Icahn School of Medicine at Mount Sinai

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NIH PRIOR APPROVAL REQUIREMENTS and REBUDGETING POLICY

Pre-award expenditures as well as certain post-award programmatic changes and budget revisions must have the prior approval of the Icahn School of Medicine at Mount Sinai (ISMMS) and/or the appropriate National Institute Health (NIH) Institute or Center (I/C).

The Table in Section I identifies those transactions that require ISMMS and/or NIH prior approval. Section II outlines the procedures Principal Investigators (PIs) must follow when submitting a prior approval request. Section III provides definitions of commonly used terms used in the prior approval process. Section IV is devoted to the topic of a change in scope.

Failure to obtain required prior approval from the appropriate awarding NIH I/C may result in the disallowance of costs, termination of the award, or other enforcement action within NIH's authority.

I. Table of Prior Approval Activities that Require ISMMS and/or NIH Approval

The information in the table below is primarily excerpted from section 8.1.2 Prior Approval Requirements of the National Institutes of Health Grants Policy Statement (NIHGPS). In the activity or expenditure descriptions where ISMMS approval is blank and NIH is YES, the GCO reviews and endorses a request letter prepared by the PI. On the rows where ISMMS approval is YES, there is another process that may be in addition to submitting a request letter to the NIH. Please see section II for additional instructions on prior approval procedures.

Activity or Expenditure	ISMMS Prior Approval	NIH Prior Approval
Alterations and Renovations (A&R) Under the following circumstances: - Rebudgeting into A&R costs exceeding 25% of the total approved budget for a budget period. - If rebudgeting would not meet threshold above, but would result in a change in scope. - Any single A&R project exceeding $500,000.		YES
Capital (i.e., construction, land, or building) Acquisition Also, any proposals to convey, transfer, assign, mortgage, lease or in any other manner encumber real property acquired with NIH funds.		YES
Carryover of Unobligated Balances		No, unless Notice of Award (NOA) indicates that the recipient does not have the authority to automatically carry over unobligated funds.

Change in Scope - see section IV		YES
Change of Recipient Organization (e.g., transfer applications)		YES
Change in Status of the PD/PI or Senior/Key Personnel Named in the NOA: Under the following circumstances: - Withdrawal from the project - Absence for any continuous period of 3 months or more - Reduction of level of effort devoted to project by 25 percent or more from what was approved in the initial competing year award.		YES
Deviations from Award Terms and Conditions Includes undertaking any activities disapproved or restricted as a condition of the award.		YES
Foreign Component Added to a Grant to a Domestic or Foreign Organization		YES
Multiple PI Plan or Status Change Includes changes to the plan as described in the competitive application or a change to the Multiple PI status including number of PIs or the make up.		YES
Need for Additional NIH funding (i.e., supplements, "Revision applications")		YES
No-Cost Extension (NCE): Initial (does not apply to K99 awards; late requests, see below)	YES	NO
No Cost Extension: Additional NCEs after initial request or late notification of initial NCE		YES
Pre-Award Costs	YES, if PI requests a fund # for award prior to receiving the NOA.	YES, if greater than 90 days prior to start date of new/ competing awards.
Rebudgeting Activity at High Risk of Indicating a Change in Scope Under the following circumstances: - Significant Rebudgeting - Research Patient Care Cost Incurrence - Purchase of a Unit of Equipment Exceeding 25,000	YES	May require NIH Approval .
Rebudgeting Funds from Trainee Costs (stipends, tuition, and fees) to Other Expense Categories		YES
Retention of Research Grant Funds (i.e., from a R series or other research grant) when a Career Development Award (i.e., K series) is Issued		YES
Subawards Based on Fixed Amounts	YES	YES
Travel: Foreign Travel (Outside of the U.S. and Canada.)	YES, via Sinai Central	NO, unless change in scope or addition of foreign component

II. Prior Approval Procedures

NIH prior approval procedures included in this section were adapted from the NIHGPS section 8.1 "Changes in Project and Budget."

NIH prior approval requests are made in writing to the NIH no later than 30 days prior to the proposed change.

A. Submission and Review Process

1. Address request letter or email to your NIH Grants Management Specialist (GMS) and Program Officer (PO). Contact information is also provided in each NOA and available by logging into eRA Commons and locating your award.
2. E-Mail the request to your designated Grants Specialist at the GCO for review and approval.
3. Your designated Authorized Organization Representative endorses the communication.
4. GCO sends communication to the NIH GMS and PO.
5. The NIH GMS reviews the request and provides a response to the AOR indicating the final disposition of the request with copies to the PI and NIH PO.
   Only responses provided by the GMS are considered valid. Recipients that proceed on the basis of actions by unauthorized officials do so at their own risk, and NIH is not bound by such responses.

