



SOCIETY OF  
RESEARCH  
ADMINISTRATORS  
INTERNATIONAL

# **Legal Update 2023: Key Research Grant Developments, From Regulatory Changes to Enforcement Priorities**

Mindy B. Pava

FELDESMAN TUCKER LEIFER FIDELL LLP

# PRESENTER: MINDY B. PAVA



## Contact Information:

[MPava@ftlf.com](mailto:MPava@ftlf.com)  
(202) 466-8960

- Ms. Pava serves as counsel in the firm's Litigation and Investigations, Federal Grants and Health Care and Education practice groups
- Mindy's practice focuses on helping federal grantees as they navigate all facets of agency and/or judicial review. She is a seasoned litigator who represents federal grant recipients, including research institutions, health centers, and Head Start programs, when dispute resolution needs arise.
- In addition to Mindy's work in federal and state courts, she represents organizations in responding to civil investigative demands and subpoenas. Mindy also advises clients on how to mitigate compliance risk through internal investigations.

# DISCLAIMER

---

Portions of these materials have been prepared by the attorneys of Feldesman Tucker Leifer Fidell LLP. **The opinions expressed in these materials are solely their views and not necessarily the views of Feldesman Tucker Leifer Fidell LLP.**

The materials are being issued with the understanding that the authors are not engaged in rendering legal or other professional services. **If legal assistance or other expert assistance is required, the services of a competent professional with knowledge of your specific circumstances should be sought.**

# COPYRIGHT NOTICE OF ORIGINAL MATERIALS

---

- These slides are being made available to you and your organization as a participant of an FTLF presentation. You are **ONLY** permitted to duplicate, reproduce and/or distribute these materials within your organization.
- Note: a membership organization may not consider its members to be “within the organization” for purposes of sharing materials.
- **These slides may not be otherwise photocopied, reproduced, duplicated, and/or distributed outside your organization and/or posted on a website without prior written permission from the authors.**
- Any other use or disclosure is a violation of federal copyright law and is punishable by the imposition of substantial fines.
- Copyright is claimed in all original material, including but not limited to these slides and other resources or handouts provided in connection to this training, exclusive of any materials from federal laws and regulations and any documents published by the federal government.

# AGENDA

---

1. Pending Changes to the Uniform Guidance
2. Changes to NSF's PAPPG
3. NIH Grants Policy Guidance – Research Records from Foreign Entity Subrecipients
4. Enforcement Discussion: 2023 Noteworthy Cases

---

# **1. Pending Changes to the Uniform Guidance**

# UNIFORM GUIDANCE, BACKGROUND

---

- The “Default” Rule applicable to federal grants, sub-grants, and cooperative agreements is the **Uniform Guidance – 2 CFR part 200** (updated 11/12/20).
- Each federal agency has adopted 2 C.F.R. Part 200 as its own with amendments specific to that agency in subsequent parts of Title 2, starting with 2 C.F.R. Part 300 (HHS) through 2 C.F.R. Part 5900 (Gulf Coast Restoration)
- HHS separately issued the UG in 45 C.F.R. Part 75:
  - As a result, the amendments to Part 200 from November 2020 have not been incorporated into Part 75
  - Expect HHS to: (i) adopt the revised Part 200 or (ii) keep Part 75 with a separate rulemaking to make changes

# CHANGE IS COMING

---

- Proposed revisions: OMB released a pre-publication draft of substantial pending changes to Part 200 on September 22, 2023.
- Publication: The official version of proposed changes will post to the Federal Register in the upcoming weeks, available in:
  - the Government Printing Office's FDsys website, <https://www.gpo.gov/fdsys/>
  - Regulations.gov, <https://www.regulations.gov/>
- Comments on the proposed changes will be due to OMB within 60 days after publication in the Federal Register. Thus, OMB will release a notice of final rule after comment period closes (expected by early 2024).



