Research Administration Update

Wednesday, January 31 , 2018

Lazare Auditorium (S1-607)
1:00 - 2:00 pm

Agenda

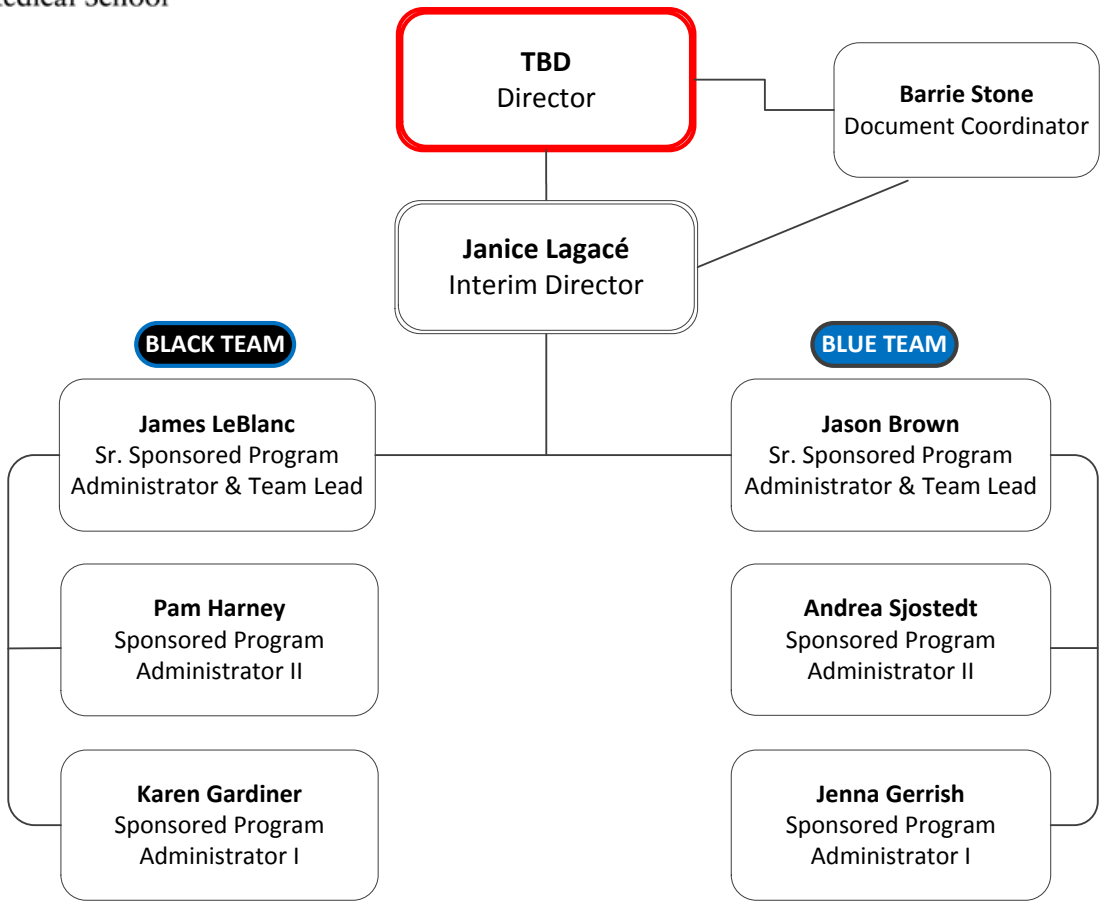
University of Massachusetts UMASS Medical School

- OSP Updates
  - OSP Staffing
  - Indirect Waiver requests/Cost Share approvals
  - Other AOR related changes
  - Change in IDP language
  - Proposal Information Worksheet
- NIH Updates
  - NOT-OD-17-062 FORMS-E
  - NOT-GM-18-011 MIRA R35 Letter of Support
  - NOT-OD-18-107 Enforcement of Closeout Policy
- Proposal & Progress Report Statistics

OSP Updates

University of Massachusetts UMASS Medical School

Office of Sponsored Programs



OSP Updates

University of Massachusetts UMASS Medical School

- Indirect Waivers & Cost Share Approvals
  - PI requests Department Chair Approval
  - Submit to Interim Director Janice Lagacé
  - OSP will consult with RAC Subcommittee Chair Dr. Catarina Kiefe MD, PhD

Reminder that all IDC waivers will have a direct impact on the allocation to Departments

OSP Updates

University of Massachusetts UMASS Medical School

- Cayuse Proposals – Adding the AOR

1. TYPE OF SUBMISSION
- Pre-application
- Application
- Changed/Corrected Application

4. a. Federal Identifier

b. Agency Routing Number

c. Previous Grants.gov Tracking ID

5. APPLICANT INFORMATION

Legal Name:	University of Massachusetts Medical School	Organizational DUNS:	603847393
Department:		Division:	
Street1:	55 Lake Avenue North	Street2:	
City:	Worcester	County/Parish:	Worcester
State/Province:	Massachusetts	Zip/Postal Code:	01655-0002
Country:	United States of America		

Person to be contacted on matters involving this application

Prefix: First Name: Middle Name: Last Name: Suffix:

Position/Title:			
Street1:		Street2:	
City:		County/Parish:	
State/Province:	Please Select...	Zip/Postal Code:	
Country:	Please Select...		

Phone Number: Fax Number: Email:

6. EMPLOYER IDENTIFICATION NUMBER(EIN) or (TIN):
1-043167352-A1

7. TYPE OF APPLICANT:
H: Public/State Controlled Institution of Higher Education

Other (Specify):

Small Business Organization Type
- Women Owned
- Socially and Economically Disadvantaged

8. TYPE OF APPLICATION:
- New
- Resubmission
- Renewal
- Continuation
- Revision

OSP Updates

University of Massachusetts UMASS Medical School

- Cayuse Proposals – Adding the AOR

Secure | https://umassmed.cayuse424.com/1/listPeopleToAutofill.do?subsessionId=0&role=ac&contactNumber=&listType...

