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SEE ORA WEBSITE FOR ORA AND SPONSOR FORMS
I.  ORA STAFF DIRECTORY

Vice President for Research  Joseph Waner, Ph.D.  271-1083

Assistant to the VP for Research Sheri Melton  271-1083

Executive Director, Research Administration Patricia A. Benton, PhD  271-2090

Associate Director, Research Administration Lisa C. Asch, MS, MPH  271-2090

FAX Numbers

ORA  271-8651
VP Research  271-8655

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Kasie Nichols  271-2090
Crystal Keene  271-2090

Grants

Proposal Preparation, Modifications, and Legal Review Adrienne Blalack  271-2090
Danielle Luper  271-2090
Aimee Van Wagoner  271-2090
Lynn Whitby  271-2090

Service Agreements

Preparation, Modifications, Legal Review and Negotiation Joy Johnson  271-2090
Angela Hawpe  271-2090

OTHER IMPORTANT CONTACTS

Environmental Health and Safety Office
http://w3.ouhsc.edu/ehso/

Grants and Contracts Accounting
http://www.ouhsc.edu/financialservices/GC/Grants.asp

IACUC – Institutional Animal Care and Use Committee, Laboratory Animals
http://www.ouhsc.edu/iacuc/

IBC – Institutional Biosafety Committee, Recombinant DNA, Microorganisms and Biological Toxins
http://www.ouhsc.edu/ibc/

IRB – Institutional Review Board, Human Subjects Research
http://www.ouhsc.edu/irb/

Office of Compliance
http://www.ouhsc.edu/compliance/

Office of Technology Development
http://otd.ou.edu/
<table>
<thead>
<tr>
<th>Name</th>
<th>Email</th>
</tr>
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<tbody>
<tr>
<td>ASCH, Lisa</td>
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<tr>
<td>BENTON, Patricia</td>
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<td>HIGBY, Linda</td>
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<td>JONES, Mitzi</td>
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<td>KEENE, Crystal</td>
<td><a href="mailto:crystal-keene@oushc.edu">crystal-keene@oushc.edu</a></td>
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<tr>
<td>LUPER, Danielle</td>
<td><a href="mailto:danielle-luper@ouhsc.edu">danielle-luper@ouhsc.edu</a></td>
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<tr>
<td>MELTON, Sheri</td>
<td><a href="mailto:sheri-melton@ouhsc.edu">sheri-melton@ouhsc.edu</a></td>
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<tr>
<td>NICHOLS, Kasie</td>
<td><a href="mailto:kasie-nichols@ouhsc.edu">kasie-nichols@ouhsc.edu</a></td>
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<td>TYRELL, Nicole</td>
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<tr>
<td>VANWAGONER, Aimee</td>
<td><a href="mailto:aimee-vanwagoner@ouhsc.edu">aimee-vanwagoner@ouhsc.edu</a></td>
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<tr>
<td>WANER, Joseph</td>
<td><a href="mailto:joseph-waner@ouhsc.edu">joseph-waner@ouhsc.edu</a></td>
</tr>
<tr>
<td>WHITBY, Lynn</td>
<td><a href="mailto:lynn-whitby@ouhsc.edu">lynn-whitby@ouhsc.edu</a></td>
</tr>
</tbody>
</table>
II. ORA MISSION AND SERVICES

MISSION:

The Office of Research Administration (ORA) serves as a central resource to faculty and staff for all aspects of research and for processing service contracts. The office provides information regarding funding sources, assistance in the submission of proposals to external sponsors, review of budgets and other form pages for compliance with University, federal, state and sponsor requirements, and negotiation of research and service contracts. ORA reviews, negotiates, and executes all basic research, clinical research, public service, professional service, provider, and affiliation agreements. ORA serves as the institutional liaison with external agencies and organizations on all research administration and service contract matters. ORA has Institutional signature authority for submission of grants and execution of research and service-related contracts.

SERVICES:

Research Grants and Contracts

Pre-Award

- Assistance with Proposal Preparation (non-technical)
- Proposal Review for Sponsor and University Compliance
- Review and Approval of All Proposal Budgets (Paper and Electronic) Prior to Submission to Prospective Funding Agencies
- Review and Assistance with Sponsor Certifications and Business Plans
- Obtain Legal Review of Grant and Contract Terms and Conditions
- Preparation of Institutional Approval Letters for Sponsors
- Preparation of Letters of Intent for Subcontracts
- Assist in Obtaining Approvals/Signatures from Affiliated Institutions
- Negotiation of Contract Terms with Sponsors
- Transfer of Incoming Grants

Post-Award

- New Award and Renewal Receipt and Processing
- Coordinate C account Set Up with Grants and Contracts Accounting
- Rebudget Approvals (IPAS form)
- Subcontract Preparation and Execution
• Preparation and Execution of Subagreements on Grants and Contracts
• No-Cost Extension Requests
• Supplement Application Review and Signature
• Carry Forward Requests
• Compliance Monitoring
• Amendment Preparation and Execution
• Contract Modification Review and Approval
• Award Reporting
• Transfer of Outgoing Grants (when PI leaves University)

Industry-Sponsored Contracts/Agreements
 • Contract Preparation, Review and Negotiation
 • Obtain Legal Review
 • Contract Extensions and Modifications

Service Contracts
 Obtain Legal Review, Negotiate, and Execute:
 • Affiliation Agreements
 • Professional Service Agreements
 • Public Service Agreements
 • Provider Agreements

Other Contracts & Agreements
 Obtain Legal Review, Negotiate, and Execute:
 • Material Transfer Agreements
 • Software License Agreements (w/o cost)

Funding Information
 • Sponsored Funding Information Collection and Dissemination
 • ORA Home Page: http://w3.ouhsc.edu/ORA
 • Community of Science: http://www.cos.com
III. SPONSORED RESEARCH GRANTS

A. PRE-AWARD PROCESS

1. Funding Opportunities
The Office of Research Administration (ORA) aids faculty and staff in identifying potential external sources for research and training funding, and in gathering additional program information necessary or helpful for application preparation. ORA fulfills this mission with the following resources:

a. ORA Website:  http://w3.ouhsc.edu/ORA

b. Community of Science:  www.cos.com

Community of Science (COS) is the leading Internet site for the global R&D community. COS offers scientists, scholars, and R&D professionals direct access to the information, people, and technologies that they need to succeed.

COS members depend on COS Web-based products and services to promote their work, find funding, access experts, consult, and collaborate with colleagues. Researchers rely on COS to help them stay current on research activities, news and publications; track funded research; and purchase supplies and services that are relevant to their work. COS services include:

- **COS Funding Opportunities** – updated daily, this database contains more than 22,000 records, representing over 400,000 funding opportunities, worth over $33 billion. Subscribers with Expertise profiles receive a weekly Funding Alert customized to their area of expertise.
- **COS Expertise** – a knowledge management service, this database contains more than 480,000 first-person profiles of scholars from over 1300 institutions worldwide. Creating a profile takes only a little time and gives a highly visible vehicle to promote experience and research interests.
- **COS Funded Research** – enables members to research and track information on active research projects funded by NIH, NSF, USDA, SBIR, and the Medical Research Council of the UK.
- **COS Quick Form for Online CV** – enables members to generate a personalized CV using information from their COS Expertise profile.
- **COS Quick Form for PHS 398 Biographical Sketch for NIH** – enables members to easily create the Biosketch form when submitting proposals to NIH.
- **COS Workbench** – a customized Web “work space” based on details in the COS Expertise profile, the Workbench platform provides access to numerous databases and services available from COS.
- **FedBizOpps/Commerce Business Daily** – updated daily, this database contains current notices of proposed government procurement actions, contract awards, sales of government property, and other procurement information over $25,000 as issued by the U.S Government Printing Office.
- **Federal Register** – updated daily, this database contains current notices from the Federal Register, a government publication of Federal notices and meetings.
• **U.S. Patents** – a comprehensive bibliographic database containing records for each of the 2.6 million U.S. patents issued since 1975.
• **Meetings and Conferences** – enables members to keep track of upcoming conferences and Calls for Papers.

c. **Acquisition** of guidelines and application forms for specific programs as requested.

d. **Funding announcements** via ORA Newsletter via email regarding agency, institution and foundation funding opportunities and upcoming deadlines.

e. **Links to additional resources material are available through ORA home page**

   NIH Guide to Grants and Contracts
   Federal Register
   Commerce Business Daily
   Federal Funding Sources
   Non-Federal Funding Sources
2. Proposal Preparation and Routing

These guidelines are applicable for ALL grant applications, including electronic grant submissions.

In order to better serve each investigator, it is preferable for the Principal Investigator to submit his/her budget and form pages to ORA for review as early in the proposal writing process as possible. We gladly receive faxed or e-mailed copies to review and assist with Sponsor guidelines for submission. Keep in mind: At deadline time, there will be several proposals in ORA for review at the same time and we want to be able to process your grant as efficiently as possible.

Required Procedure for Routing Grants
All grant applications, including new, continuation, supplements, and competing renewals must be routed through the Office of Research Administration for review and signature, including hard copy and electronic submissions. This includes applications for which OUHSC will be the prime awardee as well applications for which OUHSC will be a subcontractor to another institution. Please see Appendix I for the University’s required procedures for routing and approval of grants and contracts. These guidelines specify that all grants must be routed through the Office of Research Administration prior to submission to the funding agency.

Routing Forms
An ORA Routing Form is required to accompany all proposals. It provides important information regarding the application, ensures compliance with institutional and sponsor requirements for submission of the application, and provides for necessary institutional signatures.

a) For Sponsored Research and Training use the Grant and Sponsored Programs Routing Form:

b) For Industry Sponsored Research and Clinical Trials (see Section V) use the Industry-Sponsored Research Routing Form

c) For Professional Service, Provider, and Affiliation agreements use the Service Contract Routing Form

Always use the most current version found on the ORA website.

Proposal Review
ORA staff review all form pages of proposal applications to insure institutional compliance with federal, state, and sponsor regulations prior to obtaining the appropriate institutional signature(s). Technical pages are not required for review by ORA. Please fax, email, or deliver the form proposal pages to the appropriate Sponsored Programs Administrator (SPA) for review prior to submitting your proposal for signature. This will help ensure that institutional signature(s) are obtained by the sponsor deadline.

ORA will review the proposal for the following:
1. Accuracy of institutional information
2. Use of current fringe benefit rate
3. Use of current F&A rate
4. Accuracy of budget and F&A calculations
5. Allowability of budgeted costs
6. Completeness of budget justification
7. Proper formatting, per Sponsor guidelines
8. Inclusion of all required form & certification pages
9. Inclusion of required letters of intent and letters of support
10. Required institutional paperwork has been submitted for approval (IRB, IACUC, IBC, etc.)

**Special Notes regarding Formatting**

Always adhere strictly to the agency’s application guidelines, such as page limitations, and margin or type-face size guidelines. Some sponsors may return proposals without peer review if specific formatting guidelines are not followed exactly.

For NIH applications see:

[http://grants.nih.gov/grants/funding/phs398/section_1.html#format_specifications](http://grants.nih.gov/grants/funding/phs398/section_1.html#format_specifications)

and

[http://grants.nih.gov/grants/funding/phs398/section_1.html#page_limits](http://grants.nih.gov/grants/funding/phs398/section_1.html#page_limits)
SPONSOR FORM PAGES TO BE REVIEWED BY ORA

NIH – NATIONAL INSTITUTES OF HEALTH

A. NEW APPLICATIONS (PHS 398): Use when OUHSC will be the Prime Awardee or Subcontractor on another institution's NIH grant.

NOTE: ALWAYS CHECK THE NIH WEBSITE FOR THE MOST CURRENT INSTRUCTIONS AND FORMS. THESE INSTRUCTIONS ARE CURRENT AS OF THIS PRINTING.

See NIH website for PHS 398 Instructions and Form Pages.

See NIH website for NIH Cost Principles, or Appendix II. See Appendix III for definitions.

ORA will review the following proposal pages of new applications prior to obtaining required institutional signature(s) on the grant application. The technical text is not required for ORA review.

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<td>Project description and key personnel (Form Page 2)</td>
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<tr>
<td>Modular Budget Format Page</td>
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<td>Detailed Budget (Form Page 4)</td>
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<td>Budget justification (Form Page 5)</td>
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<td>Biographical Sketch Format Pages – all key personnel</td>
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<td>Subcontract Information (budget pages, budget justification, and scope of work)</td>
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<tr>
<td>Letter(s) from all Consultants, Collaborators and Subcontractors</td>
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B. NON-COMPETING PROGRESS REPORTS (PHS 2590)

See [http://grants1.nih.gov/grants/funding/2590/2590.htm](http://grants1.nih.gov/grants/funding/2590/2590.htm) for most current PHS 2590 Instructions and Form pages.

Non-competing progress reports (formerly called Continuation Applications) for grants that are subject to Streamlined Noncompeting Award Process (SNAP) must include the THREE NIH form pages specified below. ORA will review these pages prior to obtaining required institutional signature(s) on the Progress Report. A new routing form is not required for SNAP progress reports.

1. Original Face Page (Form Page 1) – Do not fill in items 9a and 9b

2. Progress Report Summary (Form Page 5)—Provide a brief 2 page summary following the answers to these questions:
   1. Has there been a change in the other support of key personnel since the last reporting period?
   2. Will there be, in the next budget period, a change in the level of effort for key personnel from what was approved for this project?
   3. Is it anticipated that an estimated unobligated balance (including prior year carryover) will be greater than 25 percent of the current year’s total budget?

(3) Personnel Report (Form Page 7)

The Checklist Page (Form Page 6) is ONLY REQUIRED if there is a change in performance site that will affect facilities and administrative costs (IDC).

Non-Competing Progress Reports that are NOT subject to SNAP must include the following pages in this order (number pages consecutively):

1. Face Page
2. Detailed Budget for Next Period (Form Page 2)
3. Budget Justification (Form Page 3)
4. Biographical Sketch (Format Page 4) – for all NEW KEY PERSONNEL
5. Other Support – ONLY ACTIVE SUPPORT for all key personnel
6. Progress Report Summary (Form Page 5)
7. Checklist (Form Page 6)
8. Personnel Report (Form Page 7)
OTHER SPONSORS

Comparable form and budget pages from other sponsors (e.g., PHF, OCAST, AHA, etc.) are needed to complete the review process. If applications include additional administrative forms such as certification pages, these forms will be required before the routing form and proposal can be signed. The ORA staff will gladly help identify these additional application pages for you. Please call us with any questions you have at any time during your proposal preparation.

AHA Instructions:

  National: http://www.americanheart.org/presenter.jhtml?identifier=3514
  Heartland: http://www.americanheart.org/presenter.jhtml?identifier=182

College of Medicine Alumni Association: http://w3.ouhsc.edu/ORA

OCAST Health Research Instructions: http://www.oast.state.ok.us/ohrp.htm

OCAST Applied Research Instructions: http://www.oast.state.ok.us/oars.htm

PHF Instructions: http://w3.ouhsc.edu/ORA
3. OUHSC Facilitative & Administrative (Indirect) Cost Rates

Facilities and Administrative (F&A) costs are to be included in the budgets of ALL grant applications, research agreements, clinical trial agreements, public service agreements, training agreements (see the Indirect Cost Policy on the ORA website). Some sponsors have restrictions on the allowable F&A rate and the University honors those restrictions on grant applications. Call ORA if you have any questions regarding which rate applies to your particular application or need assistance in calculating F&A for your budget.

