

Agenda



NIH Update

- NOT-OD-17-062: New NIH "FORMS-E" Grant Application Forms and Instructions Coming for Due Dates On or After January 25, 2018
- Maximizing Investigators' Research Award (MIRA R35)
 - Finalizing Award/Relinquishing Requirements
- Reminder to Investigators regarding NIH two-day application viewing window
- Potential NIH PI Award Cap (Grant Support Index)
- Proposed Federal Budget F&A Rate Reduction Discussions

Other Updates

- Single Audit/A-133 Audit Certifications
- 2 CFR 200 Extension to Implementation of Procurement Standards
 Requirements
- Proposal & Progress Report Statistics
- Research Administration Training Topic:

Managing Compliance at the Just in Time (JIT) Stage

Tammy LeBlanc, Pam Harney & Heather Morello, Office of Sponsored Programs

NOT-OD-17-062: New NIH FORMS-E Grant Application Forms and Instructions Coming for Due Dates On or After January 25, 2018



- Applicants must use FORMS-E application packages for due dates on or after <u>January 25, 2018</u> 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.
- 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 NIH for future data exchanges 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.

Maximizing Investigators' Research Award (MIRA R35) – Relinquishing Guidance



- Investigators receiving a MIRA (R35) award are required to relinquish all other NIGMS research grants.
- NIGMS GMS's have requested relinquishing statements from OSP. We have received the following guidance:
- The relinquishing statement is only needed when a PI has NIGMS grants that end more than 1 year beyond the current budget period.
- This new process requires that a zero dollar relinquishing statement be submitted to remove the out years of an existing R01:
- Separate relinquishing statements for each affected grant are required and must be submitted through an AOR directly to the Grants Management Specialist listed on the Notice of Award.
- Please do not submit through the eRA Commons.
- To finalize the R35 award, the funding for the first year of the R35 will be adjusted to reflect any overlapping support. Please note that any adjustments made to the MIRA award will be calculated based on pro-rated overlapping support. The relinquishing statement should reflect \$0.

Reminder to Investigators Regarding NIH Two-Day Application Viewing Window



- In 2011 eliminated the error correction window from the application submission process. The elimination of the error correction window does not affect the two-business-day application viewing window (i.e. the time an applicant has to view the electronic application image in eRA Commons upon NIH's receipt of an error-free application).
- Applicants still will be able to view their application and reject and submit a corrected application prior to the submission deadline.
- NIH encourages applicants to submit in advance of the due date to take advantage of the opportunity to correct errors and warnings and to review the application in the eRA Commons before the deadline.
- All applications submitted after 5 p.m. local time of the applicant organization on the due date will be subject to the NIH late policy and may not be accepted for review.

Potential NIH PI Award Cap (Grant Support Index)



- Currently 10% of NIH investigators receive over 40% of funding. Data show that research productivity diminishes after three R01s.
- NIH is concerned about a leadership gap over the coming decades and is attempting to address this.
- NIH is planning to cap total support to an individual investigator using a new tool, the Grant Support Index (GSI), previously the research commitment index (RCI).
- The index is not focused on the amount of funding an investigator receives, but rather assigns a point value to the various kinds of grants based on type, complexity or size.
- Investigators with GSIs over 21 (the equivalent of three R01s) will have to include a plan with any new grant application for how they will reduce their existing commitments (adjust their grant load) to retain a score of 21 with a new grant.
- NIH will make the GSI calculations for individual investigators.
- The GSI is a work in progress and scoring has not yet been established and there is currently no way to calculate it.
- For a rough index, the tipping point is the equivalent of 3 R01s but they are still working on how you meet that tipping point.
- Intent is to use it to enhance the funding of these at-risk groups.
- OSP is monitoring the issue and will continue to report on developments.