Add Applicant Contact to Proposal

Close

Search

Show Recently Used

eRA Role Filter: Any/all (unfiltered)

Any/all (unfiltered)
Administrative Official
Assistant
Principal Investigator
Signing Official / AOR
Payee

All 4064 Available Professional Profiles:

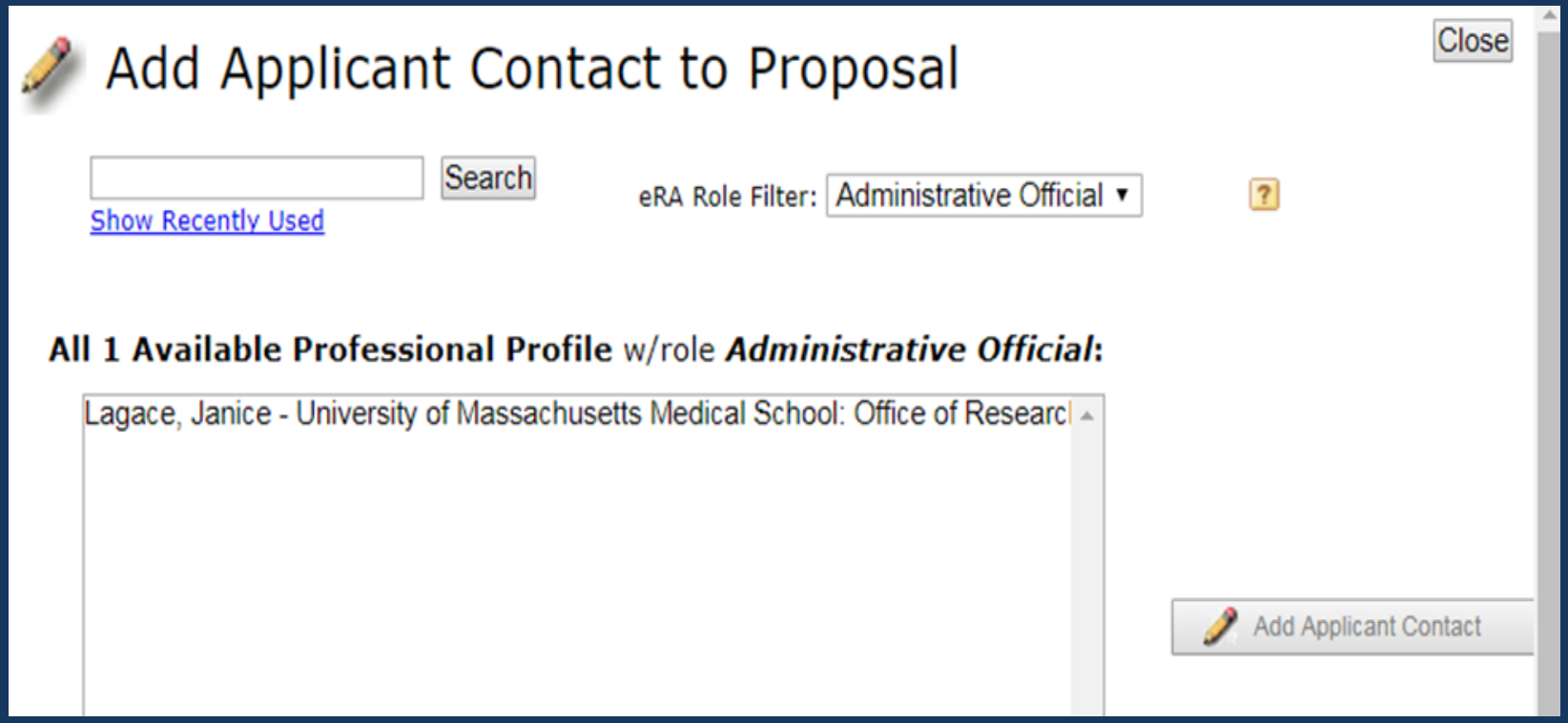
Aaker, Elizabeth - University of Massachusetts Medical Scho
Abar, Beau - University of Massachusetts Medical School
Abdel-Motal, Ussama M. - University of Massachusetts Medical School: Medicin
Abdi, Reza - Brigham and Women's Hospital: Medicine
Abel, Gregory A - Dana-Farber Cancer Institute
Acar, Ceren - University of Massachusetts Medical School: Pulmonary
Acharya, Jairaj - National Institutes of Health
Acharya, Usha - University of Massachusetts Medical School: PGFE
Adachi-Mejia, Anna - N/A
Adair, Robin - University of Massachusetts Medical School
Adams Jr., Spencer Todd - University of Massachusetts Medical School: Biocher
Adams, Jena - Central MA Area Health Education Center: Central MA AHEC
Adams, Jodi - University of Massachusetts Medical School
Adams, Kenneth - HealthPartners Research Foundation: HealthPartners Resear
Adams, Michael - Georgetown University: Medicine
Addis, Michael - Clark University : Psychology
Adkins, Nicholas L. - University of Massachusetts Medical School: Molecular Me
Adler, Ronald N. - University of Massachusetts Medical School
Adler, Stuart - Virginia Commonwealth University: Pediatrics, Microbiology and M
Adshead, Richard A. - University of Massachusetts Medical School: Microbiology

Add Applicant Contact

OSP Updates

University of Massachusetts Medical School
UMASS

- Cayuse Proposals – Adding the AOR



OSP Updates

University of Massachusetts UMASS Medical School

- Cayuse Proposals – AOR in Routing Chain

Routing & Approval

Routing Chain Edit Chain?

Begin

- Pagoto, Sherry L - University of Massachusetts Medical School: Preventive & Behavioral Med.
- RFS, - University of Massachusetts Medical School: Office of Research
- Lagace, Janice - University of Massachusetts Medical School: Office of Research

End

An AOR is on the routing chain, but has not yet approved this proposal. The proposal will not be submittable until an AOR has approved the proposal.