Check the ORA or Grants and Contract Accounting website for the current F&A (indirect cost) rates.

F&A costs are calculated on a modified total direct cost base (MTDC) per the OUHSC federally negotiated rate with DHHS. F&A costs are calculated on the MTDC base.

**MTDC includes:**
- Salaries and wages
- Fringe benefits
- Materials & supplies
- Services
- Travel
- Stipends
- Subgrants and subcontracts up to $25,000 of each subgrant and subcontract for the first year of the award only

**MTDC excludes:**
- Equipment
- Capital expenditures
- Charges for patient care
- Tuition remission
- Scholarships
- Fellowships
- The portion of each subgrant and subcontract in excess of $25,000

4. OUHSC Fringe Benefit Rates

Check the ORA or Grants and Contract Accounting website for the current fringe benefit rates.
5. Frequently Used Institutional Data

CAGE (Commercial & Government Entity Code) 4B862

CEC (Contractors Establishment Code) 8796539B

Congressional District: 05

DHHS IDC Agreement Date: Check the ORA Website for current date

DUNS (Duns and Bradstreet No.) 87-864-8294

Federal ID No. (Taxpayer ID No, TIN): 73-6017987E8

FICE (Federal Interagency Committee on Education) 005889

IRB Assurance No.: FWA 00007961

IACUC Assurance Number: A-3165-01

SIC (Standard Industrial Classification) 8221

DHHS Audit Office: Region 6
1200 Main Tower Bldg.
Dallas, TX 75202

Official Signatory for Grant Applications and Sponsored Research Contracts:
Patricia A. Benton, Ph.D., Executive Director
Office of Research Administration

Official Signatory for Non-research related Service Contracts/Agreements:
Lisa C. Asch, MS, MPH, Associate Director
Office of Research Administration

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University of Oklahoma Health Sciences Center
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Oklahoma City, OK 73190-1046

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University of Oklahoma Health Sciences Center
1000 Stanton L. Young Blvd., Room 121
Oklahoma City, OK 73117-1213

Type of Organization: State, Nonprofit, Educational Institution
6. Compliances, Assurances, and Institutional Approvals

a. Research Involving Human Subjects

OUHSC follows a “just-in-time” procedure for timing of submission of protocols for Institutional Review Board (IRB) approval. IRB applications should be submitted immediately following notification from the Sponsor that the grant will likely be funded. Protocols for human subjects research must be submitted to the IRB for review prior to submission of the grant application and routing form to ORA for signature ONLY if required by the Sponsor. The title and sponsor must match exactly on both the IRB application, the ORA routing form, and the grant application.

For most sponsors, approval is not required at the time of proposal submission. NIH requires the University to certify that IRB approval has been obtained prior to issuing a Notice of Grant Award, in accordance with their “just in time” policy. Also, in accordance with this policy, NIH requires certification of completion of institutional education requirements in human subjects protection. More information regarding the IRB educational requirements see the NIH and OUHSC IRB websites.

b. Research Involving Vertebrate Animals

OUHSC follows a “just-in-time” procedure for timing of submission of protocols for Institutional Animal Care and Use Committee (IACUC) approval. IACUC applications should be submitted immediately following notification from the Sponsor that the grant will likely be funded. Protocols for the humane use of vertebrate animals should be submitted to the IACUC for review prior to submission of the grant application and routing form to ORA for signature ONLY if required by the Sponsor. The title and sponsor must match exactly on both the IACUC application, the ORA routing form, and the grant application.

For most sponsors, approval is not required at the time of proposal submission. Effective September 1, 2002, NIH requires the University to certify that IACUC approval has been obtained prior to issuing a Notice of Grant Award, in accordance with their “just in time” policy.

Please contact the IACUC website or IACUC office at 271-7381 for the most current application forms and instructions.

c. Research Involving Recombinant DNA, Gene Therapy, Toxins, and/or Microorganisms

To comply with the guidelines for grant applications to most granting agencies, OUHSC requires that the protocols for the use of hazardous substances, toxins and organisms be submitted to the Institutional Biosafety Committee (IBC) prior to setting up the sponsored account. For most sponsors, approval is not required at the time of proposal submission, but is required by the time the grant or contract is awarded.
Titles of projects and sponsors on the IBC application and the ORA routing form must match exactly in order to complete the processing each grant application.

Please contact the IBC website or the IBC office at 271-3000 for the most current application forms and instructions.

d. **Research Involving Radioactive Materials**

The Radiation Safety Office must approve all research at the University of Oklahoma Health Sciences Center involving the use of radioactive materials. The goal of the OUHSC Office of Radiation Safety is to:

- Maintain radiation safety for the staff, students and employees and to protect the general public and environment;
- Insure the compliance of federal and state regulatory requirements and license conditions and to assure that individuals working with radiation know their rights and responsibilities under federal and state laws;
- Promote the concept of ALARA (As Low As Reasonably Achievable). Time, distance and shielding are the three keys in radiation protection.

Contact the Radiation Safety Office at 271-6121 or their website for additional guidance and the most current application forms and instructions. Please also refer to the Radiation Safety procedure manual online for detailed information regarding the proper use and disposal of radioactive materials.

e. **Research Involving Other Sites**

Most institutions and centers affiliated with OUHSC require notification that their facility will be utilized in the course of a research project. Institutional signatures on the ORA routing form and/or specific paperwork is currently required for the following affiliated institutions:

- Dean McGee Eye Institute (DMEI)
- Oklahoma Medical Research Foundation (OMRF)
- OU Medical Center*
- Veterans Administration Medical Center (VAMC)

*OU Medical Center requires the completion of Exhibits A & B prior to the start of a clinical or basic research project involving OU Medical Center facilities.

The **General Clinical Research Center** (GCRC) reviews all studies requesting the use of the Center. Contact the GCRC for further information regarding their requirements to obtain approval for use of the GCRC.
f. Conflict of Interest

The University of Oklahoma Health Sciences Center Conflict of Interest policy requires the disclosure of certain external relationships that may pose an apparent, actual, or potential conflict of interest. The disclosure, review, and management process protects the University and its employees from legal and ethical criticism. The appropriate Conflict of Interest Disclosure forms are to be submitted to the Office of Research Administration for review in the following circumstances, although disclosure is not limited to these cases:

1. When two different professional relationships are established with the same sponsor. For example, if a consulting agreement AND a research or clinical trial agreement are to be executed with the same company.

2. When the PI enters into a sponsored research agreement with a company that has licensed his/her intellectual property.

3. To annually update any previously disclosed external relationships.

Contact ORA for Conflict of Interest Disclosure Forms or if you have any questions regarding whether or not Conflict of Interest Forms need to be completed.

Consult the OUHSC policy regarding conflicts of interest for clarification:
http://admin-scb.ouhsc.edu/policy

g. Ethics in Research

“The University of Oklahoma is responsible both for promoting scholarly practices that prevent misconduct and for developing policies and procedures for dealing with allegations or other evidence of scholarly or research misconduct. The OUHSC Ethics in Research “policy establishes uniform policies and procedures for investigating and reporting instances of alleged or apparent misconduct involving research.” The policy applies to faculty, staff, and students.

Consult the OUHSC Ethics in Research Policy for complete details:
http://admin-scb.ouhsc.edu/policy
B. AWARD PROCESS

1. Notice of Grant Award or Receipt of Contract

The Office of Research Administration receives all Notice of Grant Awards (NGA) and Contracts from the Sponsoring Agency. NIH and AHA send the NGA electronically; other sponsors send paper copies of the award to ORA. NGAs and contracts are handled slightly differently.

Following receipt of a NGA:

a. ORA compares the budget to the original proposal
b. ORA reviews NGA for special terms and conditions (sometimes these require approval by the PI and/or OUHSC Legal Counsel)
c. ORA sends a copy of the NGA to the Principal Investigator (PI)
d. ORA sends the original NGA to Grants and Contracts Accounting (GCA), along with a copy of the proposal, budget, and routing form.

If the NIH grant was originally submitted in the modular format, an itemized budget (and budget justification in some cases) are required from the PI so GCA can set up the sponsored research account (C account). This also necessary to ensure that the budget is in compliance with Cost Accounting Standards (OMB A-21). See Appendix II for NIH cost principles.

If there are any budgetary differences in the original proposal submission and the NGA, ORA will notify the PI regarding the modified direct costs and will request a revised itemized budget.

Following receipt of a Research Contract:

a. ORA and Legal Counsel will review the contract to ensure University can legally comply with the terms and conditions.
b. Authorized institutional official will sign contract and ORA will return a fully executed contract to sponsor. If the sponsor has not signed the contract, ORA will return the contract to the sponsor for signature.
c. ORA will send a copy of the fully executed contract to the PI.
d. The original contract is sent to GCA, along with a copy of the proposal, budget, and routing form for the C account to be set-up.

2. Establishing the Sponsored Research Account

Grants and Contracts Accounting (GCA) establishes the C account for each sponsored research award. ORA forwards GCA the NGA and other necessary information to establish the account. GCA e-mails the account number and other important compliance information to the PI.
C. POST-AWARD PROCESS

ORA prepares all necessary subrecipient contracts when a grant or contract is awarded to the University. This includes subcontracts, independent contractor agreements, and service agreements. The next three sections provide information regarding such agreements.

1. Subcontracts (through an OUHSC Grant or Contract)

Subcontractors provide programmatic input into the research project and collaborate closely with the OUHSC PI regarding the scientific design and completion of the research project. Subcontractors are also referred to as “subrecipients”. Subcontractor costs are usually for personnel, supplies, equipment, etc.

ORA prepares the OUHSC template subcontract for all Subcontractors associated with a grant or contract. For collaborators at the University of Oklahoma, Norman campus, a Memorandum of Understanding will be prepared. Information required to prepare the subcontract:

   a. Period of performance: This time period usually correlates with the budget period of the grant or contract.
   b. Amount of contract: This is the amount awarded by the sponsoring agency for the subrecipient and usually correlates with the proposal
   c. Legal name and address of the subcontractor.
   d. Statement of work—research to be performed by the subcontractor.
   e. Itemized budget including subcontractor’s F&A, if any

ORA will forward the subcontract to the Subcontractor for signature. A copy of the fully executed subcontract is sent to the PI of the project and Grants & Contracts Accounting maintains the original subcontract. The PI receives all invoices from the Subcontractor for review and approval. The signed invoice is forwarded by the PI to Grants & Contracts Accounting for payment.

2. Independent Contractor Agreements (through an OUHSC Grant or Contract)

Independent Contractors provide a variety of services on research projects, ranging from data analysis to serving on advisory committees. University policy requires that all Independent Contractors on a research project sign an Independent Contractor Agreement for the services they will perform. Departments are also required to follow the policies on the Accounts Payable website regarding the use of Independent Contractors.

ORA will prepare the OUHSC template Independent Contractor Agreement for signature by the Independent Contractor(s).

Information that is required to complete the Independent Contractor Agreement:

   a. Name and address of Independent Contractor & TIN or SSN
b. Period of performance – may or may not be the same as the award, depending on the services provided

c. Maximum amount of contract and rate of pay (i.e., $/per hour x # hours)
d. Is travel included in the rate or will it be in addition to the consulting fee? If it is additional, a statement will be included in the contract that pre-approved reasonable travel costs will also be reimbursed.
e. Address for Consultant to send invoices.

3. Service Agreements (through an OUHSC Grant or Contract)

Service Agreements are required for person(s) or entities providing services at a predetermined fixed rate. Performing laboratory tests or assays at a cost per test are common examples services that would be covered in a Service Agreement.

University policy requires that services provided by non-OUHSC service unit(s) or external professional(s) enter into a Service Agreement to provide services on a research project. ORA will prepare the Service Agreement for signature. When all parties have signed the Service Agreement, services may be performed.

Information that is required to complete the Service Agreement:

a. Name and address of person or company providing services
b. Period of performance – may or may not be the same as the award, depending on when the services provided
c. Maximum amount of contract and rate of pay (i.e., $/per test times # tests)
d. Address to send invoices.

4. Rebudget Requests

The University has a system for proper approval of all rebudget requests. All rebudget requests are routed through ORA for review and approval. ORA reviews the request for compliance with University and Sponsor guidelines, then forwards it to Grants & Contracts Accounting. GCA implements the budgetary changes to the C account once approval is obtained.

Requests that can be approved by the University: The PI completes the Institutional Prior Approval System (IPAS) form, obtains the necessary signatures, and submits it to ORA for review and approval.

Requests that require Sponsor approval: The PI completes the IPAS form or a revised budget along with a letter of justification to the Sponsor. The letter must be co-signed by the PI and authorized institutional official. ORA will fax the letter and revised budget page to the sponsor for approval. When approval is obtained, ORA will forward the approval to GCA for budget modification.

Requests that require contract modification: ORA will forward the rebudget request to the Sponsor for approval. In some cases, the Sponsor issues an amendment to the contract for signature by the authorized institutional official. In some cases, a revised contract or amendment is issued indicating approval of the rebudget.
See the ORA website Forms section for the IPAS form. See chart below for general sponsor guidelines. ORA will provide guidelines for other Sponsors upon request.

5. **No-Cost Extension Requests**

No-cost extension requests must be submitted to ORA, and ORA will submit the request, signed by an authorized institutional official, to the Sponsor. The PI should submit the request to the appropriate Sponsored Programs Administrator, providing appropriate justification for the extension. Extensions cannot be granted merely to spend unobligated funds; extensions are only allowable to complete the programmatic obligations of the grant.

**Federal grants subject to Expanded Authorities:** The University has the authority to grant a one-year no-cost extension with suitable justification from the PI. NIH requires the requests to be submitted at least 10 days prior to the end date. Requests for an initial no-cost extension can be submitted through eRA Commons by ORA no earlier than 60 days prior to the grant end date. Approval may not be granted merely to spend unobligated funds, but to fulfill the specific aims of the original research project.

**Grants not subject to Expanded Authorities:** A formal letter signed by an authorized institutional official and the PI will be submitted to the Sponsor by ORA at least 30 days prior to the end date.

6. **Change of Principal Investigator**

ORA will submit a letter to the sponsor requesting a change in Principal Investigator. The letter must include the reason(s) the change is necessary and a copy of the proposed new PI’s Curriculum Vitae.

7. **Change of Grantee Institution (Transfers in to OUHSC)**

Change in Grantee Institution requests are submitted by ORA to the Sponsor on behalf of new OUHSC Principal Investigators. Most Sponsors require a full new application from the new Grantee (OUHSC). ORA assists the PI in the preparation of the new application and any other paperwork required by the Sponsor.

