FDP Meeting
September 5-7, 2018

The Federal Demonstration Partnership (FDP) is a cooperative initiative among federal agencies and 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 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.

Faculty Workload Survey: Data analysis is ongoing and will be reported out in modules. Module 1 is an overview of participation and participant characteristics. Overall, there was 72% (111 of 154) response rate from FDP institutions (this is lower than 2012 – 83%, 99 of 119). PIs invited: 56,869, got 11,167 participants (20%), a little lower than 2012 (24%), but this is considered respectable for this type of survey. The participant characteristics were remarkably similar to previously (age, gender, etc). The perceived research climate (e.g. how important is sponsored research) came in a little higher than in 2012 – if you had to do it over, would still choose an academic research career. But there were some changes – particularly the feeling that administrative responsibilities have increased. This may be discouraging my graduate students from pursuing a research academic career. Module 2, the total time taken away from research, is the one big number to take away from the preliminary data. In previous surveys (2005 and 2012), this was 42.5%. Has it changed? In the 2018 survey, there was a small but discernable difference – now up to 44.3%! Particulars – there was a small uptick in pre-award proposal prep, but the biggest uptick was in post-award report preparation. The median number of proposals submitted in the past year is 6. This number was surprisingly about the same whether or not an award was received.   The success rates looks promising but an issue with the survey parameters is that the non-funded people did not participate in the survey so missing that data (because the only info publicly available is for awardees, so there is no info available listing submitted but not funded applications). Workloads vary according to institution type. At very high research institutions (84% respondents were in this group) there was generally less time taken away from research and the workload increases as the level of research goes down. Of the 84%, the lowest burden was at private universities. Module 3 will address specific responsibilities: high priority need for change. The highest priority was IACUC/animal subjects with 40% of those people reporting a high priority need for change (lost time). Different this time was that clinical trials has jumped to the second slot. Data management has also bumped up. Module 4 will address agency specific data. For example, the DoD is complex and stands out on the pre-award side. Also animal care and use and human subjects stand out; these are separate agency requirements. On the post-award side, clinical trials monitoring is jumping to the top. COI is now one of the lower ones. Module 5 will include the open-ended feedback – there were over 1000 agency

related and 1000 institution related comments. We will be reviewing and compiling these. Module 6 will be Summary and Recommendations – We will work together as a committee to strengthen our actionable items, recommendations, and suggestions. Module 7 will be individual institutional data. There will be a call for interested institutions before the January meeting – these will cost about $500-$5000. The reports will include results of their researchers' experience as well as general comparisons to similar institutions.

Federal Agency updates:

NIH (Kristen Ta, Senior Advisor, Office of Policy for Extramural Research Administration): NIH is funded under the Consolidated Appropriations Act, 2018. NIH's FY 2018 budget amount is $37.3 billion which represents a $3 billion increase over FY 2017. Updates on NIH policy included: 1) Simplified acquisitions (to $250,000) and micro-purchase thresholds (to $10,000). 2) Common rule implementation has been delayed again (to January 21, 2019), and there are options of implementing some burden-related provisions during the delay period (see Human Subjects subcommittee below). There are also inclusion policy changes – expanded to include individuals of all ages. 3) RPPR changes – Institutional delegations for Interim and Final RPPRs now align with delegations for annual RPPRs. 4) Prospective basic science studies involving human participants (studies that meet both definition of clinical trials and basic science) – there will be new Funding Opportunities (FOA) for these. Also, there will be more leniency if incorrectly submitted (to clinical trial or non-clinical trial). 5) For clinical trial awards, the total amount is negotiated upfront. While there is a negotiated cost per unit, e.g. per patient cost in a clinical trial (or participant in a non-Clinical Trial Human Subjects Study) the total amount of the award may be unknown when the agreement is created. Agreement is based on a "fixed rate" as opposed to a "fixed amount" as defined by 45 CFR 75.201. 5) NIH is participating in a Pilot with ORCID ID to link PI publications and other aspects of a researcher's profile. This is being done as part of the response to the 2017 American Innovation and Competitiveness Act (AICA) which directed the Research Business Models (RBM) Working Group to review regulations and recommend ways to minimize burden. NIH will continue to participate in RBM as they highlight additional ways to reduce administrative burden across the Federal research enterprise.

