



Office of Sponsored Programs (OSP) Roundtable

Demystifying National Institutes of Health (NIH) for Research Administrators

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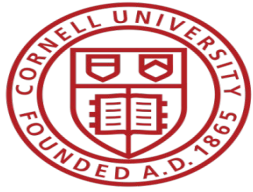
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Agenda

- 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

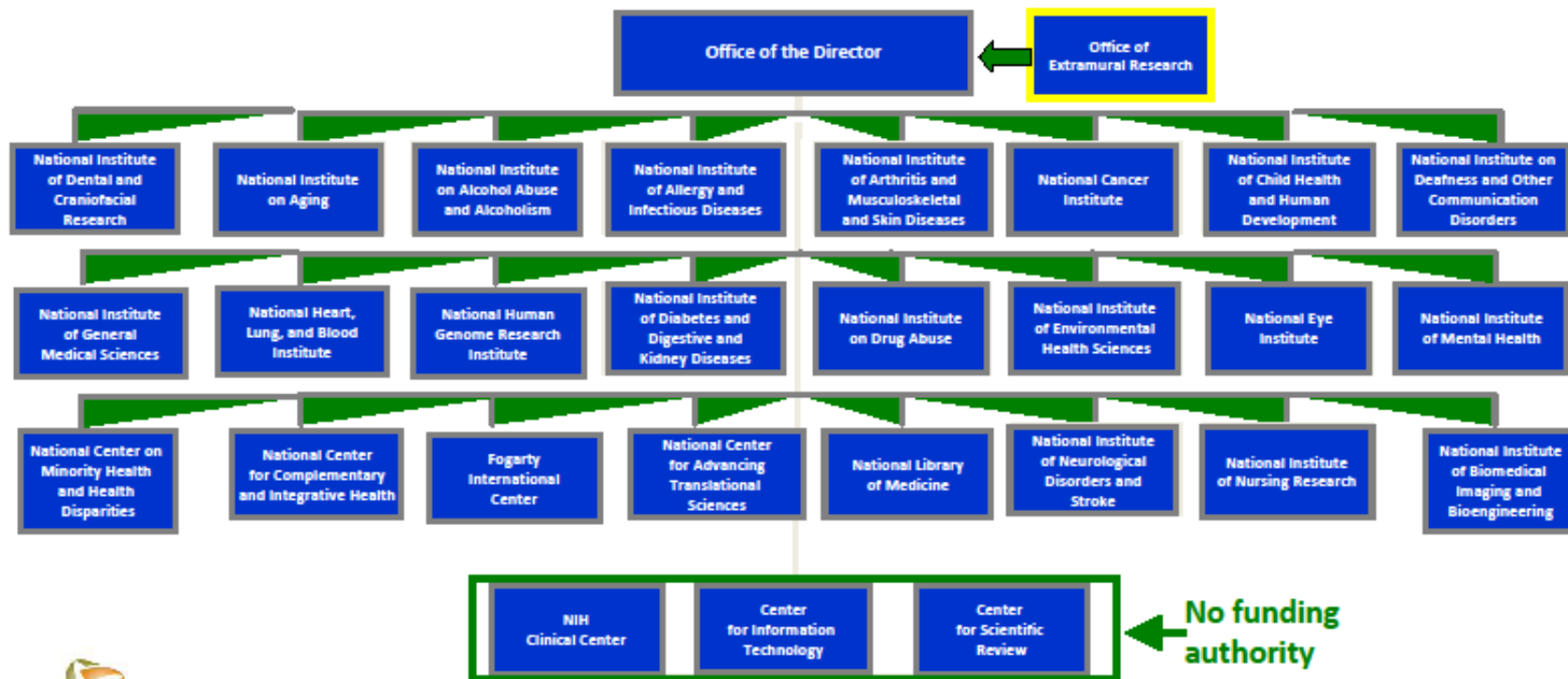
NIH Overview

HHS ORGANIZATION

- HHS has 11 Operating Divisions, including NIH



NATIONAL INSTITUTES OF HEALTH





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

<u>Application Type</u>	<u>Activity Code</u>	<u>Institute Code (IC)</u>	<u>Serial Number</u>	<u>Support Year</u>	<u>Other Suffixes</u>
1	R01	CA	654321	01	A1