# POLICY CHANGES AND CLARIFICATIONS

---

- OMB listed four major goals of the proposed revisions:
  1. Incorporate statutory provisions and administrative priorities
  2. Reduce agency and recipient burden
  3. Clarify sections that recipients and agencies have interpreted differently
  4. Rewrite applicable sections to include plain language (*e.g.*, “recipient” and “subrecipient” rather than “non-federal entity”)

# OVERALL IMPACT ON RESEARCH INSTITUTIONS

- **Various thresholds have been increased** to provide added flexibility, which means fewer administrative obligations for grantees. Equipment used to have a threshold value of \$5,000 or less to be disposed of with no further responsibility to the awarding agency; that has been increased to \$10,000.
- Removing **prior written approval requirements** for ten items, including entertainment costs, memberships, taxes and participant support costs.
- Raising the **de minimis indirect cost rate** from 10 percent to 15 percent over Modified Total Direct Costs (MTDC).
- **Increasing the amount of subaward costs** that can be counted within the MTDC base from \$25,000 to \$50,000. (Takeaway: subawards can be counted in your base, up to \$50,000 per subaward).

# SUBAWARDS

---

- **Issue:** Revision clarifies a switch of subrecipients does not need prior approval, only need prior approval to subaward in the first place
- **Citation:** § 200.308(f)(6) [Subawards]
- **Takeaway:** Prior approval no longer required for change of intended subrecipient named in proposal, unless the agency requires prior approval in the NOA

# EXPANDED AUTHORITY IN RESEARCH GRANTS

---

- **Issue:** Explicitly adopts, consistent with typical agency practice, “expanded authorities” for research grants with respect to: **(i)** Pre-award costs, **(ii)** No-cost extensions and **(iii)** Unobligated balance carry forward
- **Citation:** § 200.308(h) [Research grants]
- **Takeaway:** Prior approval is waived for pre-award costs, no-cost extensions, and carry forward of unobligated balances for research grants irrespective of the granting agency

# ORGANIZATION COSTS: COLLECTIVE BARGAINING

---

- **Issue:** Adds a new provision rendering unallowable the organization's costs of promoting or opposing employees' right to organize and bargain collectively
- **Citation:** § 200.455(b), Organization costs
- **Takeaway:** Promoting or opposing collective bargaining is an unallowable cost

# NEXT STEPS

---

- Consider submission of comments as to how proposed changes will impact research institutes (positive or negative).
- Due to OMB within 60 days after publication in the Federal Register (timetable: end of 2023 or early 2024).
- Comments should explain why you are an interested party and be specific. No need to comment on every proposed change.

---

## **2. Changes to NSF's PAPPG**

# OVERVIEW

---

- **Effective for proposals submitted on or after January 30, 2023.**
- Changes made throughout NSF's Proposal & Award Policies & Procedures Guide (PAPPG) to clarify meanings of certain sections.
- Focus on ensuring consistency with data contained in NSF systems or terminology used in other NSF or federal policy documents.



# NOTABLE SECTION CHANGES

- **Chapter I.G.2:** Requirements relating to Unique Entity Identifier (UEI) and Registration in SAM: Clarifies that subrecipients must obtain a UEI and register in Research.gov; but do not need to be registered in SAM.
- **Chapter II.D.1.e:** New certification requiring senior personnel to certify that the information provided in their Biographical Sketch and Current and Pending Support documents are accurate and complete. Certification is included in SciENcv format for proposals.
- **Chapter II.D.2.h(ii):** Section on “Current and Pending Support” has been revised to require the use of SciENcv for the preparation of this document, and for the biographical sketch, as of **10/23/23**.
  - NSF fillable PDF formats will no longer be acceptable.
  - Will not pass the submission validations on Research.gov after Friday, October 20, 2023.

# NOTABLE SECTION CHANGES

- **Chapter II.E.5, Proposals Involving Human Subjects:** New language clarifies that a PI may conduct preliminary work that does not involve human subjects, while the protocol is being developed or under review, consistent with organizational guidelines.
- **Chapter IX.B.1, Responsible and Ethical Conduct of Research:** Amended to require appropriate training and oversight in responsible and ethical conduct of research to students and post-docs. As of **July 31, 2023**, the requirement was expanded to include faculty and senior personnel. The revised section also specific expected mentor and mentorship training content.
- **Chapter IX.C, Research Security:** New section added to address NSF policy on research security including organizational requirements for post-award disclosure of current support and when PIs must update current support in annual and final project reports.

