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Regulatory Changes Since 1991

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COUNCIL ON GOVERNMENTAL RELATIONS

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Federal Regulatory Changes, Since 1991

*The regulations listed below have been implemented or amended since the imposition of the 26 per cent cap on administrative costs in the Facilities and Administrative Cost recovered under OMB Circular A-21. 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. **This list does not include the reporting requirements associated with the American Recovery and Reinvestment Act (ARRA) funding support.***

Federal Policy for the Protection of **Human Subjects (Common Rule)**, 1991)

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

NIH Guidelines for Research Involving **Recombinant DNA** Molecules (1994)

Deemed Exports (1994, EAR & ITAR)

DFARS Export Control Compliance Clauses (2010)

Conflicts of Interest

Public Health Service/NIH Objectivity in Research (1995; Amendments August 2012)

NSF Financial Disclosure Policy (1995)

Lobbying Disclosure Act of 1995 (Amended 2007; 2013)

Cost Accounting Standards (**CAS**) in OMB Circular A-21(1995)

Health Insurance Portability & Accountability Act of 1996 (**HIPAA**) Privacy Rule (Amendments January 2013)

OMB Elimination of **Utility Cost Studies** (UCA) (1998)

Data Access /**Shelby Amendment** (FY 1999 Omnibus Appropriations Act); related amendments to OMB Circular A-110

Policy on Sharing of **Biomedical Research Resources** (NIH, 1999)

Misconduct in Science (Federalwide 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

Health and Human Services/FDA **Clinical Trials Registry** (2000, Food and Drug Administration 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)

Select Agents & Toxins (under CDC and USDA/APHIS) Public Health Security & Bioterrorism Preparedness & Response Act of 2002; companion to the USA PATRIOT Act (2001); revised October 2012

FISMA Federal Information Security Management Act (Title III, E Government Act of 2002) OMB Circular A-130, Management of Federal Information Resources, Appendix III, **Security of Federal Automated Information Systems**

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

Data Sharing Policy (NIH, 2003)

Homeland Security Presidential Directive (**HSPD**) – **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)

Model Organism Sharing Policy (NIH, 2004)

Constitution & Citizenship Day (2005, Consolidated Appropriations Act FY 2005)

Genomic Inventions Best Practices (2005)

Office of Management & Budget **Guidance for Governmentwide Debarment and Suspension [Nonprocurement]** (2CFR Part 180, 2006) Consolidation of agencies' Governmentwide 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)

National Institutes of Health **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)

National Institutes of Health Policy for **Genome-Wide Association Studies** (GWAS, 2008)

Federal Funding Accountability and Transparency Act (**FFATA**) **Executive Compensation and Subrecipient 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)

National Institutes of Health **Guidelines for Human Stem Cell Research** (2009)

National Science Foundation **Post-Doctoral Fellows Mentoring** (America COMPETES Act 2006; implemented 2009)

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

National Science Foundation **Responsible Conduct of Research** Training (America COMPETES Act 2006; implemented 2010)

National Science Foundation **Public Outcomes Reporting** (America COMPETES Act 2006; implemented 2010)

Federal Acquisition Regulations (FAR) and Office of Management & Budget **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)

National Institutes of Health, **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)

Food and Drug Administration **Reporting Information Regarding Falsification of Data** (April 2012)

National Science Foundation **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)

Defense/DFAR **Safeguarding of Unclassified Controlled Technical Information** (November 2013)

OMB/COFAR **Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards** (December 2013)

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)

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

Federal Financial Reporting (FFR) (2011)
Subrecipient Monitoring (OMB Circular A-133, Compliance Supplement)
 Changes to A-21 **F&A Proposal Format**
 Federal Policy for the Protection of Human Subjects:
 Federalwide 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
 National Institutes of Health Trainee **Instruction in the Responsible Conduct of Research** (1989; 1994; Updated 2009)
 Health & Human Services, Office of Grants and Acquisition Policy and Accountability **Guidance Regarding Funding of Contracts Exceeding One Year of Performance** (APM 2010-01, June 2010)
 National Science Foundation, **Data Sharing Policy** (Updated 2011)
 National Institutes of Health Implementation of the 2011 8th Edition of the National Academy of Sciences **Guide for the Care and Use of Laboratory Animals** (January 2012)
Export Controls: Export Administration Regulations (EAR) & International Traffic in Arms Regulations (ITAR) Reform (2013 Implementation)
 Defense Federal Acquisition Regulations 252.204--**7000 Disclosure of Information** Clause Revised (2013)
 National Institutes of Health, **Costing of Core Facilities** (2013)
 National Institutes of Health Implementation of the American Veterinary Medical Association **Guidelines for Euthanasia**, 2013 Edition (2013)
 National Science Foundation **Award Cash Management Service** (2012)
 National Science Foundation Revised **Merit Review Criteria** (2013)
 National Institutes of Health **Payment Management System Sub-Accounts** (2013)
 OMB/COFAR **Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards** (December 2013)

Significant Proposed Changes

Food and Drug Administration **Requirements for an Investigative New Drug (IND)** covering food and plants claiming therapeutic benefit
 USDA **Animal Welfare Act, Contingency Planning** (2008)
 FAR **Organizational Conflicts of Interest** (NPRM April 2011)
 HHS Office for Human Research Protections **Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay and Ambiguity for Investigators**; proposed changes to 45 CFR 46 Subpart A (ANPRM, September 2011)
 FAR **Privacy Act Training** (Proposed 2011)
 OSTP **US Governmental Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern** (Proposed February 2013)
 National Institutes of Health **Genome Data Sharing Policy** (September, 2013)