Research Administration Brown Bag

March 28, 2016
11:45 am – 12:45 pm
Amphitheater I (S2-102)

Agenda

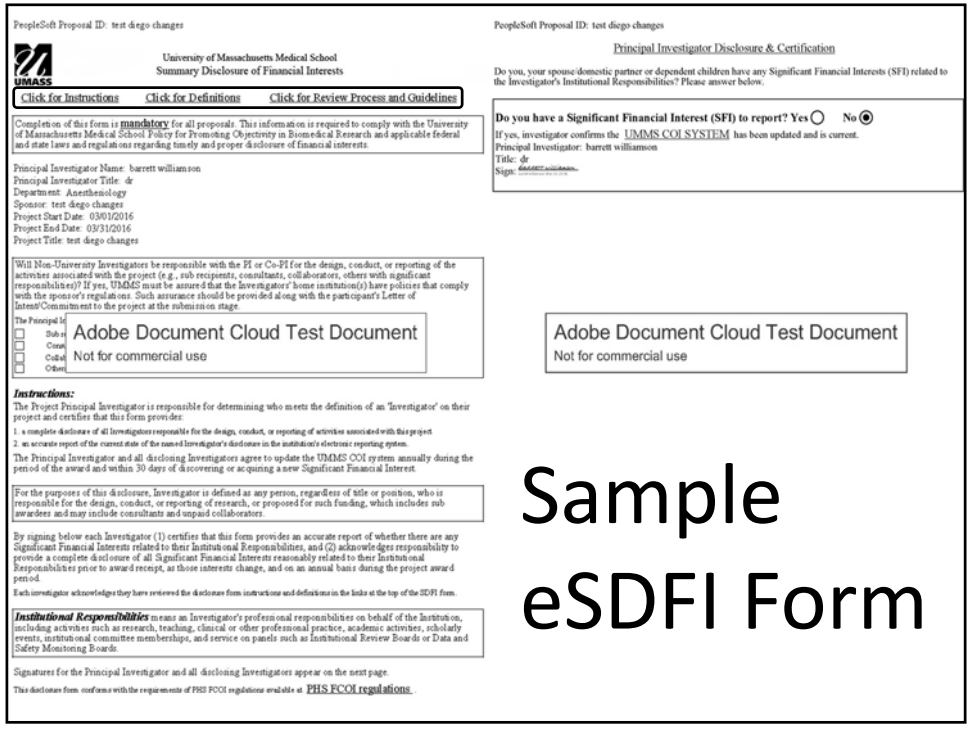
University of Massachusetts UMASS Medical School

- Upcoming Release of eSDFI
- FY17 Increase to Fringe Benefit Rate
- FCOI Training Requirement
- NIH Update
  - NOT-OD-16-081: NIH & AHRQ Grant Application Changes for Due Dates On or After May 25, 2016
  - NOT-OD-16-064 Impact of Grant Application Form Update (FORMS-D) on Late and Continuous Submission Applications
  - NOT-OD-16-080: Clarifications & Consolidated Biosketch Instructions and Format Pages Available for Application Due Dates On or After May 25, 2016
  - Update on Rigor and Transparency – RPPR
  - Update on Authentication of Key Biological and/or Chemical Resources
- Proposal & Progress Report Statistics
  - Review of OSP Report Methodology

eSDFI Form Release Plan

University of Massachusetts Medical School

- OSP and IT will deploy the electronic version of the SDFI form this week.
- The eSDFI is accessible at:
  - http://w3.umassmed.edu/ResearchForms/SDFI
  - Link will also be accessible via the OSP forms page and the FCOI forms page.
- An admin panel has been created for departments users to view the status of their SDFI forms:
  - http://w3.umassmed.edu/ResearchForms/SDFI



PeopleSoft Proposal ID: test diego changes

University of Massachusetts Medical School
Summary Disclosure of Financial Interests

Click for Instructions | Click for Definitions | Click for Review Process and Guidelines

Completion of this form is **mandatory** for all proposals. This information is required to comply with the University of Massachusetts Medical School Policy for Promoting Objectivity in Biomedical Research and applicable federal and state laws and regulations regarding timely and proper disclosure of financial interests.

Principal Investigator Name: barrett williamson
Principal Investigator Title: dr
Department: Anesthesiology
Sponsor: test diego changes
Project Start Date: 03/01/2016
Project End Date: 03/31/2016
Project Title: test diego changes

Will Non-University Investigators be responsible with the PI or Co-PI for the design, conduct, or reporting of the activities associated with the project (e.g., sub recipients, consultants, collaborators, others with significant responsibilities)? If yes, UMMS must be assured that the Investigators' home institution(s) have policies that comply with the sponsor's regulations. Such assurance should be provided along with the participant's Letter of Intent/Commitment to the project at the submission stage.

