Federal Regulatory Changes, Since 1991

The regulations listed below have been implemented or amended since the imposition of the 26 percent cap on administrative costs in the Facilities and Administrative Cost recovered under OMB Circular A-21, now the Uniform Guidance. The listed regulations directly affect the conduct and management of research under Federal grants and contracts. The list of current regulations is in chronological order. Significant changes in the implementation or interpretation of regulations or management processes are listed below in a separate section. The list concludes with significant proposed regulations.

Nonindigenous Aquatic Nuisance Prevention & Control Act of 1990 (Implemented, 1992)
National Institutes of Health (NIH) Guidelines for Research Involving Recombinant DNA Molecules (1994)
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)
Conflicts of Interest
Public Health Service/NIH Objectivity in Research (1995; Amended August 2011)
NIH Reminders of NIH Policies on Other Support and on Policies Related to Financial Conflicts of Interest and Foreign Components (2019)
Office of Management & Budget (OMB) Cost Accounting Standards (CAS, 1995)
Health Insurance Portability & Accountability Act of 1996 Privacy Rule (HIPAA, Amended January 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)
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, CDC and USDA/APHIS; 2001; revised October 2012)
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)
Higher Education Act, Section 117, Reporting of Foreign Gifts, Contracts and Relationships (20 USC 1011f, 2004)
   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)
   Federal Acquisition Regulations (FAR) Flowdown of Debarment/Suspension to Lower Tier Subcontractors (December 2010; amendment to FAR Subpart 9.4)
NSF Responsible Conduct of Research Training (America COMPETES Act 2006; implemented 2010)
NSF Public Outcomes Reporting (America COMPETES Act 2006; implemented 2010)
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 21B)
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)
NSF Post-Doctoral Fellows Mentoring (America COMPETES Act 2006; implemented 2009)
Executive Order 13513, Federal Leadership on Reducing Text Messaging While Driving (October 2009)
Budgeting for Genomic Arrays for NIH Grants, Cooperative Agreements and Contracts (2010)
OSTP, Memorandum on Scientific Integrity, (2010)
Homeland Security/Citizenship & Immigration Services 1129 Deemed Export Certification for H1B Visitors (November 2010; implementation postponed to February 2011)

Nuclear Regulatory Commission – Statement concerning the Security and Continued Use of Cesium-137 Chloride Sources (July 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 (March 2012)

NIH, Mitigating Risks of Life Science Dual Use Research of Concern (2013)

FDA Reporting Information Regarding Falsification of Data (April 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 (February 2013)

Executive Order 13642 Making Open and Machine Readable the New Default for Government Information (May 2013)

The Digital Accountability and Transparency (DATA) Act (OMB; May 2014)

National Institutes of Health, Genomic Data Sharing Policy (August 2014, Updated 2018)

OMB/COFAR Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (December 2014)

Updates to OMB Uniform Guidance (2020)

OSTP US Governmental Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (September 2014)


DFARS Cyber Reporting and Safeguarding Requirements (2013, August 2015)


Service Contract Act reporting requirements (labor hours; implemented 2015)

NSF Public Access Policy (Effective January 2016)

Department of Labor, Defining and Delimiting the Exemptions for Executive, Administrative, Professional, Outside Sales and Computer Employees (May 2016)


National Archives and Records Administration (NARA) Controlled Unclassified Information Final Rule (September 2016) HHS, Clinical Trials Registration and Results Information Submission (September 2016)

NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information (September 2016)

Policy on Good Clinical Practice Training for NIH Awardees Involved in NIH-funded Clinical Trials (September 2016)

NSF, Important Notice No. 144, Sexual Harassment Policy (2018)

USDA, Agriculture Improvement Act of 2018 (“Farm Bill”) (December 2018)

DEA Interim Final Rule 2018 Agricultural Improvement Act (2020)

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)