Federal Sponsors require the submission of a full grant application from OUHSC (new Grantee) for PI’s transferring grants into the University. Each NIH Institute has specific requirements for requesting the change in grantee institution that ORA will obtain to ensure that all the appropriate paperwork is submitted to the Sponsor.

The Sponsor will send a new Notice of Grant Award to OUHSC (ORA) when the application has been reviewed and approved by the Sponsor. ORA will forward a copy of the new NGA to the PI and Grants & Contracts Accounting to set up the C account.

Please call ORA for assistance with such transfers.
8. Transfer of Grants & Contracts to new academic institution

When an OUHSC PI is transferring to another academic institution, ORA will contact the sponsor regarding the transfer the grant or contract.

**Transfer of NIH grants:** See the NIH Grants Policy Statement on the NIH website.

At the minimum, OUHSC must submit the following to NIH:

a. Final Invention Statement and Certification

b. Relinquishing Statement (includes unobligated balance & any equipment purchased on the grant)

The PI will be required to submit a new application through his/her new institution and should contact the Research Administration office at that institution for assistance with the application. A change of grantee organization request must be made prior to the anticipated start date at the new organization and preferably several months in advance.

**Transfer of Other Grants:**

ORA will contact Sponsor for their specific guidelines regarding the allowability and guidelines for transferring the grant to the new institution.

**Transfer of Contracts:**

ORA will contact Sponsor for allowability of transfer and Sponsor requirements.

**Transfer of Equipment:**

ORA will assist PIs in determining Sponsor guidelines and University guidelines ([http://admin-scb.ouhsc.edu/policy](http://admin-scb.ouhsc.edu/policy)).
IV. SPONSOR GUIDELINES & DEADLINES FOR GRANT APPLICATIONS

A. National Institutes of Health - NIH


The Office of Research Administration is a valuable resource for information about NIH grant policies and procedures relating to application preparation, rebudget requests, no-cost extension requests, etc. Please contact your Sponsored Programs Administrator (SPA) for assistance with NIH grant applications or post-award administrative questions. The NIH Grants Policy Statement on the NIH website should be consulted for the most current guidelines: [http://grants1.nih.gov/grants/oer.htm](http://grants1.nih.gov/grants/oer.htm). Cost Principles for NIH awards are found in abbreviated form in Appendix II and on the NIH websites.

**Expanded Authorities:** NIH has waived the requirement for its prior approval of certain expenditures and activities for grants that are subject to “Expanded Authorities”. This designation is indicated in the Notice of Grant award. Under expanded authorities, grantees can take certain actions without NIH prior approval, including the following:

1) Extension of a period without additional funds (no-cost extension),
2) Automatic carry-forward of unobligated funds up to 25% of the total current year’s budget,
3) Use of program income,
4) Transferring performance of programmatic work to third party by way of a consortium agreement or contract, **unless** it involves a change in scope or transfer to a foreign institution, and
5) Individual costs, including patient care and equipment, including rebudgeting for them, **unless** they constitute a change in scope.

In using these expanded authorities, grantees must ensure that they exercise proper stewardship over Federal funds and that costs charged to the awards are allowable, allocable, reasonable, and consistently applied regardless of the source of funds.

Expanded authorities usually apply to “R” series (Research Project Grants), except R41, Phase I Small Business Technology Transfer (STTR) Grants, and R43, Phase I Small Business Innovation Research (SBIR) Grants; Program Project Grants (P01), and “K” series (Career Awards).
**Exhibit 3. Summary of Expanded Authorities**


<table>
<thead>
<tr>
<th>May exercise as expanded authority</th>
<th>Except</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carryover of unobligated balances from one budget period to the next</td>
<td>Centers (P50, P60, P30, other), cooperative agreements (U), Kirschstein-NRSA institutional research training grants (T), non-Fast Track Phase I SBIR and STTR awards (R43 and R41), clinical trials, and awards to individuals, or if the NGA indicates otherwise.</td>
</tr>
<tr>
<td>Cost-related prior approvals, including research patient care costs and equipment</td>
<td>If the scope would change.</td>
</tr>
<tr>
<td>Extension of final budget period of a project period without additional NIH funds</td>
<td>If the grantee already has given itself one extension of up to 12 months.</td>
</tr>
<tr>
<td>Transfer of performance of substantive programmatic work to a third party (by consortium agreement)</td>
<td>If the transfer would be to a foreign component or it would result in a change in scope.</td>
</tr>
</tbody>
</table>

**Prior Approval:** Prior approval is required for the following types of actions, whether or not a budgetary change is involved or not:

- Addition of Foreign Component
- Alterations & Renovations greater than $300,000
- Change in Scope
- Change in Status of Key Personnel
- Change of Grantee Organization
- Equipment purchase exceeding $25,000 per unit
- Transfer (rebudget) from Training Costs to another category

For a comprehensive review of prior approval requirements see the table on the following page from the NIH Grants Policy Statement (3/20/01 version).
<table>
<thead>
<tr>
<th>NIH prior approval is required for</th>
<th>Under the following circumstances</th>
</tr>
</thead>
<tbody>
<tr>
<td>A&amp;R</td>
<td>Rebudgeting into A&amp;R costs that would exceed 25 percent of the total approved budget for a budget period. If rebudgeting would not meet this threshold but would result in a change in scope. Any single A&amp;R project exceeding $300,000.</td>
</tr>
<tr>
<td>Capital expenditures (construction, land, or building acquisition)</td>
<td>All instances when purchase proposed; any proposal to convey, transfer, assign, mortgage, lease, or in any other manner encumber real property acquired with NIH grant funds.</td>
</tr>
<tr>
<td>Change in scope</td>
<td>All instances.</td>
</tr>
<tr>
<td>Changes in status of key personnel</td>
<td>Withdrawal from the project; absence for any continuous period of 3 months or more; reduction of time devoted to project by 25 percent or more from level in approved application.</td>
</tr>
<tr>
<td>Change of grantee organization</td>
<td>All instances.</td>
</tr>
<tr>
<td>Carryover of unobligated balances</td>
<td>If the NGA indicates that the grantee does not have the authority to automatically carry over balances.</td>
</tr>
<tr>
<td>Deviation from award terms and conditions</td>
<td>All instances. Includes undertaking any activities disapproved or restricted as a condition of the award.</td>
</tr>
<tr>
<td>Foreign component added to a grant to a domestic organization</td>
<td>All instances.</td>
</tr>
<tr>
<td>Need for additional NIH funding</td>
<td>All instances, including extension of a final budget period of a project period with additional funds.</td>
</tr>
<tr>
<td>Pre-award costs</td>
<td>More than 90 days before effective date of the initial budget period of a new or competing continuation award, at grantee’s own risk.</td>
</tr>
<tr>
<td>Retention of research grant funds when K award made</td>
<td>All instances.</td>
</tr>
<tr>
<td>Second no-cost extension or extension greater than 12 months</td>
<td>All instances.</td>
</tr>
</tbody>
</table>
**Grant Close-Out:** Grantees are required to submit a final Financial Status Report, Final Invention Statement and Certification, and final progress report within 90 days of the end of grant support unless an extension is granted by the GMO. Failure to submit timely and accurate final reports may affect future funding to the organization or awards with the same PI.

- **Final Invention Statement:** ORA sends to PI for signature; ORA counter-signs and submits to NIH
- **Final Progress Report:** PI submits to NIH, with a copy to ORA
- **Financial Status Report:** Grants & Contracts Accounting submits to NIH

**NIH Receipt Deadlines:** NIH publishes its Receipt Deadlines in the PHS 398 Instructions.

*NOTE:*

Receipt date for UNSOLICITED applications is the date the application must be post-marked.

Receipt for SOLICITED applications is the date the application must be received by NIH. Competing renewal applications must be received by the deadline, as well as any applications submitted in response to a Program Announcement (PA) or Request for Application (RFA) or Request for Proposal (RFP)

See the NIH website for the current listing of deadlines. See the following page for the NIH Application Receipt Deadlines as of March 2006.
Table 2. Submission Dates, Review, and Award Cycles
http://grants2.nih.gov/grants/funding/phs398/phs398.doc

<table>
<thead>
<tr>
<th>Submission Cycles:</th>
<th>Cycle I</th>
<th>Cycle II</th>
<th>Cycle III</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Non-AIDS Applications</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Institutional Ruth L. Kirschstein National Research Service – T Series</em></td>
<td>new, competing continuation, revised, supplemental</td>
<td>January 10</td>
<td>May 10</td>
</tr>
<tr>
<td>Academic Research Enhancement Award (AREA) – R15</td>
<td>new, competing continuation, revised, supplemental</td>
<td>February 25</td>
<td>June 25</td>
</tr>
<tr>
<td><strong>Program Project Grants and Center Grants – P Series</strong></td>
<td>February 1</td>
<td>June 1</td>
<td>October 1</td>
</tr>
<tr>
<td>Research Grants – e.g., R01, R03, R21</td>
<td>new</td>
<td>February 1</td>
<td>June 1</td>
</tr>
<tr>
<td>Research Career Development – K Series</td>
<td>Education Grants – R25</td>
<td>March 1</td>
<td>July 1</td>
</tr>
<tr>
<td>Small Business Innovation Research (SBIR), Small Business Technology Transfer (STTR) Grants – R41, R42, R43 and R44</td>
<td>new, competing continuation, revised, supplemental</td>
<td>April 1</td>
<td>August 1</td>
</tr>
<tr>
<td><em><strong>Individual Ruth L. Kirschstein National Research Service Awards (Standard) – e.g., F30, F31, F32, F33</strong></em></td>
<td>new, revised, competing continuation</td>
<td>April 5</td>
<td>August 5</td>
</tr>
<tr>
<td>Conference Grants and Conference Cooperative Agreements – R13, U13</td>
<td>new, competing continuation, revised, supplemental</td>
<td>April 15</td>
<td>August 15</td>
</tr>
<tr>
<td>Postmark/Submission Cycles:</td>
<td>Cycle I</td>
<td>Cycle II</td>
<td>Cycle III</td>
</tr>
<tr>
<td>AIDS and AIDS-Related Applications</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AIDS and AIDS-Related Grants</td>
<td>All</td>
<td>new, competing continuation, revised, supplemental</td>
<td>May 1</td>
</tr>
</tbody>
</table>

NOTE for all applications:
- RFAs and some PARs have special receipt dates indicated in the specific NIH Guide Announcement.
- *Institutional Research Training Grants (T32)* are accepted by many NIH Institutes and Centers (IC) for only one or two of the dates.
- **Program Project and Center Grants** – Applicants should check with individual ICs since some ICs do not accept P series applications three times a year.
- ***Individual Pre-Doctoral Fellowships (F31)** for Minority Students and Students with Disabilities has special receipt dates.
- All AIDS and AIDS-related applications (no matter the type) are submitted on the AIDS and AIDS-related dates.
<table>
<thead>
<tr>
<th>Scientific Merit Review</th>
<th>June - July</th>
<th>October - November</th>
<th>February - March</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advisory Council Review</td>
<td>September - October</td>
<td>January - February</td>
<td>May - June</td>
</tr>
<tr>
<td>Earliest Project Start Date</td>
<td>December</td>
<td>April</td>
<td>July</td>
</tr>
</tbody>
</table>

Note:
- Awarding components may not always be able to honor the requested start date of an application; therefore, applicants should make no commitments or obligations until confirmation of the start date by the awarding component.
B. National Science Foundation – NSF

NSF instructions for preparing and submitting proposals through NSF FastLane: https://www.fastlane.nsf.gov/a1/newstan.htm

If you HAVE NOT submitted a proposal to NSF before:

1) Send the following information to patti-benton@ouhsc.edu requesting a password for NSF FastLane:
   
   Name:
   Highest Degree and Year Conferred:
   Present Institution:
   Department:
   Street Address:
   City, State, Zip:
   Social Security Number:
   E-Mail Address:
   Business Phone:
   FAX Number:

2) A password will be emailed to you so that you can enter your proposal into NSF FastLane (https://www.fastlane.nsf.gov/fastlane.jsp). You will be able to change your password at that time.

3) Please send the budget pages (by fax or email) to the appropriate Sponsored Programs Administrator in the Office of Research Administration for pre-review and assistance.

4) Submit a completed blue Routing Form to ORA along with a hard copy of your NSF form pages and proposal.

5) When your proposal pages are complete, electronically submit the proposal through FastLane to the ORA. NOTE: NSF refers to ORA as the SRO, Sponsored Research Office.

6) ORA will review your electronic proposal and submit to NSF if everything is in order. NSF will notify PI of successful submission via email notification.

IF you HAVE submitted a proposal through NSF FastLane previously: Follow steps 3 through 6 above.

Rebudget and no-cost extension requests should be submitted to ORA for submission to the Sponsor. Sponsor guidelines will be consulted prior to submission of such requests. All correspondence with NSF is required to be electronic.
C. **OCAST - Oklahoma Center for the Advancement of Science and Technology**

Guidelines for application preparation and post-award administrative functions can be located at the OCAST website (http://www.ocast.state.ok.us/ohrp.htm).

**Contracts:** OCAST awards are provided through a contract mechanism. Each year’s contract renewal is dependent on submission of the **required annual progress report** to OCAST by the deadline, **60 days prior to the end date** of the contract period.

Instructions for submitting the progress report are found at: http://www.ocast.state.ok.us/PDF/OHRP-Eval-Instr.pdf.

**Rebudget Requests:** OUHSC can approve rebudget requests that are less than 25% of the entire annual award. Rebudget requests should be submitted to ORA on the OCAST Budget Modification form (http://www.ocast.state.ok.us/PDF/MOD-budget.PDF). Rebudget requests greater than 25% of the budget must be submitted by ORA to OCAST for approval.

**No-cost Extensions:** Unallowable.

**OCAST Annual Health Research Conference:** All PIs are required to participate in and attend the Annual Health Research Conference, as a condition of continued funding.

D. **Presbyterian Health Foundation - PHF**

Sponsored Research Grants through the Presbyterian Health Foundation are granted in the following three categories: Bridge, Seed, and Equipment. The ORA website maintains the most current announcements regarding application cycles.

**Rebudget Requests:** Submit rebudget requests the appropriate Sponsored Programs Administrator in ORA. Rebudget requests of less than 25% of the annual budget may normally be approved internally by ORA with proper justification. For requests greater than 25% **ORA** will submit a formal request to PHF for review and approval.

**No-cost Extensions:** Unallowable in most situations. Justification must be very strong for approval by PHF. **ORA** will contact PHF with the request and justification.

**Final Progress Report:** Due to PHF by the Principal Investigator within thirty (30) days after grant end date.

E. **College of Medicine Alumni Association - COMAA**

The COMAA grants research awards once per year with grant period dates of July 1 - June 30. Instructions for the application process are located on the ORA website.
Rebudget Requests: Submit rebudget requests to the appropriate Sponsored Programs Administrator in ORA. Rebudget requests of less than 25% of the annual budget can be approved internally by ORA with proper justification. For requests greater than 25%, ORA will submit a formal request to COMAA for review and approval.