Adobe Document Cloud Test Document
Not for commercial use

Instructions:

The Project Principal Investigator is responsible for determining who meets the definition of an 'Investigator' on their project and certifies that this form provides:

1. a complete disclosure of all Investigators responsible for the design, conduct, or reporting of activities associated with this project
2. an accurate report of the current state of the named Investigator's disclosure in the institution's electronic reporting system.

The Principal Investigator and all disclosing Investigators agree to update the UMMS COI system annually during the period of the award and within 30 days of discovering or acquiring a new Significant Financial Interest.

For the purposes of this disclosure, Investigator is defined as any person, regardless of title or position, who is responsible for the design, conduct, or reporting of research, or proposed for such funding, which includes sub awardees and may include consultants and unpaid collaborators.

By signing below each Investigator (1) certifies that this form provides an accurate report of whether there are any Significant Financial Interests related to their Institutional Responsibilities, and (2) acknowledges responsibility to provide a complete disclosure of all Significant Financial Interests reasonably related to their Institutional Responsibilities prior to award receipt, as those interests change, and on an annual basis during the project award period.

Each investigator acknowledges they have reviewed the disclosure form instructions and definitions in the links at the top of the SDFI form.

Institutional Responsibilities means an Investigator's professional responsibilities on behalf of the Institution, including activities such as research, teaching, clinical or other professional practice, academic activities, scholarly events, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Signatures for the Principal Investigator and all disclosing Investigators appear on the next page.

This disclosure form conforms with the requirements of PHS FCOI regulations available at PHS FCOI regulations

PeopleSoft Proposal ID: test diego changes

Principal Investigator Disclosure & Certification

Do you, your spouse/domestic partner or dependent children have any Significant Financial Interests (SFI) related to the Investigator's Institutional Responsibilities? Please answer below.

Do you have a Significant Financial Interest (SFI) to report? Yes ○ No ◉

If yes, investigator confirms the UMMS COI SYSTEM has been updated and is current.
Principal Investigator: barrett williamson
Title: dr
Sign:

Adobe Document Cloud Test Document
Not for commercial use

Sample eSDFI Form

FY17 Increase to Fringe Benefit Rate

University of Massachusetts Medical School
UMASS

- The University has been notified by the State Comptroller's Office that the state's fringe benefit rate for FY17, July 1, 2016 through June 30, 2017, is expected to increase from the current 31.89% to 36.34%. This will impact all UMass employees paid from grant funds and all grant proposals going forward.
- To comply with this notice which projects a required 4.45% increase in the state's fringe rate effective July 1, 2016, all new grant proposals should immediately incorporate the new fringe benefit rate.
- The Office of Sponsored Programs has updated the Fact Sheet, Cayuse and the internal budget worksheet to reflect the 36.34% fringe benefit rate.

FCOI Training Requirement

University of Massachusetts Medical School
UMASS

- UMMS's new FCOI training requirement was implemented in August 2012.
- Per regulatory requirement each Investigator must complete training at least every four years.
- Most UMMS Investigators completed their training after August 2012 and will need to retake the training again beginning in August 2016 to comply with the four year retraining requirement.
- The FCOI Implementation Presentation from 2011 (hyperlink below) provides a good overview of the FCOI regulatory requirements if anyone needs a refresher on the requirements.
  - http://www.umassmed.edu/globalassets/office-of-research/compliance/fcoi/overview/fcoi-brown-bag-7-9-12.pdf
- OSP is unable to set up awards for those projects where Investigators have not met the training requirement.
- Please check the Training Completion Report available on the OSP FCOI page to see when your Investigators will need to retrain.
- The report is available at:
  - http://www.umassmed.edu/globalassets/office-of-research/compliance/fcoi/citi-training-report/coi-training-completion-report.pdf

NOT-OD-16-081: NIH & AHRQ Grant Application Changes for Due Dates On or After May 25, 2016

University of Massachusetts Medical School

- Released 3/25/16, this Notice reminds the biomedical and health services research communities of announced changes to grant application policies and instructions for due dates on or after 5/25/16.
- These changes are implemented within the FORMS-D application forms and instructions. Applicants must use FORMS-D for due dates on or after May 25, 2016 and must use FORMS-C for due dates on or before May 24, 2016.
- The changes focus on the following areas:
- Rigor and transparency in research grant applications (including small business and complex research grant applications)
  - Applicants must use the new "Authentication of Key Biological and/or Chemical Resources" attachment to briefly describe methods used to ensure the identity and validity of key biological and/or chemical resources.
  - Similar changes for institutional training and individual fellowship applications will be implemented as early as FY2017. Until that time, applicants **must not** use the "Plan for Instruction in Methods for Enhancing Reproducibility" attachment or the "Authentication of Key Biological and/or Chemical Resources" attachment unless specifically requested in a funding opportunity announcement.
- Vertebrate animals (NIH only)
  - Applicants must answer new euthanasia questions on the PHS 398 Cover Page Supplement and PHS Fellowship Supplemental forms when vertebrate animals are involved, instead of addressing the method of euthanasia in the Vertebrate Animals attachment.
- Inclusion
  - Applicants must provide inclusion data on a new, consolidated PHS Inclusion Enrollment Report form.
- Data Safety Monitoring Plans
  - Applicants must provide a new "Data Safety Monitoring Plan" attachment when their project includes a clinical trial.
- Research Training
  - Applicants must use new FORMS-D Training Tables
- PHS Awarding Component and Peer Review Requests
  - Applicants must use a new PHS Assignment Request Form to communicate requests pertinent to the assignment and initial peer review of applications.
- New Font Guidelines & Biosketch Clarifications

