



Council On Governmental Relations

1200 New York Avenue, N.W., Suite 460, Washington, D.C. 20005
(202) 289-6655/(202) 289-6698 (FAX)

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)**

Nonindigenous Aquatic Nuisance Prevention & Control Act of 1990 (Implemented, 1992)

National Institutes of Health (NIH) **Guidelines for Research Involving Recombinant DNA Molecules** (1994)

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)

NSF Financial Disclosure Policy (1995)

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)

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 Centers for Medicare and Medicaid Services (CMS) **National Coverage Determination for Routine Clinical Trials** (Clinical Trials Policy, 2000)

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)

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



Council On Governmental Relations

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

NIH Data Sharing Policy (2003)

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 (December 2010; amendment to FAR Subpart 9.4)

Combating Trafficking in Persons (2008)

Code of Business Ethics & Conduct (FAR 2008)

Homeland Security Chemical Facilities Anti-Terrorism Standards (CFATS) (2008)

E-Verify (2009)

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)

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

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)

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

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

NSF Responsible Conduct of Research Training (America COMPETES Act 2006; implemented 2010)

NSF Public Outcomes Reporting (America COMPETES Act 2006; implemented 2010)

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 February 2016

Budgeting for Genomic Arrays for NIH Grants, Cooperative Agreements and Contracts (2010)

Homeland Security/Citizenship & Immigration Services I129 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; 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)



Council On Governmental Relations

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)
OMB/COFAR **Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards** (December 2014)
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)
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)
USDA, **Agriculture Improvement Act of 2018** (“Farm Bill”) (December 2018)

Implementation/Interpretation that Changes Business Practices, Since 1991

Foreign Nationals (See COGR/AAU/FDP Troublesome Clause Report, 2008¹)
Publication Restrictions (see COGR/AAU/FDP Troublesome Clauses, 2008)
PL 106-107/Grants.gov: Electronic Applications, Financial Reporting, Progress Reports, iEdison Invention Reporting, etc.
CCR/DUNS Registry requirements (Subrecipients implemented 2010)
Research Performance Progress Report (RPPR) (January 2010)
Federal Financial Reporting (FFR) (2011)
OMB Subrecipient Monitoring
F&A Proposal Format (OMB A-21)
Federal Policy for the Protection of Human Subjects:
Federal-wide Assurance (2004), mandatory training
IRB Registration (2008)
Proposed Changes (2011, see below)
Title IX of Education Amendments of 1972: Access to science and math educational programs (2007+)
EPA Hazardous Waste, Subpart K (2008)
IRS 990 Reporting

¹ The Report is available at: www.cogr.edu/docs/COGRAAUTroublesomeClausesReport.pdf

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)
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, **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)

Significant Proposed Changes

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)
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)