, 2) no time for science, 3) extreme competition...to cut corners, 4) dependence on senior scientists, 5) administrative overload...no help, 6) long hours. The fight for funding was considered the biggest challenge (44% respondents), with work-life balance being second (19%). Young researchers are having to fight harder than past generations for a smaller share of the academic pie. There has been a continuous aging workforce over time. The increase in grants to the 31-55 age group was steady until about 10 years ago and then flattened while the over 55 group has steadily increased (although overall numbers are lower than other brackets). In contrast, funding has been flat for the younger group (it used to be the highest funded group in 1980). Although NIH managed to even out its success rate by giving first time applicants a boost, the average age to obtain a first major grant has been 42 since 2000 (compared with 35 in 1980). Thus, biomedical scientists are essentially apprentices until middle age. And the tendency is to give grants to scientists who already have them, making it increasingly difficult to break into the system. Two core problems have been identified (NY Times Judith Kimball): 1) Too many researchers are vying for too few dollars; 2) Too many postdocs are competing for too few positions. Most other issues can be viewed as symptoms.

The AAAS Federal dashboard shows some interesting graphical data plotting NIH funding (inflation-adjusted) 1976-2016 steadily increasing culminating in doubling in 2003. Since then, the real funding (in equivalent dollars) has been decreasing (since 2003). Also, since 2003, there have been approximately the same number of awardees, but the number of applicants has increased from 60,000 to 90,000. A look at who is being funded by age distribution (Sally Rockey) showed that R01 grantees and medical school faculty age distribution graphs were about the same in 1980, but the age distribution of NIH grantees has gradually shifted rightward throughout the 90s and 2000s and there is now a gap in the younger medical school faculty and the % of R01s obtained by them. A PLoS One article (Marc Charotte) suggest, when successful getting their first R01, there is difficulty in getting it renewed despite good work, thus there is a reduction in awards to mid-career scientists. There seem to be 3 types of “players”: 1) no grants, 2) two or more grants, 3) only one grant. Those with more than one grant have a survival advantage since they won’t have to close the lab if one of the grants fails to renew. But players with only one grant and fail to renew may be forced out of the “game”; repeated cycles of this select out the mid-career scientists. The decline % funding for early career scientists has leveled out since the implementation of young investigator programs (2002), but the mid-career demographic has declined since then. In contrast, the % funding for early late (61-70) and late (over 70) career researchers has increased. The age distribution of scientists in the

workforce is higher than that in the general population (PNAS, Blau, Weinberg). There has been a decline in the retirement rate of older scientists since the end of mandatory retirement; this will increase as the baby boom cohort is aging, continuing to squeeze out the mid-career scientists.

With regard to the second identified problem (too many postdocs), the F and T grant numbers have remained about the same, but there has been a dramatic increase in the postdoc support from research grants, leading to a big increase in the number of postdocs. There is a “postdoc penalty” – although postdocs are necessary for entry into tenure-track jobs, they do not increase earnings (over time) more than those in other job sectors who have not had post-doc training (Nature Biotechnology 2017, Kahn and Ginther). There is also a diversity gap from trainee levels up the tenured career ladder, with women and underrepresented minorities, who are high in training, being well underrepresented later as tenured associate and full professors (in contrast to white men who are well represented in tenured ranks).

For efficiency of science, maybe it makes sense to promote early or later career scientists? Some scientists do their highest impact work early in their careers. However, a study evaluating scientists’ sequence of publications showed that impact is random within this sequence and highest impact papers can come early or late. Also, there was no ramp up or ramp down (before or after the highest impact work).

10% of scientists receive 40% of the money, but there are diminishing marginal returns (data from comparing publication impact vs number of grant equivalents; Mongeon et al., 2016): 1 grant substantially increases productivity, some further increase with two, but 3 or more only incrementally increase productivity. A risk is that scientists with one grant or less (which are 2/3 of the biomedical scientists), they are 1-2 years away from losing all of their funding.

NIH wants to fund more scientists and more diverse scientists, as this will increase research productivity. Also, the increased spread of funding will increase serendipity – the likelihood that some may make great discoveries. The Cures Act addresses investing in the next generation of scientists, by increasing opportunities for new researchers to be funded, enhancing training and mentorship programs, and enhancing workforce diversity.

NIH is looking into limiting grant dollars/number of grants given to individual laboratories, to enable more people actively engaged in research, which might increase productivity overall. Francis Collins worries that the current system may delay progression of early career scientists, and NIH is discussing curbing lab size to fund more mid-career scientists. In an NIH Extramural Nexus blog released May 2, Mike Lauer wrote on “Implementing limits on grant support to strengthen the biomedical workforce”. The worry is that, if well-trained early-mid career scientists do not get funds now, we will lose them to other careers. Then, 20 years down the road, they will be doing something else, and we face another problem with shortages of scientists.

Re post-doc problem, they are currently viewed as cheap labor on grants and there are too many of them on grants instead of NRSAs. The solution is to increase the post-doc salary to the level of staff scientists; this will decrease demand for them and increase staff scientists (which are more stable jobs and don’t have to be re-trained every 3 years). Also, currently NRSAs are only for US citizens, while about 60% of post-docs are non-US. Some of them stay here (less doing that now due to difficulty getting funding).

The R35 model may be worthwhile looking into more – the number of grants would go down, everyone would get one, also peer review burden would go down. These can be based on the researcher rather than the project. It may increase productivity as researchers can take more risk and spend less time writing grants.

Research Pipeline Working Group: There are Title IX rules for federal employees – Michelle Obama initiated efforts to get similar work-life balance in academic settings. It is getting increasingly difficult to navigate academic careers, with pressures of shrinking resources, increasing burdens, increasing pressure to get funding, relatively long apprenticeships to gain full tenure, and balancing this with family constraints. FDP’s involvement in this will result in a Policy, Practice, and Resource Guide prepared by the Faculty Pipeline Working Group. The document will serve as a guide and a resource (not advocating policies). The first part will be an overview of the problems (and Title IX connection to this) for academic professionals. It will be inclusive with examples of practices at various institutions to inform and provide tools to institutions to make choices on the range of possibilities. Some examples in the draft report are wellness benefits, paid family leave, pre-tax for child care and

illness, elder care, back-up child care, emergency loans, SEPTA, tuition benefits, etc. Links to successful programs will also be provided. NSF has posted good toolkits and cited good programs (e.g. Univ. Florida). Cheryl Kitt mentioned that the Office of Civil Rights from HHS plans to do random compliance reviews for Title IX compliance for NIH funded institutions (per a 2015 memo).

Single IRB (sIRB): The implementation date has been extended to September 25, 2017, effective for applications submitted on or after this date. Direct charges for administrative salaries are allowed but certain conditions must be met. Recipient institutions are given the flexibility to develop their own fee structures for sIRB costs and would be considered a specialized service facility subject to certain requirements. Details of these costing issues and examples of expenses and FTEs were given in the presentation: http://sites.nationalacademies.org/cs/groups/pgasite/documents/webpage/pga_179339.pdf

Common Rule: The revised rule goes into effect in January of 2020. The purpose is better protection of human subjects and reduced administrative burden. Summary of key changes include: Definition of “human subject”, Definition of “research”. Informed consent, Exemptions, Expedited review, Continuing review, Single IRB review, and other changes that reduce burden and create flexibility. Any study started on or after January 19, 2018 must comply with the revised Common Rule. The requirement for single IRB review in multi-institutional studies goes into effect January 20, 2020. For details on key changes:

http://sites.nationalacademies.org/cs/groups/pgasite/documents/webpage/pga_179247.pdf

CUSP (Compliance Unit Standard Procedure): The goal in developing this site is to create a repository where an index of substances and procedures that are commonly used for animal care protocols can be included for use by the broader animal welfare compliance community. The University of Washington is doing this with success and would like to do an FDP demonstration project. The working group is currently in the process of formalizing their ideas on site design and function