

Research Administration Update



Wednesday, September 27, 2017

Lazare Auditorium (S1-607)

1:00 pm



Agenda

- OSP Update
 - Office of Research Leadership Change & OSP Staffing Update
- NIH Update
 - Updated NIH Grants Policy Statement (GPS) will be available October 6, 2017
 - NOT-OD-16-148: Good Clinical Practice (GCP) Training Requirement
 - NOT-OD-16-149: NIH Policy on Dissemination of NIH Funded Clinical Trial Information
 - NOT-OD-17-043: Funding Opportunity Announcements (FOAs) for Clinical Trials
 - NOT-OD-17-062: New NIH FORMS-E Grant Application Forms and Instructions Coming for Due Dates On or After January 25, 2018
 - NOT-OD-17-076: Single Institutional Review Board (sIRB) Policy for Multi-site Research
 - NOT-OD-17-086: NIH Fiscal Policy for Grant Awards – FY 2017
 - NOT-OD-17-094: Clarification and Update: Salary Supplementation and Compensation on Research Career Development (K) Awards
 - NOT-OD-17-095: Additional Guidance on 'Full-Time Training' for NRSA Awards
 - NOT-OD-17-105: NIH Applications Must Be Complete and Compliant With NIH Policy and Application Instructions At Time Of Submission
 - NOT-OD-17-118: NIH Announces New Review Criteria for Research Project Applications Involving Clinical Trials
 - NOT-OD-17-115: Review the Accuracy of Grants Information for Fiscal Year 2017
- Cayuse Update
 - Updating Investigator Profiles
 - Change in Company Ownership (Evisions to Cayuse)
- Other Updates
 - CDMRP Non-Compliance
 - Foreign Project Registrations (new website, process)
- Proposal & Progress Report Statistics
- Training Recommendations for FY18

Office of Research Leadership Change



- Jean King, Vice Provost for Research accepted the Deanship of the College of Arts & Sciences at Worcester Polytechnic Institute (WPI)
- The Office of Sponsored Programs is now reporting directly to Dean Terence Flotte.
- Indirect cost reduction requests should be referred to Diego Vazquez, Assistant Vice Provost, Sponsored Programs.



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- ```
graph TD; DV[Diego Vazquez
Assistant Vice Provost
x 6-5600] --- BS((Barrie Stone
Document Coordinator
x 6-2119)); DV --- JL[Janice Lagacé
Associate Director
x 6-8980]; JL --- JLB[James LeBlanc
Sr. Sponsored Program
Administrator & Team Lead
x 6-6073]; JL --- JB[Jason Brown
Sr. Sponsored Program
Administrator & Team Lead
x 6-6092]; JLB --- PH[Pam Harney
Sponsored Program
Administrator II
x 6-5752]; JLB --- KG[Karen Gardiner
Sponsored Program
Administrator I
x 6-8126]; JB --- ASJ[Andrea Sjostedt
Sponsored Program
Administrator II
x 6-4407]; JB --- JG[Jenna Gerrish
Sponsored Program
Administrator I
x 6-6160];
```
- Diego Vazquez**  
Assistant Vice Provost  
x 6-5600
- Barrie Stone**  
Document Coordinator  
x 6-2119
- Janice Lagacé**  
Associate Director  
x 6-8980
- BLACK TEAM**
- James LeBlanc**  
Sr. Sponsored Program  
Administrator & Team Lead  
x 6-6073
- Pam Harney**  
Sponsored Program  
Administrator II  
x 6-5752
- Karen Gardiner**  
Sponsored Program  
Administrator I  
x 6-8126
- BLUE TEAM**
- Jason Brown**  
Sr. Sponsored Program  
Administrator & Team Lead  
x 6-6092
- Andrea Sjostedt**  
Sponsored Program  
Administrator II  
x 6-4407
- Jenna Gerrish**  
Sponsored Program  
Administrator I  
x 6-6160



## OSP Teams - Department Assignments

Associate Director - Janice Lagacé



### Team Black

SPA Sr Team Lead - Jim LeBlanc

SPA II - Pam Harney

SPA I - Karen Gardiner

### Team Blue

SPA Sr Team Lead - Jason L. Brown

SPA II - Andrea Sjostedt

SPA I - Jenna Gerrish

Anesthesiology & Perioperative Medicine

Animal Medicine

Commonwealth Medicine

Dermatology

Emergency Medicine

Environmental Health & Safety

Graduate School of Biomedical Sciences

Library

Medicine:

-Cardiovascular Medicine

-Diabetes

-Endocrinology

-Gastroenterology

-General Medicine

-Geriatric Medicine

-Hematology/Oncology

-Hospital Medicine

-Infectious Diseases & Immunology

-Preventive & Behavioral Medicine

-Pulmonary Medicine

-Renal Medicine

-Rheumatology

Microbiology & Physiological Systems

Molecular Cell and Cancer Biology

Neurology

-Wellstone Program

Newborn Screening

Quantitative Health Sciences

Student Affairs

Biochemistry & Molecular Pharmacology

Bioinformatics & Integrative Biology

Center for Clinical & Translational Sciences

Diabetes Center of Excellence

Drugs of Abuse Laboratory

Family Medicine & Community Health

Gene Therapy Center

Graduate School of Nursing

MassBiologics

Meyers Primary Care Institute

Molecular Medicine

Neurobiology

Neurosurgery

OB/GYN

Office of Medical Education

Office of Research

Ophthalmology

Orthopedics & Physical Rehabilitation

Otolaryngology

Pathology

Pediatrics

Program in Systems Biology

Psychiatry

-Brudnick Neuropsychiatric Research Inst. (BNRI)

Radiation Oncology/QARC

Radiology

-Cell Biology & Imaging

RNA Therapeutics Institute (RTI)

Shriver Center

Student Services

Surgery

Urology

# Updated NIH Grants Policy Statement

## Available October 6, 2017



- The revised Grants Policy Statement will be applicable to all NIH grants and cooperative agreements with budget periods beginning on or after October 1, 2017.
- Until publication, NIH will continue to publish interim grants policy changes through the issuance of NIH Guide Notices via the NIH Guide for Grants and Contracts.

## NOT-OD-16-148: Policy on Good Clinical Practice Training for NIH Awardees Involved in NIH Funded Clinical Trials



- Effective January 1, 2017 NIH expects all NIH-funded clinical investigators and clinical trial staff who are involved in the design, conduct, oversight, or management of clinical trials to be trained in Good Clinical Practice (GCP)
- Good Clinical Practice training establishes:
  - Standards for clinical trial implementation, data collection, monitoring, and reporting
  - Responsibilities of investigators, sponsors, monitors, and institutional review boards

# NOT-OD-16-149: NIH Policy on Dissemination of NIH Funded Clinical Trial Information



- Effective January 18, 2017 – All NIH-funded awardees and investigators conducting clinical trials must register and report the results of their trial in ClinicalTrials.gov
- NIH dissemination policy:
  - Extends previous HHS policies to apply to all NIH-funded clinical trials instead of defining a subset of “applicable clinical trials”
  - Increases the availability of information to the public about clinical trials

Learn more at <https://grants.nih.gov/policy/clinical-trials/reporting/index.htm>



# NOT-OD-17-043: Funding Opportunity Announcements (FOAs) for Clinical Trials



- Effective for due dates on/after January 25, 2018 all grant applications involving one or more clinical trials must be submitted through an FOA specifically designated for clinical trials.
- Clinical Trial-specific FOAs will allow NIH to:
  - Identify proposed clinical trials
  - Ensure that key pieces of clinical trial-specific information are submitted with each application
  - Uniformly apply clinical trial-specific review criteria

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



- Applicants must use FORMS-E application packages for due dates on or after **January 25, 2018** and must use FORMS-D application packages for due dates on or before January 24, 2018. Applications submitted using the wrong forms for their intended due date will not be reviewed.
- Focus of changes:
  - Consolidation of human subjects, inclusion enrollment, and clinical trial information previously collected across multiple agency forms
  - Expansion and use of discrete form fields for clinical trial information to provide the level of information needed for peer review; lead applicants through clinical trial information collection requirements; present key information to reviewers and agency staff in a consistent format; and align with ClinicalTrials.gov (where possible) and position NIH for future data exchanges with ClinicalTrials.gov
  - Incorporation of recent Grants.gov changes to R&R Budget and SBIR/STTR Information forms
  - These changes will be implemented with application form packages identified with a Competition ID of "FORMS-E" and associated application guide instructions.

# NOT-OD-17-076: Single Institutional Review Board (sIRB) Policy for Multi-site Research



- Effective for due dates on/after January 25, 2018  
NIH expects that all multi-site studies which involve non-exempt human subjects research funded by the NIH, will use a single Institutional Review Board (sIRB) to conduct the ethical review required for the protection of human subjects.
- sIRB policy aims to:
  - Streamline IRB review process to enhance research efficiency
  - Reduce unnecessary administrative burdens and inefficiencies

Learn more at <https://grants.nih.gov/policy/clinical-trials/single-irb-policy-multi-site-research.htm>

# NOT-OD-17-086: NIH Fiscal Policy for Grant Awards – FY 2017



- This NOT provides guidance about the FY17 NIH Fiscal Operations and implements Public Law 115-31. With its passage, NIH received a \$2 billion increase above FY2016, for a total of \$34.30 billion in budget authority.
- The following NIH fiscal policies are instituted in FY 2017:
  - FY 2017 Funding Levels: Non-competing continuation awards that were generally funded at levels below that indicated on the most recent Notice of Award (generally up to 90% of the previously committed level) will be fully restored, and non-competing continuation grants (research and non-research) including those that remain to be issued in FY 2017 will be made at the commitment level indicated on the Notice of Award. Out-year commitments for continuation awards in FY 2018 and beyond will remain unchanged.
  - NIH will increase NRSA stipends by approximately 2 percent on average. The full range of postdoctoral stipend adjustments for FY 2017 is described at NOT-OD-17-003. NIH will issue additional guidance on predoctoral stipends as appropriate.
  - NIH will continue to support new investigators on R01 equivalent awards at success rates comparable to that of established investigators submitting new (Type 1) R01 equivalent applications.
  - Payments for salaries under grants and other extramural mechanisms in excess of Executive Level II previously set at \$185,100, and effective January 8, 2017, increased to \$187,000.

- For effort not directly committed to a Career “K” award, NIH will allow recipients to devote effort, with compensation, on Federal or non-Federal sources as the Program Director/Principal Investigator (PD/PI) or in another role (e.g., co-Investigator).
  - Recipients may devote effort while serving in these roles as long as the specific aims of the other supporting grants(s) differ from those of the “K” award.
- This is a significant policy change.