NOT-OD-16-064: Impact of Grant Application Form Update (FORMS-D) on Late and Continuous Submission Applications

University of Massachusetts Medical School

- If your PI is eligible for submission under NIH's late, continuous submission, and system issue policies, you will need to pay special attention to the cutover dates to the new forms.
- **Use the forms and instructions for the intended due date (not actual submission date)**. The intended due date is the date listed in the Application Due Date or AIDS Application Due Date row of the Key Dates table in the funding opportunity announcement (FOA).
- The intended due date is the due date specified in the key dates table of the announcement.
- NOTE: The continuous submission policy only applies to R01, R21 and R34 activities that follow the standard submission schedule. The dates specified for these three activities are the intended due dates for continuous submission applications.
- Be sure to use the FOA with the FORMS-C application package if applying to an intended due date before May 25.
- In some cases, the FOA will include both a FORMS-C and FORMS-D application package and you will need to choose FORMS-C.
- In other cases, FOAs will be closed on the last due date prior to May 25 and reissued with new FOA numbers and FORMS-D application packages for due dates on or after May 25. We expect to reissue all Parent announcements, as well as all fellowship, and individual career development FOAs.
- FOAs that close early will be configured to allow submissions for 14 days after the close date to accommodate late, continuous submission and system issue policies.
- If your intended due date is the May 7, 2016, AIDS due date, you must complete your submission using a FORMS-C application package by May 23, 2016.
- NOTE: This is an earlier cutoff date for continuous submission applications than is typical – plan accordingly
- Be sure to use an FOA with a FORMS-D application package if submitting to an intended due date on or after May 25, 2016.

NOT-OD-16-080: Clarifications & Consolidated Biosketch Instructions and Format Pages Available for Application Due Dates On or After 5/25/16

University of Massachusetts Medical School

- This Notice informs the biomedical and health services research communities that in accordance with NOT-OD-16-004, the biosketch instructions and format pages have been updated. The updated instructions and formats should be used for application due dates on or after May 25, 2016.
- Updates to the biosketch instructions will include:
  - A consolidated biosketch format and instructions for research, institutional research training, institutional career development, research education, fellowship, and dissertation awards, as well as diversity supplements.
- Clarified instructions:
  - Indicate that a URL for a publication list is optional and, if provided, must be to a government website (.gov) like My Bibliography.
  - Allow publications (peer-reviewed and non-peer-reviewed) and research products to be cited in both the personal statement and the contributions to science sections
  - State that graphics, figures and tables are not allowed.
  - Remove the requirement that the past 3 years of research support are listed in order of relevance.
  - Option to add other names used to author research products in section A.
  - Research products can include conference proceedings such as meeting abstracts, posters, or other presentations.
  - Research products that are under development, such as manuscripts that have not yet been accepted for publication, can be mentioned in the narrative sections. However, they cannot be cited as one of their citations.
- The FORMS-D application instructions will be posted on March 25, 2016. They will have a single set of biosketch instructions and a link to the new format page for use with all mechanisms. This information will also be available from the NIH Forms page.

Updates to NIH RPPR to Address Rigor and Transparency

University of Massachusetts Medical School

- NOT-OD-16-031 (released 12/15/15)
  - This notice informed the biomedical and health services research community of planned changes to the to address Rigor and Transparency.
- OSP has begun receiving requests from NIH program officials for additional information on rigor and transparency:

From: Program Official @ NIH
Sent: Friday, March 25, 2016 12:50 PM
To: UMMS Principal Investigator, research.funding@umassmed.edu
Subject: RPPR for R01XX555555-01

Dear UMMS PI,

I am in the process of reviewing the progress report for the above grant. However, I will need additional information on Rigor and Transparency per current instructions for the respective sections as follows:

B.2 What was accomplished under these goals?

Include the approaches taken to ensure robust and unbiased results.

B.6 What do you plan to do for the next reporting period to accomplish these goals?

Discuss efforts to ensure that the approach is scientifically rigorous and results are robust and unbiased.

