NIH Prior Approvals

The Madness Behind A Prior Approval Request: The What’s, Why’s and How’s

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The "What’s"

What is a “prior approval”?

- Based on the terms & conditions of the award, administrative changes that may require written approval by the NIH Grants Management Officer (GMO), evidencing prior consent before a recipient undertakes certain activities or incurs specific costs.

- Only approvals from the GMO can be accepted as an official approval. A Program Officer (PO) cannot approve administrative changes.
What are “expanded authorities”?  

- Expanded authorities waive the requirement for certain prior approval requests automatically granted to Universities participating in the Federal Demonstration Partnership (FDP) who are in good audit standing.
- These Universities (including UNC) have greater autonomy with managing their awards and will not need to seek prior approval for certain changes to the award.

For your reading pleasure:  https://thefdp.org/default/
The “When’s”

- Second No-Cost Extension
- Change in Principal Investigator or Key Personnel
- Carryover
- Change of Scope
- Foreign Component added not included in original proposal
- Change in effort for Key Personnel named in the NOA
- Significant rebudgeting

This list represents the most common requests for prior approval requests. Visit the following link to learn about other types of prior approval requests:
The “How’s”
How do I start to write that perfect letter??

Header Information* for All Requests:

- Name & address of NIH Grants Management Specialist (GMS) and Project Officer (PO)
- Award Number
- Title of project
- Name of Principal Investigator

* Information can be found in the Notice of Award (NOA) on first and end pages.
There are now two ways to submit certain prior approval requests to the NIH.

- Paper submission to Grants Management Specialist and Program Officer
- Via eRA Commons aka “the Commons”

Note: Not all prior approval requests can be submitted via the Commons
And back to even more “How’s”
Second No-Cost Extension Requests

- Period of extension requested by months
- Estimated unobligated balance (direct and indirect) available to be used in the extension period
- Confirmation that the PI maintains measurable effort
- IRB date, if applicable
- Provide a detailed budget and budget justification on a PHS 398 form to match the unobligated balance (direct and indirect) including the PHS 398 checklist
- Progress report (not RPPR) to include aims completed to date and aims to be completed during extension period **
- Scientific justification and brief explanation of aims to be completed during extension

* Can be submitted through the Commons

** Required for Commons submission only
* Change in PI/PD

- Proposed change (adding, removing, deleting, change in Contact PI)
- Scientific justification of proposed change
- Provide NIH biosketch
- Provide Other Support information
- Address level of effort for PI/PD in Persons Months
- Multi-PI Leadership plan, if applicable
- Effective date

* Can be submitted through the Commons
Change in Key Personnel Named in the NOA

- Proposed change (replacing, removing, deleting)
- Scientific justification of proposed change
- Provide NIH biosketch
- Provide other support information
- Address level of effort for key personnel
Change in Effort for Key Personnel named in the NOA (≥ 25%)

• Strong scientific justification for change
• Address whether there will be a scope of work change and justify, if applicable
• Key personnel role
• Specify the duration of change, if applicable
• Indicate the effort reduction (from % to %)
• State any budget changes resulting from proposed change
*Carryover Requests*

- Amount of funds requested for carryover
- Explanation of unobligated balance
- Scientific justification of work to be completed
- Prepare a detailed budget, budget justification, and checklist on PHS 398 forms

- NOTE: the Federal Financial Report (FFR) must be submitted by the Sponsored Accounting Specialist before a request can be considered by the NIH

* Can be submitted through the Commons
Change of Scope

- Explain and justify the proposed changes
- Indicate any changes in funding and/or budget category reallocations
- If changes in budget, provide a PHS 398 budget for NIH review

**Changes in scope could result from change in specific aims, animal work, human subjects, transfer of scientific work to a third party, significant re-budgeting, etc.**
**Foreign Component not included in original proposal**

- Scientific justification for establishing the new subrecipient
- Indicate the change in scope, if applicable
- Provide letter of intent, detailed budget and justification from the proposed subrecipient
- Provide other support information for key personnel
- Provide NIH biosketch for key personnel

**Foreign consortiums, regardless of the dollar amount and scope, require prior approval from the NIH**
How do I submit the prior approval request?

1. Draft a prior approval letter (see slides 6-15 for details)
2. Collect supporting documentation (see slides 6-15 for details)
3. Complete the OSR Prior Approval Form
4. Submit prior approval package to your department’s Sponsored Projects Specialist (SPS) for review and submission to NIH

Prior approval requests should be submitted no later than 30 days before the proposed change. Late requests could result in disallowance of costs, termination of the award, or other action by the NIH.
Additional tips
There are so many!!

- BE TRANSPARENT
- Make sure the letter is on UNC letterhead before submitting to your SPS
- Submit OSR Prior Approval request form at time of request
- Reach out to your SPS when unsure if prior approval is required
- See General Information grid on p. 19 below
- Submit prior approval to OSR earlier than the due date of the request to the NIH for review and any necessary revisions

- Note: The FDP matrix is a tool that can be used for a quick glance but may not always be up-to-date. It’s recommended to always check agency guidelines for prior approval.
## Prior Approval Information

### When is prior approval necessary?

<table>
<thead>
<tr>
<th>Item</th>
<th>Internal Approval</th>
<th>NIH Approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alterations &amp; Renovations</td>
<td>When &lt;$25K</td>
<td>When &gt;$25K</td>
</tr>
<tr>
<td>Capital Equipment Purchase</td>
<td>If not outlined in proposal</td>
<td>When &gt;$25K</td>
</tr>
<tr>
<td>Carryover</td>
<td>N/A if automatically provided by Award</td>
<td>Required if not automatically provided by award</td>
</tr>
<tr>
<td>Change in Project Objective or Scope</td>
<td></td>
<td>Always required</td>
</tr>
<tr>
<td>Foreign Travel</td>
<td>If not outlined in proposal</td>
<td>If considered new Foreign Component</td>
</tr>
<tr>
<td>Institution Change</td>
<td></td>
<td>Always required</td>
</tr>
<tr>
<td>Key Personnel Change/Effort Reduction</td>
<td>If not named in Notice of Award</td>
<td>If named in Notice of Award</td>
</tr>
<tr>
<td>New Foreign Component</td>
<td></td>
<td>Always required</td>
</tr>
<tr>
<td>No-Cost Extension (NCE)</td>
<td>First 12-month request</td>
<td>Second 12-month request</td>
</tr>
<tr>
<td>Patient Care Costs</td>
<td></td>
<td>Always required</td>
</tr>
<tr>
<td>PI Status</td>
<td>Leave &lt; 3 months, effort reduction &lt;25%</td>
<td>Leave &gt; 3 months, effort reduction ≥25%</td>
</tr>
<tr>
<td>Change in PI</td>
<td></td>
<td>Always required</td>
</tr>
<tr>
<td>Pre-Award Spending</td>
<td>Period &lt;90 days</td>
<td>Period &gt;90 days</td>
</tr>
<tr>
<td>Trainee Expenses</td>
<td></td>
<td>Rebudgeting stipends, tuition and fees</td>
</tr>
<tr>
<td>New Subrecipient</td>
<td>Not transferring substantive portion of project, or scope change</td>
<td>Substantive programmatic work transferred</td>
</tr>
<tr>
<td>Significant Rebudgeting</td>
<td>Change &lt;25% of total costs, rebudgeting in a modular budget</td>
<td>Scope change, change &gt;25% of total costs</td>
</tr>
</tbody>
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