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YEAR 2024 LEGAL UPDATE: Navigating Important Regulatory Changes and Enforcement Priorities

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AGENDA

1. Uniform Guidance Changes
2. Research Misconduct Policy
3. Notable Enforcement Actions
   - Foreign Funding Disclosures
   - Cybersecurity Compliance Certifications
4. Qui Tam Cases – A Change on the Horizon?

1. Uniform Guidance Changes

Why Is the Uniform Guidance Changing?

OMB listed four major goals of the revisions:

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

UG Changes: Timeline

- **Proposed revisions:** OMB released a pre-publication draft of changes to Part 200 on September 22, 2023.
- **Publication:** OMB published the official version of proposed changes on October 5, 2023 and the comments period closed in December 2023.
- **Final rule:** OMB released the notice of final rule with the Uniform Guidance changes on April 4, 2024.
- **Effective date:** The amendments became effective on October 1, 2024 but federal agencies were free to implement them, earlier starting June 4, 2024.

UG Changes for Research Institutions: Equipment Definition Threshold Increases

- **Change**: Equipment threshold increased from $5,000 to $10,000
- **Citation**: § 200.1, Equipment Definition
- **Takeaway**: Grantees may wish to reconsider their capitalization thresholds and policies if they were retaining $5,000 thresholds for purposes of consistency with the Uniform Guidance.

UG Changes for Research Institutions: MTDC Base: Subaward Value Increase

- **Change**: Increase eligible value in modified total direct costs (MTDC) indirect base from $25,000 to $50,000 per subaward
- **Citation**: § 200.1, MTDC Definition
- **Takeaway**: Subawards can be counted in your base up to $50,000 per subaward. Impactful for IHEs that have sub-recipients– at many universities, implemented upon approval of the university's Negotiated Indirect Cost Rate Agreement with cognizant agency.

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UG Changes for Research Institutions: De Minimis Indirect Cost Rate Increase

- **Issue**: The *de minimis* rate is increased from 10% to up to 15% over MTDC; clarification that *de minimis* rate cannot be used on cost-reimbursement procurement contracts under the FAR
- **Citation**: § 200.414(f), Indirect costs
- **Takeaway**:
  - Recipients and subrecipients now have the potential to increase their indirect recovery using the enhanced *de minimis* rate

UG Changes for Research Institutions: Prior Approvals – Expansion for Research Grants

- **Change**: 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**: Irrespective of granting agency, prior approval is waived automatically in **research grants** with respect to:
  - pre-award costs (up to 90 days – need prior approval for expenditures more than 90 days before award date)
  - no-cost extensions, and
  - carry forward of unobligated balances

UG Changes for Research Institutions: Cybersecurity Standards

- **Issue**: No clarification on specific standards
- **Citation**: § 200.303(e), Internal Controls
- **Takeaways**:
  - Final language states: "Take **reasonable** cybersecurity and other measures to safeguard information including protected personally identifiable information (PII) and **other types of information**."
  - Does not designate specific standards, but likely to lead to application of NIST SP 800-53 in the future, available here: https://csrc.nist.gov/pubs/sp/800/53/r5/upd1/final.
  - OMB "agrees with commenters that this is a topic worthy of consideration for future updates. In the interim, Federal agencies may consider providing more specific guidance on this topic as appropriate for their federal assistance programs."

UG Changes for Research Institutions: Mandatory Disclosure Language

- **Issue**: Mandatory disclosures clarified to be only upon "credible evidence" and add civil false claims
- **Citation**: § 200.113, Mandatory disclosures
- **Takeaways**:

–Clarify that reporting triggered only by credible evidence of a violation

–Civil False Claims Act violations added to reportable events

HHS Adopts Federal Grant Regulations

- In late September 2024, HHS announced it would abandon its separate Part 75 codification that dates to 2014 and would align with other federal agencies in adopting 2 C.F.R. Part 200.

- Change is effective on October 1, 2025.

- But HHS will not delay implementation of important UG changes.
  - For awards issued on or after October 1, 2024, HHS will apply the increased thresholds in Part 200 applicable to:
    (i) subaward costs for modified total direct costs (MTDC),
    (ii) equipment,
    (iii) fixed amount subawards,
    (iv) de minimis indirect cost rates, and
    (v) audits.

2. Research Misconduct Policy

The 411 on the Final Rule

- In September 2024, Office of Research Integrity (ORI) issued a final rule adopting changes to federal regulations governing research misconduct. 42 C.F.R. Part 93.
- Applies to all institutions that receive Public Health Service funding for research activities (universities, medical centers, health care systems)—including NIH funding.
- Regulations had not been updated since 2005.
- Proposed Rule – not popular! (Issued October 2023).
- Nearly 200 unique commenters requested that ORI reconsider revisions that would have been burdensome. Final Rule – intended to strike a balance.
- Effective date – January 1, 2025 (but institutional compliance required as of January 1, 2026, giving extra time for compliance).

What Was Deleted From the Proposed Rule?