# NOT-OD-17-095: Additional Guidance on 'Full-Time Training' for NRSA Awards



- NIH recognizes that NRSA fellows and trainees may seek part-time employment incidental to their training program to offset their expenses.
- As such, NIH issued additional guidance clarifying that fellows and trainees may spend on average, an additional 25% of their time (e.g., 10 hours per week) conducting the following activities part time:
  - Research
  - Teaching, or
  - Clinical employment
- As long as the activities do not interfere with, or lengthen, the duration of their research training.

## NOT-OD-17-105: NIH Applications Must Be Complete and Compliant With NIH Policy and Application Instructions At Time of Submission



- In fairness to all applicants NIH will consistently apply standards for application completeness and for compliance with all submission requirements and NIH policies.
- NIH may withdraw any application identified during the receipt, referral, and review process that is incomplete or noncompliant.
- NIH strongly discourages the practice of using placeholder attachments for required elements in an application. While it may allow an application to successfully pass eRA system-enforced validations, applications that include such attachments are incomplete and will be withdrawn.
- Applicants are expected to examine their applications for problems, errors, omissions, and oversights and must make any necessary or desired changes **before** the application submission deadline.
  - The application submission deadline is 5 PM local (applicant organization) time on the application due date.
  - Applicants are encouraged to submit two or more days early to allow time for application viewing and corrections before the application submission deadline.
  - **Corrective applications submitted after the application submission deadline are late and will overwrite any previous on-time submission for that application and permanently remove the on-time submission from consideration.**
  - Applications submitted after the application submission deadline will be considered late, and only accepted under the limited circumstances described in the NIH/AHRQ/NIOSH Late Policy
- Post-submission materials to complete an application or to correct problems, errors, oversights, and omissions discovered after submission of the application will not be accepted per the Post-Submission Materials Policy.
- If an application is withdrawn because it is incomplete or does not comply with the application preparation and submission instructions, a letter will be placed in the eRA Commons Status page and the PI and the AOR from the applicant organization will be notified by via e-mail to access their account and view the explanatory letter.

## NOT-OD-17-118: NIH Announces New Review Criteria for Research Project Applications Involving Clinical Trials



- This notice informs the community of additional review criteria that NIH will apply to clinical trial applications for research projects submitted to due dates on or after January 25, 2018.
- The review questions in the Notice are effective for all clinical trial applications for research project grants and cooperative agreements that are submitted for funding consideration for due dates on or after January 25, 2018.
- Please share the notice with your investigators so that they can become familiar with the new criteria.

# NOT-OD-17-115: Review the Accuracy of Grants Information for Fiscal Year 2017



- As the federal fiscal year comes to an end on 9/30/17, NIH encourages Grantee Institutions to verify the accuracy of their grant departments in eRA Commons. Any corrections to the data must be made by 8:00 PM EDT on Monday, October 9, 2017 to be reflected in NIH annual reports.
- The Office of Research has been working with the Dean and Chairs to confirm department assignments in NIH's systems.
  - As of 9/22/17, all UMMS award data in eRA Commons and the RePORT website has been reviewed and revised where needed to ensure that all funds are counted in the appropriate department and roll up under the School of Medicine.

# Cayuse – Updating Investigator Profiles


- Please review your investigators' Professional Profiles in Cayuse to ensure that the department information is up to date.
- Focus on departments that have consolidated and investigators that have switched departments.
- The department field selected in Cayuse drives departmental reporting in NIH's systems.


People » Flotte, Terence R.

Professional Profile: **Flotte, Terence R.**


**General Personal Information**

[Name](#)  
[Degrees](#)  
[Demographics](#)  
[Biosketches](#)

**1 Institutional Association** 

 **University of Massachusetts... (Chancellor's Office)**

[Contact Info](#)  
[eRA Role](#)  
[\\* Dept / Division / Title](#) ▶  
[Salary and Fringe Worksheet](#)  
[Performance Site](#)

 **Routing Profile**

University of Massachusetts Medical School (Chancellor's Office)  
**Department / Division / Title**

|                        | Code                                          | Title               |
|------------------------|-----------------------------------------------|---------------------|
| <b>Department:</b>     |                                               | Chancellor's Office |
| <b>Division:</b>       |                                               |                     |
| <b>Position/title:</b> | Dean, Provost and Deputy Executive Chancellor |                     |

NASA

**Is this appointment an employee of the U.S. Government?**

If yes, select U.S. Government agency:

**Is this appointment an employee of a foreign organization?**



# Cayuse – Company Change



- The research suite of solutions previously under Evisions, Inc. is now held under Cayuse, Inc.
- The change in corporate ownership will not impact services currently provided to UMMS.

# CDMRP

## Non-Compliance

- The Administrative Section of the FY17 Discovery Award Program Announcement (II.H.2.a.) states that:
  - Use of “I,” “we,” “our,” “this organization,” or similar phrases that refer to the PI(s), collaborator(s), or their organization(s) through the references listed, or the use of formatting (e.g., bolding, underlining, names in headers/footers), inclusion of citations to unpublished manuscripts, or in any other way highlighting (and therefore revealing) the names of the PI(s), collaborator(s), or their organization(s) will result in administrative rejection of the application.



REPLY TO  
ATTENTION OF

DEPARTMENT OF THE ARMY  
US ARMY MEDICAL RESEARCH ACQUISITION ACTIVITY  
820 CHANDLER STREET  
FORT DETRICK MD 21702-5014

Date: Aug 22, 2017

MCMR-AAA-A Customer Service Group - Assistance

[REDACTED]  
[REDACTED]  
[REDACTED]research.funding@umassmed.edu  
Subject: CDMRP eBRAP: Application [REDACTED] Deemed Non-Compliant

[REDACTED]  
University of Massachusetts Medical School  
[REDACTED]  
[REDACTED]  
Worcester, Massachusetts 01605-0002  
[REDACTED]

RE: [REDACTED]

STATUS: Non-Compliant

Dear [REDACTED]

I regret to inform you that the Discovery Award Full Application you submitted to the Fiscal Year 2017 Department of Defense Peer Reviewed Medical Research Program (PRMRP) did not comply with the requirements specified in the PRMRP Discovery Award Program Announcement issued by the U.S. Army Medical Research and Materiel Command's Office of the Congressionally Directed Medical Research Programs (CDMRP).

Administrative screening identified the following reason(s) your application was non-compliant:

PI is identified through a reference made to their published work in the Project Narrative, "We have also previously performed [REDACTED] (7, 8).

As stated in the Administrative Actions in the FY17 Discovery Award program announcement "Use of I, we, our, this organization, or similar phrases that refer to the PI(s), collaborator(s), or their organization(s) through the references listed..." will result in administrative rejection of the application.

Your interest in the PRMRP is appreciated. I hope that you will participate in the future. Please direct your question to the CDMRP at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507. A copy of this letter is being sent to the Grants and Contracts Office at your institution.

Sincerely,

[REDACTED]  
Grants Officer

# Foreign Project Registrations



- In May 18, 2017 memo regarding the closing of the Office of Global Health (OGH), Dean Flotte notified the UMMS community that the Office of Research under Diego Vazquez's direction would take over review of Foreign Project Registration Forms (FPRs).
- We transferred the FPR information from OGH's website to the OOR website and are working with OGH staff to revise the form and site guidance during this transition.
- The FPR can be accessed at:
- <https://www.umassmed.edu/research/compliance/project-policy/>

# Training Recommendations for FY 18



Seeking input from user community on topics to cover this FY.

Topics covered last year were:

- Using OSP Resources to Facilitate Application Preparation
- Award Setup Procedures
- Cayuse Navigation & Overview
- Departmental Grants Management
- Annual Progress Reporting
- Financial Monitoring Tools
- Departmental Subrecipient Monitoring Tools
- Managing Compliance at the Just in Time (JIT) Stage

# PROPOSAL SUBMISSIONS TO OSP

## August 2016 – August 2017



|                                       | August 2016 | September 2016 | October 2016 | November 2016 | December 2016 | January 2017 | February 2017 | March 2017 | April 2017 | May 2017 | June 2017 | July 2017 | August 2017 |
|---------------------------------------|-------------|----------------|--------------|---------------|---------------|--------------|---------------|------------|------------|----------|-----------|-----------|-------------|
| Count                                 | 86          | 121            | 106          | 71            | 48            | 103          | 108           | 90         | 52         | 87       | 98        | 47        | 64          |
| On Time                               | 44%         | 56%            | 46%          | 35%           | 46%           | 53%          | 52%           | 55%        | 40%        | 46%      | 47%       | 57%       | 45%         |
| Late                                  | 50%         | 40%            | 49%          | 62%           | 46%           | 41%          | 43%           | 44%        | 58%        | 54%      | 50%       | 34%       | 49%         |
| After the fact                        | 6%          | 4%             | 5%           | 3%            | 8%            | 5%           | 5%            | 1%         | 2%         | 0%       | 3%        | 9%        | 6%          |
| Withdrawn                             | 0%          | 0%             | 0%           | 0%            | 0%            | 1%           | 0%            | 0%         | 0%         | 0%       | 0%        | 0%        | 0%          |
| <b>Total</b>                          | 100%        | 100%           | 100%         | 100%          | 100%          | 100%         | 100%          | 100%       | 100%       | 100%     | 100%      | 100%      | 100%        |
| Expedited Request<br>(3 days or less) | 35%         | 28%            | 32%          | 35%           | 33%           | 22%          | 28%           | 33%        | 44%        | 28%      | 36%       | 21%       | 34%         |

**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

## August 2016 to August 2017 Comparison



| PROPOSALS                          | 2016 | 2017 | Change |
|------------------------------------|------|------|--------|
| Count                              | 86   | 64   | -22    |
| On Time                            | 44%  | 45%  | +1     |
| Late                               | 50%  | 49%  | -1     |
| After the fact                     | 6%   | 6%   | -      |
| Withdrawn                          | 0%   | 0%   | -      |
| Total                              | 100% | 100% | -      |
| Expedited Request (3 days or less) | 35%  | 34%  | -1     |

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

## August 2016 – August 2017



|                                       | August 2016 | September 2016 | October 2016 | November 2016 | December 2016 | January 2017 | February 2017 | March 2017 | April 2017 | May 2017 | June 2017 | July 2017 | August 2017 |
|---------------------------------------|-------------|----------------|--------------|---------------|---------------|--------------|---------------|------------|------------|----------|-----------|-----------|-------------|
| Count                                 | 17          | 27             | 34           | 32            | 35            | 43           | 38            | 59         | 50         | 51       | 49        | 30        | 23          |
| On Time                               | 41%         | 67%            | 62%          | 59%           | 63%           | 68%          | 58%           | 54%        | 62%        | 59%      | 63%       | 37%       | 52%         |
| Late                                  | 41%         | 22%            | 35%          | 38%           | 37%           | 30%          | 39%           | 42%        | 32%        | 35%      | 29%       | 50%       | 39%         |
| After the fact                        | 18%         | 11%            | 3%           | 3%            | 0%            | 2%           | 3%            | 4%         | 6%         | 6%       | 8%        | 13%       | 9%          |
| <b>Total</b>                          | 100%        | 100%           | 100%         | 100%          | 100%          | 100%         | 100%          | 100%       | 100%       | 100%     | 100%      | 100%      | 100%        |
| Expedited Request<br>(3 days or less) | 35%         | 19%            | 29%          | 19%           | 23%           | 21%          | 32%           | 25%        | 26%        | 22%      | 22%       | 40%       | 26%         |

**On Time:** Received by OSP 5 business days prior to the requested return date.

**Late:** Received by OSP less than 5 business days prior to the requested return date.

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

# SUBMISSIONS TO OSP

## August 2016 to August 2017 Comparison



| PROGRESS REPORTS                   | 2016        | 2017        | Change   |
|------------------------------------|-------------|-------------|----------|
| Count                              | 17          | 23          | +6       |
| On Time                            | 41%         | 52%         | +11      |
| Late                               | 41%         | 39%         | -2       |
| After the fact                     | 18%         | 9%          | -9       |
| Withdrawn                          | 0%          | 0%          | -        |
| <b>Total</b>                       | <b>100%</b> | <b>100%</b> | <b>-</b> |
| Expedited Request (3 days or less) | 35%         | 26%         | -9       |

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.

