

**ICAHN SCHOOL OF MEDICINE at MOUNT SINAI
PRIOR APPROVAL REQUIREMENTS and
REBUDGETING POLICY**

The National Institutes of Health (NIH) permits a certain degree of latitude in making post-award programmatic changes and budget revisions. The rebudgeting of certain cost items must have the prior approval of Mount Sinai and/or the appropriate PHS awarding unit. Use the chart that follows to identify those transactions that require Mount Sinai prior approval and/or those that must be presented to the PHS for authorization.

Activity or Expenditure Requiring Prior Approval	MSSM Prior Approval Required	PHS Prior Approval Required
Travel: Foreign Travel outside of the U.S. and Canada. Only key personnel working on the grant are eligible to request foreign travel	YES (accomplished through Sinai Central - be sure to list GCO number and justification)	NO (unless change in scope or addition of foreign component)
Alterations and Renovations (rebudgeting into A&R costs exceeding 25% of the total approved budget for a budget period)	YES	YES
Pre-award Costs Costs incurred prior to effective date of a new/competing award	YES (use Prior approval form on GCO website)	YES (If greater than 90 days prior to start date of new/competing awards)
No-Cost Extension Extension of the project period beyond the final date of approval. <i>See definition</i>	YES (One no-cost extension for up to 12 months can be authorized by the GCO 10 days prior to the date of grant expiration or earlier upon submission of NCE application to GCO in InfoEd)	YES (When the request for a no-cost extension is following the date of grant expiration or requesting a 2 nd or 3 rd no-cost extension)
Carryover of unobligated balances The carryover of expenses from one budget period to the next. <i>See definition</i>	NO	NO (Unless not under expanded authorities)
Subcontracting Transferring performance of substantive programmatic work to a third party	NO, unless change in scope or the third party is a foreign organization or component	NO, unless change in scope or the third party is a foreign organization or component
Change in grantee organization A Relinquishing Statement must be prepared by Fund Accounting to effect the transfer.	YES (Notification required prior to the effective date of transfer; expenditures beyond approved budget must be reconciled prior to transfer)	YES (in writing to the Program Officer and Grants Management Official)

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Change in key personnel named in notice of grant award <i>See definition</i>	YES	YES
Change in Scope <i>See definition</i>	YES	YES
Activities restricted as per terms of award	YES	YES
Transferring amounts from trainee costs The transfer of amounts previously awarded for trainee costs (stipends, tuition, and fees) to other expense categories.	YES	YES
Capital expenditures (construction, land, or building acquisition)	YES	YES
Retention of research grant funds when Career Development (K) grant awarded	YES	YES
Foreign component added	YES	YES
Change to multiple PI status Any change to number or make-up of PIs	YES	YES

DEFINITIONS

Change in Scope is a change in the methodology, approach or other aspects of the project objectives. PIs should be alert that they should consider whether or not there has been a change in scope whenever one of the following has occurred. The Grants Management Officer may be consulted with when in doubt.

- Change in the specific aims approved at the time of award. (GCO strongly advises consultation with NIH in this instance)
- Substitution of one animal model for another.
- Change from the approved use of live vertebrate animals.
- Change from the approved involvement of human subjects that would result in an increased risk. This includes:
 - An addition or change that would result in changing the overall human subjects or clinical trial designation of the award from No to Yes;
 - The new inclusion of subject populations that are covered by additional regulatory protections under 45 CFR 46;
 - Any change to the study protocol that would increase the risk level for subjects;
 - New information indicating a higher level of risk to participants than previously recognized for a study intervention, procedure, or pharmacological treatment.

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- Shift of the research emphasis from one disease area to another.
- A clinical hold by FDA under a study involving an IND or an IDE.
- Application of a new technology, e.g., changing assays from those approved to a different type of assay.
- Transfer of the performance of substantive programmatic work to a third party through a consortium agreement, by contract, or any other means. If the third party is a foreign component, NIH prior approval is always required.
- Change in other senior/key personnel not specifically named in the NoA (see [Change in Status, Including Absence, of PD/PI and Other Senior/Key Personnel Named in the NoA](#) below for requirements for NIH approval of alternate arrangements for or replacement of named senior/key personnel).
- [Significant rebudgeting](#), whether or not the particular expenditure(s) require prior approval. Significant rebudgeting occurs when expenditures in a single direct cost budget category deviate (increase or decrease) from the categorical commitment level established for the budget period by 25 percent or more of the total costs awarded. For example, if the award budget for total costs is \$200,000, any rebudgeting that would result in an increase or decrease of more than \$50,000 in a budget category is considered significant rebudgeting. The base used for determining significant rebudgeting excludes the effects of prior-year carryover balances but includes competing and non-competing supplements. Significant rebudgeting does not apply to modular grants.
- Incurrence of research patient care costs if costs in that category were not previously approved by NIH or if a grantee desires to rebudget additional funds beyond those approved into or rebudget funds out of the research patient care category.
- Purchase of a unit of equipment exceeding \$25,000.

Carryover of Unobligated Balances is the carryover of funds unspent as of the expiration of a budget period. The PI must report carryover greater than 25% as part of the Non-Competing application process for all NIH grants; NIH will determine necessity to complete the project. Grant mechanisms excluded from automatic carryover of unobligated balances are centers (P50, P60, P30, etc.); cooperative agreements (U's); National Research Service Awards (T's, and F's); and Phase I SBIR & STTR (R43, R41).

Please note that unobligated funds at the end of a project period or expiration of the grant can only be carried forward and expended under an authorized no-cost extension period.

Change in Key Personnel named in the Notice of Grant Award must be reported to NIH when the PI or other key personnel named in the Notice of Grant Award will withdraw from the project entirely, be absent from the project during any continuous period of 3 months or more, or reduce his/her time devoted to the project by 25% or more from the level that was approved at the time of award. NIH must approve any alternate arrangement, including any replacement PI or other key personnel proposed by the grantee.

The request for approval of alternate PI/key personnel should include:

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- ◆ A justification for the change
- ◆ Biographical sketch of the individual proposed
- ◆ Other sources of support
- ◆ Any budget changes resulting from the proposed change

Expanded Authorities waive the requirement for NIH approval of specific actions under *most* award mechanisms unless restricted or otherwise specified in the Notice of Grant Award (NGA). The mechanisms that currently do NOT have routine automatic carryover of unobligated balances are Centers (P50, P60, P30, etc.); Cooperative Agreements (U's); National Research Service Awards (T's and F's) and Phase I SBIR & STTR (R43, R41). Grantees must exercise proper stewardship over Federal funds and ensure that the costs charged are allowable, allocable, reasonable and consistently applied regardless of the source of funds. (e.g. Authority to issue a 12-month, no-cost extension beyond the original expiration date shown in the NGA).

A **No-Cost Extension** is an authorized extension of a project period.