

Processing Pre-Award Submissions to Granting Agencies in Support of Pending Applications and New Budget Periods

Introduction

Applications for extramural funding often require communications with granting agencies after the initial proposal submission in order to a) update the existing application prior to review or b) provide administrative and compliance documentation that facilitates the issuance or extension of an award. When the transmitted information requires formal approval of, or direct submission by, institutional officials, this type of submission of post-application/pre-award information will be termed “OPAS” (Other Pre-Award Submissions). OPAS will include the transmission of information in support of both pending competing and non-competing applications. Other types of submissions requiring institutional approval may also use the OPAS procedures described here despite being only indirectly related to pending grant review or award. Examples include requests for no-cost extensions and withdrawal of proposals.

The procedures described herein will pertain primarily to two of the most common examples of OPAS: the National Institutes of Health (NIH) “Supplemental Materials” and “Just-in-Time” processes. However, the following basic principles apply to all OPAS:

- 1) Preparation and transmission of OPAS must conform to the guidelines and procedures adopted by the grantor agency.
- 2) Central administration approval required for OPAS must be obtained using Cayuse424.
- 3) Certifications made in the signed PI-PD Certification that is submitted with competing and non-competing applications apply to all subsequent OPAS.

OPAS Procedures

Overview

- PI/Administrator creates “Other Proposal” in Cayuse
 - Two step routing chain: 1) Principal Investigator (PI), 2) OPAS Reviewer
 - OPAS details described in Proposal Summary
 - Files to be transmitted to agency attached in Documents
- OPAS reviewer determines need for additional review by other departments
- Office of Grant Support (OGS) transmits documents to agency
- PI confirms receipt by agency

Obtaining OPAS Internal Approvals in Cayuse

Obtaining internal approvals for OPAS requires the creation of a proposal package in the Cayuse system: <https://einstein.cayuse424.com>. All questions related to Cayuse, including requests for training, should be directed to the Einstein Office of Grant Support ogs@einsteinmed.edu; 718 430-3642.

After logging into Cayuse, enter Proposals ① and click the Create Proposal ② button (Figure 1).

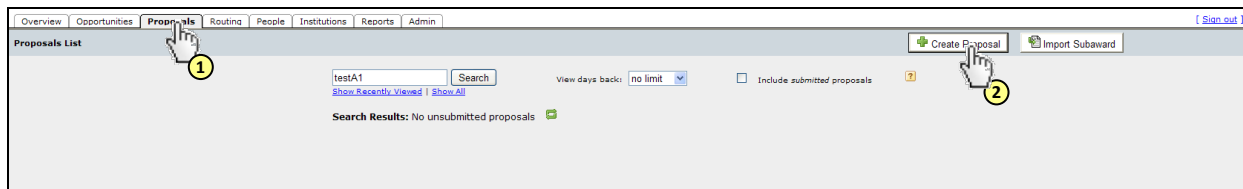


Figure 1

Select the Other Proposal bullet ① (Figure 2), then select the Create button ②. A screen is displayed where the new proposal will be formatted.

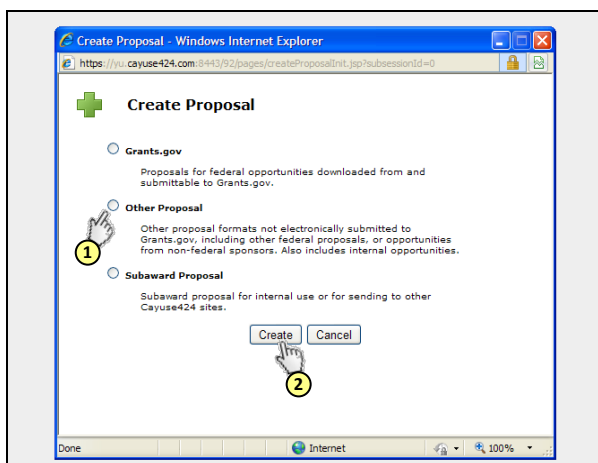


Figure 2

Populate the Create New Proposal pop-up screen (Figure 4) with the information/format from Figure 3. [NOTE: format for proposal name is *OPAS-PI Last Name Agency/Mechanism Submission Date*] Then click the Create Proposal button on Figure 4.

