Sponsored Program Administration

November, 2017



AGENDA

OVPR/SPS News and Information

- New Research Initiatives Supported by the OVPR
- Internal Proposal Review Form (IPR)
- Publication of Revised Grants Policy **Statement**

NIH News and Information

- NIH Operating Under Continuing Resolution
- FORMS-E Application Packages
- PHS Human Subjects & Clinical Trial Info
- Single IRB for Multi-Site Research
- NIH Career Development Awards (K)
- Reminders

NSF News and Information

NSF Research Terms and Conditions

Grants.gov News and Information

UCONN

- Legacy PDF Application Package
- Workspace

RESEARCH



OVPR

New Research Initiatives Supported by the OVPR

In an effort to guarantee the UConn proposals have the best chances of success, The Office of the Vice President for Research will provide faculty with additional assistance and initiatives in helping submit new grant proposals.

- Reduction in Overhead Costs
- Faculty Grant Mentorship Incentive Program
- SBIR/STTR Funding

First set of workshops to assist faculty with the program and how to successfully apply:

SBIR/STTR Programs

November 29 and 30 400 Farmington Avenue UConn Health Campus To register, visit the <u>CTNext site</u>



OVPR – Social Media



In efforts to share news about UConn's research, scholarship and endeavors more broadly, The OVPR has launched new social media accounts on two platforms: <u>LinkedIn</u> and <u>Twitter</u>. Please like, share, retweet from these accounts to spread the news of UConn's accomplishments!



UCONN | RESEARCH

Internal Proposal Review Form (IPR)



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		HEA									
INTERNAL PROPOSAL REVIEW FORM (IPR) Note that fields identified as either the University of Connecticut (Storrs) or UConn Health (UCH) need only be completed by that compus.											
PRINCIPAL INVESTIGATO	OR/C	ONTACT	PI								
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Managing Dept., Center or Institute (Manag	ting Dept. He	ad/Center or In	stitute D	ir. signature	required on		-			
Other Affiliated Center(s) (Storrs):											
PI Title:		% Ef	fort Committed	(UCH):	%	Phone:			Email:		
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Include information for all individu http://research.uconn.edu/fcot-hos	als ide ne/fco	intified by the	: PI as key and/c /se supplementa	or respon I form if	sible person needed (not	nel (respons 1: all UCH p	tble for the de. ersonnel who i	sign, are ki	conduct, or rep ey are automati	orting of re cally respo	search). msible)
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If pass-through funding, list origi	nating	g sponsor:									
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SPECIAL REVIEWS/APPE	ROV	ALS/NOT	IFICATION	IS							
Human Subjects			Yes	No	If yes, w	hat year(s)	of the projec	t?			
Animal Subjects			Yes [No			of the projec				
Human Stem Cells	1-0		Yes	No	Biologic	al Agents/I	l'oxins/Recon	nbina	ant DNA	Yes	No
(http://revearch.uchc.edu/rcs/stem-cells/) Controlled Substances Yes No Radioactive Materials and/or Radiation Devices Yes No											
Subject to Export Control Laws Unsure Yes			No								
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Publication of the Revised NIH Grants Policy Statement for FY 2018 (Rev. 10/17)

This revised policy statement is applicable to all NIH grants and cooperative agreements with budget periods beginning on or after October 1, 2017.

NOT-OD-18-005

Summary of Significant Changes for October 2017





National Institutes of Health Turning Discovery Into Health

NIH Operates Under a Continuing Resolution Through December 8, 2017

NIH will issue non-competing research grant awards at a level below that indicated on the most recent Notice of Award (up to 90% of the previously committed level).

Notice Number: NOT-OD-17-124



New NIH "FORMS-E"



National Institutes of Health Turning Discovery Into Health

- > Notice <u>NOT-OD-17-062</u>: New forms and <u>application guide</u> instructions for due dates on or after January 25, 2018.
- Majority of changes focus on Human Subject and Clinical Trial information. All Applications involving clinical trials must be submitted to FOAs specifically designed for clinical trials beginning with due dates on or after January 20, 2018 (NOT-OD-16-147, NOT-OD-17-043).
- NIH "Parent" announcements will be reissued with new FOA numbers on January 25, 2018. Applications started on or after January 25, 2018 must use the new FOAs and FORMS-E application packages.

If your due date is	You must use…
On or before January 24, 2018, including:	FORMS-D application package
 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 	
 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





National Institutes of Health Turning Discovery Into Health

PHS Human Subjects and Clinical Trials Information

The PHS forms for the human subject and clinical trials application will be changed for the application submission due dates on or after January 25, 2018.

All applications involving clinical trials must be submitted to FOAs specifically designed for clinical trials beginning with due dates on or after January 20, 2018 (<u>NOT-OD-16-147</u>, <u>NOT-OD-17-043</u>).