Please submit this information to me through your institutional official by April 1, 2016. Please feel free to contact me if you have any questions.

Sincerely,

Program Official, Ph.D.

Update on Authentication of Key Biological and/or Chemical Resources

University of Massachusetts Medical School

- Per NOT-OD-16-011 - Applications due on or after 1/25/16, except for training grants and individual fellowships must include a new PDF attachment related to the authentication of key biological and/or chemical resources.
- NIH has provided clarification on what to do if the research strategy does not propose use of key biological and/or chemical resources:
  - In this scenario, an authentication plan does not need to be included and no attachment is necessary.
- OSP guidance had been to upload a document in Cayuse and state N/A to take care of the warning notification. Given NIH's clarification the upload document is no longer necessary.
- Please note this in your proposal review process.

PROPOSAL SUBMISSIONS TO OSP

February 2015 – February 2016

University of Massachusetts Medical School

	February 2015	March 2015	April 2015	May 2015	June 2015	July 2015	August 2015	September 2015	October 2015	November 2015	December 2015	January 2016	February 2016
Count	117	89	72	69	111	90	62	112	129	60	67	107	121
On Time	40%	47%	33%	39%	55%	47%	47%	52%	43%	37%	42%	59%	38%
Late	56%	46%	63%	58%	42%	47%	52%	43%	56%	60%	54%	39%	60%
After the fact	4%	7%	4%	3%	3%	6%	2%	5%	1%	3%	4%	2%	2%
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)	44%	34%	34%	35%	23%	33%	39%	31%	39%	40%	33%	25%	46%

On Time: Received by OSP 5 days prior to the requested return date.
Late: Received by OSP less than 5 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 days or less to review before requested return date.

SUBMISSIONS TO OSP
February 2015 to February 2016 Comparison

University of Massachusetts Medical School
UMASS

PROPOSALS	2015	2016	Change
Count	117	121	+4
On Time	40%	38%	-2
Late	56%	60%	+4
After the fact	4%	2%	-2
Withdrawn	0%	0%	-
Total	**100%**	**100%**	-
Expedited Request (3 days or less)	44%	46%	+2

On Time: Received by OSP 5 days prior to the requested return date.
Late: Received by OSP less than 5 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 days or less to review before requested return date.

PROGRESS REPORT SUBMISSIONS TO OSP
February 2015 – February 2016

University of Massachusetts Medical School
UMASS

	February 2015	March 2015	April 2015	May 2015	June 2015	July 2015	August 2015	September 2015	October 2015	November 2015	December 2015	January 2016	February 2016
Count	33	50	50	52	53	32	11	19	30	19	26	36	44
On Time	46%	42%	50%	46%	38%	38%	27%	37%	43%	26%	42%	64%	48%
Late	39%	52%	40%	37%	51%	37%	46%	47%	40%	63%	50%	22%	45%
After the fact	15%	6%	10%	17%	11%	25%	27%	16%	17%	11%	8%	14%	7%
Total	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**
Expedited Request (3 days or less)	27%	38%	36%	19%	38%	31%	36%	26%	20%	58%	42%	19%	30%

On Time: Received by OSP 5 days prior to the requested return date.
Late: Received by OSP less than 5 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 days or less to review before requested return date.

SUBMISSIONS TO OSP
February 2015 to February 2016 Comparison

University of Massachusetts Medical School
UMASS

PROGRESS REPORTS	2015	2016	Change
Count	33	44	+11
On Time	46%	48%	+2
Late	39%	45%	+6
After the fact	15	7%	-8
Withdrawn	0%	0%	-
Total	**100%**	**100%**	-
Expedited Request (3 days or less)	27%	30%	+3

On Time: Received by OSP 5 days prior to the requested return date.
Late: Received by OSP less than 5 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 days or less to review before requested return date.

How does OSP compute the on-time metric?

OSP's formula is:

The Requested Return Date minus

The Date Received

=(*RRD – DR*)

1. The date received counts as a full day irrespective of whether the proposal packet is received at 8:00 am or 5:00 pm.
2. OSP's formula accounts for weekends and School holidays.
    1. On Time: Received 5 business days prior to the requested return date
    2. Late: Received less than 5 business days prior to the requested return date
    3. After the Fact: Received after the requested return date
    4. Expedited: Received with 3 business days or less prior to the requested return date

Report ID: UMGM7002
Environment: Production

UNIVERSITY OF MASSACHUSETTS
PROPOSAL ROUTING FORM

Page No: 1
Run Date: 01/17/2013
Run Time: 11:51:03 AM

Proposal No. 000000000015033 Status: STSR - Submit to Sponsor

I. Principal Investigator Information

PI Name: Investigator,Principal
Department: W4164800000 - Achee & Paine
PI Phone:
PI Email:

Alt. Name Wonderland,Alison
Alt. Phone 508/856-4063
Alt. Email alison.wonderland@umassmed.edu
Requested Return Date: 02/04/2013

