NIAID Grants Policy and Management Training

Selected Grants Compliance Requirements – Including FCOI

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What are grantees responsible for?

- Safeguarding all assets
- Spending funds in accordance with the authorized purpose
- Developing and implementing systems to ensure proper stewardship of funds
  - Financial management systems
  - Procurement systems
  - Time and effort reporting systems
  - Monitoring activities
  - Adherence to terms and conditions of award
Tools and resources to help with award monitoring:

- NIH Grants Policy Statement (NIHGPS)
- NIH Guide to Grants and Contracts
- Notice of Award (NoA) terms and conditions
- The Grants Management contact in the FOA
- The named Grants Specialist in eRA for the individual award
Sign up for the LISTSERV for the NIH Guide for Grants and Contracts
Public policy requirements

- Many requirements are applicable to foreign organizations
- When an application is submitted, the Authorized Organization Representative assures that it will follow these requirements
- Found in the NIHGPS – Chapter 4: Public Policy Requirements
### Exhibit 4: Public Policy Requirements, Objectives and Appropriation Mandates *

<table>
<thead>
<tr>
<th>Requirement, Objective, or Appropriation Mandate</th>
<th>Grantee</th>
<th>Subaward/Consortium Participant</th>
<th>Contractor under Grant (routine goods/services)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acknowledgment of Federal Funding (Appropriation Mandate) 4.2.1</td>
<td>Y</td>
<td>Y</td>
<td>NA</td>
</tr>
<tr>
<td>Age Discrimination Act of 1975 4.1.2.4</td>
<td>(NA to foreign and international organizations)</td>
<td>(NA to foreign and international organizations)</td>
<td>(NA to foreign and international organizations)</td>
</tr>
<tr>
<td>Animal Welfare 4.1.1</td>
<td>Y</td>
<td>Y</td>
<td>NA</td>
</tr>
<tr>
<td>Architectural Barriers Act of 1968 10.10</td>
<td>(Construction grants and any grant involving major A&amp;R)</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Certificate of Confidentiality 4.1.3.1</td>
<td>Y</td>
<td>Y</td>
<td>NA</td>
</tr>
<tr>
<td>Certification of Filing and Payment of Taxes (Appropriation Mandate) 4.2.2</td>
<td>Y</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Civil Rights Act of 1954 (Title VI) 4.1.2.1</td>
<td>(NA to foreign and international organizations)</td>
<td>(NA to foreign and international organizations)</td>
<td>(NA to foreign and international organizations)</td>
</tr>
<tr>
<td>Clean Air and Clean Water Act 10.10</td>
<td>(Construction grants only); for contracts exceeding $100,000</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Clinical Trials.gov 4.1.3</td>
<td>Y</td>
<td>Y</td>
<td>NA</td>
</tr>
<tr>
<td>Coastal Zone Management Act of 1972 10.10</td>
<td>(Construction grants only)</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Confidentiality of Alcohol and Drug Abuse Patient/Client Records 4.1.4.2</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Conservation of Petroleum and Natural Gas (EO 12105) 10.10</td>
<td>(Construction grants only)</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Controlled Substances 4.1.5</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Copeland Act, when required by statute 10.10</td>
<td>(Construction grants only)</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Data and Safety Monitoring 4.1.15.6</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Davis-Bacon Act, when required by statute 10.10</td>
<td>(Construction grants only)</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Debarment and Suspension 4.1.5</td>
<td>(NA to certain foreign organizations)</td>
<td>(NA to certain foreign organizations)</td>
<td>If contract equals or exceeds $25,000 (NA to certain foreign organizations)</td>
</tr>
<tr>
<td>Dissemination of False or Deliberately Misleading Scientific Information (Appropriation Mandate) 4.2.3</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
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<tr>
<td>Drug-Free Workplace 4.1.7</td>
<td>Y</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Earthquake Hazards Reduction Act of 1977 and Seismic Safety of Federal and Federally Assisted or Regulated New Building Construction (EO 12699) 10.10</td>
<td>(Construction grants only)</td>
<td>Y</td>
<td>NA</td>
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<tr>
<td>Education Amendments of 1972 (Title IX) 4.1.2.2</td>
<td>(NA to foreign and international organizations)</td>
<td>(NA to foreign and international organizations)</td>
<td>(NA to foreign and international organizations)</td>
</tr>
</tbody>
</table>
Animal Welfare

- Animal defined as live, vertebrate animals
- Foreign grantees must provide the Office Laboratory Animal Welfare (OLAW) with an Animal Welfare Assurance for Foreign Institutions
- Institutional Care and Use Committee (IACUC) approval is not required; however, OLAW encourages use of the standards in the *Guide for the Care and Use of Laboratory Animals*
- Comply with all applicable laws, regulations for their country of jurisdiction
- Detailed information at: [http://grants.nih.gov/grants/foreign/animal_welfare.htm](http://grants.nih.gov/grants/foreign/animal_welfare.htm)
Human Subjects protections

