

RESEARCH ADMINISTRATION



Wednesday, October 26, 2016

Hiatt Auditorium (S1-608) 1:00 pm - 3:00 pm

The second half of the update will be dedicated to the training topic:

Award Setup Procedures



Agenda



- Foreign Project Registration (FPR) Process Update
Teresa Zash, Director of Operations, Office of Global Health
- NIH Update
 - eRA Browser Update Requirements
 - NIH Operates Under a Continuing Resolution (NOT-OD-17-001)
 - Optional Electronic Submission Method to Request to Submit An Unsolicited Application That Will Exceed \$500,000 In Direct Costs (NOT-OD-17-005)
 - NIH Natural Disaster Policy (NOT-OD-17-007)
 - NIH Late Application Submission Policy (NOT-OD-15-039)
 - NIH Loan Repayment Program (LRP)
- Proposal & Progress Report Statistics
- Research Administration Training Topic: Award Setup Procedures



Teresa Zash, J.D., LL.M.
Director of Operations, Office of Global Health

Contact the Office of Global Health: globalhealth@umassmed.edu or x 6-2840

What is considered a foreign project?

Any project that includes one or more of the following...

- research, education, or clinical work outside of the US;
- US funding to an international organization or external funding from foreign sponsor;
- involvement of a foreign collaborator beyond consultation;
- activity that may be subject to export control; or
- any activity that may have an impact on US foreign policy throughout the involvement of a foreign country.



*If a project includes **any of the above**, a Foreign Project Registration form must be completed and submitted to OGH.*

Why have an FPR process... and why change it now?



Objective of FPR process: To anticipate and address potential administrative, financial and/or legal issues that may arise in the development and implementation of foreign projects

Why change now?

- Timing concerns (too early/funding unknown)
- Paper-based process is cumbersome/data when printed
- Confusion around OSCs
- Inability to easily track funding
- FPR seems to be more of a burden

Overview of streamlined FPR Process



1. Review the FPR form (online) at start of submission
BUT DO NOT SUBMIT
2. Reach out to OGH with front-end questions/issues
 - a) Visa/Permit questions
 - b) Currency/bank accounts
 - c) Contracting with local partners/contractors
3. Submit FPR form either:
 - a) At the just in time (JIT) stage (for NIH); or
 - b) as soon as the investigator is made aware the project will be funded

*Note: Ensure information you provide on your form should be **accurate and complete**. This will ensure that your form will be turned around to you in a timely manner. An incomplete form will be returned with questions.*

Moving to new Online FPR Process



1. Review new form/process (today)
2. Finalize and launch new paper format/timing (Nov 1)
3. Solicit feedback on new form (Jan 15)
4. Develop and beta test online submission form (Jan 30)
5. Launch online form (Early 2017)

Completing the FPR

To complete the FPR, you will need the following critical information:



- How your project meets the criteria of a Foreign Project
- Project title (this should match the title on your grant application)
- PeopleSoft Proposal ID
- PI's and Project Administrator's name and contact information
- Foreign Partner's institution and location
- IRB and/or IACUC docket #s (if applicable)
- Project details (will vary based on the nature of the project)
- Export and data control information (e.g. proprietary data, involvement of toxins, viruses, bacteria, physical export of materials or equipment, etc.)
- Signature of the Department Chair

Anyone initiating, renewing or participating in a foreign project under University of Massachusetts Medical School auspices must complete this registration form. A foreign project is any project that includes one or more of the following: research, education, or clinical work outside of the US, US funding going to an outside organization or external funding from a foreign sponsor, involvement of a foreign collaborator beyond consultation, activity that may be subject to export control, or any activity that may have an impact on US foreign policy throughout the involvement of a foreign country. Depending on the nature of the project, further consultation may be required. The foreign project registration form must be completed at the just in time stage (for NIH) or as soon as the investigator is made aware the project will be funded.

Foreign Project Component (please check all that apply)

- a) Performance of any significant scientific element or segment of a project outside the United States, either by the grantee or by a researcher employed by the grantee.
- b) Clinical work or direct patient care (please refer to UMass Memorial malpractice policy [here](#))
- c) Human subject or animal research in a foreign country (please refer to [QHRP Intl Compilation of Human Research](#))
 - If your work involves clinical research and/or human subjects, please provide IRB Docket #
 - If your work involves animal research, please provide IACUC Docket #
 - If your work involves human subjects, please describe any personal data or personally identifiable information
- d) Foreign travel by grantee project staff for the purpose of data collection, surveying, sampling, and similar activities.
- e) Any international travel by UMass personnel who are non-US citizens
- f) Any travel by foreign collaborators to UMMS
- g) US funding going to a foreign organization or external funding from a foreign sponsor or export control
- h) Any activity of the grantee having an impact on US foreign policy through involvement in the affairs or environment of a foreign country (e.g., USAID)
- i) The only Foreign Project Component on your project is the involvement of Other Significant Contributor(s) (OSC(s)) outside the United States.

If you checked (i), please proceed to j).

j) The sole purpose of the OSC's engagement in your project is to provide peer review and technical advice without travel or exchange of samples and/or PII. Yes / No

If you checked YES, the FPR is NOT required for your project. If you checked no, please answer k)

k) Please describe the nature of the contribution by the OSC(s)

Will (or could) the project involve any of the following? Please select all that apply:

- Establishing an office or leasing space in a foreign location
- Hiring non-UMass faculty/staff in a foreign location
- Long-term (>6 months) presence of UMMS faculty/staff on ground in foreign location

STOP: If you did not select any of foreign components listed on this page, you do NOT need to complete a foreign project registration.