Routing History

username	person	type	date/time	comments
LagaceJ		Modify	2018-01-23 09:26	Auto-built chain at create time from PI

OSP Updates

University of Massachusetts UMASS Medical School

- PeopleSoft Proposal Routing Forms

  If PI has not been added to the system, please use:

Report ID: UMGM7002
Environment: Production

UNIVERSITY OF MASSACHUSETTS
PROPOSAL ROUTING FORM

Page No: 1
Run Date: 01/30/2018
Run Time: 12:23:26_PM

Proposal No. 000000000027943

Status: STSR - Submit for Approval

I. Principal Investigator Information

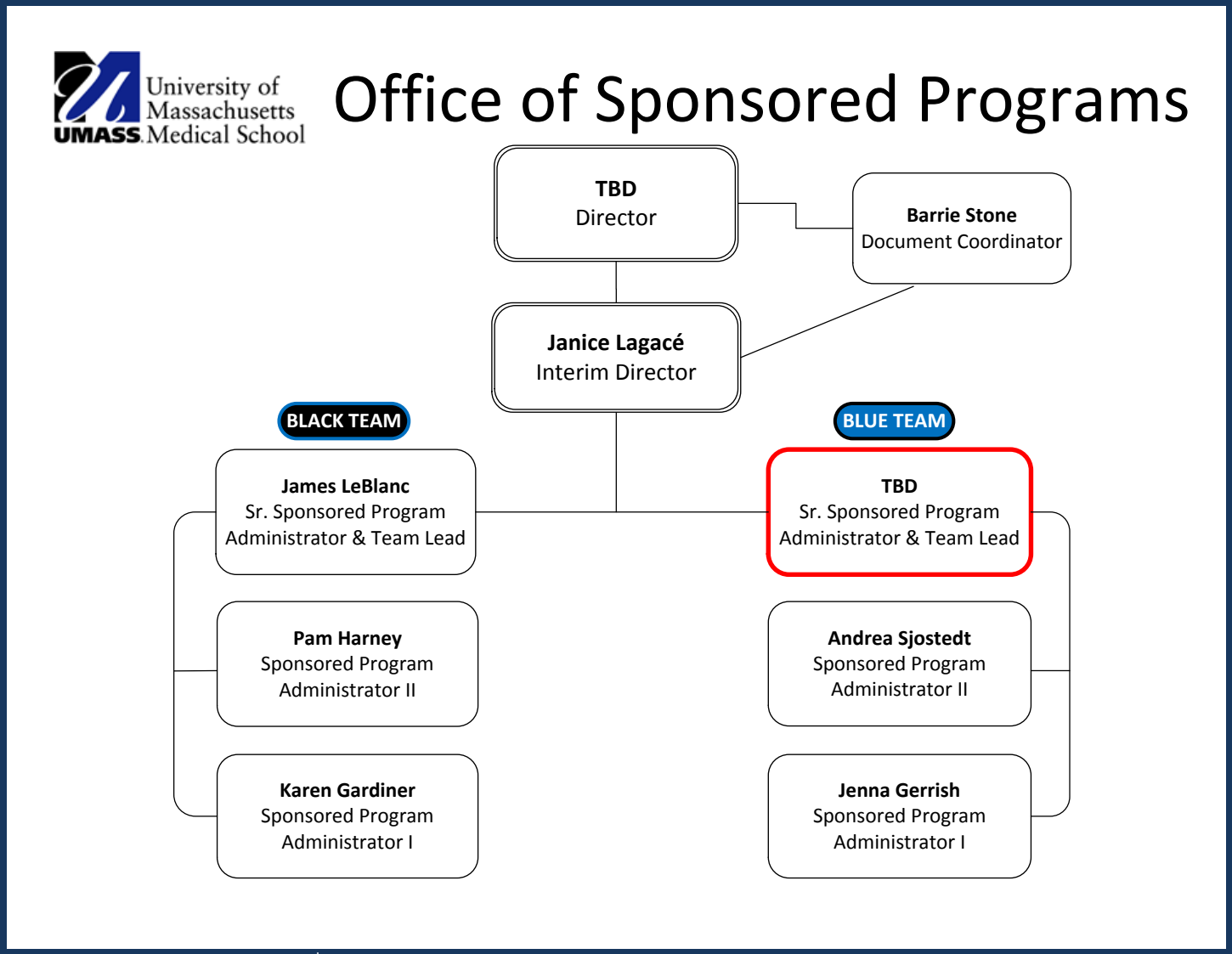
PI Name: Lagace,Janice E
Department: W495000000 - Molecular Cell & Cancer Biolog
PI Phone:
PI Email:

Alt Name: eddy,jenna
Alt. Phone 508/341-4405
Alt. Email jenna.eddy@umassmed.edu
Requested Return Date: 02/01/2018

II. Proposal Information

OSP Updates

University of Massachusetts UMASS Medical School



OSP Updates

University of Massachusetts
UMASS Medical School

Blue Team Administrators

- All February Blue Team RPPR's should be routed to Jenna Gerrish.
- List Janice Lagacé as the AOR and Jason Brown as the SO.
- After 2/16/2018 contact Janice Lagacé or SPA II Andrea Sjostedt.

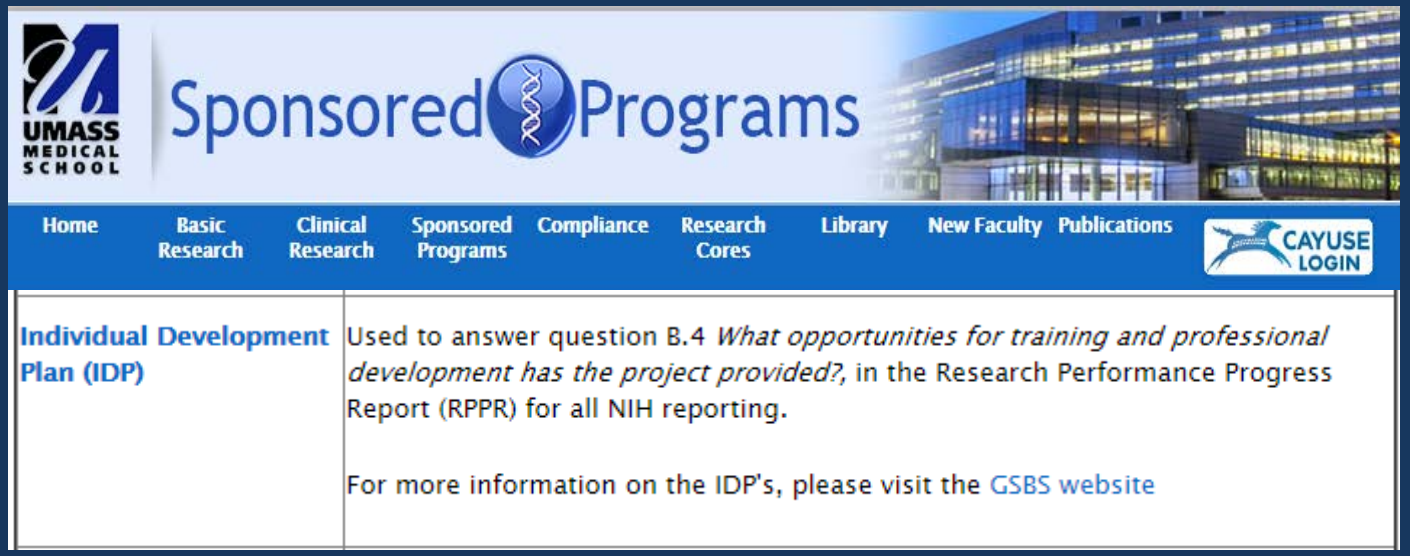
OSP Updates

University of Massachusetts UMASS Medical School

Individual Development Plan

Revised language has been issued by the GSBS for responding to the IDP question:

B.4 WHAT OPPORTUNITIES FOR TRAINING AND PROFESSIONAL DEVELOPMENT HAS THE PROJECT PROVIDED?



https://www.umassmed.edu/research/funding/rfsform/

OSP Updates

University of Massachusetts UMASS Medical School

Individual Development Plan

UMass Medical School recognizes the critical importance of preparing our graduate students and postdoctoral scholars for success within a broad spectrum of scientific careers. All graduate students in year 3 and above are required to create an annual Individual Development Plan (IDP). The curriculum for graduate students now incorporates a course in the fall of the third year called Professionalism and Research Conduct (PARC) in which career planning and development and responsible conduct of research are taught. Included in the course is creation of the students' first IDP. Updates and re-evaluation are required and monitored by the Graduate School of Biomedical Sciences annually. All incoming postdocs receive training in how to create an IDP as part of the required onboarding course in Responsible Conduct of Research. All trainees at UMMS have the resources of the Office for Postdoctoral Scholars and the Center for Biomedical Career Development open to them. This includes one-on-one mentoring and/or problem solving, internal workshops and career exploration options, as well as series of external speakers who discuss career choices or who present lectures and/or workshops on a wide range of skills relevant to biomedical scientists.

OSP Updates

University of Massachusetts UMASS Medical School

Proposal Information Worksheet

- Suggested by the Grants Focus Group
- Work group under the direction of Rik Madison
- Assist with capturing the required information when building a proposal

https://www.umassmed.edu/research/funding/rfsform/

OSP Updates

University of Massachusetts UMASS Medical School

Proposal Information Worksheet

1. General Information

Proposal Information Worksheet

This worksheet is a standardized form used to obtain and communicate essential information pertaining to the initiation of a proposal submission between the PI and Department Administration. Please complete as much information as known at this time and forward to the appropriate administrative contact in your department who is responsible for coordinating the application process.

Administrative Use:

Initial Notification (When/How):

Meeting/Forum and Date:

OSP Request Return Due Date:

Administrative Coordinator:

Proposal ID #: **Project ID #:**

General Information

Principal Investigator (PD/PI) Name: _____ **Multi PD/PI:** ◯ Yes ◯ No **Are you the Contact PI:** ◯ Yes ◯ No

Other PD/PI Name(s): _____ **Outside Contact(s):** _____

Sponsor: ◯ NIH ◯ CDC ◯ HRSA ◯ DOD ◯ NSF ◯ State ◯ Non-Profit ◯ Hughes ◯ Industry ◯ Subcontract (Other Institution is Prime)

Other/Specify: _____

Application in Response to a Specific Opportunity: ◯ Yes ◯ No PA/RFP/RFA# _____ Agency Due: _____ (Date) _____ (Time)

Award Type/Code: ◯ R01 ◯ R21 ◯ R37 ◯ K-Award ◯ P01 ◯ U19 ◯ SBIR/STTR ◯ Contract ◯ Fellowship ◯ Other/Specify:

Application Type: ◯ New ◯ Resubmission (Include ID# _____) ◯ Renewal ◯ Revision ◯ Continuation ◯ Supplement ◯ Transfer In

◯ Other: _____

Type of Submission: ◯ Cayuse ◯ Sponsor Website ◯ Paper ◯ Email/Electronic ◯ Other/Specify: _____

Provide a Quick/Nickname to refer to: _____

Title if Known: _____

OSP Updates

University of Massachusetts UMASS Medical School

Proposal Information Worksheet

2. Budget/Personnel Information

Budget/Personnel Information

Budget Type: ◯ Modular ◯ Detailed ◯ No Budget Required ◯ Other: _____ **Project Start Date:** _____ **Number of Years:** _____

Cost Sharing Requirements (Personnel or Other): ◯ Yes ◯ No

If Yes, Provide Specifics: _____

Target Amount: Direct $ _____ Total $ _____ **Equipment:** ◯ Yes ◯ No $ _____

Item(s): _____

Other Budgetary Restrictions: _____

List Personnel/Effort and who's Key:

1. _____	**Role:** PD/PI	**Effort:** ____ %	**Key:** ◯ Yes ◯ No	**Incl on SDFI:** ◯ Yes ◯ No
2. _____	**Role:** _____	**Effort:** ____ %	**Key:** ◯ Yes ◯ No	**Incl on SDFI:** ◯ Yes ◯ No
3. _____	**Role:** _____	**Effort:** ____ %	**Key:** ◯ Yes ◯ No	**Incl on SDFI:** ◯ Yes ◯ No
4. _____	**Role:** _____	**Effort:** ____ %	**Key:** ◯ Yes ◯ No	**Incl on SDFI:** ◯ Yes ◯ No
5. _____	**Role:** _____	**Effort:** ____ %	**Key:** ◯ Yes ◯ No	**Incl on SDFI:** ◯ Yes ◯ No
6. _____	**Role:** _____	**Effort:** ____ %	**Key:** ◯ Yes ◯ No	**Incl on SDFI:** ◯ Yes ◯ No
7. _____	**Role:** _____	**Effort:** ____ %	**Key:** ◯ Yes ◯ No	**Incl on SDFI:** ◯ Yes ◯ No

Are there any Other Significant Contributors: ◯ Yes ◯ No

If yes, list Name/Institution/Department: _____

Are there Outgoing Sub-Recipients: ◯ Yes ◯ No

If yes, List Who and Projected Amounts: _____

Will project involve foreign travel and activities outside the US or partnerships with international collaborators: ◯ Yes ◯ No