B. PI and Multiple PI (MPI) Approval

Include the PI's approval when submitting to the GCO. PI/PD (i.e., Project Director) signature is not required as part of the submission to the NIH. However, the GCO must secure and retain such approval for each prior
approval request and make it available to NIH or other authorized Department of Health and Human Services (DHHS) or Federal officials upon request. This requirement applies to all PI/PDs in a Multiple PI grant.

C. Subawards

Prior approval responsibility is usually with the prime recipient. However, the prime recipient may not approve any action or cost that is inconsistent with the purpose or terms and conditions of the NIH grant. If an action by a subawardee will result in a change in the overall grant project or budget requiring NIH approval, the prime recipient must obtain approval from the NIH before giving its approval to the subawardee.

D. Additional Instructions by Activity or Expenditure

Activity or Expenditure	**Additional Instructions**
Carryover of Unobligated Balances if the NOA Indicates that the Recipient Does Not Have the Authority to Automatically Carryover Unobligated Funds	Refer to GCO Memo "NIH Prior Approval: Guidance for Grants that Do Not Allow for Automatic Carryover of Funds."

Rebudgeting Activity at High Risk of Indicating a Change in Scope	Complete the GCO Form "NIH Prior Approval Request Form for Rebudgeting Activity at High Risk of Indicating a Change of Scope." Under the following circumstances: - Significant Rebudgeting - Research Patient Care Cost Incurrence - Purchase of a Unit of Equipment Exceeding 25,000 *If you are submitting a prior approval letter to the NIH for a change in scope, completion of this form is not necessary.*
Change in Status of the PI/PD or Senior/Key Personnel Named in the NOA	The request for approval of alternate PI/key personnel should include: - A justification for the change - Biographical sketch of the individual proposed - Other sources of support - Any budget changes resulting from the proposed change
Change in Recipient Organization	When transferring an award from ISMMS, - Contact Sponsored Projects Accounting (SPA) to prepare a relinquishing statement to effect the transfer. Notify SPA prior to effective date. Expenditures beyond approved budget must be reconciled prior to transfer. - Submit InfoEd application to close out project. A PI may also submit as a new, unfunded project if he/she wishes to continue the research at ISMMS and retains a faculty appointment. - Submit change of grantee application through new institution under Funding Opportunity Announcement (PA-16-285). Do not submit a prior approval letter as described in this section above. - Complete PI Exit Checklist.
No Cost Extension	Refer to GCO Memo "No-Cost Extension Application Policies and Procedures." Complete optional GCO form "NIH Initial No Cost Extension Request and Progress Reports."
Pre-Award Costs	Complete "Prior Approval Request Form for Establishment of a Fund Number Prior to Award" if the NIH has not yet issued the NOA and Scenario #1 - It is likely to be less than or exactly 90 days prior to start date of a new/ competing award. Scenario #2 - It is a transfer application. Remember: Only complete the form if the PI is requesting a fund number for the award prior to the NIH issuing the NOA.
Subawards Based on Fixed Amounts	Refer to GCO Memo "Budgeting and Prior Approval Requirements for NIH Grants that Include Fixed Price Subawards."
Travel: Foreign Travel	Submit request on Sinai Central before the trip and read GCO's Memo

outside of the U.S. and Canada.	"Foreign Travel Request Reminder" for additional instructions.

III. Definitions

The following commonly used terms in the prior approval process are defined in GCO's Glossary of Common Terms:

Term
Key Personnel
No Cost Extension
Revision Application ("Need for Additional Funding")
Transfer Applications (Change of Recipient Application")

Below are definitions of other common terms, excerpted primarily from Section 1.2 "Definition of Terms" of the NIHGPS.

Term	Definition
Allowable Cost	A cost incurred by a recipient that is: (1) reasonable for the performance of the award; (2) allocable; (3) in conformance with any limitations or exclusions set forth in the Federal cost principles applicable to the organization incurring the cost or in the NOA as to the type or amount of cost; (4) consistent with regulations, policies, and procedures of the recipient that are applied uniformly to both federally supported and other activities of the organization; (5) accorded consistent treatment as a direct or indirect cost; (6) determined in accordance with generally accepted accounting principles; and (7) not included as a cost in any other federally supported award (unless specifically authorized by statute).
Alteration and Renovation	Work that changes the interior arrangements or other physical characteristics of an existing facility or of installed equipment so that it can be used more effectively for its currently designated purpose or adapted to an alternative use to meet a programmatic requirement. See also definitions for Major A&R and Minor A&R.
Carryover	Unobligated Federal funds remaining at the end of any budget period that, with the approval of the Grants Management Officer (GMO) or under an automatic authority, may be carried forward to another budget period to cover allowable costs of that budget period (whether as an offset or additional authorization). Obligated, but unliquidated, funds are not considered carryover.
Change in Scope	A change in the direction, aims, objectives, purposes, or type of research training, identified in the approved project.
Clinical Trial	A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. See complete definition in Section 1.2 "Definition of Terms" of the NIHGPS.

