

# NIH Post-Award Prior Approvals



## WHEN YOU NEED TO CALL NIH

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# Overview

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What doesn't require prior approval

16 items that do require NIH prior approval

Questions

# What doesn't require prior approval

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Carryover of unobligated balances from one budget period to any subsequent period\*

- \*With some Exceptions

Rebudgeting of funds for any Direct Cost Item\*

- \*Unless the Rebudgeting constitutes a change in Scope

Extension of final budget period of a project period without additional NIH funds (no-cost extension)\*

- \*First time only, some Mechanisms may be excluded.

Transfer of performance of substantive programmatic work to a third party (by consortium agreement)\*

- \*Excludes Foreign components

# 16 items that require NIH prior approval

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Additional no-cost extension, extension greater than 12 months, or late notification of initial no-cost extension ([8.1.2.1](#))

A&R ([8.1.2.2](#))

Capital expenditures (construction, land, or building acquisition) ([8.1.2.3](#))

Carryover of unobligated balances ([8.1.2.4](#))

Change in scope ([8.1.2.5](#))

Change in status of the PD/PI or senior/key personnel named in the NoA ([8.1.2.6](#))

Change of recipient organization ([8.1.2.7](#))

Change of recipient organization status ([8.1.2.8](#))

Deviation from award terms and conditions ([8.1.2.9](#))

Foreign component added to a grant to a domestic or foreign organization ([8.1.2.10](#))

Make subawards based on fixed amounts ([8.1.2.11](#))

Need for additional NIH funding ([8.1.2.11](#) and [8.1.2.12](#))

Pre-award costs ([8.1.2.13](#))

Rebudgeting funds from trainee costs ([8.1.2.14](#))

Rebudgeting of funds between construction and non-construction work ([8.1.2.15](#))

Retention of research grant funds when CDA awarded ([8.1.2.16](#))

# Additional No Cost Extension

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Any additional project period extension beyond the initial extension of up to 12 months requires NIH prior approval.

# Additional No Cost Extension

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Generally The final budget period can be extended one time for a period of up to 12 months beyond the original expiration date shown in the Notice of Award.

- No additional funds are required.
- The project's originally approved scope will not change, and
- any one of the following applies:
  - Additional time is required to ensure adequate completion of the originally approved project
  - Continuity of NIH grant support is required while a competing continuation application is under review
  - The extension is necessary to permit an orderly phase-out of a project that will not receive continued support

# Alterations & Renovations (A & R)

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NIH prior approval required if rebudgeting more than 25 percent of the total approved budget for a budget period into A&R costs.

NIH prior approval required for lesser rebudgeting into A & R costs if the rebudgeting would result in a change in scope.

If rebudgeting results in an A&R project exceeding \$500,000, NIH always will consider the rebudgeting to be a change in scope. (See the Grants Policy Statement [Construction Grants](#) chapter in IIB for documentation requirements for A&R projects exceeding \$500,000).

# Capital Expenditures

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Expenditures to acquire capital assets or expenditures to make additions, improvements, modifications or renovations, or alterations to capital assets that materially increase their value or useful life.

Conveyed, transferred, assigned, mortgaged, leased, or in any other manner encumbered



# Carryover of Unobligated Balances

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A detailed budget by direct cost category with the F&A cost information (base and rate).

A scientific justification for the use of funds.

The reason for the unobligated balance.

# Change in Scope

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An activity whereby the objectives or specific aims identified in the approved grant application are significantly changed by the recipient after award.



# Possible Change in Scope Indicators

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Change in the specific aims approved at the time of award.

Substitution of one animal model for another.

Change from the approved involvement of human subjects that would result in an increased risk.

A clinical hold by FDA under a study involving an IND or an IDE.

Application of a new technology.

Transfer of the performance of substantive programmatic work to a third party.

Significant rebudgeting.

Purchase of a unit of equipment exceeding \$25,000.

# Change in Status of PD/PI

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## PD/PI or other personnel named in NOA

- withdraw from the project entirely
- Will be absent for 3 months or longer (contiguous)
- Reduce effort 25% or more from the NIH approved level.

There is a change from a multiple PD/PI model to a single PD/PI model.

There is a change from a single PD/PI model to a multiple PD/PI model.

There is a change in the number or makeup of the PD/PIs on a multiple PD/PI award.

# Change of recipient organization

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- NIH prior approval is required for the transfer of the legal and administrative responsibility for a grant-supported project or activity from one legal entity to another before the expiration date of the approved project period.



# Change of recipient organization

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## **The old institution must submit**

- Relinquishing Statement (PHS Form 3734) or signed letter in lieu of the form (only if transfer is taking place prior to award of competitive application).
- Final Invention Statement (PHS Form 568)
- Final Federal Financial Report (FFR) (SF 425)

# Change of recipient organization

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## The New Institution must submit

- Project Performance Site Primary Location information.
- A progress report for the current year, including a statement regarding the goals of the upcoming year.
- A statement concerning the current research plan and an indication of whether the original plan has changed.
- Revised Multiple PD/PI leadership plan (if applicable).
- A resources page including a description of the facilities at the new institution.
- Revised budget pages.
- Updated biographical sketches for new key personnel.
- Updated other support pages for all key personnel, if applicable.
- A checklist page, including F&A cost calculations for the transfer period and all future years.
- Human and Animal Assurances and IRB and IACUC approval dates.
- Human subjects education certification for key personnel, if applicable.
- A list of equipment being transferred.

# Change of recipient organization status

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## Merger

- Legal action resulting in the unification of two or more legal entities. When such an action involves the transfer of NIH grants, the procedures for recognizing a successor-in-interest will apply. When the action does not involve the transfer of NIH grants, the procedures for recognizing a name change normally will apply.

## Successor-in-Interest (SII)

- Process whereby the rights to and obligations under an NIH grant(s) are acquired incidental to the transfer of all of the assets of the recipient or the transfer of that part of the assets involved in the performance of the grant(s). A SII may result from legislative or other legal action, such as a merger or other corporate change.

## Name Change

- Action whereby the name of an organization is changed without otherwise affecting the rights and obligations of that organization as a recipient.



# Deviation from Award Terms and Conditions

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- NIH prior approval is required for any deviation from terms or conditions stated or reference in the NoA, including those in the NIHGPS.
  - This includes undertaking **any** activities disapproved or restricted as condition of award.

TERMS AND  
CONDITIONS



# Addition of a Foreign Component

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Foreign Components includes collaborators and consultants where no money changes hands and or materials are exchanged.

- All contact information of the foreign component including email and phone numbers.
- Detailed description of the collaborative relationship

# Need for Additional NIH Funding

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Administrative supplements are funds awarded above study section-recommended levels or outside the fiscal year funding policies.

Generally pay only for items resulting from unforeseen events placing the overall success of the project in question

# Need for Additional NIH Funding

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A rationale for the supplement.

A detailed budget with narrative justification.

A discussion of what other funding options have been explored (rebudgeting, carryover from prior years, departmental funds, cost-sharing, etc.).

An up-to-date unobligated balance and a statement about the impact on the project if the supplement is not approved.

# Pre-award costs

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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

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- The rebudgeting of funds on Training grants previously awarded for trainee costs to other categories of expense
  - This excludes trainee travel, which NIH does not consider to be a trainee cost, and training-related expenses.

# Rebudgeting of Funds between Construction and Non-construction work

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- Under awards that provide for both construction and non-construction work, NIH prior approval is required to transfer funds between the two types of work.



# Retention of Research grant funds when CDA (K Mechanisms) awarded

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Related salary funds normally removed from grant awards when a Career Development award is issued.

CDA awardees may retain royalties and fees from:

- activities such as scholarly writing
- service on an advisory group
- honoraria from other institutions for lectures or seminars
- fees resulting from clinical practice, professional consultation, or other comparable activities.



# Helpful Hints

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When in doubt contact the NIH Grants Specialist.

Use the eRA commons as much as possible when submitting documents.

Follow-up phone conversations with an email.

Make sure all requests are routed through the AOR/SO.

# Questions

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