PROJECT INFORMATION

Project Title
*If your project is a grant, please ensure the project title matches that of your grant application

Project Start Date (mm/dd/yy)

PeopleSoft Proposal ID (if applicable)

Scope of work (Please insert your scope of work here OR briefly summarize here and include detailed scope of work as a PDF with the submission of this FPR)

Nature of work (please check all that apply)

- Educational
- International Clinical Work/Patient Care
- Research

Foreign Project Component (please check all that apply)

- a) Performance of any significant scientific element or segment of a project outside the United States, either by the grantee or by a researcher employed by the grantee.
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If you checked (i), please proceed to j).

j) The sole purpose of the OSC's engagement in your project is to provide peer review and technical advice without travel or exchange of samples and/or PII. Yes / No

If you checked YES, the FPR is NOT required for your project. If you checked no, please answer k)

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Nature of work (please check all that apply)

- Educational
- International Clinical Work/Patient Care
- Research

Other (please specify in scope of work above)

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EXPORT AND DATA CONTROLS

Does your project involve company or other proprietary data or technical information? If yes, describe.

If no, enter N/A.

Does your project involve the use of select agents, toxins, viruses or bacteria including shipment of such items to foreign locations?

If yes, describe.

If no, enter N/A.

Does your project involve physical (hand carried or shipment) export abroad or import of any materials or equipment?

If yes, describe.

If no, enter N/A.

LEGAL/INFRASTRUCTURE

Yes / No Is this project covered by a current MDU? If not, please contact OGH (globalhealth@umassmed.edu) to

FINANCIAL INFORMATION

Grant or Contract International Other (Specify)
 Philanthropy Federal

If you have selected "Grant or Contract", please indicate who the sponsor is

Will the budget require any of the following? (Please check all that apply)

Sub-awards In-Country Bank Account*
 Service Contracts *If selected, please fill out the following information
 Purchase or Rental of Real Estate Intended use of funds
 Purchase or Rental of Vehicles Estimated funding amount
 Field Advances

GENERAL INFORMATION

Principal Investigator

Name:

Email:

Phone:

Project Administrator

Name:

Email:

Phone:

Preferred Contact for this Foreign Project Registration (select one)

Principal Investigator or Project Administrator

FOREIGN PARTNER INFORMATION

Institution/Organization

City:

Country:

DEPARTMENTAL AGREEMENT

Department:

Department Chair Signature _____ Date _____

PACKET CHECKLIST- INCLUDE ALL APPLICABLE

Fill out this form and combine into a PDF with all necessary supporting documents. Email the form to globalhealth@umassmed.edu. An approval letter will be provided to the PI and department administrator.



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Does your project involve company or other proprietary data or technical information? If yes, describe.

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Yes / No Is this project covered by a current MDU? If not, please contact OGH (globalhealth@umassmed.edu) to create one.

Other (please specify in scope of work above)

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GENERAL INFORMATION

Principal Investigator

Name:

Email:

Phone:

Project Administrator

Name:

Email:

Phone:

Preferred Contact for this Foreign Project Registration (select one)

Principal Investigator or Project Administrator

FOREIGN PARTNER INFORMATION

Institution/Organization

City:

Country:

DEPARTMENTAL AGREEMENT

Department:

Department Chair Signature _____ Date _____

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If no, enter N/A.

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If no, enter N/A.

Does your project involve physical (hand carried or shipment) export abroad or import of any materials or equipment? If yes, describe: _____
If no, enter N/A.

LEGAL/INFRASTRUCTURE
Yes / No Is this project covered by a [UConn LTSA](#)?

FINANCIAL INFORMATION
 Grant or Contract International Other (Specify) _____
 Fellowship Federal

If you have selected "Grant or Contract", please indicate who the sponsor is: _____

Will the budget require any of the following? (Please check all that apply)
 Sub-awards In-Country Bank Account*
 Service Contracts *If selected, please fill out the following information:
 Purchase or Rental of Real Estate intended use of funds _____
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 Field Advances

GENERAL INFORMATION
Principal Investigator
Name: _____
Email: _____
Phone: _____

Project Administrator
Name: _____
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Phone: _____

Preferred Contact for this Foreign Project Registration (select one)
 Principal Investigator or Project Administrator

FOREIGN PARTNER INFORMATION
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DEPARTMENTAL AGREEMENT
Department Chair Signature _____ Date _____

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LEGAL/INFRASTRUCTURE
Yes / No Is this project covered by a [UConn LTSA](#)? If not, please contact CDR globalhealth@umassmed.edu to create one.

FINANCIAL INFORMATION
 Grant or Contract International Other (Specify) _____
 Fellowship Federal

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Phone: _____

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FOREIGN PARTNER INFORMATION
Institution/Organization _____
City _____
Country _____

DEPARTMENTAL AGREEMENT
Department Chair Signature _____ Date _____

PACKET CHECKLIST- INCLUDE ALL APPLICABLE

Fill out this form and combine into a PDF with all necessary supporting documents. Email the form to globalhealth@umassmed.edu. An approval letter will be provided to the PI and department administrator.