(if Yes, Contact Travel Office for approval)

OSP Updates

University of Massachusetts UMASS Medical School

Proposal Information Worksheet - Three Areas

3. Certifications/Other

Certifications/Other Information

Human Subjects: ◯ Yes ◯ No ◯ Pending Protocol/Docket#: _____ Approval Date: _____ Expiration Date: _____

Code/Description: _____

Clinical Trial: ◯ Yes ◯ No Phase III: ◯ Yes ◯ No

Animal Subjects: ◯ Yes ◯ No ◯ Pending Protocol/Docket#: _____ Approval Date: _____ Expiration Date: _____

Code/Description: _____

Other Requirements/Certificates: _____

Provide Key Words (up to 3): _____ _____ _____

https://www.umassmed.edu/research/funding/rfsform/

NIH Updates

University of Massachusetts UMASS Medical School

NOT-OD-17-062 Forms E

Use FORMS-D for…	Use FORMS-E for…
Applications submitted for due dates on or before January 24, 2018 Applications submitted under NIH Late Policy 2-week window of consideration for intended due dates on or before January 24, 2018 Applications submitted by February 7, 2018 under NIH Continuous Submission Policy for January 7, 2018 AIDS intended due date	Applications submitted for due dates on or after **January 25, 2018** All application types (New, Resubmission, Renewal, Revision) Applications submitted early for intended due dates on or after January 25, 2018

NIH Updates

University of Massachusetts UMASS Medical School

NOT-OD-17-062 Forms E

Directly effects all February 5th submissions.

There are now two Parent Opportunities for R01's & R21's

+	PA-18-484	NIH Research Project Grant (Parent R01 Clinical Trial Not Allowed)	FORMS-E
+	PA-18-345	NIH Research Project Grant (Parent R01 Clinical Trial Required)	FORMS-E

– Verify that you have chosen the correct PA

+	PA-18-344	NIH Exploratory/Developmental Research Grant Program (Parent R21 Clinical Trial Required)	FORMS-E
+	PA-18-489	NIH Exploratory/Developmental Research Grant Program (Parent R21 Clinical Trial Not Allowed)	FORMS-E

NIH Updates

University of Massachusetts UMASS Medical School

NOT-OD-17-062 Forms E

- The most significant change with the new FORMS-E Application Package is the addition of a new PHS Human Subjects and Clinical Trials Information form.
- This form consolidates human subjects, inclusion enrollment, and clinical trial information previously collected across multiple agency forms.
- The information is collected at the study level.
- Allows for multiple studies.

NIH Updates

University of Massachusetts UMASS Medical School

NOT-OD-17-062 Forms E

PHS Human Subjects and Clinical
1
RR Subaward Budget Attachment
1
PHS 398 Cover Page Supplement
1
2
PHS 398 Research Plan
1
PHS Assignment Request
1

Proposal Summary
Summary
Documents

Proposal Management
Permissions
Routing & Approval
Electronic Submission
Proposal History
Export

Add a record for each proposed Human Subject Study by selecting 'Add New Study' or 'Add New Delayed Onset Study' as appropriate. Delayed onset studies are those for which there is no well-defined plan for human subject involvement at the time of submission, per agency policies on Delayed Onset Studies. For delayed onset studies, you will provide the study name and a justification for omission of human subjects study information.

Other Requested Information

(no pdf) (no src) Add Attachment Delete Attachment

Study Record(s)

Attach human study records using unique filenames.

Add New Study Import Study

#	Study Title	Is a Clinical Trial
1	LEAVE Safe with DOACs	✓

Delayed Onset Study(ies)

Add New Delayed Onset Study

#	Study Title	Anticipated Clinical Trial?	Justification

NIH Updates

University of Massachusetts UMASS Medical School

NOT-OD-17-062 Forms E

Section 1 - Basic Information

1.1. * Study Title (each study title must be unique)

LEAVE Safe with DOACs

1.2. * Is this Study Exempt from Federal Regulations? ○ Yes ◉ No

1.3. Exemption Number ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8

1.4. * Clinical Trial Questionaire

If the answers to all four questions below are yes, this study meets the definition of a Clinical Trial.

1.4.a. Does the study involve human participants? ◉ Yes ○ No

1.4.b. Are the participants prospectively assigned to an intervention? ◉ Yes ○ No

1.4.c. Is the study designed to evaluate the effect of the intervention on the participants? ◉ Yes ○ No

1.4.d. Is the effect that will be evaluated a health-related, biomedical, or behavioral outcome? ◉ Yes ○ No

1.5. Provide the ClinicalTrials.gov Identifier (e.g., NCT87654321) for this trial, if applicable

If there is not a related number, leave this field blank.
Do not enter N/A.

NIH Updates

University of Massachusetts UMASS Medical School

NOT-OD-17-062 Forms E

Section 2 - Study Population Characteristics

2.1. Conditions or Focus of Study

Anticoagulation in VTE Patients

Add New Condition

2.2. Eligibility Criteria

Inclusion:
1. Age 18 years or older

2.3. Age Limits Minimum Age 18 Years Maximum Age N/A (No limit)

2.4. Inclusion of Women, Minorities, and Children

Kapoor_AHRQ_LEAVE-Safe_InclusionWomenMinoritiesChildren_FINAL pdf (no src) Add Attachment Delete Attachment

2.5. Recruitment and Retention Plan

Kapoor_AHRQ_LEAVE-Safe_RecruitmentRetention_FINAL pdf (no src) Add Attachment Delete Attachment

2.6. Recruitment Status Not yet recruiting

2.7. Study Timeline Kapoor_AHRQ_LEAVE-Safe_StudyTimeline_FINAL pdf (no src) Add Attachment Delete Attachment

2.8. Enrollment of First Subject 01/01/2019 Anticipated

Be careful with any text box fields and avoid the use of symbols or character such as the < and >

NIH Updates

University of Massachusetts UMASS Medical School

NOT-OD-17-062 Forms E – Helpful Links and Info

G.500 - PHS Human Subjects and Clinical Trials Information

The PHS Human Subjects and Clinical Trials Information form is used to collect information on human subjects research, clinical research, and/or clinical trials, including study population characteristics, protection and monitoring plans, and a protocol synopsis.