Proposal Name: OPAS-PI Last Name Agency/Mechanism Submission Date
(e.g., OPAS-SmithR01Apr2011; OPAS-JonesACSJuly2012) (examples)

Select the Principal Investigator, Organization, and Default IDC (indirect cost) Rate

of Budget Periods: 1

Validation Type: "Other Minimal"

Figure 3

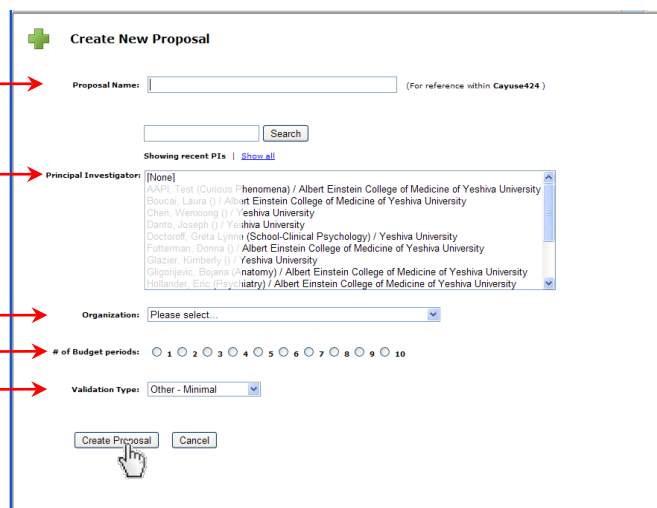


Figure 4

The proposal will appear showing the Proposal Summary page.

Guidelines for completion of Cayuse proposals for OPAS include:

- 1) Do not complete RR Performance Sites or RR Key Persons.
- 2) Complete RR Fed Non-Fed Budget only if a full revised budget is being submitted to the agency.
- 3) In the Proposal Summary, complete Sponsor Deadline at top of page (see Figure 5)

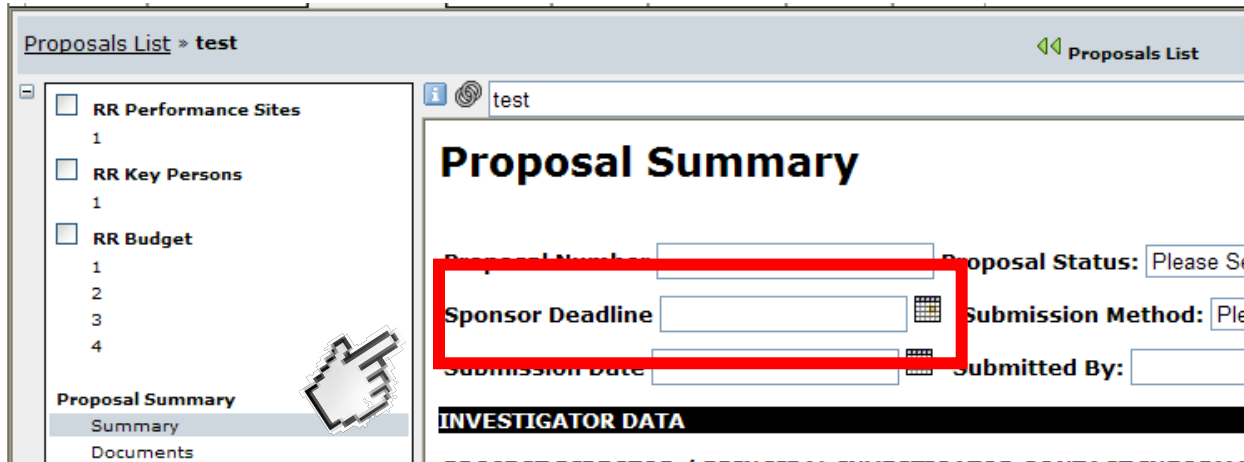


Figure 5

- 4) In the Proposal Summary, under Sponsor Data, provide the following information using the any of the fields provided (see example in Figure 6):
 - Funding agency (e.g. NIH, DOD, ACS)
 - OPAS Type (e.g. JIT, Suppl Mat, Non-Competing Update, NCE)
 - Original Cayuse proposal name for the competing or non-competing application being supported/updated by the OPAS, if applicable
 - Agency grant number (e.g. R01MH123456 for NIH), if applicable
 - Submission method (e.g. eRA Commons, email, fax, mail)

