Submitting a Multi-Component National Institutes of Health (NIH) Proposal Toolkit

Prepared by the Office of Research, Sponsored Programs

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Understand the Task

What is a Multi-Component NIH application?

A multi-component application is a single submission with multiple, interrelated components - each with their own budgets - that share a common focus or objective.

Multi-component programs share the following features:

- At least two interrelated components related to a theme with each capable of standing on its own but complementing one another.
- Collaboration and interaction among components and investigators to achieve a common goal.
- Synergy among components
- Support as needed for shared resources—core resources or facilities—that provide services or resources to at least two research projects internal or external to the center (P30s).

Multi-component funding opportunities come in several forms as described in the following table.

<table>
<thead>
<tr>
<th>NIH Activity Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>P01</td>
<td>Multidisciplinary, long term program headed by a Principal Investigator (PI) or PIs who bring in other investigators to conduct research projects and share resources.</td>
</tr>
<tr>
<td>P30</td>
<td>A center core grant that supports shared resources and facilities for a multidisciplinary research team or group of investigators focusing on a common research topic.</td>
</tr>
<tr>
<td>P50</td>
<td>Specialized center award that supports a multidisciplinary group of investigators who share a common research topic.</td>
</tr>
<tr>
<td>U19</td>
<td>Award for multidisciplinary projects that require substantial involvement from NIH staff.</td>
</tr>
<tr>
<td>U54</td>
<td>Support for research and development from basic to clinical, including ancillary supportive activities that create a multidisciplinary focus on a disease or a biomedical problem. Centers may also serve as regional or national resources for special research purposes.</td>
</tr>
<tr>
<td>UM1</td>
<td>Support for large scale, complex clinical trials with multiple research strategies, e.g., clinical networks.</td>
</tr>
<tr>
<td>UM2</td>
<td>Support for large scale centers with complicated structures that cannot be appropriately categorized into an available multicomponent activity code, e.g., clinical networks, research programs, or consortiums.</td>
</tr>
</tbody>
</table>

Table 1: NIH Activity Codes
How do Multi-Component Applications Differ from Single Component Applications?

Although multi-project applications use the same forms used for single-project applications, there are some differences in the way multi-project applications are structured.

Every multi-component application includes:

1. A Single Overall Component: The Overall Component describes the entire application and provides an overview of how each of the other components fit together.
2. One or more Other Component Types: Other Component types (e.g., Admin Core, Project, Core) will vary by opportunity and will be specified in the Funding Opportunity Announcement (FOA).
3. Summaries: Information is automatically compiled from the data provided by the applicant in the individual components and included as part of the Overall Component in the agency assembled application to help reviewers and staff work with the application.

How do I Determine the Required Number and Type of Components for a Specific Application?

The funding opportunity announcement (FOA) will provide essential information on the required number and type of components for each specific application. NIH includes a chart and additional information in most FOAs that appear as follows:

<table>
<thead>
<tr>
<th>Component Types Available in ASSIST</th>
<th>Research Strategy/Program Plan Page Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>6 pages</td>
</tr>
<tr>
<td>Admin Core</td>
<td>12 pages</td>
</tr>
<tr>
<td>Core (Investigator Development Core and Community Engagement and Dissemination Core)</td>
<td>6 pages</td>
</tr>
<tr>
<td>Project (Research Projects)</td>
<td>12 pages</td>
</tr>
</tbody>
</table>

Additional page limits described in the SF424 Application Guide and the Table of Page Limits must be followed.

The application should consist of the following components:

- Overall: required
- Administrative Core: required
- Investigator Development Core: required
- Research Project: required, maximum of 3
- Community Engagement and Dissemination Core: required
NIH provides the following multi-component application structure example. This example includes the overarching "overall component" as well as administrative core, two facilities/service cores and three research projects.

- Note that in this example, the PI does not lead the administrative core. In most cases, however, the PI is the administrative core lead as he or she is responsible for the overall management and administration of the program.