# APPENDIX

## Policy on Good Clinical Practice Training for NIH Awardees Involved in NIH-funded Clinical Trials

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Notice Number: NOT-OD-16-148

### Key Dates

**Release Date:** September 16, 2016

### Related Announcements

None

### Issued by

National Institutes of Health ([NIH](#))

### Purpose

### Policy Statement

This policy establishes the expectation that all NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials should be trained in Good Clinical Practice (GCP), consistent with principles of the International Conference on Harmonisation (ICH) E6 (R2).<sup>[1](#)</sup>

The principles of GCP help assure the safety, integrity, and quality of clinical trials. GCP provides a standard for ensuring clinical trial compliance, implementation, data collection, monitoring, and reporting (e.g., safety data, accrual reports, study status, protocol deviations, unanticipated problems, or final data), and outline the responsibilities of Institutional Review Boards (IRBs), investigators, sponsors and monitors. GCP addresses elements related to the design, conduct and reporting (e.g., safety data, accrual reports, study status, protocol deviations, unanticipated problems, or final data) of clinical trials.

### Background

GCP principles constitute an international ethical and scientific quality standard for designing, conducting, recording, and reporting clinical trials. The principles were developed in 1996 by the ICH in collaboration with representatives from the European Union, Japan, and the United States. The U.S. Food and Drug Administration (FDA) requires GCP compliance for studies conducted under an investigational new drug application or investigational device exemption.

GCP describes the responsibilities of investigators, sponsors, monitors and IRBs in the conduct of clinical trials. Compliance with GCP provides assurance that the rights, safety and well-being of human subjects are protected, that clinical trials are conducted in accordance with approved plans with rigor and integrity, and that data derived from clinical trials are reliable.

GCP training complements other required training on protections for human research participants. Since June 2000, the NIH Extramural Research Program has required training on protections for

human research participants for all NIH-funded investigators and individuals responsible for the design or conduct of a research involving human subjects.<sup>[2](#)</sup>

### Scope and Applicability

This Policy applies to NIH-funded investigators and clinical trial site staff who are responsible for the conduct, management and oversight of NIH-funded clinical trials.<sup>[3](#)</sup> GCP training includes the Principles of ICH GCP found in Section 2 of ICH E6.<sup>[4](#)</sup> GCP training may be achieved through a class or course, academic training program, or certification from a recognized clinical research professional organization. Completion of GCP

training will demonstrate that individuals have attained the fundamental knowledge of clinical trial quality standards for designing, conducting, recording and reporting trials that involve human research participants. GCP training should be refreshed at least every three years in order remain current with regulations, standards and guidelines. Recipients of GCP training are expected to retain documentation of their training.

*Investigator:* The individual responsible for the conduct of the clinical trial at a trial site. If a clinical trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.

*Clinical trial staff:* Individuals, identified by the investigator, who are responsible for study coordination, data collection and data management. The central focus of clinical trial staff is to manage participant recruitment and enrollment, to maintain consistent study implementation, data management, and to ensure integrity and compliance with regulatory and reporting requirements. These individuals may also seek informed consent from prospective participants, enroll and meet with research participants, and collect and record information from research participants. Clinical trial staff may also be called the research coordinator, study coordinator, research nurse, study nurse or sub-investigator.

## Effective Date

This policy is effective as of January 1, 2017

## Inquiries

Contact the program official at the funding NIH IC

Or

Clinical Trials Program  
Office of the Director (OD)  
Office of Extramural Programs (OEP)  
Office of Extramural Research (OER)  
National Institutes of Health (NIH)  
Email: [oeppmailbox@od.nih.gov](mailto:oeppmailbox@od.nih.gov)

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<sup>1</sup>International Conference on Harmonisation (ICH) E6  
<http://www.fda.gov/downloads/Drugs/.../Guidances/ucm073122.pdf>

<sup>2</sup>Required Education in the Protection of Human Research Participants, see  
<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>

<sup>3</sup>A clinical trial is defined by NIH as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. See  
<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-015.html>.

<sup>4</sup>Acceptable GCP courses include the NIAID GCP Learning Center website  
(<http://gcplearningcenter.niaid.nih.gov>) and National Drug Abuse Treatment Clinical Trials Network  
(<https://gcp.nihtraining.com/>).

## NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information

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Notice Number: NOT-OD-16-149

### Key Dates

**Release Date:** September 16, 2016

**Effective Date:** January 18, 2017

### Related Announcements

[NOT-OD-15-019](#)

### Issued by

National Institutes of Health ([NIH](#))

### Purpose

### Summary

The National Institutes of Health (NIH) is issuing this policy to promote broad and responsible dissemination of information from NIH-funded clinical trials through ClinicalTrials.gov. The policy establishes the expectation that all investigators conducting clinical trials funded in whole or in part by the NIH will ensure that these trials are registered at ClinicalTrials.gov, and that results information of these trials is submitted to ClinicalTrials.gov. The policy is complementary to the statutory and regulatory reporting requirements. These are section 402(j) of the Public Health Service Act, as amended by Title VIII of the Food and Drug Administration (FDA) Amendments Act of 2007 (FDAAA), and the regulation Clinical Trial Registration and Results Information Submission, at 42 CFR Part 11. Hereafter, we refer to section 402(j) as the statute and 42 CFR Part 11 as the rule or regulation. This [policy](#) as well as the [rule](#) were posted in the Federal Register.

### Supplemental Information

On November 19, 2014, and in tandem with the publication of the Notice of Proposed Rulemaking (NPRM) on Clinical Trial Registration and Results Submission, the NIH issued a complementary draft policy for public comment on the Dissemination of NIH-funded Clinical Trial Information<sup>1,2</sup>.

The draft policy proposed that all NIH-funded awardees and investigators conducting clinical trials, funded in whole or in part by the NIH, regardless of study phase, type of intervention, or whether they are subject to the statutory registration and results information submission requirements, would be expected to ensure that those clinical trials are registered and results information is submitted to ClinicalTrials.gov. It further stated that submission of the same type of registration and results information would be expected and in the same timeframes as the trials subject to the statute, and that this information would be made publicly available through the ClinicalTrials.gov website.

The NIH received approximately 240 public comments on its proposed policy. The comments came from a range of stakeholders including researchers, academic/research institutions, medical practitioners, patients, patient/disease advocacy groups, scientific/professional societies and associations, device manufacturers, trade associations, not-for-profit non-governmental organizations, and the general public<sup>3</sup>. The NIH appreciated the public interest in the proposed policy and the time made and effort taken by stakeholders to provide comments. The NIH carefully considered those comments in the development of the final policy. In the next section, we provide an overview of the



comments on the proposed policy. Because those in compliance with the policy would be expected to follow specific provisions of the rule, a number of commenters on the policy reiterated comments that they submitted to the docket in response to the NPRM<sup>4</sup>. Since these comments are discussed at length in the preamble of the rule, we are limiting the discussion of comments here primarily to those that identified issues specific to the policy, such as its scope, applicability, and impact on NIH-funded awardees and investigators.

## Overview of the Public Comments

A significant majority of the public comments were supportive of the proposed NIH policy and of its application to the full range of NIH-funded clinical trials. Most commenters appreciated the impetus behind the policy and agreed that it was important to provide ways other than journal publication for clinical trial results to be disseminated and made publicly available to researchers, health care providers, and patient communities. They recognized that increased availability of information from NIH-funded clinical trials would help researchers by informing the design and development of their future studies, address the needs of patients and healthcare providers seeking information about NIH-funded trials, and serve the public's interest by preventing duplication of unsafe and unsuccessful trials and mitigating publication bias. They also agreed that improving the availability of clinical trial information will strengthen the public's trust in biomedical research as well as assure volunteers that their participation in clinical trials has advanced knowledge on human health and disease. A number of commenters also suggested that the policy is particularly appropriate because NIH-funded clinical trials are supported by public funding, and recipients of those funds have a special obligation to ensure that the nation's investment is maximized.

A number of comments from academic investigators and stakeholder organizations were supportive of the policy and its goals. Others, however, disagreed with the policy, suggesting that it was ill-advised and/or unnecessary. These commenters suggested that the benefit of greater transparency was outweighed by the burden and cost of the policy to those who conduct clinical trials and that the NIH had not made a sufficient case for the policy or that it was not evidence-based. Some commenters suggested that the NIH should simply encourage investigators to be more transparent or that the NIH's public access policy made the policy unnecessary since it requires NIH-funded investigators to make their published articles publicly available through PubMed Central.

**Scope and Applicability of the Policy.** Although the majority of commenters fully supported the scope of the policy, i.e., that it should apply to NIH-funded clinical trials of FDA-regulated drugs regardless of phase, small feasibility studies of devices, and trials of interventions not regulated by FDA, including surgical and behavioral interventions, there were comments suggesting that the scope was too narrow, or conversely, too broad.

One commenter suggested that the policy ought to encompass more detailed summary results, such as Clinical Study Reports, as well as de-identified individual patient-level data. One commenter suggested that the NIH should consider extending the policy to preclinical in vivo (laboratory) animal studies because the arguments for the registration and required reporting of preclinical in vivo (laboratory) animal studies are similar to those of human clinical trials. Some commenters suggested that the policy should be retroactive and apply to clinical trials that are underway as of the policy's effective date as well as those that have already been completed as of the effective date.