No-cost Extensions: The COMAA must approve any extension requests and they require strong justification. Submit all requests to ORA and ORA will contact COMAA with the request.

Final Progress Report: Due to PHF within thirty (30) days after grant end date.

F. Other

ORA will consult Sponsor guidelines as required for post-award requirements. Please call for assistance.

See ORA Website for links to other sponsors: http://w3.ouhsc.edu/ORA/
V. INDUSTRY-SPONSORED RESEARCH AGREEMENTS

A. OUHSC Contract Approval Process
All industry-sponsored agreements (research or clinical) are routed according to the approved institutional process as outlined in Appendix I. Each agreement requires a completed routing form and all required institutional approvals (IRB, etc.) before it may be signed by an authorized institutional official.

B. Contract Negotiation
The contract negotiation process begins with receipt of the contract in the Office of Research Administration (ORA). The Sponsored Programs Administrator (SPA) will pre-review the agreement for compliance with University and legal requirements. The contract is forwarded to Legal Counsel for review and once legal review has been obtained, the SPA will negotiate the legal terms of the contract with the sponsor. The SPA may contact the Principal Investigator (PI) regarding certain legal issues should any questions arise in the review process. When all of the legal terms have been negotiated, the contract will be signed at OUHSC. If it has not been signed by the sponsor, the contract will be returned to the sponsor for signature. After all parties have signed and a fully executed contract is obtained by ORA, the study may begin and the sponsored research C account will be established.

1. Confidentiality Agreements
In most circumstances, the Confidentiality Agreement is negotiated prior to receipt of the Protocol and Investigator’s Brochure for Clinical Trials. If the Protocol is Investigator-Initiated and is written by the OUHSC PI or in collaboration with the potential sponsor, a Confidentiality Agreement should be finalized PRIOR to discussing the protocol with a potential sponsor. This will protect the PI’s intellectual property and ideas from disclosure and/or use by the Sponsor.

For Research Agreements that involve a protocol or project designed by OUHSC faculty or staff, a Confidentiality Agreement should be finalized PRIOR to discussing the project with a potential Sponsor.

All Confidentiality agreements are reviewed by OUHSC legal and any terms that require modification are negotiated by ORA. Confidentiality agreements are to be signed only by an authorized official of the University (see Appendix I for OUHSC policy).

2. Clinical Trial Agreements
The University must enter into a Clinical Trial Agreement with the sponsor (pharmaceutical company) PRIOR to the start of a sponsored clinical study. The Clinical Trial Agreement should be forwarded to ORA along with a completed Industry-Sponsored Research routing form. The appropriate SPA will obtain legal review and negotiate the terms and conditions of the contract. The PI is responsible for negotiating the budget with the Sponsor.
For Investigator-Initiated studies, contact the appropriate SPA to prepare a Confidentiality Agreement PRIOR to discussing the protocol with a potential Sponsor. If a funding source is located, please provide ORA with two copies of the protocol. ORA will work with the Sponsor to negotiate a clinical trial agreement for the study. ORA will work with appropriate University officials to determine if an IND/IDE number or IND exemption is required. ORA will notify the PI of any necessary paperwork that needs to be submitted to the FDA.

The study cannot begin until all institutional and other required approvals are obtained (IRB, routing form, Exhibits A&B, FDA paperwork, etc.).

3. Research Agreements

Industry-sponsored research agreements should be forwarded to ORA along with a completed industry-sponsored routing form. The appropriate SPA will obtain legal review and negotiate the legal terms and conditions of the agreement. The PI is responsible for negotiating the budget with the Sponsor. All institutional approvals (IACUC, Routing forms, Exhibits A & B, etc.) must be in place PRIOR to starting the research study.

For projects that are OUHSC Investigator-Initiated, ORA has a template Research Agreement that will be forwarded to the Sponsor for signature. The PI should provide the following information to ORA to prepare the agreement:

- a. Period of Performance
- b. Total amount of contract
- c. Scope of work/protocol
- d. Itemized budget
- e. Preference for timing of payments (monthly, quarterly)

C. Compliance, Assurances, & Institutional Approvals

1. Research involving Human Subjects

Institutional Review Board (IRB) approval must be obtained PRIOR to the start of any Clinical or Industry-Sponsored Research Study. Contact the IRB for the required paperwork. IRB approval must remain current throughout the course of the trial. Any changes to the protocol, the PI, etc. must be reported to the IRB for approval.

2. Research involving Vertebrate Animals

Institutional Animal Care and Utilization Committee (IACUC) approval must be obtained PRIOR to the start of any research project involving animals. Contact the IACUC office for additional information and assistance with the necessary paperwork.
3. **Research involving Recombinant DNA, Gene Therapy, Toxins, and/or Microorganisms**

All research involving the use of Recombinant DNA, Gene Therapy, Toxins, and/or Microorganisms requires the approval of the Institutional Biosafety Committee (IBC) PRIOR to the start of the research project.

4. **Research involving other sites**

All affiliated institutional approvals (OU Medical Center, VA, etc.) must be obtained PRIOR to the start of any industry-sponsored research project.

D. **Facilities & Administrative Costs (Indirect Costs)**

See the Indirect Cost Policy on the ORA website for the most current information regarding applicable F&A (indirect cost) rates.

**Clinical Trial Agreements with Pharmaceutical Companies:**

- F&A of 10% is recovered by the Office of the Provost (mandatory)
- Additional F&A may be recovered by the Principal Investigator’s Department and/or Section (usually 10 – 15%)—check with your department manager regarding its policy for Clinical Trials.

**Clinical Trial Agreements with Federal sponsors:**

- The current OUHSC federally negotiated rate should be used, unless restrictions are imposed by the agency.

**Research Agreements:**

- The federally negotiated research rate is required on industry-sponsored research agreements.

E. **Establishing a sponsored research C account**

ORA will request a C account from Grants and Contracts Accounting (GCA) for the PI when the agreement has been fully executed and all institutional approvals are obtained. GCA will contact the PI with the C account information.

F. **Extensions & Rebudgets**

All extension and rebudget requests are to be forwarded to ORA for review and final approval. If the terms of the agreement require sponsor approval, ORA will contact the sponsor to obtain approval. The necessary paperwork will then be sent to GCA for modification of the C account.
G. Amendments

All amendments to the clinical trial agreement or research agreement must be reviewed by ORA, and sometimes OUHSC legal. An authorized institutional official of the University signs all amendments.
VI. SERVICE CONTRACTS

A. OUHSC Contract Approval Process

All service contracts are to be routed according to the approved institutional process as detailed in the Appendix I. Each contract requires a completed routing form and any required institutional approvals before the contract may be signed by an authorized institutional official.

B. Contract Negotiation

The contract negotiation process begins with receipt of the contract in ORA. The Sponsored Programs Administrator will pre-review the contract for legal and fiscal matters and then forward the contract to Legal Counsel for review. Once legal review has been obtained, the SPA will negotiate the legal terms of the contract with the sponsoring agency. The SPA may contact the Principal Investigator regarding budgetary or legal issues should any questions arise in the review process. When all of the legal and budgetary issues have been resolved, the contract will be signed at OUHSC and returned to the sponsor for signature.

a. Professional Service Agreements (Service Routing Form)
   - Professional Service agreements define contractual conditions for providing professional services, such as expert advice, consulting, etc.
   - Payment terms are generally on a “per hour”, “per month”, “per year”, or “per client” rate.
   - Compensation from Professional Service agreements are placed into the Professional Practice Plan (not C accounts).

b. Affiliation Agreements (Service Routing Form)
   - Affiliation agreements establish contractual relationships between the University of Oklahoma Health Sciences Center and other institutions for services without fees.
   - Affiliation agreements are generally for OUHSC students and residents to gain training and/or clinical experience at external sites.
   - Affiliation agreements do not generally involve transfer of funds.

c. Medical Provider Agreements (Service Routing Form)
   - Provider agreements establish contractual relationships between OUHSC medical providers with insurance providers, such as Blue Cross Blue Shield.
   - Provider agreements provide for billing and payment of medical care by the covered providers.

d. Public Service Agreements (Sponsored Programs Routing Form)
   - Public Service agreements provide for specific services for the ultimate benefit of the public.
   - Public service agreements often involve the Oklahoma State agencies or other federal agencies.
• Public service agreement accounts are set up as C accounts and have line item budgets.

C. Institutional Approvals

In some instances, IRB or IACUC approval may be required to fulfill the terms of a Public Service agreement. In these circumstances, IRB or IACUC approval must be obtained before the agreement can be signed by the University.

D. Facilities & Administrative Costs (indirect costs) on Service Contracts

See the ORA website for the current applicable F&A rates.

The OUHSC calculated rate should be utilized on all Public Service agreements if the sponsor allows the inclusion of F&A costs in the budget. The Oklahoma State Department of Health allows OUHSC to request F&A costs in most contracts.

Facilities and Administrative costs are calculated on a modified total direct cost base (MTDC). MTDC includes all salaries and wages, fringe benefits, materials & supplies, services, travel, subgrants, and subcontracts up to $25,000 of each subgrant and subcontract (for year one of the award). Equipment, capital expenditures, charges for patient care and tuition remission, scholarships, and fellowships as well as the portion of each subgrant and subcontract in excess of $25,000 shall be excluded from modified total direct costs.

E. Accounts

For public service agreements, ORA will send the appropriate paperwork to Grants and Contracts Accounting to set up the C account. Grants and Contracts Accounting will notify the Principal Investigator with C account information.

For professional service agreements, funds will be forwarded directly to the Principal Investigator’s department for deposition into the appropriate departmental PPP account.

F. Amendments and Renewals

All amendments and renewals to service contracts and renewals are to be routed through ORA for review and signature according to University policy.
APPENDIX II.

NIH Costs Principles – Allowability of Selected Costs

This appendix is directly from the NIH Grants Policy Statement:

“The Cost Principles
In general, NIH grant awards provide for reimbursement of actual, allowable costs incurred and are subject to Federal cost principles. The cost principles establish standards for the allowability of costs, provide detailed guidance on the cost accounting treatment of costs as direct or F&A costs, and set forth allowability and allocability principles for selected items of cost. Applicability of a particular set of cost principles depends on the type of organization making the expenditure. For example, a for-profit organization collaborating with a university grantee would be subject to the cost principles for commercial organizations, while the university would be subject to the cost principles for educational institutions.
The cost principles are set forth in the following documents and are incorporated by reference in 45 CFR 74.27 and 92.22:
OMP Circular A-21—Cost Principles for Educational Institutions
OMP Circular A-87—Cost Principles for State and Local Governments and Indian Tribal Governments
OMP Circular A-122—Cost Principles for Non-Profit Institutions
45 CFR Part 74, Appendix E—Principles for Determining Costs Applicable to Research and Development under Grants and Contracts with Hospitals
48 CFR Subpart 31.2 (Federal Acquisition Regulation)—Contracts with Commercial Organizations.
The cost principles apply to all NIH award instruments, award mechanisms, and special programs and authorities, including modular awards and awards under SNAP with one exception: they do not apply to Kirschstein-NRSA individual fellowship awards. The allowable use of funds under those awards is included in “Ruth L. Kirschstein National Research Service Awards” in Subpart B of this part.
Grantees can use their own accounting systems, policies, and procedures to implement the cost principle requirements as long as the standards prescribed in 45 CFR 74.21 or 92.20 for financial management systems are met.
The cost principles address four tests that NIH follows in determining the allowability of costs. The tests are as follows:
- Reasonableness (including necessity). A cost may be considered reasonable if the nature of the goods or services acquired or applied and the associated dollar amount reflect the action that a prudent person would have taken under the circumstances prevailing when the decision to incur the cost was made. The cost principles elaborate on this concept and address considerations such as whether the cost is of a type generally necessary for the organization’s operations or the grant’s performance, whether the recipient complied with its established organizational policies in incurring the cost or charge, and whether the individuals responsible for the expenditure acted with due prudence in carrying out their responsibilities to the Federal government and the public at large as well as to the organization.
• **Allocability.** A cost is allocable to a specific grant, function, department, or other component, known as a cost objective, if the goods or services involved are chargeable or assignable to that cost objective in accordance with the relative benefits received or other equitable relationship. A cost is allocable to a grant if it is incurred solely in order to advance work under the grant; it benefits both the grant and other work of the institution, including other grant-supported projects; or it is necessary to the overall operation of the organization and is deemed to be assignable, at least in part, to the grant.

• **Consistency.** Grantees must be consistent in assigning costs to cost objectives. Therefore, under NIH grants, although costs may be charged as either direct costs or F&A costs, depending on their identifiable benefit to a particular project or program. They must be treated consistently for all work of the organization under similar circumstances, regardless of the source of funding, so as to avoid duplicate charges.

• **Conformance.** This test of allowability—conformance with limitations and exclusions as contained in the terms and conditions of award, including those in the cost principles—varies by the type of activity, the type of recipient, and other characteristics of individual awards. “**Allowability of Costs/Activities**” provides information common to most NIH grants and, where appropriate, specifies some of the distinctions if there is a different treatment based on the type of grant or grantee. Subpart B of this part contains additional information on allowability of costs for particular types of grants, grantees, and activities.

These four tests apply regardless of whether the particular category of costs is one specified in the cost principles or one governed by other terms and conditions of an award. These tests also apply regardless of treatment as a direct cost or an F&A cost. The fact that a proposed cost is awarded as requested by an applicant does not indicate a determination of allowability”.

**Selected Items of Cost form the NIH Grants Policy Statement**


<table>
<thead>
<tr>
<th>Advertising</th>
<th>Allowable only for recruitment of staff or trainees, procurement of goods and services, disposal of scrap or surplus materials, and other specific purposes necessary to meet the requirements of the grant-supported project or activity.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcoholic Beverages</td>
<td>Unallowable as an entertainment expense, but allowable if within the scope of an approved research project.</td>
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</table>
### Alteration and Renovation

Individual A&R projects that are treated as direct costs and that will not exceed $500,000 will be subject to the A&R policies specified in this subsection and in the “Construction Grants” section, as applicable. Individual A&R projects exceeding $500,000 in direct costs will be subject to the requirements specified in the “Construction Grants” section.

Routine maintenance and repair of the organization’s physical plant or its equipment, which is allowable and is ordinarily treated as an F&A cost, is not considered A&R for purposes of applying this policy. Certain allowable costs of installing equipment, such as the temporary removal and replacement of wall sections and door frames to place equipment in its permanent location, or the costs of connecting utility lines, replacing finishes and furnishings, and installing any accessory devices required for the equipment’s proper and safe utilization, may be considered either equipment costs or A&R costs, depending on the grantee’s accounting system.

A&R costs are not allowable under grants to individuals, foreign grants, and grants in support of scientific meetings (conference grants). In all other cases, these costs are allowable unless the program legislation, implementing regulations, program guidelines, or other terms and conditions of the award specifically exclude such activity. The A&R must be consistent with the following criteria and documentation requirements:

1. The building has a useful life consistent with program purposes and is architecturally and structurally suitable for conversion to the type of space required
2. The A&R is essential to the purpose of the grant-supported project
3. The space involved will be occupied by the project
4. The space is suitable for human occupancy before A&R work is started except where the purpose of the A&R is to make the space suitable for some purpose other than human occupancy, such as storage
5. If the space is rented, evidence is provided that the terms of the lease are compatible with the A&R proposed and cover the duration of the project period.

