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Background: As part of the **HMS NEXT** initiative, a group of Central & Department research administrators were tasked with minimizing duplication of effort while maintaining compliance. To this end, the group created a pilot program whereby departments were responsible for review and submission of select proposals and post submission administrative tasks. The pilot proved very successful and has been expanded to other departments. Member departments include:

- Biological Chemistry and Molecular Pharmacology (BCMP),
- Cell Biology,
- Genetics,
- Microbiology and Immunobiology,
- Neurobiology, and
- Systems Biology

This document outlines the specific types of proposals and post-submission actions that are being ceded to these departments, without routing through SPA for additional review and approval.

**LIST OF ACTIONS CEDED TO DEPARTMENTS**

**PRE-AWARD**

**New and Competing continuation proposals**

- NIH R01, R21, R03 grant applications totaling less than $5 million in cumulative total costs, with no outgoing subawards, part-of accounts (POAs), or international components.

- Subaward research grant proposals to other universities, hospitals, and other non-profit research institutes under NIH R01, R21 or R03 awards. This rule excludes proposals submitted to industry sponsors applying to these grant mechanisms.

- Graduate student and postdoctoral fellowship applications to the sponsors listed below. We have made the determination that these sponsors can be included on the EP list based on the information available at this time. This list will continue to be a subject of frequent conversations between EPDs and SPA, which will result in additions of sponsors to the list or deletions due to sponsor’s changes in terms and conditions or operating principles. Should these sponsors change their application materials in between reviews such that we are required to accept the sponsor’s terms at the time of the proposal, the department should not proceed with the submission under EP and alert SPA to this change. SPA reserves the right to negotiate terms from these sponsors should an award be funded.
  - NIH F31 and F32 NRSA applications
  - American Heart Association
  - Cancer Research Institute
  - Damon Runyon Cancer Research Foundation
  - Helen Hay Whitney Foundation
  - Human Frontiers in Science Program

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1 SBIR/STTR proposals must be reviewed by SPA.
• EMBO²
• Life Sciences Research Foundation
• Jane Coffin Childs
• L’Oréal USA Women in Science

**POST-AWARD**

- **All NIH supplement requests**
- **ALL progress reports, including NIH RPPRs.**
- Submission of **NIH JIT** information (Other Support, IRB/IACUC approvals, other info as requested) on the eRA Commons
- **xTrain** forms for NRSA fellowships and training grants on eRA Commons: Appointment, Reappointment, Termination actions (make sure trainee routes to mentor/program director for signature before routing to BO for submission)
- **NIH initial 12-month No Cost Extensions** in eRA Commons (Department should forward the eRA Commons confirmation email to SPA; no new COI form is needed)
- **NIH final invention reports** (Department should confirm accuracy with OTD via patents@harvard.edu before submission)
- Closeout of requests in GMAS upon notification from PI/sponsor that the proposal wasn’t funded

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² Any “Acceptance Form” requires SPA signature. This form is required to be submitted with the application materials for **short term fellowships**.
### Proposal Review & Approval Checklist

<table>
<thead>
<tr>
<th>Type of Project</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is the type or purpose of project clearly defined (e.g., research, fellowship, training grant, other)?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Type of Application</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is this proposal a new (initial) application, a competing renewal, a non-competing continuation, an administrative supplement, or a competitive revision (additional time and money for an existing award)?</td>
</tr>
<tr>
<td>Is the sponsor federal or nonfederal? (Industry proposals are submitted through OTD) If the organization is not in GMAS as a sponsor, the proposal must be reviewed by SPA</td>
</tr>
<tr>
<td>Is the award mechanism a grant, a cooperative agreement, or a contract? Contracts and cooperative agreements must be reviewed by SPA</td>
</tr>
<tr>
<td>Check the sponsor website for application guidelines/instructions and forms. Have the forms been completed correctly?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Required Forms</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Conflict of Interest (COI) Disclosure Statement</strong></td>
</tr>
<tr>
<td>Required for HMS key personnel and investigators listed on the proposal. Consultants or collaborators/Other Significant Contributors who are not at HMS or on a subaward must also complete an HMS COI disclosure form</td>
</tr>
<tr>
<td>Award title on COI form should match the title in GMAS</td>
</tr>
<tr>
<td>Signature and date should be current; first box on page one must be checked</td>
</tr>
<tr>
<td>Completed COI forms must be uploaded into the Request Documents, in a separate folder labeled “COI”</td>
</tr>
<tr>
<td>NIH proposals over $500k in annual direct costs will need approval letter from NIH attached to application</td>
</tr>
<tr>
<td><strong>Modular budget proposals</strong> – upload internal budget spreadsheet into GMAS Request Documents (Optional)</td>
</tr>
<tr>
<td><strong>Participation Agreement</strong> (must be electronically signed in GMAS before award/account setup)</td>
</tr>
<tr>
<td>Each individual performing research at Harvard should sign either the Harvard University Participation Agreement or the Visitor Participation Agreement, as applicable: <a href="https://gmas.harvard.edu/gmas/participationagreement">https://gmas.harvard.edu/gmas/participationagreement</a></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Personnel</th>
</tr>
</thead>
<tbody>
<tr>
<td>For NIH proposals, do any salaries exceed the NIH salary cap? (The salary cap applies to NIH only, not to other federal sponsors)</td>
</tr>
<tr>
<td>Are the personnel named in the proposal/budget HMS-paid faculty members? Check MARS (<a href="https://itmrsp01.med.harvard.edu/">https://itmrsp01.med.harvard.edu/</a>) to ensure they are paid by HMS (not by an affiliated hospital), and to verify salary amounts</td>
</tr>
<tr>
<td>Make sure any consultants on the proposal are not Harvard personnel</td>
</tr>
<tr>
<td>Ensure post docs are paid a salary (not a stipend) for research awards</td>
</tr>
<tr>
<td>Is each individual’s proposed level of effort commensurate with the actual costs that will be charged to the award? If not, this may indicate cost sharing. Proposals including cost sharing must be reviewed by SPA.</td>
</tr>
<tr>
<td>Ensure the proposal is compliant with minimum or maximum amounts of effort specified in the guidelines and in accordance with the HMS effort policy. Faculty total effort should not exceed 95% on research awards at any time.</td>
</tr>
<tr>
<td>PI effort below 1% is not allowed at HMS.</td>
</tr>
<tr>
<td>Period of Performance</td>
</tr>
<tr>
<td>----------------------</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Place of Performance</td>
</tr>
<tr>
<td>Space</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Cost Sharing</td>
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<tr>
<td>Human Subjects</td>
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<tr>
<td>Animal Subjects</td>
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<tr>
<td></td>
</tr>
<tr>
<td>Research Risks</td>
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</tbody>
</table>
**Publications, Patents and Copyrights**

