HHS’ Publication of Interim Final Rule Implementing Uniform Guidance

- On December 19, 2014, HHS published in the Federal Register, an interim final rule adapting OMB’s final guidance in 2 CFR part 200 with certain amendments, based on existing HHS regulations, to supplement the guidance as needed for the Department.

- HHS made this interim final rule effective on December 26, 2014.
  - However, HHS acknowledged that it would consider and address comments that were received within 60 days of the date the interim final rule was published in the Federal Register.

- See NOT-OD-15-046
• NIH is working with other Federal Research Agencies to develop a Research Terms and Conditions Overlay document.
  
  ○ Overlay will serve as a companion document to provide additional clarity for select provisions consistent with government-wide research policy.

• Until the Overlay document is complete, Federal Research Agencies have been encouraged to develop their own Interim Terms and Conditions.
On February 5, 2015, NIH published interim general conditions of NIH grant awards aligned with HHS’ regulation implementing OMB’s Uniform Guidance at 45 CFR Part 75.

The Interim Grant General Conditions document was issued in order to serve as the applicable terms and conditions for recipients of NIH awards, until such time as revised Research Terms and Conditions become effective.

- The conditions are effective for Notices of Award (NoA) issued on or after December 26, 2014, that obligate new or supplemental funds.
- NoAs issued on or after December 26, 2014 that do not involve obligation of new or supplemental funds remain subject to 45 CFR Part 74 or Part 92, as applicable, until such time that new funds are obligated.

See NOT-OD-15-065 for more information.
How Will this Impact NIH Grants Management?

• Interim document aligns with the format of the NIH GPS as follows;
  
  o Part I: NIH Grants – General Information
    • 1 Definitions
  
  o Part II: Terms and Conditions of NIH Grant Awards
    • 2 Public Policy Requirements
    • 3 Special Provisions for Awards to Commercial Organizations as Recipients
    • 4 The Notice of Award
    • 5 Cost Considerations
    • 6 NIH Standard Terms of Award
    • 7 Management Systems
    • 8 Audits
How Will this Impact NIH Grants Management?

- Part II: Terms and Conditions of NIH Grant Awards (cont.)
  - 9 Special Award Conditions
  - 10 Closeout
  - 11 Grant Appeals Procedures
• Definitions:

The following are new definitions that have been incorporated into the NIH GPS as follows;

- 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.”

- Expenditure report - Means: (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).
1 Definitions (cont.):

- **Federal award** - Depending on the context, in either paragraph (1) or (2) of this section:
  
  (1)(i) The Federal financial assistance that a non-Federal entity receives directly from a Federal awarding agency or indirectly from a pass-through entity, as described in 45 CFR 75.101; or
  
  (ii) The cost-reimbursement contract under the Federal Acquisition Regulations that a non-Federal entity receives directly from a Federal awarding agency or indirectly from a pass-through entity, as described in 45 CFR 75.101.
  
  (2) The instrument setting forth the terms and conditions. The instrument is the grant agreement, cooperative agreement, or other agreement for assistance covered in paragraph (2) of Federal financial assistance, or the cost-reimbursement contract awarded under the Federal Acquisition Regulations.
  
  (3) Federal award does not include other contracts that a Federal agency uses to buy goods or services from a contractor or a contract to operate Federal government owned, contractor operated facilities (GOCOs).
  
  (4) See also definitions of Federal financial assistance, grant agreement, and cooperative agreement.
1 Definitions (cont.):

- **Federal program** - (1) All Federal awards which are assigned a single number in the CFDA.
  
  (2) When no CFDA number is assigned, all Federal awards to non-Federal entities from the same agency made for the same purpose should be combined and considered one program.
  
  (3) Notwithstanding paragraphs (1) and (2) of this definition, a cluster of programs. The types of clusters of programs are:
    
    (i) **Research and development (R&D)**;
    
    (ii) **Student financial aid (SFA)**; and
    
    (iii) “Other clusters,” as described in the definition of Cluster of Programs.

- **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**.
1 Definitions (cont.):

- **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.

- **Personal property** - Property of any kind except real property. It may be tangible, having physical existence, or intangible, such as copyrights, patents, or securities.
1 Definitions (cont.):

The following are definitions that have been modified within the NIH GPS as follows;

- *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. (See also capital assets, computing devices, general purpose equipment, information technology systems, special purpose equipment, and supplies.)
1 Definitions (cont.):

- **Federal share** - The portion of the total project costs that are paid by Federal funds.

- **Grantee** - See Recipient.

- **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. See also Non-Federal entity.
• **Definitions (cont.):**

  - **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.

  - **Termination** - The ending of a Federal award, in whole or in part at any time prior to the planned end of period of performance.
• 2 Public Policy Requirements

  o 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:

How Will this Impact NIH Grants Management?

• 3 Special Provisions for Awards to Commercial Organizations

  o 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

- Developed a revised NoA that aligns with the Fed-wide requirements. The revised NoA was deployed on December 29, 2014, and identifies the following information:
  - Federal award date
  - Total approved cost sharing or matching (replaced Non-Federal share)
  - Total Amount of Federal Funds Obligated (Federal Share)
  - Adds Catalog of Federal Domestic Assistance (CFDA) name in addition to the CFDA Number
  - Adds Period of Performance above the Budget Period and Project Period
  - Adds Research & Development (R&D) Indicator
• **4.1 Funding**

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.
How Will this Impact NIH Grants Management?

- **4.2 Additional Payments**
- 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.
• 5 Cost Considerations

• 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.

  o More significant post-award changes require NIH prior approval.

• 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.
• 5.1 The Cost Principles
• The cost principles are set forth in HHS regulations at 45 CFR 75, Subpart E and Appendix IX (hospitals) to Part 75.
  o OMB Circulars A-21, A-87 and A-122 have been consolidated and into a single source document relocated to 2 CFR Part 200, Subpart E—Cost Principles.

• The cost principles address four tests to determine the allowability of costs. The tests are as follows:
  o Reasonableness (Including Necessity).
  o Allocability
  o Consistency
  o Conformance
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.
5.3 Reimbursement of Facilities and Administrative Costs

- F&A rates are negotiated by DCA, DFAS in the Office of Acquisition Management and Policy, NIH, or other agency with cognizance for F&A/indirect cost rate (and other special rate) negotiation.
  
  Consistent with 45 CFR 75.414(f), any non-Federal entity that has never received a negotiated indirect cost rate, except for certain types of non-Federal may elect to charge a de minimis rate of 10% of modified total direct costs (MTDC).
• 5.3 Reimbursement of Facilities and Administrative Costs (cont.)
• NIH does not reimburse indirect costs under the following classes of awards:
  o Fellowships
  o Construction and Modernization
  o Grants to Individuals
  o Grants to Federal Institutions.
  o Grants in Support of Scientific Meetings (Conference Grants).
  o Endowment Grants

• NIH limits the amounts included in the F&A base for the following type of costs:
  o Genomic Arrays (GA)
5.3 Reimbursement of Facilities and Administrative Costs (cont.)

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
- Grants to Foreign Organizations and International Organizations

5.4 Revised Selected Items of Cost

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

- Value Added Tax Policy
- Participant Support Cost Policy
- Temporary Dependent Care Cost Policy
• 5.4 Revised Selected Items of Cost (cont.)
• Alteration and Renovation (Rearrangement and Reconversion cost)
  o 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.
• 5.4 Revised Selected Items of Cost (cont.)

• 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.
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.

- Certain award instruments, grant programs, and types of recipients are routinely excluded from the authority to automatically carry over unobligated balances.

- 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

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.

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.
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.

- Incur pre-award cost up to 90 days before the beginning date of the initial budget period of a new or renewal award.
- Initiate a one-time extension of the final budget period of a previously approved project period without additional funds.
- Carryforward Unobligated balances from one budget period to any subsequent budget period.
- Rebudget among budget categories
- Rebudget between direct and F&A costs
- Provide subawards based on fixed amounts, provided that the subawards meet the requirements for fixed amount awards in 45 CFR 75.201.
6.2 Cost Related Prior Approvals (cont.)

- Direct charge the salaries of administrative and clerical staff if conditions in 45 CFR § 75.413 are met.
- 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).
- Include charges for Intra-IHE faculty consulting on sponsored agreements that exceed a faculty member’s base salary, but only in unusual cases.
- Direct charge capital expenditures for general purpose equipment.
- Direct charge capital expenditures for special purpose equipment with a unit cost over $5,000.
Recipients must follow the requirements in 45 CFR parts 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.
How Will this Impact NIH Grants Management?

8 Audits

NIH recipients (other than Federal institutions) are subject to the audit requirements of OMB 2 CFR 200, Subpart F—Audit Requirements, as implemented by HHS at 45 CFR Subpart F and in the NIHGPS.

- In general, Subpart F 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.
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.

- 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.

- This provisions is aligned with the clarification being proposed for the Closeout provision within the Research Terms and Conditions Overlay document.
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).
Frequently Asked Questions (FAQs)

• We developed FAQs for the Uniform Guidance and NIH Interim Grant General Conditions to address topics such as the following:

  o Why is NIH issuing “Interim Grant General Conditions?”
  o I received an NoA on or after December 26, 2014, documenting the approved carryover amount from a previous fiscal year. Which HHS regulations apply?
  o Has NIH changed its policy regarding cost-related prior approval requirements?
  o Are participant support costs allowable?
  o What is allowable regarding child care costs when travelling under a research grant?
How we implement these changes at the operational level will have a major impact on the success of reaching the Uniform Guidance’s goal of “…deliver[ing] on the promise of a 21st Century government that is more efficient, effective and transparent.”
Thank You!

Questions?