SPONSOR DATA	
Agency:	<input type="text" value="NIH"/>
Proposal Type:	<input type="text" value="Supplemental Materials"/>
Sponsor Mechanism:	<input type="text" value="Other"/>
Sponsor Type:	<input type="text" value="SmithR01Aug2010"/>
Sponsor:	<input type="text" value="[Select Sponsor]"/>
Code:	<input type="text"/>
Name:	<input type="text" value="1R01DK229371-01"/>
SubDivision 1:	<input type="text" value="Email to SRO"/>
SubDivision 2:	<input type="text"/>

Figure 6

- 5) For submissions by email or surface mail only, go to the bottom of the Proposal Summary page to the Comments and Explanations section and provide the COMPLETE address of the person who will receive the OPAS transmission. For example, see Figure 7:

COMMENTS AND EXPLANATIONS

PLEASE INDICATE ANY SPECIAL INSTRUCTIONS BELOW:

Arlo Guthrie, Ph.D. guthriea@csr.nih.gov
 Scientific Review Administrator, NRBQ
 Center for Scientific Review, NIH
 6701 RockOut Drive, Rm 4182
 Bethesda, MD

Figure 7

- 6) The Documents section must have the following files attached:
- a) Copy of agency communication requesting the OPAS submission, if available.
 - b) Documents to be transmitted to Agency; use pdf format.
 - c) Any internal forms required for an anticipated additional review by Einstein departments (e.g IRB, Animals, Finance)
 - d) If applicable, for non-NIH OPAS, attach the agency’s relevant form.

NOTE: Do not include other forms or signed letters for standard OPAS approvals. In rare cases, additional forms may be requested. The new PI-PD Certification required for submission of competing and non-competing applications covers the contents of the associated OPAS.

- 7) Default routing chains must show only PI and OPAS, [Routing Contact]; see Figure 8.

Routing & Approval ?

Routing Chain + X ↓... **Edit Chain?**

Begin

Dr. Smith, Principal Investigator - Albert Einstein College of Medicine of Yeshiva University

*OPAS, [Routing Contact] - Albert Einstein College of Medicine of Yeshiva University

End

⚡ There is no AOR on this routing chain. The proposal will not be submittable until an AOR has been added to the chain and has approved the proposal.

Figure 8

The absence of an Authorized Organization Representative in the Cayuse Routing Chain for OPAS submissions prevents the system from sending “Authorized for Submission” emails to Administrators and other users. Administrators who wish to be automatically notified of the completion of routing (i.e., approval by the OPAS reviewer) may insert themselves into the Routing Chain as the final step.

NOTE: When preparing OPAS proposals in Cayuse, you may ignore all errors and warnings that appear in the error validation indicator at the bottom of the page. These proposals are not being submitted via Cayuse and, therefore, do not need to conform to any agency rules.

After the OPAS submission is approved for submission, the OGS, acting as the institutional NIH Signing Official (SO), will submit the documents to the funding agency. The method of transmission will vary according to the type of OPAS and the agency’s instructions.

Confirming Receipt by Agency of OPAS Materials

PIs must be certain that any submission to a funding agency has been successfully transmitted, received, and accepted. While this verification is an integral and automatic part of the submission process for NIH electronic competing and non-competing applications via eRA Commons, it is often incomplete or non-existent for other types of submissions, including OPAS.

Each type of OPAS submission will require a different approach for verification of receipt (see next section on common NIH OPAS). PIs and departmental administrators are encouraged to learn and understand the types of notification and web-based confirmation of OPAS receipt and processing. In all cases of doubt, emails and phone calls to program officers and grants management personnel should be used to ensure that an OPAS submission is finalized.