For projects with human subject or animal research the following is required: 1) IRB Docket # and/or IACUC, 2) IRB and/or IACUC approval letter as an attachment. The PI name on the IRB/IACUC must be the same as the name of the PI of this Foreign Project, otherwise please provide a letter of explanation.

If the project involves export or data controls please provide the ECC form.

If the project involves import of supplies, reagents or samples, please provide a copy of the signed Material Transfer Agreement (MTA).

Obtain departmental chair signoff for the project.

PACKET CHECKLIST- INCLUDE ALL APPLICABLE

Fill out this form and combine into a PDF with all necessary supporting documents. Email the form to globalhealth@umassmed.edu. An approval letter will be provided to the PI and department administrator.



Submission of Completed FPR and Approval Notification



- ***Until online form submission process is ready:*** Saved completed form as a PDF and email it to the Office of Global Health: globalhealth@umassmed.edu for review. Once our office reviews and approves it, you will receive an email with an approval letter that indicates the OGH's support of your project.
- ***Proposed online submission process:*** Complete online form and click submit. OGH will review online form and correspond in case any needed data is missing or additional info is needed. Once OK'd by OGH, a completed will go back to the Submitter to secure Dept. Head signature. Completed FPR (w/Dept. Signature) submitted to OSP.

QUESTIONS? SUGGESTIONS?

OFFICE OF
GLOBAL HEALTH
AT UMASS MEDICAL SCHOOL

globalhealth@umassmed.edu

x 6-2840

Ambulatory Care Center: AC7-129

eRA Browser Update Requirements



- NIH has been working on strengthening the security of its eRA modules, web services and websites to the federally mandated 'https only' secure connection required for all federal agencies.
- **Effective November 30, 2016**, all eRA modules (eRA Commons, ASSIST, IAR and iEdison), web services and websites will use 'https only' secure connections.
- UMMS users may need to update their web browser to continue using eRA modules as some browser versions will no longer work.
- Below is a list of browsers and versions that will still work properly following the update:
 - Google Chrome® version 4.0.211.0 and higher
 - Firefox® version 4 and higher; with Firefox 17, Mozilla® integrates a list of websites supporting the new protocol
 - Internet Explorer® 11 on Windows® 8.1 and Windows® 7 when KB 3058515 or higher is installed (Released on Windows Update in June 2015)
- These four are the other browser versions that will work with the security upgrade, but are not included in the in the eRA Browser Compatibility statement:
 - Chromium®
 - Opera® version 12 and later
 - Safari® as of OS X Mavericks
 - Microsoft® Edge™ and Internet Explorer® 11 on Windows® 10
- More information is available at <https://https.cio.gov/> and OMB M-15-13.

NOT-OD-17-001: NIH Operates Under A Continuing Resolution



- DHHS, including NIH, is operating under a continuing resolution signed by President Obama on September 29, 2016. This Act (CR) continues government operations through December 9, 2016 at 99.504 percent of the FY 2016 enacted level.
- Continuing the procedures identified under NOT-OD-16-046 and consistent with NIH practices during the CRs of FY 2006 – 2016, the NIH will issue non-competing research grant awards at a level below that indicated on the most recent Notice of Award (generally up to 90% of the previously committed level).
- Upward adjustments to awarded levels will be considered after FY 2017 appropriations are enacted, but NIH expects institutions to monitor their expenditures carefully during this period.
- All legislative mandates that were in effect in FY 2016 remain in effect under this CR, as well as the salary limitation set at Executive Level II of the Federal Pay Scale and the Ruth L. Kirschstein NRSA stipend levels and tuition/fees

NOT-OD-17-005: Optional Electronic Submission Method to Request to Submit An Unsolicited Application That Will Exceed \$500,000 In Direct Costs



- NIH requires any applicant requesting \$500,000 or more in direct costs (excluding consortium F&A costs) in any one budget period within a competitive segment to contact the NIH Institute or Center Program Official (PO), in writing or by telephone, as early as possible during development of the application but no later than 6 weeks before submission for prior approval.
 - This notice informs applicants that requests to submit an unsolicited application that will exceed \$500,000 in direct costs will now have an option to submit this request electronically through eRA Commons, under a new Prior Approval Module.
 - After initial communication with the NIH, a PO may open up a request form for the Principal Investigator (PI) in eRA Commons. The PI will complete the form and submit it back to the initiating PO for review.
 - Instructions for how to use this new system can be found in the Prior Approval User Guide. For more information on the policy, see section 2.3.7.2 of the NIH Grants Policy Statement.
- Please note that this notice does not reflect a change in policy. This notice is only being issued to identify an optional submission process change in line with NIH's efforts to move toward electronic submission of prior approval requests.

NOT-OD-17-007: NIH Natural Disaster Policy



- NIH realizes that Hurricane Matthew and other seasonal natural disasters may negatively impact an affected applicant organization's ability to make an on-time grant application submission.
- When applications cannot be submitted because the applicant organization is officially closed due to a natural disaster or other emergency, the NIH will consider accepting those applications late, on a case-by-case basis, under the following circumstances:
 - Applications must be submitted as soon as possible after the applicant organization/institution re-opens, not to exceed the number of days the applicant organization was officially closed.
 - A cover letter must be submitted with the application, with enough detail about the delay so that NIH staff can make a determination whether circumstances justify accepting the application late.
- Advance permission to submit late after a disaster-related delay is not required.
- The NIH has established a web page about the NIH Extramural Response to Natural Disasters that provides information on a variety of topics:
 - https://grants.nih.gov/grants/natural_disasters.htm.