Removal of IHE Exemption (Feb 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 Advancing Racial Equity & Support for Underserved Communities through the Federal Government (2021)
  Replaced by Order 142.3B Unclassified Foreign National Access Program (2021)
NDAA FY 19 Prohibition on Procuring “Covered” Telecommunications Equipment Sec. 889 (2020)
DoD Cybersecurity Maturity Model Certification Requirements (2020)
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/Interpretation that Changes 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, June 2010) NSF, Data Sharing Policy (Updated 2011)
NIH Implementation of the 2011 8th Edition of the National Academy of Sciences Guide for the Care and Use of Laboratory Animals (Updated March 17, 2015)
NIH Costing of Core Facilities (2013)
NIH Responsibilities of Recipient Institutions in Communicating Research Misconduct to the NIH (2018)
NIH Payment Management System Sub-Accounts (2013)
OSTP, Increasing Access to the Results of Federally Funded Scientific Research (February 2013)
DOE, National Nuclear Security Administration (NNSA), 10 CFR Part 810, Assistance to Foreign Atomic Energy Activities (March 2015)
OHRP Posting Human Subjects Consent Forms NOT-HS-19-23 (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)
**Significant Proposed Changes**

While the following non-exhaustive list constitutes significant proposed changes there were either revoked, never implemented, still awaiting action, etc., they are included, as proposed action could eventually become final action, be reintroduced as part of a new action, and nevertheless requires institutional resources in terms of time, expertise, and planning in order to respond and address.

**FDA Requirements for an Investigative New Drug (IND)** covering food and plants claiming therapeutic benefit

FAR Organizational Conflicts of Interest (NPRM April 2011)
IHHS Office for Human Research Protections, Federal Policy for the Protection of Human Subjects; proposed changes to 45 CFR 46 Subpart A (NPRM, September 2015)
FAR Privacy Act Training (Proposed 2011)
DHS Chemical Facility Anti-Terrorism Standards (CFATS) ANPRM (August 2014)
DHHS, OHRP’s Guidance on Disclosing Reasonably Foreseeable Risks in Research Evaluating Standards of Care (Proposed October 2014)
USAID, Development Data, ADS Chapter 579 (new chapter added)
GSA, Submission to OMB for Review; Reporting and Use of Information Concerning Integrity and Performance of Recipients of Grants and Cooperative Agreements (January 2015)
GSA, Reporting and Use of Information Concerning Integrity and Performance of Recipients of Grants and Cooperative Agreements (January 2015)
Department of Education Open Licensing Requirement (Proposed 2015)
DEA NPRM Controls to Enhance the Cultivation of Marihuana for Research in the United States (2020)
BIS Identification and Review of Controls for Certain Foundational Technologies (2020)
DEA NPRM Reporting of Theft or Significant Loss of Controlled Substances (2020)
Doled NPRM Documentation of Foreign Source Gifts and Contracts “True Copies” (2020)
Withdrawn (2021)
NIST SP 800-171B, Protecting Controlled Unclassified Information in Nonfederal Systems and Organizations (2020, Withdrawn, Reissued 2/2021)
USDA NPRM Animal Welfare Act Regulations (2020)
EPA Supplemental Notice of Proposed Rulemaking (2020)
NIST NPRM Rights to Federally Funded Inventions and Licensing of Government Owned Inventions (2021)
USDA National List of Reportable Animal Diseases (2021)
DHHS, NPRM Establishment of Safeguards & Program Integrity Requirements for HHS Funded Extramural Research Involving Human Fetal Tissue [86 FR 2615] (2021)
DHHS, Grants Regulation [86 FR 2257] (2021)
DHHS, Proposed Modifications to the HIPAA Privacy Rule to Support and Remove Barriers to Coordinated Care and Individual Engagement [86 FR 6446] (2021)
   Revoked per EO on "Revocation of Certain Executive Orders Concerning Federal Regulation"
DEA, Amending Regulations to Require Online Submissions of Applications for and Renewals of DEA
   Registration [86 FR 1030] (2021)
DHS, Modification of Registration Requirement for Petitioners Seeking to File Cap-Subject H-1B Petitions
   [86 FR 1676] (2021)