- No unanimous investigation committee decisions for a finding of research misconduct;
- No requirement that institutional assessments proceed automatically to inquiry if not completed in 30 days;
- No requirement that ORI signs off on final decisions as to whether the Subsequent Use Exception requires review of allegations involving older work;
- No requirement that all determinations of honest error or difference of opinion be resolved only at investigation and not during the earlier inquiry or assessment stages; and
- No permission given to ORI to publish information about final institutional actions that did not result in settlements or findings of misconduct.

What Are The Key Changes?

- Codifications of Existing Best Practices, and
- New Requirements.

Codification of Best Practices

- Sets forth a three-part investigational process consisting of (1) institutional assessment of allegation, (2) inquiry to determine whether the allegation has substance (can be conducted by Research Integrity Officer), and (3) investigation that requires full review of evidence and development of investigation report. 42 C.F.R Section 93.310.

- "Confidentiality" restrictions only apply until institution has made its final determination—allows the RIO authority to communicate with journals during a research misconduct proceeding about data integrity concerns. 42 C.F.R. § 93.108(a).

- Revised definition of "plagarism"– excludes the "limited use of identical or nearly-identical phrases that describe a commonly-used methodology" or credit disputes. Final Rule, p. 70.

- All research records necessary to conduct the proceeding must be "sequestered" on or before the date when the inquiry begins. The Final Rule clarifies that when original records cannot be obtained, copies will fulfill the requirement. It also requires more specificity as to how sequestration was conducted. Final Rule, pp. 82, 86.

New Key Requirements and Impact

- Interview transcripts: ORI removes the transcription requirement for interviews conducted at the institutional assessment and inquiry stages but retains the transcription requirement for interviews conducted at the investigation stage. Also requires that respondents be given a copy of all interview transcripts. (Will this disincentivize witnesses from providing honest testimony?) *See* 42 C.F.R. §§ 93.310(g).

- Failure to provide records: Part 93 currently states that a respondent's failure to provide records adequately documenting the questioned research is evidence of misconduct if it is established that the respondent failed to maintain the records. Final Rule only permits this conclusion if the respondent claims to possess the records but refuses to provide them. (Will respondents now simply deny that they have relevant research records?) 42 C.F.R. § 93.105(b).

- Record reporting to ORI: Modifies the ORI reporting requirement to mandate that the entire institutional record (documentation of assessment, inquiry report, investigation report, all records considered, all transcripts, index, etc.) be filed with ORI – will lead to enhanced labeling, organization and record-keeping throughout a proceeding. 42 C.F.R. §§ 93.311(a); 93.315(a); Final Rule p. 69, 85,88.

Focus Area: Subsequent Use Exception

- Rules only apply to misconduct occurring within 6 years prior to the date when the allegation was received.

- Exception: subsequent use of tainted research – when a respondent uses or cites to a portion of the research record that allegedly was fabricated within 6 years of the receipt of the allegation. 42 C.F.R. § 93.105(a).

- Final Rule: clarifies that the Subsequent Use Exception applies to "the portions of the research record" alleged to have been fabricated in processed data, journal articles, funding proposals, manuscripts, grant applications, progress reports, posters and other research records.

- Institutions must document (and retain) how they determined that the Subsequent Use Exception does not apply.

3. Year 2024 Notable Enforcement Actions

Cleveland Clinic Foundation - $7.6M to Settle Foreign Funding False Statement Allegations

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PRESS RELEASE

Cleveland Clinic to Pay Over $7 Million to Settle Allegations of Undisclosed Foreign Sources of Funding on NIH Grant Applications and Reports

Friday, May 17, 2024

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U.S. Attorney's Office, Northern District of Ohio

Cleveland Clinic Foundation Settlement

Allegations:

- CCF made false statements to the NIH in three grant applications and subsequent updates between November 1, 2013 and May 31, 2020.
- Associated with the work of Qing Wang, a researcher who was terminated in 2020 following federal charges that he misrepresented the sources of his grant funding and failed to disclose foreign sources of funding.

The Settlement:

- CCF's failure to disclose Wang's foreign funding, compounded by its improper use of NIH's eRA Commons system, led to multiple false grant submissions.
- Of the $7.6 million settlement, $3.8 million is restitution.
- As part of the settlement, CCF will also be subject to NIH-imposed Specific Award Conditions on all of its grants for a one-year period. The conditions require: (i) a high-level CCF employee personally attest to the truth, and accuracy of all "other grant support" information that CCF provides to NIH; (ii) the development of a corrective action plan that includes an assessment of internal controls related to other grant support and foreign-component reporting; and (iii) creation of a mandatory training program addressing requirements for disclosing other grant support.

Cleveland Clinic Foundation Settlement

Takeaways:

- The NIH maintains strict foreign funding disclosure requirements—for the disclosure of all sources of research support, foreign components, and financial conflicts of interest for senior/key personnel on research applications and awards. Know these requirements! (See NIH's Foreign Interference web page for pre- and post-award requirements at https://grants.nih.gov/policy-and-compliance/policy-topics/foreign-interference);

- Review your internal protocols for checking grant applications prior to submission and throughout the grant lifecycle; and

- Recognize that malign foreign influence in research remains an enforcement priority, even in a "post-China Initiative" world.

DOJ Enforcement Focus on Cybersecurity

- DOJ's **Civil Cyber-Fraud Initiative**, announced in October 2021, uses the False Claims Act to promote cybersecurity compliance by government contractors and grantees who "knowingly":
  - Provide deficient cybersecurity products or services.
  - Misrepresent their cybersecurity practices or protocols.
  - Violate obligations to monitor and report cybersecurity incidents and breaches.
- DOJ's CY 2024 enforcement priorities include holding contractors/grantees accountable for "knowing" violation of applicable cybersecurity requirements.
- We expect enforcement efforts to continue to ramp up.

Cyber Enforcement Example 1: Penn State

- October 2022, Penn State was sued by a former CIO for alleged false claims related to DoD contracts.
- Allegations:
  - Knowing failure to safeguard CUI as contractually required and submission of false security compliance reports.
- Obligation:
  - DFARS clause 252.204-7012 requires DoD contractors to provide “adequate security” to protect CUI—at minimum includes implementing NIST SP 800-171 security controls.
  - Clauses 252.204-7019 and -7020 require self-assessment and self-certification of compliance with NIST SP 800-171.
  - 2024 update: case has been stayed to finalize settlement, status update required on November 1, 2024

Cyber Enforcement Example 2: Georgia Tech

- July 2022, Georgia Tech Research Corporation sued by two whistleblowers for alleged false claims related to DoD contracts.
- February 2024, DOJ intervened.
  - First cybersecurity-related FCA intervention since DOJ unveiled the Civil Cyber-Fraud Initiative.
- Allegations:
  - Knowing failure to adhere to proper standards in processing and storing CUI.
  - Retaliation.
- Obligation:
  - DFARS hook to NIST SP 800-171 compliance, self-assessment, and self-certification.

Takeaways

- DOJ is actively pursuing noncompliance with cybersecurity requirements, including by encouraging whistleblowers to file suits for financial reward.
- False Claims Act risk extends beyond actual knowledge
  - Cybersecurity obligations are myriad and complex, but recipients of federal funds are expected to be on top of them;
  - Liability can attach to "turning a blind eye" to an issue, "sweeping problems under the rug," and "burying one's head in the sand" when confronted with a potential cybersecurity gap or failure.
- Violations must be "material" to trigger FCA liability.

Risk Mitigation

- IHEs and research institutions can mitigate cybersecurity False by:
  - Evaluating the accuracy of representations and certifications made to funding agencies.
  - Creating and retaining organized, contemporaneous documentation supporting the accuracy of representations/certifications.
  - Ensuring internal policies and procedures meet ongoing updates to regulatory requirements and industry best practices.
  - Encouraging internal whistleblowing through a robust reporting structure for any potential cybersecurity gaps or issues.

4. Qui Tam – A Change on the Horizon?

False Claims Act History

- First enacted during the Civil War to protect Union Army from fraud
- Amended numerous times, in particular impacting the role of “relators” in *qui tam* actions
- In 2023, around $2.3 billion in FCA settlements and judgments resulted from lawsuits filed under the qui tam provision, out of a total of $2.68 billion in recoveries.
- Big business for whistleblowers:
  - Relator share of 15–25% if DOJ intervenes
  - Relator share of 25–30% if DOJ does not

Zafirov v. Florida Medical Associates LLC (M.D. Fla.)

- On September 30, Florida court ruled that the provision of the FCA allowing whistleblowers to bring suits on behalf of the federal government is unconstitutional. The court dismissed claims against a group of Medicare Advantage and provider organizations, finding that the qui tam provision violated the "appointments clause" of the U.S. Constitution.

- Reasoning: The qui tam provision permits anyone to perform a "traditional, exclusive [state] function" by appointing themselves as the federal government's "avatar" in litigation, and "that arrangement directly defies the appointments clause by permitting unaccountable, unsworn, private actors to exercise core executive power with substantial consequences to members of the public."

Zafirov v. Florida Medical Associates LLC (M.D. Fla.)

- Court's reasoning, continued:

- Whistleblower authority shifts power to execute laws from the executive branch to private, third parties.

- Whistleblowers have immense power to spearhead litigation, to choose whether to appeal, and to seek treble damages.

- Relators occupy a "continuous" office, if it is not always filled, satisfying Supreme Court precedent for what constitutes a "federal officer."

Impact of the *Zafirov* Decision

- Ruling only applies specifically to the defendants in the Medicare Advantage case, but it marks the first time that a court has found the FCA's qui tam clause unconstitutional.
- Decision can be viewed as an aberration following decades of case law that have upheld the constitutionality.
- Will the decision – if reasoning is adopted by other courts – allow more fraud against the government to occur or will there just be a larger burden on the DOJ?
- Will the decision – if reasoning is adopted by other courts – drive up the costs of federal programs?
- Prediction: Decision could open the door for a potential circuit split, and for the issue to eventually wind up before the Supreme Court, where three justices have signaled that they want to address qui tam constitutionality.

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