On the other hand, there were other comments suggesting that the policy should not apply to phase 1 or so called phase 0 trials, pilot trials designed to examine the feasibility of an approach, trials

mounted by an investigator at a small organization, or trials that are unable to enroll a statistically significant number of participants. One suggested that even pilot trials that reach their enrollment target should not be expected to submit results information because the results might be more misleading than helpful. Another proposed that reporting on phase 1 clinical trials should be limited to adverse events information because these trials are designed to assess safety rather than efficacy, and reporting non-safety outcomes could be misleading. Another suggested that clinical trials not covered under the statute should not submit adverse event information unless a regulatory authority or equivalent body has first performed an analysis of the event in order to prevent public misunderstanding. Another commenter suggested that submission of data from early phase research could divert limited research resources and time from phase 3 studies. Another suggested that only information about phase 3 clinical trials should be included in ClinicalTrials.gov because information

about early stage trials could confound, rather than enhance, public understanding of human health and could, thereby, inadvertently adversely affect patient safety.

One commenter suggested that the policy should apply only to the registration of clinical trials, not the submission of results information. This commenter asserted that registration information was sufficient because any interested party could follow up with an investigator to learn more about the trial and because submission of registration information takes a fraction of the time needed to submit results information.

There were a few commenters who took issue with the application of the policy to trials that are only partially funded by the NIH. They asserted that the policy would entail the disclosure of confidential commercial information and that the NIH's authority to do so is limited to a trial that is wholly NIH-funded and involves a product with research and development costs wholly government-funded. A few other commenters suggested that the policy should exclude clinical trials that use NIH-supported infrastructure, but involve no NIH funds.

**NIH Definition of Clinical Trial.** Some commenters addressed the NIH definition of clinical trial, which is key to determining the policy's applicability. There was support for the breadth of the definition, i.e., encompassing all interventional studies with biomedical outcomes (e.g., pharmacokinetic and behavioral outcomes, as well as health-related outcomes). One commenter, however, thought more elaboration on the definition was needed to clarify the meaning of "health-related biomedical or behavioral outcomes." They thought that without such specificity, the definition might be interpreted to exclude studies that contain valuable information for public health research, science, and clinical medicine. Commenters believed that addressing this issue would be vital to ensure a common understanding that the NIH policy applies to all clinical trials involving a biomedical or behavioral intervention. Another suggested that a study involving only one participant should not be considered a clinical trial since a trial with a sample size of one would not provide any valid data to share with the public.

Some commenters noted that the wording of the NIH definition was not identical to the wording of the definition of clinical trial in the proposed rule or to how other organizations, e.g., the World Health Organization (WHO), International Committee of Medical Journal Editors (ICMJE), and Centers for Medicare & Medicaid Services (CMS), use the term. They were concerned that investigators would have difficulty understanding their obligations under the policy and under the rule and in meeting requirements of others. They called for reconciliation of any actual or apparent differences in the definitions.

A commenter urged the NIH to issue guidance to help determine whether a study is a clinical trial under the definition and to clarify how disagreements in the matter would be resolved and communicated.

**Results Information Submission Timeline.** A few commenters raised concerns about the proposed rule's timeline for reporting results information, asserting that 12 months after the primary completion date of the clinical trial (i.e., the date of final data collection for the primary outcome measure) is too soon, particularly for NIH-funded academic investigators. These commenters suggested that academic investigators will have more difficulty meeting the timeframe because they must also spend time teaching, fulfilling clinical care responsibilities, and writing grant applications. Another commenter suggested that a 12-month timeframe would also be more challenging for academic investigators because, unlike industry investigators, they generally cannot count on support from a central administrative service to help them carry out their reporting responsibilities. Decentralization of information in academic centers would also present a particular challenge to those covered by the NIH policy, according to another commenter, who also suggested that the mobility of new investigators may make it difficult to meet timelines. These commenters urged the NIH to allow a longer submission timeframe, e.g., 18 or 24 months. A few noted that providing more time would also give investigators time to prepare journal publications, and one also expressed concern about the possibility that journal editors will begin to consider submission of results information to ClinicalTrials.gov as prior publication, which could thwart journal publication altogether.

**Structured Results Data Elements.** A few commenters suggested that the data submission structure, which is determined by the provisions of the statute, does not work well for clinical trial types that will be covered only the policy, e.g., phase 1 trials of drugs/biologics, small feasibility device studies, trials of social and behavioral interventions, or those with non-standard designs. These commenters thought that other fields would need to be added to the ClinicalTrials.gov to enable investigators to report data elements for those trials appropriately and accurately. They also suggested increasing the character limit on data fields to allow for more careful and nuanced explanations. Commenters also suggested that if the ClinicalTrials.gov cannot accommodate these types of trials, investigators should be exempted from the policy. One commenter requested that an additional data element should be included to allow an investigator to indicate that the trial's hypothesis had been confirmed.

**Protecting Privacy.** One commenter raised a concern about the policy's impact on the privacy of clinical trial participants suggesting that it might be easy to re-identify participants in many NIH-funded pilot studies with small sample sizes. The commenter pointed to the five percent threshold for non-serious adverse events and site location information as the data elements creating the vulnerability. The commenter urged the NIH to allow an investigator to obtain a waiver from results information submission where participant privacy was at risk.

**Compliance Issues.** The proposed policy noted that compliance with the policy would be a term and condition of award and that non-compliance may provide a basis for enforcement actions, including termination. A few commenters discussed the importance of compliance. One suggested that the NIH should take compliance records into account when considering future applications for funding. They suggested that such an approach could be more effective than terminating funding of a current grant since most of the research may already be completed. Another thought that making compliance a term and condition of award was important and that it would incentivize good behavior and help change attitudes about the value of enhancing availability of clinical trial information.

Other commenters raised concerns about the costs that will be incurred by NIH-funded academic institutions to ensure that clinical investigators are following the policy. They suggested institutions

will need to provide more administrative support and other resources to help investigators comply and that this would be difficult given the indirect cost cap of 26 percent. Commenters urged the NIH to allow the time and effort required for ClinicalTrials.gov compliance to be included as a direct cost on NIH grants. Another commenter suggested that the increased results information submissions brought on by the NIH policy will stretch the NIH's capabilities and that it will be important for the NIH to ensure that sufficient resources are available to manage high volume data uploads and customer service requests.

## **Overview of Final NIH Policy**

The NIH considered all the comments received on the proposed policy as well as those that were submitted in response to the NPRM. There was overwhelming support for both the proposed policy and the NPRM, particularly among concerned citizens, scientific societies, medical practitioners, and individual scientists. There were also concerns expressed, particularly in the comments from academic commenters. We appreciate those concerns and understand that the policy will create additional work for many investigators. However, we believe that the work should not be seen as a burden, but, rather, an inherent part of an investigator's commitment to the advancement of science. The benefits will, in the long run, accrue to the investigators as well as to the public, patients, and the enterprise as a whole because transparency will improve future research designs and maximize the public's investment – and their trust – in research. Equally important, it will help investigators fulfill the ethical obligation they have to clinical trial participants, namely to ensure that the findings from their participation contribute to generalizable knowledge and the advancement of public health.

As we noted in the preamble to the proposed policy, a fundamental premise of all NIH-funded research is that the results of such work must be disseminated in order to contribute to the general body of scientific knowledge and, ultimately, to the public health. The NIH awardees have always been expected to make the results of their activities available to the research community and to the public at large because it is intrinsic to the scientific process. In research involving human beings, moreover, scientists also have an ethical obligation to ensure that the burden and risk that volunteers

assume by participating in research comes to something, at the very least by ensuring that others are aware of the study and that its findings contribute to the advancement of human health.

We disagree with commenters who suggested that there is no need for coverage of certain types of trials, such as early exploratory trials, small trials, trials assessing only safety, or trials that terminate before reaching enrollment targets. The benefits of transparency and the need to fulfill the ethical obligation to participants is as relevant to these types of trials as to any other type. We were also not persuaded that the timeframe for results information submission should be longer for academic investigators because of their competing responsibilities or that they should be allowed more time to publish their results in a journal. The timeframe of 12 months from the primary completion date should provide enough time for investigators to organize their data and submit results information. We are also confident that academic institutions can develop central support services as necessary to assist investigators should they need it. We also believe that 12 months represents an appropriate balance between investigators' interests and the interests of the public in having access to the results of a publicly funded trial. In addition, it will be possible to delay results information submission for up to two years beyond the initial deadline with a certification that regulatory approval of the trial product is being sought.

Some commenters suggested that a policy on clinical trial information dissemination is not needed because it duplicates other NIH policies. This policy is certainly in keeping with our principles, longstanding expectations, and other policies as well as the more recent broad policy call for scientific agencies to increase public access to scientific data <sup>5</sup>. However, it does not duplicate any other NIH policy, nor does any other NIH policy accomplish what this one will.

Some commenters also contended that this policy is not necessary because the results of clinical trials will be published or because they can be obtained via direct requests to the trial's principal investigator. In fact, research has shown that the results of a significant portion of clinical trials are not published or published in a timely manner. For example, a 2012 study of NIH-funded clinical trials found that after a median of 51 months following trial completion, 32 percent were unpublished <sup>6</sup>. A more recent study of the trial publication rate among 51 U.S. academic medical centers found that 43 percent of their clinical trials were unpublished two years after the trial was completed <sup>7</sup>. While the ability to seek results information from the original investigator is useful to facilitate collaborations, to access individual-level data, and to gain insights from those who conducted the trial, it is not a surefire way to increase access to trial results nor is it efficient or transparent, particularly for the public.

We believe that the public availability of clinical trial results information will be beneficial to all parties in the long run, including those who are covered by this policy. All investigators stand to benefit from this policy. For example, science may progress more quickly because investigators will be able to learn from trials to which they otherwise would not have had access because they were unpublished. In addition, the public availability of results information helps investigators design trials and Institutional Review Boards (IRBs) review proposed trials, by allowing them to weigh the proposed study's risks and benefits against a more complete evidence base than is currently available through the scientific literature <sup>8</sup>. Submission and posting of results information will also help investigators avoid repeating trials on interventions that have been found to be unsafe or unsuccessful while also providing access to information that may help verify findings.

For all of these reasons, we have not changed the essential contours of the policy. In terms of scope, the policy still applies to all NIH-funded awardees and investigators conducting clinical trials funded in whole or in part by the NIH regardless of study phase, type of intervention, or whether they are subject to the statute and to the rule. It clarifies that the policy is an expectation, that applicants and offerors are required to submit a plan outlining how they will meet the policy's expectations, and, that upon receipt of an award, an awardee will be obligated to adhere to their plan through the terms and conditions of the award. The required plan can be a brief statement explaining whether the applicant/offeror intends to register and submit results information to ClinicalTrials.gov as outlined in the policy or to meet the expectations in another manner. It is important to remember that an NIH-funded clinical trial that meets the definition of an applicable clinical trial is subject to the regulation and, therefore, register and submission of results information to ClinicalTrials.gov is a requirement.

The policy applies to both the extramural and intramural programs. For the NIH extramural program, the policy applies to applications for funding including for grants, other transactions, and contracts submitted on or after the policy's effective date that request support for the conduct of a clinical trial that is initiated on or after the policy's effective date. This means that the policy does not apply to clinical trials in ongoing, non-competing awards, but that it will apply if the grantee submits a competing renewal application that includes a new clinical trial, i.e., a clinical trial initiated on or after the effective date of the policy. For the intramural program, the policy applies to clinical trials initiated on or after the policy's effective date. The policy's effective date is January 18, 2017. The

policy clarifies that a clinical trial that uses NIH-supported infrastructure, but does not receive NIH funds to support its conduct, is not subject to the policy.

The policy outlines the responsibilities for NIH-funded investigators according to whether the trial is covered by the policy only or also the rule. For those covered by the policy only, NIH-funded awardees and investigators will be expected to submit the same registration and results information in the same timeframes as those subject to the statute and rule. The timeline for registration is not later than 21 calendar days after the enrollment of the first participant. The standard timeline for results information is not later than one year after the trial's primary completion date, but the policy also allows for delayed submission of results information in certain circumstances for up to two additional years for trials of products regulated by the FDA that are unapproved, unlicensed, or uncleared or for trials of products for which approval of a new use is being sought.

Although the policy does not apply to NIH-funded clinical trials initiated before the effective date, we encourage all ongoing NIH-funded clinical trials to follow it. It is also critical for investigators conducting NIH-funded applicable clinical trials that are subject to the statute and rule to be sure they are in compliance with those requirements.

The policy continues to use the NIH definition of "clinical trial" as proposed in the draft policy to determine which research studies are covered by the policy. This definition was developed in 2014 to reflect the NIH research mission and the scope of clinical trials within the NIH portfolio. With regard to the concern expressed by a public commenter that the phrase "health-related biomedical or behavioral outcomes" might be too narrow, we note that the definition considers biomedical and behavioral outcomes to be health-related outcomes in interventional studies that meet the other components of the definition. Also, regarding the concern that the wording of the definitions of clinical trial in this policy and the rule differ, this is so mainly in reference to outcomes, i.e., the NIH definition explicitly references behavioral outcomes whereas the definition in the rule encompasses them within the term "health related." These distinctions are not significant in terms of defining what is covered by the NIH policy. All NIH-funded clinical trials, whether they are assessing biomedical or behavioral outcomes or whether they are employing an FDA regulated product, are covered by the policy. An NIH-funded clinical trial assessing a behavioral intervention that is not regulated by the FDA would meet both definitions of clinical trial, and, thereby, be covered by the policy. However, such a trial would not be subject to the rule because it does not meet the rule's definition of "applicable clinical trial." Guidance available on the NIH's website can help awardees and investigators understand whether a research study is a clinical trial for purposes of the NIH policy (see first website listed below). Questions should be directed to the NIH program staff. To understand whether an NIH-funded clinical trial is also subject to the statute and the rule, awardees and investigators should look to the rule's definition of "applicable clinical trial."

NIH-funded awardees and investigators will be expected to follow the provisions of the rule in terms of when they register their trials, what information they provide as part of the registration process, when they submit their results information, and what results information is submitted. All of the alternate approaches in the rule will also be available to those covered by the policy, e.g., for delayed posting of device registration information, delayed submission of results information for trials involving unapproved products or products for which a new use is sought, extensions for good cause, and waivers that might be needed for privacy or national security reasons.

With regard to the concern that ClinicalTrials.gov is not set up to accept NIH-funded trials that are small or exploratory in nature or involve behavioral interventions, it is important to note that the ClinicalTrials.gov does accommodate the submission of all trial types and that a variety of study and

trial types have been entered into ClinicalTrials.gov since its inception. In addition, ClinicalTrials.gov

has resources available to assist investigators in navigating the registration and results information submission processes. These resources will continue to be updated over time to be responsive to investigators' needs and the evolving clinical research enterprise. Therefore, it should not be necessary for a clinical investigator of an NIH-funded clinical trial to seek an exemption from the policy for reasons related to the capacity of ClinicalTrials.gov to accommodate all types of clinical trials.

Registration and results information submission to ClinicalTrials.gov complements publication of trial results in peer-reviewed scientific journals. Information submitted to ClinicalTrials.gov is displayed in a structured way and includes a complete list of all pre-specified outcome measures and all adverse events. Journal articles, on the other hand, typically focus on a select set of outcome measures and adverse events and include background and discussion of the implications of the results. Information submitted to ClinicalTrials.gov undergoes a quality control review whereas journal articles will be peer reviewed. With regard to the concern that submission of results could make journal publication more difficult or impossible, the ICMJE has stated that submission of summary results to ClinicalTrials.gov will not be considered prior publication and will, thus, not interfere with journal publication<sup>2</sup>. We encourage all NIH-funded investigators to publish the results of their studies in peer-reviewed journals.

We have no doubt that this policy will be beneficial for the research community as well as the public generally, but we recognize that adhering to it will be a new obligation. We will provide additional guidance to facilitate implementation and help awardees and investigators understand the policy as well as the tasks described in the rule that they will be expected to undertake. In terms of the costs of complying with the policy, grantees are permitted to charge the salaries of administrative and clerical staff as a direct cost<sup>10</sup>. Such staff could assist investigators in meeting their responsibilities under the policy. In addition, administrative costs can be covered through indirect cost recovery.

We intend for this policy to benefit all communities who seek information about NIH-funded clinical trials, and we are confident that the benefits of transparency will become evident soon after the policy is implemented. We plan to evaluate the implementation and impact of the policy from the perspective of those who comply with it as well as from the perspective of ClinicalTrials.gov users, including patients, providers, and investigators.

We look forward to engaging with NIH-funded investigators and awardees as they work to meet the expectations of this important public policy. Information to assist applicants, offerors, and investigators is available at the following websites. The NIH will continue to add guidance materials to these sites as the policy's implementation continues.

<http://osp.od.nih.gov/office-clinical-research-and-bioethics-policy/clinical-research-policy/clinical-trials>  
<https://clinicaltrials.gov/ct2/manage-recs>  
[https://grants.nih.gov/clinicaltrials\\_fdaaa/faq.htm](https://grants.nih.gov/clinicaltrials_fdaaa/faq.htm)

The NIH policy is set forth below.

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## NIH Policy on Dissemination of NIH-Funded Clinical Trial Information

### Purpose

The National Institutes of Health (NIH) Policy on Dissemination of NIH-funded Clinical Trial Information establishes the expectation that all NIH-funded awardees and investigators conducting clinical trials, funded in whole or in part by the NIH, will ensure that their NIH-funded clinical trials are registered at, and that summary results information is submitted to, ClinicalTrials.gov for public

posting1 The purpose of the policy is to promote broad and responsible dissemination of information from NIH-funded clinical trials through ClinicalTrials.gov. Disseminating this information supports the NIH mission to advance the translation of research results into knowledge, products, and procedures that improve human health.

This policy is complementary to requirements in the Clinical Trial Registration and Results Information Submission regulation at 42 CFR Part 11, hereinafter referred to as the regulation 2. Clinical trials that are subject to the regulation are, in general, clinical trials of drug, biological, and device products regulated by the Food and Drug Administration (FDA), except phase 1 trials of drug and biological products and small feasibility studies of device products. A pediatric post-market surveillance study of a device product required by the FDA is also subject to the regulation. Clinical trials subject to the regulation are generally called "applicable clinical trials." Applicable clinical trials are required to be registered in ClinicalTrials.gov not later than 21 calendar days after the enrollment of the first participant. Results information from those trials generally must be submitted not later than one year after the trial's primary completion date. Submission of results information can be delayed in certain circumstances for up to two additional years for trials of products regulated by the FDA that are unapproved, unlicensed, or uncleared or for trials of products for which approval, licensure, or clearance of a new use is being sought.

#### Scope and Applicability

This policy applies to all NIH-funded clinical trials regardless of study phase, type of intervention, or whether they are subject to the regulation. For example, NIH-funded phase 1 clinical trials of an FDA-regulated product are covered by this policy as are clinical trials studying interventions not regulated by the FDA, such as behavioral interventions. As such, the policy encompasses all NIH-funded clinical trials, including applicable clinical trials subject to the regulation. All NIH-funded clinical trials will be expected to register and submit results information to ClinicalTrials.gov.

This policy applies to clinical trials funded in whole or in part through the NIH extramural and intramural programs. For the NIH extramural program, the policy applies to applications for funding including for grants, other transactions, and contracts submitted on or after the policy's effective date that request support for the conduct of a clinical trial that is initiated on or after the policy's effective date. For the NIH intramural program, the policy applies to clinical trials initiated on or after the policy's effective date.

This policy does not apply to a clinical trial that uses NIH-supported infrastructure but does not receive NIH funds to support its conduct.

#### Responsibilities

As part of their applications or proposals, applicants and offerors seeking NIH funding will be required to submit a plan for the dissemination of NIH-funded clinical trial information that will address how the expectations of this policy will be met. NIH-funded awardees and investigators conducting clinical trials funded in whole or in part by the NIH will be required to comply with all terms and conditions of award, including following their plan for the dissemination of NIH-funded clinical trial information.

Consistent with those terms and conditions, the responsibilities of such awardees and investigators will fall within one of the three categories. The category depends on whether, under the regulation, the clinical trial is also an "applicable clinical trial" and the awardee or investigator is the "responsible party."

1. If the NIH-funded clinical trial is an applicable clinical trial under the regulation and the awardee or investigator is the responsible party, the awardee or investigator will ensure that all regulatory requirements are met.
2. If the NIH-funded clinical trial is an applicable clinical trial under the regulation but the awardee or investigator is not the responsible party, the awardee or investigator will coordinate with the responsible party to ensure that all regulatory requirements are met.
3. If the NIH-funded clinical trial is not an applicable clinical trial under the regulation, the awardee or investigator will be responsible for carrying out the tasks and meeting the timelines described in regulation. Such tasks include registering the clinical trial in ClinicalTrials.gov and submitting results information to ClinicalTrials.gov.

In addition, informed consent documents for clinical trials within all three categories are to include a specific statement relating to posting of clinical trial information at ClinicalTrials.gov.

Each NIH-funded clinical trial should have only one entry in ClinicalTrials.gov that contains its registration and results information. Awardees and investigators need not and should not create a separate record of the applicable clinical trial to comply with this policy.

The NIH will publicly post registration information and results information in ClinicalTrials.gov.

## Definitions

*Clinical Trial.* For purposes of this policy, a "clinical trial" means "a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes."<sup>3</sup> This definition encompasses phase 1 trials of FDA-regulated drug and biological products, small feasibility studies of FDA-regulated device products, and studies of any intervention not regulated by the FDA, e.g., behavioral interventions. This definition of "clinical trial"<sup>4</sup> is broader than the term "applicable clinical trial" as defined in the regulation.<sup>5</sup>

*Responsible Party.* In the policy, the awardee or the investigator is responsible for meeting the expectations of this policy. In the regulation, a "responsible party" means, in part, "with respect to a clinical trial, the sponsor of the clinical trial, as defined in 21 CFR 50.3 (or any successor regulation); or the principal investigator of such clinical trial if so designated by a sponsor, grantee, contractor, or awardee, so long as the principal investigator is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial, and has the ability to meet all of the requirements under [42 CFR Part 11] for the submission of clinical trial information."<sup>6</sup>

*Primary Completion Date.* In the policy, this term has the same meaning as the term "primary completion date" in the regulation, which is "the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the pre-specified protocol or was terminated."<sup>7</sup>

*Registration Information.* In the policy, this term has the same meaning as the term "registration information" in the regulation. In the regulation, registration information consists of descriptive information, recruitment information, location and contact information, and administrative data.<sup>8</sup>

*Results Information.* In the policy, this term has the same meaning as the term "results information" in the regulation. In the regulation, results information includes participant flow, demographic and baseline characteristics, outcomes and statistical analyses, adverse events, the protocol and statistical analysis plan, and administrative information.<sup>9</sup>

### **Compliance**

If the clinical trial is NIH-funded in whole or in part, expectations for clinical trial registration and summary results submission will be included in the terms and conditions of the award. Failure to comply with the terms and conditions of the NIH award may provide a basis for enforcement actions, including termination, consistent with 45 CFR 75.371 and/or other authorities, as appropriate. If the NIH-funded clinical trial is also an applicable clinical trial, non-compliance with the requirements specified in 42 USC 282(j) and 42 CFR Part 11 may also lead to the actions described in 42 CFR 11.66.

### **Effective Date**

This policy is effective January 18, 2017.

### **Footnotes**

1. ClinicalTrials.gov is operated by the National Library of Medicine within the NIH.
2. The Clinical Trial Registration and Results Information Submission regulation at 42 CFR Part 11 was issued in the Federal Register in September 2016. The regulation implements section 402(j) of the Public Health Service Act.
3. Further information about this definition is available from the NIH Office of Science Policy at <http://osp.od.nih.gov/office-clinical-research-and-bioethics-policy/clinical-research-policy/clinical-trials>.
4. Note that the regulation also includes a definition of "clinical trial." That definition is "a clinical investigation or a clinical study in which human subject(s) are prospectively assigned, according to a protocol, to one or more interventions (or no intervention) to evaluate the effect(s) of the intervention (s) on biomedical or health related outcomes" (see 42 CFR 11.10 (a)). For the purposes of this policy, the regulatory definition and the definition in this policy are treated as synonymous.
5. In the regulation, applicable clinical trial is defined as an applicable device clinical trial or an applicable drug clinical trial. The regulation defines an applicable device clinical trial to mean, in part, "a prospective clinical study of health outcomes comparing an intervention with a device product subject to section 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360 (k), 21 U.S.C. 360e, 21 U.S.C. 360j(m)) against a control in human subjects (other than a small clinical trial to determine the feasibility of a device product, or a clinical trial to test prototype device products where the primary outcome measure relates to feasibility and not to health outcomes)." The regulation defines an applicable drug clinical trial to mean, in part, "a controlled clinical investigation, other than a phase 1 clinical investigation, of a drug product subject to section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or a biological product subject to section 351 of the Public Health Service Act (42 U.S.C. 262), where "clinical investigation" has the meaning given in 21 CFR 312.3 (or any successor regulation) and "phase 1" has the meaning given in 21 CFR 312.21 (or any successor regulation).
6. See 42 CFR 11.10 (a) and 42 CFR 11.4.
7. See the complete definition at 42 CFR 11.10 (a).
8. See 42 CFR 11.10 (b) and 42 CFR 11.28 for the specific data elements.
9. See 42 CFR 11.28 for complete results information and specific data elements.

## Inquiries

Please direct all inquiries to:

NIH Office of Science Policy

Telephone: 301-496-9838

Email: [clinicaltrials.disseminationpolicy@mail.nih.gov](mailto:clinicaltrials.disseminationpolicy@mail.nih.gov)

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## Update on Clinical Trial Funding Opportunity Announcement Policy

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Notice Number: NOT-OD-17-043

### Key Dates

**Release Date:** February 17, 2017

### Related Announcements

[NOT-OD-17-114](#)

[NOT-OD-17-062](#)

[NOT-OD-16-147](#)

### Issued by

National Institutes of Health ([NIH](#))

### Purpose

In September we announced a new policy requiring all applications involving one or more clinical trials be submitted through a Funding Opportunity Announcement (FOA) specifically designed for clinical trials ([NOT-OD-16-147](#)). The policy improves our ability to identify clinical trials, ensure appropriate clinical trial data collection, and uniformly apply trial-specific review criteria. This notice updates the community on our evolving plans in this area, including an adjustment to the effective date.

### New Effective Date

Effective January 25, 2018, all grant applications with plans to conduct clinical trials must be submitted in response to an FOA which specifically states that clinical trials are allowed.

After that date, applications planning a clinical trial that are submitted to a non-clinical trial FOA will be returned without review.

### High-level Plan

- Spring 2017
  - Complete Office of Management and Budget approval process for new "PHS Human Subjects and Clinical Trials Information" form which consolidates human subject information currently collected across several PHS forms and expands our data collection requirements for clinical trials.
  - Provide additional information to the community on our new form and implementation plans.
- Fall 2017
  - Expire existing clinical trial FOAs by January 24, 2018.
  - Update remaining active FOAs to include the latest approved forms and to indicate that clinical trial applications are not allowed for due dates on or after January 25, 2018.
  - Issue new clinical trial FOAs with clinical trial-specific review criteria, forms, and instructions for due dates on or after January 25, 2018.

### Contracts

Requests for proposals (RFPs) will be updated with comparable clinical trial data collection requirements for proposal due dates on or after January 25, 2018.

#### Inquiries

Please direct all inquiries to:

NIH Grants Information

Email: [grantsinfo@od.nih.gov](mailto:grantsinfo@od.nih.gov) (preferred method of contact)

Telephone: 301-945-7573

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## New NIH "FORMS-E" Grant Application Forms and Instructions Coming for Due Dates On or After January 25, 2018

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Notice Number: NOT-OD-17-062

### Key Dates

**Release Date:** April 27, 2017

### Related Announcements

[NOT-OD-17-114](#)

[NOT-OD-16-147](#)

[NOT-OD-17-043](#)

### Issued by

National Institutes of Health ([NIH](#))

### Purpose

This notice informs the biomedical and health services research communities of changes to grant application form and application guide instructions for due dates on or after January 25, 2018.

### Focus of changes:

- Consolidation of human subjects, inclusion enrollment, and clinical trial information previously collected across multiple agency forms
- Expansion and use of discrete form fields for clinical trial information to
  - provide the level of information needed for peer review;
  - lead applicants through clinical trial information collection requirements;
  - present key information to reviewers and agency staff in a consistent format; and
  - align with ClinicalTrials.gov (where possible) and position us for future data exchange with ClinicalTrials.gov
- Incorporation of recent Grants.gov changes to R&R Budget and SBIR/STTR Information forms

These changes will be implemented with application form packages identified with a Competition ID of "FORMS-E" and associated application guide instructions. See [High-level Summary of Form Changes in FORMS-E Application Packages](#) for a full list of changes.

### Effective Date

Applicants must use FORMS-E application packages for due dates on or after January 25, 2018 and must use FORMS-D application packages for due dates on or before January 24, 2018. Applications submitted using the wrong forms for their intended due date will not be reviewed.

### Availability of FORMS-E Application Guides

Application guides for FORMS-E application packages will be posted to the [How to Apply - Application Guide](#) page no later than October 25, 2017.

### Availability of FORMS-E Application Packages

We will begin posting new funding opportunity announcements (FOAs) with FORMS-E application packages on October 25, 2017.

- New FOAs posted before October 25, 2017 with initial due dates on or after January 25, 2018 will be posted without application forms. Application packages will be added to these FOAs by November 10, 2017.

All [NIH "parent" announcements](#) that use standard due dates will be expired and reissued with new FOA numbers, FORMS-E application packages and instructions. The FORMS-E parent announcements will be posted no later than 60 days before their standard due date. For a transition period, both FORMS-D and FORMS-E parent announcements will be active. Applicants must choose the announcement with the appropriate application package for their due date (see table below).

All active FOAs with due dates both before and after January 25, 2018 will be updated to add FORMS-E application packages between October 25, 2017 and November 25, 2017. For a transition period, both FORMS-D and FORMS-E application packages will be active. Applicants must choose the appropriate application package for their due date when presented with both FORMS-D and FORMS-E application packages on the same FOA (see table below).

| If your due date is...                                                                                                                                                                                                                                                                                                                                                                                                                                                               | You must use...             |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|
| On or before January 24, 2018, including: <ul style="list-style-type: none"> <li>• Applications submitted for due dates on or before January 24, 2018</li> <li>• Applications submitted under <a href="#">NIH Late Policy</a> 2-week window of consideration for intended due dates on or before January 24, 2018</li> <li>• Applications submitted by February 7, 2018 under NIH <a href="#">Continuous Submission Policy</a> for January 7, 2018 AIDS intended due date</li> </ul> | FORMS-D application package |
| On or after January 25, 2018, including: <ul style="list-style-type: none"> <li>• Applications submitted for due dates on or after January 25, 2018</li> <li>• All application types (New, Resubmission, Renewal, Revision)</li> <li>• Applications submitted early for intended due dates on or after January 25, 2018</li> </ul>                                                                                                                                                   | FORMS-E application package |

Additional guide notices for individual FOAs with unique due date considerations will be issued as needed and referenced in the Related Notices section of each FOA.

### Form Update Timing for Administrative Supplement, Successor-in-Interest (Type 6) and Change of Institution (Type 7) Parent Announcements

Parent announcements for administrative supplements and post award administrative actions (successor-in-interest and change of institution applications) do not have set due dates and, consequently, will follow a different timeline than other parent announcements.

The FOAs in the table below will be reissued with new FOA numbers, FORMS-E application packages and instructions on January 25, 2018. Applications started on or after January 25, 2018 must use the new FOAs and FORMS-E application packages.

These FOAs will expire on February 25, 2018 giving applicants one month to complete their initiated FORMS-D applications.

| FOA# | FOA Title |
|------|-----------|
|------|-----------|

|                           |                                                                                                       |
|---------------------------|-------------------------------------------------------------------------------------------------------|
| <a href="#">PA-16-285</a> | Change of Grantee Organization (Type 7 Parent)                                                        |
| <a href="#">PA-16-286</a> | Successor-in-Interest (Type 6 Parent)                                                                 |
| <a href="#">PA-16-287</a> | Administrative Supplements to Existing NIH Grants and Cooperative Agreements (Admin Supp)             |
| <a href="#">PA-16-288</a> | Research Supplements to Promote Diversity in Health-Related Research (Admin Supp)                     |
| <a href="#">PA-16-289</a> | Research Supplements to Promote Re-Entry into Biomedical and Behavioral Research Careers (Admin Supp) |

## Applications Proposing Clinical Trials

As previously announced, all applications involving clinical trials must be submitted to FOAs specifically designed for clinical trials beginning with due dates on or after January 25, 2018 ([NOT-OD-16-147](#), [NOT-OD-17-043](#)).

We will take the following steps to accommodate this new policy:

- Issue new clinical trial FOAs with clinical trial-specific review criteria, FORMS-E application packages, and FORMS-E instructions for due dates on or after January 25, 2018
- Add a new "Clinical Trials" item to the table in Section II of all FOAs (just below "Application Types Allowed") which will include one of the following statements:
  - Only accepting applications that propose clinical trial(s)
  - Only accepting applications that do **not** propose clinical trials
  - Accepting applications that either propose or do not propose clinical trial(s)
- Expire existing (FORMS-D) clinical trial FOAs by January 24, 2018

## Resources:

- [High-level Summary of Form Changes in FORMS-E Application Packages](#)
- [Annotated Form Set for NIH Grant Applications](#)
- [Do I Have the Right Form Version For My Application?](#)
- [Application Forms, Form Updates, and Choosing the Correct Forms FAQs](#)

## Inquiries

Please direct all inquiries to:

NIH Grants Information

Email: [grantsinfo@od.nih.gov](mailto:grantsinfo@od.nih.gov) (preferred method of contact)

Telephone: 301-945-7573

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## Revision: Notice of Extension of Effective Date for Final NIH Policy on the Use of Single Institution Review Board for Multi-Site Research

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Notice Number: NOT-OD-17-076

### Key Dates

**Release Date:** June 16, 2017

### Related Announcements

[NOT-OD-17-119](#)

[NOT-OD-16-094](#)

[NOT-OD-17-027](#) Rescinded

### Issued by

National Institutes of Health ([NIH](#))

### Purpose

This revised Notice replaces [NOT-OD-17-027](#) to inform the research community that NIH is extending the effective date of the NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research to January 25, 2018. The policy will apply to all competing grant applications for due dates on or after January 25, 2018. For R&D contracts, the policy will apply to all solicitations issued on or after this effective date.

Guidance and Frequently Asked Questions to assist in the implementation of the policy will be available at: <https://osp.od.nih.gov/clinical-research/irb-review/>.

### Inquiries

Please direct all inquiries to:

NIH Office of Science Policy

Telephone: 301-496-9838

Email: [SingleIRBPolicy@mail.nih.gov](mailto:SingleIRBPolicy@mail.nih.gov)

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## NIH Fiscal Policy for Grant Awards - FY 2017

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Notice Number: NOT-OD-17-086

### Key Dates

**Release Date:** June 30, 2017

### Related Announcements

[NOT-OD-17-049](#)

[NOT-OD-17-048](#)

[NOT-OD-17-003](#)

[NOT-OD-17-001](#)

### Issued by

National Institutes of Health ([NIH](#))

### Purpose

This Notice provides guidance about the NIH Fiscal Operations for FY 2017 and implements the Consolidated Appropriations Act, 2017 (Public Law 115-31), signed by President Trump on May 5, 2017. With the passage of the Act, NIH received a \$2 billion increase above FY2016, for a total of \$34.30 billion in budget authority or equivalent (program level), including \$352,000,000 from the 21st Century Cures Act.

The following NIH fiscal policies are instituted in FY 2017:

**FY 2017 Funding Levels:** Non-competing continuation awards that have already been made in FY 2017 were generally funded at levels below that indicated on the most recent Notice of Award (generally up to 90% of the previously committed level) as described in [NOT-OD-17-048](#). In general, such reductions will be fully restored, and non-competing continuation grants (research and non-research) including those that remain to be issued in FY 2017 will be made at the commitment level indicated on the Notice of Award. Any exceptions will be posted at the site listed under "Additional Information" below. Out-year commitments for continuation awards in FY 2018 and beyond will remain unchanged. The NIH awarding Institutes/Centers (IC) will develop and post their fiscal policies consistent with overall NIH goals and available FY 2017 funds.

**Ruth L. Kirschstein National Research Service Awards (NRSA):** Consistent with the recommendations of the [Advisory Committee to the Director](#) regarding the [Biomedical Research Workforce](#), the NIH will increase NRSA stipends by approximately 2 percent on average. The full range of postdoctoral stipend adjustments for FY 2017 is described at [NOT-OD-17-003](#). NIH will issue additional guidance on predoctoral stipends as appropriate.

**New Investigators:** NIH will continue to support new investigators on R01 equivalent awards at success rates comparable to that of established investigators submitting new (Type 1) R01 equivalent applications. Achievement of comparable success rates should permit the NIH to support new investigators in accordance with the policies established in FY 2009 and subsequent years as described at <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-013.html> and at [https://grants.nih.gov/grants/new\\_investigators/index.htm](https://grants.nih.gov/grants/new_investigators/index.htm).

**Salary Limits:** Section 202 of the Consolidated Appropriations Act, 2017 prohibits payments for salaries under grants and other extramural mechanisms in excess of [Executive Level II](#) previously set at \$185,100, and effective January 8, 2017, increased to \$187,000. See [NOT-OD-17-049](#) for additional information.

**Other Legislative Mandates:** Other statutory requirements are described in [NOT-OD-17-075](#).

**Additional Information:** Additional details on Fiscal Operations, including specific funding strategies for ICs will be posted at <https://grants.nih.gov/grants/financial/index.htm>.

#### Inquiries

Please direct all inquiries to:

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

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## Clarification and Update: Salary Supplementation and Compensation on Research Career Development ("K") Awards

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Notice Number: NOT-OD-17-094

### Key Dates

**Release Date:** July 24, 2017

### Related Announcements

None

### Issued by

National Institutes of Health ([NIH](#))

Agency for Health Care Research and Quality ([AHRQ](#))

### Purpose

The purpose of this notice is to clarify and update policies for [Research Career Development \("K"\) Awards](#).

### Salary Supplementation and Compensation during the Entire Career ("K") award

The recipient institution may supplement the NIH or AHRQ salary contribution on "K" awards up to a level that is consistent with the institution's salary scale. *For effort directly committed to the "K" award*, salary supplementation is allowable, but must be from non-Federal sources (including institutional sources). Non-Federal or institutional supplementation of salary must not require extra duties or responsibilities that would interfere with the goals of the "K" award. *For effort not directly committed to the "K" award*, "K" award recipients may devote effort, with compensation, on Federal or non-Federal sources as the Program Director/Principal Investigator (PD/PI) or in another role (e.g., co-Investigator), as long the specific aims of the other supporting grant(s) differ from those of the "K" award.

### Inquiries

Please direct all inquiries to:

Division of Biomedical Research Workforce

Office of Extramural Programs

Office of Extramural Research

Website: <https://researchtraining.nih.gov>

Email: [NIHTrain@mail.nih.gov](mailto:NIHTrain@mail.nih.gov)

Please direct all AHRQ inquiries to:

Division of Research Education

Office of Extramural Research, Education, and Priority Populations

Agency for Healthcare Research and Quality

Website: <http://www.ahrq.gov/training>

Email: [TrainingTA@ahrq.hhs.gov](mailto:TrainingTA@ahrq.hhs.gov)

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## Additional Guidance on 'Full-Time Training' for Ruth L. Kirschstein National Research Service Awards

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Notice Number: NOT-OD-17-095

### Key Dates

**Release Date:** July 24, 2017

### Related Announcements

None

### Issued by

National Institutes of Health ([NIH](#))

Agency for Health Care Research and Quality ([AHRQ](#))

### Purpose

The purpose of this notice is to clarify and update the guidance on full-time training for [Ruth L. Kirschstein National Research Service Awards](#).

### Full-Time Training

All Kirschstein-NRSA fellows (individual fellowships), and trainees (institutional training grants) are required to pursue their research training full time. Full-time is generally defined as devoting at least 40 hours per week to research training activities, or as specified by the awardee institution in accordance with its own policies.

Beyond the full-time training, NIH recognizes that Kirschstein-NRSA fellows and trainees may engage in part-time employment incidental to their training. Fellows and trainees may spend on average, an additional 25% of their time (e.g., 10 hours per week) in part time research, teaching, or clinical employment, so long as those activities do not interfere with, or lengthen, the duration their NRSA training. (See [NIH Grants Policy Statement](#), Section 11.2.10.2 and 11.3.10.2, for more details.)

### Inquiries

Please direct all inquiries to:

Division of Biomedical Research Workforce

Office of Extramural Programs

Office of Extramural Research

Email: [NIHTrain@mail.nih.gov](mailto:NIHTrain@mail.nih.gov)

Please direct all AHRQ inquiries to:

Division of Research Education

Office of Extramural Research, Education, and Priority Populations

Agency for Healthcare Research and Quality

Website: <http://www.ahrq.gov/training>

Email: [TrainingTA@ahrq.hhs.gov](mailto:TrainingTA@ahrq.hhs.gov)

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## Reminder: NIH Applications Must Be Complete and Compliant With NIH Policy and Application Instructions At Time Of Submission

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Notice Number: NOT-OD-17-105

### Key Dates

**Release Date:** September 12, 2017

### Related Announcements

[NOT-OD-11-080](#)

[NOT-OD-15-095](#)

### Issued by

National Institutes of Health ([NIH](#))

### Purpose

The purpose of this notice is to remind applicants, both sponsored programs officials as well as investigators, that to be fair to all concerned the NIH will consistently apply standards for application completeness and for compliance with all submission requirements and NIH policies. This longstanding NIH policy is outlined in NIH Grants Policy Statement [2.3.2, Eligibility](#) along with [2.4.4, Disposition of Applications](#). NIHs implementation of this requirement is based out of 45 CFR Part 75.203(c3) and (c5) and 45 CFR Part 75.204.

### Policy

NIH may withdraw any application identified during the receipt, referral, and review process that is incomplete or noncompliant with instructions in the [SF424 \(R&R\) Application Guide](#), the Funding Opportunity Announcement, and relevant NIH Guide Notices.

- NIH applications must be complete, and compliant with all submission requirements and NIH policies, at the time of submission.
- NIH strongly discourages the practice of using placeholder attachments for required elements in an application. While it may allow an application to successfully pass eRA system-enforced validations, applications that include such attachments are incomplete and will be withdrawn.