Work necessary to obtain an initial occupancy permit for the intended use is not an allowable A&R cost.

A grantee may rebudget up to 25 percent of the total approved budget for a budget period into A&R costs without NIH prior approval unless such rebudgeting would result in a change in scope. If the rebudgeting results in an A&R project exceeding $300,000, NIH will consider the rebudgeting to be a change in scope, and the grantee must submit to the NIH awarding office the documentation specified in “Construction Grants” for approval of A&R projects above that dollar level.

### Animals

Allowable for the acquisition, care, and use of experimental animals, contingent upon compliance with the applicable requirements of the *PHS Policy on Humane Care and Use of Laboratory Animals* (see “Public Policy Requirements and Objectives—Animal Welfare”). If the grantee operates an animal resource facility, charges for use of the facility should be determined in accordance with the *Cost Analysis and Rate Setting Manual for Animal Resource Facilities* (May 2000), available from NCRR at its website: [http://www.ncrr.nih.gov/newspub/CARS.pdf](http://www.ncrr.nih.gov/newspub/CARS.pdf) or from NCRR’s Office of Science Policy and Public Liaison (telephone: 301-435-0888; e-mail: info@ncrr.nih.gov).
### Audiovisual Activities

Allowable for the production of an audiovisual. “Audiovisual” means any product containing visual imagery, sound, or both, such as motion pictures, films, videotapes, live or recorded radio or television programs or public service announcements, slide shows, filmstrips, audio recordings, multimedia presentations, or exhibits where visual imagery, sound, or both are an integral part. “Production” refers to the steps and techniques used to create a finished audiovisual product including, but not limited to, design, layout, scriptwriting, filming or taping, fabrication, sound recording, and editing.

A recipient with in-house production capability must determine whether it would be more efficient and economical to use that capability or to contract for the production of an audiovisual.

If an audiovisual intended for members of the general public (i.e., people who are not researchers or health professions personnel or who are not directly involved in project activities as employees, trainees, or participants such as volunteers or patients) is produced under an NIH grant-supported project, the grantee must submit two prints or tapes of the finished product along with its annual or final progress report (see “Administrative Requirements—Monitoring—Reporting” and “Administrative Requirements—Closeout”). The costs of such prints or tapes are allowable project costs.

Audiovisuals produced under an NIH grant-supported project must bear an acknowledgment and disclaimer, such as the following:

> The production of this [type of audiovisual (motion picture, television program, etc.)] was supported by Grant No.__________ from [name of NIH awarding office]. Its contents are solely the responsibility of [name of grantee organization] and do not necessarily represent the official views of [name of NIH awarding office].

### Audit Costs

Allowable (see “Administrative Requirements—Monitoring—Audit” and section 230 of OMB Circular A-133). The charges may be treated as a direct cost when the audit’s scope is limited to a single NIH grant-supported project or program, as specified in 45 CFR 74.26(d), or when it includes more than one project but the costs can be specifically identified with, and allocated to, each project on a proportional basis, and this practice is followed consistently by the grantee. Otherwise, charges for audits should be treated as F&A costs.

### Bad Debts

Unallowable.

### Bid and Proposal Costs

Allowable as an F&A cost. See 45 CFR 74.27(b)(1) for policy for non-profit organizations covered by OMB Circular A-122.

### Bonding

Allowable. See 45 CFR 74.21, 74.47(c) and 92.36 for policies and requirements concerning bonding.

### Books and Journals

Allowable. If an organization has a library, books and journals generally should be provided as part of normal library services and treated as F&A costs.

### Building Acquisition

Unallowable unless building acquisition or construction is specifically authorized by program legislation and is provided for in the NGA. For real property acquired with NIH grant support, the cost of title insurance may be charged to the grant in proportion to the Federal share of the acquisition cost. Filing fees for recording the Federal interest in the real property in appropriate records of the applicable jurisdiction also may be charged to the grant. (Also see “Construction Grants—Allowable and Unallowable Costs and Activities” in Subpart B of this part)

### Child Care Costs

Allowable if incurred to assist individuals to participate as subjects in research projects. Such costs also may be allowable as a fringe benefit for individuals working on a grant-supported project (see “Fringe Benefits” in this subsection).

### Communications

Allowable. Such costs include local and long-distance telephone calls, telegrams, express mail, and postage, and usually are treated as F&A costs.
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<tbody>
<tr>
<td>Conference Grant Costs</td>
<td>See “Support of Scientific Meetings (Conference Grants)” in Subpart B of this part for allowability of costs for scientific meetings (conferences).</td>
</tr>
<tr>
<td>Consortium Agreements/</td>
<td>Allowable to carry out a portion of the programmatic effort or for the acquisition of routine goods Grants under or services under the grant. Such arrangements may require NIH approval as specified in “Administrative Requirements—Changes in Project and Budget.” (See “Administrative Requirements—Management Systems and Procedures—Procurement System Standards and Requirements” for policies that apply to the acquisition of routine goods and services and “Consortium Agreements” in Subpart B of this part for policies that apply to grantee collaboration with other organizations in carrying out the grant-supported research.)</td>
</tr>
<tr>
<td>Construction</td>
<td>Allowable only when program legislation specifically authorizes new construction, modernization, or major A&amp;R, and NIH specifically authorizes such costs in the NGA. When authorized, construction activities may include construction of a new facility or projects in an existing building that are considered to be construction, such as relocation of exterior walls, roofs, and floors; attachment of fire escapes; or completion of unfinished shell space to make it suitable for human occupancy (see “Construction Grants” in Subpart B of this part).</td>
</tr>
<tr>
<td>Consultant Services</td>
<td>Allowable. A consultant is an individual retained to provide professional advice or services for a fee but usually not as an employee of the requiring organization. The term “consultant” also includes a firm that provides paid professional advice or services. Grantees must have written policies governing their use of consultants that are consistently applied regardless of the source of support. Such policies should include the conditions for paying consulting fees. The general circumstances of allowability of these costs, which may include fees and travel and subsistence costs, are addressed in the applicable cost principles under “professional services costs.” In unusual situations, a person may be both a consultant and an employee of the same party, receiving compensation for some services as a consultant and for other work as a salaried employee as long as those separate services are not related to the same project and are not charged to the same project. For example, consulting fees that are paid by an educational institution to a salaried faculty member as extra compensation above that individual’s base salary are allowable, provided the consultation is across departmental lines or involves a separate or remote operation and the work performed by the consultant is in addition to his or her regular departmental workload.</td>
</tr>
<tr>
<td>Grantees, consortium participants, and contractors under grants that want to be able to charge employee consulting costs to grant-supported projects must establish written guidelines permitting such payments regardless of the source of funding and indicating the conditions under which the payment of consulting fees to employees is proper. Unless subject to OMB Circular A-21, the grantee, consortium participant, or contractor also must document that it would be inappropriate or infeasible to compensate the individual for those services through payment of additional salary. Under no circumstances can an individual be paid as a consultant and an employee under the same NIH grant.</td>
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</table>
Authorization for consulting fees paid to individuals serving as both employees and consultants of the same party must be provided in writing, on a case-by-case basis, by the head of the recipient organization, consortium participant, or contractor incurring the costs, or his/her designee. If the designee is personally involved in the project, the authorization may be given only by the head of the recipient organization, consortium participant, or contractor. This authorization must include a determination that the required conditions are present and that there is no apparent or actual conflict of interest.

Grantees, consortium participants, and contractors under grants are encouraged to obtain written reports from consultants unless such a report is not feasible given the nature of the consultation or would not be useful. Documentation maintained by the receiving organization should include the name of the consulting firm or individual consultant; the nature of the services rendered and their relevance to the grant-supported activities, if not otherwise apparent from the nature of the services; the period of service; the basis for calculating the fee paid (e.g., rate per day or hour worked or rate per unit of service rendered); and the amount paid. This information may be included in the consultant’s invoice, in the report, or in another document.

See “Grants to Federal Institutions and Payments to (or on Behalf of) Federal Employees under Grants” in Subpart B of this part for allowable costs associated with consultant payments to Federal employees and the circumstances of allowability.

<p>| Contingency Funds | Unallowable. Contributions set aside for events whose occurrence cannot be foretold with certainty as to time, intensity, or assurance of their happening are unallowable under nonconstruction grants. Contingency funds do not include pension funds, self-insurance funds, and normal accruals (also see “Reserve Funds” in this subsection). (See “Construction Grants—Allowable and Unallowable Costs and Activities” in Subpart B of this part concerning contingency funds under construction grants.) |
| Customs and Import Duties | Allowable under grants to domestic organizations when performance will take place entirely within the United States, its possessions, or its territories, or when foreign involvement in the project is incidental to the overall grant-supported project. Charges may include consular fees, customs surtaxes, value-added taxes, and other related charges. (Also see “Grants to Foreign Institutions, International Organizations, and Domestic Grants with Foreign Components—Allowable and Unallowable Costs” in Subpart B of this part for the allowability of these costs.) |
| Depreciation or Use Allowances | Allowable. Such costs usually are treated as F&amp;A costs. Depreciation or use charges on equipment or buildings acquired under a federally supported project are not allowable. |
| Donor Costs | Allowable for payment to volunteers or research subjects who contribute blood, urine samples, and other body fluids or tissues that are specifically project-related. |
| Drugs | Allowable if within the scope of an approved research project. Project funds may not be used to purchase drugs classified by FDA as “ineffective” or “possibly effective” except in approved clinical research projects or in cases where there is no alternative other than therapy with “possibly effective” drugs. |
| Dues or Membership Fees | Allowable as an F&amp;A cost for organizational membership in business, professional, or technical organizations or societies. Payment of dues or membership fees for an individual’s membership in a professional or technical organization is allowable as a fringe benefit or an employee development cost, if paid according to an established organizational policy consistently applied regardless of the source of funds. |
| Entertainment Costs | Unallowable. This includes the cost of amusements, social activities, and related incidental costs. |
| Equipment | Allowable for purchase of new, used, or replacement equipment as a direct cost or as part of F&amp;A costs, depending on the intended use of the equipment. NIH prior approval may be required as specified in “Administrative Requirements—Changes in Project and Budget.” In accordance with the requirements of NIH appropriations acts, American-made items should be purchased to the extent possible. Funds provided under a conference grant may not be used to purchase equipment. For policies governing the classification, use, management, and disposition of equipment, see “Administrative Requirements—Management Systems and Procedures—Property Management System Standards.” For policies governing the allowability of costs for rental of equipment, see “Rental or Lease of Facilities and Equipment” in this subsection. |
| Federal (U.S. Government) Employees | See “Grants to Federal Institutions and Payments to (or on Behalf of) Federal Employees under Grants—Allowable and Unallowable Costs” for the allowability of payments made to, or on behalf of, Federal employees under NIH grants, including grants to Federal institutions. |
| Fines and Penalties | Unallowable except when resulting from violations of, or failure of the organization to comply with, Federal, State, or local laws and regulations and incurred as a result of compliance with specific provisions of an award, or when such payments are authorized in advance in writing by the NIH awarding office. |
| Fringe Benefits | Allowable as part of overall compensation to employees in proportion to the amount of time or effort employees devote to the grant-supported project, provided such costs are incurred under formally established and consistently applied policies of the organization (see “Salaries and Wages” in this subsection). Tuition or tuition remission for regular employees is allowable as a fringe benefit. For organizations subject to OMB Circular A-21, tuition benefits for family members other than the employee are unallowable. For policies applicable to tuition remission for students working on grant-supported research projects, see “Salaries and Wages” in this subsection. See “Ruth L. Kirschstein National Research Service Awards—Individual Fellowships—Allowable and Unallowable Costs—Tuition and Fees” and “Ruth L. Kirschstein National Research Service Awards—Institutional Research Training Grants—Allowable and Unallowable Costs—Trainee Tuition, Fees, and Health Insurance” in Subpart B of this part for the allowability of tuition costs for fellows and trainees. |
| Fundraising Costs | Unallowable. |
| Honoraria | Unallowable when the primary intent is to confer distinction on, or to symbolize respect, esteem, or admiration for, the recipient of the honorarium. A payment for services rendered, such as a speaker’s fee under a conference grant, is allowable. |
| Hospitalization | See “Research Patient Care” in this subsection. |
| Indemnification | Allowable to the extent expressly provided in the award for indemnification against liabilities to third parties and any other loss or damage not compensated by insurance or otherwise. |
| Independent Research and Development Costs | Unallowable, including their proportionate share of F&amp;A costs. |
| <strong>Insurance</strong> | Allowable. Insurance usually is treated as an F&amp;A cost. In certain situations, however, where special insurance is required as a condition of the grant because of risks peculiar to the project, the premium may be charged as a direct cost if doing so is consistent with organizational policy. Medical liability (malpractice) insurance is an allowable cost of research programs at educational institutions only if the research involves human subjects. If so, the insurance should be treated as a direct cost and assigned to individual grants based on the manner in which the insurer allocates the risk to the population covered by the insurance. The cost of insuring equipment, whether purchased with project funds or furnished as federally owned property, normally should be included in F&amp;A costs but may be allowable as a direct cost if this manner of charging is the normal organizational policy. Health insurance for trainees and fellows is addressed in “Ruth L. Kirschstein National Research Service Awards” in Subpart B of this part. |
| <strong>Interest</strong> | Allowable as an F&amp;A cost for certain assets as specified in the applicable cost principles. Unallowable for hospitals. |
| <strong>Invention, Patent, or Licensing Costs</strong> | Unallowable as a direct cost unless specifically authorized on the grant award. May be allowable as F&amp;A costs, provided they are authorized under applicable cost principles and are included in the negotiation of F&amp;A cost rates. Such costs include licensing or option fees, attorney's fees for preparing or submitting patent applications, and fees paid to the U.S. Patent and Trademark Office for patent application, patent maintenance, or recordation of patent-related information. (This Section Revised per May 27, 2004 NIH Guide notice.) |
| <strong>Leave</strong> | Allowable for employees as a fringe benefit (see “Fringe Benefits” in this subsection). See “Ruth L. Kirschstein National Research Service Awards—Individual Fellowships—Other Terms and Conditions—Leave” and “Ruth L. Kirschstein National Research Service Awards—Institutional Research Training Grants—Other Terms and Conditions—Leave” in Subpart B of this part for NIH policy on leave for fellows and trainees. |
| <strong>Legal Services</strong> | Allowable. Generally treated as an F&amp;A cost but, subject to the limitations described in the applicable cost principles, may be treated as a direct cost for legal services provided by individuals who are not employees of the grantee organization. Before a grantee incurs legal costs that are extraordinary or unusual in nature, the grantee should make an advance agreement regarding the appropriateness and reasonableness of such costs with the GMO. Legal costs incurred in defending or prosecuting claims, whether equitable or monetary, including administrative grant appeals, are unallowable charges to NIH grant-supported projects, except as provided in the applicable cost principles. |
| <strong>Library Services</strong> | General library support is not allowable as a direct cost but may be included in the grantee’s F&amp;A pool. However, such services are allowable as a direct cost when specifically required for the conduct of the project and when identifiable as an integral part of the grant-supported activity (e.g., in those programs designed to develop and support such services). |
| <strong>Lobbying</strong> | Generally unallowable, including costs of lobbying activities to influence the introduction, enactment, or modification of legislation by the U.S. Congress or a State legislature. Under certain circumstances, as provided in the applicable cost principles, costs associated with activities that might otherwise be considered “lobbying” that are directly related to the performance of a grant may be allowable. The grantee should obtain an advance understanding with the GMO if it intends to engage in these activities. (Also see “Public Policy Requirements and Objectives—Ethical and Safe Conduct in Science and Organizational Operations—Lobbying” and “Administrative Requirements—Monitoring—Reporting” concerning lobbying restrictions, the required certification, and reporting.) |</p>
<table>
<thead>
<tr>
<th>Meals</th>
<th>Allowable for subjects and patients under study, or where specifically approved as part of the project activity, provided that such charges are not duplicated in participants’ per diem or subsistence allowances, if any.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moving</td>
<td>See “Recruitment Costs,” “Relocation Costs,” and “Transportation of Property” in this subsection.</td>
</tr>
<tr>
<td>Nursery Items</td>
<td>Allowable for the purchase of items such as toys and games to allow patients to participate in research protocols.</td>
</tr>
<tr>
<td>Overtime</td>
<td>See “Salaries and Wages” in this subsection.</td>
</tr>
</tbody>
</table>
| Pension Plan Costs | Allowable. For institutions of higher education and non-profit organizations, such costs must be incurred according to the established policies of the organization consistently applied regardless of the source of funds, the organization’s policies must meet the test of reasonableness, the methods of cost allocation must be equitable for all activities, the amount assigned to each fiscal year must be determined in accordance with generally accepted accounting principles, and the cost assigned to a given fiscal year must be paid or funded for all plan participants within 6 months after the end of that fiscal year.  
State, local, or Indian tribal governments or hospitals may use the “pay-as-you-go” cost method (i.e., when pension benefits are paid by the grantee directly to, or on behalf of, retired employees or their beneficiaries) in lieu of the method described above. Under this method, the benefits may be charged in the grantee’s fiscal year in which the payments are made to, or on behalf of, retired employees or their beneficiaries, provided that the grantee follows a consistent policy of treating such payments as expenses in the year of payment. See the applicable cost principles for additional information on the allowability of costs associated with pension plans. |
| Pre-Award (Pre-Agreement) Costs | Allowable. A grantee may, at its own risk and without NIH prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new or competing continuation award if such costs:  
1. are necessary to conduct the project, and  
1. would be allowable under the grant, if awarded, without NIH prior approval.  
If specific expenditures would otherwise require prior approval, the grantee must obtain NIH approval before incurring the cost. NIH prior approval is required for any costs to be incurred more than 90 days before the beginning date of the initial budget period of a new or competing continuation award.  
Grantees may incur pre-award costs before the beginning date of a non-competing continuation award without regard to the time parameters stated above.  
The incurrence of pre-award costs in anticipation of a competing or non-competing award imposes no obligation on NIH either to make the award or to increase the amount of the approved budget if an award is made for less than the amount anticipated and is inadequate to cover the pre-award costs incurred.  
NIH expects the grantee to be fully aware that pre-award costs result in borrowing against future support and that such borrowing must not impair the grantee’s ability to accomplish the project objectives in the approved time frame or in any way adversely affect the conduct of the project. |
| Public Relations Costs | Allowable only for costs specifically required by the award or for costs of communicating with the public and the press about specific activities or accomplishments under the grant-supported project or other appropriate matters of public concern. Such costs may be treated as direct costs but should be treated as F&A costs if they benefit more than one sponsored agreement or if they benefit the grant and other work of the organization. |
| **Publications** | Allowable. Page charges for publication in professional journals are allowable if the published paper reports work supported by the grant and the charges are levied impartially on all papers published by the journal, whether or not by government-sponsored authors. The costs of reprints and publishing in other media, such as books, monographs, and pamphlets, also are allowable. Publications and journal articles produced under an NIH grant-supported project must bear an acknowledgment and disclaimer, as appropriate, as provided in “Administrative Requirements—Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources.” |
| **Recruitment Costs** | Allowable subject to the conditions and restrictions contained in the applicable cost principles. These costs may include help-wanted advertising costs, costs of travel by applicants to and from preemployment interviews, and travel costs of employees while engaged in recruiting personnel. Project funds may not be used for a prospective trainee’s travel costs to or from the grantee organization for the purpose of recruitment. However, other costs incurred in connection with recruitment under training programs, such as advertising, may be allocated to a grant-supported project according to the provisions of the applicable cost principles (also see “Travel” and “Relocation Costs” in this subsection). |
| **Registration Fees (for Symposiums and Seminars)** | Allowable if necessary to accomplish project objectives. |
| **Relocation Costs** | Allowable—in other than change of grantee organization situations—when such costs are incurred incidental to a permanent change of duty assignment (for an indefinite period or for a stated period of no less than 12 months) for an existing employee working on a grant-supported project, or when a new employee is recruited for work on the project, provided that the move is for the grantee’s benefit rather than the individual’s and that payment is made according to established organizational policies consistently applied regardless of the source of funds. Relocation costs may include the cost of transporting the employee and his or her family, dependents, and household goods to the new location and certain expenses associated with the sale of the former home. If relocation costs have been incurred in connection with the recruitment of a new employee, whether as a direct cost or an F&A cost, and the employee resigns for reasons within his or her control within 12 months after hire, the grantee must credit the grant account for the full cost of the relocation charged to the grant. When there is a change in the grantee organization, the personal relocation expenses of the PI and others moving from the original grantee to the new grantee are not allowable charges to NIH grants (see “Administrative Requirements—Changes in Project and Budget—Prior-Approval Requirements”). |
| **Rental or Lease of Facilities and Equipment** | Allowable subject to the limitations below. Rental costs are allowable to the extent that the rates are reasonable at the time of the decision to lease in light of such factors as rental costs of comparable property, if any; market conditions in the area; the type, life expectancy, condition, and value of the property leased; and available alternatives. Because of the complexity involved in determining the allowable amount under certain types of leases, grantees are encouraged to consult the GMO before entering into leases that will result in direct charges to the grant project.