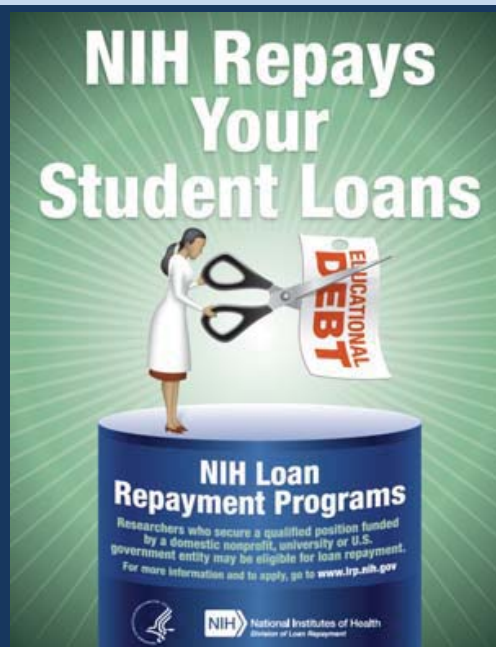
NOT-OD-15-039: Late Application Submission Policy

- There is a two week window of consideration after the application due date, during which time NIH might consider accepting a late application.
- Acceptance of late applications will be made on a case-by-case basis, dependent upon the explanation provided in the cover letter submitted with the application.
- Examples of Reasons Why Late Applications Might Be Accepted
 - Death of an immediate family member of the PD/PI (or MPI).
 - Sudden acute severe illness of the PD/PI (MPI) or immediate family member.
 - Temporary or ad hoc service by a PD/PI on an NIH advisory group during the two months preceding or the two months following the application due date. Refer to notice for examples of qualifying service.
 - Delays due to weather, natural disasters, or other emergency situations, not to exceed the time the applicant organization is closed.
 - For PD/PIs who are eligible for continuous submission the late application policy applies to activities not covered under the continuous submission policy (i.e., other than R01, R21, and R34 funding opportunities that use standard due dates).

NIH Loan Repayment Programs (LRPs)

Summary

- **Up to \$35k/year in educational loan repayment**
 - Depending on debt level
- **Coverage of most Federal taxes resulting from the NIH LRP**
- **2 year initial contracts**
 - 1 or 2 year competitive renewal
- **Approximately 1,600 researchers funded yearly**
- **50% application success rate**



NIH LRP email sent out to UMMS community on 9/16/16. Application cycle closes 11/15/16.

<https://www.lrp.nih.gov/apply>

PROPOSAL SUBMISSIONS TO OSP

September 2015 – September 2016



| | September 2015 | October 2015 | November 2015 | December 2015 | January 2016 | February 2016 | March 2016 | April 2016 | May 2016 | June 2016 | July 2016 | August 2016 | September 2016 |
|------------------------------------|----------------|--------------|---------------|---------------|--------------|---------------|------------|------------|----------|-----------|-----------|-------------|----------------|
| Count | 112 | 129 | 60 | 67 | 107 | 121 | 89 | 72 | 101 | 106 | 78 | 86 | 121 |
| On Time | 52% | 43% | 37% | 42% | 59% | 38% | 45% | 29% | 57% | 40% | 44% | 44% | 56% |
| Late | 43% | 56% | 60% | 54% | 39% | 60% | 55% | 70% | 39% | 59% | 56% | 50% | 40% |
| After the fact | 5% | 1% | 3% | 4% | 2% | 2% | 0% | 1% | 4% | 1% | 0% | 6% | 4% |
| Withdrawn | 0% | 0% | 0% | 0% | 0% | 0% | 0% | 0% | 0% | 0% | 0% | 0% | 0% |
| Total | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% |
| Expedited Request (3 days or less) | 31% | 39% | 40% | 33% | 25% | 46% | 42% | 44% | 21% | 36% | 42% | 35% | 28% |

On Time: Received by OSP 5 business days prior to the requested return date.
Late: Received by OSP less than 5 business days prior to the requested return date.
After the Fact: Received by OSP after the requested return date.
Expedited Request: Received by OSP with 3 business days or less to review before requested return date.

SUBMISSIONS TO OSP

September 2015 to September 2016 Comparison



| PROPOSALS | 2015 | 2016 | Change |
|------------------------------------|------|------|--------|
| Count | 112 | 121 | +9 |
| On Time | 52% | 56% | +4 |
| Late | 43% | 40% | -3 |
| After the fact | 5% | 4% | -1 |
| Withdrawn | 0% | 0% | - |
| Total | 100% | 100% | - |
| Expedited Request (3 days or less) | 31% | 28% | -3 |

On Time: Received by OSP 5 business days prior to the requested return date.
Late: Received by OSP less than 5 business days prior to the requested return date.
After the Fact: Received by OSP after the requested return date.
Expedited Request: Received by OSP with 3 business days or less to review before requested return date.

