

NATIONAL INSTITUTES OF HEALTH (NIH)

Interim Grant General Conditions

Effective December 26, 2014

Effective December 26, 2014, new NIH grants and funding amendments to existing NIH grants will begin referencing, and are subject to, the *Grant General Conditions* dated 12/26/14.

Preamble

This document contains Interim Grant General Conditions for NIH awards based regulations at 45 CFR Part 75, which implements 2 CFR Part 200, *Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards* (“Uniform Guidance”) for the Department Health and Human Services (HHS) operating divisions. It is intended to highlight changes to NIH general grant conditions resulting from implementation of the Uniform Guidance. Although Uniform Guidance related updates are the focus of this document, in some cases—e.g., cost considerations, NIH standard terms of award, special award conditions, and grants appeal procedures—current policy is reiterated to provide recipients with further context.

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PART I: NIH GRANTS—GENERAL INFORMATION

1. Definitions

Based on 45 CFR 75, NIH is adding or modifying definitions of the following terms:

| Term | Definition |
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| Acquisition cost | The cost of the asset including the cost to ready the asset for its intended use. Acquisition cost for equipment, for example, means the net invoice price of the equipment, including the cost of any modifications, attachments, accessories, or auxiliary apparatus necessary to make it usable for the purpose for which it is acquired. Acquisition costs for software includes those development costs capitalized in accordance with generally accepted accounting principles (GAAP). Ancillary charges, such as taxes, duty, protective in transit insurance, freight, and installation may be included in or excluded from the acquisition cost in accordance with the non-Federal entity's regular accounting practices. |
| Additive alternative | A use of program income earned during or after the project period that permits income that is generated under a grant to be added to funds committed to the project by the Federal awarding agency and recipient and used to further eligible project or program objectives. (<i>See definitions for deductive alternative and cost sharing or matching alternative and Administrative Requirements—Management Systems and Procedures—Program Income in the most recent edition of the NIH Grants Policy Statement.</i>) |
| Advance payment | A payment that a Federal awarding agency or pass-through entity makes by any appropriate payment mechanism, including a predetermined payment schedule, before the non-Federal entity disburses the funds for program purposes. |
| Allocation | The process of assigning a cost, or a group of costs, to one or more cost objective(s), in reasonable proportion to the benefit provided or other equitable relationship. The process may entail assigning a cost(s) directly to a final cost objective or through one or more intermediate cost objectives. |
| Alteration and renovation | 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. <i>See also definitions for Major A&R and Minor A&R.</i> |
| Audit finding | Deficiencies which an auditor is required by 45 CFR 75.516(a) to report in the schedule of findings and questioned costs. |
| Award | 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. |
| Budget | The financial plan for the project or program that the Federal awarding agency or pass-through entity approves during the Federal award process or in subsequent amendments to the Federal award. It may include the Federal and non-Federal share or only the Federal share, as determined by the Federal awarding agency or pass-through entity. The approved budget specified in the NoA 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 recipient in the same proportion as the percentage of Federal/non-Federal participation in the overall budget. |

| Term | Definition |
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| Capital assets | Tangible or intangible assets used in operations having a useful life of more than one year which are capitalized in accordance with GAAP. Capital assets include: (1) Land, buildings (facilities), equipment, and intellectual property (including software) whether acquired by purchase, construction, manufacture, lease-purchase, exchange, or through capital leases; and (2) Additions, improvements, modifications, replacements, rearrangements, reinstallations, renovations or alterations to capital assets that materially increase their value or useful life (not ordinary repairs and maintenance). |
| Capital expenditures | Expenditures to acquire capital assets or expenditures to make additions, improvements, modifications, replacements, rearrangements, reinstallations, renovations, or alterations to capital assets that materially increase their value or useful life. |
| Change of recipient organization | Transfer of the legal and administrative responsibility for a grant-supported project or activity from one legal entity to another before the completion date of the approved project period (competitive segment). |
| Claim | Depending on the context, either: (1) A written demand or written assertion by one of the parties to a Federal award seeking as a matter of right: (i) The payment of money in a sum certain; (ii) The adjustment or interpretation of the terms and conditions of the Federal award; or (iii) Other relief arising under or relating to a Federal award. (2) A request for payment that is not in dispute when submitted. |
| Closeout | The process by which the Federal awarding agency or pass-through entity determines that all applicable administrative actions and all required work of the Federal award have been completed and takes actions as described in 45 CFR 75.381. |
| Cluster of programs | A grouping of closely related programs that share common compliance requirements. The types of clusters of programs are research and development (R&D), student financial aid (SFA), and other clusters. "Other clusters" are as defined by OMB in the compliance supplement or as designated by a state for Federal awards the state provides to its subrecipients that meet the definition of a cluster of programs. When designating an "other cluster," a state must identify the Federal awards included in the cluster and advise the subrecipients of compliance requirements applicable to the cluster, consistent with 45 CFR 75.352(a). A cluster of programs must be considered as one program for determining major programs, as described in 45 CFR 75.518, and, with the exception of R&D as described in 45 CFR 75.501(c), whether a program-specific audit may be elected. |
| Cognizant agency for audit | The Federal agency designated to carry out the responsibilities described in 45 CFR 75.513(a). The cognizant agency for audit is not necessarily the same as the cognizant agency for indirect costs. A list of cognizant agencies for audit may be found at the FAC Web site. |
| Cognizant agency for indirect costs | The Federal agency responsible for reviewing, negotiating, and approving cost allocation plans or indirect cost proposals developed under this part on behalf of all Federal agencies. The cognizant agency for indirect cost is not necessarily the same as the cognizant agency for audit. For assignments of cognizant agencies see the following: (1) For IHEs: 45 CFR 75, Appendix III, C.11. (2) For nonprofit organizations: 45 CFR 75, Appendix IV, C.2. (3) For state and local governments: 45 CFR 75, Appendix V, F.1. (4) For Indian tribes: 45 CFR 75, Appendix VII, D.1. |

| Term | Definition |
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| Commercial organization | An organization, institution, corporation, or other legal entity, including, but not limited to, partnerships, sole proprietorships, and limited liability companies, that is organized or operated for the profit or benefit of its shareholders or other owners. The term includes small and large businesses and is used interchangeably with “for-profit organization.” |
| Compliance Supplement | Appendix XI to 45 CFR 75 (previously known as the Circular A-133 Compliance Supplement). |
| Computing devices | Machines used to acquire, store, analyze, process, and publish data and other information electronically, including accessories (or “peripherals”) for printing, transmitting and receiving, or storing electronic information. <i>See also “supplies” and “information technology systems.”</i> |
| Contract | A legal instrument by which a non-Federal entity purchases property or services needed to carry out the project or program under a Federal award. The term does not include a legal instrument, even if the non-Federal entity considers it a contract, when the substance of the transaction meets the definition of a Federal award or subaward. <i>See Subaward.</i> |
| Contractor | An entity that receives a contract. <i>See Contract.</i> |
| Cooperative agreement | A legal instrument of financial assistance between a Federal awarding agency or pass-through entity and a non-Federal entity that, consistent with 31 U.S.C. 6302–6305: (1) Is used to enter into a relationship the principal purpose of which is to transfer anything of value from the Federal awarding agency or pass-through entity to the non-Federal entity to carry out a public purpose authorized by a law of the United States (see 31 U.S.C. 6101(3)); and not to acquire property or services for the Federal government or pass-through entity’s direct benefit or use; (2) Is distinguished from a grant in that it provides for substantial involvement between the Federal awarding agency or pass-through entity and the non-Federal entity in carrying out the activity contemplated by the Federal award. (3) The term does not include: (i) A cooperative research and development agreement as defined in 15 U.S.C. 3710a; or (ii) An agreement that provides only: (A) Direct United States Government cash assistance to an individual; (B) A subsidy; (C) A loan; (D) A loan guarantee; or (E) Insurance. |
| Cost allocation plan | Central service cost allocation plan or public assistance cost allocation plan. |
| Cost objective | A program, function, activity, award, organizational subdivision, contract, or work unit for which cost data are desired and for which provision is made to accumulate and measure the cost of processes, products, jobs, capital projects, etc. A cost objective may be a major function of the non-Federal entity, a particular service or project, a Federal award, or an indirect (Facilities & Administrative (F&A)) cost activity, as described in 2 CFR 200, Subpart E—Cost Principles |
| Cost principles | The government-wide principles, issued by OMB (or, in the case of commercial organizations, the Federal Acquisition Regulation [48 CFR 31], or, in the case of hospitals, 45 CFR 75, Appendix IX, "Principles For Determining Costs Applicable to Research and Development Under Grants and Contracts with Hospitals"), on allowability and unallowability of costs under federally sponsored agreements. |
| Cost-type contract | A contract or subcontract under a grant in which the contractor or subcontractor is paid on the basis of the allowable costs it incurs, with or without a fee. |