In general, the rental costs for facilities and equipment applicable to each budget period should be charged to that period. However, see “Administrative Requirements—Management Systems and Procedures—Procurement System Standards and Requirements” for an exception to this general rule.

Rental costs under leases that create a material equity in the leased property, as defined in the applicable cost principles, are allowable only up to the amount that would be allowed had the grantee purchased the property on the date the lease agreement was executed. This would include depreciation or use allowances, maintenance, taxes, and insurance, but would exclude unallowable costs.

When a grantee transfers property to a third party through sale, lease, or otherwise and then leases the property back from that third party, the lease costs that may be charged to NIH projects generally may not exceed the amount that would be allowed if the grantee continued to own the property.

Rental costs under “less-than-arms-length” leases are allowable only up to the amount that would be allowed under the applicable cost principles had title to the property been vested in the grantee. A less-than-arms-length lease is one in which one party to the lease agreement is able to control or substantially influence the actions of the other. Such leases include, but are not limited to, those between divisions of an organization; between organizations under common control through common officers, directors, or members; and between an organization and its directors, trustees, officers, or key employees (or the families of these individuals), directly or through corporations, trusts, or similar arrangements in which they hold a controlling interest. |

| **Research Patient Care** | The costs of routine and ancillary services provided by hospitals to individuals, including patients and volunteers, participating in research programs are allowable. Incurrence of patient care costs if not previously approved by NIH and rebudgeting additional funds into, or rebudgeting approved amounts out of, the research patient care costs category may be considered a change in scope and require prior approval by the NIH awarding office.

“Routine services” include the regular room services, minor medical and surgical supplies, and the use of equipment and facilities for which a separate charge is not customarily made.

“Ancillary services” are those special services for which charges customarily are made in addition to routine services, e.g., x-ray, operating room, laboratory, pharmacy, blood bank, and pathology. See “Research Patient Care Costs” in Subpart B of this part for NIH policy concerning reimbursement of these costs.

The following otherwise allowable costs are not classified as research patient care costs items of personal expense reimbursement, such as patient travel; consulting physician fees; and any other direct payments to individuals, including inpatients, outpatients, subjects, volunteers, and donors. Such costs should be included in the “Other Expenses” category of the grant budget. |

<p>| <strong>Reserve Funds</strong> | Contributions to a reserve fund for self-insurance are allowable as specified in the governing cost principles (also see “Contingency Funds” in this subsection). |
| <strong>Sabbatical Leave Costs</strong> | Sabbatical leave costs may be included in a fringe benefit rate or in the organization’s F&amp;A rate. Salary may be charged directly to a project for services rendered to the project by individuals while they are on sabbatical leave, provided the salary is proportional to the service rendered and is paid according to established organizational policies applicable to all employees regardless of the source of funds. Sabbatical leave paid by an individual’s employer, in combination with other compensation (e.g., partial salary from an NIH grant), may not exceed 100 percent of that individual’s regular salary from his or her organization. |
| <strong>Salaries and Wages</strong> | Allowable. Compensation for personal services covers all amounts, including fringe benefits, paid currently or accrued by the organization for employee services rendered to the grant-supported project. Compensation costs are allowable to the extent that they are reasonable, conform to the established policy of the organization consistently applied regardless of the source of funds, and reflect no more than the percentage of time actually devoted to the NIH-funded project. As required in its annual appropriations act, NIH will not reimburse grantees for the direct salaries of individuals at a rate in excess of the level specified in the appropriations language. Direct salary is exclusive of fringe benefits and F&amp;A costs. This salary limitation does not apply to consultant payments or to contracts for routine goods and services but it does apply to consortium participants (see “Consortium Agreements” in Subpart B of this part). |
| <strong>Payroll Distribution</strong> | Salary and wage amounts charged to grant-supported projects for personal services must be based on an adequate payroll distribution system that documents such distribution in accordance with generally accepted practices of like organizations. Standards for payroll distribution systems are contained in the applicable cost principles (other than those for for-profit organizations). Briefly summarized, acceptable systems are as follows: |
|  | <strong>Hospitals</strong> |
|  | Ø Monthly after-the-fact reports of the distribution of time or effort for professional staff members. |
|  | Ø Time and attendance and payroll distribution records for non-professional employees. |
|  | <strong>Non-profit organizations</strong> |
|  | Ø Monthly after-the-fact reports, including a signed certification, by the employee, or by a responsible supervisory official having first-hand knowledge of the work performed, that the distribution of activity represents a reasonable estimate of the actual work performed by the employee during the period covered by the report. Each report must account for the total activity required to fulfill the employee’s obligations to the organization as well as the total activity for which he or she is compensated. |
|  | Ø For non-professional employees, additional supporting reports, indicating the total number of hours worked each day, must be maintained in conformance with DoL regulations implementing the Fair Labor Standards Act (29 CFR Part 516). |
|  | Ø The distribution of salaries and wages must be supported by personnel activity reports as described above, except when a substitute system has been approved, in writing, by the Federal cognizant agency designated under OMB Circular A-122. |</p>
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<tr>
<th>Category</th>
<th>Requirements</th>
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| State, local, and Indian tribal governments | Ø Time and attendance or equivalent records for all employees.  
Ø Time distribution records for employees whose compensation is chargeable to more than one grant or other cost objective. |
| Educational institutions       | Ø A plan confirmation system for professorial and other professional staff members that is based on budgeted, planned, or assigned work activity and that is updated to reflect any significant changes in work distribution. This system must be incorporated into the organization’s official records and must identify activity applicable to each sponsored agreement and to each category needed to identify F&A costs and the functions to which they are allocable. At least annually, the employee, PI, or responsible officials will verify, by suitable means, that the work was performed and that the salaries and wages charged to sponsored agreements, whether as direct charges or in other categories of cost, are reasonable in relation to the work performed; or  
Ø A system, supported by after-the-fact activity reports, that reflects the distribution of covered employees’ activity allocable to each NIH grant and includes identification and recording of significant changes in work activity when initial charges were based on estimates. The system also must specify each category of activity needed to identify F&A costs and the functions to which they are allocable. For professorial and other professional staff members, the activity reports will be prepared each academic term, but at least every 6 months. For other employees, unless NIH agrees to alternate arrangements, the reports will be prepared at least monthly and will coincide with one or more pay periods; or  
Ø A multiple confirmation records system, for professorial and other professional staff members, that is supported by records certifying costs separately for direct costs and F&A costs, with reports prepared each academic term, but at least every 6 months, that confirm the activities as allocable to direct or F&A costs; or  
Ø By mutual agreement, any other method meeting the criteria specified in paragraph J.8.b.(2) of OMB Circular A-21. |
| For-profit organizations      | Ø NIH requires for-profit organizations to conform with industry standards to support salary and wage charges to NIH grants. Therefore, unless an alternate system is approved by the GMO, the grantee must maintain a time-and-effort reporting system for both professional and other-than-professional staff reflecting daily after-the-fact reporting of hours expended on individual projects or indirect activities. The system must record both hours worked and hours absent. This information must be certified by an AOO no less frequently than every pay period. |

### Overtime Premiums

Premiums for overtime generally are allowable; however, such payments are not allowable for faculty members at institutions of higher education. If overtime premiums are allowable, the categories or classifications of employees eligible to receive overtime premiums should be determined according to the formal policies of the organization consistently applied regardless of the source of funds.

### Bonus Funds/Incentive Payments

Allowable as part of a total compensation package, provided such payments are reasonable and are made according to a formal policy of the grantee that is consistently applied regardless of the source of funds.
**Payments for Dual Appointments**

For investigators with university and clinical practice plan appointments, compensation from both sources may be considered the base salary if the following criteria are met:

1. Clinical practice compensation must be guaranteed by the university
2. Clinical practice effort must be shown on the university appointment form and must be paid through the university
3. Clinical practice effort must be included and accounted for on the university’s effort report.

**Support from Multiple Grants**

See “Cost Considerations—Allocation of Costs and Closely Related Work.”

**Compensation of Students**

Tuition remission and other forms of compensation paid as, or in lieu of, wages to students (including fellows and trainees) under research grants are allowable, provided the following conditions are met:

1. The individual is performing activities necessary to the grant
2. Tuition remission and other forms of compensation are consistently provided, in accordance with established institutional policy, to students performing similar activities conducted in nonsponsored as well as in sponsored activities
3. During the academic period, the student is enrolled in an advanced degree program at a grantee or affiliated institution and the activities of the student in relation to the federally sponsored research project are related to the degree program.

