Aggregated Regulatory Requirements
Impacting Federally Funded Research Since 1991

**Overview:** Research institutions take seriously their responsibility to conduct high-quality research, steward taxpayer funding, and comply with all federal regulations and reporting requirements to ensure safety, security, and financial transparency and accountability. This is vital to the partnership between research institutions and the federal government and the partnership’s continuing ability to bolster our nation’s health, security, and economic prosperity.

The regulations, laws, policies, and guidance documents referenced below directly affect the conduct and management of federal research grants and contracts (collectively referred to as “Requirements”). Although regulations affecting research have been in place for decades, 1991 is the baseline year for this list because in that year the federal government, by way of OMB Circular A-21 – now the Uniform Guidance – imposed the 26-percent cap on administrative costs that can be recovered under Facilities and Administrative Costs (F&A)\(^1\).

The Requirements listed below in chronological order\(^2\) have been implemented or amended since 1991. Significant changes in the implementation or interpretation of the Requirements and associated management processes are listed in a separate section. This year, we have added a visual representation (see Figure 1) to illustrate the cumulative total of new or modified regulatory requirements and substantial updates to business practices or interpretations since 1991.

COGR has long advocated for reduced administrative and cost burdens for U.S. institutions conducting federal research and has published several papers over the years detailing the cost of compliance and analyzing F&A cost reimbursement. Recent papers include:

- *Data Management and Sharing and the Cost of Compliance (2023)*
- *Excellence in Research: The Funding Model, F&A Reimbursement, and Why the System Works (2019)*
- *Coming Fall 2023: Facilities & Administrative Costs Institutional Survey*

Additional resources and information can be found on COGR's website at [www.cogr.edu](http://www.cogr.edu).

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1. 2 CFR 200 Appendix III to Part 200—Indirect (F&A) Costs Identification and Assignment, and Rate Determination for Institutions of Higher Education (IHEs)
2. Chronological by initial year, subsequent revisions, amendments, etc. are listed with the initial year.
List of Requirements Affecting Federally Funded Research That Were Adopted or Substantially Modified Since 1991


Nonindigenous Aquatic Nuisance Prevention & Control Act of 1990 (Implemented, 1992)
National Institutes of Health (NIH) Guidelines for Research Involving Recombinant DNA Molecules (1994), NIH Guidelines for Research Involving Recombinant DNA Molecules or Synthetic Nucleic Acid Molecules (Updated, 2019)

Deemed Exports (Export Controls; 1994), Export Administration Regulations (EAR) & International Traffic in Arms Regulations (ITAR) Reform; (Amended 2013, 2015 further changes pending for ITAR), DFARS Export Control Compliance Clauses (2010)

Office of Management & Budget (OMB) Cost Accounting Standards (CAS, 1995)

Conflicts of Interest
Public Health Service/NIH Objectivity in Research (1995; Amended 2011)
NIH Reminders of NIH Policies on Other Support and on Policies Related to Financial Conflicts of Interest and Foreign Components (2019)
DOE Interim COI Policy (2022, FAQs released Sept. 2022)


Health Insurance Portability & Accountability Act of 1996 Privacy Rule (HIPAA, Amended 2013)
Data Access/Shelby Amendment (FY 1999 Omnibus Appropriations Act)

NIH Policy on Sharing of Biomedical Research Resources (1999)
HHS Centers for Medicare and Medicaid Services (CMS) National Coverage Determination for Routine Clinical Trials (Clinical Trials Policy, 2000)

Misconduct in Science (Federal-wide Policy, 2000)
NEH, 2001
NSF, 2002
Labor, 2004
HHS/PHS, 2005
NASA, 2005
Energy, 2005
Veterans Affairs, 2005
Education, 2005
Transportation, 2005
USDA, 2010

HHS/Food and Drug Administration (FDA) Clinical Trials Registry (2000, FDA Amendments Act of 2007; Mandated Reporting, 2008; expanded registration and results reporting requirements 2016)

Executive Order 13224, Blocking Property and Prohibiting Transactions with Persons Who Commit, Threaten to Commit or Support Terrorism (September 2001, also EO 12947, 1995)

Confidential Information Protection and Statistical Efficiency Act (CIPSEA; Title V, E Government Act of 2002; OMB Implementation Guidance 2007)