Proposed Federal Budget F&A Rate Reduction Discussions



- The President's FY2018 Budget Proposal, released on May 23, includes major reductions for scientific research funding including over 20% in proposed cuts to the NIH budget.
- An area of additional concern for institutions is that the President's Budget proposes to make these cuts to F&A costs with respect to the NIH budget. The following is from the NIH section of the budget document:
 - The budget proposes to reduce reimbursement of indirect costs, so that available funding can be better targeted toward supporting the highest priority research on diseases that affect human health.
 - As a result of these changes to the reimbursement structure, significant reductions in 2018 will come from lower indirect cost payments.
 - The budget includes an indirect cost rate for NIH grants that will be capped at 10 percent of total research. This approach would be applied to all types of grants with a rate higher than 10 percent currently and will achieve significant savings in 2018 and would bring NIH's reimbursement rate for indirect costs more in line with the reimbursement rate used by private foundations.
 - In addition, the budget proposes that NIH will streamline select Federal research requirements for grantees through targeted approaches. In tandem, the Budget supports burden reduction measures that will further reduce grant award recipient costs associated with research.

Flowthrough Single Audit/ A-133 Audit Certifications



- Prime recipients that sub to UMMS routinely request compliance certifications in order to comply with the Single Audit requirements in 2 CFR 200.
- If you receive an audit certification request, please forward it to the Office of Sponsored Programs via our email address:
 - research.funding@umassmed.edu

2 CFR 200: Extension to Implementation of Procurement Standards Requirements



- The Office of Management and Budget has announced an extension of the grace period for non-Federal entities to implement the procurement standards included in Uniform Guidance.
- These entities are granted an additional year, meaning the implementation date for the procurement standards (2 CFR 200.317 through 200.326) will start for fiscal years beginning on or after December 26, 2017.
- For complete information, please see the Federal Register notice at:
 - https://www.gpo.gov/fdsys/pkg/FR-2017-05-17/html/2017-09909.htm

PROPOSAL SUBMISSIONS TO OSP





	April 2016	May 2016	June 2016	July 2016	August 2016	September 2016	October 2016	November 2016	December 2016	January 2017	February 2017	March 2017	April 2017
Count	72	101	106	78	86	121	106	71	48	103	108	90	52
On Time	29%	57%	40%	44%	44%	56%	46%	35%	46%	53%	52%	55%	40%
Late	70%	39%	59%	56%	50%	40%	49%	62%	46%	41%	43%	44%	58%
After the fact	1%	4%	1%	0%	6%	4%	5%	3%	8%	5%	5%	1%	2%
Withdrawn	0%	0%	0%	0%	0%	0%	0%	0%	0%	1%	0%	0%	0%
Total	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
Expedited Request (3 days or less)	44%	21%	36%	42%	35%	28%	32%	35%	33%	22%	28%	33%	44%

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.

SUBMISSIONS TO OSP April 2016 to April 2017 Comparison



PROPOSALS	2016	2017	Change
Count	72	52	-29
On Time	29%	40%	+11
Late	70%	58%	-12
After the fact	1%	2%	+1
Withdrawn	0%	0%	-
Total	100%	100%	-
Expedited Request (3 days or less)	44%	44%	_

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.

PROGRESS REPORT SUBMISSIONS TO OSP April 2016 – April 2017



	April 2016	May 2016	June 2016	July 2016	August 2016	September 2016	October 2016	November 2016	December 2016	January 2017	February 2017	March 2017	April 2017
Count	58	43	50	25	17	27	34	32	35	43	38	59	50
On Time	64%	49%	52%	60%	41%	67%	62%	59%	63%	68%	58%	54%	62%
Late	36%	51%	42%	28%	41%	22%	35%	38%	37%	30%	39%	42%	32%
After the fact	0%	0%	6%	12%	18%	11%	3%	3%	0%	2%	3%	4%	6%
Total	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
Expedited Request (3 days or less)	26%	37%	36%	16%	35%	19%	29%	19%	23%	21%	32%	25%	26%

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.