| Term | Definition |
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| Departmental Grants Appeals Board | The independent office established in the Office of the Secretary with delegated authority from the Secretary to review and decide certain disputes between recipients of HHS funds and HHS awarding agencies under 45 CFR Part 16 and to perform other review, adjudication and mediation services as assigned. |
| Disallowed costs | Those charges to a Federal award that the Federal awarding agency or pass-through entity determines to be unallowable, in accordance with the applicable Federal statutes, regulations, or the terms and conditions of the Federal award. |
| Equipment | Tangible personal property (including information technology systems) having a useful life of more than one year and a per-unit acquisition cost which equals or exceeds the lesser of the capitalization level established by the non-Federal entity for financial statement purposes, or \$5,000. <i>(See also capital assets, computing devices, general purpose equipment, information technology systems, special purpose equipment, and supplies).</i> |
| Expenditure report | (1) For non-construction grants, the SF-425 Federal Financial Report (FFR) (or other OMB-approved equivalent report); (2) for construction grants, the SF-271 "Outlay Report and Request for Reimbursement" (or other OMB-approved equivalent report). |
| Expenditures | <p>Charges made by a non-Federal entity to a project or program for which a Federal award was received.</p> <p>(1) The charges may be reported on a cash or accrual basis, as long as the methodology is disclosed and is consistently applied.</p> <p>(2) For reports prepared on a cash basis, expenditures are the sum of:</p> <ul style="list-style-type: none"> (i) Cash disbursements for direct charges for property and services; (ii) The amount of indirect expense charged; (iii) The value of third-party in-kind contributions applied; and (iv) The amount of cash advance payments and payments made to subrecipients. <p>(3) For reports prepared on an accrual basis, expenditures are the sum of:</p> <ul style="list-style-type: none"> (i) Cash disbursements for direct charges for property and services; (ii) The amount of indirect expense incurred; (iii) The value of third-party in-kind contributions applied; and (iv) The net increase or decrease in the amounts owed by the non-Federal entity for: <ul style="list-style-type: none"> (A) Goods and other property received; (B) Services performed by employees, contractors, subrecipients, and other payees; and (C) Programs for which no current services or performance are required such as annuities, insurance claims, or other benefit payments. |
| Facilities and Administrative (F&A) costs (or indirect costs) | Costs incurred by a recipient for a common or joint purpose benefitting more than one cost objective, and not readily assignable to the cost objectives specifically benefitted, without effort disproportionate to the results achieved. To facilitate equitable distribution of indirect expenses to the cost objectives served, it may be necessary to establish a number of pools of F&A (indirect) costs. F&A (indirect) cost pools must be distributed to benefitted cost objectives on bases that will produce an equitable result in consideration of relative benefits derived. |
| Federal agency | An "agency" as defined at 5 U.S.C. 551(1) and further clarified by 5 U.S.C. 552(f). |

| Term | Definition |
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| Federal Audit Clearinghouse (FAC) | The clearinghouse designated by OMB as the repository of record where non-Federal entities are required to transmit the reporting packages required by Subpart F—Audit Requirements of 2 CFR 200. The mailing address of the FAC is Federal Audit Clearinghouse, Bureau of the Census, 1201 E. 10th Street, Jeffersonville, IN 47132 and the web address is: http://harvester.census.gov/sac/ . Any future updates to the location of the FAC may be found at the OMB Web site. |
| Federal award date | The date when the Federal award is signed by the authorized official of the Federal awarding agency. |
| Federal awarding agency | The Federal agency that provides a Federal award directly to another entity. <i>See also Awarding IC.</i> |
| Federal financial assistance | <p>(1) For grants and cooperative agreements, Federal financial assistance means assistance that non-Federal entities receive or administer in the form of:</p> <ul style="list-style-type: none"> (i) Grants; (ii) Cooperative agreements; (iii) Non-cash contributions or donations of property (including donated surplus property); (iv) Direct appropriations; (v) Food commodities; and (vi) Other financial assistance (except assistance listed in paragraph (2) of this section). <p>(2) For Subpart F of 45 CFR 75, Federal financial assistance also includes assistance that non-Federal entities receive or administer in the form of:</p> <ul style="list-style-type: none"> (i) Loans; (ii) Loan Guarantees; (iii) Interest subsidies; and (iv) Insurance. <p>(3) Federal financial assistance does not include amounts received as reimbursement for services rendered to individuals as described in 45 CFR 75.502(h) and (i).</p> |
| Federal institution | 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. For the purposes of this document, this term is used in the context of a Federal institution as a recipient. <i>See also Awarding IC.</i> |
| Federal interest | For purposes of 45 CFR 75.343 or when used in connection with the acquisition or improvement of real property, equipment, or supplies under a Federal award, the dollar amount that is the product of the: (1) Federal share of total project costs; and (2) Current fair market value of the property, improvements, or both, to the extent the costs of acquiring or improving the property were included as project costs. |
| Federal program | <p>(1) All Federal awards which are assigned a single number in the CFDA.</p> <p>(2) When no CFDA number is assigned, all Federal awards to non-Federal entities from the same agency made for the same purpose must be combined and considered one program.</p> <p>(3) Notwithstanding paragraphs (1) and (2) of this definition, a cluster of programs. The types of clusters of programs are:</p> <ul style="list-style-type: none"> (i) Research and development (R&D); (ii) Student financial aid (SFA); and (iii) “Other clusters,” as described in the definition of Cluster of Programs. |
| Federal share | The portion of the total project costs that are paid by Federal funds. |

| Term | Definition |
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| Foreign organization | <p>An entity that is:</p> <p>(1) A public or private organization located in a country other than the United States and its territories that is subject to the laws of the country in which it is located, irrespective of the citizenship of project staff or place of performance;</p> <p>(2) A private nongovernmental organization located in a country other than the United States that solicits and receives cash contributions from the general public;</p> <p>(3) A charitable organization located in a country other than the United States that is nonprofit and tax exempt under the laws of its country of domicile and operation, and is not a university, college, accredited degree granting institution of education, private foundation, hospital, organization engaged exclusively in research or scientific activities, church, synagogue, mosque or other similar entities organized primarily for religious purposes; or</p> <p>(4) An organization located in a country other than the United States not recognized as a <i>Foreign Public Entity</i>.</p> |
| Foreign public entity | <p>(1) A foreign government or foreign governmental entity; (2) A public international organization, which is an organization entitled to enjoy privileges, exemptions, and immunities as an international organization under the International Organizations Immunities Act (22 U.S.C. 288–288f); (3) An entity owned (in whole or in part) or controlled by a foreign government; or (4) Any other entity consisting wholly or partially of one or more foreign governments or foreign governmental entities.</p> |
| General purpose equipment | <p>Equipment which is not limited to research, medical, scientific or other technical activities. Examples include office equipment and furnishings, modular offices, telephone networks, information technology equipment and systems, air conditioning equipment, reproduction and printing equipment, and motor vehicles. (<i>See also Equipment and Special Purpose Equipment</i>).</p> |
| Generally Accepted Accounting Principles (GAAP) | <p>The meaning specified in accounting standards issued by the Government Accounting Standards Board (GASB) and the Financial Accounting Standards Board (FASB).</p> |
| Generally Accepted Government Auditing Standards (GAGAS) | <p>Also known as the Yellow Book, generally accepted government auditing standards issued by the Comptroller General of the United States, which are applicable to financial audits.</p> |

| Term | Definition |
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| Grant or grant agreement | <p>A legal instrument of financial assistance between a Federal awarding agency or pass-through entity and a non-Federal entity that, consistent with 31 U.S.C. 6302, 6304:</p> <p>(1) Is used to enter into a relationship the principal purpose of which is to transfer anything of value from the Federal awarding agency or pass-through entity to the non-Federal entity to carry out a public purpose authorized by a law of the United States (see 31 U.S.C. 6101(3)); and not to acquire property or services for the Federal awarding agency or pass-through entity's direct benefit or use;</p> <p>(2) Is distinguished from a cooperative agreement in that it does not provide for substantial involvement between the Federal awarding agency or pass-through entity and the non-Federal entity in carrying out the activity contemplated by the Federal award.</p> <p>(3) Does not include an agreement that provides only:</p> <p>(i) Direct United States Government cash assistance to an individual;</p> <p>(ii) A subsidy;</p> <p>(iii) A loan;</p> <p>(iv) A loan guarantee; or</p> <p>(v) Insurance.</p> <p><i>See also Cooperative Agreement.</i></p> |
| Grantee | <i>See Recipient.</i> |
| Hospital | <p>A facility licensed as a hospital under the law of any state or a facility operated as a hospital by the United States, a state, or a subdivision of a state. Also includes a non-profit or for-profit hospital or a medical care provider component of a non-profit organization (for example, a foundation).</p> |
| Improper payment | <p>(1) Any payment that should not have been made or that was made in an incorrect amount (including overpayments and underpayments) under statutory, contractual, administrative, or other legally applicable requirements; and</p> <p>(2) Includes any payment to an ineligible party, any payment for an ineligible good or service, any duplicate payment, any payment for a good or service not received (except for such payments where authorized by law), any payment that does not account for credit for applicable discounts, and any payment where insufficient or lack of documentation prevents a reviewer from discerning whether a payment was proper.</p> |
| Indian tribe (or "federally recognized Indian tribe") | <p>Any Indian tribe, band, nation, or other organized group or community, including any Alaska Native village or regional or village corporation as defined in or established pursuant to the Alaska Native Claims Settlement Act (43 U.S.C. Chapter 33), which is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians (25 U.S.C. 450b(e)). See annually published Bureau of Indian Affairs list of Indian Entities Recognized and Eligible to Receive Services.</p> |
| Information technology systems | <p>Computing devices, ancillary equipment, software, firmware, and similar procedures, services (including support services), and related resources. (<i>See also computing devices and equipment.</i>)</p> |
| Institutions of Higher Education (IHEs) | <i>IHE</i> is defined at 20 U.S.C. 1001. |
| Intangible property | <p>Property having no physical existence, such as trademarks, copyrights, patents and patent applications and property, such as loans, notes and other debt instruments, lease agreements, stock and other instruments of property ownership (whether the property is tangible or intangible).</p> |

| Term | Definition |
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| Internal controls | A process, implemented by a non-Federal entity, designed to provide reasonable assurance regarding the achievement of objectives in the following categories: (1) Effectiveness and efficiency of operations; (2) Reliability of reporting for internal and external use; and (3) Compliance with applicable laws and regulations. |
| Internal control over compliance requirements for Federal awards | A process implemented by a non-Federal entity designed to provide reasonable assurance regarding the achievement of the following objectives for Federal award : (1) Transactions are properly recorded and accounted for, in order to: (i) Permit the preparation of reliable financial statements and Federal reports; (ii) Maintain accountability over assets; and (iii) Demonstrate compliance with Federal statutes, regulations, and the terms and conditions of the Federal award; (2) Transactions are executed in compliance with: (i) Federal statutes, regulations, and the terms and conditions of the Federal award that could have a direct and material effect on a Federal program; and (ii) Any other Federal statutes and regulations that are identified in the Compliance Supplement; and (3) Funds, property, and other assets are safeguarded against loss from unauthorized use or disposition. |
| Local government | Any unit of government within a state, including a: (1) County; (2) Borough; (3) Municipality; (4) City; (5) Town; (6) Township; (7) Parish; (8) Local public authority, including any public housing agency under the United States Housing Act of 1937; (9) Special district; (10) School district; (11) Intrastate district; (12) Council of governments, whether or not incorporated as a nonprofit corporation under state law; and (13) Any other agency or instrumentality of a multi-, regional, or intra-state or local government. |
| Matching or cost sharing | The portion of project costs not paid by Federal funds (unless otherwise authorized by Federal statute). This may include the value of allowable third party in-kind contributions, as well as expenditures by the recipient. |
| Micro-purchase | A purchase of supplies or services using simplified acquisition procedures, the aggregate amount of which does not exceed the micro-purchase threshold. Micro-purchase procedures comprise a subset of a non-Federal entity's small purchase procedures. The non-Federal entity uses such procedures in order to expedite the completion of its lowest-dollar small purchase transactions and minimize the associated administrative burden and cost. The micro-purchase threshold is set by the Federal Acquisition Regulation at 48 CFR Subpart 2.1 (Definitions). It is \$3,000 except as otherwise discussed in Subpart 2.1 of that regulation, but this threshold is periodically adjusted for inflation. <i>(Note: OMB has provided a one-year grace period for implementation of these subsections for IHEs and nonprofit organizations. Thus, these requirements are expected to take effect for these entities for their first fiscal year after December 26, 2015.)</i> |
| Modified Total Direct Cost (MTDC) | All direct salaries and wages, applicable fringe benefits, materials and supplies, services, travel, and subawards up to the first \$25,000 of each subaward (regardless of the period of performance of the subawards under the award). MTDC excludes equipment, capital expenditures, charges for patient care, rental costs, tuition remission, scholarships and fellowships, participant support costs and the portion of each subaward in excess of \$25,000. Other items may only be excluded when necessary to avoid a serious inequity in the distribution of indirect costs, and with the approval of the cognizant agency for indirect costs. |

| Term | Definition |
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| Non-Federal entity | A state, local government, Indian tribe, institution of higher education (IHE), or nonprofit organization that carries out a Federal award as a recipient or subrecipient. |
| Non-profit organization | Any corporation, trust, association, cooperative, or other organization, not including IHEs, that: (1) Is operated primarily for scientific, educational, service, charitable, or similar purposes in the public interest; (2) Is not organized primarily for profit; and (3) Uses net proceeds to maintain, improve, or expand the operations of the organization. |
| Notice of Award | <p>The official, legally binding document, signed (or the electronic equivalent of signature) by a Grants Management Officer that:</p> <p>(1) notifies the recipient of the award of a grant;</p> <p>(2) contains or references all the terms and conditions of the grant and Federal funding limits and obligations; and,</p> <p>(3) provides the documentary basis for recording the obligation of Federal funds in the NIH accounting system.</p> |
| Obligations | When used in connection with a non- Federal entity’s utilization of funds under a Federal award, obligations means orders placed for property and services, contracts and subawards made, and similar transactions during a given period that require payment by the non-Federal entity during the same or a future period. |
| Office of Management and Budget (OMB) | The Executive Office of the President, Office of Management and Budget. |
| Oversight agency for audit | The Federal awarding agency that provides the predominant amount of funding directly to a non-Federal entity not assigned a cognizant agency for audit. When there is no direct funding, the Federal awarding agency which is the predominant source of pass-through funding must assume the oversight responsibilities. The duties of the oversight agency for audit and the process for any reassignments are described in 2 CFR 75.513(b). |
| Participant support costs | Direct costs for items such as stipends or subsistence allowances, travel allowances, and registration fees paid to or on behalf of participants or trainees (but not employees) in connection with conferences, or training projects. For the purposes of Kirschstein-NRSA programs, this term does not apply. NIH will continue to use the terms trainees, trainee-related expenses, and trainee travel in accordance with NRSA Regulations. |
| Pass-through entity | A non- Federal entity that provides a subaward to a subrecipient to carry out part of a Federal program. |
| Payment Management System | The HHS centralized grants payment system operated by the Payment Management Service, Program Support Center. Most HHS (and some other Federal government agencies’) recipients receive grant payments through this system. |
| Period of performance | The time during which the non-Federal entity may incur new obligations to carry out the work authorized under the Federal award. The Federal awarding agency or pass-through entity must include start and end dates of the period of performance in the Federal award. |
| Personal property | Property of any kind except real property. It may be tangible, having physical existence, or intangible, such as copyrights, patents, or securities. |

| Term | Definition |
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| Personally Identifiable Information (PII) | Information that can be used to distinguish or trace an individual’s identity, either alone or when combined with other personal or identifying information that is linked or linkable to a specific individual. Some information that is considered to be PII is available in public sources such as telephone books, public Web sites, and university listings. This type of information is considered to be Public PII and includes, for example, first and last name, address, work telephone number, email address, home telephone number, and general educational credentials. The definition of PII is not anchored to any single category of information or technology. Rather, it requires a case-by-case assessment of the specific risk that an individual can be identified. Non-PII can become PII whenever additional information is made publicly available, in any medium and from any source, that, when combined with other available information, could be used to identify an individual. |
| Prior approval | Written approval by an authorized HHS official, e.g., a designated IC GMO, evidencing prior consent before a recipient undertakes certain activities or incurs specific costs. |
| Program income | Gross income earned by the non-Federal entity that is directly generated by a supported activity or earned as a result of the Federal award during the period of performance except as provided in 45 CFR 75.307(f). (<i>See Period of performance</i>). Program income includes but is not limited to income from fees for services performed, the use or rental or real or personal property acquired under Federal awards, the sale of commodities or items fabricated under a Federal award, license fees and royalties on patents and copyrights, and principal and interest on loans made with Federal award funds. Interest earned on advances of Federal funds is not program income. Except as otherwise provided in Federal statutes, regulations, or the terms and conditions of the Federal award, program income does not include rebates, credits, discounts, and interest earned on any of them. See also 45 CFR 75.307, 45 CFR 75.407 and 35 USC §§ 200-212 (applies to inventions made under Federal awards). (See Administrative Requirements—Management Systems and Procedures—Program Income in the most recent edition of the NIH Grants Policy Statement). |
| Project period | The total time for which Federal support of a project has been programmatically approved as shown in the NoA; however, it does not constitute a commitment by the Federal government to fund the entire period. The total project period comprises the initial competitive segment, any subsequent competitive segments resulting from a renewal award(s), and extensions. |
| Property | Real property or personal property. |
| Protected Personally Identifiable Information (Protected PII) | An individual’s first name or first initial and last name in combination with any one or more of types of information, including, but not limited to, social security number, passport number, credit card numbers, clearances, bank numbers, biometrics, date and place of birth, mother’s maiden name, criminal, medical and financial records, educational transcripts. This does not include PII that is required by law to be disclosed. (<i>See also Personally Identifiable Information (PII)</i>). |
| Questioned cost | A cost that is questioned by the auditor because of an audit finding: (1) Which resulted from a violation or possible violation of a statute, regulation, or the terms and conditions of a Federal award, including for funds used to match Federal funds; (2) Where the costs, at the time of the audit, are not supported by adequate documentation; or (3) Where the costs incurred appear unreasonable and do not reflect the actions a prudent person would take in the circumstances. |

| Term | Definition |
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| Real property | Land, including land improvements, structures and appurtenances thereto, but excludes moveable machinery and equipment. |
| Recipient | An entity, usually but not limited to non-Federal entities, that receives a Federal award directly from a Federal awarding agency to carry out an activity under a Federal program. The term may also include an Individual. The term recipient does not include subrecipients, except as indicated below. <i>See also Non-Federal entity.</i> |
| Research & Development (R&D) | All research activities, both basic and applied, and all development activities that are performed by HHS award recipients. The term research also includes activities involving the training of individuals in research techniques where such activities utilize the same facilities as other research and development activities and where such activities are not included in the instruction function. "Research" is defined as a systematic study directed toward fuller scientific knowledge or understanding of the subject studied. "Development" is the systematic use of knowledge and understanding gained from research directed toward the production of useful materials, devices, systems, or methods, including design and development of prototypes and processes. |
| Simplified acquisition threshold | The dollar amount below which a non-Federal entity may purchase property or services using small purchase methods. Non-Federal entities adopt small purchase procedures in order to expedite the purchase of items costing less than the simplified acquisition threshold. The simplified acquisition threshold is set by the Federal Acquisition Regulation at 48 CFR Subpart 2.1 and in accordance with 41 USC § 1908. <i>(See also Micro-purchase).</i> |
| Special purpose equipment | Equipment which is used only for research, medical, scientific, or other technical activities. Examples of special purpose equipment include microscopes, x-ray machines, surgical instruments, and spectrometers. <i>See also Equipment and General purpose equipment.</i> |
| State | Any state of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, and any agency or instrumentality thereof exclusive of local governments. |
| Subaward | An award provided by a pass-through entity to a subrecipient for the subrecipient to carry out part of a Federal award received by the pass-through entity. It does not include payments to a contractor or payments to an individual that is a beneficiary of a Federal program. A subaward may be provided through any form of legal agreement, including an agreement that the pass-through entity considers a contract. The term includes consortium agreements. |
| Subrecipient | A non-Federal entity that receives a subaward from a pass-through entity to carry out part of a Federal program; but does not include an individual that is a beneficiary of such program. A subrecipient may also be a recipient of other Federal awards directly from a Federal awarding agency. The term includes consortium participants. |
| Supplies | All tangible personal property other than those described in Equipment. A computing device is a supply if the acquisition cost is less than the lesser of the capitalization level established by the non-Federal entity for financial statement purposes or \$5,000, regardless of the length of its useful life. <i>See Computing devices and Equipment.</i> |
| Suspension of award activities | An action by the NIH awarding IC requiring the recipient to cease all activities on the award pending corrective action by the recipient. It is a separate action from suspension under HHS regulations (2 CFR part 376) implementing Executive Orders 12549 and 12689. |

| Term | Definition |
|-----------------------------------|---|
| Termination | The ending of a Federal award, in whole or in part at any time prior to the planned end of period of performance. |
| Third-party in-kind contributions | The value of non-cash contributions (i.e., property or services) that: (1) Benefit a federally assisted project or program; and (2) Are contributed by non-Federal third parties, without charge, to a non-Federal entity under a Federal award. |
| Total costs | The total allowable costs (both direct costs and F&A costs) incurred by the recipient to carry out a grant-supported project or activity. Total project costs include costs charged to the NIH grant and costs borne by the recipient to satisfy a matching or cost-sharing requirement. |
| Unliquidated obligations | For financial reports prepared on a cash basis, obligations incurred by the non-Federal entity that have not been paid (liquidated). For reports prepared on an accrual expenditure basis, these are obligations incurred by the non-Federal entity for which an expenditure has not been recorded. |
| Unobligated balance | The amount of funds authorized under a Federal award that the non-Federal entity has not obligated. The amount is computed by subtracting the cumulative amount of the non-Federal entity's unliquidated obligations and expenditures of funds under the Federal award from the cumulative amount of the funds that the Federal awarding agency or pass-through entity authorized the non-Federal entity to obligate. |

Part II: Terms and Conditions of NIH Grant Awards

2 Public Policy Requirements

A listing of Public Policy Requirements that recipients must adhere to, where applicable, is available in the most recent edition of the NIH Grants Policy Statement located at:

<http://grants.nih.gov/grants/policy/policy.htm#gps>.

3 Special Provisions for Awards to Commercial Organizations as Recipients

The provisions that apply to awards to commercial organizations are located in 45 CFR 75.215 and in Grants to For-profit organizations in IIB in the most recent edition of the NIH Grants Policy Statement.

4 The Notice of Award

The Notice of Award (NoA) is the legal document issued to notify the recipient that an award has been made and that funds may be requested from the designated HHS payment system or office. The NoA is issued for the initial budget period and each subsequent budget period in the approved project period. The NoA reflects any future-year commitments. A revised NoA may be issued during a budget period to effect an action resulting in a change in the period or amount of support or other change in the terms and conditions of award. NIH will not issue a revised NoA to reflect a recipient's post-award rebudgeting. Until an IC has issued the NoA for the initial award, any costs incurred by the applicant for

the project are incurred at its own risk (see the most recent edition of the NIH Grants Policy Statement for NIH policy on the allowability of pre-award costs).

The NoA sets forth pertinent information about the grant, including, but not limited to, the following:

- Federal award date
- Application/grant identification number (grant number)
- Federal award identification number (FAIN)
- Name of recipient organization
- Name(s) of the PD/PI(s)
- Name(s) of Senior/key personnel that are subject to NIH prior approval requirements if a significant change in level of effort occurs
- Approved period of performance start and end dates
- Budget approved by the NIH awarding IC
- Total amount of Federal funds obligated (Federal share)
- Total approved cost sharing or matching, where applicable (Non-Federal share)
- Total amount of the Federal award
- Amount of anticipated future-year commitments (if applicable)
- Federal award project description (Project title)
- Names of the cognizant IC PO, GMO, and GMS
- CFDA Name and Program Name
- Indirect cost rate for the Federal award (including if the de minimis rate is charged per 45 CFR 75.414)
- Applicable terms and conditions of award, either by reference or inclusion
- Federal award performance goals (as required by the periodic report in the RPPR or in the final progress report when applicable)
- Any restriction on the use of funds

As specified in the NoA, all awards issued by the National Institutes of Health (NIH) meet the definition of “Research and Development” at 45 CFR 75.2. As such, NIH grant awards are subject to the R&D cluster of program requirements in the compliance supplement. NIH recognizes that some awards may

have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

A grantee indicates acceptance of an NIH award and its associated terms and conditions by drawing or requesting funds from the designated HHS payment system or office. If the grantee cannot accept the award, including the legal obligation to perform in accordance with its provisions, it should notify the GMO immediately upon receipt of the NoA. If resolution cannot be reached, the GMO will void the grant. NIH's determination of applicable terms and conditions of award or a GMO's denial of a request to change the terms and conditions is discretionary and not subject to appeal (post-award appeal rights are discussed in Grant Appeals Procedures). Once the award is accepted by the grantee, the contents of the NoA are binding on the grantee unless and until modified by a revised NoA signed by the GMO.

4.1 Funding

For most grants, NIH uses the project period system of funding. Under this system, projects are programmatically approved for support in their entirety but are funded in annual increments called budget periods. The length of an initial project period (competitive segment) or of any subsequent competitive segment is determined by the NIH awarding IC on the basis of:

- any statutory or regulatory requirements,
- the length of time requested by the applicant to complete the project,
- limitation on the length of the project period recommended by the peer reviewers,
- the awarding IC's programmatic determination of the frequency of competitive review desirable for managing the project, and
- NIH funding principles.

The total project period consists of the initial competitive segment, any additional competitive segments authorized by approval of a competing continuation application, and any non-competing extensions. NIH policy limits each competitive segment to a maximum of 5 years (exclusive of non-competing extensions). A single award covering the entire period of support generally is used only if the project is solely for construction or modernization of real property, if the total planned period of support will be less than 18 months, or if the project is awarded under a special support mechanism.

The initial NoA provides funds for the project during the first budget period. Budget periods usually are 12 months long; however, shorter or longer budget periods may be established for compelling programmatic or administrative reasons. The NoA that documents approval of a project period that extends beyond the budget period for which funds are provided (including anticipated levels of future support) expresses NIH's intention to provide continued financial support for the project. The amounts shown for subsequent years represent projections of future funding levels based on the information available at the time of the initial award. Such projected levels of future support are contingent on satisfactory progress, the availability of funds, and the continued best interests of the Federal

government. They are not guarantees by NIH that the project will be funded or will be funded at those levels and create no legal obligation to provide funding beyond the ending date of the current budget period as shown in the NoA.

Recipients are required to submit an annual progress report as a prerequisite to NIH approval and funding of each subsequent budget period (non-competing continuation award) within an approved project period. A decision to fund the next budget period will be formalized by the issuance of the NoA indicating the new budget period and the amount of new funding. The NoA also will reflect any remaining future-year commitments. NIH may decide to withhold support for one or more of the reasons cited in Administrative Requirements—Enforcement Actions—Suspension, Termination, and Withholding of Support in the most recent edition of the NIH Grants Policy Statement. A recipient may appeal this decision only if the withholding was for the recipient's failure to comply with the terms and conditions of a previous award (see Grant Appeals Procedures).

All Federal agencies are required by 31 U.S.C. §1552(a) to close fixed year appropriation accounts and cancel any remaining balances by September 30 of the fifth fiscal year after the year of availability. In order for the NIH to meet its obligation to close these accounts and cancel any remaining balances by September 30, recipients must report disbursements on the quarterly cash transaction report (using the FFR) no later than June 30 of the fifth fiscal year after the year of availability. This provision may limit the availability of funds for carryover. It may also limit or eliminate the authority to extend the final budget period when an entire project period is funded by a single award.

4.2 Additional Payments

In addition to, or in lieu of, the standard terms and conditions of award, NIH may use terms and conditions for program-specific or award-specific reasons. For example, if, on the basis of a recipient's application or other available information, the GMO finds—at the time of award or at any time subsequent to award—that the grantee's management systems and practices are not adequate to ensure the appropriate stewardship of NIH funds or to achieve the objectives of the award, the GMO may impose special, more restrictive terms and conditions on the award in accordance with 42 CFR 52.9 and 45 CFR 75.371. For example, NIH could require a recipient to obtain prior approval for expenditures that ordinarily do not require such approval or to provide more frequent reports. In addition to closer monitoring, NIH may assist the recipient in taking any necessary corrective action.

5 Cost Considerations

Cost considerations are critical throughout the life cycle of a grant. An applicant's budget request is reviewed for compliance with the governing cost principles and other requirements and policies applicable to the type of recipient and the type of award. Any resulting award will include a budget that is consistent with these requirements.

NIH anticipates that, because of the nature of research, the recipient may need to modify its award budget during performance to accomplish the award's programmatic objectives. Therefore, NIH provides some flexibility for recipients to deviate from the award budget, depending on the deviation's

significance to the project or activity. More significant post-award changes require NIH prior approval. Prior approval requirements and authorities are discussed under Administrative Requirements—Changes in Project and Budget in the most recent edition of the NIH Grants Policy Statement.

During post-award administration, the GMO, or a GMO designee, monitors expenditures for conformance with cost policies. The GMO's monitoring includes, among other things, responding to prior approval requests and reviewing progress reports, audit reports, and other periodic reports. The GMO also may use audit findings as the basis for final cost adjustments (see Administrative Requirements—Closeout in the most recent edition of the NIH Grants Policy Statement).

This chapter addresses the general principles underlying the allowability of costs, differentiates direct costs from F&A costs, and highlights a number of specific costs and categories of cost for NIH applicants and recipients. It is not intended to be all-inclusive and should be used as a supplement to the applicable cost principles.

5.1 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 (regardless whether domestic or foreign) making the expenditure. For example, a for-profit organization collaborating with a university recipient would be subject to the cost principles for commercial organizations, while the university would be subject to the cost principles for Institutions of Higher Education (IHEs).

The cost principles are set forth in HHS regulations at 45 CFR 75, Subpart E and Appendix IX (hospitals) to Part 75. OMB Circulars A-21, A-87 and A-122 have been consolidated into a single source document relocated to 2 CFR 200, Subpart E—Cost Principles. Commercial organizations are subject to the cost principles located at 48 CFR 31.2 (Federal Acquisition Regulation).

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 IIB in the most recent edition of the NIH Grants Policy Statement.

Recipients may use their own accounting systems, policies, and procedures to implement the cost principle requirements as long as they meet the standards prescribed in 45 CFR 75.302 for financial management systems.

The cost principles address four tests to determine 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. A cost is allocable as a direct cost to a grant if it is incurred solely in order to advance work under the grant or meets the criteria for closely related projects determination (see Cost Considerations—Allocation of Costs and Closely Related Work in the most recent edition of the NIH Grants Policy Statement).
- **Consistency.** Recipients must be consistent in assigning costs to cost objectives. Costs may be charged as either direct costs or F&A costs, depending on their identifiable benefit to a particular project or program, but all costs must be treated consistently for all work of the organization under similar circumstances, regardless of the source of funding.
- **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. Cost Considerations—Allowability of Costs/Activities in the most recent edition of the NIH Grants Policy Statement 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 recipient. IIB contains additional information on allowability of costs for particular types of grants, recipients, 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.

5.2 Direct Costs and Facilities and Administrative Costs

A direct cost is any cost that can be specifically identified with a particular project, program, or activity or that can be directly assigned to such activities relatively easily and with a high degree of accuracy. Direct costs include, but are not limited to, salaries, travel, equipment, and supplies directly benefiting

the grant-supported project or activity. Most organizations also incur costs for common or joint objectives that cannot be readily identified with an individual project, program, or organizational activity. Facilities operation and maintenance costs, depreciation, and administrative expenses are examples of costs that usually are treated as F&A costs. The organization is responsible for presenting costs consistently and must not include costs associated with its F&A rate as direct costs.

Note, the term facilities and administrative costs and the term indirect costs may be used interchangeably to determine applicable policies. For NIH purposes, including the NIHGPS, these costs will be referred to as F&A costs; however, other documents or non-NIH entities may refer to them as indirect costs.

Project costs consist of the allowable direct costs directly related to the performance of the grant plus the allocable portion of the allowable F&A costs of the organization, less applicable credits (as described below and in the cost principles).

The amount NIH awards for each budget period will reflect the total approved budget for the grant, including direct costs and, if applicable, F&A costs. (SBIR and STTR awards also may include a fee as specified in Grants to For-Profit Organizations—Small Business Innovation Research and Small Business Technology Transfer Programs in IIB in the most recent edition of the NIH Grants Policy Statement.) If a recipient waives reimbursement of full F&A costs, NIH will either not award F&A costs or will award only partial F&A costs, as appropriate. The NIH award amount shown in the NoA constitutes NIH's maximum financial obligation to the recipient under that award.

5.3 Reimbursement of Facilities and Administrative Costs

For grant programs that can provide F&A cost reimbursement, NIH will generally not provide F&A costs unless the recipient has established an F&A cost rate covering the applicable activities and period of time, except for awards under which F&A costs are reimbursed at a fixed rate.

In addition, NIH will not require a recipient to establish an F&A rate if the organization's total operations consist of a single grant-supported project or if the organization appropriately and consistently treats all costs as direct costs to projects and accounts for them as such. In the latter case, the GMO must be satisfied that the organization's accounting system can adequately identify and support all costs as direct costs to the project. This includes being able to identify and segregate costs on the basis of a process that assigns costs commensurate with the benefits provided to individual projects.

F&A rates are negotiated by DCA, DFAS in the Office of Acquisition Management and Policy, NIH (responsible for negotiating F&A cost rates for for-profit entities receiving awards from HHS), or other agency with cognizance for F&A/indirect cost rate (and other special rate) negotiation. If an applicant is advised by the GMO of the need to establish a rate, the GMO will indicate the responsible office to be contacted.

F&A cost proposals must be prepared in accordance with the applicable cost principles and guidance provided by the cognizant office or agency for indirect costs, and must conform to cost policies in the

NIHGPS. Further information concerning the establishment of F&A rates and the reimbursement of F&A costs may be obtained from DCA or DFAS. DCA should be consulted to determine the need to submit a Disclosure Statement (DS-2) pursuant to the requirements of 2 CFR 200, Subpart E – Cost Principles. Consistent with 45 CFR 75.414(f), any non-Federal entity that has never received a negotiated indirect cost rate, except for those non-Federal entities described in Appendix VII to part 75 (D)(1)(b) may elect to charge a de minimis rate of 10% of modified total direct costs (MTDC) which may be used indefinitely. As described in 45 CFR 75.403, costs must be consistently charged as either indirect or direct costs, but may not be double charged or inconsistently charged as both. If chosen, this methodology once elected must be used consistently for all Federal awards until such time as a non-Federal entity chooses to negotiate for a rate, which the non-Federal entity may apply to do at any time.

Regardless of the type of recipient, the negotiated rate(s) in effect at the beginning of the competitive segment will be used to determine the amount budgeted for F&A costs for each year of the competitive segment. If the rate agreement does not extend to the end of the project period, the last rate in effect will be used to establish the total cost commitment for any remaining future years. NIH generally will not award additional F&A costs beyond those calculated in the approved budget.

F&A costs awarded may be subject to upward or downward adjustment, depending on the type of rate negotiated and recipient type. Generally, recipients may rebudget between direct and F&A costs (in either direction) without NIH prior approval, provided there is no change in the scope of the approved project. F&A cost reimbursement on grants formerly subject to OMB Circular A-21 (IHEs) is based on the rates used in the award, which are not subject to adjustment in reimbursement except for the establishment of permanent rates when a provisional rate was used for funding. Therefore, recipients formerly subject to OMB Circular A-21 (IHEs) may not rebudget from direct costs to accommodate a rate increase if the F&A costs provided for a period were based on negotiated (fixed or predetermined) rates rather than provisional rates (defined as not “negotiated” for the application of the 2 CFR 200, Subpart E – Cost Principles requirement). However, for recipients that were not formerly subject to OMB Circular A-21, F&A cost reimbursement is based on the negotiated F&A rate agreement consistent with the time period when the cost is incurred, except if F&A costs were limited or not provided, SBIR/STTR awardees, and other recipients that have never established a rate. F&A costs are subject to downward adjustment if the proposal that served as the basis for the negotiation included unallowable costs.

Some grants require negotiation of project costs annually, e.g., clinical trials. For these awards, the policies pertain to each year of support rather than to a multiyear competitive segment.

Once NIH awards a grant, it is not obligated to make any supplemental or other award for additional F&A costs or for any other purpose. There are limited circumstances under which the GMO may award F&A costs where none were previously awarded or may increase the amount previously awarded. If an award does not include an amount for F&A costs because the applicant or recipient did not submit a timely F&A cost proposal and the recipient subsequently establishes a rate, the GMO may amend the award to provide an appropriate amount for F&A costs if the amendment can be made using funds from the same Federal fiscal year in which the award was made. However, the amount will be limited to the F&A costs applicable to the period after the date of the recipient’s F&A cost proposal submission. This

provision does not affect local governmental agencies that are not required to submit their F&A (indirect) cost proposals to the Federal government. They may charge F&A costs to NIH grants based on the rate computations they prepare and keep on file for subsequent Federal review.

If funds are available, a GMO may amend an award to provide additional funds for F&A costs, but only under the following circumstances:

- NIH made an error in computing the award. This includes situations in which a higher rate than the rate used in the grant award is negotiated and the date of the rate agreement for the higher rate is before 1 calendar month prior to the beginning date of the grant budget period.
- NIH restores funds previously recaptured as part of a recipient's unobligated balance.
- The recipient is eligible for additional F&A costs associated with additional direct costs awarded for the supplementation or extension of a project.

NIH does not reimburse indirect costs under the following classes of awards:

- **Fellowships.** F&A costs will not be provided on Kirschstein-NRSA individual fellowships or similar awards for which NIH funding is in the form of fixed amounts or is determined by the normal published tuition rates of an institution and for which the recipient is not required to account on an actual cost basis.
- **Construction and Modernization.** F&A costs will not be provided on construction or modernization grants.
- **Grants to Individuals.** F&A costs will not be provided on awards to individuals.
- **Grants to Federal Institutions.** F&A costs will not be provided on grants to Federal institutions.
- **Grants in Support of Scientific Meetings (Conference Grants).** F&A costs will not be provided under grants in support of scientific meetings.
- **Endowment Grants.** F&A costs will not be provided for endowment grants.

NIH limits the amounts included in the F&A base for the following type of costs:

- **Genomic Arrays (GA)** are a high-throughput genetic analysis technology which enables the study of genetic variation and gene expression at high resolution. Approaches such as genome-wide association and gene expression profiling often depend upon manufactured products known as microarrays or bead arrays. These tools are exceptional among laboratory supplies in that they are almost always procured from a commercial source; have a relatively high unit cost and are often utilized in large numbers. The treatment of the costs for purchase of GA as "supplies" in these specialized award budgets at high levels of usage

would result in the application of F&A cost recovery that is disproportionate to the actual administrative burden associated with the relatively high cost of the procurement of these GA. Accordingly, for purposes of budgeting for and award of high volume purchases of GA in excess of \$50,000 per year, the standard treatment of these resources as supplies in determining the F&A base of an award will be non-applicable. Instead the requested and reimbursed costs for GA will utilize as a surrogate the concept of subcontracts (consortium/contractual cost). Therefore for each budget year, the first \$50,000 of GA will be treated as “supplies”, and any GA in excess of \$50,000 (for high volume requirements) will use as a surrogate the budgeting and reimbursement concept utilized for subcontracts (consortium/contractual cost), providing consistent budgeting, accounting and reimbursement of these costs.

NIH continues to provide F&A costs without the need for a negotiated rate under the following classes of awards:

- ***Research Training and Education Grants (e.g., R25), and K Awards.*** F&A costs under Kirschstein-NRSA institutional research training grants and K awards will be budgeted and reimbursed at a rate of 8 percent of modified total direct costs, exclusive of tuition and fees, health insurance (when awarded as part of tuition and fees), expenditures for equipment, and consortiums in excess of \$25,000. State, local, and Indian tribes (or “federally recognized Indian tribes”) may receive full F&A cost reimbursement under NIH Kirschstein-NRSA institutional research training grants and K awards. For this policy, State universities or hospitals are not considered governmental agencies.
- ***Grants to Foreign Organizations and International Organizations.*** With the exception of the American University of Beirut and the World Health Organization, which are eligible for full F&A cost reimbursement, F&A costs under grants to foreign and international organizations will be funded at a rate of 8 percent of modified total direct costs, exclusive of expenditures for equipment. NIH provides F&A costs under these grants to support the costs of compliance with applicable public policy requirements including, but not limited to, the protection of human subjects, animal welfare, financial conflict of interest, and invention reporting. NIH will not support the acquisition of or provide for depreciation on any capital expenses (facilities) or the normal general operations of foreign and international organizations. Awards to domestic organizations with a foreign or international consortium participant may include 8 percent of modified total direct costs, less equipment, for the consortium.

5.4 Revised Selected Items of Cost

Please note the following policies implemented based on 45 CFR 75.

Value Added Tax Policy. In accordance with 45 CFR 75.470(c), foreign taxes charged for the purchase of goods or services that a non-Federal entity is legally required to pay in country is an allowable expense under Federal awards. However, for many countries an exemption of this tax for research exists.

Consequently, requesting this cost is unallowable for research grants involving such countries as a performance site.

Participant Support Cost Policy. Participant support costs as defined in 45 CFR 75.2 are direct costs for items such as stipends or subsistence allowances, travel allowances and registration fees paid to or on behalf of participants (but not employees) in connection with conferences, or training projects. For NIH awards these cost are only allowable when identified in the funding opportunity announcement (FOA). For the purposes of Kirschstein-NRSA programs, this term does not apply. NIH will continue to use the terms trainees, trainee-related expenses, and trainee travel in accordance with NRSA Regulations.

Temporary Dependent Care Cost Policy. In accordance with 45 CFR 75.474, temporary dependent care costs (as dependent is defined in 26 USC § 152) above and beyond regular dependent care that directly results from travel to conferences is allowable provided that:

- (i) The costs are a direct result of the individual's travel for the Federal award;
- (ii) The costs are consistent with the non-Federal entity's documented travel policy for all entity travel; and
- (iii) Are only temporary during the travel period.

Travel costs for dependents are unallowable, except for travel of duration of six months or more with prior approval of the HHS awarding agency. However, as indicated in 45 CFR 75.432, as needed, the costs of identifying, but not providing, locally available dependent-care resources are allowable.

The table presents specific additional or revised cost items NIH is incorporating based on 45 CFR 75.

| Items | Explanation of Allowable Costs |
|---------------------------|--|
| Alteration and Renovation | <p>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 exhibit and in the Construction Grants chapter in the most recent edition of the NIH Grants Policy Statement, as applicable. Individual A&R projects exceeding \$500,000 in direct costs will be subject to the requirements specified in the Construction Grants chapter in the most recent edition of the NIH Grants Policy Statement.</p> <p>Routine maintenance and repair of the organization’s physical plant or 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 recipient’s accounting system.</p> <p>A&R costs are not allowable under grants to individuals, 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</p> |

| Items | Explanation of Allowable Costs |
|------------------------|--|
| | <p>the award specifically exclude such activity.</p> <p>The A&R must be consistent with the following criteria and documentation requirements:</p> <ul style="list-style-type: none"> The building has a useful life consistent with program purposes and is architecturally and structurally suitable for conversion to the type of space required. The A&R is essential to the purpose of the grant-supported project. The space involved will be occupied by the project. 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. 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. If the A&R will affect a site listed in (or eligible for inclusion in) the National Register of Historic Places, the requirements specified in “Preservation of Cultural and Historic Resources” have been followed. <p>Work necessary to obtain an initial occupancy permit for the intended use is not an allowable A&R cost.</p> <p>A recipient 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 will result in an A&R project exceeding \$500,000, NIH will consider the rebudgeting to be a change in scope, and the recipient must submit to the NIH awarding IC the documentation specified in the Construction Grants chapter in the most recent edition of the NIH Grants Policy Statement for prior approval of A&R projects above that dollar level.</p> <p>Under foreign grants or foreign components under domestic grants, major A&R (>\$500,000) is unallowable. Minor A&R (<\$500,000) is generally allowable on grants made to foreign organizations or to the foreign component of a domestic grant, unless prohibited by the governing statute or implementing program regulations.</p> |
| Contingency Provisions | <p>Unallowable. Payments made by the HHS awarding agency to the non-Federal entity's “contingency reserve” or any similar payment made for events the occurrence of which cannot be foretold with certainty as to the time or intensity, or with an assurance of their happening, are unallowable under non-construction grants. Contingency funds do not include pension funds, self-insurance funds, and normal accruals. (See also Construction Grants— Allowable and Unallowable Costs and Activities in IIB in the most recent edition of the NIH Grants Policy Statement concerning contingency funds under construction grants).</p> |

| Items | Explanation of Allowable Costs |
|---|---|
| Materials and Supplies Costs, including Costs of Computing Devices. | <ul style="list-style-type: none"> (a) Costs incurred for materials, supplies, and fabricated parts necessary to carry out a Federal award are allowable. (b) Purchased materials and supplies must be charged at their actual prices, net of applicable credits. Withdrawals from general stores or stockrooms must be charged at their actual net cost under any recognized method of pricing inventory withdrawals, consistently applied. Incoming transportation charges are a proper part of materials and supplies costs. (c) Materials and supplies used for the performance of a Federal award may be charged as direct costs. In the specific case of computing devices, charging as direct costs is allowable for devices that are essential and allocable, but not solely dedicated, to the performance of a Federal award. (d) Where federally-donated or furnished materials are used in performing the Federal award, such materials will be used without charge. |
| Participant Support Costs | Only allowable when identified in specific FOAs. |
| Proposal Costs | Proposal costs are the costs of preparing bids, proposals, or applications on potential Federal and non-Federal awards or projects, including the development of data necessary to support the non-Federal entity's bids or proposals. Proposal costs of the current accounting period of both successful and unsuccessful bids and proposals normally should be treated as indirect (F&A) costs and allocated currently to all activities of the non-Federal entity. No proposal costs of past accounting periods will be allocable to the current period. |
| Rearrangement and Reconversion Costs | See Alteration and Renovation costs. |

| Items | Explanation of Allowable Costs |
|------------------|---|
| Recruiting Costs | <p>(a) Subject to paragraphs (b) and (c) of this section, and provided that the size of the staff recruited and maintained is in keeping with workload requirements, costs of “help wanted” advertising, operating costs of an employment office necessary to secure and maintain an adequate staff, costs of operating an aptitude and educational testing program, travel costs of employees while engaged in recruiting personnel, travel costs of applicants for interviews for prospective employment, and relocation costs incurred incident to recruitment of new employees, are allowable to the extent that such costs are incurred pursuant to the non-Federal entity’s standard recruitment program. Where the non-Federal entity uses employment agencies, costs not in excess of standard commercial rates for such services are allowable.</p> <p>(b) Special emoluments, fringe benefits, and salary allowances incurred to attract professional personnel that do not meet the test of reasonableness or do not conform with the established practices of the non-Federal entity, are unallowable.</p> <p>(c) Where relocation costs incurred incident to recruitment of a new employee have been funded in whole or in part as a direct cost to a Federal award, and the newly hired employee resigns for reasons within the employee's control within 12 months after hire, the non-Federal entity will be required to refund or credit the Federal share of such relocation costs to the Federal government. See also Relocation Costs of Employees.</p> <p>(d) Short-term, travel visa costs (as opposed to longer-term, immigration visas) are generally allowable expenses that may be proposed as a direct cost. Since short-term visas are issued for a specific period and purpose, they can be clearly identified as directly connected to work performed on a Federal award. For these costs to be directly charged to a Federal award, they must:</p> <ol style="list-style-type: none"> (1) Be critical and necessary for the conduct of the project; (2) Be allowable under the applicable cost principles; (3) Be consistent with the non-Federal entity’s cost accounting practices and non-Federal entity policy; and (4) Meet the definition of “direct cost” as described in the applicable cost principles. <p>Project funds may not be used for a prospective trainee’s travel costs to or from the recipient 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 (see also Visa Costs in the most recent edition of the NIH Grants Policy Statement).</p> |

| Items | Explanation of Allowable Costs |
|-----------------------|---|
| Transportation Costs | Costs incurred for freight, express, cartage, postage, and other transportation services relating either to goods purchased, in process, or delivered, are allowable. When such costs can readily be identified with the items involved, they may be charged directly as transportation costs or added to the cost of such items. Where identification with the materials received cannot readily be made, inbound transportation cost may be charged to the appropriate indirect (F&A) cost accounts if the non-Federal entity follows a consistent, equitable procedure in this respect. Outbound freight, if reimbursable under the terms and conditions of the Federal award, should be treated as a direct cost. |
| Value Added Tax (VAT) | Foreign taxes charged for the purchase of goods or services that a non-Federal entity is legally required to pay in country is an allowable expense under Federal awards. Foreign tax refunds or applicable credits under Federal awards refer to receipts, or reduction of expenditures, which operate to offset or reduce expense items that are allocable to Federal awards as direct or indirect costs. To the extent that such credits accrued or received by the non-Federal entity relate to allowable cost, these costs must be credited to the NIH awarding IC either as costs or cash refunds. If the costs are credited back to the Federal award, the non-Federal entity may reduce the Federal share of costs by the amount of the foreign tax reimbursement, or where Federal award has not expired, use the foreign government tax refund for approved activities under the Federal award with prior approval of the NIH awarding IC. For many countries an exemption of this tax for research exists. Consequently, requesting this cost is unallowable for research grants involving such countries as a performance site. |

6 NIH Standard Terms of Award

Federal administrative requirements allow agencies to waive certain cost-related and administrative prior approvals; these are known as expanded authorities. In 2001, NIH extended expanded authorities to all NIH awards except for the provision to automatically carry over unobligated balances. Certain award instruments, grant programs, and types of recipients are routinely excluded from the authority to automatically carry over unobligated balances. This includes centers (P50, P60, P30, and others); cooperative agreements (U); Kirschstein-NRSA institutional research training grants (T); non-Fast Track Phase 1 SBIR and STTR awards (R43 and R41); clinical trials (regardless of activity code); and awards to individuals.

One or more of these authorities may be overridden by a special term or condition of the award. Recipients must review the NoA to determine if a particular authority is withheld for a specific grant.

Recipients must exercise proper stewardship over Federal funds and ensure that costs charged to awards are allowable, allocable, reasonable, necessary, and consistently applied regardless of the source of funds. NIH may disallow the costs if it determines, through audit or otherwise, that the costs do not meet the tests of allowability, allocability, reasonableness, necessity, and consistency.

Several authorities have specific deadlines for submission of reports or for timely notification to the NIH awarding IC. Recipients should be aware that any consistent pattern of failure to adhere to those

deadlines for reporting or notification will be grounds for excluding that recipient from a specific authority.

6.1 Carryover of Unobligated Balances from One Budget Period to Any Subsequent Budget Period

Recipients should be aware that there is a difference between unliquidated obligations and unobligated balances. Unliquidated obligations are commitments of the recipient and are considered to be obligations and, therefore, should not be reported as unobligated balances.

The NoA will include a term and condition to indicate the disposition of unobligated balances. The term and condition will state whether the recipient has automatic carryover authority, or if prior approval is required by the NIH awarding IC. Note the authority to automatically carry over unobligated balances includes the authority to carryover from one competitive segment to another.

Automatic carryover of unobligated balances applies to all awards except 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 (regardless of activity code), and awards to individuals. For these grants, carryover of unobligated balances requires NIH awarding IC prior approval unless otherwise noted in the NoA. Other awards may be excluded from this authority through a special term or condition in the NoA.

For awards under SNAP (see Administrative Requirements—Monitoring—Reporting—Streamlined Non-Competing Award Process in the most recent edition of the NIH Grants Policy Statement for applicability), funds are automatically carried over to the subsequent budget period. However, the recipient will be required to indicate, as part of the grant's progress report, whether any estimated unobligated balance (including prior-year carryover) is expected to be greater than 25 percent of the current year's total approved budget. The total approved budget amount includes current year and any carryover from prior years of the project period. If the unobligated balance is greater than 25 percent of the total approved budget, the recipient must provide an explanation and indicate plans for expenditure of those funds within the current budget year.

For awards that require an annual FFR, the amount to be automatically carried over must be specified under item 12, "Remarks."

For both SNAP and non-SNAP, when a recipient reports a balance of unobligated funds in excess of 25 percent of the total amount awarded for the budget period, the GMO will review the circumstances resulting in the balance to ensure that these funds are necessary to complete the project, and may request additional information from the recipient, including a revised budget, as part of the review.

If the GMO determines that some or all of the unobligated funds are not necessary to complete the project, the GMO may restrict the recipient's authority to automatically carry over unobligated balances in the future, use the balance to reduce or offset NIH funding for a subsequent budget period, or use a combination of these actions. The GMO also may indicate whether the balance may be carried forward

to a budget period other than the succeeding one. The GMO's decision about the disposition of the reported unobligated balance will be reflected in the terms and conditions of the NoA.

All Federal agencies are required by 31 U.S.C. §1552(a) to close fixed year appropriation accounts and cancel any remaining balances by September 30 of the fifth fiscal year after the year of availability. In order for the NIH to meet its obligation to close these accounts and cancel any remaining balances by September 30, recipients must report disbursements on the quarterly cash transaction report (using the FFR) no later than June 30 of the fifth fiscal year after the year of availability. At the end of five years, the funds are cancelled and returned to the Treasury. This provision may limit the availability of funds for carryover.

6.2 Cost Related Prior Approvals

NIH prior approval is not required to rebudget funds for any direct cost item that the applicable cost principles identify as requiring the Federal awarding agency's prior approval, unless the incurrence of costs is associated with or is considered to be a change in scope. As a result, recipients' authorities include but are not limited to the following;

- I. Incur pre-award cost up to 90 days before the beginning date of the initial budget period of a new or renewal award.
- II. Initiate a one-time extension of the final budget period of a previously approved project period without additional NIH funds.
- III. Carryforward Unobligated balances from one budget period to any subsequent budget period.
- IV. Rebudget among budget categories.
- V. Rebudget between direct and F&A costs.
- VI. Provide subawards based on fixed amounts, provided that the subawards meet the requirements for fixed amount awards in 45 CFR 75.201.
- VII. Direct charge the salaries of administrative and clerical staff if conditions in 45 CFR 75.413 are met.
- VIII. Direct charge payments of Incidental activities for which supplemental compensation is allowable under written institutional policy (at a rate not to exceed the institutional base salary) and not include them in the records described in paragraph (h)(i) of 45 CFR 75.430.
- IX. Include charges for Intra-IHE faculty consulting on sponsored agreements that exceed a faculty member's base salary, but only in unusual cases where: (a) consultation is across departmental lines or involves a separate or remote operation; and (b) the consulting work is in addition to the faculty member's regular departmental load.
- X. Direct charge capital expenditures for general purpose equipment. However, prior written approval is required for capital expenditures for buildings and land as a direct charge.
- XI. Direct charge capital expenditures for special purpose equipment with a unit cost over \$5,000.

Items VI – IX above are additional authorities NIH is providing recipients based on 45 CFR 75.

Activities and/or expenditures that require NIH prior approval are as follows;

| NIH prior approval is required for | Under the following circumstances |
|---|--|
| Additional no-cost extension, extension greater than 12 months, or late notification of initial no-cost extension | All instances. |
| A&R | <p>Rebudgeting into A&R costs that would exceed 25 percent of the total approved budget for a budget period.</p> <p>If rebudgeting would not meet this threshold but would result in a change in scope.</p> <p>Any single A&R project exceeding \$500,000.</p> |
| Capital expenditures (construction, land, or building acquisition) | All instances. Also, any proposals to convey, transfer, assign, mortgage, lease, or in any other manner encumber real property acquired with NIH grant funds. |
| Carryover of unobligated balances | If the NoA indicates that the recipient does not have the authority to automatically carry over unobligated balances. |
| Change in scope | All instances. |
| Change in status of the PD/PI or senior/key personnel named in the NoA | Withdrawal from the project; absence for any continuous period of 3 months or more; reduction of the level of effort devoted to project by 25 percent or more from what was approved in the initial competing year award. |
| Change of recipient organization | All instances. |
| Change of recipient organization status | All instances. |
| Deviation from award terms and conditions | All instances. Includes undertaking any activities disapproved or restricted as a condition of the award. |
| Foreign component added to a grant to a domestic or foreign organization | All instances. |
| Need for additional NIH funding | All instances, including extension of a final budget period of a project period with additional funds. |
| Pre-award costs | More than 90 days before effective date of the initial budget period of a new or competing continuation award; always at the recipient's own risk. |
| Rebudgeting funds from trainee costs | All instances. |
| Rebudgeting of funds between construction and non-construction work | All instances. |
| Retention of research grant funds when CDA awarded | All instances. |

* This table must be read along with other provisions located in the most recent edition of the NIH Grants Policy Statement.

7. Management Systems and Procedures

Procurement System Standards and Requirements

Recipients may acquire a variety of goods or services in connection with a grant-supported project, ranging from those that are routinely purchased goods or services to those that involve substantive programmatic work. States may follow the same policies and procedures they use for procurements from non-Federal funds and ensure that every purchase order or other contract includes any clauses required by 75.335. All other recipients must follow the requirements in 45 CFR 75.327 through 75.335 for the purchase of goods or services through contracts under grants. ***Note: OMB has provided a one-year grace period for implementation of these subsections for IHEs and nonprofit organizations. Thus, these requirements are expected to take effect for these entities for their first fiscal year after December 26, 2015.***

A contract under a grant must be a written agreement between the recipient and the third party. The contract must, as appropriate, state the activities to be performed; the time schedule; the policies and requirements that apply to the contractor, including those required by 45 CFR 75, Appendix II – Contract Provisions for Non-Federal Entity Contracts Under Federal Awards and other terms and conditions of the grant (these may be incorporated by reference where feasible); the maximum amount of money for which the recipient may become liable to the third party under the agreement; and the cost principles to be used in determining allowable costs in the case of cost-type contracts. The contract must not affect the recipient's overall responsibility for the direction of the project and accountability to the Federal government. Therefore, the agreement must reserve sufficient rights and control to the recipient to enable it to fulfill its responsibilities.

When a recipient enters into a service-type contract in which the term is not concurrent with the budget period of the award, the recipient may charge the costs of the contract to the budget period in which the contract is executed even though some of the services will be performed in a succeeding period if the following conditions are met:

- The NIH awarding IC has been made aware of this situation either at the time of application or through post-award notification.
- The project has been recommended for a project period extending beyond the current year of support.
- The recipient has a legal commitment to continue the contract for its full term.

However, costs will be allowable only to the extent that they are for services provided during the period of NIH support. To limit liability if continued NIH funding is not forthcoming, it is recommended that recipients insert a clause in such contracts of \$100,000 or less stipulating that payment beyond the end of the current budget period is contingent on continued Federal funding. The contract provisions prescribed by 45 CFR 75, Appendix II, Provisions for Non-Federal Entity Contracts Under Federal Awards, paragraph B specify termination provisions for contracts in excess of \$100,000.

8 Audits

NIH recipients (other than Federal institutions) are subject to the audit requirements of 2 CFR 200, Subpart F—Audit Requirements, as implemented by HHS at 45 CFR 75, Subpart F and in the NIHGPS (for types of organizations to which 2 CFR 200, Subpart F—Audit Requirements does not directly apply). In general, 2 CFR 200, Subpart F—Audit Requirements requires a State government, local government, or non-profit organization (including institutions of higher education) that expends \$750,000 or more per year under Federal grants, cooperative agreements, and/or procurement contracts to have an annual audit by a public accountant or a Federal, State, or local governmental audit organization. The audit must meet the standards specified in generally accepted government auditing standards (GAGAS). The audit requirements for foreign recipients and for-profit recipients are addressed in the chapters of the NIHGPS that provide specific requirements for those types of recipients.

Summary of Audit Requirements

| Recipient Type | Source of Audit Requirement (Non-Federal Entity Fiscal Years Beginning Prior to 12/26/2014) | Source of Audit Requirement (Non-Federal Entity Fiscal Years Beginning On/After 12/26/2014) | Where to Submit Audit Reports |
|---------------------------|---|---|--|
| State & Local Governments | OMB Circular A-133 | 45 CFR 75.501 | Federal Audit Clearinghouse |
| Colleges & Universities | OMB Circular A-133 | 45 CFR 75.501 | Federal Audit Clearinghouse |
| Non-Profits | OMB Circular A-133 | 45 CFR 75.501 | Federal Audit Clearinghouse |
| Hospitals | OMB Circular A-133 | 45 CFR 75.501(h) through 75.501(j) | Federal Audit Clearinghouse |
| For-Profits | 45 CFR 74.26(d) | 45 CFR 75.501(h) through 75.501(j) | National External Audit Review Center |
| Foreign | NIH Grants Policy Statement (same as For-Profits) | NIH Grants Policy Statement (same as For-Profits) | National External Audit Review Center (same as For-Profits) |

9 Special Award Conditions

A recipient's failure to comply with the terms and conditions of award, including confirmed instances of research misconduct, may cause NIH to take one or more actions, depending on the severity and duration of the non-compliance. NIH will undertake any such action in accordance with applicable statutes, regulations, and policies. NIH generally will afford the recipient an opportunity to correct the deficiencies before taking action unless public health or welfare concerns require immediate action. However, even if a recipient is taking corrective action, NIH may take proactive actions to protect the Federal government's interests, including placing special conditions on awards or precluding the

recipient from obtaining future awards for a specified period, or may take action designed to prevent future non-compliance, such as closer monitoring.

Provisions described in the most recent edition of the NIH Grants Policy Statement remain in effect for:

- Modification of the Terms of Award;
- Enforcement Actions: Suspension, Termination, and Withholding of Support;
- Other Enforcement Actions;
- Recovery of Funds; and
- Debt Collection.

10 Closeout

Recipients must submit a final FFR, final progress report, and Final Invention Statement and Certification within 120 calendar days of the end of grant support. The reports become overdue the day after the 120 day period ends.

11 Grants Appeal Procedures

The grant appeals procedure—as described in the most recent edition of the NIH Grants Policy Statement—remains in effect. Specifically:

HHS permits recipients to appeal certain post-award adverse administrative decisions made by HHS officials (see 45 CFR 16 and appendix to part 16). NIH has established a first-level grant appeal procedure that must be exhausted before an appeal may be filed by the recipient with the Departmental Appeals Board (DAB) (see 42 CFR 50, Subpart D). NIH will assume jurisdiction for the following adverse determinations set forth in 42 CFR 50.404:

- Termination, in whole or in part, of a grant for failure of the recipient to carry out its approved project in accordance with the applicable law and the terms and conditions of award or for failure of the recipient otherwise to comply with any law, regulation, assurance, term, or condition applicable to the grant.
- Determination that an expenditure is not allowable under the grant has been charged to the grant or that the recipient has otherwise failed to discharge its obligation to account for grant funds.
- Denial (withholding) of a non-competing continuation award for failure to comply with the terms of a previous award.
- Determination that a grant is void (i.e., a decision that an award is invalid because it was not authorized by statute or regulation or because it was fraudulently obtained).

The formal notification of an adverse determination will contain a statement of the recipient's appeal rights. In the first level appeal of an adverse determination, the recipient must submit a request for review to the NIH official specified in the notification, detailing the nature of the disagreement with the

adverse determination and providing supporting documents in accordance with the procedures contained in the notification.

“The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of the recipient’s position with respect to such issue(s) and the pertinent facts and reasons in support of the recipient’s position. In addition to the required written statement, the recipient shall provide copies of any documents supporting its claim.” 42 CFR 50.406(b).

The recipient’s request to NIH for review must be submitted no later than 30 days after the written notification of the adverse determination is received; however, an extension may be granted if the recipient can show good cause why an extension is warranted (42 CFR 50.406(a)).

If the NIH decision on the appeal is adverse to the recipient or if a recipient’s request for review is rejected on jurisdictional grounds, the recipient then has the option of submitting a request to the DAB for a further review of the case in accordance with the provisions of 45 CFR 16. A prospective appellant must submit a notice of appeal to the DAB within 30 days after receiving the final NIH decision. “The appellant must have exhausted any preliminary appeal process required by regulation.” 45 CFR 16.3(c).

In addition to the adverse determinations indicated above, the DAB is the single level of appeal for disputes related to the establishment of F&A cost rates, research patient care rates, and certain other cost allocations used in determining amounts to be reimbursed under NIH grants (e.g., cost allocation plans negotiated with State or local governments and computer, fringe benefit, and other special rates); <http://www.hhs.gov/dab/divisions/appellate/index.html>. The determination leading to such disputes may be made by an HHS official other than the GMO and may affect NIH grants as well as other HHS grants.