Demystifying National Institutes of Health (NIH) for Research Administrators

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Agenda

• National Institutes of Health (NIH) Overview
• Budgeting
  ✓ NIH Salary Limitation
  ✓ Graduate Student / Postdoc Considerations
  ✓ Single IRB
• Just-in-Time Submission
• Carry-forward of Unobligated Funds
• Research Performance Progress Report (RPPR)
• Human Subjects and Clinical Trial Form
• Post-award Prior Approval Requests
• Questions
OSP Roundtable – Demystifying NIH

NIH Overview
HHS ORGANIZATION

- HHS has 11 Operating Divisions, including NIH

- Administration for Children and Families (ACF)
- Administration for Community Living (ACL)
- Agency for Healthcare Research and Quality (AHRQ)
- Agency for Toxic Substances and Disease Registry (ATSDR)
- Centers for Disease Control and Prevention (CDC)
- Centers for Medicare & Medicaid Services (CMS)
- Food and Drug Administration (FDA)
- Health Resources and Services Administration (HRSA)
- Indian Health Service (IHS)
- National Institutes of Health (NIH)
- Substance Abuse and Mental Health Services Administration (SAMHSA)
NATIONAL INSTITUTES OF HEALTH

Office of the Director

Office of Extramural Research

National Institute of Dental and Craniofacial Research
National Institute on Aging
National Institute on Alcohol Abuse and Alcoholism
National Institute of Allergy and Infectious Diseases
National Institute of Arthritis and Musculoskeletal and Skin Diseases
National Cancer Institute
National Institute of Child Health and Human Development
National Institute on Deafness and Other Communication Disorders

National Institute of General Medical Sciences
National Heart, Lung, and Blood Institute
National Human Genome Research Institute
National Institute of Diabetes and Digestive and Kidney Diseases
National Institute on Drug Abuse
National Institute of Environmental Health Sciences
National Eye Institute
National Institute of Mental Health

National Center on Minority Health and Health Disparities
National Center for Complementary and Integrative Health
Fogarty International Center
National Center for Advancing Translational Sciences
National Library of Medicine
National Institute of Neurological Disorders and Stroke
National Institute of Nursing Research
National Institute of Biomedical Imaging and Bioengineering

NIH Clinical Center
Center for Information Technology
Center for Scientific Review

No funding authority

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Each with a different:

- Mission & priorities
- Budget
- Funding strategy

NIH Funding Strategies by IC: https://grants.nih.gov/policy/nih-funding-strategies.htm
# Deciphering NIH Application/Grant Numbers

<table>
<thead>
<tr>
<th>Application Type</th>
<th>Activity Code</th>
<th>Institute Code (IC)</th>
<th>Serial Number</th>
<th>Support Year</th>
<th>Other Suffixes</th>
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<td>CA</td>
<td>654321</td>
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### Application Types
1. **New**: Request for support of a project that has not yet been funded.
2. **Renewal**: Request for additional funding for a period subsequent to that provided by a current award.
3. **Revision**: Request for (or the award of) additional funds during a current project period to support new or additional activities that are not identified in the current award. This request reflects an expansion of the scope of the grant-approved activities. Competitive revisions require peer review. An administrative supplement is a request for (or the award of) additional funds during a current project period to provide for an increase in costs due to unforeseen circumstances. All additional costs must be within the scope of the peer-reviewed and approved project.
4. **Extension**: Request for additional years of support beyond the years previously awarded. (Used only for select programs.)
5. **Non-competing Continuation**: Request or award for a subsequent budget period within a previously approved project for which a recipient does not have to compete with other applications.
6. **Change of Organization Status (Successor-In-Interest)**: Process whereby the rights to and obligations under an NIH grant is acquired incidental to the transfer of all the assets of the grantee or the transfer of that part of the assets involved in the performance of the grant. May result from legislative or other legal action, such as a merger or other corporate change.
7. **Change of Grantee or Training Institution**: 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 (noncompetitive segment).
8. **Change of Institute or Center**: Change of awarding NIH institute or center for the noncompeting continuation (Type 5).
9. **Change of Institute or Center**: Change of awarding NIH institute or center for the renewal (Type 2).

### Activity Codes: [http://grants.nih.gov/grants/funding/funding_program.htm](http://grants.nih.gov/grants/funding/funding_program.htm)

### NIH Funding Institutes
- **FIC**: John E. Fogarty International Center
- **NCATS**: National Center for Advancing Translational Sciences (NCATS)
- **NCCIH**: National Center for Complementary and Integrative Health
- **NCI**: National Cancer Institute
- **NEI**: National Eye Institute
- **NHGRI**: National Human Genome Research Institute
- **NHLBI**: National Heart, Lung, and Blood Institute
- **NIA**: National Institute on Aging
- **NIAAA**: National Institute on Alcohol Abuse and Alcoholism
- **NIAID**: National Institute of Allergy and Infectious Diseases
- **NIAMS**: National Institute of Arthritis and Musculoskeletal and Skin Diseases
- **NIBIB**: National Institute of Biomedical Imaging and Bioengineering
- **NICHD**: Eunice Kennedy Shriver National Institute of Child Health and Human Development
- **NIDA**: National Institute on Drug Abuse
- **NIDCD**: National Institute on Deafness and Other Communication Disorders
- **NIDCR**: National Institute of Dental and Craniofacial Research
- **NIDDK**: National Institute of Diabetes and Digestive and Kidney Diseases
- **NIEHS**: National Institute of Environmental Health Sciences
- **NIGMS**: National Institute of General Medical Sciences
- **NIMH**: National Institute of Mental Health
- **NIMHD**: National Institute on Minority Health and Health Disparities
- **NINDS**: National Institute of Neurological Disorders and Stroke
- **NINR**: National Institute of Nursing Research
- **NLM**: National Library of Medicine

### Serial Number: Six-digit number assigned within an Institute/Center

### Support Year: Two-digit number indicating segment or budget period of a project.

### Other Suffixes: ‘A’ and related number identifies the amendment number (e.g., A1 = submission); ‘S’ and related number identifies the revision record and follows the grant year or the amendment designation to which additional funds have been awarded.
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Budgeting

OSP Roundtable
“Developing Budgets to Aid in Post-Award Project Management”
May 2019
https://vod.video.cornell.edu/media/May+2019+OSP+Round+Table+Zoom+Recording/1_f51n37tf
NIH Salary Limitation

• NOT-OD-19-099 Effective January 6, 2019, the salary limitation of the Executive Level II rate has increased to $192,300 for 12 months, or a 9-month rate of $144,225 (75% FTE)

• Effort: Person Months
  - Calendar vs. Academic/Summer months
  - 12 month vs. 9 month appointment

https://grants.nih.gov/grants/policy/person_months_faqs.htm
https://grants.nih.gov/grants/policy/salcap_summary.htm (Salary Cap Summary (FY 1990 - Present))
NIH Salary Limitation

• **Salary Cap Exceedance**
  - NOT Voluntary Committed Cost Share
  - Must be tracked in a sub-account entitled “NIH CAP” per Cornell Policy 3.11 Salary Confirmation

• **Voluntary Committed Effort**
  - Documented in the Budget or Budget Justification
  - Documented and Approved on the Form 10
  - Must be tracked in a cost share sub-account

Percent SALARY requested ≤ Percent EFFORT

Example:
Devote 1.2 person-months [10%] effort (12 month appointment)
May request between 0% to 10% of salary* *up to legislated salary cap

NH Salary Limitation

- Detailed budget: recommend to base the request on actual institutional base salaries (not the cap)
  - Help NIH know the current pay scales and justify increases
  - Grants Management Specialists will adjust to meet the cap at the time of award
  * In all instances, whether the cap is used for budgeting purposes or not, the PIs actual salary must be listed in the SF 424 R&R Budget field “Base Salary”.
- In future years, if the salary cap increases, grantees may rebudget to pay investigator salaries up to the new salary cap.
- Federal Contracts: refer to solicitations/terms and conditions
- Modular budget: use the current cap when determining the appropriate number of modules

https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/develop-your-budget.htm#modbud
Modular Budget Flow Chart

1. Do your direct costs (minus any consortium/subcontract F&A costs) equal less than $250,000 per year?
   - Yes
   - No

2. Are you applying for an R01, R03, R15, R21 or R34 grant?
   - Yes
   - No

3. Is the applicant organization based in the United States?
   - Yes
   - No

Use Detailed Budget (SF 424(R&R) Budget Form)

Use Modular Budget (PHS 398 Modular Budget Form)

https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/develop-your-budget.htm#modbud
Graduate Student / Postdoc Considerations

• NOT-OD-02-017 Graduate Student Support (Stipend, Tuition and Fees) is awarded up to zero level NRSA stipend in effect at the time the grant award is issued.

• NOT-OD-19-036 Ruth L. Kirschstein National Research Service Award (NRSA) Stipends, Tuition/Fees and Other Budgetary Levels Effective for Fiscal Year 2019

• Zero level NRSA stipend = Cornell postdoc minimum salary
  - The minimum postdoc salary for 2019-2020 is $50,004.

https://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-017.html
https://postdocs.cornell.edu/benefits/cornell-funded-postdocs-benefits/
https://gradschool.cornell.edu/financial-support/
NRSA Addendum Form

• Required per NOT-OD-09-007 for NRSA Individual Fellowships
• Must be signed by Applicant (Individual Fellow) and Sponsor(s)
  - Co-Sponsor should also be listed as a Co-PI on the Form 10
• Must be available to the sponsoring agency or other authorized HHS or Federal officials upon request

https://researchservices.cornell.edu/forms/form-10
Single IRB

- Single IRB Policy for Multi-site Research
- Cornell CANNOT serve as a sIRB
  - Ithaca and Weill
- How may sIRB affect RAs’ work?
  - It may affect the budget
  - It can be very expensive
  - Contact ORIA at oria-help@cornell.edu for quotes ASAP

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Just-in-Time Submission
What’s required for Just-in-Time submission?

• Other Support / Current and Pending Support
  - For ALL INDIVIDUALS designated in an application as senior/key personnel-those devoting measurable effort to a project
  - "Zero percent" effort is not acceptable for NIH projects
  - Total effort on all awards CANNOT exceed 12 calendar months

• Budget clarification

• Compliances
  - Certification of IRB Approval*
  - Verification of IACUC Approval*
  - Human Subjects Education Requirement
  * Pending or out-of-date approvals are not acceptable

• Other information as needed

https://grants.nih.gov/grants/policy/person_months_faqs.htm
Two Types of Just-in-Time Requests

• Automatic Email Request
  - Impact score of 30 or less regardless of the IC’s payline
  - NO specific due date

• Request from Grants Management Officer/Specialist
  - High likelihood of award
  - Specific due date

• Timing of Compliances Processing
What does NIH look for in Just-in-Time submission?

• Sufficient levels of EFFORT are committed to the project
• There is NO scientific, budgetary, or commitment overlap
  - Commitment overlap occurs when an individual's time commitment exceeds 100 percent (i.e., 12 person months), whether or not salary support is requested in the application
• Only funds necessary to the approved project are included in the award
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Carry-forward of Unobligated Funds
What is carry-forward of unobligated funds?

Carryover is the process by which unobligated funds remaining at the end of a budget period may be carried forward to the next budget period to cover allowable costs in that budget period. The carryover of funds enables grantees to use unexpended prior year grant funds in the current budget period.

NIH Grants Policy Statement 8.1.1.1 Carryover of Unobligated Balances: NoA will include a term and condition to indicate the disposition of unobligated balances.

Where can we find the term in a NoA?

SECTION III – TERMS AND CONDITIONS

• Automatic carryover authority *

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

• Prior approval is required by the NIH awarding IC

Carry over of an unobligated balance into the next budget period requires Grants Management Officer prior approval.

*However, estimated unobligated balance that is greater than 25% of the current year’s total approved budget must be justified in the Research Performance Progress Report (RPPR)
What’s required for a carry-forward of unobligated funds request?

- NIH Grants Policy Statement 8.1.2.4 Carryover of Unobligated Balances: Carry-forward request should include at a minimum the following information
  - A detailed budget by direct cost category with the F&A cost information (base and rate) for the proposed use of the carryover funds
  - A scientific justification for the use of funds
  - The reason for the unobligated balance

- ICs may have detailed instruction online. Example: NIAMS Carryover Unobligated Funds

- Contact NIH GMS for detailed instructions

https://www.niams.nih.gov/grants-funding/post-award-grants-administration/carryover-unobligated-funds
What may GMOs do if they determine some or all of the unobligated funds are not necessary to complete the project?

- 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
- Use a combination of these actions
- Indicate whether the balance may be carried forward to a budget period other than the succeeding one

GMO’s decision about the disposition of the reported unobligated balance will be reflected in the terms and conditions of the NoA.

Carry-forward of Unobligated Funds

SECTION I – AWARD DATA

<table>
<thead>
<tr>
<th>Description</th>
<th>Amount</th>
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<tr>
<td>Federal Direct Costs</td>
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<td>Federal F&amp;A Costs</td>
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<tr>
<td><strong>Approved Budget</strong></td>
<td><strong>$489,509</strong></td>
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<tr>
<td>Total Amount of Federal Funds Obligated (Federal Share)</td>
<td><strong>$489,509</strong></td>
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<tr>
<td>Less Unobligated Balance</td>
<td><strong>$227,400</strong></td>
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<tr>
<td><strong>TOTAL FEDERAL AWARD AMOUNT</strong></td>
<td><strong>$262,109</strong></td>
</tr>
</tbody>
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**AMOUNT OF THIS ACTION (FEDERAL SHARE)**  $262,109

SECTION IV – Special Terms and Conditions

OFFSET
Unobligated funds in the amount of $227,400 have been used as an offset to this award. The total approved budget for this period, $489,509, is shown in Section I, Award Data, on the “Approved Budget” line.
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Research Performance Progress Report (RPPR)
Research Performance Progress Report (RPPR)

- Different Types of RPPR
  - Annual, Final, Interim
  - SNAP and Non-SNAP
- Follow NIH RPPR Instruction Guide

https://grants.nih.gov/grants/rppr/index.htm
Who can submit RPPRs?

- Effective July 1, 2018, Principal Investigators for Streamlined Noncompeting Award Process (SNAP) awards have the option to submit annual, interim, and final RPPRs directly to NIH in eRA Commons without Grant & Contract Officer (GCO) review and submission.

- Non-SNAP RPPRs must be submitted by GCO.

- NoA includes the following term for SNAP awards:

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).
How may RPPR submission affect RAs’ work?

• Annual RPPR must be submitted and approved for NIH to non-competitively fund each additional budget period within a previously approved project period (competitive segment).
• PIs may reach out for information needed to complete RPPR
  - Project participants and their efforts
  - Significant change in senior/key personnel effort
  - Estimated unobligated funds
  - Other Support documents
  - Biosketches
Project participants and their efforts

D.1 What individuals have worked on the project?

- Provide or update the information for: (1) program director(s)/principal investigator(s) (PDs/PIs); and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours or 8.3% of annualized effort).

- Provide the name and identify the role the person played in the project. Indicate the nearest whole person month (Calendar, Academic, Summer) that the individual worked on the project.

- A Commons ID is required for all individuals with a postdoctoral, graduate or undergraduate role.
Significant Change in Senior/Key Personnel Effort

D.2.a Level of effort.

- Will there be, in the next budget period, either (1) a reduction of 25% or more in the level of effort from what was approved by the agency for the PD/PI(s) or other senior/key personnel designated in the Notice of Award, or (2) a reduction in level of effort below the minimum amount of effort required by the Notice of Award?

Selecting **Yes** constitutes a prior approval request* to the agency and the issuance of a subsequent year of funding constitutes agency approval of the request

* Only exception to the rule that RPPR MAY NOT be used for prior approval requests
Estimated Unobligated Balance

G.10 Estimated unobligated balance.

- G.10.a Is it anticipated that an estimated unobligated balance (including prior year carryover) will be greater than 25% of the current year’s total approved budget? If yes, provide the estimated unobligated balance.

- G.10.b Provide an explanation for unobligated balance.

- G.10.c If authorized to carryover the balance, provide a general description of how it is anticipated that the funds will be spent. To determine carryover authorization, see the Notice of Award.
Changes in Other Support

D.2.c Changes in other support.

- Has there been a change in the active other support of senior/key personnel since the last reporting period?

If yes, upload annotated active other support for senior/key personnel whose support has changed and indicate what the change has been.
Biosketches and Other Support

D.2.b New senior/key personnel

- Are there, or will there be, new senior/key personnel?

- If yes, upload biosketches and other support for all new senior/key personnel.
Progress Report Additional Materials (PRAM)

- PI must initiate in NIH Commons for GCO submission
- Common Hurdles
  - Efforts
  - Publications: Compliant papers have a status of Complete, N/A (not applicable), PMC Journal in Process, or In process at NIHMS
  - Justification for High Estimated Unobligated Balance

Include PMCID in Citations: https://publicaccess.nih.gov/include-pmcid-citations.htm
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Human Subjects and Clinical Trials Information Form
Human Subjects and Clinical Trials Information Form

• Used to collect information on human subjects research, clinical research, and/or clinical trials
• Follow How to Apply - Application Guide
• All applicants must use the form regardless of answer to the question “Are human subjects involved?” on the R&R Other Project Information Form

- If "Yes", add a Study Record for each proposed study involving human subjects or "Add New Delayed Onset Study," as appropriate.

sIRB Question

3.2 Is this a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site?
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Post-award Prior Approval Requests
Post-award Prior Approval Requests

- NIH Grants Policy Statement 8.1.2 Prior Approval Requirements
- Exhibit 7. Summary of Actions Requiring NIH Prior Approval
- Any question about the need for prior approval for an activity or cost under a specific NIH award should be directed to GCO
- GCO will contact NIH GMO as needed


OSP Roundtable
“Post-Award Prior Approvals”
March 2019
https://vod.video.cornell.edu/media/March+2019+OSP+Round+Table+Zoom+Recording/1_axlvd74
OSP Roundtable – Demystifying NIH for Research Administrators

Questions?
Thank you for coming!

Special thanks to Linda Griswold, Chris Brown, Jamie Sprague, Janet Strait, Brianne Rockefeller, Mindy McGill-Carlison