SUBMISSIONS TO OSP April 2016 to April 2017 Comparison



PROGRESS REPORTS	2016	2017	Change
Count	58	50	-8
On Time	64%	62%	-2
Late	36%	32%	-4
After the fact	0%	6%	+6
Withdrawn	0%	0%	-
Total	100%	100%	-
Expedited Request (3 days or less)	26%	26%	-

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.



Managing Compliance at the Just in Time (JIT) Stage

May 31, 2017

Diego Vazquez, Tammy LeBlanc, Pam Harney and Heather Morello

Overview



- JIT Stage 1
- JIT Stage 2
- IACUC Approval
- IRB Approval
- Human Subjects Education Certification
- Other Support for Key Personnel
- Other Uploads

JIT Stage 1



Automated JIT Request

- The NIH will send a standard notice to the PI and OSP for all applications that have an impact score of 30 or less
- OSP is not privy to the score, therefore, we send a follow up email to the PI and Administrator
- It is up to the PI to determine if s/he would like to respond

JIT Stage 2



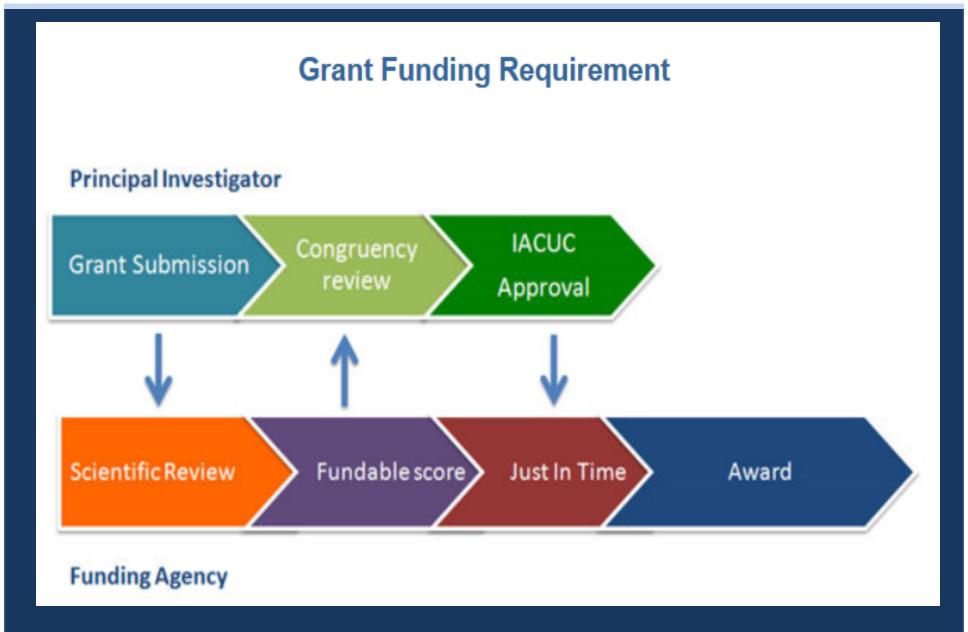
Non-Automated JIT Request

- A non-automated JIT request comes from the Grants
 Management Specialist (GMS) if the grant has a score within a fundable range.
- The request will indicate specific information the GMS is looking for such as:
 - IACUC Approval
 - o IRB Approval
 - Human Subjects Training
 - Other Support
 - Institutional F & A Agreement

It is important to note that these requirements also apply to the subrecipient sites.

IACUC Approval





IACUC Approval



Why is Congruency required?

Public Health Service (PHS) policy requires institutions to verify congruence between components of PHS grant application related to animal care and use, and the approved IACUC protocol. The NIH will not release funds unless animal research activities in the grant have IACUC approval. Lack of IACUC approval for fundable grants will cause unnecessary delays in accepting funding or potential loss of funding.