- Institution required to have a Federal Wide Assurance (FWA)
- Annual review-approval of proposed activities by an Institutional Review Board (IRB)
- Human subjects education for all personnel involved with the design or conduct of human subjects research
- Comply with all local regulations
- Refer to: http://www.hhs.gov/ohrp/index.htm
Institutions engaged in human subjects research must have an FWA if

- The institution’s employees or agents intervene or interact with human subjects for research OR
- They obtain individually identifiable private information about human subjects for research OR
- The institution receives a direct NIH award, where all the activities involving human subjects are conducted by a subcontractor or collaborator
Financial Conflict of Interest (FCOI) Regulations

- 42 CFR Part 50 Subpart F (grants and cooperative agreements)

- 45 CFR Part 94 (contracts)

  Initial Regulation effective October 1, 1995

  Revised Final Rule published on August 25, 2011
Key FCOI Requirements

Institutional policies and procedures for compliance and for training Investigators

- Initial and annual FCOI Reports are provided to NIH through the eRA Commons module
  - Prior to the expenditure of funds
  - During the period of award within 60 days of identifying a new FCOI
  - Annually when the annual progress report or multiyear progress report is due or at time of extension
Key FCOI Definitions

- **Significant Financial Interest (SFI)**
  - Minimum threshold of $5,000 generally applies to payments and equity interests.
  - Includes any equity interest in non-publicly traded entities.
  - Exclusions include income from seminars, lectures, or teaching, and service on advisory or review panels for government agencies, Institutions of higher education, academic teaching hospitals, medical centers, or research institutes affiliated with an Institution of higher education.
  - Excludes income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.

- **Investigator Disclosure**
  - All SFIs related to Investigators’ institutional responsibilities.
  - Institutions responsible for determining whether SFIs relate to PHS-funded research and are financial conflicts of interest (FCOI).
Public Access

All investigators funded by the NIH submit or have submitted for them to the National Library of Medicine’s PubMed Central an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication

http://publicaccess.nih.gov
Non-competing continuation awards

- Awards will be placed on hold until grantees have demonstrated compliance with the public access policy.
- Use of My NCBI will be required to report papers, when electronically submitting progress reports using the Research Performance Progress Report (RPPR).
- PDF report generated from My NCBI will be required, when submitting paper progress reports using the form PHS 2590 (replaces publication section).
What is My NCBI?

A tool integrated with PubMed to track literature searches, collections of citations, and public access compliance. Key features include:

- Can be linked to eRA Commons accounts
- Commons linked users can associate publications with NIH grants
- Tracks NIH Public Access compliance
- The only way to enter publications into RPPR
- Creates the publications section (Section E) of PHS 2590s
Audit Requirements

All NIH Grantees that expend $750,000 or more within a year in Federal awards are subject to an audit requirement.

- Audits are due within the earlier of 30 days after receipt of the auditor’s report(s) or 9 months after the end of the grantee’s audit period.
- Grantees delinquent in submitting audits risk the imposition of sanctions and potential loss of Federal funds.
FFATA Reporting

- Notice of Award (NOA) term indicates if FFATA reporting is required
- Federal Award Identification Number (FAIN) is included in NOA
- Reports submitted at https://www.fsrs.gov/#top
- Contact the Federal Service Desk for help
- Email GrantsPolicy@nih.gov with NIH questions
- Additional information at NOT-OD-12-010,
  NOT-OD-11-005, and NOT-OD-11-006
Grantee awarded a federal grant are required to file a FFATA sub-award report by the end of the month following the month in which the prime awardee awards any sub-grant equal to or greater than $25,000. The reporting requirements are as follows:

- This requirement is for both mandatory and discretionary grants awarded on or after October 1, 2010.
- All sub-award information must be reported by the prime awardee.
- For those new Federal grants as of October 1, 2010, if the initial award is equal to or over $25,000, reporting of sub-award and executive compensation data is required.
- If the initial award is below $25,000 but subsequent grant modifications result in a total award equal to or over $25,000, the award will be subject to the reporting requirements, as of the date the award exceeds $25,000.
- If the initial award equals or exceeds $25,000 but funding is subsequently de-obligated such that the total award amount falls below $25,000, the award continues to be subject to the reporting requirements of the Transparency Act and this Guidance.
The Total Compensation and Names of the top five executives if:
- More than 80% of annual gross revenues from the Federal government, and those revenues are greater than $25M annually

The following data about sub-awards greater than $25K:
- Name of entity receiving award
- Amount of award
- Funding agency
- CFDA program number for grants
- Program source
- Award title descriptive of the purpose of the funding action
- Location of the entity (including congressional district)
- Place of performance (including congressional district)
- Unique identifier of the entity and its parent
- Total compensation and names of top five executives (same thresholds as for primes)
Closeout - Final Reports

- Failure to submit timely reports may affect future funding to the organization.
- Documents are due within 120 days of project period end date:
  - Final Federal Financial Report (FFR) SF-425 Expenditure Data (submitted through eRA Commons)
  - Final Inventions Statement & Certification
  - Final Progress Report
- Grantees must ensure there are no discrepancies between the final FFR expenditure data (in eRA Commons) and the FFR cash transaction data in the Payment Management System.
Questions?