Charges for tuition remission and other forms of compensation paid to students as, or in lieu of, salaries and wages are subject to the reporting requirements in section J.8. of OMB Circular A-21, or an equivalent method for documenting the individual’s effort on the research project. Tuition remission may be charged on an average rate basis. NIH will determine the allowability and reasonableness of such compensation under a grant on the basis of OMB Circular A-21 and its current operating guidelines.

The maximum amount NIH will award for compensation of a graduate student receiving support from a research grant is tied to the zero-level Kirschstein-NRSA stipend in effect when NIH issues the grant award (see current levels posted at [http://grants.nih.gov/training/nrsa.htm](http://grants.nih.gov/training/nrsa.htm)).

Payments made for educational assistance (e.g., scholarships, fellowships, and student aid costs) may not be paid from NIH research grant funds even when they would appear to benefit the research project.

**Service Charges**

Allowable. The costs to a user of organizational services and central facilities owned by the grantee organization, such as central laboratory and computer services, are allowable and must be based on organizational fee schedules consistently applied regardless of the source of funds.

**Severance Pay**

Allowable only to the extent that such payments are required by law, are included in an employer-employee agreement, are part of an established policy effectively constituting an implied agreement on the part of the organization, or meet the circumstances of the particular employment. The amount of severance pay to be provided should be determined according to established organizational policy consistently applied regardless of the source of funds and should be reasonable, taking into consideration the practice of similar types of organizations and the extent of the organization’s dependence on Federal funds. The applicable cost principles should be consulted regarding the different treatment of severance pay in regular and mass termination situations.
<p>| <strong>Stipends</strong> | Allowable as cost-of-living allowances for trainees and fellows only under Kirschstein-NRSA individual fellowships and institutional research training grants. These payments are made according to a preestablished schedule based on the individual’s experience and level of training. A stipend is not a fee-for-service payment and is not subject to the cost accounting requirements of the cost principles. Additional information, including NIH policy on stipend supplementation, is included in “Ruth L. Kirschstein National Research Service Awards—Individual Fellowships—Supplementation of Stipends, Compensation, and Other Income—Stipend Supplementation” and “Ruth L. Kirschstein National Research Service Awards—Institutional Research Training Grants—Stipend Supplementation, Compensation, and Other Income—Stipend Supplementation” in Subpart B of this part. Stipends are not allowable under research grants even when they appear to benefit the research project. |
| <strong>Subject Costs</strong> | See “Research Patient Care” in this subsection. |
| <strong>Supplies</strong> | Allowable. |
| <strong>Taxes</strong> | Allowable. Such costs include taxes that an organization is required to pay as they relate to employment, services, travel, rental, or purchasing for a project. Grantees must avail themselves of any tax exemptions for which activities supported by Federal funds may qualify. State sales and use taxes for materials and equipment are allowable only when the State does not grant a refund or exemption on such taxes. |
| <strong>Termination or Suspension Costs</strong> | Unallowable except as follows. If a grant is terminated or suspended, the grantee may not incur new obligations after the effective date of the termination or suspension and must cancel as many outstanding obligations as possible (see “Administrative Requirements—Enforcement Actions—Suspension, Termination, and Withholding of Support”). NIH will allow full credit to the grantee for the Federal share of otherwise allowable costs if the obligations were properly incurred by the grantee before suspension or termination—and not in anticipation of it—and, in the case of termination, are not cancelable. The GMO may authorize other costs in, or subsequent to, the notice of termination or suspension. See 45 CFR 74.62(c) and 92.43. |
| <strong>Trailers and Modular Units</strong> | Allowable only if considered equipment as provided below. A “trailer” is defined as a portable vehicle built on a chassis that is designed to be hauled from one site to another by a separate means of propulsion and that serves, wherever parked, as a dwelling or place of business. A “modular unit” is a prefabricated portable unit designed to be moved to a site and assembled on a foundation to serve as a dwelling or a place of business. The determination of whether costs to acquire trailers or modular units are allowable charges to NIH grant-supported projects depends on whether such units are classified as real property or equipment. The classification will depend on whether the grantee’s intended use of the property is permanent or temporary. A trailer or modular unit is considered real property when the unit and its installation are designed or planned to be installed permanently at a given location so as to seem fixed to the land as a permanent structure or appurtenance thereto. Units classified as real property may not be charged to an NIH grant-supported project unless authorizing legislation permits construction or acquisition of real property and the specific purchase is approved by the NIH awarding office. |
| <strong>Trainee Costs</strong> | Allowable only under predoctoral and postdoctoral training grants. (See “Ruth L. Kirschstein National Research Service Awards—Institutional Research Training Grants—Allowable and Unallowable Costs” in Subpart B of this part for detailed information.) |</p>
<table>
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<tr>
<th><strong>Transportation of Property</strong></th>
<th>Allowable for freight, express, cartage, postage, and other transportation services relating to goods either purchased, in process, or delivered, including instances when equipment or other property is moved from one grantee to another. In a change-of-grantee situation, the cost of transportation may be charged to the grant at either the original or the new organization, depending on the circumstances and the availability of funds in the appropriate active grant account (see “Administrative Requirements—Changes in Project and Budget—Prior-Approval Requirements”).</th>
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<tr>
<td><strong>Travel</strong></td>
<td>Allowable as a direct cost where such travel will provide direct benefit to the project.</td>
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<td><strong>Employees</strong></td>
<td>Consistent with the organization’s established travel policy, these costs for employees working on the grant-supported project may include associated per diem or subsistence allowances and other travel-related expenses, such as mileage allowances if travel is by personal automobile. Domestic travel is travel performed within the recipient’s own country. For U.S. and Canadian recipients, it includes travel within and between any of the 50 States of the United States and its possessions and territories and also travel between the United States and Canada and within Canada. Foreign travel is defined as any travel outside of Canada and the United States and its territories and possessions. However, for an organization located outside Canada and the United States and its territories and possessions, foreign travel means travel outside that country. In all cases, travel costs are limited to those allowed by formal organizational policy and, in the case of air travel, the lowest reasonable commercial airfares must be used. For-profit grantees’ allowable travel costs may not exceed those established by the FTR, issued by GSA, including the maximum per diem and subsistence rates prescribed in those regulations. This information is available at <a href="http://www.gsa.gov">http://www.gsa.gov</a>. If a recipient organization has no formal travel policy, those regulations will be used to determine the amount that may be charged for travel costs.</td>
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<td><strong>Grantees are strongly encouraged to take advantage of discount fares for airline travel through advance purchase of tickets if travel schedules can be planned in advance (such as for national meetings and other scheduled events).</strong> Grantees must comply with the requirement that U.S. flag air carriers be used by domestic grantees to the maximum extent possible when commercial air transportation is the means of travel between the United States and a foreign country or between foreign countries. This requirement must not be influenced by factors of cost, convenience, or personal travel preference. The cost of travel under a ticket issued by a U.S. flag air carrier that leases space on a foreign air carrier under a code-sharing agreement is allowable if the purchase is in accordance with GSA regulations on U.S. flag air carriers and code shares (<a href="http://www.gsa.gov/gsa/cm_attachments/GSA_DOCUMENT/110304_FTR_R2QA53_0Z5RDZ-i34K-pR.pdf">http://www.gsa.gov/gsa/cm_attachments/GSA_DOCUMENT/110304_FTR_R2QA53_0Z5RDZ-i34K-pR.pdf</a>). (A code-sharing agreement is an arrangement between a U.S. flag carrier and a foreign air carrier in which the U.S. flag carrier provides passenger service on the foreign air carrier’s regularly scheduled commercial flights.) Applicants and grantees should consult application instructions to determine how to budget for travel costs under specific mechanisms and for certain types of travelers because they are not all required to be budgeted as travel.</td>
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<tr>
<td><strong>Research Patients</strong></td>
<td>If research patient care is an approved activity of the grant-supported project, the costs of transporting individuals participating in the research protocol to the site where services are being provided, including costs of public transportation, are allowable. The purchase of motor vehicles for this purpose also may be allowable. (See “Research Patient Care.”)</td>
</tr>
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APPENDIX III.