IACUC Approval



It is strongly recommended that investigators proactively initiate the congruency review if they have a fundable score or after they have received sustainable information regarding the funding. Submit the following:

- If active protocol, a copy of the approval letter(s) with copy of application to grant.congruency@umassmed.edu
- If pending, the PI should start the IACUC application process right away

For institutional congruency guidance go to:

http://www.umassmed.edu/research/compliance/protocol-proposal-congruency/

IRB Approval



Institutional Review Board Approval (IRB)

- If proposed project involves human subjects the research study must be reviewed & approved by the UMASS IRB before study begins
- Certification date of IRB review and approval must be submitted within the JIT module
- Pending or out of date approvals are not acceptable within the JIT module
- Federal Wide Assurance# (FWA) FWA00004009
 versus IRB # Human subjects assigned#

Human Subjects Education Certification



Collaborative Institutional Training Initiative (CITI)

- All Investigators and staff involved in the design and conduct of human subjects research must completed an education program in the protection of Human Subjects
- Also includes Principal Investigator(s), Senior/Key
 Personnel, & Consortium sites (Domestic & Foreign)
- CITI training is valid for a (3) year period after which time a refresher course must be completed

Human Subjects Education Certification



Are Investigators involved in human subjects research that is exempt from IRB review required to comply with the education requirement?

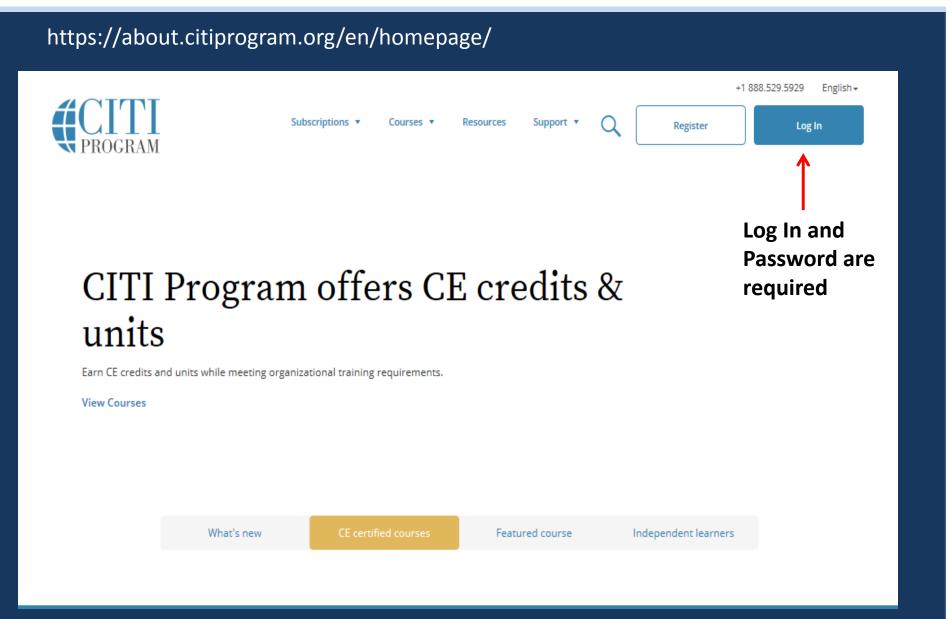
Yes

Do individuals identified as Key Personnel who are not involved in the design & conduct of human subjects need to comply with education requirement?

No

Locating CITI Certification





CITI Certification Sample



COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM) COURSEWORK REQUIREMENTS REPORT*

* NOTE: Scores on this Requirements Report reflect guiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

· Name:

• Email:

Institution Affiliation:

Institution Unit:

Phone:

• Curriculum Group:

Human Research

• Course Learner Group: Group 1.Biomedical Research Investigators and Key Personnel

University of Massachusetts Worcester (ID: 502)

Stage:

Stage 3 - Refresher Course

Report ID:

19227595

 Completion Date: Expiration Date:

05/09/2016 05/09/2019

• Minimum Passing:

80 Reported Score*: 94

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETE	D SCORE
Biomed Refresher 2 - Instructions (ID: 764)	05/09/16	No Quiz
Biomed Refresher 2 – History and Ethical Principles (ID: 511)	05/09/16	3/3 (100%)
Biomed Refresher 2 – Regulations and Process (ID: 512)	05/09/16	2/2 (100%)
Biomed Refresher 2 – Informed Consent (ID: 514)	05/09/16	2/3 (67%)
Biomed Refresher 2 – SBR Methodologies in Biomedical Research (ID: 515)	05/09/16	4/4 (100%)
Biomed Refresher 2 – Genetics Research (ID: 518)	05/09/16	2/2 (100%)
Biomed Refresher 2 – Records-Based Research (ID: 516)	05/09/16	3/3 (100%)
Biomed Refresher 2 - Populations in Research Requiring Additional Considerations and/or Protections (ID: 519)	05/09/16	1/1 (100%)
Biomed Refresher 2 – Vulnerable Subjects – Prisoners (ID: 520)	05/09/16	2/2 (100%)
Biomed Refresher 2 – Vulnerable Subjects – Children (ID: 521)	05/09/16	3/3 (100%)
Biomed Refresher 2 – Vulnerable Subjects – Pregnant Women, Human Fetuses, Neonates (ID: 522)	05/09/16	2/2 (100%)
Biomed Refresher 2 – FDA-Regulated Research (ID: 524)	05/09/16	3/3 (100%)
Biomed Refresher 2 – HIPAA and Human Subjects Research (ID: 526)	05/09/16	4/5 (80%)
Biomed Refresher 2 – Conflicts of Interest in Research Involving Human Subjects (ID: 681)	05/09/16	3/3 (100%)
How to Complete the CITI Refresher Course and Receive a Completion Report (ID: 922)	05/09/16	No Quiz

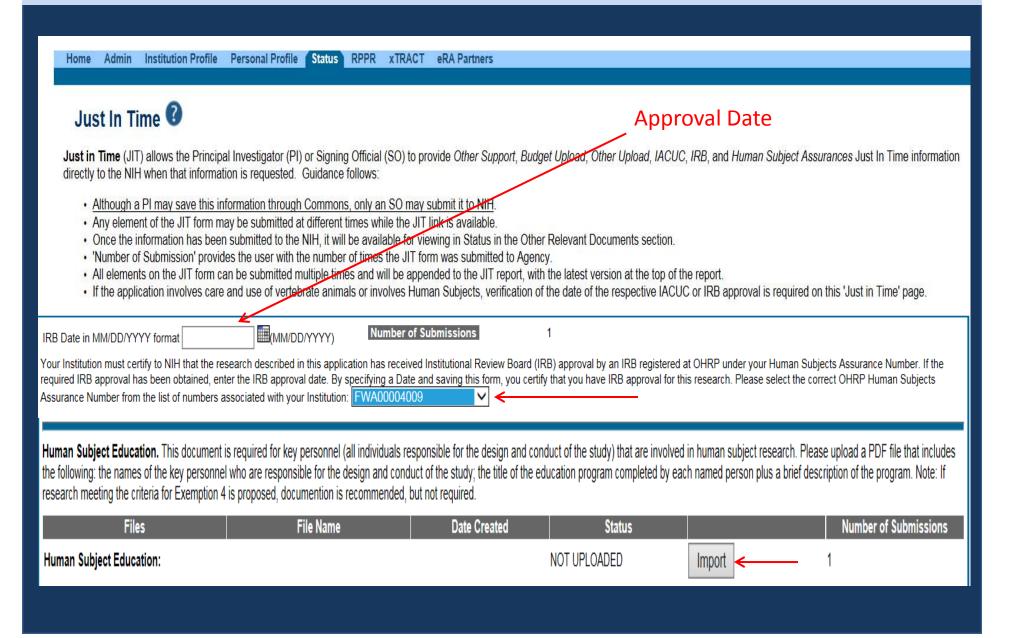
For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