The following section contains detailed descriptions of some of the most common OPAS that are required for NIH funding. In all cases, final submission of the OPAS to NIH will be performed by the OGS.

NIH Pre-Award Mechanisms

Just-in-Time (JIT)

Most documentation required to obtain a grant must be submitted as part of the original grant application prior to the proposal deadline. However, some required documents, such as Other Support and evidence of approvals by IRBs or IACUCs, may only be requested when it appears likely that a grant will actually be awarded. Just-in-Time (JIT) refers to NIH’s request for these documents “just-in-time for” a notice of grant award to be issued. Therefore, JIT is a specific set of OPAS requested by and submitted to NIH after the completion of the peer review, and prior to funding.

Because these JIT materials constitute an addition to the previous institutionally-approved grant application, all JIT materials must be submitted by an institutional SO. Thus, OPAS review and approval in Cayuse is required.

All grant applications with a priority score between 10 and 60 (no percentile) will have access to JIT links in eRA Commons. This is also true for applications that have a percentile score of 30 or less. However, the JIT OPAS submission process should only be initiated when the PI receives a specific request for JIT materials from the agency. These requests can be eRA-system generated e-mails or contacts made directly from the specific awarding agency via e-mail and/or phone.

Complete JIT procedures may be found on pages 116-121 of the eRA Commons User Guide:
http://era.nih.gov/docs/COM_UGV2630.pdf

Some requests from NIH for JIT information ask that documents be emailed by an institutional SO. However, the preferred method of submitting JIT documents is via uploads in the JIT module of the eRA Commons. NIH program officers and grants management specialists are prepared to accept JIT information in eRA Commons. If you have any questions concerning mode of transmission for JIT OPAS, contact the OGS.

JIT materials for OPAS submission should be attached in the documents section of Cayuse as described above.

NOTE: While administrators and PIs have previously uploaded these materials into eRA Commons, the new procedure transfers this duty to the NIH institutional SO.

Confirmation of submission of JIT documents is sent via email to the PI. However, to confirm the actual upload of the documents to the proposal, the PI will need to login to eRA Commons and find the up-to-date JIT file under "Other Relevant Documents" on the status screen for the proposal.

Supplemental Materials

NIH will accept certain types of materials to supplement and support a proposal after the original application deadline. These post-submission/pre-review materials must be received by the NIH Scientific Review Officer (SRO) one month (30 calendar days) prior to the peer review meeting. In most cases, the SRO will send an email invitation for applicants to submit these materials.

Because these materials constitute an addition to the previous institutionally-approved grant application, all post-submission materials must be submitted by an institutional SO. Thus, OPAS review and approval in Cayuse is required.

The type and length of acceptable post-submission materials varies somewhat by grant mechanism.

However, for most research grant mechanisms, **acceptable materials** include:

- News of an article accepted for publication (a copy of the article should not be sent)
- Revised budget page(s)

- Biographical sketches (e.g., change in key personnel)
- Letters of support or collaboration resulting from a change in senior/key personnel

Unacceptable materials include:

- Updated Specific Aims or Research Strategy pages
- Late-breaking research findings
- New letters of support or collaboration that do not result from a change in senior/key personnel due to the hiring, replacement, or loss of an investigator.

NOTE: SROs generally will not accept news of an article accepted for publication if there is any extra language included, e.g. “This publication presents our data on breast cancer biomarkers that is relevant to Aim Two” would NOT be acceptable. Limit comments to the facts of the acceptance by the journal.

Supplemental materials for OPAS submission should be attached in the documents section of Cayuse as described above.

Complete guidelines for submission of post-submission supplementary materials may be found at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-115.html> .

NOTE: The guidelines referenced above contain the sentence “Concurrence from the Authorized Organization Representative (AOR) of the applicant organization is required.” NIH often uses “AOR” and “SO” interchangeably despite the fact that AOR is a Grants.gov designation. Please ignore this mistake and seek Einstein SO (OGS) approval via OPAS procedures when institutional concurrence is requested.