Each of the components above, with the exception of the Overall component, has the same general requirements as a single component submission. Exceptions or special requirements will be noted in the FOA, so it is important to read the FOA carefully.
Getting Started

Organize the Multi-Component Application

Before setting up the application, it is beneficial to define the layout of the application:

- Read the FOA to determine the necessary application components and timeline
- Make a list of the:
  - Components to include
  - PD/PIs for entire application
  - Project lead for each component
  - Organization lead for each component
  - Project Title for each component
- Identify the project start and end dates
- Determine the order the components should appear in the final application image
- Create the application shell
- Consider creating a Proposal Checklist and/or Production Calendar
- Determine who is responsible for each proposal preparation task
- Make use of campus resources (https://research.ucdavis.edu/resources/grantwriting/)

Start the NIH ASSIST Application

NIH’s ASSIST system should be used to submit multi-component applications.

Set-up the Application in ASSIST

2. Log-in using your eRA Commons ID. Contact spoerahelp@ucdavis.edu to set up your account if you do not have an eRA Commons ID.
Initiate the Proposal

1. Once you have logged-in to initiate the application, type the FOA number into the “INITIATE APPLICATION” field shown below and select “Go”.

![Welcome to the Application Submission System & Interface for Submission Tracking (ASSIST)](image)

2. Complete the application information.
   a. Title: This can be changed later, so a temporary title is sufficient at this point.
   b. PI name. It is recommended to populate PI name from his or her ERA Commons ID. However, it can be typed in manually.

![Application for FOA #: PA-E0-P01](image)
3. Once the title and PI name are entered, select “initiate application.”

Who will have access to work on the proposal file?
ASSIST automatically provides application access to some individuals based on their Commons roles or role on the application.

- All Sponsored Programs (SPO) analysts at the applicant institution have edit access for the entire application.
- All PD/PIs listed on the Overall application have edit access for the entire application.
- The Component Leads (e.g., Project Lead) have edit access for their components.
- The person that initiates the application has edit access for the entire application*.

*SPO recommends the department administrator initiate applications in ASSIST on behalf of their PI’s. This will allow the administrator to view and edit the application. In cases where the PI initiates the application, please contact proposals@ucdavis.edu, so SPO can grant admin access to it. Please provide the ASSIST application ID and the admins eRA Commons ID, copying the PI.
Add the Components

Once the application is initiated, the application information home screen appears as shown below. The overall component will be pre-added.

1. Add the additional components to form the application shell. Select “Add New Component” from the Actions menu on the left.
2. Select the type of component to add (e.g., Administrative Core, Project) and complete the “Add Component” screen.

3. Continue to add until all planned components are associated with the proposal file.
Enter and Save Information for Each Component

1. Select the component below the associated header.
2. Once within a component, select each tab to access associated screens. Note that some Actions are only available on the summary tab. For example, update component status is only available if you return to the summary.

3. If you need to add optional forms, such as the assignment request form or subaward budget form, you can do so by choosing “add optional form” action on each component.

4. To add data to form fields and upload documents, select “edit” on the associated tab as shown below. Note that choosing edit locks out other users from the page. Additional users can make changes to other pages, but two users cannot edit a single page at the same time.
5. Select “save and keep lock” to stay on the page but to continue to make changes. Select “save and release lock” to save changes and leave the page.

Which forms and information are required for each component?
In general, the following forms are required for each component.

**Required forms Overall:**
- SF424 (R&R)
- Project/Performance Sites
- R&R Other Project Info
- R&R Senior/Key Persons
- PHS 398 Cover Page Supplement
- PHS 398 Research Plan
- PHS Human Subjects and Clinical Trials Information

**Required forms other components:**
- SF424 (R&R)
- Project/Performance Sites
- R&R Other Project Info
- R&R Senior/Key Persons
- PHS 398 Cover Page Supplement
- PHS 398 Research Plan
- PHS Human Subjects and Clinical Trials Information
- R&R Budget
- Each FOA also lists specific requirements by component or type of component. Read each carefully to determine the specific requirements for the program. Example FOA instructions for a research project are on the following page.
Research Project

When preparing your application in ASSIST, use Component Type ‘Project.’