II. Proposal Information

Type: New
Additional Attribute: GRANT
Purpose: BASIC
Proposal Title: Vectored Delivery of Oligoclonal Antibodies for Protection Against EMDD
Sponsor: NATIONAL INSTITUTES OF HEALTH
Proposed Period Start Date: 09/01/2013
Proposal Location: MEDICAL SCHOOL
Date Due to Sponsor: 02/05/2013

CFDA#: 12.190
Foreign Component: N
Proposed Period End Date: 08/31/2018
Due By:
Time:

Keywords:
Adequate Space Available: Y

III. Subawardees/Subrecipients

Name:	F-Y/N	1st Yr Budget	Total Budget
BOSTON UNIVERSITY		99,927.00	539,710.00
UNIVERSITY OF MARYLAND		147,691.00	663,144.00

IV. Proposal Budget

Initial Budget Period Start Date: 09/01/2013 Initial Budget Period End Date: 08/31/2014

	Direct Cost	Indirect Cost	Total Budget
1st Period Budget	$ 3,465,734.00	$ 281,747.00	$ 3,747,481.00
2nd Period Budget	$ 3,171,497.00	$ 472,294.00	$ 3,643,791.00
3rd Period Budget	$ 3,481,442.00	$ 671,645.00	$ 4,153,087.00
4th Period Budget	$ 2,574,846.00	$ 402,572.00	$ 2,977,418.00
5th Period Budget	$ 457,275.00	$ 6,500.00	$ 463,775.00
Total Budget-Project	$ 13,150,794.00	$ 2,034,758.00	$ 15,185,552.00

Does Proposal Involve Cost Sharing? N
Does Sponsor Require Cost Sharing? N
Does Sponsor Limit Indirect Costs? N
Has an Indirect Cost Waiver been Requested? N
Are InKind/Voluntary Costs Included? N

V. Co-Investigators

Name:	Department:	Signature(UMASS Staff only)
Gao,Guangping	Gene Therapy Center	

VI. Certifications

Cert. Code/Description	Indicator	Docket/Protocol#	Approval Date
A025 ANIMAL	PD		
H001 HUMAN SUBJECTS	NO		

APPENDIX

PeopleSoft Proposal ID: 23512354

University of Massachusetts Medical School
Summary Disclosure of Financial Interests

Click for Instructions Click for Definitions Click for Review Process and Guidelines

Completion of this form is mandatory for all proposals. This information is required to comply with the University of Massachusetts Medical School Policy for Promoting Objectivity in BioMedical Research and applicable federal and state laws and regulations regarding timely and proper disclosuer of financial interests.

Principal Investigator Name: Luke Salsich
Principal Investigator Title: PO
Department: Anesthesiology
Sponsor: IT
Project Start Date: 03/24/2016
Project End Date: 03/25/2016
Project Title: Test 3-24-16

Will Non-University Investigators be responsible with the PI or Co-PI for the design, conduct, or reporting of the activities associated with the project (e.g., subrecipients, consultants, collaborators, others with significant responsibilities)? If yes, UMMS must be assured that the Investigators' home institution(s) have policies that comply with the sponsor's regulations. Such assurance should be provided along with the participant's Letter of Intent/Commitment to the project at the submission stage.

The Principal Investigator has not identified any non-University Investigator types for this project.

☐ Subre
☐ Consu
☐ Collab
☐ Other

Instructions:

The Project Principal Investigator is responsible for determining who meets the definition of an 'Investigator' on their project and certifies that this form provides:

1. a complete disclosure of all Investigators responsible for the design, conduct, or reporting of activities associated with this project
2. an accurate report of the current state of the named Investigator's disclosure in the institution's electronic reporting system.

The Principal Investigator and all disclosing Investigators agree to update the UMMS COI system annually during the period of the award and within 30 days of discovering or acquiring a new Significant Financial Interest.

For the purposes of this disclosure, Investigator is defined as any person, regardless of title or position, who is responsible for the design, conduct, or reporting of research, or proposed for such funding, which includes subawardees and may include consultants and unpaid collaborators.

By signing below each Investigator (1) certifies that this form provides an accurate report of whether there are any Significant Financial Interests related to their Institutional Responsibilities, and (2) acknowledges responsibility to provide a complete disclosure of all Significant Financial Interests reasonably related to their Institutional Responsibilities prior to award receipt, as those interests change, and on an annual basis during the project award period.

Each investigator acknowledges they have reviewed the disclosure form instructions and definitions in the links at the top of the SDFI form.

Institutional Responsibilities means an Investigator's professional responsibilities on behalf of the Institution, including activities such as research, teaching, clinical or other professional practice, academic activities, scholarly events, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Signatures for the Principal Investigator and all disclosing Investigators appear on the next page.

