

## **Federal Demonstration Partnership (FDP) Meeting January 8-10, 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](mailto:jsagen@miami.edu).

**Faculty Workload Survey:** The committee previously published a survey of more than 6000 Federally-funded faculty members at FDP institutions. Results of the survey showed that 42% of the faculty time available for research is spent on meeting administrative requirements rather than conducting active research. The results of this survey has been widely cited, resulting in legislative initiatives to reduce regulatory burden (notably in the new 21<sup>st</sup> Century Cures Act and American Innovation and Competitiveness Act). The committee is currently developing the next survey which will focus on priorities for change, identifying those burdens that needlessly reduce faculty time for research on federally funded projects (whether on the institutional or broader levels). Preparation of the draft survey will be circulated for comment by the May meeting. As an example, IACUC-related questions will address possible solutions to protocol preparation burdens (perhaps SOPs or umbrella protocols), annual reporting (required by local institutions but not OLAW or federal agencies), animal numbers calculations (estimate vs precise numbers).

**Research pipeline working group:** The group is addressing issues of work-life balance as it pertains to faculty burden, and as they impact individuals or groups of individuals who are in the student to professional pipeline in STEM fields. An "FAQ" document containing findings of Federal regulations and agency programs/opportunities will be reviewed by the committee and released as a reference resource. A later document illustrating some best practices used by FDP institutions to address work-life balance issues is in preparation.

**Recent legislative actions** have addressed reducing regulatory burden (in 21<sup>st</sup> Century Cures, AICA, and/or NDAA). For more details, go to congress.gov or see [http://sites.nationalacademies.org/cs/groups/pgasite/documents/webpage/pga\\_176624.pdf](http://sites.nationalacademies.org/cs/groups/pgasite/documents/webpage/pga_176624.pdf)

**21<sup>st</sup> Century Cures Act** (signed into law 12/13/16). The purpose is "To accelerate discovery, development, and delivery of 21<sup>st</sup> century cures". The Cures Act is about 400 pages, but one section is particularly relevant to the mission of FDP: "Reducing Administrative Burden for

Researchers”. Within this section are directives and initiatives to reduce burdens in several areas including: Conflict of interest disclosures and reporting, subrecipient monitoring, financial reporting, animal care and use in research, documentation of personnel expenses and establishment of a Research Policy Board to provide federal government officials with information on the effects of regulations related to federal research requirements.

American Innovation and Competitiveness Act: (AICA; signed into law 01/06/17). It aims: “To invest in innovation through research and development, and to improve the competitiveness of the United States”. In particular alignment with FDP is Title II, Administrative and regulatory burden reduction. Section 201 B6 cites the FDP faculty workload survey that 42% of researchers’ time is spent complying with federal regulations including administrative tasks, eroding research funds and reducing return on investment. The AICA directive will establish an Interagency Working Group to harmonize agency unique compliances and reduce administrative burdens on federally-funded researchers. It is a matter of critical importance to United States competitiveness that administrative costs of federally funded research be streamlined so that a higher proportion of federal funding is applied to direct research activities. There are unknowns about the future of the AICA, and what the new administration will do.

National Defense Authorization Act (signed into law 12/19/16): The aim is: “To authorize appropriations for fiscal year 2017 for military activities of the Department of Defense, for military construction, and for defense activities of the Department of Energy, to prescribe military personnel strengths for such fiscal year, and for other purposes”. One section, in alignment with FDP mission and vision affecting us is 217, which increases the micro-purchase threshold to \$10,000 (applies for all federal agencies, not just DoD).

### **New rules/agency updates:**

Human Subjects/IRB: 1) The single IRB (sIRB) is a new development for each site conducting the same protocol involving non-exempt human subjects research. Exceptions can be requested, but must be approved by NIH. Costing issues are being discussed (billing as direct vs. indirect costs to implement) and may result in both increased costs and burden. The implementation of sIRB has been pushed back to Sept 25, 2017 (NOT-OD-17-027). NIH update and resources: [http://sites.nationalacademies.org/cs/groups/pgasite/documents/webpage/pga\\_176619.pdf](http://sites.nationalacademies.org/cs/groups/pgasite/documents/webpage/pga_176619.pdf). 2) The Exempt Wizard demonstration is currently in data analysis phase and will be reported later this year. The IRB administrative burden was found to be 90% due to institutions rather than regulations. The demonstration compared determination of exempt status using current institutional review vs self-determination using a 15 min standard question form. It will need to be trackable so the information is available to IRBs and in compliance with regulations. The new regulations would accept a wizard for exempt protocols. 3) The U.S. Department of Health and Human Services (HHS) and fifteen other Federal Departments and Agencies have announced revisions to modernize, strengthen, and make more effective the Federal Policy for the Protection of Human Subjects that was originally promulgated as a Common Rule in 1991. This final rule is intended to better protect human subjects involved in research, while facilitating valuable research and reducing burden, delay, and ambiguity for investigators. These revisions are an effort to modernize, simplify, and enhance the current system of oversight. It is expected that the final rule will be published in the Federal Register on January 19, 2017 and can be