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 of 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 (competitive 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

NIH Funding Institutes

<u>Acronym</u>	<u>Full Name</u>	<u>Code</u>
FIC	John E. Fogarty International Center	TW
NCATS	National Center for Advancing Translational Sciences (NCATS)	TR
NCCIH	National Center for Complementary and Integrative Health	AT
NCI	National Cancer Institute	CA
NEI	National Eye Institute	EY
NHGRI	National Human Genome Research Institute	HG
NHLBI	National Heart, Lung, and Blood Institute	HL
NIA	National Institute on Aging	AG
NIAAA	National Institute on Alcohol Abuse and Alcoholism	AA
NIAID	National Institute of Allergy and Infectious Diseases	AI
NIAMS	National Institute of Arthritis and Musculoskeletal and Skin Diseases	AR
NIBIB	National Institute of Biomedical Imaging and Bioengineering	EB
NICHD	Eunice Kennedy Shriver National Institute of Child Health and Human Development	HD
NIDA	National Institute on Drug Abuse	DA
NIDCD	National Institute on Deafness and Other Communication Disorders	DC
NIDCR	National Institute of Dental and Craniofacial Research	DE
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases	DK
NIEHS	National Institute of Environmental Health Sciences	ES
NIGMS	National Institute of General Medical Sciences	GM
NIMH	National Institute of Mental Health	MH
NIMHD	National Institute on Minority Health and Health Disparities	MD
NINDS	National Institute of Neurological Disorders and Stroke	NS
NINR	National Institute of Nursing Research	NR
NLM	National Library of Medicine	LM

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 = resubmission); 'S' and related number identifies the revision record and follows the grant year or the amendment designation to which additional funds have been awarded.



OSP Roundtable – Demystifying NIH 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/guide/notice-files/NOT-OD-19-099.html>

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 \leq 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*



NIH Salary Limitation

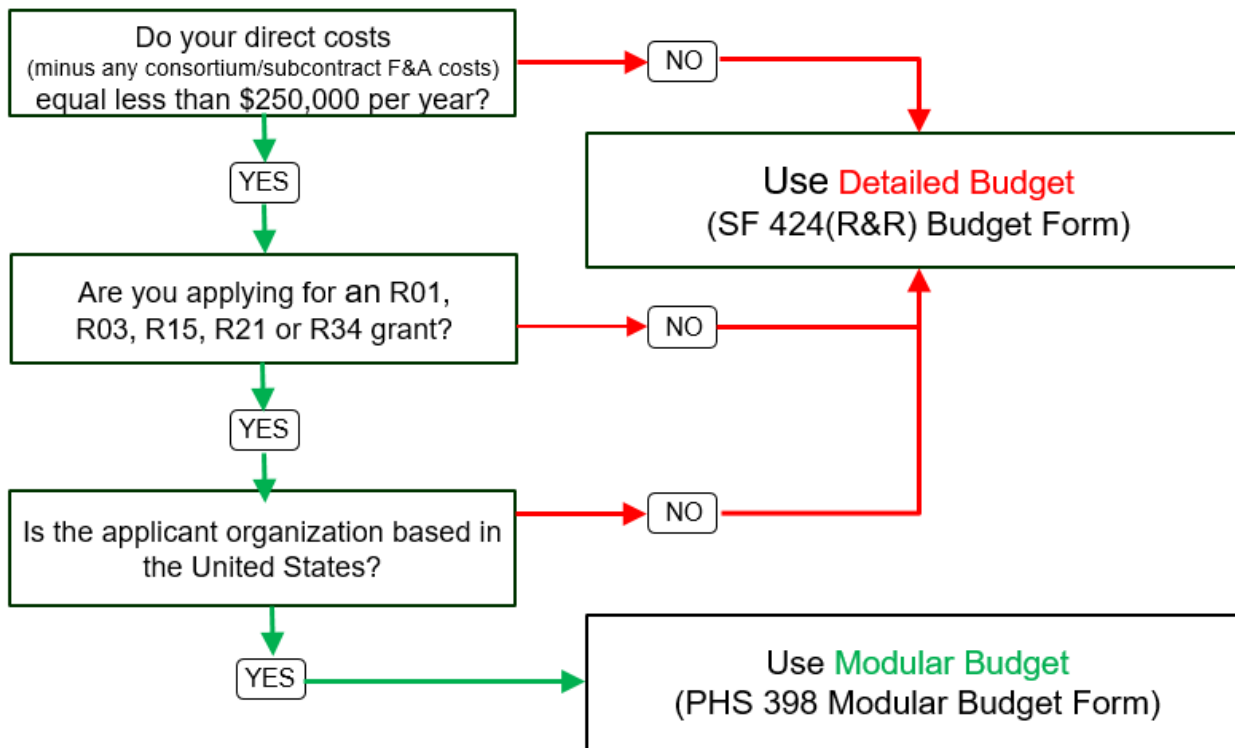
- Detailed budget: recommend to base the request on actual institutional base salaries (not the cap)
 - Help NIH know the current pay scales and justify increases
 - Grants Management Specialists will adjust to meet the cap at the time of award

* 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





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://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-036.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://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-007.html>

<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

<https://grants.nih.gov/policy/humansubjects/single-irb-policy-multi-site-research.htm>



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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* * Pending or out-of-date approvals are not acceptable
 - Verification of IACUC Approval*
 - Human Subjects Education Requirement
- Other information as needed

https://grants.nih.gov/grants/policy/nihgps/html5/section_2/2.5.1_just-in-time_procedures.htm

https://grants.nih.gov/grants/policy/person_months_faqs.htm



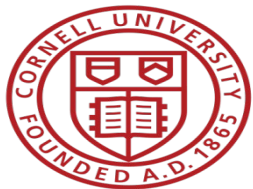
Two Types of Just-in-Time Requests

- 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.

https://grants.nih.gov/grants/policy/nihgps/html5/section_8/8.1.2_prior_approval_requirements.htm#Carryove



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://grants.nih.gov/grants/policy/nihgps/html5/section_8/8.1.2_prior_approval_requirements.htm#Carryover
<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.

https://grants.nih.gov/grants/policy/nihgps/html5/section_8/8.1.2_prior_approval_requirements.htm#Carryove



Carry-forward of Unobligated Funds

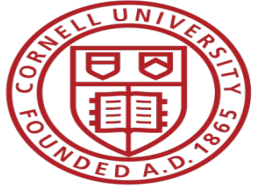
SECTION I – AWARD DATA

Federal Direct Costs	\$458,796
Federal F&A Costs	\$30,713
Approved Budget	\$489,509
Total Amount of Federal Funds Obligated (Federal Share)	\$489,509
Less Unobligated Balance	\$227,400
TOTAL FEDERAL AWARD AMOUNT	\$262,109
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

NIH Public Access Policy: <https://publicaccess.nih.gov/policy.htm>

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.

<https://grants.nih.gov/grants/how-to-apply-application-guide.html>

OSP Roundtable

“New NIH Human Subjects Requirements”

December 2017

<https://vod.video.cornell.edu/media/December+2017+OSP+Round+Table+Recording/>

[1_skrzmckp](#)



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

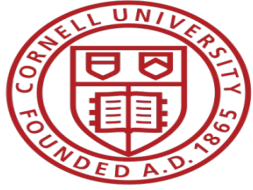
https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.1.2_prior_approval_requirements.htm?Highlight=prior%20approval

OSP Roundtable

“Post-Award Prior Approvals”

March 2019

https://vod.video.cornell.edu/media/March+2019+OSP+Round+Table+Zoom+Recording/1_axlvdc74



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Questions?



OSP Roundtable – Demystifying NIH for RAs



Thank you for coming!

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