NIH DEFINITIONS from the NIH Grants Policy Statement

Definitions of Terms

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tbody>
<tr>
<td>alteration and renovation</td>
<td>Work that changes the interior arrangements or other physical characteristics of an existing facility or of installed equipment so that it can be used more effectively for its currently designated purpose or adapted to an alternative use to meet a programmatic requirement. Major A&amp;R (including modernization, remodeling, or improvement) of an existing building is permitted under an NIH grant only when the authorizing statute for the program specifically allows that activity. (See “Allowability of Costs/Activities—Selected Items of Cost—Alteration and Renovation” and “Allowability of Costs/Activities—Selected Items of Cost—Construction.”)</td>
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<tr>
<td>application</td>
<td>A request for financial support of a project or activity submitted to NIH on specified forms and in accordance with NIH instructions. (See “Application and Review Processes” for detailed information about the application process, including an explanation of the types of applications.)</td>
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<tr>
<td>approved budget</td>
<td>The financial expenditure plan for the grant-supported project or activity, including revisions approved by NIH and permissible revisions made by the grantee. The approved budget consists of Federal (grant) funds and, if required by the terms and conditions of the award, non-Federal participation in the form of matching or cost sharing. The approved budget specified in the NGA may be shown in detailed budget categories or as total costs without a categorical breakout. Expenditures charged to an approved budget that consists of both Federal and non-Federal shares are deemed to be borne by the grantee in the same proportion as the percentage of Federal/non-Federal participation in the overall budget.</td>
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<td>authorized organizational official</td>
<td>The individual, named by the applicant organization, who is authorized to act for the applicant and to assume the obligations imposed by the Federal laws, regulations, requirements, and conditions that apply to grant applications or grant awards. This official is equivalent to the SO in NIH’s eRA Commons.</td>
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<tr>
<td>award</td>
<td>The provision of funds by NIH, based on an approved application and budget or progress report, to an organizational entity or an individual to carry out a project or activity.</td>
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<tr>
<td>awarding office</td>
<td>The NIH IC responsible for the award, administration, and monitoring of particular grants.</td>
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<tr>
<td>budget period</td>
<td>The intervals of time (usually 12 months each) into which a project period is divided for budgetary and funding purposes.</td>
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<td>capital expenditure</td>
<td>The cost of an asset (land, building, equipment), including the cost to put it in place. A capital expenditure for equipment includes the net invoice price and the cost of any modifications, attachments, accessories, or auxiliary apparatus to make it usable for the purpose for which it was acquired. Other charges, such as taxes, in-transit insurance, freight, and installation, may be included in capital expenditure costs in accordance with the recipient’s regular accounting practices consistently applied regardless of the source of funds. (See “Administrative Requirements—Changes in Project and Budget—Prior-Approval Requirements—Capital Expenditures.”)</td>
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<tr>
<td>clinical research</td>
<td>Patient-oriented research, including epidemiologic and behavioral studies, outcomes research, and health services research. Patient-oriented research is research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) in which a researcher directly interacts with human subjects. It includes research on mechanisms of human disease, therapeutic interventions, clinical trials, and development of new technologies, but does not include in vitro studies that use human tissues that cannot be linked to a living individual. Studies falling under 45 CFR 46.101(a) (4) are not considered clinical research for purposes of this definition.</td>
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<tr>
<td>clinical trial</td>
<td>A biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices). Clinical trials are used to determine whether new biomedical or behavioral interventions are safe, efficacious, and effective. Clinical trials of an experimental drug, treatment, device, or intervention may proceed through four phases: Phase I. Testing in a small group of people (e.g. 20-80) to determine efficacy and evaluate safety (e.g., determine a safe dosage range and identify side effects). Phase II. Study in a larger group of people (several hundred) to determine efficacy and further evaluate safety. Phase III. Study to determine efficacy in large groups of people (from several hundred to several thousand) by comparing the intervention to other standard or experimental interventions, to monitor adverse effects, and to collect information to allow safe use. Phase IV. Studies done after the intervention has been marketed. These studies are designed to monitor the effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with widespread use.</td>
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<tr>
<td>competitive segment</td>
<td>The initial project period recommended for support (up to 5 years) or each extension of a project period resulting from a competing continuation award.</td>
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<td>consortium agreement</td>
<td>A formalized agreement whereby a research project is carried out by the grantee and one or more other organizations that are separate legal entities. Under the agreement, the grantee must perform a substantive role in the conduct of the planned research and not merely serve as a conduit of funds to another party or parties. (See “Consortium Agreements” in Part II, Subpart B.)</td>
</tr>
<tr>
<td>contract under a grant</td>
<td>A written agreement between a grantee and a third party to acquire routine goods or services.</td>
</tr>
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<td><strong>Consultant</strong></td>
<td>An individual who provides professional advice or services for a fee, but normally not as an employee of the engaging party. In unusual situations, an individual may be both a consultant and an employee of the same party, receiving compensation for some services as a consultant and for other work as a salaried employee. Consultants also include firms that provide professional advice or services. (See “Allowability of Costs/Activities—Selected Items of Cost—Consultant Services.”)</td>
</tr>
<tr>
<td><strong>Cooperative Agreement</strong></td>
<td>A support mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means that, after award, scientific or program staff will assist, guide, coordinate, or participate in project activities.</td>
</tr>
<tr>
<td><strong>Co-Investigator</strong></td>
<td>An individual involved with the PI in the scientific development or execution of a project. The co-investigator (collaborator) may be employed by, or be affiliated with, the applicant/grantee organization or another organization participating in the project under a consortium agreement. A co-investigator typically devotes a specified percentage of time to the project and is considered “key personnel.” The designation of a co-investigator, if applicable, does not affect the PI’s roles and responsibilities as specified in the NIHGPS.</td>
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<tr>
<td><strong>Cost Overrun</strong></td>
<td>Any amount charged in excess of the Federal share of costs for the project period (competitive segment).</td>
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<td><strong>Cost Sharing</strong></td>
<td>See “matching or cost sharing” in this section.</td>
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<tr>
<td><strong>Direct Costs</strong></td>
<td>Costs that can be specifically identified with a particular project or activity.</td>
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<td><strong>Domestic Organization</strong></td>
<td>A public (including a State or other governmental agency) or private non-profit or for-profit organization that is located in the United States or its territories, is subject to U.S. laws, and assumes legal and financial accountability for awarded funds and for the performance of the grant-supported activities.</td>
</tr>
<tr>
<td><strong>Equipment</strong></td>
<td>An article of tangible nonexpendable personal property that has a useful life of more than 1 year and an acquisition cost per unit that equals or exceeds $5,000 or the capitalization threshold established by the organization, whichever is less.</td>
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<tr>
<td><strong>Expanded Authorities</strong></td>
<td>Operating authorities provided to grantees that waive the requirement for NIH prior approval for specified actions (see “Administrative Requirements—Changes in Project and Budget—Expanded Authorities”).</td>
</tr>
<tr>
<td><strong>Facilities and Administrative Costs</strong></td>
<td>Costs that are incurred by a grantee for common or joint objectives and cannot be identified specifically with a particular project or program. These costs also are known as “indirect costs.”</td>
</tr>
<tr>
<td><strong>Federal Demonstration Partnership</strong></td>
<td>A cooperative initiative among some Federal agencies, including NIH, selected organizations receiving Federal funding for research, and certain professional associations. Its efforts include demonstration projects intended to simplify and standardize Federal requirements in order to increase research productivity and reduce administrative costs.</td>
</tr>
<tr>
<td>Term</td>
<td>Definition</td>
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</tr>
<tr>
<td>Federal institution</td>
<td>A Cabinet-level department or independent agency of the executive branch of the Federal government or any component organization of such a department or agency.</td>
</tr>
<tr>
<td>fee</td>
<td>An amount, in addition to actual, allowable costs, paid to an organization providing goods or services consistent with normal commercial practice. This payment also is referred to as “profit.” (See “Grants to For-Profit Organizations—Small Business Innovation Research and Small Business Technology Transfer Programs—Allowable Costs and Fee—Profit or Fee.”)</td>
</tr>
<tr>
<td>financial assistance</td>
<td>Transfer by NIH of money or property to an eligible entity to support or stimulate a public purpose authorized by statute.</td>
</tr>
<tr>
<td>foreign component</td>
<td>The performance of any significant scientific element or segment of a project outside of the United States, either by the grantee or by a researcher employed by a foreign organization, whether or not grant funds are expended. Activities that would meet this definition include, but are not limited to, (1) the involvement of human subjects or animals, (2) extensive foreign travel by grantee project staff for the purpose of data collection, surveying, sampling, and similar activities, or (3) any activity of the grantee that may have an impact on U.S. foreign policy through involvement in the affairs or environment of a foreign country. Foreign travel for consultation is not considered a foreign component. (See “Grants to Foreign Institutions, International Organizations, and Domestic Grants with Foreign Components.”)</td>
</tr>
<tr>
<td>foreign institution</td>
<td>An organization located in a country other than the United States and its territories that is subject to the laws of that country, regardless of the citizenship of the proposed PI.</td>
</tr>
<tr>
<td>for-profit organization</td>
<td>An organization, institution, corporation, or other legal entity that is organized or operated for the profit or financial benefit of its shareholders or other owners. Such organizations also are referred to as “commercial organizations.”</td>
</tr>
<tr>
<td>full-time appointment</td>
<td>The number of days per week and/or months per year representing full-time effort at the applicant/grantee organization, as specified in organizational policy. The organization’s policy must be applied consistently regardless of the source of support.</td>
</tr>
<tr>
<td>grant</td>
<td>A financial assistance mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity. A grant is used whenever the NIH IC anticipates no substantial programmatic involvement with the recipient during performance of the financially assisted activities.</td>
</tr>
<tr>
<td>grant-supported project or activity</td>
<td>Those activities specified or described in a grant application or in a subsequent submission that are approved by an NIH IC for funding, regardless of whether Federal funding constitutes all or only a portion of the financial support necessary to carry them out.</td>
</tr>
<tr>
<td><strong>grantee</strong></td>
<td>The organization or individual awarded a grant or cooperative agreement by NIH that is responsible and accountable for the use of the funds provided and for the performance of the grant-supported project or activity. The grantee is the entire legal entity even if a particular component is designated in NGA. The grantee is legally responsible and accountable to NIH for the performance and financial aspects of the grant-supported project or activity.</td>
</tr>
<tr>
<td><strong>Grants Management Officer</strong></td>
<td>An NIH official responsible for the business management aspects of grants and cooperative agreements, including review, negotiation, award, and administration, and for the interpretation of grants administration policies and provisions. Only GMOs are authorized to obligate NIH to the expenditure of funds and permit changes to approved projects on behalf of NIH. Each NIH IC that awards grants has one or more GMOs with responsibility for particular programs or awards.</td>
</tr>
<tr>
<td><strong>Grants Management Specialist</strong></td>
<td>An NIH staff member who oversees the business and other non-programmatic aspects of one or more grants and/or cooperative agreements. These activities include, but are not limited to, evaluating grant applications for administrative content and compliance with statutes, regulations, and guidelines; negotiating grants; providing consultation and technical assistance to grantees; and administering grants after award.</td>
</tr>
<tr>
<td><strong>hospital</strong></td>
<td>A non-profit or for-profit hospital or a medical care provider component of a non-profit organization (for example, a foundation). The term includes all types of medical, psychiatric, and dental facilities, such as clinics, infirmaries, and sanatoria.</td>
</tr>
<tr>
<td><strong>human subject</strong></td>
<td>A living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual or obtains identifiable private information. Regulations governing the use of human subjects in research extend to use of human organs, tissues, and body fluids from identifiable individuals as human subjects and to graphic, written, or recorded information derived from such individuals. (See “Requirements Affecting the Rights and Welfare of Individuals as Research Subjects, Patients, or Recipients of Services—Human Subjects.”)</td>
</tr>
<tr>
<td><strong>indirect costs</strong></td>
<td>See “facilities and administrative costs.”</td>
</tr>
<tr>
<td><strong>Institute or Center</strong></td>
<td>The NIH organizational component responsible for a particular grant program or set of activities. The terms “NIH IC” or “awarding office” are used throughout this document to designate a point of contact for advice and interpretation of grant requirements and to establish the focal point for requesting necessary prior approvals or changes in the terms and conditions of award. In the latter case, the terms refer specifically to the designated GMO.</td>
</tr>
<tr>
<td>Term</td>
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<tr>
<td>institutional base salary</td>
<td>The annual compensation paid by an organization for an employee’s appointment, whether that individual’s time is spent on research, teaching, patient care, or other activities. Base salary excludes any income that an individual is permitted to earn outside of duties for the applicant/grantee organization. Base salary may not be increased as a result of replacing organizational salary funds with NIH grant funds. (See “Allowability of Costs/Activities—Selected Items of Cost—Salaries and Wages.”)</td>
</tr>
<tr>
<td>international organization</td>
<td>An organization that identifies itself as international or intergovernmental and has membership from, and represents the interests of, more than one country, without regard to whether the headquarters of the organization and location of the activity are inside or outside of the United States.</td>
</tr>
<tr>
<td>key personnel</td>
<td>The PI and other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the grant. Typically these individuals have doctoral or other professional degrees, although individuals at the masters or baccalaureate level may be considered key personnel if their involvement meets this definition. Consultants also may be considered key personnel if they meet this definition. “Zero percent” effort or “as needed” is not an acceptable level of involvement for key personnel.</td>
</tr>
<tr>
<td>matching or cost sharing</td>
<td>The value of third-party in-kind contributions and the portion of the costs of a federally assisted project or program not borne by the Federal government. Matching or cost sharing may be required by law, regulation, or administrative decision of an NIH IC. Costs used to satisfy matching or cost-sharing requirements are subject to the same policies governing allowability as other costs under the approved budget.</td>
</tr>
<tr>
<td>modular application</td>
<td>A type of grant application in which support is requested in specified increments without the need for detailed supporting information related to separate budget categories. When modular procedures apply, they affect not only application preparation but also review of the application, award, and post-award administration.</td>
</tr>
<tr>
<td>monitoring</td>
<td>A process whereby the programmatic and business management performance aspects of a grant are assessed by reviewing information gathered from various required reports, audits, site visits, and other sources.</td>
</tr>
<tr>
<td>new investigator</td>
<td>An individual who has not previously served as a PI on any PHS-supported research project other than a small grant (R03), an Academic Research Enhancement Award (R15), an exploratory development grant (R21), or certain research career awards directed principally to physicians, dentists, or veterinarians at the beginning of their research careers ((K01, K08, and K12). Current or past recipients of Independent Scientist and other non-mentored career awards (K02 and K04) are not considered “new investigators.”</td>
</tr>
<tr>
<td>Notice of Grant Award</td>
<td>The legally binding document that notifies the grantee and others that an award has been made, contains or references all terms and conditions of the award, and documents the obligation of Federal funds. The award notice may be in letter format and may be issued electronically.</td>
</tr>
<tr>
<td>Term</td>
<td>Definition</td>
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</tr>
<tr>
<td>organization</td>
<td>A generic term used to refer to an educational institution or other entity, including an individual, which applies for or receives an NIH grant or cooperative agreement.</td>
</tr>
<tr>
<td>other support</td>
<td>Includes all financial resources, whether Federal, non-Federal, commercial or organizational, available in direct support of an individual’s research endeavors, including, but not limited to, research grants, cooperative agreements, contracts, or organizational awards. Other support does not include training awards, prizes, or gifts.</td>
</tr>
<tr>
<td>Phase III clinical trial</td>
<td>As defined by NIH, a broadly based prospective Phase III clinical investigation (usually involving several hundred or more human subjects) to evaluate an experimental intervention in comparison with a standard or control intervention or to compare two or more existing treatments. The definition includes pharmacologic, non-pharmacologic, and behavioral interventions given for disease prevention, prophylaxis, diagnosis, or therapy. Community trials and other population-based intervention trials also are included. (See “clinical trial.”)</td>
</tr>
<tr>
<td>Principal Investigator/Program Director/Project Director</td>
<td>An individual designated by the grantee to direct the project or activity being supported by the grant. He or she is responsible and accountable to the grantee and NIH for the proper conduct of the project or activity.</td>
</tr>
<tr>
<td>prior approval</td>
<td>Written approval from the designated GMO required for specified post-award changes in the approved project or budget. Such approval must be obtained before undertaking the proposed activity or spending NIH funds (see “Administrative Requirements—Changes in Project and Budget—Prior-Approval Requirements”).</td>
</tr>
<tr>
<td>priority score</td>
<td>A numerical rating of an application that reflects the scientific merit of the proposed research relative to stated evaluation criteria.</td>
</tr>
<tr>
<td>profit</td>
<td>See “fee.”</td>
</tr>
<tr>
<td>program</td>
<td>A coherent assembly of plans, project activities, and supporting resources contained within an administrative framework, the purpose of which is to implement an organization’s mission or some specific program-related aspect of that mission. For the NIHGPS, “program” refers to those NIH programs that carry out their missions through the award of grants or cooperative agreements to other organizations.</td>
</tr>
<tr>
<td>program income</td>
<td>Gross income earned by a grantee that is directly generated by the grant-supported project or activity or earned as a result of the award (see “Administrative Requirements—Management Systems and Procedures—Program Income”).</td>
</tr>
<tr>
<td>Program Official</td>
<td>The NIH official responsible for the programmatic, scientific, and/or technical aspects of a grant.</td>
</tr>
<tr>
<td>Term</td>
<td>Definition</td>
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<tr>
<td>progress report</td>
<td>Periodic, usually annual, report submitted by the grantee and used by NIH to assess progress and, except for the final progress report of a project period, to determine whether to provide funding for the budget period subsequent to that covered by the report.</td>
</tr>
<tr>
<td>project period</td>
<td>The total time for which support of a project has been programmatically approved. The total project period comprises the initial competitive segment, any subsequent competitive segments resulting from a competing continuation award, and non-competing extensions.</td>
</tr>
<tr>
<td>real property</td>
<td>Land, including land improvements, structures, and appurtenances, but not movable machinery and equipment.</td>
</tr>
<tr>
<td>recipient</td>
<td>The organizational entity or individual receiving a grant or cooperative agreement. See “grantee,”</td>
</tr>
<tr>
<td>research</td>
<td>A systematic, intensive study intended to increase knowledge or understanding of the subject studied, a systematic study specifically directed toward applying new knowledge to meet a recognized need, or a systematic application of knowledge to the production of useful materials, devices, and systems or methods, including design, development, and improvement of prototypes and new processes to meet specific requirements. Also termed “research and development.”</td>
</tr>
<tr>
<td>research misconduct</td>
<td>Fabrication, falsification, or plagiarism in proposing, performing, or reporting research, or in reporting research results. Fabrication is making up data or results and recording or reporting them. Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that research is not accurately represented in the research record. Plagiarism is the appropriation of another person’s ideas, processes, results, or words without giving appropriate credit. The term does not include honest error or honest differences of opinion.</td>
</tr>
<tr>
<td>significant rebudgeting</td>
<td>A threshold that is reached when expenditures in a single direct cost budget category deviate (increase or decrease) from the categorical commitment level established for the budget period by more than 25 percent of the total costs awarded. Significant rebudgeting is one indicator of change in scope.</td>
</tr>
<tr>
<td>small business concern</td>
<td>A business that is independently owned and operated and not dominant in its field of operation; has its principal place of business in the United States and is organized for profit; is at least 51 percent owned, or in the case of a publicly owned business, at least 51 percent of its voting stock is owned by U.S. citizens or lawfully admitted permanent resident aliens; has, including its affiliates, not more than 500 employees; and meets other regulatory requirements established by the SBA at 13 CFR 121.</td>
</tr>
<tr>
<td>State government</td>
<td>The government of any State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, any U.S. territory or possession, or any agency or instrumentality of a State exclusive of local governments. For purposes of NIH grants, federally recognized Indian tribal governments generally are considered State governments. State institutions of higher education and State hospitals are not considered State governments for HHS’s general administrative requirements for grants and the NIHGPS.</td>
</tr>
<tr>
<td><strong>stipend</strong></td>
<td>A payment made to an individual under a fellowship or training grant in accordance with preestablished levels to provide for the individual's living expenses during the period of training. A stipend is not considered compensation for the services expected of an employee.</td>
</tr>
<tr>
<td><strong>suspension</strong></td>
<td>Temporary withdrawal of a grantee’s authority to obligate grant funds, pending either corrective action by the grantee, as specified by NIH, or a decision by NIH to terminate the award. This meaning of the term “suspension” differs from that used in conjunction with the debarment and suspension process (see “Public Policy Requirements and Objectives—Ethical and Safe Conduct in Science and Organizational Operations—Debarment and Suspension” and “Administrative Requirements—Enforcement Actions.”)</td>
</tr>
<tr>
<td><strong>termination</strong></td>
<td>Permanent withdrawal by NIH of a grantee’s authority to obligate previously awarded grant funds before that authority would otherwise expire, including the voluntary relinquishment of that authority by the grantee.</td>
</tr>
<tr>
<td><strong>terms and conditions of award</strong></td>
<td>All legal requirements imposed on a grant by NIH, whether based on statute, regulation, policy, or other document referenced in the grant award, or specified by the grant award document itself. The NGA may include both standard and special conditions that are considered necessary to attain the grant’s objectives, facilitate post-award administration of the grant, conserve grant funds, or otherwise protect the Federal government’s interests.</td>
</tr>
<tr>
<td><strong>total project costs</strong></td>
<td>The total allowable costs (both direct costs and F&amp;A costs) incurred by the grantee to carry out a grant-supported project or activity. Total project costs include costs charged to the NIH grant and costs borne by the grantee to satisfy a matching or cost-sharing requirement.</td>
</tr>
<tr>
<td><strong>United States</strong></td>
<td>The 50 States, territories, and possessions of the United States, the Commonwealth of Puerto Rico, the Trust Territory of the Pacific Islands, and the District of Columbia.</td>
</tr>
<tr>
<td><strong>withholding of support</strong></td>
<td>A decision by NIH not to make a non-competing continuation award within the current competitive segment.</td>
</tr>
</tbody>
</table>