This disclosure form conforms with the requirements of PHS FCOI regulations available at PHS FCOI regulations .

PeopleSoft Proposal ID: 23512354

Principal Investigator Disclosures & Certifications

Do you, your spouse/domestic partner or dependent children have any Significant Financial Interests (SFI) related to the Investigator's Institutional Responsibilities? Please answer below.

Do you have a Significant Financial Interest (SFI) to report? Yes ○ No ○
If yes, investigator confirms the UMMS COI SYSTEM has been updated and is current.
Principal Investigator: Luke Salsich
Title: PO
Sign:

Disclosures & Certifications for UMass Personnel Identified as 'Investigators'

Do you, your spouse/domestic partner or dependent children have any Significant Financial Interests (SFI) related to the Investigator's Institutional Responsibilities? Please answer below.

Do you have a Significant Financial Interest (SFI) to report? Yes ○ No ○
If yes, investigator confirms the UMMS COI SYSTEM has been updated and is current.
Disclosing Investigator: Luke Slaznicjk
Title: IT Pro
Sign:

Reminder: NIH & AHRQ Grant Application Changes for Due Dates On or After May 25, 2016

Notice Number: NOT-OD-16-081

Key Dates
Release Date: March 23, 2016

Related Announcements
NOT-OD-16-080 - Clarifications and Consolidated Biosketch Instructions and Format Pages Available for Applications with Due Dates On or After May 25, 2016
NOT-OD-16-068 - Plan to Move to Updated Forms (FORMS-D) for Administrative Supplement, Successor-In-Interest and Change of Institution Opportunities
NOT-OD-16-064 - Impact of Grant Application Form Update (FORMS-D) on Late and Continuous Submission Applications
NOT-OD-16-034 - Advanced Notice of Coming Requirements for Formal Instruction in Rigorous Experimental Design and Transparency to Enhance Reproducibility: NIH and AHRQ Institutional Training Grants, Institutional Career Development Awards, and Individual Fellowships
NOT-OD-16-012 - Implementing Rigor and Transparency in NIH & AHRQ Career Development Award Applications
NOT-OD-16-011 - Implementing Rigor and Transparency in NIH & AHRQ Research Grant Applications
NOT-OD-16-009 - NIH & AHRQ Change Font Guidelines for Applications to Due Dates On or After May 25, 2016
NOT-OD-16-008 - NIH & AHRQ Announce New Form for PHS Awarding Component and Peer Review Requests
NOT-OD-16-007 - NIH & AHRQ Announce Transition to New Research Training Table Formats for 2016 and Upcoming Release of the xTRACT System
NOT-OD-16-006 - Simplification of the Vertebrate Animals Section of NIH Grant Applications and Contract Proposals
NOT-OD-16-004 - NIH & AHRQ Announce Upcoming Changes to Policies, Instructions and Forms for 2016 Grant Applications

Issued by
National Institutes of Health (NIH)
Agency for Healthcare Research and Quality (AHRQ)

Purpose

This Notice reminds the biomedical and health services research communities of announced changes to grant application policies and instructions for due dates on or after May 25, 2016 (NOT-OD-16-004).

These changes are implemented with our FORMS-D application forms and instructions. Applicants must use FORMS-D for due dates on or after May 25, 2016 and must use FORMS-C for due dates on or before May 24, 2016.

The changes focus on the following areas:

- Rigor and transparency in research grant applications (including small business and complex research grant applications) - NOT-OD-16-011 and NOT-OD-16-012
    - Applicants must use the new "Authentication of Key Biological and/or Chemical Resources" attachment to briefly describe methods used to ensure the identity and validity of key

biological and/or chemical resources.
    - Similar changes for institutional training and individual fellowship applications will be implemented as early as FY2017 (NOT-OD-16-034).

      Until that time, applicants **must not** use the "Plan for Instruction in Methods for Enhancing Reproducibility" attachment or the "Authentication of Key Biological and/or Chemical Resources" attachment unless specifically requested in a funding opportunity announcement.
- Vertebrate animals (NIH only) - NOT-OD-16-006
    - Applicants must answer new euthanasia questions on the PHS 398 Cover Page Supplement and PHS Fellowship Supplemental forms when vertebrate animals are involved, instead of addressing the method of euthanasia in the Vertebrate Animals attachment.
- Inclusion
    - Applicants must provide inclusion data on a new, consolidated PHS Inclusion Enrollment Report form.
- Data Safety Monitoring Plans
    - Applicants must provide a new "Data Safety Monitoring Plan" attachment when their project includes a clinical trial.
- Research Training - NOT-OD-16-007
    - Applicants must use new FORMS-D Training Tables
- PHS Awarding Component and Peer Review Requests - NOT-OD-16-008
    - Applicants must use a new PHS Assignment Request Form to communicate requests pertinent to the assignment and initial peer review of applications.
- New Font Guidelines - NOT-OD-16-009
- Biosketch Clarifications - NOT-OD-16-080

Note: Appendix policy changes originally mentioned in NOT-OD-16-004 are on hold until further notice and will not be part of the initial roll-out of FORMS-D instructions.

