



July 14, 2017

Submitted via Email and Regulations.gov

Daniel Cohen
U.S. Department of Energy
Office of the General Counsel
1000 Independence Avenue SW
Washington, DC 20585

Re: Reducing Regulation and Controlling Regulatory Costs; 82 FR 24582

Dear Mr. Cohen,

The Association of American Universities (AAU) is an association of 60 U.S. and two Canadian preeminent research universities. The Association of Public and Land-grant Universities (APLU) is an organization of 235 public research universities, land-grant institutions, state university systems, and affiliated organizations. The Council on Governmental Relations (COGR) is an association of over 190 research universities and affiliated academic medical centers and research institutes. On behalf of our member institutions we appreciate the opportunity to comment on Department of Energy regulations, paperwork requirements and other regulatory obligations as part of the agency's implementation of Executive Order 13771, "Reducing Regulation and Controlling Regulatory Costs." The following are areas that our member institutions have highlighted for reform with respect to DOE-sponsored research in response to this notice and in previous communications.

Standardization: Budget and Budget Justification Requirements

The DOE budget justifications and mandatory budget templates for grants and contracts are more onerous than those from other federal sponsors and vary with each national lab. As an example, the National Nuclear Security Administration (NNSA) requires a separate form for each: travel; supplies; equipment; and per year form and a budget justification. Further, there is not a standard DOE budget justification. It varies with every lab/sub-agency.

Recommendation: Simplify and standardize budget documents.

Standardization: Solicitations and Other Requirements Across Labs and Subagencies

Each DOE lab/subagency has slightly different processes, submission forms, and contracts, and they do not follow Federal Demonstration Partnership (FDP) guidelines and processes. Varied submission processes may also lack features that are standard with other federal sponsors, such as access by multiple university administrators and print options. For example, the Nuclear Energy University Program (NEUP) can require anywhere from 15 to 70 attachments per submission and only *one* university administrator is allowed to access the proposal. This coupled with the lack of a 'print proposal' option (as there is for the National Science Foundation's (NSF) Fastlane) creates a large administrative burden, since the document must be printed for internal review. The proposal can be anywhere from 50 to 700 pages. NEUP also requires forms at the

proposal stage that other sponsors require at award (reps/certs in advance of award) and requires multiple forms on top of the solicitation form. Each person on the project requires 15 separate documents.

DOE solicitations tend to be long, with unclear language and poor support for questions about the solicitation. As an example, FedConnect, which provides assistance for DOE solicitation questions, typically cuts and pastes sections from the solicitation in response to questions.

Recommendations:

- Use the NSF as a model to create a standard template for solicitations with minor variations.
- Consider using an available federal submission system such as Fastlane.
- Provide shorter, clearer solicitations.
- Provide specific answers to questions and posted FAQs.
- Become an active member of the [Federal Demonstration Partnership](#) and use FDP templates.

Closeouts

Closeouts are subject to standard audit: patent certification, property form, and SF-425. After standard audit, it then moves through a series of additional audits with no discernible order or checklist, including Finance, Property, and Disposition. A research administrator at one major research university has spent two years trying to close out an outstanding invoice. During that time, this individual has provided duplicate information on a number of occasions for new sets of auditors, and was told that there were 10 departments that handle closeouts so it was difficult to know the status of the audit.

Recommendation: Use a standard checklist for audits and develop a system that allows transparency for auditees.

Indemnification Language

Some state universities are prohibited by law or regulation from indemnifying third parties or providing indemnification for the actions of others. In order to avoid the need to address this issue with each award, it would be helpful if DOE could modify their indemnification language to preface the requirement with, 'unless prohibited by applicable State or local laws and regulations'.

Recommendation: Modify indemnification language to include, 'unless prohibited by applicable State or local laws and regulations'.

Clauses Inappropriate for Fundamental Research

A growing number of DOE solicitations include restrictions on publication and foreign national participation, even when the solicitation states that the work is fundamental research. However, restrictions such as these contradict the concept of fundamental research. By definition, “fundamental research” means that the results of the research are open with no restrictions on access or on who can perform the work.

As defined under the U.S. Department of State, International Traffic in Arms Regulations (ITAR), 22 C.F.R. § 120.11(8), Fundamental Research is defined to mean:

“Basic and applied research in science and engineering where the resulting information is ordinarily published and shared broadly within the scientific community, as distinguished from research the results of which are restricted for proprietary reasons or specific U.S. Government access and dissemination controls. University research will not be considered fundamental research if:

“(i) The University or its researchers accept other restrictions on publication of scientific and technical information resulting from the project or activity, or

“(ii) The research is funded by the U.S. Government and specific access and dissemination controls protecting information resulting from the research are applicable” (emphasis added).

And under the U.S. Department of Commerce, Export Administration Regulations (EAR), 15 C.F.R. § 734.8(c), Fundamental Research means:

“Research in science, engineering, or mathematics, the results of which ordinarily are published and shared broadly within the research community, and for which the researchers have not accepted restrictions for proprietary or national security reasons” (emphasis added).

From the definitions above, it follows that prior approval of publications and/or foreign nationals would constitute a control on access to the research results (under the ITAR) or a restriction for national security reasons (under the EAR). In other words, these restrictions are antithetical to the definition of fundamental research.

Indeed, DOE has already recognized that University conducted fundamental research should not be subject to foreign national prior approval requirements. Section 3.c(3) of DOE Order 142.3a states:

Exemption. Portions of this Order relating to approval for foreign national access to DOE information do not apply to research conducted under grants and funding opportunities sponsored by the program offices that report to the Under Secretary for Science and Energy, performed at institutions of higher education, and for which results will be published for access by the general public. Performance of this research is not considered access to DOE sites, information, technologies, equipment, programs, or personnel for purposes of this Order. The work products of this research are not considered DOE information during the performance of the research and after completion of the research. However, the Order does apply to visits by any foreign nationals to DOE sites and any access to DOE information, equipment or personnel not exempted in this paragraph.

Recommendation: Restrictions/prior approvals of Publications and/or foreign nationals should not apply to basic fundamental research projects.

- Exclude restrictions and prior approval requirements of publications and foreign students/nationals in solicitations and agreements for basic fundamental research.
- Consider one template specifically tailored to support basic fundamental research to save time and effort negotiating contracts for such activity.

Human Subjects Research

DOE has adopted the Federal Policy for the Protection of Human Subjects (“Common Rule”) but has added additional requirements. These additional requirements increase regulatory burden without necessarily increasing participant protections. DOE should consider eliminating the following:

1. With respect to research involving intentional modification of the human environment, special review requirements and the letter from the IRB chair to the researcher indicating that the research has been approved in accordance with DOE expectations;
2. For research that involves Personally Identifiable Information (PII), [the DOE Checklist for Researchers Conducting Human Subjects Research that Utilizes Personally Identifiable Information](#), and IRB verification of compliance with those requirements in its review of the project in accordance with the [DOE IRB Template for Reviewing Human Subjects Research Protocols that Utilize Personally Identifiable Information](#);

3. Notifications to the DOE human subjects protection manager of significant adverse events, unanticipated problems or complaints about the research, study suspensions or terminations, or significant noncompliance;
4. The requirement for periodic self-assessments by DOE contractors with respect to compliance with DOE Human Subjects Protection Program requirements.

Recommendation: DOE should eliminate requirements that extend beyond those of the Federal Policy for the Protection of Human Subjects (Common Rule).

User Agreements

While DOE has simplified the User Agreement by standardization, the agreement is still a long, wordy document which requires legal review by the institution. We understand that other agencies may have shorter, simpler User Agreements.

Recommendation: We encourage DOE to consider other agency user agreements as a model for its standard agreement. The purpose of the DOE user program is to have rapid access to DOE's unique facilities. A simpler agreement would better accomplish this purpose.

Reporting

□ here is a significant lack of consistency in reporting requirements across offices within DOE. Reporting frequency (quarterly vs. annual) and submission (web based vs. emailed) varies and individual award documents are not specific about the requirements.

Recommendation: We encourage DOE to implement consistent reporting requirements across offices and to make requirements clear in award documents.

Invoicing

ARPA-E (**Advanced Research Projects Agency-Energy**) terms and conditions include onerous expenditure tracking and supporting documentation requirements. Examples include:

- Required use of a multi-tab Excel workbook called a Budget Justification Workbook/SF-424A to detail expenditures incurred as well as cost sharing.
- Funds provided for Technology Training and Outreach need to be reported separately which results in having to track the related expenditures separately.
- Invoices and supporting documents are required to be submitted both via the invoicing system, VIPERS, and as an email attachment to the Contracting Officer.

Recommendation: Streamline ARPA-E invoicing requirements.

Draw Disruptions

In DOE's efforts to comply with the GONE Act, the agency has suspended some universities ability to draw on *all* awards when a closeout condition was not met on a particular award. This action, coupled with delays in reinstating universities ability to draw down funds, can result in universities accumulating millions of dollars in DOE expenditures before being reimbursed.

Recommendation: Suspension of recipient's ability to draw on awards should be award-specific. The ability to draw on awards should be quickly reinstated once close-out conditions are met.

Subaward Agreements

Using the FDP Research Subaward Agreement would eliminate the need for individual negotiations and could facilitate more timely conduct of projects. In the past, DOE has participated in FDP, and has therefore endorsed the use of this template as being fully compliant with federal requirements. Because over 100 institutional FDP members routinely accept this standard template, inter-university interactions have been greatly simplified. Universities would welcome the ability to use these agreements rather than to engage in the lengthy negotiations that often result from the required use of the DOE model agreements.

In addition to adopting widely used standard template agreements, when partnering with universities, we strongly encourage DOE to consider the core values and suggestions reflected in the document entitled "[In the Public Interest: Nine Points to Consider in Licensing University Technology](#)." Our associations have endorsed this document because it highlights effective practices for assuring the transfer and deployment of technology into the marketplace.

Recommendations:

- When collaborating with a university, it is highly recommended that DOE adopt the FDP Research Subaward Agreement.
- Consider the core values and suggestions reflected in the document entitled "In the Public Interest: Nine Points to Consider in Licensing University Technology."

Existing and Other Agreements

As a general comment, we appreciate the flexibility provided by DOE to modify terms of standard agreements for individual contract purposes. We also appreciate that DOE has changed the former Work for Others (WFO) agreements. They are now identified as Strategic Partnership Project agreements. However, this is a recent change, and we are unclear about the implications. Our understanding is that in practice the WFOs still are in widespread use. Member institutions have had concerns about the terms frequently used in WFO agreements. The comments below apply to the experience of our institutions with WFO agreements. Some of these concerns also have been discussed above.

General Comment. The ability to access the unique resources of the DOE laboratories is of great benefit to university researchers and to the general public as a whole. Where institutions desire access to DOE facilities and/or the expertise of DOE collaborators (often to perform work under a federal or nonfederal award), the DOE access policy allows avenues of inquiry that would not otherwise be available. However, the previous DOE mandate to utilize WFOs created an unnecessary diversion from universities' normal practice of issuing subawards for a collaborator's portion of the work. DOE has substantially improved the intellectual property (IP) terms by allowing universities to elect invention rights. However, in members' view, frequently this allowance comes with substantial strings attached, in the form of federal march-in rights and multiple indemnities, including indemnity for infringement.

1. Indemnification - We discussed the indemnification issue above. The indemnities in the current WFO agreements are numerous and are all one-way in favor of the laboratory. This is in sharp contrast to the common practice among academic institutions to expect that the entity performing the work will assume liability for activities arising from its performance. The DOE provisions are a serious disincentive and may prevent institutions, particularly public institutions, from participating in collaborative activities with DOE laboratories.
2. Patent Rights - DOE currently allows the university "sponsor" to retain title to an invention, but gives the government the right to take title if the institution elects not to, regardless of the source of funds. There may be instances where a university may not want to follow the lengthy and expensive process of filing a patent application, but would rather utilize the invention in other ways. Alternatively, the source of funds to the institution may mandate the handling of inventions otherwise. In such cases, the institution should not be forced to pay the costs of patent application or forfeit invention rights as a matter of course.

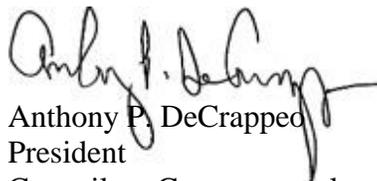
3. Advance Funding - WFOs and DOE policy have required the institution to pay the DOE facilities in advance. Generally, universities are not permitted to obtain advances from standard federal research grants. To accommodate this requirement, the institution must advance the payment using their own internal funds, causing delays in the work while it seeks to find internal funding sources. If an exception is made by the federal sponsor to pay an advance, the funds must be invested in an interest bearing account and the recipient of those advanced funds must account for any interest. However, DOE facilities generally were unwilling to assume this burden and refused to change the WFO to incorporate this requirement.
4. Government Rights - The reserved government rights are not required by statute and serve only to discourage industrial participation. DOE should consider removing the government use license, U.S. industry preference and march-in rights. Beyond being a disincentive for technology transfer to industry, they are rarely (or never) exercised, nor is DOE in a position to monitor compliance.
5. WFO IP Rights Disposition - Most institutions do not normally take title to inventions made by a subawardee under a federal award, but would reserve only those license rights required to meet the obligations to the prime sponsor. This approach is consistent with Bayh-Dole and has proven to be an effective partnering mechanism for technology transfer. When working with companies, the normal practice of research institutions is to retain title to their own inventions and to offer a first option to the partner company to negotiate a license. We think this practice also would work well for the DOE laboratories, and be consistent with responsible federal stewardship of inventions made by laboratory employees to assure public benefit.

AAU, APLU and COGR appreciate the opportunity to participate in the Department's efforts to reduce burden associated with DOE regulations and requirements. We are available to answer any questions and for further discussion on suggested reforms outlined in this letter.

Sincerely,



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Anthony P. DeCrappeo
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Relations



Peter McPherson
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