

# Research Terms and Conditions

## Appendix C

### NATIONAL POLICY REQUIREMENTS MATRIX

This listing of statutory/regulatory/and executive requirements is provided for information purposes only, and may not reflect all requirements that are applicable to a specific award.

Statutory/Regulatory/and Executive Based Requirements		Used For:		Requirement(s) that should be noted by the recipient
National Policy Requirements Applicable to all research agencies:	Type of Award	Type of Recipient	Specific Situation	
<b>Environmental Standards</b>				
By signing the agreement or accepting funds under this agreement, the recipient assures that it will:				
a. Comply with applicable provisions of the Clean Air Act (42 U.S.C. 7401, et. Seq.) and Clean Water Act (33 U.S.C. 1251, et. seq.), as implemented by Executive Order 11738 [3 CFR, 1971-1975 Comp., p. 799]  EPA at 40 CFR Part 6	All	All	All, for Clean Air Act, Clean Water Act, and Executive Order 11738.	Requirements flow down to subrecipients
b. Identify to the awarding agency all impact this award may have on:				
1. The quality of the human environment, and provide help the agency may need to comply with the National Environmental Policy Act (NEPA, at 42 U.S.C. 4321, et. seq.) and to prepare Environmental Impact Statements or other required environmental documentation. In such cases, the recipient agrees to take no action that will have an adverse environmental impact (e.g., physical disturbance of a site such as breaking of ground) until the agency provides written notification of compliance with the environmental impact analysis process.  NSF at 45 CFR Part 640 DOE at 10 CFR Part 1021 EPA at 40 CFR Part 6 NASA at 14 CFR Part 1216 USDA at 7 CFR Part 3407	All	All	All actions that may affect the environment	
2. Flood-prone areas, and provide help the agency may need to comply with the National Flood Insurance Act of 1968 and Flood Disaster Protection Act of 1973 (42 U.S.C. 4001, et. seq.), which require flood insurance, when available, for Federally assisted construction or acquisition in flood-prone areas.  DOE at 10 CFR Part 1022	All	All	Awards involving construction, land acquisition or development, with some exceptions [see 42 U.S.C. 4001, et. seq.].	The Council on Environmental Quality's regulations for implementing NEPA are at 40 C.F.R. Parts 1500-1508. Executive Order 11514 [3 CFR, 1966-1970 Comp., p. 902], as amended by Executive Order 11991, sets policies and procedures for considering actions in the U.S. Executive Orders 11988 [3 CFR, 1977 Comp., p. 117] and 11990 [3 CFR, 1977 Comp., p. 121] specify additional considerations, when actions involve floodplains or wetlands, respectively.
3. Coastal barriers, and provide help the agency may need to comply with the Coastal Barriers Resource Act (16 U.S.C. 3501, et. seq.), concerning preservation of barrier resources.  EPA at 40 CFR Part 6	Grants, cooperative agreements, and other "financial assistance" (see 42 U.S.C. 4003).	All	Awards that may affect barriers along the Atlantic and Gulf coasts and Great Lakes' shores	42 U.S.C. 4012a prohibits awards for acquisition or construction in flood-prone areas (Federal Emergency Management Agency publishes lists of such areas in the Federal Register), unless recipient has required insurance. If action is in a floodplain, Executive Order 11988 [3 CFR, 1977 Comp., p. 117] specifies additional pre-award procedures for Federal agencies. Recipients are to apply requirements to subawards ("financial assistance," defined at 42 U.S.C. 4003, includes indirect Federal assistance).

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4. All existing or proposed component of the National Wild and Scenic Rivers system, and provide help the agency may need to comply with the Wild and Scenic Rivers Act of 1968 (16 U.S.C. 1271, et seq.).  EPA at 40 CFR Part 6	Grants, cooperative agreements, and other "financial assistance" (see 16 U.S.C. 3502).	All	Awards that may affect existing or proposed element of National Wild and Scenic Rivers system.	Requirements flow to subawards (16 U.S.C. 3502 includes indirect assistance as "financial assistance").
5. Underground sources of drinking water in areas that have an aquifer that is the sole or principal drinking water source, and provide help the agency may need to comply with the Safe Drinking Water Act (42 U.S.C. 300h-3).  EPA at 40 CFR Part 6	All	All	Construction in All area with aquifer that the EPA finds would create public health hazard, if contaminated.	42 U.S.C. 300h-3(e) precludes awards of Federal financial assistance for All project that the EPA administrator determines may contaminate a sole-source aquifer so as to threaten public health
<b>General/Miscellaneous Requirements</b>				
By signing or accepting funds under the agreement, the recipient agrees that will comply with the following general national policy requirements:				
<b>a. CCR Registration - 2 CFR Part 25</b>	All	Recipient only; does not apply to subrecipients		CCR registration must be renewed annually.
<b>b. Drug Free Workplace</b>  Public Law 100-690, Title V DOC at 15 CFR Part 29 EPA at 40 CFR Part 36 HHS at 45 CFR Part 82 NSF at 45 CFR Part 630 DoD at 32 CFR Part 26 USDA at 7 CFR Part 3021 DOE at 10 CFR Part 607 NASA at 14 CFR Part 1267	All	All		41 USC 701 et seq.
<b>c. DUNS number - 2 CFR Part 25</b>	All	Recipient and 1st tier subrecipient		DUNS number required at time of application
<b>d. False Claims Act Provisions</b>				
1. Civil False Claims Act	All	All	All	31 USC 2739
2. Criminal False Claims Act  18 USC 287 and 1001	All	All	All	18 USC 287 and 1001

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National Policy Requirements Applicable to all research agencies:	Type of Award	Type of Recipient	Specific Situation	
3. Program Fraud and Civil Remedies and False Claims Act  31 USC 3801, 45 CFR 79	All	All	All	31 USC 3801, 45 CFR 79
<b>e. Government-wide Debarment and Suspension (Nonprocurement)</b>  USDA at 2 CFR Part 417 NSF at 2 CFR Part 2520 HHS at 2 CFR Part 376 DOD at 2 CFR Part 1125 EPA at 2 CFR Part 1532 DOD at 2 CFR Part 1125 NASA at 2 CFR Part 1880 DOC at 2 CFR Part 1326	All	All		42 USC 1870 (a); Sec. 2455, PL 103-355, 108 Stat. 3327 (31 USC 6101 note); EO 12549 (3 CFR, 1986 Comp., p. 189); EO 12689 (3 CFR, 1989 Comp., p. 235)
<b>f. Lobbying Prohibitions 31 USC 1352</b> , stipulates that (1) No Federal appropriated funds have been paid or will be paid, any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement. (2) If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal grant or cooperative agreement, the undersigned shall complete and submit the SF Form LLL, "Disclosure of Lobbying Activities", in accordance with its instructions.  DOC at 15 CFR Part 28 NASA at 14 CFR Part 1271 NSF at 45 CFR Part 604 DoD 32 CFR Part 28 USDA at 7 CFR Part 3018 DOE at 10 CFR Part 601 EPA at 40 CFR Part 34 HHS at 45 CFR Part 93				31 USC 1352 requires the grantee to include certification language in the award documents for all subawards at all tiers, including subcontracts, subgrants,

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National Policy Requirements Applicable to all research agencies:	Type of Award	Type of Recipient	Specific Situation	
<p><b>g. Metric System</b></p> <p>15 USC 205 a-k and Executive Order 12770</p> <p>EPA at 40 CFR Part 30, Section 15</p>	All	All	All	15 CFR Part 19, Subpart B
<p><b>h. Misconduct in Science</b></p> <p>Policies and responsibilities associated with prevention, detection, and handling of misconduct in science allegations as stipulated in agency implementing regulations:</p> <p>USDA at 7 CFR Part 3022 NSF at 45 CFR Part 620 NASA at 14 CFR Part 1275 HHS at 42 CFR Part 93, Subpart A</p>	All	All	All	[Federal Register: December 6, 2000 (Volume 65, Number 235)] [Notices] [Page 76260-76264]
<p><b>i. National Historic Preservation</b></p> <p>The recipient agrees to identify to the awarding agency all property listed or eligible for listing on the National Register of Historic Places that will be affected by this award, and to provide all the help the awarding agency may need, with respect to the award.</p> <p>16 USC 470f EPA at 40 CFR Part 6, Section 204 (b)(4)</p>	All	All	All	
<p><b>j. Paperwork Reduction Act</b></p>	All	All	When data is collected from respondents using a questionnaire or other survey instrument. See, however, M-11-07 dated 12/9/10 entitled, "Facilitating Scientific Research by Streamlining the Paperwork Reduction Act Process."	Data collection activities, if any, performed under this project are the responsibility of the recipient, and awarding agency support of the project does not constitute approval of any survey design, questionnaire content, or data collection procedures. The recipient shall not represent to respondents that such data are being collected for or in association with the awarding agency without the specific written approval of the cognizant awarding agency official of such data collection plan or instrument. However, this requirement is not intended to preclude mention of awarding agency support of the project in response to an inquiry or acknowledgment of such support in any publication of these data.
<p><b>k. Transparency Act - FFATA Public Law 109-282</b></p>	All	All, including 1st tier subrecipients	Awards of 25K or more	Reporting grants and 1st tier subrecipients of 25K or more, and executive compensatio reporting of same; limited exceptions.

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National Policy Requirements Applicable to all research agencies:	Type of Award	Type of Recipient	Specific Situation	
I. U.S. Flag Air Carriers	All	All	Any air transportation to, from, between, or within a country other than the U.S. of persons or property, the expense of which will be assisted by Federal funding, must be performed by or under a code-sharing arrangement with a U.S.-flag air carrier if service provided by such a carrier is available (see Comp Gen. Decision B-240956, dated September 25, 1991).	49 USC 40118 See also General Services Administration amendment to the Federal Travel Regulations, Federal Register (Vol. 63, No. 219, 63417-63421)

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National Policy Requirements Applicable to all research agencies:	Type of Award	Type of Recipient	Specific Situation	
<p><b>m. Trafficking in Persons</b> By signing or accepting funds under the agreement, the recipient agrees that it will comply with Trafficking Victims Protection Act of 2000 (22 U.S.C. 7104(g)) as implemented by 2 CFR 175</p> <p>DOD at 2 CFR Part 180</p>	Grants and Cooperative Agreements and contracts	175.15(b)l.a. applies to private entities 175.15(b)l.b. applies to other than private entities if award includes subrecipient award to a private entity 117.15(b)l.c.applies to all recipients		<p>A. Associated with performance under this award; or B. Imputed to you or the subrecipient using the standards and due process for imputing the conduct of an individual to an organization that are provided in 2 CFR part 180, "OMB Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement)," as implemented by the agency in its regulatory implementation of the OMB guidelines in 2 CFR part 180.</p> <p>b. Provision applicable to a recipient other than a private entity. We as the Federal awarding agency may unilaterally terminate this award, without penalty, if a subrecipient that is a private entity--</p> <p>1. Is determined to have violated an applicable prohibition in paragraph a.1 of this award term; or 2. Has an employee who is determined by the agency official authorized to terminate the award to have violated an applicable prohibition in paragraph a.1 of this award term through conduct that is either-- i. Associated with performance under this award; or ii. Imputed to the subrecipient using the standards and due process for imputing the conduct of an individual to an organization that are provided in 2 CFR part 180, "OMB Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement)," as implemented by our agency .</p> <p>c. Provisions applicable to any recipient. 1. You must inform us immediately of any information you receive from any source alleging a violation of a prohibition in paragraph a.1 of this award term. 2. Our right to terminate unilaterally that is described in paragraph a.2 or b of this section: i. Implements section 106(g) of the Trafficking Victims Protection Act of 2000 (TVPA), as amended (22 U.S.C. 7104(g)), and ii. Is in addition to all other remedies for noncompliance that are available to us under this award. 3. You must include the requirements of paragraph a.1 of this award term in any subaward you make to a private entity.</p>
<p><b>Increasing Seat Belt Use in the United States Executive Order 13043</b>, Increasing Seat Belt Use in the United States, dated, April 16, 1997</p>	Grants and Cooperative Agreements	All		<p>In accordance with the Executive Order, "grantees are encouraged to adopt and enforce on-the-job seat belt policies and programs for their employees when operating company-owned, rented, or personally owned vehicles."</p>

### Health & Safety Guidelines

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National Policy Requirements Applicable to all research agencies:	Type of Award	Type of Recipient	Specific Situation	
By signing the agreement or accepting funds under this agreement, the recipient assures it will comply with the following requirements:				
1. Applicable OSHA Standards in Laboratories	All	All	Research involving use of hazardous chemicals or bloodborne pathogens	29 CFR 1910.1030 Bloodborne Pathogens; 29 CFR 1910.1450, Occupational Exposure to Hazardous Chemicals in Laboratories
2. Handling and transport of etiologic agents	All	All	Research involving etiologic agents	Procedures for Domestic Handling and Transport of Diagnostic Specimens and Etiologic Agents, 1994 (3rd ed.), H5a3doc.75, National Committee for Clinical Laboratory Standards
3. Biosafety standards in microbiological and biomedical laboratories	All	All	Microbiological and biomedical research	Biosafety in Microbiological and Biomedical Laboratories; 5th Edition <a href="http://www.cdc.gov/biosafety/publications/bmb15/index.htm">http://www.cdc.gov/biosafety/publications/bmb15/index.htm</a>
4. Controlled Substances	All	All	Research involving controlled substances	Drug Enforcement Administration (DEA) registration, inspection and certification
5. Disposal of high-level radioactive waste and spent nuclear fuel. Note however, that some States are exempt if they have established separate requirements.	All	All	Research involving radioactive waste and spent nuclear fuel	Nuclear Regulatory Commission Standard and Regulation, pursuant to the Energy Reorganization Act of 1974, (42 USC, 5801, et seq.)
6. Investigational New Drug Applications	All	All	All clinical trial investigations of products that are subject to section 505 or 507 of the Federal Food, Drug, and Cosmetic Act or to the licensing provisions of the PHS Act (58 Stat. 632, as amended (42 USC 201, et seq.)	Food and Drug Administration (FDA), 21 CFR parts 50 and 312
7. Hotel and Motel Fire Safety Act of 1990 - P.L. 101-39	Conference or meeting support	All	Alterations and Renovations > \$500,000	40 USC 327-333
7. Labor Standards under Federally Assisted Construction: Construction Work Hours and Safety Standards Act	All	All	Alterations and Renovations > \$500,000	40 USC 327-333
8. Text Messaging While Driving - EO 13513	All	All	When performing work for or on behalf of government	Adopt and enforce policies that ban text messaging while driving.
9. Increasing Seat Belt Use in the United States Executive Order 13043, Increasing Seat Belt Use in the United States, dated, April 16, 1997	Grants and Cooperative Agreements	All		In accordance with the Executive Order, "grantees are encouraged to adopt and enforce on-the-job seat belt policies and programs for their employees when operating company-owned, rented, or personally owned vehicles."
<b>Less Than Government-wide Applicability</b>				
<b>Acknowledgement of Federal Funding</b>	All	All	All	HHS Appropriations Language (subject to Annual change)
Applies to HHS awards only				

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National Policy Requirements Applicable to all research agencies:	Type of Award	Type of Recipient	Specific Situation	
<p><b>American-made equipment and products</b> Recent Appropriation Acts provide “It is the sense of the Congress that, to the greatest extent practicable, all equipment and products purchased with funds made available in this Act should be American-made...”</p> <p>Applies to NSF &amp; DOE awards only</p>				Acts making appropriations to NSF provide “It is the sense of the Congress that, to the greatest extent practicable, all equipment and products purchased with funds made available in this Act should be American-made” and require the Foundation to notify grantees of that statement.
<p><b>Ban on Funding of Human Embryo Research</b></p> <p>Applies to HHS awards only</p>	All	All	All	42 USC 289, 45 CFR, Part 46; HHS Appropriations Language
<p><b>Certification of Filing and Payment of Taxes</b> Applies to NIH awards only</p>	All	Recipients	All	NIH Appropriations Act language (subject to annual change)
<p><b>Clinicaltrials.gov</b></p> <p>Applies to HHS awards only</p>	All	All	Clinical trials	PL 110-85
<p><b>Compliance with Buy America Act</b></p> <p>The recipient agrees that in expending funds made available under the Interior and Related Agencies Act, the recipient will comply with sections 2 through 4 of the Act of March 3, 1933 (41 U. S. C. 10a-10c; popularly known as the “Buy American Act”).</p> <p>Applies to DOE awards only</p>	Any	Any	Awards with funds made available under the Department of Interior and Related Agencies Appropriations Act.	Department of Interior and Related Agencies Appropriations Act § 307(a) (subject to change)
<p><b>Confidentiality of Patient Records</b></p> <p>Applies to PHS awards only</p>	All	All	Research involving Human Subjects	PHS Act, Section 543 42 CFR 2
<p><b>Conflict of Interest (Financial Disclosure)</b> NSF: Requires each recipient to maintain an appropriate and enforced policy on conflict of interest consistent with the provisions of NSF Award &amp; Administration Guide Chapter IV.A (which also is published at 60 Federal Register 35820).</p> <p>HHS at 42 CFR Part 50, Subpart F</p> <p>Applies to DHHS/NSF awards only</p>	Grants and cooperative agreements	Applies to each grantee institution employing more than fifty persons.	All	Flowdown to subrecipients shall be as stipulated in agency implementation of the conflict of interest requirements
		All, except SBIR Phase I recipients		
<p><b>Delinquency on Federal Debt</b></p> <p>2 CFR Part 215.22(h)(2) HHS at 45 CFR Part 74.22(h)(2)</p>	All	All	All	Agency to withhold payment to recipient or subrecipient who is delinquent in a debt to the US as defined in OMB Circular A-29.



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National Policy Requirements Applicable to all research agencies:	Type of Award	Type of Recipient	Specific Situation	
<b>Federal Information System Security Management Act - Title III of the E-Government Act of 2002, PL 107-347</b> Applies to HHS and NIFA awards only	All	Recipient and subrecipients		Applicable only when grantees collect, store, process, transmit or use information on behalf of NIFA or HHS (or any of its component organizations).
<b>Limitation on use of funds for Promotion of legalization of controlled substances</b>  Applies to HHS awards only	All	All	All	HHS Appropriations Language (subject to annual change)
<b>Inclusion of Children as subjects in Clinical Research</b>  NIH awards only	All	All	Clinical research	NIH Guide, March 6, 1998  <a href="http://grants.nih.gov/grants/guide/notice-files/not98-024.html">http://grants.nih.gov/grants/guide/notice-files/not98-024.html</a>
<b>Inclusion of Women/Minorities as subjects in clinical research</b>  NIH awards only	All	All	Research involving human subjects	PL 103-42, NIH Guide, March 18, 1994  <a href="http://grants.nih.gov/grants/guide/1994/94.04.18/notice-nih-guidelines008.html">http://grants.nih.gov/grants/guide/1994/94.04.18/notice-nih-guidelines008.html</a>
<b>Lobbying Prohibitions</b>  45 CFR 93, HHS Appropriations Language DOE appropriations language at Energy and Water Development Appropriations Act § 601 and Interior and Related Agencies Appropriations Act § 303 (subject to change).  Special Appropriation Language applies to DOE, EPA, and HHS only	All	All	The recipient agrees that none of the funds obligated on the award shall be expended, directly or indirectly, to influence congressional action on any legislation or appropriation matters pending before Congress, other than to communicate to Member of Congress as described in 18 U.S.C. 1913. In addition, the recipient agrees that none of the funds obligated on the award shall be made available for any activity or the publication or distribution of literature that in any way tends to promote public support or opposition to any legislative proposal on which Congressional action is not complete.	
<b>Military Recruiters</b>  The provision shall be as specified at 32 CFR 22.520]  Applies to DOD & DHHS awards only	All	Domestic institution of higher education (see 32 CFR 22.520).	All	

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<b>Minority Business Enterprises/Women's Business Enterprises --</b> Requires all grantees doing research under the Clean Air Act to try to reach a 10 percent goal in awarding contracts for supplies, equipment, contracts, and construction to minority business enterprises/women's business enterprises.  EPA Awards Only EPA at 40 CFR Part 30, Section 16	Grants and cooperative agreements	All	Research under the Clean Air Act	Public Law 101-549
<b>Precollege Students and Experimental Curriculum Development Projects</b>  42 USC 1869 a. and b. NSF Awards Only	Grants and cooperative agreements	All	Research projects that involve pre-college students in research or development, pilot testing, evaluation or revision of, experimental or innovative curriculum development projects	NSF Award & Administration Guide Chapter VI.M.2  <a href="http://www.nsf.gov/pubs/policydocs/pappguide/nsf08_1/aag_6.jsp#VIM2">http://www.nsf.gov/pubs/policydocs/pappguide/nsf08_1/aag_6.jsp#VIM2</a>
<b>Prohibitions on the purchase or use of dogs or cats for certain medical training purposes, in Section 8019 (10 U.S.C. 2241 note) of the Department of Defense Appropriations Act, 1991 (Pub. Law 101-511).</b>  Applies to DOD awards only	All	All	Research involving medical training	
<b>Protection of Research Subjects' Identity</b>  PHS awards only	All	All	Research involving human subjects	PHS Act Section 301 (d)
<b>Public Access Policy</b>  Applies to NIH awards only	All	All	Publications arising from NIH support	Division F, Section 217 of Public Law 111-8  PIs must submit final peer-reviewed manuscript to NIH PubMed Central database
<b>Recombinant DNA Molecules</b>  All research that falls within the scope of the Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines) shall comply with the Guidelines, including All procedural requirements. See 59 FR Volume 598, No. 127, July 5, 1994, 34495-34547  Applies to NIH/NSF/USDA-CSREES awards only	All	All	Research involving recombinant DNA	
<b>Research of Transplantation of Fetal Tissue</b>  Applies to HHS awards only	All	All	All	PHS Act, 489A

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<b>Restriction on Abortions and Exceptions on Restrictions on Abortions</b>  Applies to HHS awards only	All	All	All	NIH Appropriations Act language (subject to annual change)
<b>Restriction on Distribution of Sterile Needles</b>  Applies to PHS awards only	All	All	All	NIH Appropriations Act language (subject to annual change)
<b>Restriction on Employment of Unauthorized Alien Workers</b>  Applies to HHS awards only	All	All	All	NIH Appropriations Act language (subject to annual change)
<b>Smoke-Free Workplace</b>  Occupational Safety Health Act of 1983  Applies to PHS awards only	All	All	All	
<b>The Solid Waste Disposal Act</b> , as amended, requires grantees to use recycled paper for all reports submitted to the Agency.  EPA Awards Only EPA at 40 CFR Part 30, Section 16		All	All	PL 89-272, as amended, and Executive Order 13101
<b>Training of Graduate Students for Doctoral Degrees</b>  Applies to NIH Awards only	D43, TU2, T15, T32, T37, T90, U2R, U90, U54, TL1	Institutions that receive institutional training grant awards or cooperative agreements for the doctoral training of graduate students	All	
<b>Utilization of Small Business Concerns</b>  Applies to EPA awards only  EPA at 40 CFR Part 33	All	All		PL 95-507
<b>Live Organisms</b>				
By signing or accepting funds under the agreement, the recipient assures that it will comply with applicable provisions of the following national policies concerning live organisms:				
a. For human subjects:				

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<p>1. For human subjects, the Common Federal Policy for the Protection of Human Subjects. Codified by the:</p> <p>DOC at 15 CFR Part 27            DHHS at 45 CFR Part 46            NSF at 45 CFR Part 690            NASA at 14 CFR Part 1230            DOE at 10 CFR Part 745            EPA at 40 CFR Parts 26 and 40            USDA at 7 CFR Part 1c</p>		All	Research, development, test, or evaluation involving live human subjects, with some exceptions [see agency implementations for exemptions.	Requirements flow down to subrecipients
<p>2. Human Stem Cell Research</p> <p>In accordance with the President's Executive Order 13505 of March 9, 2009, and July 30, 2009 Memorandum for the Heads of Executive Departments and Agencies. See NIH Guidelines for Human Stem Cell Research, July 7, 2009.</p> <p>Other regulations that may apply:            HHS Human Subjects Protection Regulation, 45 CFR Pt 46            FDA Regulations governing INDs or IDEs (Title 21 CFR Parts 312 or 812)            FDA IRB &amp; informed consent regulations (Title 21 CFR Parts 50 &amp; 56)            Research on Transplantation of Fetal Tissue (PHS Act 489A)</p>	As applicable	All	Research involving Human Stem Cells	<p>NIH Guidelines and Registry of cell lines meeting the Federal requirements are found at: <a href="http://stemcells.nih.gov/index.asp">http://stemcells.nih.gov/index.asp</a></p> <p>Other Federal, State or Local laws may also apply</p>
<p>3. P.L. 104-191 Health Insurance Portability and Accountability Act (HIPAA)</p> <p>45 CFR Part 160 and Subparts A and E of Part 164 Subpart C to be effective 4/20/2005 (Security)</p>	As applicable	Covered Entities	As applicable	Limits uses of protected health information (PHI) collected or maintained by researchers within a covered entity or access to PHI from a covered entity. Research uses do not require Business Associate Agreements (defined at 45 CFR part 164 504 (e)(1) between collaborating institutions. Guidance available at <a href="http://privacyruleandresearch.nih.gov/">http://privacyruleandresearch.nih.gov/</a>
b. For animals:	All	All		Requirements flow down to subrecipients

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### NATIONAL POLICY REQUIREMENTS MATRIX

This listing of statutory/regulatory/and executive requirements is provided for information purposes only, and may not reflect all requirements that are applicable to a specific award.

Statutory/Regulatory/and Executive Based Requirements		Used For:		Requirement(s) that should be noted by the recipient
National Policy Requirements Applicable to all research agencies:	Type of Award	Type of Recipient	Specific Situation	
1. Rules on animal acquisition, transport, care, handling, and use in: (i) 9 CFR Parts 1-4, Department of Agriculture rules that implement the Laboratory Animal Welfare Act of 1966 (7 US+A160C. 2131-2156). Public Health Service Agencies must follow requirements in the PHS Policy on Humane Care and Use of Laboratory Animals, which implements PL 99-158, Sec. 495. NASA requirements for animal welfare are set forth at 14 CFR Part 1232 EPA at 40 CFR Part 40. For USDA/CSREES, "In the case of domestic farm animals housed under farm conditions, the institution should adhere to the principles stated in the Guide for the Care and Use of Agricultural Animals in Agriculture and Teaching, Federation of Animal Science Societies, 1999."			Research, experimentation, or testing involving the use of animals USDA regulations exempt birds, most rats and mice bred for research, and farm animals used for agricultural research.	
2. Rules of the Departments of Interior (50 CFR Parts 10-24) and Commerce (50 CFR Parts 217-227) implementing laws and conventions on the taking, possession, transport, purchase, sale, export, or import of wildlife and plants, including the: Endangered Species Act of 1973 (16 U.S.C. 1531-1543); Marine Mammal Protection Act (16 U.S.C. 1361-1384); Lacey Act (18 U.S.C. 42); and Convention on International Trade in Endangered Species of Wild Fauna and Flora.	All	All	Activities which may involve or impact wildlife and plants.	
<b>National Security Guidelines</b>				
By signing the agreement or accepting funds under this agreement, the recipient assures it will comply with the following requirements:				

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Statutory/Regulatory/and Executive Based Requirements		Used For:		Requirement(s) that should be noted by the recipient
National Policy Requirements Applicable to all research agencies:	Type of Award	Type of Recipient	Specific Situation	
<p>1. Executive Order 13224, Blocking Property and Prohibiting Transactions with Persons who Commit, Threaten to Commit, or Support Terrorism, dated September 23, 2001. Executive Order 13224 gives the U.S. government a powerful tool to impede terrorist funding and is part of our national commitment to lead the international effort to bring a halt to the evil of terrorist activity. President Bush issued Executive Order 13224 pursuant to the authorities of the International Emergency Economic Powers Act (50 U.S.C. 1701 et seq.)(IEEPA), the National Emergencies Act (50 U.S.C. 1601 et seq.), section 5 of the United Nations Participation Act of 1945, as amended (22 U.S.C. 287c)(UNPA), and section 301 of title 3, United States Code.</p>			<p>In general terms, the Order provides a means by which to disrupt the financial support network for terrorists and terrorist organizations by authorizing the U.S. government to designate and block the assets of foreign individuals and entities that commit, or pose a significant risk of committing, acts of terrorism. In addition, because of the pervasiveness and expansiveness of the financial foundations of foreign terrorists, the Order authorizes the U.S. government to block the assets of individuals and entities that provide support, services, or assistance to, or otherwise associate with, terrorists and terrorist organizations designated under the Order, as well as their subsidiaries, front organizations, agents, and associates.</p>	

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Statutory/Regulatory/and Executive Based Requirements		Used For:		Requirement(s) that should be noted by the recipient
National Policy Requirements Applicable to all research agencies:	Type of Award	Type of Recipient	Specific Situation	
<p>2. Select Agents and Toxins</p> <p>P.L. 107-188: Public Health Security &amp; Bioterrorism Preparedness Response Act of 2002, Title II sections 201-231                      P.L. 107-56 The USA Patriot Act of 2001 Section 175b  <a href="http://www.cdc.gov/od/sap">www.cdc.gov/od/sap</a></p> <p>Codified by the: HHS at 42 CFR Pt 73                      USDA at 7 CFR 331 and 9 CFR 121</p> <p>See also 15 CFR Chapter 7 for Export Administration Regulations (EAR)  <a href="http://www.bxa.doc.gov">www.bxa.doc.gov</a> and 49 CFR Pts 171 - 180 for transportation requirements</p>	As applicable	All	Research with or storage of Select Agents and Toxins	<p>Institution must be registered with CDC and or USDA prior to beginning work with agents. Investigator must be licensed prior to beginning work. NIH Term of Award includes notice that registration must be complete before using NIH funds and that no funds may be used for Select Agent Research if certification is denied.</p> <p>USDA inserts a term indicating that the grantee has primary responsibility for complying with Title II of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Public Law 107-188, and the regulations promulgated thereunder in 7 CFR Part 331, 9 CFR Part 121, and 42 CFR Part 72. For guidance on a biosecurity plan that includes physical security of facilities and access controls to prevent unauthorized entries see Departmental Manual 9610-1, USDA Security Policies and Procedures for Biosafety Level-3 Facilities (available via <a href="http://www.usda.gov/directives/index.html">http://www.usda.gov/directives/index.html</a>)</p> <p>Other State and Local regulations may apply</p>
<p>3. Executive Order 13526 Classified National Security Information: prescribes a uniform system for classifying, safeguarding, and declassifying national security information, including information relating to defense against transnational terrorism.</p>				
<b>Nondiscrimination</b>				
<p>By signing or accepting funds under the agreement, the recipient agrees that it will comply with applicable provisions of the following, national policies prohibiting discrimination:</p>				
<p>a. On the basis of race, color, or national origin, in Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d, et seq.), as implemented by:</p> <p>DOD at 32 CFR Part 195                      NSF at 45 CFR Part 611                      NASA at 14 CFR Part 1250                      DOE at 10 CFR Part 1040                      EPA at 40 CFR Parts 7 and 12                      USDA at 7 CFR Part 15                      DOC at 15 CFR Part 8                      HHS at 45 CFR Part 80 &amp; 81</p>	Grants, cooperative agreements, and other financial assistance	All	All	<p>The following regulations require the recipient to flow down requirements to subrecipients.</p> <p>DOD at 32 CFR Part 195                      NSF at 45 CFR Part 611                      NASA at 14 CFR Part 1250                      DOE at 10 CFR Part 1040                      EPA at 40 CFR Parts 7 and 12                      USDA at 7 CFR Part 15                      DOC at 15 CFR Part 8                      HHS at 45 CFR Part 80 &amp; 81</p>
<p>b. On the basis of race, color, religion, sex, or national origin, in Executive Order 11246 [3 CFR, 1964-1965 Comp., p. 339], as implemented by Department of Labor regulations at 41 CFR Part 60.</p> <p>EPA at 40 CFR Parts 7 and 12</p>	Grants, cooperative agreements, and other prime awards defined at 40 CFR 60-1.3 as "Federally assisted construction contract."	All	Awards under which construction is to be done.	<p>41 CFR 60-1.4(b) prescribes a clause that recipients must include in federally assisted, construction awards and subawards [60-1.4(d) allows incorporation by reference]. This requirement also is at: 32 CFR 33.36(l) (3) and at paragraphs 1. of Appendices A to 32 CFR Part 32 and 32 CFR Part 34.</p>

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Statutory/Regulatory/and Executive Based Requirements		Used For:		Requirement(s) that should be noted by the recipient
National Policy Requirements Applicable to all research agencies:	Type of Award	Type of Recipient	Specific Situation	
<p>c. On the basis of sex or blindness, in Title IX of the Education Amendments of 1972 (20 U.S.C. 1681, et seq.).</p> <p>DOE at 10 CFR Part 1040            DOC at 15 CFR Part 8a            HHS at 45 CFR Part 86            NASA at 14 CFR Part 1253            EPA at 40 CFR Parts 7 and 12</p>	Grants, cooperative agreements, and other financial assistance included at 20 U.S.C. 1682.	Educational institution [for sex discrimination, excepts all Institution controlled by religious organization, when inconsistent with the organization's religious tenets].	All educational program or activity receiving Federal financial assistance.	
<p>d. On the basis of age, in the Age Discrimination Act of 1975 (42 U.S.C. 6101, et seq.), as implemented by Department of Health and Human Services regulations at 45 CFR part 90.</p> <p>NSF at 45 CFR Part 617            NASA at 14 CFR Part 1252            DOE at 10 CFR Part 1040            HHS at 45 CFR Part 90 &amp; 91            EPA at 40 CFR Parts 7 and 12            DOC at 15 CFR Part 20</p>	Grants, cooperative agreements, and other awards defined at 45 CFR 90.4 as "Federal financial assistance."	All	All	45 CFR 90.4 requires the recipient to flow down requirements to subrecipients [definition of "recipient" at 45 CFR 90.4 includes entities to which assistance is extended indirectly, through another recipient].
<p>e. On the basis of handicap, in:</p> <p>1. Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794), as implemented by Department of Justice regulations at 28 CFR Part 41 and</p> <p>DOC at 15 CFR Part 8b            DOD at 32 CFR Part 56            NSF at 45 CFR Part 605            NASA at 14 CFR Part 1251            DOE at 10 CFR Part 1040            EPA at 40 CFR Parts 7 and 12            USDA at 7 CFR Part 15b            HHS at 45 CFR Part 84 &amp; 85</p>	Grants, cooperative agreements, and other awards included in "Federal financial assistance"	All	All	Requirements flow down to subawards ["recipient," includes entities receiving assistance indirectly through other recipients].
<p>2. The Architectural Barriers Act of 1968 (42 U.S.C. 4151, et seq.).</p>	Grant or loan	All	Construction or alteration of buildings or facilities, except those restricted to use only by able-bodied uniformed personnel.	