Availability of FORMS-D Forms and Instructions

New restructured FORMS-D application guides will be available by March 25, 2016.

In most cases, FORMS-D application packages will be available at least 60 days prior to the first due date on or after May 25, 2016. During a short transition period, applicants may need to choose between FORMS-C and FORMS-D application packages/opportunities based on due date.

See NOT-OD-16-064 for special instructions for continuous submission and late applications.

See NOT-OD-16-068 for transition plan for administrative supplement, successor-in-interest and change of institution opportunities.

Resources:

- High-level list of FORMS-D form changes
- Annotated Form Set for NIH Grant Applications
- Do I Have the Right Form Version For My Application?
- Form Update 2016 - Frequently Asked Questions

Inquiries

Impact of Grant Application Form Update (FORMS-D) on Late and Continuous Submission Applications

Notice Number: NOT-OD-16-064

Key Dates
Release Date: February 12, 2016

Related Announcements
NOT-OD-16-081
NOT-OD-16-004

Issued by
National Institutes of Health (NIH)

Purpose

As stated in NOT-OD-16-004, all NIH applications submitted for due dates on or after May 25, 2016 must use updated (FORMS-D) application packages. FORMS-C application packages must be used for due dates before May 25, 2016.

Due to the content and policy changes implemented in FORMS-D application packages, NIH plans to make a clean transition from FORMS-C to FORMS-D to ensure applications reviewed together follow the same instructions.

If you are eligible for submission under our late, continuous submission, and system issue policies, you will need to pay special attention to the cutover dates to the new forms.

- Use the forms and instructions for the intended due date (not actual submission date). The intended due date is the date listed in the Application Due Date or AIDS Application Due Date row of the Key Dates table in the funding opportunity announcement (FOA).

- The intended due date is the due date specified in the key dates table of the announcement.

  NOTE: The continuous submission policy only applies to R01, R21 and R34 activities that follow the standard submission schedule. The dates specified for these three activities are the intended due dates for continuous submission applications.

- Be sure to use the FOA with the FORMS-C application package if applying to an intended due date before May 25.

  - In some cases, the FOA will include both a FORMS-C and FORMS-D application packages and you will need to choose FORMS-C.

  - In other cases, FOAs will be closed on the last due date prior to May 25 and reissued with new FOA numbers and FORMS-D application packages for due dates on or after May 25. We expect to reissue all Parent announcements, as well as all fellowship, and individual career development FOAs.

    FOAs that close early will be configured to allow submissions for 14 days after the close

date to accommodate late, continuous submission and system issue policies.

- If you apply directly to Grants.gov (rather than using ASSIST or a system-to-system solution), you will need to download your application package or create your Grants.gov workspace by the intended due date since the FORMS-C application packages will no longer be visible using the Grants.gov user interface.

- **If your intended due date is the May 7, 2016, AIDS due date, you must complete your submission using a FORMS-C application package by May 23, 2016.**

  NOTE: This is an earlier cutoff date for continuous submission applications than is typical – plan accordingly

- Be sure to use an FOA with a FORMS-D application package if submitting to an intended due date on or after May 25, 2016.

Resources

- Do I Have the Right Form Version For My Application?

Inquiries

Please direct all inquiries to:

NIH Grants Information
Email: grantsinfo@od.nih.gov (preferred method of contact)
Telephone: 301-435-0714

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices

Note: For help accessing PDF, RTF, MS Word, Excel, PowerPoint, Audio or Video files, see Help Downloading Files.

Clarifications and Consolidated Biosketch Instructions and Format Pages Available for Applications with Due Dates On or After May 25, 2016

Notice Number: NOT-OD-16-080

Key Dates
Release Date: March 23, 2016

Related Announcements
NOT-OD-16-081
NOT-OD-16-004

Issued by
National Institutes of Health (NIH)
Agency for Healthcare Research and Quality (AHRQ)

Purpose

This Notice informs the biomedical and health services research communities that in accordance with NOT-OD-16-004, the biosketch instructions and format pages have been updated. The updated instructions and formats should be used for application due dates on or after May 25, 2016.

Updates to the biosketch instructions will include:

- A consolidated biosketch format and instructions for research, institutional research training, institutional career development, research education, fellowship, and dissertation awards, as well as diversity supplements.

