COGR

An Association of Research Institutions

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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)*
- *Research Security and the Cost of Compliance: Phase I Report (2022)*
- *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.

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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.*

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List of Requirements Affecting Federally Funded Research That Were Adopted or Substantially Modified Since 1991

Health and Human Services (HHS) **Federal Policy for the Protection of Human Subjects** (Common Rule, 1991, Revised 2017)

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

- NSF **Financial Disclosure Policy** (1995; Amended in 2023)
- 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)

Lobbying Disclosure Act of 1995 (Amended 2007; 2013)

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
- EPA, Directive, 2003
- 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)

Public Health Security & Bioterrorism Preparedness & Response Act of 2002; Companion to the USA PATRIOT Act (Select Agents & Toxins regulations 7 CFR Part 331 & 9 CFR Part 121, CDC and USDA/APHIS; 2001; last revised 2018)

Federal Information Security Management Act (FISMA Title III, E Government Act of 2002)

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)

Homeland Security Presidential Directive – 12, Common Identification Standards for Federal Employees and Contractors (2004)
Higher Education Act, Section 117, Reporting of Foreign Gifts, Contracts and Relationships (20 USC 1011f, 2004)
NIH **Model Organism Sharing Policy** (2004)
Constitution & Citizenship Day (2005, Consolidated Appropriations Act FY 2005)
Genomic Inventions Best Practices (2005)
OMB **Guidance for Government-wide Debarment and Suspension [Nonprocurement]** (2CFR Part 180, 2006) **Consolidation of agencies' Government-wide Debarment & Suspension Common Rule** (2003) **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)
Federal Funding Accountability and Transparency Act (FFATA) Executive Compensation and Subrecipient Reporting (2006; FAR, 2010; OMB Open Government Directive, 2010)
Combating Trafficking in Persons (2008)
Code of Business Ethics & Conduct (FAR 2008)
Homeland Security **Chemical Facilities Anti-Terrorism Standards** (**CFATS**) (2008)
Military Recruiting and ROTC Program Access (2008, Solomon Amendment, National Defense Authorization Act for FY 2005)
Nuclear Regulatory Commission Order Imposing Fingerprinting and Criminal History Records Check Requirements for Unescorted Access to Certain Radioactive Materials (2008, Section 652, Energy Policy Act of 2005)
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) (Compliance with § 872, National Defense Authorization Act of 2009, PL 110-417; as amended, 2010, NIH Implementation 2016)
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)
America Invents Act 2011 Patent Regulatory Changes (2012): Implementation of First Inventor to File System; Inventor Oath or Declaration; 3rd Party Submission of Prior Art; Citation of Prior Art; Statues 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)

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)
Public Health Service, **The Newborn Screening Saves Lives Reauthorization Act of 2014** (2014)
DFARS **Cyber Reporting and Safeguarding Requirements** (2013, 2015)
Department of Commerce, USPTO, **Interim Guidance on Patent Subject Matter Eligibility** (2015, Revised 2019)
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)
NIH **Final Policy on the Use of a Single Institutional Review Board for Multi-Site Research** (2016, Draft Guidance Published in 2022)
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)
Sec. 101 **Patent Eligibility in the Patent Act** (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**
NDAA FY 19 **Prohibition on Procuring "Covered" Telecommunications Equipment Sec. 889** (2020) DoD **Cybersecurity Maturity Model Certification Requirements** (2020, DOD plan released 2021, Updates expected 2023)
Racial Equity & Support for Underserved Communities through the Federal Government (2021)
Replaced by **Order 142.3B Unclassified Foreign National Access Program** (2021)
FAA **Regarding Remote Identification of Unmanned Aircraft Systems** (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)

Revoked under **EO Revocation of Certain Executive Orders Concerning Federal Regulation** (2021)
Presidential Memorandum, **Restoring Trust in Government Through Scientific Integrity and Evidence- Based Policymaking** (2021)
NIH**, Upcoming Changes to the Biographical Sketch and Other Support Format Page for Due Dates on or after May 25, 2021** (2021, implementation extended to Jan. 2022)
DOE, **Determination of Exceptional Circumstances U.S. Competitiveness Provision** (2021)
DARPA, **Countering Foreign Influence Program (CFIP)** (2021), Risk Rubric (2022) and FAQs on Risk Rubric (2022)
Executive Order, **EO 14042 Ensuring Adequate Covid Safety Protocols for Federal Contractors** (2021)
CHIPS and Science Act, P.L 117-167 (2022)
OSTP **Ensuring Free, Immediate, and Equitable Access to Federally Funded Research** (2022)
SBIR and STTR Extension Act (2022)
DOC, **Revisions to the Unverified List; Clarifications to Activities and Criteria That May Lead to Additions to the Entity List** (2022)
DOC, **Implementation of Additional Export Controls: Certain Advanced Computing and Semiconductor Manufacturing Items; Supercomputer and Semiconductor End Use; Entity List Modification** (2022)
Medical Marijuana Research Act (2022)
Animal Welfare Act Implementing Regulations (9 CFR Part 2) (Significant amendments impacting research institutions 2020-2023).
No TikTok on Government Devices (Consolidated Appropriations Act 2023)
NSF **Foreign Gifts and Contracts Disclosures** (2023)
NIH **Updated Policy Guidance for Subaward/Consortium** (GPS October 2023)
OSTP **Scientific Integrity Policy** (2023)

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 $ervice** (2012)
Defense Federal Acquisition Regulations 252.204--**7000 Disclosure of Information** Clause Revised (2013)
NIH **Costing of Core Facilities** (2013)
NIH **Implementation of the American Veterinary Medical Association Guidelines for Euthanasia, 2013 Edition** (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)
DOE, National Nuclear Security Administration (NNSA), **10 CFR Part 810, Assistance to Foreign Atomic Energy Activities** (2015)
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)
NIH **Requirement for ORCID iDs for Individuals Supported by Research Training, Fellowship, Research Education, and Career Development Awards Beginning in FY 2020** (2019)
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)

NSF **– Reporting of Other Support** (2019)
OIG's **Grant Self-Disclosure Program** (2019)
DOE O 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)
DOE **Current and Pending Support Disclosure Requirements for Financial Assistance** (PF-2022-32) (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*