PROGRESS REPORT SUBMISSIONS TO OSP

September 2015 – September 2016



| | September 2015 | October 2015 | November 2015 | December 2015 | January 2016 | February 2016 | March 2016 | April 2016 | May 2016 | June 2016 | July 2016 | August 2016 | September 2016 |
|------------------------------------|----------------|--------------|---------------|---------------|--------------|---------------|------------|------------|----------|-----------|-----------|-------------|----------------|
| Count | 19 | 30 | 19 | 26 | 36 | 44 | 71 | 58 | 43 | 50 | 25 | 17 | 27 |
| On Time | 37% | 43% | 26% | 42% | 64% | 48% | 58% | 64% | 49% | 52% | 60% | 41% | 67% |
| Late | 47% | 40% | 63% | 50% | 22% | 45% | 39% | 36% | 51% | 42% | 28% | 41% | 22% |
| After the fact | 16% | 17% | 11% | 8% | 14% | 7% | 3% | 0% | 0% | 6% | 12% | 18% | 11% |
| Total | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% |
| Expedited Request (3 days or less) | 26% | 20% | 58% | 42% | 19% | 30% | 27% | 26% | 37% | 36% | 16% | 35% | 19% |

On Time: Received by OSP 5 business days prior to the requested return date.
Late: Received by OSP less than 5 business days prior to the requested return date.
After the Fact: Received by OSP after the requested return date.
Expedited Request: Received by OSP with 3 business days or less to review before requested return date.

SUBMISSIONS TO OSP

September 2015 to September 2016 Comparison



| PROGRESS REPORTS | 2015 | 2016 | Change |
|------------------------------------|------|------|--------|
| Count | 19 | 27 | +8 |
| On Time | 37% | 67% | +30 |
| Late | 47% | 22% | -25 |
| After the fact | 16% | 11% | -5 |
| Withdrawn | 0% | 0% | - |
| Total | 100% | 100% | - |
| Expedited Request (3 days or less) | 26% | 19% | -7 |

On Time: Received by OSP 5 business days prior to the requested return date.
Late: Received by OSP less than 5 business days prior to the requested return date.
After the Fact: Received by OSP after the requested return date.
Expedited Request: Received by OSP with 3 business days or less to review before requested return date.

APPENDIX

**University of Massachusetts Medical School
(UMMS) Office of Global Health (OGH)
FOREIGN PROJECT REGISTRATION FORM**

Anyone initiating, renewing or participating in a foreign project under University of Massachusetts Medical School auspices must complete this registration form. A foreign project is any project that includes one or more of the following: research, education, or clinical work outside of the US; US funding going to an outside organization or external funding from a foreign sponsor; involvement of a foreign collaborator beyond consultation; activity that may be subject to export control; or any activity that may have an impact on US foreign policy throughout the involvement of a foreign country. Depending on the nature of the project, further consultation may be required. ***The foreign project registration form must be completed at the just in time stage (for NIH) or as soon as the investigator is made aware the project will be funded.***

Foreign Project Component (please check all that apply)

- a) Performance of any significant scientific element or segment of a project outside the United States, either by the grantee or by a researcher employed by the grantee.
- b) Clinical work or direct patient care (**please refer to UMass Memorial malpractice policy [here](#)**)
- c) Human subject or animal research in a foreign country (**please refer to [OHRP Intl Compilation of Human Research](#)**)
 - If your work involves clinical research and/or human subjects, please provide **IRB Docket #**
 - If your work involves animal research, please provide **IACUC Docket #**
 - If your work involves human subjects, please describe any personal data or personally identifiable information
- d) Foreign travel by grantee project staff for the purpose of data collection, surveying, sampling, and similar activities.
- e) Any international travel by UMass personnel who are **non-US citizens**
- f) Any travel by foreign collaborators to UMMS
- g) US funding going to a foreign organization or external funding from a foreign sponsor or any activity that may be subject to export control
- h) Any activity of the grantee having an impact on US foreign policy through involvement in the affairs or environment of a foreign country (e.g., USAID)
- i) The *only* Foreign Project Component on your project is the involvement of Other Significant Contributor(s) (OSC(s)) outside the United States.

If you checked i), please proceed to j).

- j) The sole purpose of the OSC's engagement in your project is to provide peer review and technical advice without travel or exchange of samples and/or PII. Yes / No

If you checked YES, the FPR is NOT required for your project. *If you checked no, please answer k).*

- k) Please describe the nature of the contribution by the OSC(s)

Will (or could) the project involve any of the following? Please select all that apply:

- Establishing an office or leasing space in a foreign location
- Hiring non-UMass faculty/staff in a foreign location
- Long-term (>6 months) presence of UMMS faculty/staff on ground in foreign location

STOP: If you did not select any of foreign components listed on this page, you do NOT need to complete a foreign project registration.

PROJECT INFORMATION

Project Title

**If your project is a grant, please ensure the project title matches that of your grant application*

Project Start Date (mm/dd/yy)

PeopleSoft Proposal ID (if applicable)

Scope of work (Please insert your scope of work here **OR** briefly summarize here and include detailed scope of work as a PDF with the submission of this FPR)

Nature of work (please check all that apply)

- Educational
- International Clinical Work/Patient Care
- Research

Other (please specify in scope of work above)

EXPORT AND DATA CONTROLS

Does your project involve company or other proprietary data or technical information? If yes, describe.
If no, enter N/A.

Does your project involve the use of select agents, toxins, viruses or bacteria including shipment of such items to foreign locations?
If yes, describe.
If no, enter N/A.

Does your project involve physical (hand carried or shipment) export abroad or import of any materials or equipment?
If yes, describe.
If no, enter N/A.

