RESEARCH ADMINISTRATION

UPDATE

Wednesday, March 29, 2017

Lazare Auditorium, S1-607 1:00 - 3:00 pm

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

Financial Monitoring Tools

Agenda

University of Massachusetts Medical School
UMASS

- Office of Clinical Research Update
  - Meg Johnson, Director, Office of Clinical Research
- NIH Update
  - NOT-OD-17-042: Update and Clarification: NIH Continuous Submission Policy
  - NOT-OD-17-048: NIH Operates Under a Continuing Resolution
  - NOT-OD-17-049: Interim Guidance on Salary Limitation for Grants and Cooperative Agreements
  - NOT-OD-17-050: Reporting Preprints and Other Interim Research Products
  - xTRACT Enhancements Deployed March 21, 2017
  - eRA Commons Prior Approval Requests Update (NCEs & PI Changes)
- Other Updates
  - 4/15 RPPR Deadline Falls on Saturday before Patriot's Day
  - Updating Proposal Submission Dates Using SUMMIT Pre-Award Dashboard
  - Clarification on Annual Progress Report and Proposal Routing Form Signature Requirements
  - Using the CITI Report to Verify COI Training
- Proposal & Progress Report Statistics
- Research Administration Training Topic:
  - Financial Monitoring Tools, Tara Nevins & Jessica Powers, Financial System Support

CENTER FOR CLINICAL AND TRANSLATIONAL SCIENCE

UMCCTS OCR Update

March 29, 2017

CENTER FOR CLINICAL AND TRANSLATIONAL SCIENCE

Agenda:

- Business Process Updates related to OnCore Implementation
- Updates to Clinical Research Core Service Pricing
- Staffing Updates

Business Process Updates related to OnCore Implementation

- Proposal Creation for Clinical Trials (CTMS-102, A.3.i)
  - Current:
    - OCR creates and completes proposal in PeopleSoft
  - New:
    - Department creates proposal in PeopleSoft, OCR still completes
  - Why:
    - Alignment with current grant entry process
    - Allows for earlier identification of missing sponsors/PIs in PeopleSoft to avoid delay in project setup
    - Allows for enhanced GA&C tracking of pending projects

Business Process Updates, cont.

- Project Intake (CTMS-102)
  - Current:
    - OCR: Study team forwards sponsor email w/all necessary documentation/contact info to OCR, study team receives status updates via email/phone/meeting with OCR.
    - OSP: Grant submission to OSP, clinical research pricing to OCR (see budget intake)
  - New:
    - OCR: Study team/Protocol Coordinator enters protocol into OnCore, activates task list for work queue, forwards sponsor email w/all necessary documentation to OCR, and is apprised of status via task lists in addition to methods mentioned, above.
    - OSP: Clinical service pricing available in the system (limited chargemaster) for proposal/grant development. Budget build step to OCR. (see budget intake)
  - Why:
    - Enhanced tracking and status information

Business Process Updates, cont.

- Budget Intake
  - Current:
    - OCR: Budget review and negotiation begins upon receipt of completed Coverage Analysis, Budget & Billing Grid (CABBG) form from study team
    - OSP: Clinical service pricing request to OCR from study team/OSP
  - New
    - OCR: Budget review and negotiation begins after calendar has been built, completed and validated in OnCore. OCR work begins upon notification via task list in OnCore
    - OSP: Same—but limited to budget build for patient care services only.
  - Why:
    - Budget builds off of OnCore calendar, so calendar is foundation. Budget build/review cannot start until the calendar has been built and fully validated

Business Process Updates, cont.

- Project setup
  - New Project task list gives new visibility to steps required for financial activation/financial activation status
- Sponsor/PI addition process (CTMS-103)
  - Current:
    - sponsors added to PeopleSoft when a request comes via eIRB and/or proposal setup by OCR
  - New:
    - sponsors added to PeopleSoft when OCR notified from proposal entry. Sponsor will be added to PeopleSoft, eIRB and OnCore.
  - Why:
    - missing sponsors will be detected earlier in the intake process & will be prior to eIRB

Business Process Updates, cont.

- Amendments (CTMS-701)
  - If alters schedule of events: New/updated calendar & updated budget
  - If alters payment amounts only: new budget
  - IRB Amendment fee for major amendments
  - If new calendar needed—calendar build fee negotiated in amendment budget

Additional Info: Study conduct changes

- Entry/Tracking of visits
  - Connected with new research billing processes with Epic
  - Study coordinators will need to enter visit tracking information within a specified time to 1) support financial management in departments and 2) support billing and separation of charges
  - In addition to sponsor EDC

- Resources:
  - UMCCTS Human Research: OnCore
  - Training Material from ITCTMS OnCore Onboarding
  - OCR—for business process questions
    - clinicalresearch@umassmed.edu

Updates to Clinical Research Core Service Pricing

- Memo and updated clinical research core service pricing sheet distributed 2/7/2017
- Highlights:
  - Changes to core service fees for investigator initiated projects, updates to Clinical Research Center fees
  - Updated guidance/position document to sponsors on standard startup and study costs (external use)
  - New tools for study teams to estimate startup costs (internal use only)
- Updates on website

OCR Staffing Updates

- Marsha Fox: Retired, back ½ time
  - Focus on OnCore business process training, OnCore budget support
- Kathy Beauregard: Retiring, will be back ½ time
  - Focus on OnCore budget support, OCR general support
- Anne Roussell: Shared support
  - Assisting with Educator & Clinical Research Operations roles
- Common topics:
  - EMR/Clinical System Access requests: to UMass Memorial
  - New OCR Projects/Budgets: OnCore and clinicalresearch@umassmed.edu

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Thank you!

NOT-OD-17-042: Update and Clarification: NIH Continuous Submission Policy

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- This Notice serves to consolidate NIH policy on continuous submission that was provided in earlier Notices. The earlier notices have been rescinded, but the policy has not changed.
- The full notice is included in the Appendix of this presentation.
- Please share the Notice with your Investigators.

NOT-OD-17-048: NIH Operates Under a Continuing Resolution

University of Massachusetts Medical School
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- NIH operates under the Continuing Resolution signed by President Obama on December 10, 2016 which continues government operations through April 28, 2017 at 99.8099 percent of the FY 2016 enacted level.
- NIH will issue non-competing research grant awards at a level below that indicated on the most recent Notice of Award (generally up to 90% of the previously committed level).
- Upward adjustments to awarded levels will be considered after FY 2017 appropriations are enacted, but NIH expects institutions to monitor their expenditures carefully during this period.
- All legislative mandates that were in effect in FY 2016 remain in effect under this CR.
  - The salary limitation set at Executive Level II of the Federal Pay Scale, was increased from $185,100 to **$187,000**, effective January 8, 2017.
  - The Ruth L. Kirschstein National Research Service Award postdoctoral stipend levels and tuition/fees for FY 2017 are described in NOT-OD-17-003.
  - Until further notice, the undergraduate and predoctoral stipends and tuition/fees will remain at the levels announced in NOT-OD-16-062.

NOT-OD-17-049: Interim Guidance on Salary Limitation for Grants and Cooperative Agreements

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- Since 1990, Congress has legislatively mandated a limitation on direct salary for individuals under NIH grant and cooperative agreement awards. The mandate appears in the annual appropriation act that provides authority for NIH to incur obligations for a given Fiscal Year (FY). At this time NIH has not received a FY 2017 appropriation, and is operating under a Continuing Resolution "the Further Continuing and Security Assistance Appropriations Act, 2017" that applies the terms and conditions of the Consolidated Appropriations Act, 2016.

- The Consolidated Appropriations Act, 2016, restricts the amount of direct salary to Executive Level II of the Federal Executive pay scale. The Executive Level II salary was previously set at $185,100, and increased to **$187,000** effective January 8, 2017.

- For awards issued in those years that were restricted to Executive Level II (see Salary Cap Summary, FY 1990 – FY 2016), including competing awards already issued in FY2017, if adequate funds are available in active awards, and if the salary cap increase is consistent with the institutional base salary, grantees may rebudget to accommodate the current Executive Level II salary level. However, no additional funds will be provided to these grant awards.

- Once the DHHS Appropriation for FY 2017 is enacted, NIH will publish the annual Notice of legislative mandates to provide information on any statutory provisions that limit the use of NIH grant funds in FY 2017. Additional guidance on the salary cap will also be provided at that time.

NOT-OD-17-050: Reporting Preprints and Other Interim Research Products

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- NIH released NOT-OD-17-050 last Friday (3/24/17) regarding reporting preprints and other interim research products in applications and progress reports.
- Please note that the inclusion of preprints and interim research products *is not* required. Investigators may choose to include these in their applications and progress reports effective May 25, 2017.
- NIH encourages investigators to use interim research products, such as preprints, to speed the dissemination and enhance the rigor of their work. This notice clarifies reporting instructions to allow investigators to cite their interim research products and claim them as products of NIH funding.
- Please share the Notice with your Investigators.

xTRACT Enhancements

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- Several new enhancements were added to xTRACT in a software release deployed March 21, 2017.
- xTRACT is the Extramural Trainee Reporting and Career Tracking system and can be accessed via eRA Commons. It allows applicants, grantees and assistants to create research training tables for progress reports and institutional training grant applications.
- Enhancements:
  - Participating Faculty Upload:
    - The length of each faculty member's research interest is now validated, and an error message is displayed if it exceeds the maximum of 60 characters.
  - Copy RTD Features:
    - Some users had occasionally encountered an unexpected error upon attempting to copy a prior RTD. This issue has been corrected.
  - Correct Mean Values Displayed Properly:
    - When preparing the data for Predoctoral Applicants/Entrants, the mean values for Total Applicant Pool and Applicants Eligible for Support were sometimes displayed on the Summary tab in reverse order. This has been corrected.
    - Note that this display issue only affected the values displayed on the screen under the Summary tab -- when viewing these same values in the Preview or Finalized PDF, they have always been presented in the correct order.

eRA Commons
Prior Approval Requests Update

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- As of March 2, 2017, the ability to process No Cost Extensions and PI Change prior approval requests in eRA Commons are now functional.

NCE via Prior Approval in eRA Commons

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- Signing Officials (OSP) will be able to request an NCE electronically through eRA Commons via Prior Approval once the extension flag is no longer active.
- Prior Approval tab in eRA Commons: Initiate a Prior Approval Request and select No Cost Extension.
- When is an award eligible for a NCE through Prior Approval?
  - When you have already used a NCE under expanded authority and you are within 90 days of the project end date.
  - When you are not under expanded authority and you are within 90 days of the project end date.
  - When the project end date has expired and has not been closed or has not entered unilateral closeout, whichever comes first.
- When is an award ***not eligible*** for a NCE through Prior Approval?
  - When you have never requested a NCE under expanded authority and you are within 90 days of the project end date. In this case, the NCE will be processed normally through the Extension link in Status.
  - When the award is closed.
  - When the award is a fellowship.

NCE via Prior Approval in eRA Commons:

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What information needs to be included in the request?

The NCE request form consists of 4 sections:

1. Request Detail
   a. Number of months of requested for extension; new end date
   b. Any unobligated funds available
2. Progress Report (pdf upload)
3. Budget Document (pdf upload)
4. Justification Document (pdf upload)

The exact details of what is required in the upload files will be outlined by the awarding IC.

Change in PD/PI via eRA Commons

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System allows for the change of PD/PI or adding/deleting multiple PIs through Prior Approval.

- Only a Signing Official (SO) can initiate the request. Principal Investigators cannot see Change of PD/PI Requests.

- The following conditions must be met for a grant to be eligible for a Change of PD/PI Request:

  1. The grant has a grant year awarded.
  2. The grant family is not past the Project Period End Date.
  3. The grant is not a Fellowship or Career award.
  4. The grant is from an IC/Agency that supports Change of PD/PI using the Prior Approval module.

Change in PD/PI via eRA Commons

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- The details for the request require some basic information:
  - Who is being replaced, removed/added to the grant?
  - What will their level of effort be?
  - What is the effective start date for the new PD/PI?
- Additionally, some files will be uploaded to the request:
  - Biosketch
  - Other Support
  - Justification Document
- Once the request is submitted, the system creates a PDF of all the submitted information and sends a notification to the SO, the GMS, and Program Officer so they can review the request.
-

4/15 RPPR Deadline Falls on Saturday before Patriot's Day

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- The April 15th RPPR deadline falls on a Saturday.
- This would normally bump the due date to Monday.
- However, Monday April 17th is Patriot's Day, a state holiday that is not observed by the Federal government.
- In order to comply with the deadline, all RPPR's will need to be submitted by Friday, April 14th.
- Please note that OSP requires two full business days for review/approval/submittal.

Updating Proposal Submission Dates Using SUMMIT Pre-Award Dashboard

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- School leadership reviews proposal submission and success rate metrics using SUMMIT pre-award dashboard data.
  - For non-Cayuse proposals previously submitted that appear as "In Process" without a Date Submitted, use the *RFS Submitted Proposal Form* link to update the status.
  - **Please note that this is not an electronic process. The form must be completed and submitted to OSP for updating.**
  - There are currently a significant amount of proposals out there with submit dates that have yet to be submitted to OSP for updating.
- A job aid is available on Financial Services website at:
  - http://inside.umassmed.edu/uploadedFiles/Pre%20Award%20Dashboard_040314.docx

Clarification on Annual Progress Report and Proposal Routing Form Signature Requirements

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- During the Annual Progress Reporting (APR) training session last month the question was asked about which signatures are required on the APR.
- APR Required:
  - Principal Investigator(s) – MPI's included
  - Administrator
- APR Optional:
  - Chair
- The guidance above applies only to the APR.
- The Proposal Routing Form (PRF) requires the following signatures:
  - Principal Investigator(s) – MPI's included
  - Administrator
  - Chair (for all participating departments)
- PRF Optional:
  - Co-Investigator(s)

Using the CITI Report to Verify COI Training

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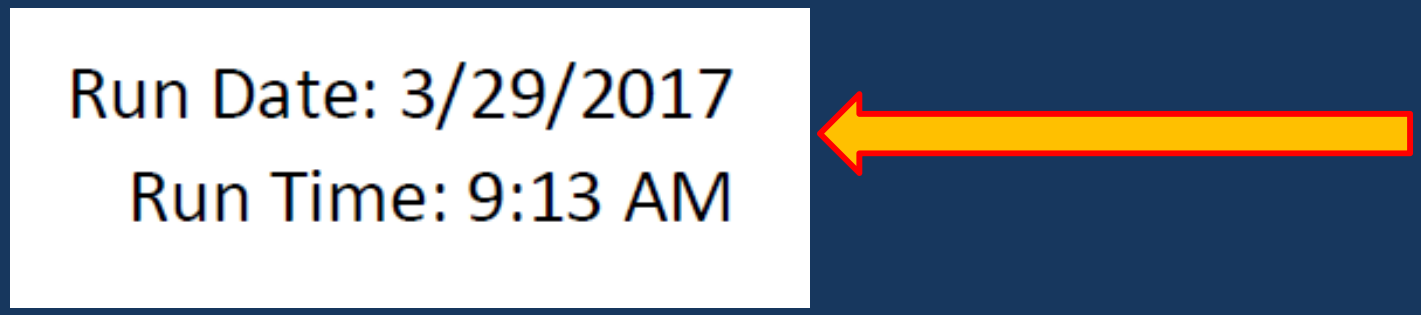
- The CITI report is updated on the OSP website Monday through Friday.
- When viewing the report please be sure that the date that appears in the upper right hand corner is current (within a day or two)



- If the date is not current, please clear your cache and recent history. If this does not work, please try a different browser.

PROPOSAL SUBMISSIONS TO OSP

February 2016 – February 2017

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	February 2016	March 2016	April 2016	May 2016	June 2016	July 2016	August 2016	September 2016	October 2016	November 2016	December 2016	January 2017	February 2017
Count	121	89	72	101	106	78	86	121	106	71	48	103	108
On Time	38%	45%	29%	57%	40%	44%	44%	56%	46%	35%	46%	53%	52%
Late	60%	55%	70%	39%	59%	56%	50%	40%	49%	62%	46%	41%	43%
After the fact	2%	0%	1%	4%	1%	0%	6%	4%	5%	3%	8%	5%	5%
Withdrawn	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	1%	0%
Total	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
Expedited Request (3 days or less)	46%	42%	44%	21%	36%	42%	35%	28%	32%	35%	33%	22%	28%

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

SUBMISSIONS TO OSP
February 2016 to February 2017 Comparison

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PROPOSALS	2016	2017	Change
Count	121	108	-13
On Time	38%	52%	+14
Late	60%	43%	-17
After the fact	2%	5%	+3
Withdrawn	0%	0%	-
Total	**100%**	**100%**	-
Expedited Request (3 days or less)	46%	28%	-18

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

PROGRESS REPORT SUBMISSIONS TO OSP
February 2016 – February 2017

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	February 2016	March 2016	April 2016	May 2016	June 2016	July 2016	August 2016	September 2016	October 2016	November 2016	December 2016	January 2017	February 2017
Count	44	71	58	43	50	25	17	27	34	32	35	43	38
On Time	48%	58%	64%	49%	52%	60%	41%	67%	62%	59%	63%	68%	58%
Late	45%	39%	36%	51%	42%	28%	41%	22%	35%	38%	37%	30%	39%
After the fact	7%	3%	0%	0%	6%	12%	18%	11%	3%	3%	0%	2%	3%
Total	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
Expedited Request (3 days or less)	30%	27%	26%	37%	36%	16%	35%	19%	29%	19%	23%	21%	32%

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

SUBMISSIONS TO OSP
January 2016 to January 2017 Comparison

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PROGRESS REPORTS	2016	2017	Change
Count	44	38	-6
On Time	48%	58%	+10
Late	46%	39%	-7
After the fact	7%	3%	-4
Withdrawn	0%	0%	-
Total	**100%**	**100%**	-
Expedited Request (3 days or less)	30%	32%	+2

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

Utilizing SUMMIT for Financial Monitoring

Introduction:

Tara Nevins and Jessica Powers from Financial System Support

SUMMIT is a Business Intelligence Tool.

- Ability to take mountains of data and present it in an organized meaningful way.
- Format is easy to read , navigate, and interpret, with powerful drill down functionality.
- Predetermined alerts and graphical representation allow users to analyze data at a glance.

SUMMIT organizes data into dashboards, each dashboard is tailor designed to meet a particular audiences need.

Summit Dashboard Facts

- Contains Financial Data from PeopleSoft Finance.
- Data is refreshed nightly. – *(One day behind PeopleSoft Production)*
- Data is easier and quicker to retrieve than PeopleSoft reports.
- Data mirrors the same departmental security as PeopleSoft.

Resources for Summit users

- You can access the SUMMIT login screen and self paced training presentations by going to the Financial Services intranet site.

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

- User Support is always available by contacting, SummitSupport@umassmed.edu.

APPENDIX

Update and Clarification: NIH Continuous Submission Policy

Notice Number: NOT-OD-17-042

Key Dates
Release Date: March 2, 2017

Related Announcements
NOT-OD-08-026 Rescinded
NOT-OD-09-114 Rescinded
NOT-OD-09-155 Rescinded
NOT-OD-10-090 Rescinded
NOT-OD-11-093 Rescinded
NOT-OD-14-028 Rescinded
NOT-OD-16-121 Rescinded

Issued by
National Institutes of Health (NIH)

Purpose

This Notice serves to consolidate NIH policy on continuous submission that was provided in earlier Notices. The policy has not changed.

Policy

NIH's continuous submission policy provides members of review and advisory groups and reviewers with recent substantial service the benefit of submitting R01, R21, and R34 applications at any time in response to active funding opportunity announcements (FOAs) that have standard due dates.

Eligibility:

Continuous submission eligibility covers:

- Appointed members of chartered NIH Study Sections.
- Appointed members of NIH Boards of Scientific Counselors.
- Appointed members of NIH Advisory Boards or Councils.
- Appointed members of NIH Program Advisory Committees.
- Peer reviewers with Recent Substantial Service.

Appointed Members:

- Appointed regular members of NIH committees are appointed by the Director, NIH (or the Director, NCI); the Secretary, DHHS; or the President of the United States.
- For Appointed members, eligibility begins on the date the appointment becomes active and continues for six weeks after the official date of retirement from appointed committee service. Thus, if retirement from appointed service occurs on June 30, continuous submission is permitted until August 16 of that year.

Recent Substantial Service:

- Recent substantial service is defined as service as an appointed, temporary, or ad hoc reviewer on a qualifying NIH study section for at least six different meetings in an 18 month period that begins January 1 of one year and ends June 30 of the following year.
- Service on the vast majority of NIH review meetings will count toward eligibility based on the Recent Substantial Service option. Check the FAQs for a list of meeting/service types that **do not qualify.**
- All meeting formats (mail review, telephone review, internet assisted meeting, video assisted meeting, and face-to-face meetings) count toward Recent Substantial Service eligibility.
- For all reviews, the effective date of service is the actual meeting date(s). Multiple related meetings occurring on the same date are counted as a single review meeting for recent substantial service requirements.
- For reviewers with Recent Substantial Service, eligibility begins August 1 and continues until September 30 of the following year. For example:

Period of Service	Time of Eligibility
January 1, 2016 – June 30, 2017	August 1, 2017 – September 30, 2018

- Accountable review service and continuous submission eligibility can be viewed in the reviewer's eRA Commons Personal Profile, in the Reviewer Information section.
- eRA Commons users with account administration roles (e.g., SO – Signing Official, AO – Administrative Official, AA – Account Administrator, BO – Business Official) can check an investigator's eligibility using the Advanced Search feature in the Admin module.
- The list of currently eligible reviewers can be found on the NIH Continuous Submission page.

Continuous Submission applies to NIH applications that satisfy both criteria:

- Submitted with continuous submission eligible Principal Investigators/Program Directors (PD/PI) including applications where one or more of the Multiple PD/PIs (MPIs) is eligible for continuous submission, and
- Submitted to R01, R21, and R34 FOAs with standard due dates, including standard AIDS due dates. It is important to note that these applications must also be compliant with policy in effect on the standard due date for which the application is submitted.

Continuous Submission **does not** *apply to*:

- Applications in which the only eligible personnel have a role other than PD/PI or MPI.
- Applications from temporary or ad hoc reviewers who have not reached minimum participation to qualify via Recent Substantial Service. Temporary or ad hoc reviewers who are not eligible for continuous submission may be eligible to use the late submission window as described in the NIH Late Policy.
- Applications from individuals who serve as appointed advisors or ad hoc reviewers / advisors for other Federal agencies or for private organizations, or for NIH groups and committees other than those listed above.
- Applications submitted in response to RFAs and PARs with non-standard receipt dates.
- Applications for activity codes other than R01, R21, or R34. These applications may be submitted on time or following the general NIH Late Policy.

How does Continuous Submission relate to the NIH Late Policy?

- Continuous Submission applies to R01, R21, and R34 applications submitted by continuous submission eligible PD/PIs and MPIs to FOAs with standard due dates, including standard AIDS due dates.
- The NIH Late Policy applies to
  - All other types of applications submitted by continuous submission eligible PD/PIs and MPIs.
  - All applications submitted by all other PD/PIs and MPIs.

Processing and Review schedule:

- Applications submitted under the continuous submission option must include a cover letter that states the eligibility of a PD/PI for continuous submission.
- Applications for each council round are accepted no later than 5 PM local (applicant organization) time on the last day of the receipt period.
- If the end of the application receipt period falls on a weekend or Federal Holiday, or during an official closure of Washington DC area Federal Offices, it automatically moves forward to the next business day.
- **No additional extensions of these Application Receipt Periods are possible.**
- Applications are required to comply with policy in effect on the standard due date for the council round in which applications are submitted.
- Depending on the timing of the submission and the number of other similar applications received during the Application Receipt Period, NIH staff will decide if the application will be reviewed in a standing Study Section or in a Special Emphasis Panel (SEP).
- Applications submitted under this option will be reviewed no later than 30 days before the corresponding Advisory Council.
- To ensure timely second level (council) review, the following Advisory Council dates and rounds will apply:

Schedule For Assignment to Advisory Council Rounds Under Continuous Submission Option

	Submitted For these Standard Due Dates		Application Receipt Period	
Advisory Council Round	R01	R21, R34	Type	Dates
May	October 5 November 5	October 16 November 16	Non-AIDS Applications	August 17 – December 16
	January 7	January 7	AIDS Applications	October 8 – February 7
October	February 5 March 5	February 16 March 16	Non-AIDS Applications	December 17 – April 16
	May 7	May 7	AIDS Applications	February 8 – June 7
January	June 5 July 5	June 16 July 16	Non-AIDS Applications	April 17 – August 16
	September 7	September 7	AIDS Applications	June 8 – October 7

Inquiries

Please direct all inquiries to:

Frequently Asked Questions and answers have been prepared (see https://grants.nih.gov/grants/peer/faq_continuous_submission.htm). Any remaining issues/appeals may be directed to a NIH Continuous Submission Committee by emailing CSR.cont.sub.comm@csr.nih.gov

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Weekly TOC for this Announcement
NIH Funding Opportunities and Notices

NIH Operates Under a Continuing Resolution

Notice Number: NOT-OD-17-048

Key Dates
Release Date: March 17, 2017

Related Announcements
NOT-OD-17-049
NOT-OD-17-001
NOT-OD-16-046

Issued by
National Institutes of Health (NIH)

Purpose

The Department of Health and Human Services (HHS), including NIH, operates under the "Further Continuing and Security Assistance Appropriations Act, 2017," (Public Law 114-254) signed by President Obama on December 10, 2016. This Act (CR) continues government operations through April 28, 2017 at 99.8099 percent of the FY 2016 enacted level.

Continuing the procedures identified under NOT-OD-17-001 and NOT-OD-16-046 and consistent with NIH practices during the CRs of FY 2006 – 2016, the NIH will issue non-competing research grant awards at a level below that indicated on the most recent Notice of Award (generally up to 90% of the previously committed level). Upward adjustments to awarded levels will be considered after FY 2017 appropriations are enacted, but NIH expects institutions to monitor their expenditures carefully during this period. All legislative mandates that were in effect in FY 2016 (see NOT-OD-16-044 and NOT-OD-16-048) remain in effect under this CR. Per NOT-OD-17-049, the salary limitation set at Executive Level II of the Federal Pay Scale, was increased from $185,100 to $187,000, effective January 8, 2017. The Ruth L. Kirschstein National Research Service Award postdoctoral stipend levels and tuition/fees for FY 2017 are described in NOT-OD-17-003. Until further notice, the undergraduate and predoctoral stipends and tuition/fees will remain at the levels announced in NOT-OD-16-062.

Inquiries

Please direct all inquiries to:

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

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices

Interim Guidance on Salary Limitation for Grants and Cooperative Agreements

Notice Number: NOT-OD-17-049

Key Dates
Release Date: March 17, 2017

Related Announcements
NOT-OD-17-048
NOT-OD-17-001
NOT-OD-16-059
NOT-OD-16-044
NOT-OD-16-048

Issued by
National Institutes of Health (NIH)

Purpose

Since 1990, Congress has legislatively mandated a limitation on direct salary for individuals under NIH grant and cooperative agreement awards (referred to here as a grant). The mandate appears in the annual appropriation act that provides authority for NIH to incur obligations for a given Fiscal Year (FY). At this time NIH has not received a FY 2017 appropriation, and is operating under a Continuing Resolution "the Further Continuing and Security Assistance Appropriations Act, 2017" (Public Law 114-254) that applies the terms and conditions of the Consolidated Appropriations Act, 2016.

The Consolidated Appropriations Act, 2016, restricts the amount of direct salary to Executive Level II of the Federal Executive pay scale. The Executive Level II salary was previously set at $185,100, and increased to $187,000 effective January 8, 2017.

For awards issued in those years that were restricted to Executive Level II (see Salary Cap Summary, FY 1990 – FY 2016), including competing awards already issued in FY2017, if adequate funds are available in active awards, and if the salary cap increase is consistent with the institutional base salary, grantees may rebudget to accommodate the current Executive Level II salary level. However, no additional funds will be provided to these grant awards.

Once the Department of Health and Human Services Appropriation for FY 2017 is enacted, NIH will publish the annual Notice of legislative mandates to provide information on any statutory provisions that limit the use of NIH grant funds in FY 2017. Additional guidance on the salary cap will also be provided at that time.

For a historical record of the salary cap, including effective dates see:
https://grants.nih.gov/grants/policy/salcap_summary.htm

Inquiries

Please direct all inquiries to:

Questions about specific awards may be directed to the Grants Management Specialist identified on the Notice of Award.

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices

Reporting Preprints and Other Interim Research Products

Notice Number: NOT-OD-17-050

Key Dates
Release Date: March 24, 2017
Effective date for application: Applications submitted for the May 25, 2017 due date and thereafter
Effective date Research Performance Progress Report (RPPR): RPPRs submitted on or after May 25, 2017

Related Announcements
NOT-OD-17-006- Request for Information (RFI): Including Preprints and Interim Research Products in NIH Applications and Reports

Issued by
National Institutes of Health (NIH)

Purpose

The NIH encourages investigators to use interim research products, such as preprints, to speed the dissemination and enhance the rigor of their work. This notice clarifies reporting instructions to allow investigators to cite their interim research products and claim them as products of NIH funding.

Definitions

Interim Research Products are complete, public research products that are not final.

A common form is the preprint, which is a complete and public draft of a scientific document. Preprints are typically unreviewed manuscripts written in the style of a peer-reviewed journal article. Scientists issue preprints to speed dissemination, establish priority, obtain feedback, and offset publication bias.

Another common type of interim product is a preregistered protocol, where a scientist publicly declares key elements of their research protocol in advance. Preregistration can help scientists enhance the rigor of their work.

Notes:

- Awardees are not required to create interim research products through their NIH award.
- Applicants are not required to cite interim research products as part of their grant applications.
- Since preprints are not published in peer-reviewed journals, they do not fall under the NIH public access policy.
- This guide notice does not apply to clinical trial registration. See ClinicalTrials.gov about registration of clinical trial protocols.

Citing interim research products in applications, proposals and reports

Interim research products can be cited anywhere other research products are cited. These sections include the following:

- R&R Other Project Information Form, Bibliography & References Cited
- R&R Senior/Key Person Profile (Expanded) Form, Biographical Sketch
- PHS 398 Research Plan, Progress Report Publication List
- PHS 398 Career Development Award Supplemental Form, Progress Report Publication List
- PHS Fellowship Supplemental Form, Progress Report Publication List
- RPPR, section C - Products

To cite the product, applicants and awardees must include the Digital Object Identifier and the Object type (e.g. preprint, protocol) in the citation. Also list any information about the document version (e.g. most recent date modified), and if relevant, the date the product was cited.

Example: Bar DZ, Atkatsh K, Tavarez U, Erdos MR, Gruenbaum Y, Collins FS. Biotinylation by antibody recognition- A novel method for proximity labeling. BioRxiv 069187 [**Preprint**]. August 11, 2016 [cited 2017 Jan 12]. Available from: https://**doi**.org/10.1101/069187.

These requirements help reviewers understand that the product is public, interim, and identify the specific version is being referenced.

Note: Applicants are responsible for providing the information necessary to review a section of an application within the page limits of that section.

Claiming interim research products as products of NIH awards

NIH intends to maximize impact of interim research products that are developed with NIH funds. Therefore, NIH expects awardees to ensure a high level of public access to NIH supported interim products. To facilitate text mining and other analysis of these products as data, the NIH expects standardized terms of use. NIH also expects awardees will adhere to other norms of responsible scientific communication.

Specifically, to claim an interim research product as a product of an NIH award, the NIH expects that the awardee will:

- Make the product publicly available. To maximize the impact of an interim research product, the NIH strongly encourages awardees to select a Creative Commons Attribution (CC-BY) license or dedicate their work to the public domain.
- In the text of the document:
  - Acknowledge NIH funding in accordance with NIH Grants Policy Statement Chapter 8.2.1
  - Clearly state that the work is not peer-reviewed
  - Declare any competing interests, as an author would do for any journal article

For applications submitted for the May 25, 2017 due date and thereafter, awardees can claim these products on their progress report publication list. They can also report them on their RPPR as of May 25, 2017, and link them to their award in their My Bibliography account.

Guidance for selecting interim research product repositories

Interim research products rely on repositories to make them public. The repository market is growing rapidly, and in many scientific disciplines, norms for interim research products are still evolving.

The NIH would like to ensure that practices for interim products facilitate the impact, measurement and the integrity of the scientific record. Specifically, the NIH strongly encourages interim research products arising from NIH funds to be deposited in repositories that ensure:

- Content is findable, accessible, interoperable and reusable.
- Interim product metadata, including usage statistics, are open, and easy to access by machines and people (e.g. via application program interfaces).
- Content is easy to use by machines and people. This access is both a function of permission (e.g. use of Creative Commons licenses) and technology (e.g. application program interfaces).
- Policies about plagiarism, competing interests, misconduct and other hallmarks of reputable scholarly publishing are rigorous and transparent.
- Records of changes to the product are maintained, and users have clear ways to cite different versions of the product.

- Links to the published version, if available.
- A robust archiving strategy that ensures long-term preservation and access.

Background and public comments

In the Request for Information (RFI) NOT-OD-17-006, the NIH sought input on the use of interim research products in NIH applications and reports, and the standards for reporting them. The NIH wanted to know if interim research products can increase the rigor and impact of NIH funded research. It also wanted to learn how interim research products arising from NIH funds can be created and used with integrity.

RFI respondents
The NIH received 351 responses, the majority (79%) submitted by scientists/authors. Twenty-two professional societies representing groups of scientists also submitted responses. Note, requests for information are not surveys. Some responses are from organizations representing thousands of people; other responses are from individuals. The NIH is grateful to receive rich responses and thoughtful advice through this information request, and used these findings to shape this policy.

Defining interim products
Some respondents were confused about what interim research products are and where they were used in the NIH grant process. The RFI could have more clearly stated that the NIH has never restricted the materials that can be cited in the reference section of a research plan. Further, several respondents referred to data and software as if NIH had not allowed them to be cited or claimed as a product of NIH funds, which is not correct. This guide notice, and related updates to application and RPPR instructions, intend to clarify these points.

Scientific impacts
Almost all respondents supported increasing the use of interim research products in NIH award processes. Many described specific scientific benefits. These include speeding dissemination by eliminating the months-long interval between submitting a manuscript to a publisher to the first public release of the manuscript. Several respondents reported that they would submit a manuscript to a journal and a preprint repository at the same time. Respondents also noted that public comments on their interim product can improve the rigor of their work, and are an opportunity to form new scientific collaborations. Finally, since interim research products are issued at the discretion of the author, they avoid publication bias.

Many respondents noted that interim research products can be especially helpful for new investigators. New investigators' best work is sometimes so recent it has not had the time to be published. Preprints can help investigators share the complete drafts of their work sooner. Further, other interim research products, such as protocols, help new investigators to document their progress and engage other scientists in discussion about their work. Hosting repositories can amplify these benefits if they track utilization, comments, and other impact measures.

A few respondents claimed that interim products could help rivals finalize their research faster, thereby scooping the authors of interim products. However, several other respondents noted that since interim products are public, they establish priority for any inventions. Further, since authors have full control over the timing of an interim product release, they can always choose to not issue an interim product until a patent application is filed.

Information quality
Almost all respondents, even those that were strongly supportive of interim research products, felt that interim research products offered lower quality information than work that was formally peer-reviewed.

A few respondents noted special risks for the general public, clinicians, patients, and the media in accessing research products that have not been peer-reviewed. These risks are especially great for clinical research, and there are examples when even peer-reviewed findings have been hyped and misinterpreted by the media. The NIH expects the research community to be judicious in its use of interim research products, and for some disciplines (and their leading journals) to explore the use of interim products more slowly than other disciplines.

Interim research products and NIH processes
Several responses, including some from prominent scientific societies, noted that NIH processes can already be burdensome and involve many peer-reviewed products. They felt that including more non-peer-reviewed information into these processes will generate more burden than benefit.

Even more respondents argued that, on balance, interim products will be helpful. Interim products are similar in quality to the preliminary data section of a research plan that reviewers are already comfortable with. These respondents suggested that reviewers should be skeptical of all claims and citations, whether peer-reviewed or not.

The NIH agrees that interim research products offer lower quality information than peer-reviewed products. This policy is not intended to replace peer-review, nor peer-reviewed journals. Instead, the NIH sees interim research products complementing final research products.

The RFI collected the fewest responses to questions about how interim research products should be cited. Many respondents wanted to make sure that reviewers were aware that the interim product citation is not peer-reviewed, and suggested adding the label 'not peer- reviewed' to the citation. This suggestion is difficult to enact because so many other standard citation formats that are not peer-reviewed do not say so in their citations (e.g. most book chapters and journal commentaries do not mention peer-review in the citation or text).

Instead, the NIH is instructing applicants and awardees that choose to cite interim research products to list the interim research product type (e.g. preprint) in the citation. Further, the NIH is instructing awardees to explicitly state in preprints text that the work is not peer-reviewed. These two practices should help reviewers easily identify interim products. The NIH will offer explicit guidance to reviewers reminding them that interim research products are not peer-reviewed. Further, since interim products are new to so many biomedical disciplines, the NIH hopes that these conventions will become the norm for all interim products, and will help the media and the public understand that interim products have undergone less review than peer-reviewed articles.

Finally, to ensure the integrity and impact of interim products, the NIH is borrowing from practices established for final products. This is why NIH is asking authors and repositories to ensure the integrity of these products by declaring competing interests, track versioning, etc. To ensure impact, the NIH is asking authors and repositories to ensure interim products are findable through DOIs, open metadata, etc. To ensure these products are usable as individual documents and in aggregate through computation analyses, the NIH is encouraging authors to adopt a number of license and technical processes (e.g. Creative Common Attribution licenses (CC-BY), application programming interfaces, archival plans, etc.), and to use repositories that support these practices.

Overall, the RFI responses described interim research products as a relatively small change that can provide benefits to NIH processes, and science as a whole. The NIH will be monitoring the use of interim products, their infrastructure, and their impacts. It may revise these standards as practice evolves.

Inquiries

Please direct all inquiries to:

Office of Policy for Extramural Research Administration (OPERA)
Email: grantspolicy@od.nih.gov

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices

ACRONYMS AND TERMS USED TODAY
OSP RA Update - 3/29/2017

ACRONYM/TERM	DESCRIPTION
APR	Annual Progress Report
CF	Carryforward
CITI	Collaborative Institutional Training Initiative
CR	Continuing Resolution
CTMS	Clinical Trial Management System
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.
GMS	Grants Management Specialist
IC	Institute/Center
NCE	No Cost Extension
NIH	National Institutes of Health
NOA	Notice of Award
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.
OCR	Office of Clinical Research
OnCore	OnCore is a Clinical Trial Management System for research, patient registry and biospecimen management.
OSP	Office of Sponsored Programs
PI	Principal Investigator
PRF	Proposal Routing Form
RPPR	Research Performance Progress Report
RTD	Research Training Dataset (xTRACT)
SO	Signing Official
SUMMIT	SUMMIT is the UMass Medical School's web based reporting tool.
UMCCTS	UMass Center for Clinical & Translational Science
xTRACT	Extramural Trainee Reporting and Career Tracking (xTRACT) is a module within eRA Commons used by applicants, grantees, and assistants to create research training tables for inclusion in progress reports and institutional training grant applications.