Does the proposal contain a potential patent or copyright? ***If yes, send to SPA for review***

Does the agency or sponsor impose any restrictions on publishing research results? ***If yes, send to SPA for review***

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**Budget**

NIH only: $500,000 or more in annual direct costs requires program officer prior approval

Have the correct budget categories been used?

Are all the costs allowable according to federal and university cost principles?

Are the proposed budget calculations correct?

On research proposals, tuition charged must be commensurate with percentages of effort for the individual for whom tuition is requested.

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**Fringe Benefits**

Have the currently approved rates been used and correctly applied to the proper salary bases? For federal proposals, use the fringe rates on the latest negotiated agreement: [http://osp.finance.harvard.edu/fringe-benefits-rates](http://osp.finance.harvard.edu/fringe-benefits-rates)

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**Indirect Costs**

Has the appropriate indirect cost rate(s) been used and applied to the correct MTDC base? For federal proposals, use the F&A rates on the latest negotiated agreement [http://osp.finance.harvard.edu/fa-cost-rates-federal-sponsors](http://osp.finance.harvard.edu/fa-cost-rates-federal-sponsors)

For nonfederal proposals, use the sponsor’s published rate. *If no published IDC rate, send proposal to SPA for review*

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**Travel/Equipment/Other Direct Costs**

Are the costs allowable, reasonable, allocable to the project, and in accordance with sponsor guidelines?

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**TOOLS FOR PROPOSAL REVIEW AND SUBMISSION**

GMAS helpdesk: 6-2001 or contactgmas@harvard.edu

Electronic Submission Tracking & Reporting (ESTR): [https://irb.harvard.edu](https://irb.harvard.edu) and [ESTRhelp@harvard.edu](mailto:ESTRhelp@harvard.edu)

Medical Area Reporting System (MARS) personnel information: [https://ltmrsp01.med.harvard.edu](https://ltmrsp01.med.harvard.edu)

HMS Policies and Guidance: [http://hlcra.harvard.edu/policies/all-policies-alphabetical/](http://hlcra.harvard.edu/policies/all-policies-alphabetical/)


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Prior to submission, review NIH’s “Applying Electronically - Avoiding Common Errors”: [http://grants.nih.gov/grants/electronicreceipt/avoiding_errors.htm](http://grants.nih.gov/grants/electronicreceipt/avoiding_errors.htm)

(See next page for “Ten Checks to Help Avoid Common Errors”)

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NIH Electronic Applications – Ten Checks to Help Avoid Common Errors

Going through the final checks below will help you avoid errors and successfully submit your application! For additional help avoiding common errors check out our Annotated Forms with field-by-field tips on completing the SF424.

1. **Does the DUNS number on the SF424 (R&R) cover form match the DUNS used for Grants.gov & Commons registration?**

2. **Did you select the correct Type of Submission, provide the Federal Identifier, and check the Type of Application information on the SF424 (R&R) cover form?**
   
   These three fields all work together – be sure to follow the application guide instructions carefully.