This form accommodates the full spectrum of all types of clinical trials, including, but not limited to, behavioral, exploratory/development, mechanistic, pilot/feasibility, early phase, efficacy, effectiveness, group-randomized, and others.

Read all the instructions in the Funding Opportunity Announcement (FOA) before completing this form to ensure your application meets all IC-specific criteria. If you are proposing a clinical trial, make sure your FOA accepts clinical trials (i.e., 'clinical trial required' or 'clinical trial optional').

The PHS Human Subjects and Clinical Trials Information form, together with the rest of your application, should include sufficient information for the evaluation of the project, independent of any other documents (e.g., previous application). Be specific, describe each study clearly, and avoid redundancies. Be especially careful to avoid redundancies with your research strategy.

NIH Updates

University of Massachusetts UMASS Medical School

NOT-OD-17-062 Forms E – Helpful Links and Info

https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general/g.500-phs-human-subjects-and-clinical-trials-information.htm

Please share this link with your PI's.

NIH Updates

University of Massachusetts UMASS Medical School

NOT-GM-18-011 MIRA R35 Letter of Support

- Letter of support from the institution's Authorized Organizational Representative (AOR) for submission of an application to PAR-17-094 "Maximizing Investigators' Research Award (R35)"
- Upload the Letter of Support to Section 9 of the Research Plan form
- Applications that omit this letter, or that do not indicate their acceptance of the conditions of an award, will be withdrawn without review.
- Contact our office if you need an example of the format

NIH Updates

University of Massachusetts UMASS Medical School

NOT-OD-18-1017 Enforcement of Closeout Policy

- NIH recipients must submit within 120 days:
  - Final Federal Financial Report (FFR)
  - Final Research Performance Progress Report (F-RPPR)
  - Final Invention Statement
- Failure to submit timely reports may cause Unilateral Closeout resulting in:
  - corrective actions
  - withholding of further awards
  - suspension or termination

NIH Updates

University of Massachusetts UMASS Medical School

NOT-OD-18-1017 Enforcement of Closeout Policy

From: Stone, Barrie
Sent: Monday, January 29, 2018 11:06 AM
To: Administrator & PI
Subject: close out language sent to PI and Admin

The Final Research Performance Progress Report (FRPPR) is submitted through the Commons in a format similar to the annual Research Performance Progress Report (RPPR). Further guidance and screenshots can be found here: https://era.nih.gov/erahelp/commons/Commons/status/closeout/Final_RPPR.htm

Please note that Section D.1 Participants is REQUIRED for the FRPPR. Your administrator, CC'ed on this email, should be able to assist in providing you the information and assistance needed to complete this section. Unlike the Annual Progress Report (RPPR), a FRPPR cannot be accessed by a delegate or routed to a delegate for assistance.

It must be completed under your Commons Account.

Once the FRPPR is completed and no errors are found on validation it can be submitted directly to the NIH. It does not require routing to our office for review.

The Final Invention Statement is also done electronically through the Commons. **There is no need to complete and submit a paper form.**
Please see attached guidance on submitting a Final Invention Statement through the Commons. The Final Invention statement does require verification and submission by the Office of Sponsored Programs. We will receive automatic notification directly from the Commons when your part has been completed.

The Final Federal Financial Report is uploaded and submitted by Grant Accounting. No action is required on your part.

If you have any questions, please do not hesitate to ask!

NIH Updates

University of Massachusetts UMASS Medical School

NOT-OD-18-1017 Enforcement of Closeout Policy

From: XXXXXXXX@od.nih.gov
Sent: Monday, January 29, 2018 12:36 AM
To: Research Funding <ResearchFunding@umassmed.edu>
Cc: XXXXXXXX @umassmed.edu>
Subject: CONTINUING FEDERAL NON-COMPLIANCE, Closeout of Grant 5R21NS095635-02

Dear Signing Official:

This is in follow up to our letters dated 09/06/2017 and 12/30/2017 regarding the closeout documents for the above referenced grant. In accepting the grant, your institution agreed to comply with our policies, including the requirement for submitting final reports in a timely manner. Despite our efforts, the following report, identified below, are now 30 days or more past due or the report submitted was unacceptable;

Final Research Performance Progress Report (FRPPR): An FRPPR is required, per section 8.6.2 of the NIH Grants Policy Statement. NIH requires submission of the FRPPR via the eRA Commons at https://commons.era.nih.gov/commons. Information on the FRPPR, including screenshots and an instruction guide, may be found at: http://grants.nih.gov/grants/rppr/index.htm

Final Invention Statement (HHS 568): The Final Invention Statement form is located at http://grants.nih.gov/grants/forms.htm

We are concerned that your institution has been unable to comply with the terms and conditions of the award by submitting the required closeout documents. As previously noted, failure to submit timely and accurate closeout documents may affect future funding to the organization. Additionally, without UNIV OF MASSACHUSETTS MED SCH WORCESTER's cooperation in submitting acceptable final reports, NIH may take unilateral action to close the grant as a measure of last resort, and may also take additional actions, including, but not limited to, enforcement actions that may affect future funding. Unilateral closeout is a measure of last resort.

Again, you are reminded that the immediate submission of these reports is imperative.

Please contact me if you have questions.

Sincerely,

Grants Closeout Specialist

PROPOSAL SUBMISSIONS TO OSP
December 2016 – December 2017

University of Massachusetts
UMASS Medical School

	December 2016	January 2017	February 2017	March 2017	April 2017	May 2017	June 2017	July 2017	August 2017	September 2017	October 2017	November 2017	December 2017
Count	48	103	108	90	52	87	98	47	64	102	112	54	53
On Time	46%	53%	52%	55%	40%	46%	47%	57%	45%	52%	46%	48%	53%
Late	46%	41%	43%	44%	58%	54%	50%	34%	49%	45%	51%	50%	41%
After the fact	8%	5%	5%	1%	2%	0%	3%	9%	6%	3%	3%	2%	6%
Withdrawn	0%	1%	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)	33%	22%	28%	33%	44%	28%	36%	21%	34%	27%	36%	30%	25%

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.