Clarified instructions:

- Indicate that a URL for a publication list is optional and, if provided, must be to a government website (.gov) like My Bibliography.
- Allow publications (peer-reviewed and non-peer-reviewed) and research products to be cited in both the personal statement and the contributions to science sections
- State that graphics, figures and tables are not allowed.
- Remove the requirement that the past 3 years of research support are listed in order of relevance.
- Option to add other names used to author research products in section A.
- Research products can include conference proceedings such as meeting abstracts, posters, or other presentations.
- Research products that are under development, such as manuscripts that have not yet been accepted for publication, can be mentioned in the narrative sections. However, they cannot be cited as one of their citations.

The FORMS-D application instructions will be posted on March 25, 2016. They will have a single set of biosketch instructions and a link to the new format page for use with all mechanisms. This information will also be available from the NIH Forms page.

Additional Information
We encourage researchers to try the Science Experts Network Curriculum Vitae (SciENcv) as a tool to build their biosketches.

SciENcv pulls information from available resources making it easy to develop a repository of information that can be readily updated and modified to prepare biosketches for submission to multiple agencies. A YouTube video provides instructions for using SciENcv. Support for fellowship application biosketches will be available in SciENcv later this year.
See FAQs for additional information

Inquiries

Please direct all inquiries to:

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Telephone: 301-435-0714

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices

National Institutes of Health
Office of Extramural Research
Department of Health and Human Services (HHS)
USA.gov Government Made Easy

NIH... Turning Discovery Into Health®

Note: For help accessing PDF, RTF, MS Word, Excel, PowerPoint, Audio or Video files, see Help Downloading Files.

UNIVERSITY OF MASSACHUSETTS
PROPOSAL ROUTING FORM

Proposal No. 000000000015033 **Status:** STSR - Submit to Sponsor

I. Principal Investigator Information

PI Name: Investigator,Principal
Department: W416800000 - Aches & Pains
PI Phone:
PI Email:
Alt. Name Wonderland,Alison
Alt. Phone 508/856-4063
Alt. Email alison.wonderland@umassmed.edu
Requested Return Date: 02/04/2013

II. Proposal Information

Type: New
Additional Attribute: GRANT
Purpose: BASIC
Proposal Title: Vectored Delivery of Oligoclonal Antibodies for Protection Against EMDD
Sponsor: NATIONAL INSTITUTES OF HEALTH
Proposed Period Start Date: 09/01/2013
Proposal Location: MEDICAL SCHOOL
Date Due to Sponsor: 02/05/2013
Keywords:
Adequate Space Available: Y
CFDA#: 12.190
Foreign Component: N
Foreign N
Proposed Period End Date: 08/31/2018
Due By:
Time:

III. Subawardees/Subrecipients

Name:	P-Y/N	1st Yr Budget	Total Budget
BOSTON UNIVERSITY		99,927.00	539,710.00
UNIVERSITY OF MARYLAND		147,691.00	663,144.00

IV. Proposal Budget

Initial Budget Period Start Date: 09/01/2013 **Initial Budget Period End Date:** 08/31/2014

	Direct Cost	Indirect Cost	Total Budget
1st Period Budget	$ 3,465,734.00	$ 281,747.00	$ 3,747,481.00
2nd Period Budget	$ 3,171,497.00	$ 672,294.00	$ 3,843,791.00
3rd Period Budget	$ 3,481,442.00	$ 671,645.00	$ 4,153,087.00
4th Period Budget	$ 2,574,846.00	$ 402,572.00	$ 2,977,418.00
5th Period Budget	$ 457,275.00	$ 6,500.00	$ 463,775.00
Total Budget-Project	$ 13,150,794.00	$ 2,034,758.00	$ 15,185,552.00

Does Proposal Involve Cost Sharing? N
Does Sponsor Require Cost Sharing? N
Does Sponsor Limit Indirect Costs? N
Has an Indirect Cost Waiver been Requested? N
Are InKind/Voluntary Costs Included? N

V. Co-Investigators

Name:	Department:	Signature(UMASS Staff only)
Gao,Guangping	Gene Therapy Center	_____

VI. Certifications

Cert. Code	Description	Indicator	Docket/Protocol#	Approval Date
A025	ANIMAL	PD		
H001	HUMAN SUBJECTS	NO		

ACRONYMS AND TERMS USED TODAY
OSP BROWN BAG - 3/28/2016

ACRONYM/TERM	DESCRIPTION
AHRQ	Agency for Health Care Research & Quality
Cayuse 424	Cayuse is a web-based system for submission of applications via grants.gov.
eSDFI	Electronic Summary Disclosure of Financial Interests form
FCOI	Financial Conflict of Interest
FOA	Funding Opportunity Announcement
IT	Information Technology
NIH	National Institutes of Health
NOT	NIH Notice
OSP	Office of Sponsored Programs
PI	Principal Investigator
RPPR	Research Performance Progress Report. Progress reports are required annually to document grantee accomplishments and compliance with terms of award. They describe scientific progress, identify significant changes, report on personnel, and describe plans for the subsequent budget period or year. See http://grants.nih.gov/grants/rppr/