LEGAL/INFRASTRUCTURE

Yes / No Is this project covered by a [current MOU](#)? If not, please contact OGH (globalhealth@umassmed.edu) to create one.

FINANCIAL INFORMATION

Grant or Contract International Other (Specify)
 Philanthropy Federal

If you have selected "Grant or Contract", please indicate who the sponsor is

Will the budget require any of the following? (Please check all that apply)

Sub-awards In-Country Bank Account*
 Service Contracts *If selected, please fill out the following information
 Purchase or Rental of Real Estate Intended use of funds
 Purchase or Rental of Vehicles Estimated funding amount
 Field Advances

GENERAL INFORMATION

Principal Investigator

Name:
Email:
Phone:

Project Administrator

Name:
Email:
Phone:

Preferred Contact for this Foreign Project Registration (select one)

Principal Investigator or Project Administrator

FOREIGN PARTNER INFORMATION

Institution/Organization
City
Country

DEPARTMENTAL AGREEMENT

Department

Department Chair Signature _____ Date _____

PACKET CHECKLIST– INCLUDE ALL APPLICABLE

- Fill out this form and combine into a PDF with all necessary supporting documents. Email the form to globalhealth@umassmed.edu. An approval letter will be provided to the PI and department administrator.

- For projects with human subject or animal research the following is required: 1) IRB Docket # and/or IACUC, 2) IRB and/or IACUC approval letter as an attachment. The PI name on the IRB/IACUC must be the same as the name of the PI of this Foreign Project, otherwise please provide a letter of explanation.
- If the project involves export or data controls please provide the [ECC form](#).
- If the project involves import of supplies, reagents or samples, please provide a copy of the signed Material Transfer Agreement (MTA).
- Obtain departmental chair signoff for the project.

NIH Operates Under a Continuing Resolution

Notice Number: NOT-OD-17-001

Key Dates

Release Date: October 7, 2016

Related Announcements

[NOT-OD-16-046](#)

Issued by

National Institutes of Health ([NIH](#))

Purpose

The Department of Health and Human Services (HHS), including NIH, operates under the "Continuing Appropriations and Military Construction, Veterans Affairs, and Related Agencies Appropriations Act, 2017, and Zika Response and Preparedness Act" ([Public Law 114-223](#)) signed by President Obama on September 29, 2016. This Act (CR) continues government operations through December 9, 2016 at 99.504 percent of the FY 2016 enacted level.

Continuing the procedures identified under [NOT-OD-16-046](#) and consistent with NIH practices during the CRs of [FY 2006 – 2016](#), the NIH will issue non-competing research grant awards at a level below that indicated on the most recent Notice of Award (generally up to 90% of the previously committed level). Upward adjustments to awarded levels will be considered after FY 2017 appropriations are enacted, but NIH expects institutions to monitor their expenditures carefully during this period. All legislative mandates that were in effect in FY 2016 (see [NOT-OD-16-044](#) and [NOT-OD-16-048](#)) remain in effect under this CR, as well as the salary limitation set at Executive Level II of the Federal Pay Scale (see [NOT-OD-16-059](#)) and the Ruth L. Kirschstein National Research Service Award stipend levels and tuition/fees (see [NOT-OD-16-062](#)).

Inquiries

Questions regarding adjustments applied to individual grant awards may be directed to the Grants Management Specialist identified on the Notice of Award.

[Weekly TOC for this Announcement](#)
[NIH Funding Opportunities and Notices](#)

Optional Electronic Submission Method to Request to Submit An Unsolicited Application That Will Exceed \$500,000 In Direct Costs

Notice Number: NOT-OD-17-005

Key Dates

Release Date: October 6, 2016

Related Announcements

[NOT-OD-02-004](#)

Issued by

National Institutes of Health ([NIH](#))

Purpose

NIH has a longstanding policy that states any applicant requesting \$500,000 or more in direct costs (excluding consortium F&A costs) in any one budget period within a competitive segment is required to contact the NIH Institute or Center (IC) Program Official (PO), in writing or by telephone, as early as possible during development of the application but no later than 6 weeks before submission for prior approval. Since NIH supports projects with large budgets, the purpose of this policy is for fiscal planning and therefore it provides NIH ICs the appropriate amount of time to consider the possibility of such awards as early as possible in the budget and program planning process.

This notice informs NIH applicants that requests to submit an unsolicited application that will exceed \$500,000 in direct costs will now have an option to submit this request electronically through eRA Commons, under a new Prior Approval Module.

After initial communication with the NIH, a PO may open up a request form for the Principal Investigator (PI) in eRA Commons. The PI will complete the form and submit it back to the initiating PO for review.

Instructions for how to use this new system can be found in the [Prior Approval User Guide](#). For more information on the policy, see section [2.3.7.2 of the NIH Grants Policy Statement](#).

Please note that this notice does not reflect a change in policy. This notice is only being issued to identify an optional submission process change in line with NIH's efforts to move toward electronic submission of prior approval requests.

Inquiries

General inquiries about this notice may be directed to:

Division of Grants Policy
Office of Policy for Extramural Research Administration
National Institutes of Health
6705 Rockledge Drive, Suite 350
Bethesda, MD 20892
Phone: 301-435-0938
Email: GrantsPolicy@od.nih.gov

Please direct all technical-related inquiries to:

eRA Service Desk
Telephone: 1-866-504-9552

Notice Number: NOT-OD-17-007

Key Dates

Release Date: October 14, 2016

Related Announcements

None

Issued by

National Institutes of Health ([NIH](#))

Purpose

NIH realizes that Hurricane Matthew and other seasonal natural disasters may negatively impact an affected applicant organization's ability to make an on-time grant application submission. When applications cannot be submitted because the applicant organization is officially closed due to a natural disaster or other emergency, the NIH will consider accepting those applications late, on a case-by-case basis, under the following circumstances:

- Applications must be submitted as soon as possible after the applicant organization/institution re-opens, **not to exceed the number of days the applicant organization was officially closed.**
- A cover letter must be submitted with the application, with enough detail about the delay so that NIH staff can make a determination whether circumstances justify accepting the application late.

Also, please note:

- Advanced permission to submit late after a disaster-related delay is not required.
- Although the NIH will often issue a Guide Notice like this one, the policy still applies to other disasters and emergencies, including those of a more limited or local nature that are not discussed in a separate NIH Guide Notice.

The NIH has established a web page about the NIH Extramural Response to Natural Disasters that provides information on a variety of topics: https://grants.nih.gov/grants/natural_disasters.htm.

Inquiries

Please direct all inquiries to:

Division of Receipt and Referral
Center for Scientific Review
Telephone: 301-435-0715
Email: csrdrr@mail.nih.gov

Simplifying the NIH Policy for Late Application Submission

Notice Number:

NOT-OD-15-039

Key Dates

Release Date: December 17, 2014

Related Announcements

[NOT-OD-11-035](#)

Issued by

National Institutes of Health ([NIH](#))

Purpose

This Notice provides information about a new simplified policy for late application submission. Specifically, there is now a **two week window of consideration** after the application due date, during which time NIH might consider accepting a late application (see details below). This is a significant change from previous policy, which tied different late windows of consideration to different types of applications, and provided no late window of consideration for applications submitted to any RFA (Request for Applications) or PAR (Program Announcement) with special application due dates.

The Notice consolidates policy from previous Notices (including [NOT-OD-11-035](#)) on late application submission, updates the policy on late applications in relation to changes in other NIH policies and procedures, and includes additional guidance on application submission policies.

This new policy is effective for applications submitted for due dates on or after January 25, 2015. The policy will not be applied retroactively. This means that RFAs and PARs with special due dates published on or before December 17, 2014 will follow the policy described in [NOT-OD-11-035](#).

Policy

Window of Consideration for Late Application Submission

There is a **two week window of consideration** after the application due date, during which time NIH might consider accepting a late application (see details below). When the application due date falls on a weekend or Federal holiday, and is extended to the next business day, the window of consideration for late submission of applications will be calculated from that business day. Acceptance of late applications will be made on a case-by-case basis, dependent upon the explanation provided in a cover letter submitted with the application.

NIH will not consider accepting late applications under the following circumstances:

- RFAs that must be reviewed on a compressed timeline and that have declared, in the Application Due Date field, “No late applications will be accepted for this Funding Opportunity Announcement”.
- New Investigator R01 applications resubmitted on special due dates (April 10, August 10, and December 10) as part of the New Investigator Initiative (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-001.html>) because the submission deadline for these applications has already been extended by several weeks.
- Additional circumstances as outlined below.

| Funding Opportunity Announcement Type | | | |
|----------------------------------------------------------|--------|--------|-----------------------------------------------------------------------------------------------------------------------|
| PA* | PAR | RFA | |
| 2 week | 2 week | 2 week | |
| | | none | Application Due Dates Field states: "No late applications will be accepted for this Funding Opportunity Announcement" |
| *Includes PAS: Program Announcement with Set-Aside Funds | | | |

NIH does not expect to accept any applications received beyond the window of consideration or for RFAs that specify no late applications will be accepted.

Please be aware that any reasons for late submission must be in relation to the individual(s) with the PD/PI role on the application. For multiple PD/PI (MPI) applications, the reasons may apply to any or all of the PD/PIs. This accommodation does not apply to co-Investigators, project leaders in a multi-component application, or other Key Persons listed in an application (unless they also have MPI status).

Examples of Reasons Why Late Applications Might Be Accepted

- Death of an immediate family member of the PD/PI (or MPI).
- Sudden acute severe illness of the PD/PI (MPI) or immediate family member.
- Temporary or ad hoc service by a PD/PI on an NIH advisory group during **the two months preceding or the two months following** the application due date. Examples of qualifying service include: participation in an NIH study section/special emphasis panel, NIH Board of Scientific Counselors, Program Advisory Committee, or an NIH Advisory Board/Council. Qualifying service does not include participation in NIH activities **other than** those involved in extramural/intramural peer review or NIH Advisory Council/Board service.
- Delays due to weather, [natural disasters, or other emergency situations](#), not to exceed the time the applicant organization is closed.
- For PD/PIs who are eligible for continuous submission (https://grants.nih.gov/grants/peer/continuous_submission.htm), the late application policy applies to activities not covered under the continuous submission policy (i.e., other than R01, R21, and R34 funding opportunities that use standard due dates).

Examples of Reasons Why Late Applications Will Not Be Accepted

- Heavy teaching or administrative responsibilities, relocation of a laboratory, ongoing or non-severe health problems, personal events, participation in review activities for other Federal agencies or private organizations, attendance at scientific meetings, or a very busy schedule.
- Review service for participants other than a PD/PI or MPI, acute health issues or death in the family of a participant other than a PD/PI or MPI.
- Problems with computer systems at the applicant organization, problems with a system-to-system grant submission service, or failure to complete or renew required registrations in advance of the application due date.
- Failure to follow instructions in the Application Guide or funding opportunity announcement.
- Correction of errors or addressing warnings after 5 PM local (applicant organization) time on the application due date. Applicants are encouraged to submit in advance of the due date to allow time to correct errors and/or address warnings identified in the NIH validation process.

No Advance Permission Is Given for Late Applications

It is important to emphasize that these various examples are just that, examples. No NIH staff member, whether in the Center for Scientific Review or any of the other NIH Institutes/Centers, has the authority to give permission in advance for submission of a late application. Contacting the Division of Receipt and Referral or any other component of the NIH will not lead to either permission to submit late or to the evaluation or approval of the reasons for a delay.

Problems with Federal Computer Systems

Applicants must follow the directions provided at <https://grants.nih.gov/grants/ElectronicReceipt/support.htm#guidelines> to report Federal computer system issues that threaten the timely submission of a grant application. NIH will investigate reports of Federal computer [system issues](#) on a case-by-case basis. If the eRA Service Desk confirms a Federal computer system issue, the application will not be considered late so long as the applicant works diligently with the Help Desk to ensure the submission process is completed in a timely manner. Federal computer systems include: Grants.gov, eRA Commons, ASSIST, SAM (Systems for Award Management), Defense Logistics Agency (CAGE code), and the US Small Business Administration.

Note that problems with computer systems at the applicant organization or system-to-system grant submission service, failure to follow instructions in the Application Guide or funding opportunity announcement, or failure to complete required registrations by the submission deadline are not considered system issues. NIH is under no obligation to accept applications that are late for these reasons.

Reminders

On Time Submission

- NIH expects that applications will be submitted on time.
- On time submission means an application is submitted error free no later than 5 P.M. local (applicant organization) time on the application due date.
- There is no error correction window that extends a submission deadline. This means that an error free, corrected application addressing any errors found by federal systems (e.g., Grants.gov or eRA Commons) must also be submitted by 5 P.M. local (applicant organization) time on the application due date.
- When application due dates fall on a weekend or Federal holiday, they are extended to the next business day.

Late Submission

The NIH policy on late application submission is stated in the [SF424 \(R&R\) Application Guide](#).

- Permission for late application submission is not granted in advance.
- In some cases (see details, below), applications might be accepted after the application due date. A cover letter explaining the reasons for the delay must be included with the application.
- While the reasons for late application submission are sometimes personal in nature, specific information about the timing and cause of the delay should be provided so an informed, objective decision can be made. Only the explanatory letter is needed; no other documentation is expected. This letter is available only to NIH staff who have a need to know (such as those with referral or review responsibilities); it is not available to reviewers or other staff.
- Applications submitted late, without an explanatory cover letter or outside the late window of consideration, will not be processed, reviewed, or considered for funding.

Terms and conditions of the NIH [Continuous Submission](#) policy are not affected by this change in the late application submission policy.

Terms and conditions of the [NIH Natural Disaster policy](#) are not affected by this change in the late application submission policy.

Inquiries

Please direct all inquiries to:

Division of Receipt and Referral
Center for Scientific Review
csrdrr@mail.nih.gov

Or

NIH Review Policy Officer
NIH Office of Extramural Research
ReviewPolicyOfficer@mail.nih.gov

[Weekly TOC for this Announcement](#)
[NIH Funding Opportunities and Notices](#)

ACRONYMS AND TERMS USED TODAY
OSP RA Update - 10/26/2016

| ACRONYM/TERM | DESCRIPTION |
|----------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| ASSIST (NIH) | Application Submission System & Interface for Submission Tracking |
| Continuing Resolution (CR) | A type of appropriations legislation that sets aside for money to specific federal government departments, agencies, and programs. The money provides funding for operations, personnel, equipment, and activities. |
| DHHS (aka HHS & USDHHS) | Department of Health & Human Services |
| eRA Commons | The eRA Commons is NIH's online interface where signing officials, principal investigators, trainees and post-docs at institutions/organizations can access and share administrative information relating to research grants and process prior approval requests. |
| FPR | Foreign Project Registration |
| IAR (NIH) | Internet Assisted Review. A web-based system used in tandem with the Peer Review module to expedite the scientific review of grant applications. |
| iEdison (NIH) | iEdison (which stands for Interagency Edison) helps government grantees and contractors comply with a federal law, the Bayh-Dole Act. Bayh-Dole regulations require that government funded inventions be reported to the federal agency who made the award. |
| LRP | NIH's Loan Repayment Program |
| MPI | Multiple Principal Investigator |
| NIH | National Institutes of Health |
| NOT | A Notice (Guide Notice) is an official NIH announcement relating to a change in policy, procedure, form, or system. Notices are posted on the NIH website and users can be notified via a variety of NIH listservs. You can search for notices and funding opportunities at the NIH Guide. |
| NRSA | National Research Service Awards |
| OGH | Office of Global Health |
| OMB | Office of Management and Budget |
| OSC | Other Significant Contributor |
| OSP | Office of Sponsored Programs |
| PI | Principal Investigator |