Currently, submissions of supplemental materials for NIH proposals are made via email (with documents attached) directly from the institutional SO to the SRO. Confirmation of receipt usually, but not always, arrives as an email from the SRO. However, to confirm the actual upload of the documents to the proposal, the PI will need to login to eRA Commons and find the documents under “Additions for Review” on the status screen for the proposal.

No-Cost Extensions

The extension of the final budget period of a project period without additional NIH funds is termed a “No-Cost Extension” (NCE). Grantee institutions have the authority to exercise the NCE option ONCE for each grant without the need for prior approval from the agency. All subsequent NCEs require that a formal request be made to the agency. The OPAS approval procedures will be used for **all** NCE requests.

Grants may be extended for a period of up to 12 months beyond the original expiration date shown in the notice of grant award IF

- Notice of award does not prohibit the extension,
- No additional funds are required to be obligated by the NIH awarding institute, and the project's originally approved scope will not change.
- The grant is not already in NCE status (2nd - nth NCEs require prior approval by NIH); and either
 - Additional work remains to be completed and resources are available to support the project,
 - or
 - Additional time is needed for an orderly close-out of the grant, or
 - Additional time is needed to provide continuity of project activities while a competing renewal is under review.

[It is important to note that the existence of unspent funds at the expiration of a grant is not, in itself, a sufficient justification for a NCE.]

Principal investigators must understand that all terms and conditions of the award apply during the extension period and that required certifications and assurances (e.g. human subjects; animal welfare) must be active.

NCEs may be processed no earlier than 90 days prior to the end date of the project and no later than the project's end date.

Follow the general OPAS instructions. In the Proposal Summary section of Cayuse:

- 1) Please specify the number of months extension that is being requested.
- 2) Requests for NCEs must state the reason for the request. This brief justification will NOT be sent to the NIH and scientific rationale is NOT necessary.
- 3) State whether sufficient funds are available for the additional work being planned.
- 4) The PI's level of effort on the grant during the NCE period and % reduction of effort for any key personnel from the last awarded budget period. **NOTE that all levels of effort dedicated to the grant during the NCE period must be charged to the grant.**

If a reduction of effort greater than 25% is planned **FOR** any of the key personnel for the NCE period, a Change of Effort request (letter to NIH) must be included with the Cayuse NCE OPAS submission for review and approval by Einstein Research Finance. This letter should be prepared on letterhead with signature lines for the PI and Charles Hathaway, Director, Office of Grant Support [NIH Signing Official for the Albert Einstein College of Medicine of Yeshiva University]

A reduction of effort less than or equal to 25% does not require a Change of Effort request to NIH. However, any effort reduction resulting in a salary reduction greater than \$5,000 must be approved by Einstein Research Finance.

Requests for NCE on non-NIH grants should be submitted through the Cayuse system in accordance with sponsor guidelines.

Confirmation of submission of NCE is sent via email to the PI. However, to confirm the actual change made to the proposal, the PI will need to login to eRA Commons and find the new “Budget End Date” on the status screen for the proposal.

Withdrawal of Proposals

There are occasions when proposals must be formally withdrawn from the peer review process at an agency. The reasons for the need to withdraw a proposal will vary but include technical problems (e.g. duplicate proposals submitted) and strategic considerations (e.g. postponement to increase competitiveness). In almost all cases, the PI makes the decision to withdraw his/her proposal.

NOTE: Formal withdrawal of a proposal does not include the “electronic rejection” of applications during the 2 day validation process at eRA Commons.

No extra documents are required for an OPAS request to withdraw a proposal. Follow the general OPAS instructions. In the Proposal Summary section of Cayuse please provide a brief justification for the request in the Comments and Explanations section (Figure 7).

Currently, withdrawals of NIH proposals are processed by hard copy transmission of the request from the institutional SO. Confirmation of the proposal withdrawal requires that the PI login to eRA Commons and find “Withdrawn” as the application status on the general “Status Result” screen for the PI’s proposals.