NIH Data Sharing Policy (2003), NIH Data Sharing & Management Policy (Updated 2020, effective 2023)
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Higher Education Act, Section 117, Reporting of Foreign Gifts, Contracts and Relationships (20 USC 1011f, 2004)
Federal Acquisition Regulations (FAR) Flowdown of Debarment/Suspension to Lower Tier Subcontractors (2010; amendment to FAR Subpart 9.4)
NSF Responsible Conduct of Research Training (America COMPETES Act 2006; implemented 2010; modified by the Chips and Science Act of 2022 to broaden training audience/requirements)
NSF Public Outcomes Reporting (America COMPETES Act 2006; implemented 2010)
NSF Post-Doctoral Fellows Mentoring (America COMPETES Act 2006; implemented 2009)
Combating Trafficking in Persons (2008)
Code of Business Ethics & Conduct (FAR 2008)
NIH Public Access Policy (2008; Consolidated Appropriations Act of 2008; Division G, Title II Section 218)
Certification of Filing and Payment of Federal Taxes (Labor, HHS, Education and Related Agencies Appropriations Act of 2008; Division G, Title V, Section 523)
NIH Policy for Genome-Wide Association Studies (GWAS, 2008)
USAID Partners Vetting System (re: EO 13224 et al re: terrorist financing 2009; Extension to Acquisitions, 2012)
NIH Guidelines for Human Stem Cell Research (2009)
E-Verify (2009)
Executive Order 13513, Federal Leadership on Reducing Text Messaging While Driving (2009)
FAR and OMB Federal Awardee Performance and Integrity Information System (FAPIIS) and Guidance for Reporting and Use of Information Concerning Recipient Integrity and Performance (2010, 2012)
Budgeting for Genomic Arrays for NIH Grants, Cooperative Agreements and Contracts (2010)
OSTP Memorandum on Scientific Integrity, (2010)
Homeland Security/Citizenship & Immigration Services I129 Deemed Export Certification for H1B Visitors (2010; implementation postponed to 2011)
Nuclear Regulatory Commission – Statement concerning the Security and Continued Use of Cesium- 137 Chloride Sources (2011)
   Inventor Oath or Declaration; 3rd Party Submission of Prior Art; Citation of Prior Art; Statutes of Limitation for Disciplinary Actions; Supplemental Examination; Post-Grant Review
   NASA/OSTP China Funding Restrictions (2012, Under PL 112-10 § 1340(2) & PL 112-55 § 539)
   US Government Policy for the Oversight of Life Sciences Dual Use Research of Concern (2012) NIH,
   Mitigating Risks of Life Science Dual Use Research of Concern (2013)
FDA Reporting Information Regarding Falsification of Data (2012)
NSF Career-Life Balance Initiatives (2012)
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**Gun Control, Prohibition on Advocacy & Promotion** (Consolidated Appropriations Act of 2012 – PL 112- 74, Sec 218)  
Office of Science and Technology Policy (OSTP), Increasing Access to the Results of Federally Funded Scientific Research (2013)  
Open Payments/Physician Sunshine provisions of the Affordable Care Act (2013; Amended 2015, 2020)  
Executive Order 13642 Making Open and Machine Readable the New Default for Government Information (2013)  
The Digital Accountability and Transparency (DATA) Act (OMB; 2014)  
NIH, Genomic Data Sharing Policy (2014, Updated 2018)  
OMB/COFAR Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (2014, Updates in 2020, 2023)  
Department of Education Section 117 Notice of Interpretation the Department’s Enforcement Authority for Failure to Adequately Report Under Section 117 of the Higher Education Act of 1965, as Amended (2020)  
OSTP US Governmental Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (2014)  
DFARS Cyber Reporting and Safeguarding Requirements (2013, 2015)  
Service Contract Act reporting requirements (labor hours; implemented 2015)  
NSF Public Access Policy (Effective 2016)  
Department of Labor, Defining and Delimiting the Exemptions for Executive, Administrative, Professional, Outside Sales and Computer Employees (2016)  
National Archives and Records Administration (NARA) Controlled Unclassified Information Final Rule (2016)  
HHS, Clinical Trials Registration and Results Information Submission (2016)  
NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information (2016)  
NIH Policy on Good Clinical Practice Training for NIH Awardees Involved in NIH-funded Clinical Trials (2016)  
NSF Important Notice No. 144, Sexual Harassment Policy (2018)  
USDA Agriculture Improvement Act of 2018 (“Farm Bill”) (2018)  
NIH Preventing and Addressing Harassment and Inappropriate Conduct (2018)  
SAMHSA Attestation Requirement for Compliance with Marijuana Use Laws (2019)  
DOE Order 142.3A Foreign National Approval Requirements (2019)  
DEA Interim Final Rule 2018 Agricultural Improvement Act (2020)  
Removal of IHE Exemption (2020)  
NASA Reporting Requirements Regarding Findings of Harassment, Sexual Harassment, Other Forms of Harassment, or Sexual Assault (2020)  
Executive Order 13950 "Combating Race and Sex Stereotyping" (2020) Revoked and replaced by EO 13985  
Advancing Racial Equity and Support for Underserved Communities Through the Federal Government  
Racial Equity & Support for Underserved Communities through the Federal Government (2021)  
Replaced by Order 142.3B Unclassified Foreign National Access Program (2021)  
USDA Establishment of a Domestic Hemp Production Program (2021)  
HHS, Establishment of Safeguards & Program Integrity Requirements for HHS Funded Extramural Research Involving Human Fetal Tissue [86 FR 2615] (2021)  
Revoked under EO Revocation of Certain Executive Orders Concerning Federal Regulation (2021)  
Transparency & Fairness in Civil Admin. Enforcement Actions [86 FR 3010] (2021)
Implementation and Interpretation of Regulations that Changed Business Practices, since 1991