3. **Did you include the eRA Commons ID in the Credential field of the R&R Sr/Key Person Profile form for all PD/PIs?**

   Including the eRA Commons ID for the PD/PIs is an NIH requirement and is critical to our ability to post errors, warnings and the assembled application image in eRA Commons. The credential field is not marked required on the federal-wide form since not all agencies that use the form need this field. NIH uses the Health and Human Services logo within the application guide to flag agency-specific instructions and clarifications for fields on federal-wide forms. Pay special attention to the HHS “birdie” or you may miss key NIH requirements.

4. **If submitting a Multiple-PD/PI application, did you give all PIs the PD/PI role on the Sr/Key Person Profile form?**

   There are several roles on the form drop-down that are similar – PD/PI, Co-PD/PI and Co-Investigator. **Only the PD/PI role is recognized by NIH as the correct designation for all PIs on a multiple-PD/PI application.**

   Using the correct designation allows the system to flag the application as multiple-PD/PI and facilitates appropriate handling of the application as it flows through review and other post-submission activities. Co-PD/PI or Co-Investigator roles hold no special meaning within NIH and should never be used with a multiple-PD/PI application. They are, however, valid roles on the form and you can use them for a single-PD/PI application. You may receive a Warning indicating the role is not appropriate for Multiple-PD/PI applications, but if Multiple-PD/PI was not your intent, then no action is necessary – simply ignore the Warning.

5. **Did you include Organization name for all Sr/Key listed on the R&R Sr/Key Person Profile form?**

   The Organization name for each Sr/Key is one element used to determine potential conflicts for review. For this reason, we require applicants to provide Organization information for ALL Sr/key entries. Again, this field is not marked required on the federal-wide forms. The Organization for the Contact PD/PI is pulled from the SF424 (R&R) cover, but you’re on your own for the other Sr/Key entries and will want to double-check to ensure Organization is included.

6. **Did you include all required attachments?**

   Often attachments are conditionally required based on how an applicant fills out specific questions. Here are a couple of examples:

   - Answering ‘Yes’ to the Human Subjects question on the R&R Other Project Information form makes the attachments in the Human Subjects section of the PHS 398 Research Plan required. Similarly, if
you answer ‘Yes’ to the Vertebrate Animals question, then the Vertebrate Animals attachment is required.

- If you have more than one entry on the R&R Sr/Key Person Profile form with the role of “PD/PI,” then the Multiple PD/PI Leadership Plan attachment on the PHS 398 Research Plan form is required.

7. Are all your attachments in PDF format?

Grants.gov will allow other document formats, but PDF is an NIH requirement. Use simple PDF-formatted files for ALL attachments. See formatting attachments page.

8. Did you follow the page limits specified in the FOA and application guide?

9. Did you include effort > 0 for all Sr/Key listed on the R&R Budget form?

It is not necessary to list every person from the R&R Sr/Key Person Profile form in the Sr/Key section of the R&R budget form. For the entries you do list, however, you must provide measureable effort using the Calendar Months OR a combination of Academic and Summer Month categories. Too little effort information (i.e., blanks or zeros in all three month categories) or too much information (i.e., providing non-zero values in Calendar Months and any other month category) will result in an error. For information about calculating person months, see http://grants.nih.gov/grants/policy/person_months_faqs.htm.

10. Did you follow all special instructions noted in Section IV. Application and Submission Information of the announcement?

The eRA validations will catch many, but not all, submission requirements. FOA-specific requirements are not typically system-enforced. Applications that do not comply with the instructions may be delayed or not accepted for review.

Two Important Points to Remember:

- Submitting early remains the best way to ensure successful submission.
- Resources to help avoid common errors should never be used in place of the Application Guide or Funding Opportunity Announcement.
Signatures in GMAS for Department Submissions

This document outlines the signatory roles in GMAS that should be selected for Departmental submissions, versus those requests that are routed to SPA for review and submission.

Requests that are being submitted by the Department should NOT include signatures for the SPA Approver role.

Step 1: Once the request has been finalized and is ready for review and submission, select the “Lock and route for signature” button from the homepage.

[NOTE: For S2S submissions, there will be additional screens where you choose which optional forms should be sent with the application, then validate all information before signatures are chosen.]
Step 2: Select and confirm required internal signatures

For all requests submitted by the Department:

- The PI signature will always default as required
- The mentor’s signature should default for fellowships
- Leave the Sponsored Programs Approver role blank
- Insert the name of the Departmental Signatory (usually the Financial/Administrative Director or Manager) in the field for the University Authorized Signatory
- (The Department Approver role becomes unnecessary if the University Authorized Signatory is in the Department.)

Add additional signatures, if needed. Then click on the “Next” button.

Step 3: Click “Finish” button on next screen.
Submitting Non-S2S Requests in GMAS

This document outlines the steps for marking a GMAS request as “Submitted to Sponsor.”

It is important to change the status of a request from “Authorized” to “Submitted” for several reasons, including:

- Accuracy of proposal submission data used in HMS and University reporting
- Ability for all GMAS users (including faculty, department staff, and SPA staff) to identify which requests have been sent to the sponsor, and which still need to be submitted
- At-risk accounts cannot be created for requests not in Submitted status
- Award notices cannot be logged against a request unless it’s in Submitted status

Immediately upon submitting a proposal/application or other request to a sponsor, the Department Submitter should note the submission in GMAS using the “Submit to Sponsor” button on the Request homepage.

