



An Association of Research Institutions

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## 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.*

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)

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**

NSF Financial Disclosure Policy (1995)

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)**

**Lobbying Disclosure Act of 1995** (Amended 2007; 2013)

**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

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)



*An Association of Research Institutions*

**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)**

**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)**

**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)**

**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 (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)**

**Federal Funding Accountability and Transparency Act (FFATA) Executive Compensation and Subrecipient Reporting (2006; FAR, July 2010; OMB Open Government Directive, April 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 (Feb 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)**

**NSF Post-Doctoral Fellows Mentoring (America COMPETES Act 2006; implemented 2009)**

**Executive Order 13513, Federal Leadership on Reducing Text Messaging While Driving (October 2009)**

**FAR and OMB Federal Awardee Performance and Integrity Information System (FAPIS) 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 February 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 (November 2010; implementation postponed to February 2011)**



*An Association of Research Institutions*

**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; 3<sup>rd</sup> 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** (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)

Public Health Service, **The Newborn Screening Saves Lives Reauthorization Act of 2014** (December 2014)

DFARS **Cyber Reporting and Safeguarding Requirements** (2013, August 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 January 2016)

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

**NIH Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research** (June 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)

**Sec. 101 Patent Eligibility in the Patent Act** (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)



*An Association of Research Institutions*

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, DOD plan released 2021, Updates expected 3/23)  
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)  
DOE **Interim COI Policy** (2022)  
DARPA, **Countering Foreign Influence Program (CFIP)** (2021) and Risk Rubric (2022)  
Executive Order, **EO 14042 Ensuring Adequate Covid Safety Protocols for Federal Contractors** (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 8<sup>th</sup> Edition of the National Academy of Sciences **Guide for the Care and Use of Laboratory Animals** (Updated March 17, 2015)  
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)  
NIH **Responsibilities of Recipient Institutions in Communicating Research Misconduct to the NIH** (2018)  
NSF **Award Cash Management Service** (2012) NSF  
**Revised Merit Review Criteria** (2013)  
NIH **Payment Management System Sub-Accounts** (2013)  
USDA **Animal Welfare Act, Contingency Planning** (Effective January 30, 2013) OMB,  
OMB, **Open Data Policy, M-13-13, Managing Information as an Asset**, (May 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)  
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)



*An Association of Research Institutions*

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)  
Presidential Memorandum, United States Government – **Supported Research and Development National Security Policy**, NSPM-33, (2021) & Guidance for Implementation (2022)  
OSTP, **Recommended Practices for Strengthening the Security and Integrity of America’s Science and Technology Enterprise**, (2021)  
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, **Request for Information (RFI) on Flexibilities to Reduce Administrative Burden While Continuing to Apply the PHS Policy to Zebrafish Immediately After Hatching** (2021)  
NIH, **NIGMS Funding for Investigators with Substantial Research Support (NOT-GM-21-053)** (2021)  
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)

## **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)  
HHS 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)



*An Association of Research Institutions*

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, Proposed Updates 4/22)

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)

DOE, **Procedures for Issuance of Guidance Documents** [86 FR 451] (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)

USDA APHIS, **Contingency Planning for Research Facilities and Others** (2021)

USICA **Research Security Provisions, Section 3138, Section 6124, Section 2308, and Section 2526 Updates** (2022)

USDA NPRM **Standards for Birds Not Bred for Use in Research Under the Animal Welfare Act** (2022)

NASA **Requirement for NASA Recipients of Financial Assistance Awards to Obtain Quotation from Small and/or Minority Businesses, Women's Business Enterprises and Labor Surplus Area Firm** (2022)