NIH Trainee Instruction in the Responsible Conduct of Research (1989; 1994; Updated 2009)
HHS, Office of Grants and Acquisition Policy and Accountability Guidance Regarding Funding of Contracts Exceeding One Year of Performance (APM 2010-01, 2010)
NSF, Data Sharing Policy (Updated 2011)
NSF Award Cash Management Service (2012)
NIH Costing of Core Facilities (2013)
Revised Merit Review Criteria (2013)
NIH Payment Management System Sub-Accounts (2013)
USDA Animal Welfare Act, Contingency Planning (Effective 2013)
OMB, Open Data Policy, M-13-13, Managing Information as an Asset, (2013)
OSTP, Increasing Access to the Results of Federally Funded Scientific Research (2013)
NIH Implementation of the 2011 8th Edition of the National Academy of Sciences Guide for the Care and Use of Laboratory Animals (Updated 2015)
NIH Responsibilities of Recipient Institutions in Communicating Research Misconduct to the NIH (2018)
OHRP Posting Human Subjects Consent Forms NOT-HS-19-23 (2019)
Grant Reporting Efficiency and Agreements Transparency “GREAT” Act (2019)
NIH Changes to Requirements Regarding Proposed Human Fetal Tissue Research (2019)
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NSF – Reporting of Other Support (2019)
OIG’s Grant Self-Disclosure Program (2019)
DOE 0 486.1 and 1(a) Foreign Government Sponsored or Affiliated Activities (2020)
BIS Expansion of Controls for Military End Use in China, Russia or Venezuela RIN 0694-AH53 (2020) BIS
License Exception Civil End Users RIN 0694-AH84 (2020)
DODGARs Definitions for DoD Grant and Agreement Regulations & Award Format for DoD Grants and
Cooperative Agreements (2020)
DFARS Assessing Contractor Implementation of Cybersecurity Requirements Interim Rule (2020)
NIST Enhanced Security Requirements for Protecting Controlled Unclassified Information (2021)
OSTP, Recommended Practices for Strengthening the Security and Integrity of America’s Science and
Technology Enterprise (2021)

Presidential Memorandum, United States Government – Supported Research and Development National
Security Policy, NSPM-33, (2021) & Guidance for Implementation (2022)
NIH, Reminders of NIH Policies Related to Closeout NOT-OD-21-102 (2021)
NIH, Update- Implementation of Requirement to Submit Federal Financial Report (FFR) in the PMS NOT- OD-
21-060 (2021)
FDA, Revised Information Guidance for Sponsors, Clinical Investigators, and IRBs: FAQs Statement of
Investigator Form (2021)
FDA, Sponsor Responsibilities – Safety Reporting Requirements and Safety Assessment for IND and
Bioavailability/Bioequivalence Studies (2021)
NIH, NIGMS Funding for Investigators with Substantial Research Support NOT-GM-21-053 (2021)
NSF Research on Transplantation of Fetal Tissue, Appendix C (2022)
NSF SORN, New Data Analytics Tool NSF-77 (2022)
NIH, Inclusion of Safety Plans NOT-OD-22-074 (2022)
NIH Changes to RCR Instruction Requirements NOT-OD-22-055 (2022)
NIH Informed Consent for Research with Data and Biospecimens: Points to Consider and Sample Language
for Future Use and/or Sharing NOT-OD-21-131 (2022)
NIH Requirements for Notification of Removal or Disciplinary Action Involving Program
Director/Principal Investigators or Other Senior/Key Personnel NOT-OD-22-129 (2022)
NIH Upcoming Changes to the Federal Financial Report (FFR) Beginning April 1, 2022 NOT-OD-22-099
(2022)
NIH Updated eRA RPPR Module and Instruction Guide: Action Required for In-Progress Budget Forms
NOT-OD-22-130 (2022)
OHRP Updated Guidance on Informed Consent Posting Instructions (45 CFR 46.116(h)) (2022)
GSA Transition from DUNS to UEI (2022)
OSTP Guidance On Scientific and Technological Cooperation with the Russian Federation for U.S.
Government and U.S. Government Affiliated Organizations (2022)
Federal Trade Commission Standards for Safeguarding Customer Information (2022)
DFARS Supplement Employment Transparency Regarding Individuals Who Perform Work in the People’s
Republic of China (2022)
NIST, New iEdison Reporting System (2022)
NIH Updated Guidance: Requirement for Instruction in the Responsible Conduct of Research, NOT-OD-22-
055 (2022)
FDA Guidance for Industry, Cannabis and Cannabis-Derived Compounds, Quality Considerations for
Clinical Research (2022)
USDA APHIS, Contingency Planning for Research Facilities and Others (2022)
FDA Expanded Access to Investigational Drugs for Treatment Use (2022)
FDA General Considerations for Animal Studies Intended to Evaluate Medical Devices (2023)
OSTP Draft Research Security Program Standards (2023)
DOD Army Risk Matrix/Rubric (2023)
FDA Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations (2023)
USDA NPRM Standards for Birds Not Bred for Use in Research Under the Animal Welfare Act (2023)

Figure 1: Cumulative Total of Regulations & Policies Adopted, and/or Substantially Modified & Changes in Interpretation of Regulations or Business Practices Affecting Federal Research Since 1991