Once a request has been submitted to the sponsor by any means other than GMAS S2S, including

- Electronic submission through any portal (e.g., proposalCENTRAL, AHA Grants@Heart, NSF FastLane, Grants.gov, eRA Commons for RPPR and no-cost extensions, etc.)
- Paper Submissions

Go to the corresponding Request homepage in GMAS and follow the steps below.

**Step 1:** Check that the request status is “Authorized,” meaning the required signatures (PI, mentor for fellowships, and University Authorized Signatory (Department Submitter) – see “Signatures in GMAS for Department Submissions” section of this guide) have been received in GMAS.
Step 2: Click on “Submit to sponsor” button
Step 3: Enter submission details as follows, and then click OK.

- **Date received by central** – use the date you, as Department Submitter, received the request for review. This is the same date that the request was “Locked and routed for signatures”
- **Date returned to department** – leave this field blank
- **Date submitted to sponsor** – enter date submitted, either through an electronic portal, or date paper application was mailed
- **Method sent** – choose from dropdown list
- **Tracking no.** – may enter if applicable (e.g., FedEx tracking number)
- **Submitted by** – enter submitter’s name. The submitter may be the PI or Department submitter (for electronic submissions), or the grants manager or other department staff (for paper or email).
Submitting S2S applications via GMAS

This document outlines the steps in GMAS for submitting a system-to-system (S2S) application to Grants.gov. It is geared toward the authorized submitter (those with the ability to sign/submit proposals on behalf of Harvard).

After a request has been signed by the required parties, the authorized submitter should click on “Prepare Grants.gov submission” to initiate the process.

On the next screen, ensure all required documents have been uploaded and that the proper budget mechanism (modular or detailed) has been chosen.

If changes need to be made, click “Cancel.” If not, click “Continue.”
In the “Person to be contacted regarding this application” field, enter your SSPO’s name then click on the “Lookup” button.

A pop-up screen will appear. Select the correct person record, and then click on “OK.”
When you return to the submission screen, the contact information for the SSPO will be pre-populated. Make sure the information is correct, and if necessary use the pull-down menus to select the correct information. **Change the SSPO’s email to spa_award@hms.harvard.edu.**

Review your own contact information and make changes if necessary.

Select the box for “I agree” to certify you are in agreement with the PHS certification and assurances and that Harvard will comply with any resulting award terms.

Then click “Submit to Grants.gov.”
Correcting a System-to-System (S2S) Application with Errors

This document outlines the steps for an authorized submitter to correct an S2S application that has an error. Please note that there is an extra GMAS step which applies to New (Initial) applications, but not to Competing Renewal or Resubmission applications.

The PI and AOR will receive an email notice from the eRA Commons (era-notify@mail.nih.gov) indicating there is an error in the application that must be corrected before the submission deadline. The subject line of the email will include: the Grants.gov tracking number (e.g., GRANT12345678); PI Name; “ACTION REQUIRED TO COMPLETE SUBMISSION” and a brief description of the error.

Using this identifying information, log in to GMAS.

From the GMAS homepage, click on the “S2S Submissions” link on right hand side of screen.

Locate the request and click on its title.
From the Request homepage, click on “Grants.gov correction” button.

Select whether you want to resubmit the corrected application without requiring new signatures (first option) or whether you want to reroute the request for review of changes and new signatures (second option). Then click “OK”.

Resubmit request 5665490 “Identification of clinically relevant variants in the non-coding genome” to Grants.gov without requiring new review from signatories.

- Request status will change to Authorized and previously retained signatures from submission on 01-21-2014 will be retained and applied for current resubmission. Prior submission information will not be impacted. (Note: If all required signatures were not previously completed, request status will change to Under Internal Review.)

Resubmit request 5665490 “Identification of clinically relevant variants in the non-coding genome” to Grants.gov and reroute request for new review by signatories.

- Request status will change to Under Development and previously retained signatures will need to be reobtained for this resubmission. Prior submission information will not be impacted.
FOR INITIAL/NEW APPLICATIONS ONLY: (Skip this step for Competing renewals or Resubmissions.)
From the Request homepage, scroll down to the “Grants.gov questions” component and click on the “Edit” button.