NSF: (Samantha Hunter): The upcoming PAPPG has significant changes. It is released to the community in the Fall 2018 with a Jan 28, 2019 anticipated effective date. Significant changes include: 1) The use of research.gov for proposal submission. This will be updated online, so follow the on-screen instructions if processes change. 2) Expands use of Dear Colleague letters for RAPID, EAGER, RAISE, and conference proposals. 3) There is a new checkbox on the proposal coversheet for non-US campuses and foreign institutions. A justification why can't be done in US must be included. 4) Unaffiliated individuals (e.g. postdocs) are not eligible to receive funding from NSF unless specifically authorized. 5) NSF will not tolerate research misconduct (not just in funded proposals, but proposals in general). 6) Biosketches will be allowed to include 5 examples of synergistic activities only, not 5 categories with 5 examples The language is made clearer. 7) Speaker vs Participant distinction is clarified to consider the primary role at conferences. 8) RAPID, EAGER, RAISE are not eligible for reconsideration. 9) NSF has some programs moved to rolling deadlines (e.g. Geosciences) but some programs may an ineligibility period for specified times following a declined proposal. 9) Several changes are in the guideline to address harassment. More info: policy@nsf.gov

USAMRAA (Jennifer Cramer): This is a customer-based organization. The workload has remained consistent at about $2 B every year. The biggest customer is CDMRP, started in 1992 with breast cancer research, it now includes 30 research programs. Congress specifies the focus area; the CDMRP determines research strategy and competitively selects the best projects. Is uses a unique public/private partnership encompasses the military, scientists, disease survivors, consumers, and policy makers. CDMRP funds high-impact, innovative medical research to find cures, reduce the incidence of disease and injury, improve survival, and enhance the quality of life for those affected. All contracts are on FedBizOpps and Grants.gov. The Broad Agency Announcement BAA for extramural medical research Includes USAMRMC Areas of Interest (Broad Topics) it is open and continues for 5 years, updated annually as needed. SBIRs and STTRs are by contract only. Changing the internet site was a major undertaking. It now provides more informative for research community and is a user friendly process: www.usamraa.army.mil For multi-year funded grants most are funded at one time, although some are incremental. Most are 1-4 years. If a no-cost extension is needed, it must be requested on time, and burn rate must be monitored to prevent a loss in funding. There are some changes in terms and conditions, including payments which can now be made in advance instead of going through cost reimbursement.

ONR: (Wade) There is a new funding approach for ONR grants: A May 2018 memo encourages funding research grants with initial increments for 24 months and annually thereafter or, if it is a new PI without a proven track record, for 12 months and then subsequent 24 months (rather than traditional incremental approach). The intent is to ensure ONR projects can attract and retain the best and brightest with a more reliable funding stream. It may also limit no-fund extensions, and will be less tolerant with having a year's funding left at 3 months before expiration. This is a departure from the usual DoD approach; we are in a technology race with China, so it is key to get it done in timely fashion! (more about this in the plenary session below). Other updates have been made to terms and conditions for grants and cooperative agreements including increased micropurchase threshold, clarifications on reporting patent disclosures, added language about recombinant DNA outside the US, and giving credit to DoD on publications and copyrights.

NIFA (Maribel Miller, Director, Policy and Oversight Division): There were 5 areas of updates. 1) NIFA relocation, will be outside of DC; there is a request for potential sites. 2) The 2018 policy guide will be published this fall. It has improved navigability with hyperlinks. Key changes are updated regulatory changes, enhanced roles and responsibility sections, post-award section (Uniform Guidance sections). 3) There have still been problems with the timely submission of annual and final reports, so administrative actions will be taken affecting future funding. Actions will be taken at institutional level, not the PI level. 4) Capacity award budgets will be required for 2020 applications, and justifications will be required for major categories of expenditures (aggregate level). There are webinars available and comments can be made through Dec 15 2018. 5) Several compliance reviews have been scheduled at various universities to make sure funds being expended for their purpose. These are not publicly released.