Overview of New NIH Policies on Human Subjects Research

Walk-through of the PHS Human Subjects and Clinical Trials Information Form

Does Your Human Subjects Research Study Meet the NIH Definition of a Clinical <u>Trial</u>?

<u>4 Questions for Researchers and Institutions Involved in Human Subjects</u> <u>Research</u>





National Institutes of Health Turning Discovery Into Health

PHS Human Subjects and Clinical Trials Information

CLINICAL TRIAL-SPECIFIC FOAS

January 25, 2018

All clinical trial applications MUST be submitted to an FOA that allows clinical trials

The purpose of this policy is...

- Improve NIH's ability to identify proposed clinical trials
- Ensure that key pieces of trial-specific information are submitted with each application
- Uniformly apply trial-specific review criteria.

CLINICAL TRIAL REVIEW CRITERIA

FOAs will include additional criteria:

Scored Review Criteria

- ✓ Significance
- Investigator
- Innovation
- Approach
- Environment

Additional Review Criteria

✓ Study Timeline

Read the FOA carefully and be sure your application addresses the review criteria appropriately







PHS Human Subjects and Clinical Trials Information

Section II. Award information of the FOA will specify that the application is for a clinical trial.

Funding Instrument	Grant: A support mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity
Application Types Allowed	New Resubmission Revision
	The OER Glossary and the SF424 (R&R) Application Guide provide details on these application types.
Clinical Trial?	Required: Only accepting applications that propose clinical trial(s)
	Need help determining whether you are doing a clinical trial?
Funds Available and Anticipated Number of Awards	The NIMH intends to commit approximately \$3,000,000 in FY 2017 to fund between 4 and 6 grants submitted to this F0 and the companion FOA PAR-16-265,
Award Budget	Direct costs are limited to \$450,000 over the R34 project period, with no more than \$225,000 in direct costs allowed in single year
Award Project Period	The total project period for an application submitted in response to this FOA may not exceed 3 years.





National Institutes of Health Turning Discovery Into Health

Clinical Trials.Gov

REGISTERING AND REPORTING						
	NIH		NIH Policy on the Disse NIH-funded Clinical Tria	mination of al Information		
WHO	WH0 All clinical trial applications requesting support for a trial that will be initiated on/after January 18, 2017					
WHAT		Register and report the results of trials in ClinicalTrials.gov				
WHY	3	Increase the availability of information about clinical trials and their results to the public in a timely manner				
WHEN			Effective for applications due on/after January 18, 2017			
				LEARN MORE >>		

Requirements for Registering & Reporting NIH-Funded Clinical Trials in ClinicalTrials.gov





Need Help Determining Whether Your Application Includes Human Subjects?

- NIH Research Involving Human Subjects Website
- Infopath Questionnaire

Information on Human Biospecimens or Data:

- Frequently Asked Questions on Human Specimens, Cell Lines, or Data
- Research Involving Private Information or Biological Specimen Flowchart

Exempt Human Subjects Research – NIH uses 3 Exemptions:

Determining the Appropriate Exemption Number: See Flowchart





Single IRB Policy for Multisite Research

The goal of this new policy is to enhance and streamline the IRB review process for multi-site research so that research can proceed as quickly as possible without compromising ethical principles and protections for human research participants.

FAQ's - Implementation of the sIRB Policy

NOT-OD-16-094

NOT-OD-18-004





National Institutes of Health Turning Discovery Into Health

Percent Effort and Support for Career Development (K) Awards

NIH Guide Notice <u>NOT-OD-17-094</u> clarifies percent effort requirements for K award PI's and acceptable sources of research support.

- Most K awardee's must commit minimum of 75% effort directly to K award.
- Remaining effort (up to 25%) can be devoted to additional research, teaching, clinical work, or efforts complementary to career development of the K awardee.

Salary Supplementation/Compensation:

- Salary supplementation for K awardee's time spent devoted to the career development award and directly related to the research project is allowable, BUT must be from non-federal sources and must <u>not</u> require extra duties or responsibilities that would interfere with the goals of the K award.
- Additional research projects where the effort is not directly committed to the K award, K awardee's may devote effort WITH compensation, from federal or non-federal sources as long as the specific aims of the research project differ from those of the K award.

Additional Information:

NIH Extramural Nexus – Clarifying Percent Effort and Support for K Awardees





National Institutes of Health Turning Discovery Into Health

NIH Application Compliance Reminders

APPENDIX MATERIALS

As of January 25, 2017, NIH is enforcing the application Appendix materials policy Notice Number: NOT-OD-16-129.

Your application will be <u>withdrawn and not reviewed</u> if you include Appendix materials that are not specifically listed as allowed or required in either the Guide notice above or the funding opportunity announcement.