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions, as noted.

SF424 (R&R) Cover (Research Project)

Complete only the following fields:

- Applicant Information
- Type of Applicant (optional)
- Descriptive Title of Applicant’s Project
- Proposed Project Start/Ending Dates

PHS 398 Cover Page Supplement (Research Project)

- Enter Human Embryonic Stem Cells in each relevant component.

Research & Related Other Project Information (Research Project)

- Human Subjects: Answer only the ‘Are Human Subjects Involved?’ and ‘Is the Project Exempt from Federal regulations?’ questions.
- Vertebrate Animals: Answer only the ‘Are Vertebrate Animals Used?’ question.
- Project Narrative: Do not complete. Note: ASSIST screens will show an asterisk for this attachment indicating it is required. However, eRA systems only enforce this requirement in the Overall component and applications will not receive an error if omitted in other components.

Project /Performance Site Location(s) (Research Project)

- List all performance sites that apply to the specific component.
- Note: The Project Performance Site form allows up to 300 sites, prior to using additional attachment for additional entries.

Research & Related Senior/Key Person Profile (Research Project)

- In the Project Director/Principal Investigator section of the form, use Project Role of ‘Other’ with Category of ‘Project Lead’ and provide a valid eRA Commons ID in the Credential field.
Guidance and Tips

Tips for Entering Information

R&R Senior/Key Persons
• Only the PI(s) will be listed in the Overall section under senior/key personnel.
• Personnel can be listed as senior in more than one component. A PI can be listed as PI and also as a component lead.
• Each component will have one lead.
  o Leads of components are not considered PIs.
  o Component leads should be given the role of Project Lead or Core Lead.
  o You can also designate a co-lead for a component.
  o Co-leads should be given the role of Core Co-Lead or Project Co-Lead.
  o A multi-PI plan is not needed for individual components, even when co-leads are listed. The multi-PI plan is only required for the overall, and only if more than one PI is designated to lead the entire center.
  o Check FOA to ensure multi-PI applications are allowable before adding more than one PI to the overall application.
• Biosketches are only uploaded once for each person in the application.
  o If professor B is listed as a project lead and also a core investigator, only upload the biosketch in one of the two components.
  o The application will compile all biosketches at the beginning of the application upon submission.
  o PI biosketches should be uploaded in the overall section. Otherwise, they will not appear first in the compiled biosketch section.
• ERA commons IDs are needed for each PI and Lead of each component. Check IDs carefully to for accuracy to avoid errors upon submission.
• Many multi-component projects have advisory committees- external or internal. These individuals can be included in the senior personnel section as “Other Significant Contributors”, which allows inclusion of their biosketches. This role means they have no defined effort, so no “Other support” will be requested for them at JIT, and commitment of effort won’t be required. Any other role requires effort. These individuals could be optionally included in the personnel section of the budget justification—preferably under a header “other significant contributors” but they should not be entered on the budget and no effort should be listed for them in the justification.

R&R Performance Sites
• In the overall only enter the primary place of performance (UCD).
• Remember to include Zip+4.
• Remember to add any subaward performance sites to any component they are participating in.

R&R Other Project Information
• The Other Project Information form on the overall will reflect a summary of the individual components. For example, if Human Subjects is yes on any of the components, it should be “yes” on the overall.
• Some form fields on the individual components will not be active. For example, the UC Davis human subjects assurance number can only be entered on the overall.
R&R Budget

• Budget Request- you will need to type in the overall budget request on the cover page. ASSIST does not auto-populate this field. To ensure you have the exact total, preview application. See preview instructions below.

• The overall component does not have a budget. The system will create an overall budget summary upon preview/submission.

• Escalations are usually cut at time of award on large center grants. If there is a budget limit, we recommend not escalating salary or benefits to avoid automatic cuts.

• Fill in each component budget in as you would for a detailed R01 budget.

Subawards

• The organization responsible for the majority of work on a component should lead it.
  o If another university is leading an entire component, that University (subawardee) can be listed as the lead on the Cover Page.
  o If UCD has some costs associated with the component led by the subawardee, UCD’s costs should be entered on the subaward budget. NIH will know UCD is not an actual subaward by the associated DUNS number.
  o If a subaward is leading a component, and we have not charged indirect on the first $25,000 on another component, the “additional indirect costs” optional form needs to be added to the overall. (See how to add optional forms above.)
  o IMPORTANT: If a subawardee is leading a component, and another subawardee has costs, enter UCD as lead if there is a direct cost budget limit even if UCD does not have a budget. Otherwise, all the indirect costs of the second subaward will show part of UCD’s direct costs for the NIH limit (instead of being excluded.)
    ▪ PI can be added at .01 months effort; this signals to NIH that no actual effort is provided.
    ▪ The budget will be $0
    ▪ The justification can indicate something similar to- “For administrative purposes, UCD is entered as the lead institution. The PIs effort on this project is through the administrative core; .01 person months are entered to allow entry. See subaward budgets for cost details.
    ▪ Note that this assumes all subawards will be administered by UC Davis. Subawards on subawards are strongly discouraged and sometimes not allowed, and the indirect costs of these third-party subawards count toward the direct cost limit.
  o If a component or subaward is not funded in all years, create a $0-dollar year with lead at .01 calendar (cal) months effort.
  o If a subawardee is on more than one component, only charge indirect costs on the first $25,000 of one - not both.
    ▪ Select “UC” for the second component when using the multi-component SPO template and include notes that indirect costs are calculated on project x.
What should I know about using ASSIST?

Returning to your application after log-out:

1. Select “Search Applications” and enter the PI name or application number to return to previously initiated application.
Changing the order of components within a component type:
1. Select “change component order”.
2. Re-order the components.

**NOTE:** Although components within a particular component type can be re-ordered, you cannot re-arrange the order of component types.
Validating the Proposal for Errors and Warnings

Once all required documents are uploaded, the application should be validated for errors and warnings. First validate each component, then the overall application.

1. Select a component and select “validate component” from the action bar as shown below.

2. Select “Return to Application” and then “Validate Application” from the action bar as shown below.
Previewing the Application

Once the application is validated (or even before while you are working toward finalization), preview the application as an ERA commons PDF.

1. Select “PREVIEW APPLICATION”.
2. Select “Generate Preview”. Note that you will need to re-generate the preview each time changes are made. In addition, you will need to refresh the preview status while waiting for it to preview. The preview is ready once you see a “view” button.

Note that the preview will not contain the cover letter, appendices or assignment form.
Finalize the Proposal for Submission
Once the application is validated, the preview is reviewed, and you are ready for submission, update the status of each component and the overall application. Each component and overall application begins in “Work in Progress” status. Change each component to “final” in order to proceed to submission.

1. Select “UPDATE COMPONENT STATUS”.
2. Select “final”.
3. Ensure that all components are in “final” status.
4. Return to application to finalize the overall application once you have checked that all components are final.

5. Select “UPDATE SUBMISSION STATUS” from the action bar. 
6. Select “All Components Final.” 
7. Select “Ready for Submission”. The proposal can then be submitted to NIH by SPO.
Resources

ASSIST: public.era.nih.gov/assist
Online help: era.nih.gov/erahelp/ASSIST/

How to Apply – Application Guide:

Annotated form set:


Office of Research Grant Writing Resources and Services:
https://research.ucdavis.edu/resources/grantwriting/