Expanded Authorities	This is a term the NIH no longer uses, but still commonly referred to, to describe certain activities in which the NIH does not require their prior approval. Activities once considered under "Expanded Authorities" are now incorporated into NIH's Standard Terms of Award as an automatic authority unless the NOA indicates otherwise.
Fixed amount award	This is a type of grant agreement under which the Federal awarding agency or pass-through entity provides a specific level of support without regard to actual costs incurred under the Federal award. Accountability is based primarily on performance and results
Foreign Component	The performance of any significant scientific element or segment of a project outside of the United States, either by the recipient or by a researcher employed by a foreign organization, whether or not grant funds are expended. Activities that would meet this definition include, but are not limited to, (1) the involvement of human subjects or animals, (2) extensive foreign travel by recipient project staff for the purpose of data collection, surveying, sampling, and similar activities, or (3) any activity of the recipient that may have an impact on U.S. foreign policy through involvement in the affairs or environment of a foreign country. Examples of other grant-related activities that may be significant are: collaborations with investigators at a foreign site anticipated to result in co-authorship; use of facilities or instrumentation at a foreign site; or receipt of financial support or resources from a foreign entity. Foreign travel for consultation is not considered a foreign component.
Notice of Award (NOA)	The official, legally binding document, signed (or the electronic equivalent of signature) by a Grants Management Officer that: (1) notifies the recipient of the award of a grant; (2) contains or references all the terms and conditions of the grant and Federal funding limits and obligations; and, (3) provides the documentary basis for recording the obligation of Federal funds in the NIH accounting system.
Pre-Award Cost	Any cost incurred prior to the beginning date of the project period or the initial budget period of a competitive segment (under a multi-year award), in anticipation of the award and at the applicant's own risk, for otherwise allowable costs.
Research Patient Care Costs	Costs of routine and ancillary services provided by hospitals to participants in research protocols.
Significant Rebudgeting	Significant rebudgeting is one indicator of a change in scope. A threshold that is reached when expenditures in a single direct cost budget category deviate (increase or decrease) from the categorical commitment level established for the budget period by more than 25 percent of the total costs awarded. 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. 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.

IV. Change in Scope

A change in scope is an activity that requires both ISMMS and NIH prior approval. The term is complex and warrants its own section in this document. The NIH defines a change in scope as "a change in the direction, aims, objectives, purposes, or type of research training, identified in the approved project."

The NIH includes, but does not limit, the following activities as potential indicators of a change in scope:

1. Specific Aims Change
   Change in the specific aims approved at the time of award.
   GCO strongly advises consultation with the NIH in this instance.
2. Animal Model Substitution
   Substitution of one animal model for another.
3. Vertebrate Animals Change
   Change from the approved use of live vertebrate animals.
4. Human Subjects Changes Resulting in Increased Risk
   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 non-human subjects research to human subjects research (exempt or non-exempt);
     - From exempt to non-exempt human subjects research; or
     - From "No Clinical Trial" to "Includes a Clinical Trial." See definition of clinical trial.
   - The new inclusion of subject populations that are covered by additional regulatory protections under 45 CFR 46 B, C, or D (pregnant women, human fetuses, and neonates; prisoners; or children;
   - Any change to the study protocol that would increase the risk level for subjects including physical, psychological, financial, legal or other risks. This could include the addition of a new study population that would be at a higher risk from existing research procedures, the addition of new study procedures that are greater than minimal irsk, any modification of existing study procedures that would increase overall risk, or the addition of a new clinical study or a new clinical trial intervention arm not originally proposed that is greater than minimal risk.

- New information indicating a higher level of risk to participants than previously recognized for a study intervention, procedure, or pharmacological treatment.

5. Research Emphasis Shift From One Disease Area to Another
6. FDA Clinical Hold of a Study Involving an IND or an IDE
7. New Technology Application
   Application of a new technology, e.g., changing assays from those approved to a different type of assay.
8. 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.
9. Change in Other Senior/Key Personnel Not Specifically Named in the NOA
10. Significant Rebudgeting, whether or not the particular expenditure(s) require prior approval. See definition.
11. Research Patient Care Costs Incurrence
    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.
12. Purchase of a Unit of Equipment Exceeding $25,000