---

# **3. NIH Grants Policy Guidance – Research Records from Foreign Entity Subrecipients**

# BACKGROUND

- New NIH policy, NOT-OD-23-182, **“New NIH Final Updated Policy Guidance for Subaward/Consortium Written Agreements.”**
- Available at <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-182.html>
- New policy requires foreign subrecipients to provide, at least once per year, copies of lab notebooks, data and documentation that support research outcomes described in a progress report to the prime award recipient.
  - Response to OIG and GAO audits raising concerns about NIH’s oversight of funds passed through to foreign subrecipients.
  - Audits recommended that NIH implement changes to its internal processes: enhanced monitoring and reporting requirements.

# MEETING THE REQUIREMENTS

---

- Policy goes into effect in January 2024, with compliance required by March 2024.
- Applies broadly to all foreign subawards and is not limited to “countries of concern.”
- Prime awardees will need to modify existing subawards within 60 days of the Notice to address the requirements and implement the policy: FAQs say more time can be given if needed to accomplish this.
- What if an existing subrecipient will not accept the new requirements? Failure to amend the subaward may leave the prime awardee no option but to terminate the subaward and search for a new collaborator.

# NIH GRANTS POLICY STATEMENT

## SECTION 15.2 AMENDED AS SUCH:

---

- “NIH will not support any agreement” that does not meet the policy’s requirements for subawards, including providing access to lab notebooks, data and documentation supporting research outcomes as described in the annual progress report, and to do so in alignment with the progress report’s submission.
- If NIH requests copies of the foreign sub-awardee’s documentation, failure to provide it may lead to enforcement actions.
- NIH expects prime awardees to have potential sub-awardees include, in their letters of support, their awareness of the policy and willingness to comply.
- Modification of existing subawards within 60 days.

# BURDEN ON THE PRIME RECIPIENT

---

- Record retention challenge: clear obligation to request and receive documentation from all foreign sub-awardees – who should track the receipt of the documentation?
- Need for coordination between project team and research administration staff.
- FAQ #3: “Prime recipients should continue to review all subaward documentation to confirm that the performance outcomes that are reported in the RPRR are accurate, complete and properly reflect programmatic goals.”
- Since the prime recipient will have “knowledge” of inaccuracies, can the prime institution’s failure to identify problems in a progress report violate the False Claims Act? Potential enforcement activity?

---

## **4. Enforcement Discussion: 2023 Noteworthy Cases**



# STANFORD UNIV. - \$1.9M SETTLEMENT

- Stanford pays \$1.94 million to DOJ (announced October 2, 2023) to settle allegations it breached the FCA by failing to report to the government that a dozen faculty members received research funding from foreign sources.
- Research grants received 2015 through 2020 from five federal agencies: U.S. Army, U.S. Navy, U.S. Air Force, NSF, NASA
- **The issue:** Grant applicants are required to disclose all current and pending support that PIs receive.
- **The problem:** Stanford did not disclose current and pending support from foreign entities for 11 of its faculty members who were PIs on 16 submitted grant proposals. One PI had undisclosed affiliations with and funding from Fudan University, a Chinese public institution, and from the National Natural Science Foundation of China.

# STANFORD UNIV. - \$1.9M SETTLEMENT

- Will pay \$1.9 million to the U.S. government, of which \$1.3 million will go to restitution.
- Agreed to work with NSF Office of the Chief of Research Security Strategy and Policy on best practices in the areas of gifts funding research projects, along with current and pending support disclosures.
- **Stanford response:** For the last 4 years, Stanford's research security policies have evolved in line with changes to federal rules. Pledges to continue working with NSF and other federal funding agencies on best practices.

# YALE UNIV. - \$1.5M SETTLEMENT

- (September 21, 2023) - Yale University and one of its professors will pay \$1.5 million to settle allegations they breached the FCA by failing to disclose patents and share royalties with the Dept. of Veterans Affairs (which funded the project).
- Settlement resolves claims that, for 11 years, Yale and the professor improperly avoided their duties to timely disclose patents to the VA and pay the department its fair share of royalties, after reaching a licensing agreement with Janssen Pharmaceuticals in 2013.
- Royalty payments began in early 2015. Yale and the professor ultimately received more than \$3 million.
- **The issue:** VA was not informed of the patents until late 2017. VA and Yale had an agreement since 2003 where parties must immediately share with one another all joint inventions, when the inventions are funded with agency funding. VA regulations also require prompt disclosure.