<table>
<thead>
<tr>
<th>Request information</th>
<th>Edit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tub</td>
<td>520. HMS*Harv Med School</td>
</tr>
<tr>
<td>Org</td>
<td>46334, HMS*Center for Biomedical Informatics</td>
</tr>
<tr>
<td>Title</td>
<td>Identification of clinically relevant variants in the non-coding genome</td>
</tr>
<tr>
<td>Project type</td>
<td>Basic research and all other</td>
</tr>
<tr>
<td>Principal investigator</td>
<td>Park, Peter Jungsoo</td>
</tr>
<tr>
<td>Sponsor</td>
<td>NIH</td>
</tr>
<tr>
<td>Sponsor type</td>
<td>US Federal Government</td>
</tr>
<tr>
<td>Prime sponsor</td>
<td></td>
</tr>
<tr>
<td>Prime sponsor type</td>
<td></td>
</tr>
<tr>
<td>OMB A21 functional code</td>
<td>Organized Research (A02)</td>
</tr>
<tr>
<td>Discipline</td>
<td>Other</td>
</tr>
<tr>
<td>Sponsor tracking number</td>
<td></td>
</tr>
<tr>
<td>Response to RFP?</td>
<td>Yes</td>
</tr>
<tr>
<td>Preponderance of effort?</td>
<td>On-campus</td>
</tr>
</tbody>
</table>

In the “Federal identifier” field enter the Grants.gov tracking number (found in the notification email from the eRA Commons or by using the “Submissions” link from the right column of the Request homepage). Do NOT enter the “GRANT” prefix of the Grants.gov tracking number; enter only the 8-digit number. Then Click “OK” at the bottom of the screen.

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In the “Federal identifier” field enter the Grants.gov tracking number (found in the notification email from the eRA Commons or by using the “Submissions” link from the right column of the Request homepage). Do NOT enter the “GRANT” prefix of the Grants.gov tracking number; enter only the 8-digit number. Then Click “OK” at the bottom of the screen.
FOR ALL APPLICATIONS: (New, Competing renewals, Resubmissions)

Make all changes to the Request necessary to correct the error(s) shown in the eRA Commons, then click on the "Prepare Grants.gov submission" button and proceed by following the steps outlined above for submitting an S2S request.

Request homepage

<table>
<thead>
<tr>
<th>Project ID</th>
<th>Fund no.</th>
<th>Request number</th>
<th>Request attributes</th>
</tr>
</thead>
<tbody>
<tr>
<td>0666435-01</td>
<td></td>
<td>5065490</td>
<td>Retroactive No</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Guidance links

- Open all
- Close all
- HMS Proposal Checklist
- OSP Proposal Information
- Administrative team
- Submissions
- 6 pending submission
- Grants.gov profile
- Preview
- Enhancements D&D Revisions
RPPR Review Checklist

(Revised 1/12/2015)

Overview:

Once you’ve been assigned the SO (Signing Official) role in eRA Commons, you can access any RPPR that’s been “Routed” to you by logging into eRA Commons and clicking on the “RPPR” button right on the top of the homepage.

From there, select “Manage RPPR” and the grant:

This pulls up the RPPR and allows you to view the different options on the Menu Screen (Edit, Check for Errors, View, View Routing History, Route, Cancel):

If you click “View” and the PDF looks good, “Check for Errors” to validate. If there are no errors, the Submit button will appear:

After clicking “Submit”, Select the I Agree button to sign off on the certification. The PI will be cc’d on an automated email from NIH once it goes through.

If changes are needed, you can “Route” the RPPR back to the PI for fixing, or select “Edit” to make some changes yourself. (In some sections, such as PI name, title, address, etc., that info is pulling from the PIs Personal Profile in eraCommons and would need to be updated logged on as them).

The next section shows the different pages that appear when “Edit” is selected. Together with the uploads, these comprise the fully-assembled RPPR PDF.

I have highlighted Page/Character Limits wherever applicable.
Required Sections

Section A – Cover Page (Most of this Pre-populates)

Section B – Accomplishments

___B.1 Specific Aims – Insert for year 1, then pre-populates for subsequent years – (No Special Characters)

___B.2 Accomplishments (2 pg limit PDF)

___B.3 Competitive Revisions – Yes/No If Yes, provide Aims and Accomplishments (700 Character Limit)

___B.4 Professional Development – Descriptions on the Use of Individual Development Plans (IDPs) for Graduate Students and Postdoctoral Researchers “RPPRs must include a report on the use of IDPs. Actual IDPs should not be included. Instead, grantees will report on whether they use IDPs for all the graduate students and postdoctoral researchers included in Section D. list of Participants.”

___B.5 Result Dissemination, if applicable– do not report routine dissemination (ie: websites and press releases)

___B.6 Future Goals (Mandatory for all) – (1 page limit) – state goals for NEXT period

Section C – Products

___C.1 Publications – If yes, must link to NCBI and associate with RPPR – could cause warning if pubs are not compliant with Public Access Policy – PI and ORA will get an email – can submit with warning

___C.2-C.4 If Applicable (these “open” based on how questions are answered)

___C.5.a Other Products – If applicable, upload description of significant products developed during THIS reporting period.