PROPOSAL SUBMISSIONS TO OSP
December 2016 – December 2017

University of Massachusetts
UMASS Medical School

PROPOSALS	2016	2017	Change
Count	48	53	+5
On Time	46%	53%	+7
Late	46%	41%	-5
After the fact	8%	6%	-2
Withdrawn	0%	0%	-
Total	**100%**	**100%**	-
Expedited Request (3 days or less)	33%	25%	-8

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
December 2016 – December 2017

University of Massachusetts
UMASS Medical School

	December 2016	January 2017	February 2017	March 2017	April 2017	May 2017	June 2017	July 2017	August 2017	September 2017	October 2017	November 2017	December 2017
Count	35	43	38	59	50	51	49	30	23	34	23	34	36
On Time	63%	68%	58%	54%	62%	59%	63%	37%	52%	47%	61%	65%	56%
Late	37%	30%	39%	42%	32%	35%	29%	50%	39%	29%	26%	29%	36%
After the fact	0%	2%	3%	4%	6%	6%	8%	13%	9%	24%	13%	6%	8%
Total	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**
Expedited Request (3 days or less)	23%	21%	32%	25%	26%	22%	22%	40%	26%	24%	9%	21%	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.

PROGRESS REPORT SUBMISSIONS TO OSP
December 2016 – December 2017

University of Massachusetts UMASS Medical School

PROGRESS REPORTS	2016	2017	Change
Count	35	36	+1
On Time	63%	56%	-7
Late	37%	36%	-1
After the fact	0%	8%	+8
Total	**100%**	**100%**	-
Expedited Request (3 days or less)	23%	19%	-4

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

NIH Forms E Human Subject Clinical Trial Forms

HS/CT Forms and Documents	Human Subjects, Exemption 4	Human Subjects, no Clinical Trial	Clinical Trial
Study Record Form	Required	Required	Required
Study Record Form: Section 1, 2, 3	Required	Required	Required
Study Record Form: Section 4-5	Do not complete	Do not complete	Required
Inclusion of Women, Minorities, & Children section 2.4	Required	Required	Required
Recruitment and Retention Plan section 2.5	Not required	Required if study involves human participants	Required
Study Timeline section 2.7	Not required	Required if study involves human participants	Required
Inclusion Enrollment Report	Not required	Required	Required
Protection of Human Subjects section 3.1	Not required	Required for all non-exempt research. For exempt, provide justification for exemption.	Required
Single IRB section 3.2	Required only for Multi-site study	Required only for Multi-site study	Required only for Multi-site study
Data and Safety Monitoring Plan section 3.3	Optional	Optional	Required
Overall Structure of the Study Team section 3.5	Optional	Optional	Required
Statistical Design and Power section 4.4	Do not include	Do not include	Required
FDA Regulated Intervention section 4.6A	Do not include	Do not include	Required for FDA-regulated intervention study
Dissemination Plan section 4.7	Do not include	Do not include	Required
Other Requested Information	Do not include	Do not include	As required by the FOA

New NIH "FORMS-E" Grant Application Forms and Instructions Coming for Due Dates On or After January 25, 2018

Notice Number: NOT-OD-17-062

Key Dates
Release Date: April 27, 2017

Related Announcements
NOT-OD-18-004
NOT-OD-17-119
NOT-OD-17-114
NOT-OD-16-147
NOT-OD-17-043
NOT-OD-18-009

Issued by
National Institutes of Health (NIH)

Purpose

This notice informs the biomedical and health services research communities of changes to grant application form and application guide instructions for due dates on or after January 25, 2018.

Focus of changes:

- Consolidation of human subjects, inclusion enrollment, and clinical trial information previously collected across multiple agency forms
- Expansion and use of discrete form fields for clinical trial information to
  - provide the level of information needed for peer review;
  - lead applicants through clinical trial information collection requirements;
  - present key information to reviewers and agency staff in a consistent format; and
  - align with ClinicalTrials.gov (where possible) and position us for future data exchange with ClinicalTrials.gov
- Incorporation of recent Grants.gov changes to R&R Budget and SBIR/STTR Information forms

These changes will be implemented with application form packages identified with a Competition ID of "FORMS-E" and associated application guide instructions. See High-level Summary of Form Changes in FORMS-E Application Packages for a full list of changes.

Effective Date

Applicants must use FORMS-E application packages for due dates on or after January 25, 2018 and must use FORMS-D application packages for due dates on or before January 24, 2018. Applications submitted using the wrong forms for their intended due date will not be reviewed.

Availability of FORMS-E Application Guides

Application guides for FORMS-E application packages will be posted to the How to Apply - Application Guide page no later than October 25, 2017.

Availability of FORMS-E Application Packages

We will begin posting new funding opportunity announcements (FOAs) with FORMS-E application packages on October 25, 2017.

- New FOAs posted before October 25, 2017 with initial due dates on or after January 25, 2018 will be posted without application forms. Application packages will be added to these FOAs by November 10, 2017.

All NIH "parent" announcements that use standard due dates will be expired and reissued with new FOA numbers, FORMS-E application packages and instructions. The FORMS-E parent announcements will be posted no later than 60 days before their standard due date. For a transition period, both FORMS-D and FORMS-E parent announcements will be active. Applicants must choose the announcement with the appropriate application package for their due date (see table below).

All active FOAs with due dates both before and after January 25, 2018 will be updated to add FORMS-E application packages between October 25, 2017 and November 25, 2017. For a transition period, both FORMS-D and FORMS-E application packages will be active. Applicants must choose the appropriate application package for their due date when presented with both FORMS-D and FORMS-E application packages on the same FOA (see table below).

If your due date is…	**You must use…**
On or before January 24, 2018, including: • Applications submitted for due dates on or before January 24, 2018 • Applications submitted under NIH Late Policy 2-week window of consideration for intended due dates on or before January 24, 2018 • Applications submitted by February 7, 2018 under NIH Continuous Submission Policy for January 7, 2018 AIDS intended due date	FORMS-D application package
On or after January 25, 2018, including: • Applications submitted for due dates on or after January 25, 2018 • All application types (New, Resubmission, Renewal, Revision) • Applications submitted early for intended dues dates on or after January 25, 2018	FORMS-E application package

Additional guide notices for individual FOAs with unique due date considerations will be issued as needed and referenced in the Related Notices section of each FOA.