# YALE UNIV. - \$1.5M SETTLEMENT

---

- **Yale's response:** An “oversight” delayed notifying the VA of the patents. When Yale learned of the oversight, it triggered a careful administrative process to determine VA's rights to the patents.
- **Of note:** VA asserted it had ownership interest in 2018. The professor appealed to the National Institute of Standards and Technology, which affirmed the VA's ownership determination.

# PENN STATE – LAWSUIT FOR FALSELY CERTIFYING CYBERSECURITY COMPLIANCE

---

- (September 1, 2023) – E.D. Penn. court unsealed a qui tam lawsuit against Penn State relating to allegations of non-compliance with DoD cybersecurity obligations.
- Lawsuit originally filed in October 2022. Alleges that Penn State failed to provide “adequate security” for Covered Defense Information.
- For DoD contractors, requirements include implementing 110 controls and conducting a self-assessment of compliance with those controls. Lawsuit alleges that Penn State falsified 20 documents relating to compliance and self-attestations since January 2018. Lawsuit further alleges that sensitive information was put at risk when Penn State migrated some of its data to a commercial cloud-storage service.

# PENN STATE – LAWSUIT FOR FALSELY CERTIFYING CYBERSECURITY COMPLIANCE

- **Who was the whistleblower?** Employee who served as interim Chief Information Officer at Penn State's Applied Research Laboratory and was part of a team assigned to evaluate the university's compliance. Alleged that he brought false certification concerns to university leadership, but was ignored.
- **Important Takeaways:**
  - Take steps to ensure that self-attestations and representations are accurate, to lower likelihood that employee will become a whistleblower.
  - Universities / institutes of higher education with government contracts are not shielded from cyber-related FCA claims.
  - Place cybersecurity compliance at the top of your list, as we expect to see significant increases in enforcement actions.

# THOMAS JEFFERSON UNIV. - \$2.7M SETTLEMENT

- (July 25, 2023) – Thomas Jefferson University enters settlement for \$2.7 million to resolve allegations that it misused and improperly retained federal funds intended to be used for student loans.
- HRSA loan program intended to address the shortage of primary care physicians: loans awarded to medical schools to establish account to provide loans to students willing to commit to practicing in primary care.
- Medical school is supposed to add any earnings that accrue on the fund back into the fund, thereby increasing the monies available to lend.
- **The issue:** Wrongful retention of federal funds.
- Between 2009 and 2016, Thomas Jefferson Univ. invested nearly all of its loan fund earnings with its endowment and retained the earnings for its own purposes.
- University returned about \$5.6 million of excess cash in its fund to HRSA in 2017. Settlement resolves claims relating to the earnings alleged as a result of the investment in the fund and the retention of those earnings.

# THOMAS JEFFERSON UNIV. - \$2.7M SETTLEMENT

---

- **The result?** University returned about \$5.6 million of excess cash in its fund to HRSA in 2017. Settlement resolves claims relating to the earnings alleged as a result of the investment in the fund and the retention of those earnings.



# THOMAS JEFFERSON UNIV. - \$2.7M SETTLEMENT

---

- **The result?** University returned about \$5.6 million of excess cash in its fund to HRSA in 2017. Settlement resolves claims relating to the earnings alleged as a result of the investment in the fund and the retention of those earnings.

# PROACTIVE STEPS

---

- Demands to recover grant funds can be reduced if universities maintain appropriate records and prepare a response.
- NSF OIG questioned \$6 million of costs claimed by the University of California Santa Barbara, including \$1.9 million of alleged overcharged summer salaries. The university's final resolution with NSF resulted in a disallowance of \$43,000.
- Cooperation agreement could include new steps such as annual training, maintaining an internal audit department, and other compliance-related changes.

# QUESTIONS?

---

**Mindy B. Pava**

[MPava@ftlf.com](mailto:MPava@ftlf.com)

**Feldesman Tucker Leifer Fidell LLP**  
**(202) 466-8960 (Reception)**  
**(855) 200-3822 (Training Team)**