Plenary: Renewing NSF and the FDP Partnership – Dr. France A. Cordova, Director, NSF. NSF's 10 Big Ideas include 6 big research ideas and 4 big process ideas. NSF is now investing in these (funding started). The 6 big research ideas are uniquely suited to NSF capabilities. Harnessing Data for 21st Century Science and Engineering; The Future of Work at the Human-Technology Frontier; Navigating the New Arctic; The Quantum Leap: Leading the Next

Quantum Revolution; Understanding the Rules of Life: Predicting Phenotype; Windows on the Universe: The Era of Multimessenger Astrophysics; Growing Convergence Research at NSF; NSF 2026: Seeding Innovation; NSF INCLUDES: Enhancing STEM through Diversity and Inclusion; Mid-scale Research Infrastructure. The big research ideas address where should the country go that will make a real impact. Two of these have become priorities of the current administration: Next quantum revolution and the Future of Work (artificial intelligence).
In big process ideas, growing convergence research will need new merit review processes and. NSF INCLUDEA will bring more diverse talents. Mid-scale research infrastructure is intended to bridge the gap (between big projects and small projects) – there will be new opportunities. We are coming up to country's anniversary – in anticipation of this, NSF is encouraging participants over 14 years old to come up with big ideas with 2026 in it.

NSF is in a renewal phase, with focus on 4 main areas: 1) making information technology work better for us, 2) adapting NSF's work and workforce, 3) streamlining, standardizing and simplifying programs and process, 4) expanding and deepening public and private partnerships. NSF has had a long relationship with FDP. They would like to build on FDP-NSF relationship as NSF is in renewal phase. E.g. getting FDP feedback/input on some of NSF pilots and new programs and changes.

Human subjects subcommittee

Common Rule update: The Final Rule delays the general compliance date of the 2018 requirements for an additional 6-month period until January 21, 2019. The transition provision in the Final Rule is structured so that regulated entities cannot implement the revised Common Rule in its entirety, in lieu of compliance with the current version of the Common Rule, until the general compliance date noted above. As a result of this delay to the general compliance date, regulated entities will be required, with an exception, to continue to comply with the requirements of the pre-2018 version of the Common Rule until January 21, 2019. The exception to this general rule is that institutions will be permitted (but not required) to implement, for certain studies, three burden-reducing provisions of the 2018 requirements during the delay period (July 19, 2018 through January 20, 2019). The three provisions for burden reduction options are: 1) Implement the revised definition of "research," which deems certain activities not to be research covered by the Common Rule (scholarly and journalistic activities not deemed to be research), 2) When Continuing Review is not required, 3) Elimination of Institutional Review Board (IRB) congruency review (review of research applications and proposals).

IRB Wizard: The IRB Exempt Wizard is a proof of concept pilot that will allow investigators to enter information about the human subjects protocol into an online decision support system in order to determine if their protocol needs to be reviewed by a full IRB committee or if it exempt from such review. This is an ongoing demonstration project, a purpose of FDP. The highest reported burdens in the last faculty administrative burden survey were IRB and IACUC. Much of the burden is at the institutional and not the federal level, but.institutions have been afraid to change anything due to regulations. But the exempt category could be expedited which led to Wizard pilot. If successful, the Wizard can reduce burden for both faculty and administrators. There are currently 4-5 institutions participating in the updated demonstration project, with 3 more interested. Federal agencies have agreed not to audit participants in the wizard demonstration. The goal is to get up to 10,000 participants. There has been positive feedback from faculty, despite some concerns that participating in the Wizard demo will just add one more

thing to do while trying to reduce not increase burden and time, but so far it has turned out that faculty understand that the purposes is to collect research data. Many of them will get through it in a minute since the project will not be determined to be exempt. This finding is also counted in the data and useful for results of the demonstration. All you need to participate is the link given to investigators and ask that they not be reviewed first before doing the Wizard, to avoid influence of one on the other. Your IRB will get an email that the participant has gone through the Wizard. We are encouraged to put resistant IRBs in touch with Dr. Jane McCutcheon, NYU, who will do a live demo with them: Jam2@nyu.edu

Compliance Unit Standard Procedure (CUSP) sharing site: 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 CUSP project is in keeping with the 21st Century Cures Act as an acceptable method to reduce burden. Section 2034 of the 21st Century Cures Act addresses reducing administrative burden for researchers (part D) animals while maintaining protections for animals.   The working group is developing a demonstration project. Examples were given showing a New Procedure entry form (see http://thefdp.org/default/assets/File/Presentations/CUSP_Working_Group_September_2018.pdf) Changes to this have been made based on recommendations, e.g. if it is different from the parent procedure, explain how and why it's different. Another page will have a drop down to species type and subtypes etc. The information will upload it to share site. Drop-down menus may be added to refine searches based on procedure type (e.g. see what other Parkinsons models are being used), species, etc to narrow search results. There is discussion on encrypting institution names.

There was an RFI for the 21st Century Cures Act seeking information to improve the coordination of regulations and policies with respect to research with laboratory animals. Responses to RFI included some good suggestions which are now being reviewed. Also there is another comment period now that will end in December. It is important to note that CUSP is optional and not a mandate –concerns have emerged because it is supported by 3 Federal agencies so it looks like a mandate. There is also concern that this takes away from IACUCs, but this is unfounded and must be clarified.

Faculty-Administrator Collaboration Team (FACT): The FACT initiative is focused on leveraging the unique opportunity provided by the FDP membership and meetings, where Faculty and Administrators attend together. The purpose is to bring together Faculty and Administrators for dialogue and joint efforts to enhance collaboration for successful research operations. Thus far, 25 interviews have been conducted, including 8 researchers, 14 admins, and 3 with both, from 6 academic institutions. Generally, both faculty and admins seem to feel disconnected from institutional research priorities, goals and strategies. Admins feel it is bottom up and comes from faculty. Faculty feel its top down and they don't have anything to do with it. Re policy and practices, both faculty and admins desire more training and feel there is insufficient internal institutional support. Admins learn from websites and documents and by looking it up; faculty learn from peers, only getting initial training as new faculty. Re measures of success, funding dollars are perceived as the primary measure by admins, while faculty responding that they either had no idea or only the dollars coming in seemed to matter. Faculty responses included feeling that they had no role in setting institutional priorities but would like to participate in that. Pre-award development and submission is a primary area of collaboration, and admins are eager to support faculty and contribute to their success. Re post-award

management, faculty were really less focused on this than admins. Here, the faculty job is perceived as doing the project and not to be managing institutional requirements, other than occasional signatures, so they need more help from the adminstrators. Admins say they do it all. With regard to overall quality of collaborations, findings ranged overall excellent to poor. Faculty say this type of collaboration is a low institutional priority, there is much administrator turnover, problems emerge when it gets to higher levels, and there is a cookie-cutter approach with any special circumstances not handled well.

Results of this pilot study will also be done quantitatively to standardize and generate benchmarks. This involves choosing data elements that describe an organization from a purely numbers and figures perspective, collecting information about organization structure around faculty and administrator collaboration, collecting information on how institutions are staffed and provide support for all stages of the proposal life cycle, and assessing differences and evaluating advantages and disadvantages amongst the various institutional models. As an example thus far, it was found across institutions of different sizes that they get around same percent that are actively submitting (75%), so this could be a benchmark. Other measures like # PIs per FTP (different across institutions) may affect faculty burden felt. These evaluations are ongoing.

Plenary: Partnering to win the Great Power Competition, Rear Admiral David Hahn, ONR:. Recent efforts undertaken by the Naval Research Enterprise (NRE) in support of the 2018 National Defense Strategy were discussed.   It was argued that we have to posture ourselves to be able to win this great power competition – historically when we don't, there are serious negative consequences. 70% of the globe covered is with water, 80% live within 200 miles of coast, and 90% trade is done over water. We are blessed to be surrounded by waters and friendly border countries. We are a maritime nation; the need to maintain a Navy is in the Constitution. In the1900s we had 2 versions of a great power competition. ONR was born from first one. WWII resulted as we were unprepared for the great power competition; so in 1946, it was recognized that we can never let this happen again. A partnership between academic institutions, industry, and government is necessary to plan, foster, and encourage scientific research for preservation of national security. The next great power competition after WWII was the Cold War. The space race was born out of that – this is an example within that competition (US vs Soviet Union). This ending without loss of life, pain and suffering, the difference is that we were not willing to go to war. We were ready and this allowed us to be in a position to deter armed conflict. There was Federal movement of dollars into research. Also industry money was flowing into academic research. As then Secretary of the Navy James Forrestal said in 1947, "It is of the utmost importance to our national security that the Navy prosecute a vigorous and well-rounded program of research and development. To fail to do so in time of peace will surely result in this country entering another war with obsolete weapons and machines of warfare. And the tempo of modern war has reached the point where this Nation will probably never again have an opportunity to arm itself successfully after the start of hostilities…."

We are now in another competition – with China – economically, technically, militarily.   Do we watch or enter and win? It's our job to protect the blue part of the globe. In the China Sea, China is constructing islands, dumping sand, destroying reefs, installing military outposts etc. in direct competition with its neighbors. But global commerce flows through the China Sea. Technical disciplines including AI (robotics, swarming etc) is the next space race. 10 years from now, we'll have to deal with a new species – AI. Beijing wants to be world leader in AI by 2030. We

as a country will dominate AI and data, but to do so we need our human capital. Moving scientific discovery to the military frictionless (patents, peer-review etc necessary). This is truly a partnership, we must move forward to get the A+ team involved. Going forward, ONR will move from incremental to fully funded multi-year grants (3 years are ideal, but the Navy is limited to 2, so they will chunk 2 years and then quickly move to a +1 year). It has to get done by 3 years (not 4!) to get outcomes in that period of time. Another goal is reduction of administrative "burden". We are going in the wrong direction; reporting is necessary but administrative burden should only be about 2%, not 44% of researchers' time. Also researchers receiving navy research dollars must be identified, including managing the flow of human capital (e.g. students). It is policy that we do not exclude any students from anywhere.

Plenary: ClinicalTrials.gov, Rebecca Williams, National Library of Medicine, acting director of clinicaltrials.gov. There are currently over 280,000 studies on the site. About 18% are observational in nature, most are interventional, others are expanded access information. ClinicalTrials.gov was launched in 2000 in response to FDA Modernization Act. Later, it was found that nearly half of the clinical trial results were not being disseminated. It is important to remember the benefits of making results available publicly. We are telling people that their participation will help others even if it doesn't help them – if we are not disseminating the results, we are not fulfilling that promise. Journal policies are being updated to encourage reporting results even if not required by law. Registration and results reported are new NIH policy. Also must understand what your own funders and organizations policies are (e.g. VA). There has been some confusion around scope and even the phrase clinical trial. This is now being clarified, based on how you respond to basic data elements. General requirements: 1) register no later than 21 days after enrollment of first patient (journals require prior to first enrollment). 2) updated trial information at least yearly. 3) Submit summary results within one year after completion. There has been progress so far – 600 new registrations each week, 40% increase in results.   Congress is really interested in how there is compliance under the law and reports and actions to enforce compliance. To increase data sharing statements are now required at the outset.   More details on expectations and potential consequences: file:///D:/FDP/Sept%202018%20meeting/Presentations/Williams_FDP%20Meeting%207%20Sept%202018.pdf

Faculty Committee business meeting: We are thinking about goals and priorities for phase VII, before an RFA is released to invite others or to renew. Phase VII starts Sept 2020, the RFA will go out Feb 2020. There has already been a planning session with some FDP members at this summer retreat (not faculty only). There have been many changes in federal agencies, funding issues, changing demographics. Also as we have grown, their relative participation is getting smaller. Newer members don't know the history of FDP. We really need a similar conversation as a faculty to start a strategic planning process. To accomplish this, we will plan a retreat on the day before the May 2019 meeting. Some faculty concerns/questions arose: it seems like the federal agencies are mainly dictatorial and we just respond; maybe we can have a conversation with them or they can get feedback from us first before implementing new rules. They have heard from us over and over (3 surveys now) and haven't seemed to address those; a suggestion was to ask them to address the high level burdens like IACUC and IRB. The agencies seem to be focused mainly on the administrative side, but the program side may be more helpful for us. Another issue for FDP is why only 1/3 of the institutions are sending faculty. If we had our 150+ institutions each sending a faculty rep we would have a much stronger group. We need to

create programming and information that keeps us all interested. Or we could require institutions to send their faculty or be dropped.