Form Update Timing for Administrative Supplement, Successor-in-Interest (Type 6) and Change of Institution (Type 7) Parent Announcements

Parent announcements for administrative supplements and post award administrative actions (successor-in-interest and change of institution applications) do not have set due dates and, consequently, will follow a different timeline than other parent announcements.

The FOAs in the table below will be reissued with new FOA numbers, FORMS-E application packages and instructions on January 25, 2018. Applications started on or after January 25, 2018 must use the new FOAs and FORMS-E application packages.

These FOAs will expire on February 25, 2018 giving applicants one month to complete their initiated FORMS-D applications.

FOA#	FOA Title
PA-16-285	Change of Grantee Organization (Type 7 Parent)
PA-16-286	Successor-in-Interest (Type 6 Parent)
PA-16-287	Administrative Supplements to Existing NIH Grants and Cooperative Agreements (Admin Supp)
PA-16-288	Research Supplements to Promote Diversity in Health-Related Research (Admin Supp)
PA-16-289	Research Supplements to Promote Re-Entry into Biomedical and Behavioral Research Careers (Admin Supp)

Applications Proposing Clinical Trials

As previously announced, all applications involving clinical trials must be submitted to FOAs specifically designed for clinical trials beginning with due dates on or after January 25, 2018 (NOT-OD-16-147, NOT-OD-17-043).

We will take the following steps to accommodate this new policy:

- Issue new clinical trial FOAs with clinical trial-specific review criteria, FORMS-E application packages, and FORMS-E instructions for due dates on or after January 25, 2018
- Add a new "Clinical Trials" item to the table in Section II of all FOAs (just below "Application Types Allowed") which will include one of the following statements:
    - Only accepting applications that propose clinical trial(s)
    - Only accepting applications that do **not** propose clinical trials
    - Accepting applications that either propose or do not propose clinical trial(s)
- Expire existing (FORMS-D) clinical trial FOAs by January 24, 2018

Resources:

- High-level Summary of Form Changes in FORMS-E Application Packages
- Annotated Form Set for NIH Grant Applications
- Do I Have the Right Form Version For My Application?
- Application Forms, Form Updates, and Choosing the Correct Forms FAQs

Inquiries

Please direct all inquiries to:

NIH Grants Information
Email: grantsinfo@od.nih.gov (preferred method of contact)
Telephone: 301-945-7573

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices

Reminder of Required Letter of Support for PAR-17-094 "Maximizing Investigators' Research Award (R35)"

Notice Number: NOT-GM-18-011

Key Dates
Release Date: December 11, 2017

Related Announcements
PAR-17-094

Issued by
National Institute of General Medical Sciences (NIGMS)

Purpose

The purpose of this Notice is to remind applicants of the requirement for a letter of support from the institution's Authorized Organizational Representative (AOR) for submission of an application to PAR-17-094 "Maximizing Investigators' Research Award (R35)".

Part 2. Section IV.2. PHS 398 Research Plan
Note that a letter of support is required from the institution's Authorized Organizational Representative (AOR) indicating acceptance of the conditions of the MIRA as defined in the instructions for the Letter of Support attachment on the PHS 398 Research Plan form. PD/PIs are encouraged to work with their AOR to make sure this letter is included in this section of the application. Applications that omit this letter, or that do not indicate their acceptance of the conditions of an award, will be withdrawn without review.

Inquiries

Please direct all inquiries to:

Vernon Anderson, Ph.D.
National Institute of General Medical Sciences (NIGMS)
Telephone: 301-594-3827
Email: NIGMS EstPI MIRA@mail.nih.gov

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices

NIH Enforcement of Closeout Policies

Notice Number: NOT-OD-18-107

Key Dates
Release Date: November 30, 2017

Related Announcements
NOT-OD-17-085
NOT-OD-17-022
NOT-OD-15-136
NOT-OD-15-135
NOT-OD-15-111
NOT-OD-14-084

Issued by
National Institutes of Health (NIH)

Purpose

The purpose of this Notice is to alert the NIH extramural community that NIH is strengthening enforcement of longstanding closeout requirements, outlined in the NIH Grants Policy Statement Section 8.6, Closeout. NIH has consistently reminded recipients of their responsibility to submit timely, accurate final grant expenditure reports, and has communicated the critical need for recipients to reconcile cash transaction reports submitted to the HHS Payment Management System (PMS) with expenditure reports submitted to NIH. In order to fulfill agency requirements under the Grants Oversight and New Efficiency (GONE) Act and HHS grants policy, NIH will no longer delay the closeout of awards unless the recipient submits a prior approval request to the IC providing an acceptable written justification.. Without prior approval from the awarding IC, NIH will initiate unilateral closeout for all awards that fail to meet closeout requirements within 120 days as required by the NIH Grants Policy Statement (NIH GPS) Section 8.6. **See below for details**.

Background

Recipient Responsibilities

The requirement for timely closeout is generally a recipient responsibility. However, NIH may initiate unilateral closeout if a recipient does not provide timely, accurate closeout reports or does not respond timely to NIH requests to reconcile discrepancies in grant records.

NIH recipients must submit a Final Federal Financial Report (FFR), Final Research Performance Progress Report (F-RPPR), and Final Invention Statement and Certification (FIS) within 120 calendar days of the end of the period of performance (project period), as required in section 8.6 of the NIH GPS. The reports become overdue the day after the 120 calendar day period ends. Cash transaction data continues to be submitted directly to and processed by PMS. It is the recipient's responsibility to reconcile reports submitted to PMS and to the NIH awarding Institute or Center.

NIH Actions

NIH is committed to addressing and reducing grant closeout delays and to enhance compliance with HHS regulations and policies, and the GONE Act. Therefore, NIH will strictly enforce its closeout policies. When recipients fail to submit timely reports, NIH will initiate unilateral closeout. It is important to note that for financial closeout, if a recipient fails to submit a final expenditure FFR, HHS policy directs NIH to close the grant using the last accepted Federal Cash Transaction Report's cash drawdown amount. This could be considered a debt or result in disallowed costs. In addition, failure to correct recurring reporting problems may

cause NIH to take one or more actions that may include, but are not limited to, corrective actions, withholding of further awards, suspension or termination.

Inquiries

Please direct all inquiries to:

Division of Grants Policy
Office of Policy for Extramural Research Administration
Office of Extramural Research
Telephone: 301-435-0949
GrantsPolicy@od.nih.gov

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices
