From: Drexel Official Mail

Sent: Thursday, July 26, 2018 3:23 PM

To: DREXEL-ANNOUNCE-FACSTAFF-ALL-L@lists.drexel.edu

Subject: Office of Research Newsletter - July 2018

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HHS Final Rule Delayed Through January 21, 2019

On June 18, 2018, the Department of Health and Human Services (HHS) released a final rule confirming the delay of the general compliance date for the revised Common Rule ("Final Rule") until January 21, 2019. This means institutions such as Drexel have until January 21, 2019, to be in compliance with the Final Rule. The Office of the Federal Register has put the Final Rule on public display.

In addition to delaying the general compliance date, the rule allows institutions to implement three "burden-reducing provisions" of the revised rule during the delay period. The Human Research Protection Program of Drexel University will not be implementing the three burden-reducing provisions at this time for reasons outlined below:

Provisions 1 and 2 – Use of the revised definition of "research," which deems four categories of activities not to be research, and the allowance for no annual continuing review of certain categories of research.

The institutional review boards (IRBs) of Drexel University have determined that implementing these provisions during the six-month additional delay would not be helpful, due to the amount of administrative time needed to change portions of the COEUS IRB module, update principal investigators, and provide clear communication to the University community. In addition, after the delay we would still need to transition the remainder of project requirements to the full changes.

Provision 3 – Elimination of the requirement that IRBs review grant applications or other funding proposals related to the research: Drexel's IRBs are in alignment with many of our peers and other IRBs across the country that have reaffirmed the importance of at least a minimal requirement for grant congruency. While we will work over time to reduce specificity of grant congruency reviews, the IRBs will continue to help ensure grants and funding sources align with human subject protocols.

For more information on the Final Rule, process updates, and how the rule impacts researchers, please visit the Human Research Protection website.

New FY19 Fringe Benefit Rates In Effect

Drexel University and the Academy of Natural Sciences have finalized the negotiations of the fiscal year 2019 fringe benefit rates for sponsored projects with the U.S. Department of Health and Human Services (HHS). The finalized rates are lower for all categories than the proposed rates. COEUS and Banner have both been updated to reflect the new rates.

The finalized fringe benefit rates for fiscal year 2019 are as follows:

- Full-time Employees: 29.7%
- Part-time Employees: 7.8%
- DUCOM Highly Compensated Faculty: 22.27%

The full-time employee rate captures all full-time, benefit-eligible faculty and professional staff. Post-doctoral students hired as full-time professional staff are also included in the full-time employee rate. This group is considered one rate pool because they are all eligible for the same benefit offerings.

The part-time employee rate includes both part-time benefit eligible and non-benefit eligible employees (e.g. temporary employees, co-ops).
The DUCOM highly compensated faculty rate, previously referred to in our agreement with HHS as Clinical Faculty Rate, is specific to full-time, benefit eligible, College of Medicine faculty in the “F5” employee class. College of Medicine faculty are automatically assigned to the highly compensated employee classification on hire or when their base salary reaches the annual threshold.

Please note that students are not subject to FICA tax per IRS regulations and as such, do not warrant a separate fringe rate.

When entering research proposal budgets in COEUS, be sure to use the sync feature to ensure that the new rates are reflected within your budget.

If you have any questions regarding the new rates they can be directed to Joseph Lucca. Current and prior year rates and rate agreements can be found on the fringe benefit page of the Research Accounting website.

New Processes For Human Research Protection

Human Research Protection (HRP) will now conduct a prereview of all protocols to assess whether all required documentation has been included in submissions. If forms or documents are missing, submissions will be rejected and returned to the principal investigator so that the missing documents can be added. The goal of this new process is to improve efficiency of protocol reviews by ensuring that a complete protocol is available at the review stage. To determine which forms are required, please refer to the Human Research Protection website and the new Submission Checklist. HRP will also be sending a receipt of submission to principal investigators, which will include Institutional Review Board Coordinator assignment details.

To expedite processing of approval documents, HRP is only stamping consent documents. Questionnaires, flyers, surveys, etc. will no longer be stamped. All other document approvals will be listed on the approval letters.

PreAward Scoop: Using the Correct FOA in NSF FastLane

Be sure to double check that you are using the correct funding opportunity announcement (FOA) number when submitting a proposal through the National Science Foundation's (NSF) FastLane portal. If a proposal is submitted with the incorrect FOA number, the system will reject the submitted proposal. From there, the proposal will need to be withdrawn and re-entered in full into the NSF FastLane portal.

Human Research Protection Website Enhancements

Human Research Protection (HRP) has updated information on its website to enhance support for researchers. The changes are as follows:

- **Student Guidance Page:**
  - Guidance and helpful tips to support the first-time researcher and facilitate students' submissions.

- **New Forms:**
  - Submission checklists researchers can use to avoid commonly omitted submission documents.
  - Guidance for the types of Institutional Review Board (IRB) reviews and requirements, to give researchers a clearer understanding how the HRP officer determines the level of review for each project.
  - HRP Human Subject Regulations Decision Charts, which are intended to provide guidance to investigators interested in non-human subjects research, exempt, expedited determinations, and more. The Drexel IRB will need to review all applications and provide final determinations regarding the level of review.

- **Letters of Reliance (LOR):**
NIH Clarifies Continuous Submission Deadlines

The National Institutes of Health (NIH) has clarified that submission is continuous, but council deadlines are not. Continuous submission is limited to R01, R21, and R34 applications that are eligible under the policy and would otherwise be due on the standard due dates. Eligible applications may be submitted at any time, but they will be assigned to Advisory Council rounds based on a schedule. For example, an R01 application due October 5 for May council review may be submitted by a continuous submission eligible PD/PI through December 16. Applications received on or after December 17 will be assigned to October council for second level review and funding consideration.

- If a funding opportunity announcement (FOA) has a mix of standard and special receipt dates, continuous submission applications may only be submitted for the standard due dates on the FOA.
- If the receipt deadline falls on a weekend or a federal holiday, it automatically rolls to the next business day.
- The NIH late policy described in NOT-OD-15-039 cannot be used to extend these receipt deadlines. Applications submitted for continuous submission eligibility after the receipt deadlines will be assigned to the next council round for second-level review.
- Direct any submission issues, including Grants.gov rejection messages indicating the opportunity is closed, to the eRA Service Desk.

For more information, please reference NOT-OD-18-178.

NIH Issues Notice of Legislative Mandates

The Consolidated Appropriations Act, 2018 (Public Law 115-141), signed into law on March 23, 2018, provides funding to NIH for the fiscal year ending September 30, 2018. The intent of this notice is to provide current requirements outlined by the statutory provisions that limit or condition the use of funds on NIH grant, cooperative agreement, and contract awards for FY 2018.

NIH Updates Fiscal Policies

This notice provides guidance about the NIH Fiscal Operations for FY 2018 and implements the Consolidated Appropriations Act, 2018 (Public Law 115-141), signed into law on March 23, 2018. With the passage of the Act, NIH received a 9 percent increase over FY 2017, for a total of $37.311 billion in program level funding, including $496 million authorized under the 21st Century Cures Act. A general increase of over 5 percent was received, as well as specific increases for opioid/pain research, Alzheimer's disease, and other high priority research initiatives.

Synchronized Delegation & Decimals in NIH RRPR

NIH has made two recent enhancements within eRA Commons to streamline and improve the Research Performance Progress Report (RPPR) process for recipients. First, institutional delegations for Interim-RPPRs (I-RPPR) and Final-RPPRs (F-RPPR) have been modified to align with the delegations that institutional users have specified for annual RPPRs. Second, data fields for effort reporting will be modified to enable use of decimals rather than requiring entry of a whole number.
Synchronization of Institutional Delegations for RPPRs
When NIH initially implemented the I-RPPR and F-RPPR, system submission features were modeled on those associated with the form report previously known as the Final Progress Report (FPR). In NIH's efforts to obtain user feedback on system features, it became clear that utilizing the institutional delegation features available for annual RPPRs would improve efficiency and ease administrative burden for recipient institutions. Therefore, NIH has modified RPPR module within eRA Commons to automatically incorporate the same delegation options available to institutions within the annual RPPR. Specifically, a PD/PI may delegate initiation of any type of RPPR to a program assistant. Additionally, if consistent with institutional policy a signing official (SO) may delegate authority to a PD/PI to submit an RPPR (any RPPR -- annual, interim, or final) directly to NIH without having to be formally submitted by the SO.

Decimals in Effort Reporting
As another opportunity to reduce administrative burden on NIH recipients, NIH has changed its RPPR format to allow effort reported in grant applications to include decimals. Until now, the system only allowed whole numbers and rounded up or down accordingly. The lack of the ability to include decimals contributed to significant inaccurate reporting when a PD/PI has contributed 20-percent effort or 2.4 calendar months, and the previous system feature rounded effort down to two calendar months.

Latest NSF Proposal & Award Policy Newsletter
The Policy Office in the Division of Institution & Award Support at the National Science Foundation (NSF) has released the latest edition of the NSF Proposal & Award Policy Newsletter. You may sign up to receive this newsletter automatically via NSF Update. This mechanism allows you to choose to be notified about NSF programs, policies and events. To do this, navigate to www.nsf.gov, and click on the envelope icon in the “Follow Us” section of the website. After entering your email address, you can select the topics you’re interested in learning about. To receive this newsletter, check the boxes for Newsletters/ Journals and Publications: Policies and Procedures. If you have ideas for future topics to be addressed in the newsletter, please send them to policy@nsf.gov.

NCURA Offers Regional Professional Development for Researchers
Penn State (Hershey, PA, campus) will be hosting the Region II Professional Development workshop, Uniform Guidance for Researchers, on August 28, 2018, at the Penn State University College of Medicine University Conference Center, 500 University Drive, Hershey, PA. The workshop will run from 9 a.m. to 5 p.m. Continental breakfast will be available from 8:15 - 9, and lunch is included. The cost of the day-long workshop is $175/person. For registration and hotel information, please follow the registration link.

NIH Answers Your Questions via "You Ask, We Answer" Segment
The NIH has released a new segment titled “You Ask, We Answer” in the NIH Extramural Nexus, a newsletter that provides regular updates on NIH grants policies and activities impacting the grants community. The intent of this segment is to answer community questions in a forum that is made available to the public. The below topics were discussed in the June/early July edition:

Does the NIH inclusion policy apply to research using existing datasets or other types of existing resources involving human subjects?

If the study is considered human subjects research and meets the NIH definition of clinical research, then it is subject to the NIH inclusion policy.
What do I do if my proposed study involves both an existing dataset/resource AND recruitment of new participants? How do I address inclusion and complete the forms?

If you are proposing a study that will include both an existing dataset and recruitment of new participants, you should provide separate inclusion forms for the existing dataset and the participants to be prospectively recruited. The existing dataset sample can … Continue reading?

In part D of the F-RPPR (participants), should we report time worked for the final budget period or time worked for the final budget period + the no cost extension period?

In the Final RPPR you should report on the individuals that worked on the project during the last budget period minus any approved no-cost extensions. You can find this and more in the RPPR FAQs.

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Funding Opportunity Resources

**Spotlighted External Funding Opportunities**

Susan G. Komen Foundation: Career Catalyst Research Grants (CCR)

DARPA Defense Sciences Office: The Physics of Artificial Intelligence (PAI)

NIH: Investigator Initiated Research in Computational Genomics and Data Science

NIH: The National Health and Aging Trends Study (U01 Clinical Trial Not Allowed)

NSF: Robert Noyce Teacher Scholarship Program

NSF: Research Experiences for Undergraduates (REU)

PCORI: Implementation of Effective Shared Decision Making Approaches in Practice Settings

DOD CDMRP: Pharmacotherapies for Alcohol and Substance Abuse (PASA) Consortium

**Extramural Funding**

University Libraries

**Internal Funding and Limited Submissions**

Drexel University Funding Portal

Margaret Q. Landenberger Research Foundation Grant

Mallinckrodt Foundation Grant

Searle Scholars Program
Meet Our Staff

Terrence Finney
Manager, Accounts Receivable

Terrence has been with Drexel for nine months as the new Manager of Accounts Receivable with the Research Accounting group under the Office of the Comptroller. Terrence brings six years of post-award research experience by way of Temple University, where he reported to Patty Russo, currently the Associate Vice President and Comptroller at Drexel. Terrence looks forward to having a long and promising career with Drexel University and assisting with taking the AR Research Accounting Group to the next level. When Terrence is not working, he’s enjoying a nice cigar while playing a couple holes at the golf course.

Events & Education

The Office of Research regularly offers a wide variety of workshops. Log into Career Pathway via DrexelOne to view the full schedule, access detailed descriptions of the topics, and to register. We look forward to seeing you!

The Office of Research will also create personalized presentations for faculty, support staff, students and anyone involved in the administration or conduct of research at Drexel. For more information about developing a session tailored to the needs and location of your group, please contact us.

We Want To Hear From YOU!
Let us know what you like (or don’t like) about our newsletter and which research administration topics you’d like to learn more about. All feedback is welcome.

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This message sent to all Faculty and Staff via Drexel Announcement Mail was approved by Aleister J. Saunders, PhD, Senior Vice Provost for Research