- Applicants are expected to examine their applications for problems, errors, omissions, and oversights and must make any necessary or desired changes **before** the application submission deadline.
  - The application submission deadline is 5 PM local (applicant organization) time on the application due date.
  - Applicants are encouraged to submit two or more days early to allow time for application viewing and corrections before the application submission deadline.
  - Corrective applications submitted after the application submission deadline are late and will overwrite any previous on-time submission for that application and permanently remove the on-time submission from consideration.
  - Applications submitted after the application submission deadline will be considered late, and only accepted under the limited circumstances described in the NIH/AHRQ/NIOSH Late Policy
- Post-submission materials to complete an application or to correct problems, errors, oversights, and omissions discovered after submission of the application will not be accepted per the [NIH/AHRQ/NIOSH Post-Submission Materials Policy](#)

When a recipient is in doubt about this longstanding grants policy, contact Office of Policy for Extramural Research Administration or the Division of Receipt and Referral as listed below.

If an application is withdrawn because it is incomplete or does not comply with the application preparation and submission instructions, a letter will be placed in the eRA Commons Status page for that application. The PD/PI

and the AOR from the applicant organization will be notified by eRA Commons via e-mail to access their account and view the explanatory letter.

## Inquiries

Please direct all inquiries to:

Office of Policy for Extramural Research Administration (OPERA)  
Office of Extramural Research (OER)  
Division of Grants Policy  
National Institutes of Health  
Telephone: 301-435-0949  
Email: [grantspolicy@od.nih.gov](mailto:grantspolicy@od.nih.gov)

Division of Receipt and Referral  
Center for Scientific Review (CSR)  
National Institutes of Health  
Telephone: 301-435-0715  
Email: [csrdr@mail.nih.gov](mailto:csrdr@mail.nih.gov)

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## The NIH Announces New Review Criteria for Research Project Applications Involving Clinical Trials

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Notice Number: NOT-OD-17-118

### Key Dates

**Release Date:** September 21, 2017

### Related Announcements

None

### Issued by

National Institutes of Health ([NIH](#))

### Purpose

This notice informs the community of *additional* review criteria that NIH will apply to clinical trial applications for research projects submitted to due dates on or after January 25, 2018.

### Background

NIH is utilizing a multi-faceted approach to strengthen policies across the life cycle of a clinical trial, from development of the funding opportunity announcement (FOA), to the information collected in a grant application or contract proposal, to peer review of the application/proposal, and through to monitoring of the award. These actions include the implementation of new and more rigorous review criteria for evaluating clinical trial applications. Addressing these challenges will ensure the highest likelihood of translating research results into knowledge that will improve human health.

### Implementation

The review questions below will be effective for all clinical trial applications for research project grants and cooperative agreements that are submitted for funding consideration for due dates on or after January 25, 2018. For the evaluation of those applications, the questions below will be added to the existing review questions (see: <https://grants.nih.gov/grants/peer/critiques/rpg.htm>), which will not change for research project applications that do not involve clinical trials. Some Program Announcements and Requests for Applications may include FOA-specific questions in addition to those below.

### Criteria

#### **In addition, for applications involving clinical trials:**

A proposed Clinical Trial application may include study design, methods, and intervention that are not by themselves innovative but address important questions or unmet needs. Additionally, the results of the clinical trial may indicate that further clinical development of the intervention is unwarranted or lead to new avenues of scientific investigation.

### *Scored Review Criteria*

The following questions are in addition to the existing research review questions:

***Significance***

Are the scientific rationale and need for a clinical trial to test the proposed hypothesis or intervention well supported by preliminary data, clinical and/or preclinical studies, or information in the literature or knowledge of biological mechanisms? For trials focusing on clinical or public health endpoints, is this clinical trial necessary for testing the safety, efficacy or effectiveness of an intervention that could lead to a change in clinical practice, community behaviors or health care policy? For trials focusing on mechanistic, behavioral, physiological, biochemical, or other biomedical endpoints, is this trial needed to advance scientific understanding?

***Investigator(s)***

With regard to the proposed leadership for the project, do the PD/PI(s) and key personnel have the expertise, experience, and ability to organize, manage and implement the proposed clinical trial and meet milestones and timelines? Do they have appropriate expertise in study coordination, data management and statistics? For a multicenter trial, is the organizational structure appropriate and does the application identify a core of potential center investigators and staffing for a coordinating center?

***Innovation***

Does the design/research plan include innovative elements, as appropriate, that enhance its sensitivity, potential for information or potential to advance scientific knowledge or clinical practice?

***Approach***

Does the application adequately address the following, if applicable?

***Study Design***

Is the study design justified and appropriate to address primary and secondary outcome variable(s)/endpoints that will be clear, informative and relevant to the hypothesis being tested? Is the scientific rationale/premise of the study based on previously well-designed preclinical and/or clinical research? Given the methods used to assign participants and deliver interventions, is the study design adequately powered to answer the research question(s), test the proposed hypothesis/hypotheses, and provide interpretable results? Is the trial appropriately designed to conduct the research efficiently? Are the study populations (size, gender, age, demographic group), proposed intervention arms/dose, and duration of the trial, appropriate and well justified?

Are potential ethical issues adequately addressed? Is the process for obtaining informed consent or assent appropriate? Is the eligible population available? Are the plans for recruitment outreach, enrollment, retention, handling dropouts, missed visits, and losses to follow-up appropriate to ensure robust data collection? Are the planned recruitment timelines feasible and is the plan to monitor accrual adequate? Has the need for randomization (or not), masking (if appropriate), controls, and inclusion/exclusion criteria been addressed? Are differences addressed, if applicable, in the intervention effect due to sex/gender and race/ethnicity?

Are the plans to standardize, assure quality of, and monitor adherence to, the trial protocol and data collection or distribution guidelines appropriate? Is there a plan to obtain required study agent(s)? Does the application propose to use existing available resources, as applicable?

***Data Management and Statistical Analysis***

Are planned analyses and statistical approach appropriate for the proposed study design and methods used to assign participants and deliver interventions? Are the procedures for data management and quality control of data adequate at clinical site(s) or at center laboratories, as applicable? Have the methods for standardization of procedures for data management to assess the effect of the intervention

and quality control been addressed? Is there a plan to complete data analysis within the proposed period of the award?

### ***Environment***

If proposed, are the administrative, data coordinating, enrollment and laboratory/testing centers, appropriate for the trial proposed?

Does the application adequately address the capability and ability to conduct the trial at the proposed site(s) or centers? Are the plans to add or drop enrollment centers, as needed, appropriate?

If international site(s) is/are proposed, does the application adequately address the complexity of executing the clinical trial?

If multi-sites/centers, is there evidence of the ability of the individual site or center to: (1) enroll the proposed numbers; (2) adhere to the protocol; (3) collect and transmit data in an accurate and timely fashion; and, (4) operate within the proposed organizational structure?

### ***Additional Review Criteria***

#### ***Study Timeline***

Is the study timeline described in detail, taking into account start-up activities, the anticipated rate of enrollment, and planned follow-up assessment? Is the projected timeline feasible and well justified? Does the project incorporate efficiencies and utilize existing resources (e.g., CTSAs, practice-based research networks, electronic medical records, administrative database, or patient registries) to increase the efficiency of participant enrollment and data collection, as appropriate? Are potential challenges and corresponding solutions discussed (e.g., strategies that can be implemented in the event of enrollment shortfalls)?

Inquiries

Please direct all inquiries to:

Sally Amero, Ph.D.  
Review Policy Officer  
[ameros@od.nih.gov](mailto:ameros@od.nih.gov)

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[NIH Funding Opportunities and Notices](#)

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## Review the Accuracy of Grants Information for Fiscal Year 2017

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Notice Number: NOT-OD-17-115

### Key Dates

**Release Date:** September 20, 2017

### Related Announcements

None

### Issued by

National Institutes of Health ([NIH](#))

### Purpose

As the fiscal year comes to an end on September 30, 2017, NIH encourages Grantee Institutions to verify the accuracy of their grant assignments to Departments or Components within Institutions of Higher Education in eRA Commons through the Grant Re-assign function. Any corrections to the data must be made by 8:00 PM EDT on Monday, October 9, 2017 to be reflected in NIH annual reports.

### Background

NIH develops reporting files used to produce data found on the [RePORT](#) website, to increase transparency about funded grants, address inquiries from the Department of Health and Human Services, Congress, and the research community, and to fulfill annual reporting requirements on NIH's expenditures. The data in these files are "frozen" annually to ensure the reporting files produce consistent and meaningful results. It is imperative that corrections to Departments or Components within Institutions of Higher Education occur through the Grant Re-assign function in eRA Commons before these files are frozen to ensure the veracity of NIH's FY2017 reports.

### Authorized Organization Representative or Signing Official

Only the Authorized Organization Representative (AOR) or Signing Official (SO) has the authority to submit corrections for a grantee organization or investigator. The AOR is the designated representative of the grantee organization in matters related to the award and administration of its NIH grants, including those that require NIH approval. The AOR role is documented as part of the electronic submission process and is authenticated through the Grants.gov registration process. In the eRA Commons, this individual holds the "SO" role. Although NIH requires that the grantee organization designate such an official, NIH does not specify the organizational location or full set of responsibilities for this official.

### Verifying Your Information

Verify the accuracy of the grant award information for your organization by going to the NIH RePORT Awards by Location and Organization site at <https://report.nih.gov/award/index.cfm>, selecting FY2017, location and organization. Once the search results return, click on the Excel Export icon (green) located in the right-hand corner. Note: Only awards that have passed their budget start date at the time of the data load will appear. This most often affects fellowships that have not been activated, but can also affect a small number of awards that have delayed budget start dates.



## Making Corrections

There is an option on the Commons Status page for Signing Officials that allows for grants assigned to the current fiscal year to be re-assigned within the institution. The search page for the grants allows a search by NIH grant number, Contact Principal Investigator name, or for grants currently assigned to a School or School/Department combination. One or more grants may be selected from the hit list for reassignment, and the destination School/Department can be selected from the current institution hierarchy as mapped in the eRA database. Requests for changes of department names or creation of new schools or departments should be submitted to the eRA Commons Help Desk as is currently the practice. Changes made in the Commons will be visible in the Commons immediately. During the current fiscal year, changes that occur before each Friday evening will appear on RePORTER on the following Monday and on the Awards by Location and Organization website on the following Wednesday if the awards have passed their budget start date as noted in the section above. In all cases, the listings in Commons should be considered official for FY2017 until the deadline for correction. The official frozen awards data are expected to be released through the Awards by Location and Organization page in December.

For more information, please see Section 12.4 Steps for SO to Re-assign a Grant, in the latest version of the Commons User Guide at [https://era.nih.gov/docs/Commons\\_UserGuide.pdf](https://era.nih.gov/docs/Commons_UserGuide.pdf).

### