

NIAID Post Award Grants Policy and Management Training

**Subcontracting Under NIH Grants
NIH Expectations**



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Allergy and
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OVERVIEW

- Definition of a Grantee
- Definition of a Subcontract/Consortium
- Consortium versus Fee for Service
- Roles and Responsibilities of the Parent or Primary Grantee
- Roles and Responsibilities of Subcontract/Consortium
- Subcontract/Consortium Agreements

What is a Grantee?

- The organization or individual awarded a grant or cooperative agreement by NIH that is
 - Responsible and accountable for the use of the funds provided, by all parties, and for the performance of the grant-supported project or activity
 - All other obligations as specified in the NIH GPS.
 - The grantee is the sole direct legal entity even if a particular component is designated in NoA.
 - The grantee is legally responsible and accountable to NIH for the performance and financial aspects of the grant-supported project or activity.
 - Also known as Awardee or Recipient.

What is a Consortium?

A collaborative arrangement between the primary or parent Grantee institution and one or more other institutions or organizations where a portion of the programmatic or scientific activity of the research is carried out at the subawardee organization.

The involvement of the collaborating institution is that of actually performing a portion of the programmatic activity of the grant.

CONSORTIUM

VS.

**FEE-FOR-SERVICE
CONTRACT**

CONSORTIUM VS. FEE-FOR-SERVICE CONTRACT

■ Consortium/Subcontract:

- The consortium carries out grant supported programmatic (scientific) activity.
- The consortium investigator provides scientific input which could affect the direction of the project.
- The consortium research makes an intellectual contribution to the project aims.
- Consortium work is both scientific and administrative
- Parent grantee closely monitors activities at the consortium institution.

CONSORTIUM VS. FEE-FOR-SERVICE CONTRACT

- **Fee for Service Contracts** are used to provide a routine service to the grantee such as equipment fabrication or repair, data processing, routine analytical testing services, or management services. The service is not a programmatic activity.

ROLES AND RESPONSIBILITIES OF THE PARENT GRANTEE

ROLES OF THE PARENT GRANTEE

The grantee, as the direct and primary recipient of NIH grant funds, is accountable for the following:

- The performance of the project.
- The appropriate expenditure of grant funds by all parties.
- Reporting requirements and all other obligations of the grantee as specified in the NIHGPS.

ROLES OF THE PARENT GRANTEE

- Award made to a single primary organization that is **legally** responsible for all research and activities performed under the grant.
- The primary grantee must have written policies in place that address agreements with consortium participants, purchase services, and consultants. Those written policies must include procedures for monitoring and reporting requirements for all parties involved in the grant.
- As the recipient of Federal funds, the Grantee is responsible for the timely and appropriate disbursement of funds to all consortium participants and consultants in order to keep research activities running smoothly.

ROLES OF THE PARENT GRANTEE

The Grantee:

- Must have a formal written consortium agreement with EACH consortium participant
- Must perform a substantive role in the conduct of the planned research
- Does not serve as only a vehicle for getting funds to another party.
- NIAID does not allow third tier subcontracts!

RESPONSIBILITIES OF THE PARENT GRANTEE

- Has the responsibility for ensuring that all required assurances are obtained:
 - Human subjects: responsible for ensuring that all sites engaged in human subjects research have a Federal Wide Assurance (FWA) and IRB/IEC approval of the research consistent with 45 CFR Part 46
 - Ensure all human subject education documentation requirements are met (see <http://www.hhs.gov/ohrp/>)
 - Vertebrate Animals: ensure that all sites engaged in research involving the use of live, vertebrate animals have an appropriate Animal Welfare Assurance (AWA)
<http://grants.nih.gov/grants/olaw/olaw.htm>

RESPONSIBILITIES OF THE PARENT GRANTEE

- Grantee submits all administrative requirements/ documentation for all components to NIH, for example, the Progress Report and annual FFR.
- Responsible for all changes in regards to the project and budget for all components.
 - responsible for obtaining prior approval from NIH for any subcontract changes that may represent a change in scope of the project or a change of project aims, the addition or change of collaborators/subcontractors and in all cases involving the addition of a new foreign component.

RESPONSIBILITIES OF THE PARENT GRANTEE

- Audit Requirements
- Ensure consortium participants (foreign and domestic) comply with the requirements of the Uniform Administrative Requirements, 45 CFR Part 75 Subpart F
 - Two options – 45 CFR 74.26 (d) “Yellowbook Audit” or the OMB Circular A-133 Audit
 - <http://www.gao.gov/govaud/ybk01.htm>
 - <http://www.whitehouse.gov/OMB/circulars/a133/a133.html>

If a consortium participant meets the audit requirement threshold of receiving \$750,000 total Federal funds, an audit is required.

POST AWARD ACTIVITIES FOR THE PARENT GRANTEE

- Develop and implement written consortium agreement
- Obtain banking details
- Develop schedule of payments
- Set up performance monitoring system – regular meetings, scientific review committee

POST-AWARD ACTIVITIES FOR THE PARENT GRANTEE

- Set up necessary systems to ensure timely submission of required reports:
 - Progress reports due to NIH 60 days before the next budget period start date begins (45 days for grants that fall under the Streamlined Non-Competing Application Procedures)
 - Annual FFRs (when applicable) due to NIH 90 days after end of calendar quarter in which budget period ends
 - Final FFRs due 120 days after end of project period.

REQUIREMENTS FOR THE CONSORTIUM PARTICIPANT

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The Consortium Participant:

- Must enter into a **formal written consortium agreement** with the parent grantee.
- Must adhere to the Government-wide **cost principles and NIH cost policies.**
- Expenditures must conform to the requirements of **allowable and unallowable** costs.
- Must have their funding and payment information reflected in a **formal written agreement.**

POLICY REQUIREMENTS

Foreign consortium participants under NIH grants must adhere to the public policy requirements set forth in the NIH Grants Policy Statement. In addition, they must have assurances filed with NIH that cover the activities within the subcontract in relation to the project. These requirements must be part of the formal written subcontract agreement. Some of the requirements are below:

- ~ Human Subjects
- ~ Research Misconduct
- ~ Animal Subjects
- ~ Inclusiveness in Research Design
- ~ Non-Delinquency Federal Debt
- ~ Lobbying
- ~ Drug-free workplace
- ~ Financial Conflict of Interest
- ~ Debarment and Suspension*

* apply to all except for foreign government or public international orgs

REQUIREMENTS FOR THE CONSORTIUM PARTICIPANT

- If engaged in human subjects research:
 - Must have a Federal Wide Assurance (FWA) if engaged and IRB/IEC approval of the proposed research consistent with 45 CFR part 46.
<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>
 - Must satisfy the requirements for Education on the Protection of Human Subjects for any key personnel involved in human subject work
- If engaged in animal subjects research:
 - Must have an appropriate Animal Welfare Assurance.
<http://grants.nih.gov/grants/olaw/olaw.htm>

REQUIREMENTS FOR THE CONSORTIUM PARTICIPANT

- Post award activities for consortium participants
 - Participate in development and execution of consortium agreement
 - Submit invoices to parent grant on time for review and approval
 - Communicate regularly with parent grant to discuss progress, issues or concerns, prior approval requests, questions, etc.



CONSORTIUM AGREEMENT

CONSORTIUM AGREEMENT

- The grantee must enter into a **formal written agreement** with each consortium participant organization. This agreement must be negotiated in accordance with NIH Grants Policy requirements and should address the following:
 - **FAIN number**
 - **Name of PI and individuals responsible for the research activity at consortium organization**
 - When multiple PD/PIs are involved at different organizations, only the Contact PD/PI is required to have an official relationship with the applicant organization.
 - Procedures for directing and monitoring the research effort
 - Procedures for reimbursement of costs – invoice methods and deadlines, etc.
 - **Cost considerations** – applicable government-wide and NIH cost principles
 - **Cost reimbursement issues:** exchange rate fluctuation and invoicing methods
 - **Specific Cost item policies** to be followed (e.g., travel, salary)

CONSORTIUM AGREEMENT

- Formal agreement requirements (continued):
 - Requirements and provisions for compliance with the **Conflict of Interest** policy
 - Provisions related to **ownership and disposition of data** produced
 - Provisions related to **Inventions and Patent policy** applicable
 - Provisions related to authorship-and co-authorship on publications
 - As applicable, provisions regarding property, program income, publications, reporting and audits
 - Provisions regarding compliance with the requirements for a DUNS number and subrecipient reporting under FFATA
 - Incorporation of applicable public policy requirements

Exhibit 4: Public Policy Requirements, Objectives and Appropriation Mandates *

| Requirement, Objective, or Appropriation Mandate | Grantee | Subaward/Consortium Participant | Contractor under Grant (routine goods/services) |
|---|--|--|---|
| Acknowledgment of Federal Funding (Appropriation Mandate) 4.2.1 | Y | Y | NA |
| Age Discrimination Act of 1975 4.1.2.4 | Y (NA to foreign and international organizations) | Y (NA to foreign and international organizations) | Y (NA to foreign and international organizations) |
| Animal Welfare 4.1.1 | Y | Y | Y |
| Architectural Barriers Act of 1968 10.10 | Y (Construction grants and any grant involving major A&R) | Y | Y |
| Certificates of Confidentiality 4.1.4.1 | Y | Y | Y |
| Certification of Filing and Payment of Taxes (Appropriation Mandate) 4.2.2 | Y | NA | NA |
| Civil Rights Act of 1964 (Title VI) 4.1.2.1 | Y (NA to foreign and international organizations) | Y (NA to foreign and international organizations) | Y (NA to foreign and international organizations) |
| Clean Air and Clean Water Act 10.10 | Y (Construction grants only); for contracts exceeding \$100,000 | Y | Y |
| Clinical Trials.gov 4.1.3 | Y | Y | NA |
| Coastal Zone Management Act of 1972 10.10 | Y (Construction grants only) | Y | Y |
| Confidentiality of Alcohol and Drug Abuse Patient/Client Records 4.1.4.2 | Y | Y | Y |
| Conservation of Petroleum and Natural Gas (EO 12185) 10.10 | Y (Construction grants only) | Y | Y |
| Controlled Substances 4.1.5 | Y | Y | Y |
| Copeland Act, when required by statute 10.10 | Y (Construction grants only) | Y | Y |
| Data and Safety Monitoring 4.1.15.6 | Y | Y | Y |
| Davis-Bacon Act, when required by statute 10.10 | Y (Construction grants only) | Y | Y |
| Debarment and Suspension 4.1.6 | Y (NA to certain foreign organizations) | Y (NA to certain foreign organizations) | Y If contract equals or exceeds \$25,000 (NA to certain foreign organizations) |
| Dissemination of False or Deliberately Misleading Scientific Information (Appropriation Mandate) 4.2.3 | Y | Y | Y |
| Drug-Free Workplace 4.1.7 | Y | NA | NA |
| Earthquake Hazards Reduction Act of 1977 and Seismic Safety of Federal and Federally Assisted or Regulated New Building Construction (EO 12699) 10.10 | Y (Construction grants only) | Y | NA |
| Education Amendments of 1972 (Title IX) 4.1.2.2 | Y (NA to foreign and international organizations) | Y (NA to foreign and international organizations) | Y (NA to foreign and international organizations) |

CONSORTIUM POLICY REQUIREMENTS

Foreign consortia under NIH grants must also adhere to the public policy requirements set forth in the NIH Grants Policy Statement. For example, they must have the required Assurances filed with NIH that cover the human or animal activities within the subcontract in relation to the project. These policy requirements must be part of the formal written subcontract agreement. Some of the requirements are below:

- ~ Human Subjects
- ~ Research Misconduct
- ~ Animal Subjects
- ~ Inclusiveness in Research Design
- ~ Non-Delinquency Federal Debt
- ~ Lobbying
- ~ Drug-free workplace
- ~ Debarment and Suspension***
- ~ Financial Conflict of Interest
- ~ Inventions and Patents

*** apply to all except for foreign public international organizations

CONSORTIUM AGREEMENT

- Sample Agreement - http://sites.nationalacademies.org/PGA/fdp/PGA_063626
- When a Grantee submits and signs an application for funding, through their authorized business official, they are certifying that they and any subawardee under the grant are going to comply with these rules and regulations.
- Consortium Agreement must be clear and complete on these compliance expectations.
- Communication is important in order to have a smooth and orderly arrangement.

CONSORTIUM AGREEMENT

■ Applicability of this Agreement

- Only applies to the individual project and identified parties with that project.
- Separate consortium agreement formulated for EACH separate consortium arrangement
 - If two parties collaborate on more than one grant - separate subcontract agreements must be generated in relation to each separate grant
 - If grant has more than one subcontract on a grant to different institutions, a subcontract agreement must be formulated for each subcontract
- Most grants – 1 subcontract per institution.
- Revise existing subcontract agreement if additional scientific research added to existing consortium relationship.

IMPORTANT LINKS

- National Institutes of Health - Grants Policy Statement
 - Foreign:
http://grants.nih.gov/grants/policy/nihgps_2012/nihgps_ch16.htm#_Toc271265275
 - Consortium Agreements:
http://grants.nih.gov/grants/policy/nihgps_2012/nihgps_ch15.htm#_Toc271265264
 - Public Policy Requirements:
http://grants.nih.gov/grants/policy/nihgps_2012/nihgps_ch4.htm#public_policy_requirements_other_mandates
- Sample consortium Agreement -
http://sites.nationalacademies.org/PGA/fdp/PGA_063626
- OMB Circulars: http://www.whitehouse.gov/omb/circulars_default
- OLAW: <http://grants.nih.gov/grants/olaw/olaw.htm>
- OHRP: <http://www.hhs.gov/ohrp/>
- Intellectual Property: <http://grants.nih.gov/grants/intell-property.htm>
- A-110: http://www.whitehouse.gov/omb/circulars_a110