CITI Program

Email: citisupport@miami.edu Phone: 305-243-7970 Web: https://www.citiprogram.org

Upload Via Commons





Other Support



Purpose: NIH does an administrative review before award issued for:

- Scientific Overlap
- Over commitment of Effort
- Duplication of Financial Support

Other Support includes <u>all</u> financial resources, whether Federal, non-Federal, commercial or institutional, available in direct support of an individual's research endeavors, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards. This includes <u>active</u> clinical trials.

Other Support



INCLUDES:

- Required for all key personnel including subrecipient key.
- For each key person include under sections of Active and Pending:

Name of individual

Project number (PI Last Name)

Source (Sponsor)

Title of Project

Major goals

Overlap statement

Project Period
Annual Direct Costs

Effort (in cal. months)

DOES NOT INCLUDE:

- Consultants or other significant contributors (OSCs)
- Training grants, fellowships, scholarships, prizes or gifts
- Grants under consideration
- Do not list zero effort, unless it is a supplement on a parent grant

Sample Other Support University of Massachusetts Medical School



OMB No. 0925-0001 (Rev. 11/16 Approved Through 10/31/2018)

For New and Renewal Applications - DO NOT SUBMIT UNLESS REQUESTED PHS 398 OTHER SUPPORT

Samples

ANDERSON, R.R.

ACTIVE

2 R01 HL 00000-13 (Anderson) 3/1/2012 - 2/28/2017 3.60 calendar

Chloride and Sodium Transport in Airway Epithelial Cells

The major goals of this project are to define the biochemistry of chloride and sodium transport in airway epithelial cells and clone the gene(s) involved in transport.

5 R01 HL 00000-07 (Baker) 4/1/2001 - 3/31/2012 1.20 calendar

NIH/NHLBI \$122,717

Ion Transport in Lungs

The major goal of this project is to study chloride and sodium transport in normal and diseased lungs.

R000 (Anderson) 9/1/2014 - 8/31/2017 1.20 calendar

Cystic Fibrosis Foundation \$43,123

Gene Transfer of CFTR to the Airway Epithelium

The major goals of this project are to identify and isolate airway epithelium progenitor cells and express human CFTR in airway epithelial cells.

PENDING

DCB 950000 (Anderson) 12/1/2014 - 11/30/2016 2.40 calendar

National Science Foundation \$82,163

Liposome Membrane Composition and Function

The major goals of this project are to define biochemical properties of liposome membrane components and maximize liposome uptake into cells.

There is scientific overlap between aim 2 of NSF DCB 950000 and aim 4 of the application under consideration. If both are funded, the budgets will be adjusted appropriately in conjunction with agency

RICHARDS, L.

NONE

HERNANDEZ, M.

5 R01 CA 00000-07 (Hernandez) 4/1/2010 - 3/31/2017 3.60 academic

\$110,532

Gene Therapy for Small Cell Lung Carcinoma

The major goals of this project are to use viral strategies to express the normal p53 gene in human SCLC cell lines and to study the effect on growth and invasiveness of the lines.

5 P01 CA 00000-03 (Chen) 7/1/2014 - 6/30/2016 1.80 academic

> Page Other Support Format Page

OMB No. 0925-0001 (Rev. 11/16 Approved Through 10/31/2018)

\$104,428 (sub only)

3.00 summer

Mutations in p53 in Progression of Small Cell Lung Carcinoma

The major goals of this subproject are to define the p53 mutations in SCLC and their contribution to tumor progression and metastasis.

BE 00000 (Hernandez) 9/1/2014 - 8/31/2017

\$86.732

1 80 academic

American Cancer Society p53 Mutations in Breast Cancer

The major goals of this project are to define the spectrum of p53 mutations in human breast cancer samples and correlate the results with clinical outcome.

Potential commitment overlap for Dr. Hernandez between 5 R01 CA 00000-07 and the application under consideration. If the application under consideration is funded with Dr. Hernandez committed at 3.60 person months, Dr. Hernandez will request approval to reduce her months on the NCI grant.

BENNETT, P.

ACTIVE

Investigator Award (Bennett)

9/1/2015 - 8/31/2017

9.00 calendar

Howard Hughes Medical Institute \$581,317 Gene Cloning and Targeting for Neurological Disease Genes

This award supports the PI's program to map and clone the gene(s) implicated in the development of

Alzheimer's disease and to target expression of the cloned gene(s) to relevant cells

OVERLAP: None

Overlap Statement Samples University of Massachusetts Medical School



- Budgetary overlap occurs when duplicate or equivalent budgetary items (e.g., equipment, salary) are requested in an application but are already provided for by another source.
- Commitment overlap occurs when a person's time commitment exceeds 100 percent (i.e., 12 person months), whether or not salary support is requested in the application. While information on other support is only requested for senior/key personnel (excluding consultants and other significant contributors (OSC's).
- Scientific overlap occurs when: (1) substantially the same research is proposed in more than one application or is submitted to two or more different funding sources for review and funding consideration, or (2) a specific research objective and the research design for accomplishing that objective are the same or closely related in two or more applications or awards, regardless of the funding source. Potential scientific overlap is to be addressed by the Scientific Review Group (SRG) only by its identification in an Administrative Note in the Summary Statement.
- Resolution of Overlap. Resolution of overlap occurs at the time of award in conjunction with applicant institution officials, the PD/PI, and awarding agency staff.
- UMMS *maximum* allowed commitment is *95% or 11.4cm* for faculty

SUMMIT-JIT (Other Support)

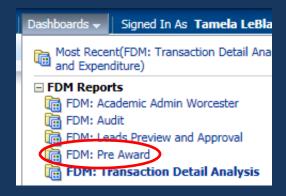


Navigation in SUMMIT:

http://inside.umassmed.edu/financialservices/



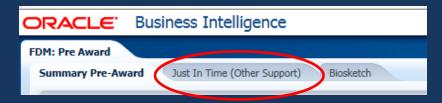
Under Dashboards, select FDM: PreAward



SUMMIT-JIT (Other Support)

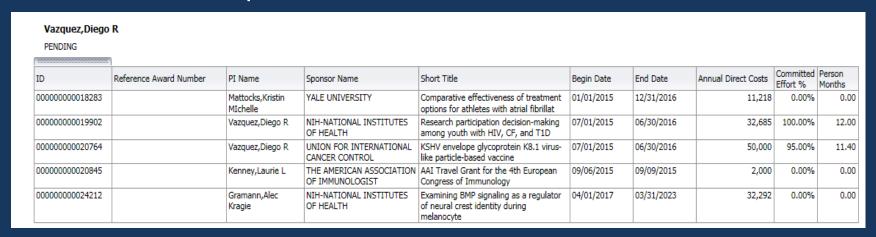


Choose tab: Just In Time (Other Support)



Select a Team Member by either scrolling or searching for the name.

Hit Apply button and a list will show of all active and pending research for that person.



Pay attention to notes at the bottom of SUMMIT screen

Other Uploads Section



- Current F&A rate agreement
- Revised budgets (only if requested)
- Institutions EIN number
- Awarding Center may request additional information on a case by case bases
- Cover Letter addressed to requester listing documents requested or pending

Sponsored Programs

http://www.umassmed.edu/research/funding/

Sponsored Programs Fact Sheet

UMMS Institutional Information for Sponsored Projects

Applicant Organization for all grantproposals: University of Massachusetts Medical School Legal Entity for contracts and agreements: University of Massachusetts, Worcester

> Public/State-Controlled Inst. of Higher Education Institution Type:

DUNS Number: 603847393

NIH IPF Number: 0850903

NSF Organization ID: 0097568000

County: Worcester

Congressional District: MA-002

Federal Wide Assurance (FWA) Number: 00004009

Animal Welfare Assurance (AWA) Number: D16-00196 (A3306-01), effective 1/4/2017 -11/30/2020

Date of AAALAC Accreditation: November 15, 2013 - Site #000343

Federal Tax Exemption Status: Exempt under IRC §115 - State University

Federal Tax ID Number (TIN): 04-3167352

Entity Identification Number (EIN): 1043167352A1

NAICS Code: 611310

CAGE Code: 6R004

FICE Number: 009756

System for Award Management (SAM) Expiration 11/16/2017

Current NIH Salary Cap: \$187,000

UMass Medical School W-9 Form W-9 Form

DHHS Indirect Cost Rate Agreement, 2/23/17

Cognizant Agency:

US Department of Health and Human Services POC: Michael Stanco, HHS Representative 26 Federal Plaza, Rm. 41-122 New York, NY 10278 (212) 264-2069

Cover Letter- Uploads Section University of Massachusetts Medical School







April 21, 2017

David Madoo Grants Management Specialist NIH/NIAID/DEA/GMP 5601 Fisher Lane, Room 4E44 Rockville, MD 20852

Phone: (301)761-6446

Email: david.madoo@nih.gov

RE: Just in Time Information for

Dear Mr. Madoo,

In response to your request for JIT information concerning application R21 enclose the following items:

- 1) Current Other support for individuals designated in an application as key personnel.
- 2) CITI Education documentation for the protection of human subjects for senior/key personnel involved in the project
- 3) Confirmation that EIN number confirm it is 1043167352A1

Animal protocol approval is under congruency review & will forward when approved.

Sincerely yours,

Departmental Tools



Links to assist you with the JIT response:

OSP: http://www.umassmed.edu/research/

IACUC: http://www.umassmed.edu/research/compliance/iacuc/

IRB: http://www.umassmed.edu/ccts/irb/

CITI: https://about.citiprogram.org/en/homepage/

Other Support: https://grants.nih.gov/grants/funding/phs398/competing othersupport.pdf

UMass Effort Policy:

http://www.umassmed.edu/uploadedFiles/research/funding/RFS/Research Policies/10%2006 %2005%20Effort%20Commitments%20and%20Salary%20Charges%20on%20Sponsored%20Projects.pdf

APPENDIX

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-16-147 NOT-OD-17-043

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;
 - o 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 <u>High-level Summary of Form Changes in FORMS-E Application Packages</u> 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 <u>How to Apply - Application Guide</u> 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 <u>NIH "parent" announcements</u> 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.

5/30/2017	NOT-OD-17-062: New "FORMS-E" Grant Application Forms and Instructions Coming for Due Dates On or After January 25, 2018

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 FAOs

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

ACRONYMS AND TERMS USED TODAY OSP RA Update - 5/31/2017

ACRONYM/TERM	DESCRIPTION
2 CFR 200	Uniform Administrave Requirements, Cost Principles and Audit Requirements for Federal Awards
CITI	Collaborative Institutional Training Initiative
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.
F&A Costs	Facilities & Administrative Costs
FWA	Federal Wide Assurance
GMS	Grants Management Specialist
GSI	Grant Support Index
IACUC	Institutional Animal Care and Use Committee
IRB	Institutiona Review Board
JIT	Just in Time
MIRA	Maximizing Investigators' Research Award (R35)
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.
OSC	Other Significant Contributor
OSP	Office of Sponsored Programs
PHS	Public Health Service
PI	Principal Investigator
R01	Activity Code for NIH Research Projects - Research Project
R35	Maximizing Investigators' Research Award (R35)
RAU	Research Administration Update
SRG	Scientific Review Group
SUMMIT	SUMMIT is the UMass Medical School's web based reporting tool.
UMMS	University of Massachusetts Medical School