___C.5.b Resource Sharing – If plan was required, describe process in implementing plan. If implemented, provide final statement on data being shared

Section D – Participants

___D.1 Participants – anyone who has worked 1 Cal Month must be listed. eRA Commons IDs should be included for anyone with PostDoc level or lighter (Note: Must round calendar months to nearest whole number)

___D.2.a Level of Effort – Selecting Yes = prior approval request – Provide explanation (700 Character limit)

___D.2.b New Senior/Key Personnel – If yes, upload biosketch(es)

___D.2.c Changes in Other Support of Senior/Key personnel - If yes, upload Other Support
D.2.d. New Other Significant Contributors - If yes, upload biosketch(es)
D.2.e Change in MPI Leadership Plan – If yes, upload revised plan

Section E – Impact
E.1 Not applicable for most grant types
E.2 Impact – Describe impact on physical, institutional or information resources (1 page limit)
E.3 Not applicable for most grant types
E.4 Foreign Dollars - Provide $ amount obligated to first tier subs THIS period – enter aggregate if you have 2 subs in same country

Section F – Changes
F.1 Not applicable for most grant types
F.2 Anticipated Delays – Describe changes/delays and plans to resolve (1 page limit)
F.3.a-d If changes to Human Subjects, Vertebrate Animals, Biohazards or Select Agents provide revisions

Section G – Special Reporting Requirements
G.1 Address any special reporting requirements in NOA or FOA
G.2 Not applicable for most grant types
G.3 Letter from mentor – required for training grants
G.4.a Human Subjects - If yes, more questions open
G.4.b Inclusion Enrollment Data – if required, this looks just like eSnaps used to.
G.4.c Clinical Trials- If yes, NCT number is required – system will validate
G.5 Human Subjects Education – If yes, name new individuals involved, enter CITI training and one sentence description of the program (1/2 page)
G.6 Human Embryonic Stem Cells – If yes, HESC number is required – if changed, explain (700 Characters)
G.7 Vertebrate Animals – Should pre-populate
G.8 Project Performance Site – Congressional District and DUNS required (delete duplicates)
G.9 Foreign Component – If yes, provide name, country and description (700 Characters)
G.10.a Unobligated Balance – If greater than 25% (including prior year carryover) must select yes and provide estimated unobligated balance
G.10.b Provide an explanation for unobligated balance
G.10.c If carryover is authorized, provide a general description of how balance will be spent. Determine carryover authorization by reviewing in NIH Notice of Award
G.11 Program Income – If yes, enter amount and source(s)
G.12 F&A Costs – Is there a change in performance site that will affect F&A? If yes, explain changes F&A (1300 characters)

Section H – Budget
Budget – Currently N/A for all grants because only

Please note
1) Investigators should list the grant this RPPR is being submitted for on their Other Support Pages (see http://grants.nih.gov/grants/rpprfaqs.htm#3573).

2) If a publication validates as “Non-Compliant”, NIH will come back asking for an explanation. Below is an email that has recently been accepted by NIH:

This email is to certify (in response to the automated Non-Compliance Warning below) that Dr. --'s RPPR for 5 XXXXXXXXX-XX was prepared in compliance with the NIH’s Public Access Policy. Dr. -- used the “My NCBI” feature to enter publications and/or update compliance status for all applicable publications.

It was scientifically important, however, in showing year-to-year progress, that Publications not yet Peer-Reviewed or recently submitted to Journals were included in the RPPR (directly resulting from this grant).

As soon as possible, Dr. -- agrees to follow the NIH Public Access Policy and bring the publications into compliance, like the other publications included in the report. Please let me know if you require anything further from Harvard Medical School on this issue.
NIH Just-in-Time (JIT) Review and Submission

NIH grants policy allows the submission of certain elements of a competing application to be deferred for certain programs and award mechanisms, as referenced in the NIH Grants Policy Statement (see section titled Just-In-Time Procedures under Completing the Pre-Award Process). These elements, that can be submitted Just-in-Time by the authorized department submitter when requested by the NIH Grants Management Specialist (GMS), include:

- NIH-Formatted Other Support (in Calendar Months for all Senior/Key personnel)
- Certification of Institutional Review Board (IRB) Approval of the project’s proposed use of human subjects (when applicable)
- Verification of Institutional Animal Care & Use Committee (IACUC) Approval of the project’s proposed use of live vertebrate animals (when applicable)
- Genomic Data Sharing Institutional Certification
- Biosketch of any new Senior/Key person being added to grant since the initial submission
- Evidence of compliance with the education in the protection of human subjects requirement

The additional JIT information is requested after peer review of a grant application has been completed and prior to funding. Requests may come in the form of eRA-system generated e-mails or contact made directly from the awarding agency via e-mail and/or phone. Applicants should not submit JIT information until it is requested by the grantor agency.

As soon as a JIT request arrives, email OPSI at ciforms@hms.harvard.edu with the GMAS project number to alert them that the award is arriving soon. This allows OPSI time to review the project’s disclosures and clear its COI approvals before the award arrives so that account setup is not delayed.

Other Support

List active and pending awards for all key personnel. Other Support includes all financial resources, whether Federal, non-Federal, commercial or institutional, available in direct support of an individual’s research endeavors, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards. Training awards, prizes, or gifts do not need to be included.

For each project, list the following:

- Project Number
- PI name
- Sponsor
- Project title
- Dates of Approved/Proposed Project
- Annual Direct Costs
- Effort in Person Months
- For each key personnel, summarize any Overlap, whether scientific, budgetary, or commitment (effort)
Review of Other Support:

Check that the HMS investigator’s total committed annual effort on active awards (including the award currently under JIT review) does not exceed the HMS Maximum Effort Threshold of 90%. Only in exceptional circumstances should faculty research effort and salary exceed 95%. (See HMS/HSDM POLICY FOR FACULTY EFFORT ON SPONSORED AWARDS at http://hlcra.harvard.edu/files/hlcra/files/hms_hsdm_faculty_maximum_effort_policy_0.pdf)

IACUC approvals

Contact the HMA Standing Committee on Animals (IACUC@hms.harvard.edu) at the JIT stage for projects involving vertebrate animals. If an existing animal protocol will be used, the Standing Committee must add the new NIH grant to the protocol. If a new protocol is required, the PI should submit a protocol application as soon as possible using eIACUC.

IRB approvals

An approval letter from the Office of Human Research Administration (OHRA) is needed before a human subjects approval date is entered into eRA Commons. The approval letter must list the grant in question.

Revised budget (if requested by NIH)

Occasionally, NIH asks for a revised budget at the JIT stage. Most NIH Institutes will only request a revised budget if there is a substantial (25% or more) reduction of the budget from what was proposed. If a budget is requested, it should be uploaded into the eRA Commons as a separate JIT attachment. NIH may also ask that we submit our current federal F&A rate agreement with the JIT info.

JIT Step-By-Step Submission in eRA Commons

- Log on to eRA Commons at https://commons.era.nih.gov/commons/
- Click on the “Status” and select “Just In Time”
- Search by Grant number, PI name, etc.
- Click on the “JIT” link under the “Action” column
- Import or enter the required information:
- Import (upload) the Other Support information in PDF
- Enter IACUC approval date if applicable
- Enter IRB approval date if applicable
- Enter Human Subjects Education date(s). Note: option to enter dates is only available when animals and/or humans are being used
- Press the SAVE button
- Click “View Just In Time Report” to make sure everything looks as intended
- Submit:
Processing a Termination Notice (TN) in the eRA Commons

Please see [http://era.nih.gov/files/termination_appointment.pdf](http://era.nih.gov/files/termination_appointment.pdf) for the xTrain Termination of Appointments Quick Reference Guide to view the entire process for termination notices. This document outlines the steps for the Business Official (the authorized department submitter) to approve and submit the notice to NIH after it has gone through the routing steps. The example below is for a Training Grant. *Please note: the process is the same for Individual Fellowships as for Training Grants.

Log in to eRA Commons and search eRA Commons for the grant:

- Go to the “xTrain” tab
- Insert grant identifiers (e.g., Institution Code and Serial Number)

On the next screen, click the link to “View trainee roster”
You will only be able to process the TN if it has been routed to you. **Make sure the TN went through the program director/sponsor for electronic signature first.** This can be verified either by clicking on the view TN link or by making sure the routing has gone through all needed steps (student/faculty/BO).

If all necessary steps have been taken, and if the termination status is “in progress BO” with your name as the “Current Reviewer,” click on the “Process TN” link on the right-hand side.

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**Trainee Roster**

**Notes and Tips:**
- If an institutional research training appointment or fellowship is ending earlier than initially planned, the PD/PI should initiate a Termination with the new end date, which will automatically amend the period of appointment for a trainee or trigger the process for Agency staff to revise the period of the fellowship award.
- For appointments to institutional career development (K12, KL2, KL1) and research education (R25, R90, RL5, RL9) awards that are ending early, the PD/PI should only use the Termination Notice if specifically instructed to do so by the awarding IC. If a Termination Notice is not required, the new appointment end date should be documented by an amendment to the appointment.
Please verify award's information for correctness against the PER. If the amounts match and are correct, and if the form is complete, click the "Save & Submit to Agency" button.
**Processing an Initial NIH No Cost Extension (NCE) in GMAS and the eRA Commons**

**GMAS Entry**
The grants manager should enter a **no cost extension request in GMAS**, including the following information:

- Justification - scientific/programmatic justification from PI (i.e., not just that there’s a balance)
- Requested new end date (usually 12 additional mos. for an initial NIH extension)
- Approximate remaining balance
- Address the following 2 questions in the Request Comments:
  - If applicable: will any part-of accounts or subawards on the project be extended as well?
  - For NIH: will the PI’s effort will be reduced by more than 25% during the extension period? *For budget periods beginning on or after October 1, 2015, NIH no longer requires prior approval for reduction of effort for key personnel during NCE.*
- The Research Team (segment) should be updated to remove anyone no longer working on the project.
- Approvals should be checked to make sure they cover the duration of the extension period, where applicable. Get updated approval information as needed; enter comments and/or upload docs into the Approval section(s) in the GMAS segment.

**Department Submitter Review of Request**
As part of reviewing the components of the request outlined above:

- Will the PI's effort be reduced by more than 25% during the extension period?
- Does the budget period begin on or after October 1, 2015?

If answers to both questions are “yes”, then send a request to the NIH Program Official and copy the NIH Grants Management Specialist. Once approval for the effort reduction has been received, upload the approval email into the NCE request Documents in GMAS.

**Authorization of Extension in eRA Commons**
Once the above considerations have been addressed, the department submitter should log in to the **eRA Commons** and search for the grant by

- going to “**Status**” tab, under “**General Search**”, and
- inserting grant identifiers, e.g. Institution Code and Serial Number (make sure you clear all dates), then
- clicking on “**Search**” button
On the right-hand side there should be an “Extension” link. Click the link to extend the end date of the grant.

---

**Status Result - General Search**

If your grant was not awarded, please do not use the MYP link in the Action column to submit a Progress Report for Multi-Year Grant.

Tips and Notes:
- PDP/PI column shows Contact PI for multi-PI grants.

<table>
<thead>
<tr>
<th>Application ID</th>
<th>Grants.gov Tracking #</th>
<th>Proposal Title</th>
<th>PDP/PI</th>
<th>Application Status</th>
<th>Budget Start Date</th>
<th>FFATA</th>
<th>Show All Prior Errors</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1K09GM102372-01</td>
<td>GRANT10962387</td>
<td>Dynamics of cellular senescence in single human cells</td>
<td>PURVIS, JEREMY</td>
<td>Awarded; Non-fellowships only</td>
<td>09/01/2012</td>
<td>Yes</td>
<td>Show All Prior Errors</td>
<td>Extension</td>
</tr>
<tr>
<td>1K09GM102372-01A1</td>
<td>GRANT111890627</td>
<td>Dynamics of cellular senescence in single human cells</td>
<td>PURVIS, JEREMY</td>
<td>Withdrawn by IC - Other Version Encumbered</td>
<td>04/01/2013</td>
<td>Yes</td>
<td>Show All Prior Errors</td>
<td>Transmittal Sheet</td>
</tr>
</tbody>
</table>
From the drop-down menu, select the number of extension months requested. **SPA strongly recommends extending the project for full 12 months, as second NCEs must be requested and are rarely approved.**

**In order to extend the account(s) in GMAS, please forward the confirmation email you receive to your SPA representative.**
NIH Final Invention Statement Submission (Closeout)

Email patents@harvard.edu for the final confirmation of inventions on the grant. When you have received a response from the patents office and have either
- a list of reported inventions; or
- a confirmation that no inventions were reported, the Department authorized submitter should follow the steps outlined below.

Search eRA Commons for the grant by
- going to the “Status” tab,
- selecting the “Closeout” option on the menu, then
- inserting grant identifiers (e.g. Institution Code and Serial Number)
- clicking on the “Search” button.
On the next screen, click on the right-hand side link “Requires Closeout”

Click on the link to Process “Final Invention Statement”
If OTD has reported **no inventions**, then select "No" and certify by clicking "OK" on the verification statement (pop-up). For submission, Final Invention Statement requires verification by the Signing Official of the Institution only. PI verification is not required.
If inventions were reported, please refer to the spreadsheet that patents@harvard.edu will send as a response to your initial email requesting the verification. To avoid misspellings or incorrect reported dates, copy from the spreadsheet and paste into the appropriate fields.

Select "Yes," and begin entering information in each field. Click on the "Add Invention" button and repeat until all inventions have been entered.
Once finalized, "Save" and "Submit" the Final Invention Report.
HMS Guide for GMAS: How and Why to Close Requests

**Introduction**

This guide tells you how to close requests in GMAS and why it matters.

**Responsible role within GMAS**

Department Administrator  
SPA Administrator

**Why this matters**

Once it is known that a request will not be funded, it should be closed in GMAS as soon as possible to stop unnecessary downstream review activities and to ensure accurate reporting. (This guide applies to requests that have been submitted to the sponsor. Requests that have not been submitted, and will never be submitted, should be deleted rather than closed.)

**How to close out requests**

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Navigate to the request in GMAS you wish to close out.</td>
</tr>
<tr>
<td>2</td>
<td>On the Request Home page, click on the Request closeout button.</td>
</tr>
</tbody>
</table>

![Request homepage](image)
3 On the next screen, select the reason for the close out:

- **Declined per HU** – For requests being declined by the University
- **Rejected by Sponsor** – For requests where communication from the sponsor has been received that it was not selected for funding
- **Withdrawn** – For requests that were withdrawn from funding consideration
- **Closed** – For requests that will not be funded that do not fit the above criteria (i.e., a proposal that has been pending for a significant period of time without response from the sponsor)

4 Enter a comment if necessary to explain the close out.

5 Click **OK**. (The request status will move to the reason selected, and the segment status will move to “Not funded” if the closed request is the only request in the segment.)

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**If the request was closed in error or needs to be reopened**

If the request was closed out in error or needs to be reopened, contact SPA to request a “Request rollback.”

GMAS “Super users” in the central offices have access to a **Request rollback** button to bring the request back to open status.

The request can be rolled all the way back to “Under development” and deleted if necessary.