accessed at: <https://www.federalregister.gov/documents/2017/01/19/2017-01058/federal-policy-for-protection-of-human-subjects>.

NIH funded clinical trials: Recent studies showed that only 29% of completed clinical trials are published within 2 years of study completion, and even after 80 months, 40% are not published; academic medical centers get an “F” in sharing research results. This is problematic since negative findings are also important and will reduce further wasted resources. So there is going to be a new NIH rule that all funded clinical research must be reported within 1 year of completion. This will not need to be peer-reviewed and may be simple tables and charts, but it at least has to be posted on grants.gov. Penalties for not complying with this are severe: if one investigator doesn’t report, all pending NIH studies at the institution could be placed on hold and FDA may impose fines. All new NIH funded clinical trials will have to go through the new registration process with clinicaltrials.gov (as of 01/18/17). Journals will expect the study to be registered first on clinicaltrials.gov (within 21 days of the first subject) or deny publication.

Preclinical research: Dr. Mike Lauer, Deputy Director, NIH Extramural Program spoke on “How Do We Measure the Value and Output of Research? Thoughts from NIH”. In addition to the new mandate to report all federally funded clinical trial results, other topics of interest addressed included development of a new scoring system to capture productivity that would use a field-normalized citation ratio to account for differences in various fields, “diminishing returns” per dollar investment as the number and amounts of NIH funding for individual labs increase, and reproducibility issues in preclinical research (up to 50% of published preclinical work cannot be replicated). NIH wants a power analysis with endpoints and expected effect size, and a sample size calculation included in all journal methods sections. The presentation can be accessed here: [http://sites.nationalacademies.org/cs/groups/pgasite/documents/webpage/pga\\_176618.pdf](http://sites.nationalacademies.org/cs/groups/pgasite/documents/webpage/pga_176618.pdf)

Data stewardship/Data sharing: A 2013 OSTP memorandum “Increasing access to results of federally-funded scientific research” sought to insure that results of federally funded research is made available to the public to the extent possible, including peer-reviewed publications and digital scientific data. Goals include easy public search and access to scholarly publications, maximizing free access to digital data while protecting confidentiality and intellectual property rights, and assessing solutions for long-term preservation and public repositories. The NIH Public Access Plan (Feb. 2015) includes the requirements for submission of data management plan (DMPs) by all NIH-funded researchers, and that data sharing plans are considered during the peer review process. The 21<sup>st</sup> Century Cures Act Authorizes the NIH Director to require funding recipients to share data. Support for data management plans can be requested in application budgets. The use of publicly accessible online data repositories for archiving, preserving, and maintaining scientific data is being discussed. More info: [http://sites.nationalacademies.org/cs/groups/pgasite/documents/webpage/pga\\_176629.pdf](http://sites.nationalacademies.org/cs/groups/pgasite/documents/webpage/pga_176629.pdf)

Research performance and progress reports: Key changes in the implementation of final research performance and progress reports (F-RPPR) – the general format is the same as the interim annual RPPR, but it is now required to report on Project Outcomes. As of Jan. 1, 2017, this replaces the Final Progress Report for closeout. Annual progress reports must be submitted in RPPR format. The updated RPPR format was published in the Federal Register on November 16, 2016. The final version of the updated standardized RPPR format is to be used for both

interim and final reports, and an interim RPRR will be required while type 2 renewal applications are under consideration.

NSF: New PAPPG and significant changes can be reviewed at:

[http://sites.nationalacademies.org/cs/groups/pgasite/documents/webpage/pga\\_176631.pdf](http://sites.nationalacademies.org/cs/groups/pgasite/documents/webpage/pga_176631.pdf)

NSF announced 2 new proposal types: GOALI (Grant Opportunities for Academic Liaison with Industry) which seeks to stimulate academic-industry collaborations and RAISE (Research Advanced by Interdisciplinary Science and Engineering) to support bold, interdisciplinary projects <= \$1M for 5 years). The NSF INCLUDES Project is for enhancing science and engineering through diversity. The new solicitation is for a fully diversified STEM workforce.

Under consideration to reduce administrative burden are implementation of some pre-populated forms, simplifying budgets, phased submissions and just-in-time sections, and eliminating program deadlines. Note that Grants.gov-submitted proposals are not compliance-checked by the FastLane system and therefore do not undergo the same set of automated compliance checks at submission as those submitted directly via FastLane. If NSF receives a proposal via Grants.gov that is not compliant, it will be returned without review.

USAMRAA: updates at:

[http://sites.nationalacademies.org/cs/groups/pgasite/documents/webpage/pga\\_176626.pdf](http://sites.nationalacademies.org/cs/groups/pgasite/documents/webpage/pga_176626.pdf)

Changes and clarifications: There will no longer be “scheduled” advances except in unusual circumstances; recipient payment requests can be “advance” (must be justified and approved) or as cost “reimbursement” (preferred). Charges must be invoiced and paid within 5 years, so be cognizant of this for 4 and 5 year grants, especially when under no-cost extension. Funds must be disbursed by DoD by the expiration date of the award terms.

### **Other points of interest in pipeline – stay tuned!**

The Compliance Unit Standard Procedures (CUSP) sharing site: This is being developed by the University of Washington’s Office of Animal Welfare in response to their investigators’ wish list for reducing time and effort needed to prepare and review animal protocols. Their goal is to create a repository where participating institutions can share standard substances and procedures to be used in animal care protocols. This could reduce administrative burden for both researchers and IACUCs, standardize common procedures, and increase knowledge dissemination. The vision is to create an electronic site that will be searchable and sortable (e.g. by species, substances, procedure type, etc.), and downloadable for protocol insertion or reference to an SOP code number. All entries would require review and approval by the institutional IACUC approval before posting. It will also be important to maintain updates as they are approved by the institutional IACUCs and required by OLAW at least every 3 years or as new regulations come out or guidelines change. NIH would support this development of SOPs with the caveat that changes are updated over time to remain in compliance (per Susan Silk, NIH). An FDP project may be developed, to include participation from FDP institutions. A copy of the presentation at:

[http://sites.nationalacademies.org/cs/groups/pgasite/documents/webpage/pga\\_176877.pdf](http://sites.nationalacademies.org/cs/groups/pgasite/documents/webpage/pga_176877.pdf)

Nurturing Discovery (Dr. Richard Buckius, Chief Operating Officer of NSF) plenary session: [http://sites.nationalacademies.org/cs/groups/pgasite/documents/webpage/pga\\_176616.pdf](http://sites.nationalacademies.org/cs/groups/pgasite/documents/webpage/pga_176616.pdf). NSF has a \$7.5 B budget, 94% of this goes to research and education. NSF does not do research or have laboratories unlike other agencies. It receives about 50,000 proposals per year and makes about 12,000 awards (20-25%). NSF funds every area of STEM except medical (NIH domain). Recent trends showed large increases in the number of proposals (up 70-80%), with funding rate flat. It is calculated that, in order to fund all of the best ones (with average score 4.2), approx. \$2 B additional is needed. Working collaboratively both internally and externally, NSF has developed a number of initiatives and bold ideas for the future. Advances related to these efforts, community input, and proposal and award processes were discussed. “Big Ideas” include both research ideas and process ideas, seizing new opportunities and identifying and closing gaps. Another problem is increased number of proposals which also increases burden of reviews –proposed solutions being considered are to require submitters to review as many applications as you submit or eliminating program deadlines.

Lab Safety: APLU safety report – there will be possible grant requirements regarding safety and also changes to journal policies. The DoD and others may move to asking for certifications due to an uptick in lab safety concerns.

SciEnCV: Agency adoption of this has been slow since there are concerns about the ability to update and change over the course of a proposal review. Currently it is just being used as a document producer and it is not clear how much better it is than creating a Word document. But the longer term goals are to have online updateable biosketches and to be utilizable by the agencies requiring different formats. The new AICA law requires standard profile development to reduce burden, so SciEnCV fits well with that initiative.