

## Agenda

- Office of Clinical Research Update Meg Johnson
- Chief Research Officer Role
- New Supplemental Funding Routing Form
- Vendor Setup New Subrecipients & DUNs Numbers
- NIH Updates
  - Salary Limitation Update
  - eRA Commons Reminder
  - eRA Commons Alert
  - NIH ASSIST (Multi-Project Applications) Reminder
- FCOI Update
- Research Administration Training Program Upcoming Courses
- Updated Proposal & Progress Report Statistics

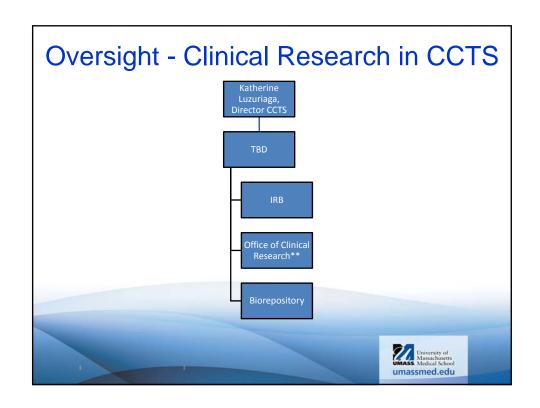


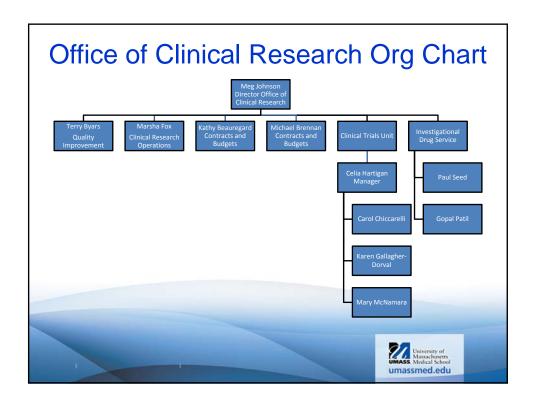


## Meg Johnson - OCR

- Background:
  - HIPAA privacy regulation
  - Human Subject research regulation
- Started 11/1/2012
- Current responsibilities:
  - Subset of Sheila Noone's responsibilities, with oversight of:
    - Clinical Trial Agreements & Budgeting (Industry)
    - Quality Assurance/Quality Improvement
    - Clinical Trials Unit/Investigational Drug Service
    - Research Operations/Coordination







### **OCR** Initiatives

- Designated points of contact (Kathy Beauregard or Mike Brennan) for assistance with Industry Clinical Trial Agreements
- Research billing coordination with the clinical system, including: refined invoicing process and preparing for a revised process to reduce errors and enhance compliance
- Working with IDS for revised pricing structure
- Working with CTU for greater awareness of services and flexibility.



### Questions? Pease contact me:

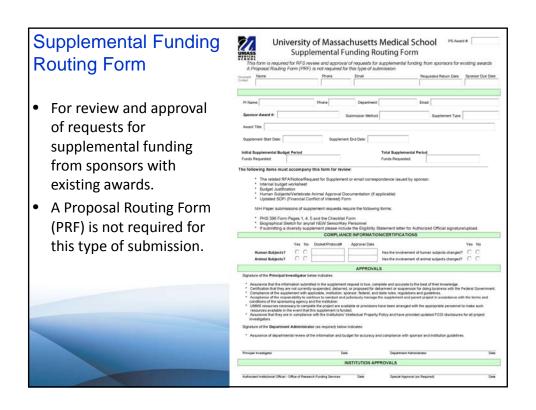
Meg Johnson, JD, CIP Director, Office of Clinical Research

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meg.johnson@umassmed.edu



TO: University of Massachusetts Medical School Faculty FROM: Terence R. Flotte, MD Celia and Isaac Haidak Professor of Medical Education Executive Deputy Chancellor, Provost and Dean April 18, 2013 DATE: SUBJECT: Chief Research Officer Role In our efforts to prioritize our investments in faculty who serve our academic mission and in the interests of maximizing efficiency, the Chancellor and I have decided to put the search for an Executive Vice Chancellor for Research on hold at the present time. As you know, I have been fulfilling the Chief Research Officer responsibilities for the past nine months; I will to continue to subsume this role within the scope of my responsibilities. I have begun meeting with small groups of chairs, program directors and other faculty for advice on various issues that benefit from their input as to the scientific merit and impact of investments made through the Office of Research. I look forward to continuing to do so, as the breadth of knowledge and experience our scientific leaders possess is a core strength of our enterprise. In conjunction with the Scientific Council, I also continue to welcome feedback from faculty as to the adequacy of support they receive from the infrastructure in the Office of Research, including research funding services, research core services and research compliance functions. Thank you all for your support.



## New Subrecipient - Vendor Setup Up

- New subrecipients need to be set up as a vendor in PeopleSoft before RFS can generate the subaward and Purchase Order
- Use the Vendor Add/Update Information Form to add the vendor. The form is available at:

http://www.umassmed.edu/uploadedFiles/APVendorForm.doc

A W-9 must be submitted for all new vendors. The UMW-9 is available at:

http://inside.umassmed.edu/uploadedfiles/policies/Vol5 forms/UMW-9.pdf

 Subrecipients are required to have a valid DUNS number. If they do not, they can request a DUNS number at:

https://iupdate.dnb.com/iUpdate/companylookup.htm



## **NIH Salary Limitation Update**

- The NIH Salary Limitation remains at \$179,700.
- In January, the President issued Executive Order 13635, which would have allowed for certain rates of pay to be adjusted after March 27, 2013, effectively resulting in an increase in the Executive Level II NIH Salary Limitation from \$179,700 to \$180,600.
- However, on April 5, 2013, Executive Order 13641 was signed and superseded Executive Order 13635.
- Executive Order 13641 provides for no increase in the Executive Level pay scale and the Executive Level II salary level remains at \$179,700.
- Potential for Executive Salary Level III to come into play with the FY2014 federal budget.



## eRA Commons Reminder

- Do not bookmark the eRA Commons login page.
  - -Bookmarking the login page can lead to error messages due to changes to the NIH network infrastructure.
- If you wish to bookmark a URL for Commons, keep it generic. Use:
  - -https://public.era.nih.gov/commons



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## eRA Commons Alert

#### RPPR Errantly Made Available for Non-SNAP Eligible Awards

Due to a technical issue, eRA Commons is currently allowing for the initiation of a Research Performance Progress Report (RPPR) for non-SNAP awards. Per Guide Notice NOT-OD-13-035, the RPPR process can only be used for SNAP and Fellowship awards.

#### Please do NOT initiate RPPRs for non-SNAP grants.

RPPR currently only supports streamlined progress reports for SNAP and Fellowship awards, as it lacks the functionality to provide detailed budgets. As such, the RPPR is not currently an acceptable format for a progress report for non-SNAP awards.

**Submit your non-SNAP progress report using the standard paper process** as described in the instruction guide for Non-Competing Continuation Progress Report PHS 2590 (Revised 08/2012).

If you inadvertently initiate an RPPR for a non-SNAP award, please revert back to the standard paper process and contact RFS who will ask NIH to delete the electronic report from their database.

#### Electronic Submission of Multi-Project Applications (ASSIST)

- NIH plans to transition all multi-project applications to electronic submission using the SF 424 (R&R) form set by January 2014.
- November 2012 Launched ASSIST and began issuing a series of pilot funding
  opportunity announcements of varying activity codes that will require electronic
  submission for due dates between January and September 2013. These FOAs will be
  listed on the multi-project application electronic submission transition timeline as they
  are published;
- September 25, 2013 All applications submitted in response to FOAs with the following activity codes intended for September 25, 2013 due dates and beyond will require electronic submission: P01, P20, P50, R24, U24, U19.
- January 25, 2014 All applications submitted in response to FOAs with the following activity codes intended for January 25, 2014 due dates and beyond will require electronic submission: G12, P30, P40, P41, P42, P51, P60, R28, U10, U41, U42, U45, U54, U56, UC7, UM1.
- Organizations that use system-to-system solutions to transmit applications via data stream to Grants.gov rather than using the Grants.gov forms will be able to send multiproject applications through Grants.gov using the same interfaces they do now.



## **FCOI** Update

- 1,601 UMMS faculty/staff have completed the FCOI training
- Institutional FCOI policy applicable to all UMMS sponsored project activity (not just PHS)
- Reminder all individuals identified on the SDFI form must have completed FCOI training before a project can be set up
- NIH Intramural Investigators participating on NIH extramural funded projects are not subject to the FCOI regulation
- RFS is working with Grant Accounting to develop a process whereby department administrators can view submitted SDFI forms in PeopleSoft to ensure individuals have completed disclosure and training requirements before being appointed to the project



## Research Administration Training Program Upcoming Courses

• Effort Management

4/30/13 9:00 – 11:00 Location - S1-607 (Lazare Auditorium)

Cost Sharing/Cost Transfers

5/14/13 9:00 – 11:00 Location - LRB-1 (Michelson Conference Room)

Clinical Research for Administrators

5/23/13 9:00 – 11:00 Location - HR Training Room @ South Street

Contributions & Gifts

6/4/13 9:00 – 11:00 Location - TBD

To register go to: http://i.umassmed.edu/Inside/registration/Register.aspx?pid=77



#### PROPOSAL SUBMISSIONS TO RFS March 2012 - March 2013 December 2012 February 2013 January 2013 2013 March 2012 2012 May 2012 **June 2012** August 201 september November March Count 61 104 100 84 62 100 125 75 75 139 111 93 On Time 45% 33% 51% 50% 50% 60% 62% 50% 41% 43% 52% 40% 32% Late 48% 40% 43% 48% 35% 37% 48% 49% 48% 47% 55% 59% 57% After the fact 5% 1% 9% 7% 10% 9% 7% 2% 2% 9% 9% 1% 5% Total 100% 100% 100% 100% 100% 100% 100% 100% 100% 100% 100% 100% 100% **Expedited Request** 39% 31% 31% 29% 26% 22% 31% 29% 35% 32% (3 days or less) On Time: Received by RFS 5 days prior to the requested return date. Late: Received by RFS less than 5 days prior to the requested return date. After the Fact: Received by RFS after the requested return date. Expedited Request: Received by RFS with 3 days or less to review before requested return date. umassmed.edu

# SUBMISSIONS TO RFS March 2012 to March 2013 Comparison

PROPOSALS	2012	2013	Change
Count	95	93	-2
On Time	45%	32%	-13%
Late	48%	59%	+11%
After the fact	7%	9%	+2%
Total	100%	100%	-
Expedited Request (3 days or less)	35%	41%	+6%

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

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#### PROGRESS REPORT SUBMISSIONS TO RFS March 2012 - March 2013 2012 September 2012 October 2012 February 2013 January 2013 August 2012 March 2012 March 2013 2012 **April 2012** July 2012 November December May Count 40 22 20 45 39 29 26 10 11 23 25 45 30 On Time 45% 47% 34% 38% 23% 30% 37% 26% 27% 55% 40% 49% 50% Late 38% 42% 56% 41% 62% 50% 27% 43% 41% 25% 48% 40% 40% After the fact 17% 11% 10% 21% 15% 20% 36% 30% 32% 20% 12% 11% 10% Total 100% 100% 100% 100% 100% 100% 100% 100% 100% 100% 100% 100% 100% Expedited Request 30% 29% 31% 17% 31% 30% 0% 35% 36% 10% 44% 24% 17% (3 days or less) On Time: Received by RFS 5 days prior to the requested return date. Late: Received by RFS less than 5 days prior to the requested return date. After the Fact: Received by RFS after the requested return date. Expedited Request: Received by RFS with 3 days or less to review before requested return date.

### SUBMISSIONS TO RFS March 2012 to March 2013 Comparison

PROGRESS REPORTS	2012	2013	Change
Count	40	30	-10
On Time	45%	50%	+5%
Late	38%	40%	+2%
After the fact	17%	10%	-7%
Total	100%	100%	-
Expedited Request (3 days or less)	30%	17%	-13%

On Time: Received by RFS 5 days prior to the requested return date.

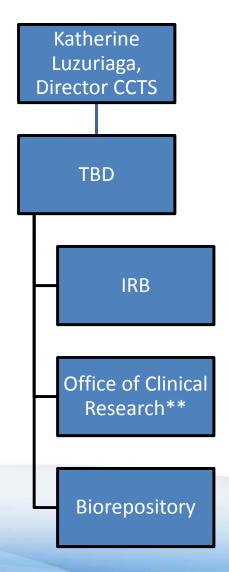
Late: Received by RFS less than 5 days prior to the requested return date.

After the Fact: Received by RFS after the requested return date.

Expedited Request: Received by RFS with 3 days or less to review before requested return date.

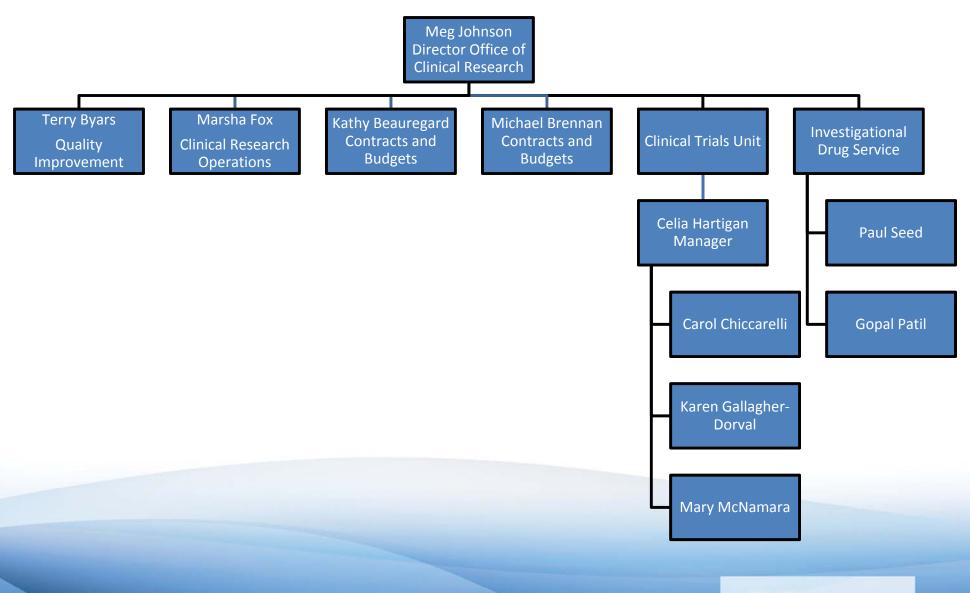


## Oversight - Clinical Research in CCTS





## Office of Clinical Research Org Chart







## University of Massachusetts Medical School Supplemental Funding Routing Form

PS Award #:	
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This form is required for RFS review and approval of requests for supplemental funding from sponsors for existing awards. A Proposal Routing Form (PRF) is not required for this type of submission.

Document	Name	ung re	ו) ווווע	-KF)	Phone	iirea ioi	Ema		JIIIISSIOII.	Requ	ested Return Date	Spon	sor Due Date
Contact													
PI Nan	ne:				Phone:		De	epartment:		Email	:		
Sponsor Award #: Submission Method: Supplement Type:													
Award	Award Title:												
Supple	ment Start Dat	te:			Su	ıpplement	t End Da	te:					
Initial S	Supplemental	Budget F	Period						Total Supplementa	al Period			
Funds F	Requested:								Funds Requested:				
The follo	owing items	must a	ccom	pany	this form fo	or revie	w:						
<ul> <li>* The related RFA/Notice/Request for Supplement or email correspondence issued by sponsor.</li> <li>* Internal budget worksheet</li> <li>* Budget Justification</li> <li>* Human Subjects/Vertebrate Animal Approval Documentation (if applicable)</li> <li>* Updated SDFI (Financial Conflict of Interest) Form</li> <li>NIH Paper submissions of supplement requests require the following forms:</li> </ul>													
<ul> <li>PHS 398 Form Pages 1, 4, 5 and the Checklist Form</li> <li>Biographical Sketch for any/all NEW Senior/Key Personnel</li> <li>If submitting a diversity supplement please include the Eligibility Statement letter for Authorized Official signature/upload.</li> </ul>													
	II Subiliitii	ing a div	Croity	Зирр					N/CERTIFICATION		a Omolal Signature	ларюа	
			Yes	No	Docket/Prot	ocol#	Approv	val Date				Yes	No
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	Animal Subje	ects?	$\bigcirc$	$\bigcirc$					Has the involvemen	nt of anima	al subjects changed?	$\bigcirc$	$\bigcirc$
							AP	PROVAL	S				
Signatu	ire of the Princ	cipal Inve	estiga	t <b>or</b> be	low indicates:								
<ul> <li>* Assurance that the information submitted in the supplement request is true, complete and accurate to the best of their knowledge.</li> <li>* Certification that they are not currently suspended, debarred, or proposed for debarment or suspension for doing business with the Federal Government.</li> <li>* Compliance of the supplement with applicable, institution, sponsor, federal, and state rules, regulations and guidelines,</li> <li>* Acceptance of the responsibility to continue to conduct and judiciously manage the supplement and parent project in accordance with the terms and conditions of the sponsoring agency and the institution.</li> <li>* UMMS resources necessary to complete the project are available or provisions have been arranged with the appropriate personnel to make such resources available in the event that this supplement is funded.</li> <li>* Assurance that they are in compliance with the Institutions' Intellectual Property Policy and have provided updated FCOI disclosures for all project investigators.</li> </ul>													
Signature of the <b>Department Administrator</b> (as required) below indicates:													
* Assurance of departmental review of the information and budget for accuracy and compliance with sponsor and institution guidelines.													
Principa	I Investigator					Date	-		Department Adm	ninistrator			Date
						IN	ISTITUT	TION APE	PROVALS				



### Vendor Add / Update - Information Form

#### A W9 or MW9 MUST be submitted for all NEW Vendors

For Department Use Only								
Current Vendor ID:	Requested by: Phone:							
Action Required:	dd Update UMASS Campus:							
	ess Change Tax Reporting Status Add Additional Remittance Address							
Change FEI / SSN / T	☐ Change FEI / SSN / TIN ☐ Change Legal Name ☐ Add New Vendor							
To Be Completed by Ven	idor							
Vendor Name:								
A a manuscript A marking black	FEI □ SS#; □							
Acronym if Applicable:	FEI SS#: U							
Order Address:								
City:	State: Zip:							
Remit Address:								
City:	State: Zip:							
A/R Email:								
Contact Name:	Contact Title:							
Contact Tel:	s?							
Do you accept Fax order								
	PO Email:							
U.S. Citizen? Yes  Are you a current or form	□ No U.S. Business? □ Yes □ No ner Commonwealth of Massachusetts Employee? □ Yes □ No							
Vendor Type: Minority-Owned Woman-Owned Small Disabled Owned (Please see reverse for Vendor Type Definitions – Check all applicable Vendor Types)								
Certification Type:	Expiration Date of Certification:							
Performer Speaker/Lecturer Entertainer/Entertainment Related Athletic Official								
Services Provided:								
If business, # of employe	es							
Vendor Signature:								
I, the Contractor, or acting in behalf of the contractor, certify under pains and penalties of perjury that to the best of my knowledge and belief, the above information is true, correct, and complete.								

rev: 03/06

## Form UMW-9 University of Massachusetts Substitute W-9 Form (Pay December 2012)

## Request for Taxpayer Identification Number and Certification

Give form to the requester. Do not send to the IRS

	<b>W-9 Form</b> ember 2012)	Identification Number and	d Certifica	tion	send to the IRS.				
<del>ر </del>	,	on your income tax return):							
page 3	Business name, if different from above:								
pe ons or	Check appropriate b								
or tyl tructic	Limited liability company. Enter the tax classification: (C =Corporation, S = S Corporation, P = Partnership)  Exemple Partnership)								
Print ic Ins	Other (see instructions)								
Specif	Business name, if different from above:  Check appropriate box:								
Sec	City, state, and ZII	P code:							
ğ	Order Email Addre	ess:	Order Fa	ax Number:					
uire			Contact Pho	ne Number:					
Required	Vendor's preferred	d method for Purchase Orders:	_	Fax					
Part I	Taxpayer Identi	fication Number (TIN)							
		priate box. The TIN provided must match the nar		Social secu	urity number				
		ckup withholding. For individuals, this is your so wever, for a resident alien, sole proprietor, or disr		-	-				
entity, se	ee the Part I instruct	ions on page 3. For other entities, it is your empl	oyer	Employer iden	or ntification number				
		. If you do not have a number, see <i>How to get a T</i> ore than one name, see the chart on page 4 for gui		Employer luci	itilication number				
	umber to enter.	ore main one name, see the chart on page 4 for gui	defines on	-					
Vendors: Dunn and Bradstreet Universal Numbering System (DUNS)									
	Certification	sai Numbering System (DONS)							
	enalties of perjury, I number shown on t	certify that:  this form is my correct taxpayer identification nur	nber (or I am wa	niting for a number t	to be issued to me), and				
2. I am not subject to backup withholding because: (a) I am exempt from backup withholding, or (b) I have not been notified by the Internal Revenue Service (IRS) that I am subject to backup withholding as a result of a failure to report all interest or dividends, or (c) the IRS has notified me that I am no longer subject to backup withholding, and									
3. I am a U.S. citizen or other U.S. person (defined below).									
<b>Certification instructions:</b> You must cross out item 2 above if you have been notified by the IRS that you are currently subject to backup withholding because you have failed to report all interest and dividends on your tax return. For real estate transactions, item 2 does not apply. For mortgage interest paid, acquisition or abandonment of secured property, cancellation of debt, contributions to an individual retirement arrangement (IRA), and generally, payments other than interest and dividends, you are not required to sign the Certification, but you must provide your correct TIN. See the instructions on page 4.									
Sign Here	Signature of U.S. person: Date:								
If you have questions on completing this form, please contact Vendor Maintenance at: (508) 856-2234.									
Upon completion of this form, please return to: University of Massachusetts Department you are doing business with. (UMWOR)									
Part III For University Verification Purposes Only – Do Not Write Below This Line Business Name Acronym									
	TIN Matching	□ OFAC Signature		Date	e:				