Allowable Appendix Materials:

For applications proposing clinical trials:

- Clinical trial protocols
- Investigator's brochure from Investigational New Drug (IND), as appropriate

For all applications:

- Blank informed consent/assent forms
- Blank surveys, Blank questionnaires, Blank data collection instruments
- FOA-specified items

Frequently Asked Questions – Appendix Policy





APPENDIX MATERIALS IN CLINICAL TRIAL APPLICATIONS

As of January 25, 2018, (NOT-OD-17-098) NIH's plans to eliminate Appendix materials related to clinical trials for applications submitted to NIH, AHRQ, or NIOSH.

Clinical trial-related materials will be specified and required in the new PHS Human Subjects and Clinical Trials Information Form and NO LONGER ALLOWED IN THE APPENDIX unless specifically required in the FOA.

All information submitted with an application except the cover letter, assignment request form, and the appendix information is assembled into a single application and correspond to the standard review criteria. Therefore, all information required for the peer review process must be contained within those designated sections of the application unless the FOA specifies otherwise. Information that expands upon or complements information provided in any section of the application is not allowed in the appendix unless it is listed in the allowable appendix material.

Allowable Appendix Materials

The following information applies to all competing NIH, AHRQ, and NIOSH applications and activity codes.

Beginning with applications submitted to the NIH, AHRQ, or NIOSH for due dates on or after January 25, 2018, the only allowable Appendix materials are:

- Blank data collection forms, blank survey forms and blank questionnaire forms -- or screenshots thereof.
- Simple lists of interview questions.

For clarification, these blank forms and lists are not and do not include items such as: data, data compilations, lists of variables or acronyms, data analyses, publications, manuals, instructions, descriptions or drawings/figures/diagrams of data collection methods or machines/devices.

- · Blank informed consent/assent forms
- Other items only if they are specified in the FOA as allowable Appendix materials

Some FOAs further restrict allowable appendix materials and/or may specify that some materials listed above must be provided in another part of the application. Applications submitted to those FOAs must follow instructions in the FOA and must not put those items in the Appendix.

No other items are allowed in the Appendix. Simply relocating disallowed materials to other parts of the application will result in a noncompliant application.

Consequence for Submitting Disallowed Materials:

Applications submitted for due dates on or after January 25, 2018 will be withdrawn as noncompliant if they are submitted with Appendix materials that are not specified in this Notice or specified in the individual FOA as allowed or required.



NIH Application Compliance Reminders

Biographical Sketches

PMCID IN BIOSKETCH REFERENCES

 NIH does not require a DOI, or PMID with references in the biosketch. NIH does require a PMCID or other evidence of compliance with the <u>public access policy</u> for the papers that fall under the policy and are authored by the applicant or arise from an applicant's NIH award

Frequently Asked Questions – Biosketches

Include PMCID in Citations





National Science Foundation Research Terms & Conditions



Agency Specific Requirements, Effective October 11, 2017

New <u>PAPPG</u> Effective for Proposals Submitted or Due on or After January 29, 2018

Significant Changes Include:

- Addition of new eligibility subcategory on international branch campuses of U.S. Institutions of Higher Education,
- Revision of eligibility standards for foreign organizations;
- Implementation of the standard Collaborators and Other Affiliations (COA) template that has been in pilot phase since April;
- Increase in the Budget Justification page limitation from three pages to five pages;
- Restructuring of coverage on grantee notifications to and requests for approval from NSF, including referral to the <u>Prior Approval Matrix</u> available on the NSF website;
- Numerous clarifications and other changes throughout the document.

Webinar on the new PAPPG will be held on December 8 at 2PM EST.

Sign up to be notified when registration is available on the <u>outreach notifications</u> <u>website</u>



Grants.Gov News and Information



Legacy PDF Application Package will be phased out on December 31, 2017

Although WORKSPACE is the Grants.Gov shared, online environment to complete and submit federal grant applications, the following federal agencies also have application systems available for grant proposal preparation and submission and we recommend using the following systems:

- > National Institutes of Health and Other PHS Sponsored Funding Opportunities:
 - > <u>ASSIST</u>
- Department of Defense Sponsored Funding Opportunities:
 - WORKSPACE
- National Science Foundation Sponsored Funding Opportunities:
 - NSF Fastlane



Grants.Gov News and Information

WORKSPACE Must Be Used For Preparation and Submission of Applications in Response to DOD Funding Opportunities.

- Register as a User in <u>Grants.gov</u>
- > Contact your SPS Project Officer to assign you the "Manage Workspace Role".
- Search for the funding opportunity to make sure your grantor agency forms are compatible with Workspace. On the "Package" tab create your "Workspace" - you are now the "Owner" of the Workspace.
- Add "Participants" to your Workspace (including your Project Officer) to help you complete the forms.
- > Complete the application forms and "Check Application".
- > Send final application to SPS by clicking "Complete and Notify AOR".
- > Your SPS Project Officer will "Sign and Submit" your application.



Grants.Gov News and Information

WORKSPACE TRAINING RESOURCES

[WEBINAR] Getting Started with Grants.gov Workspace: Become a Workspace Wizard





Department Administrators News and Information





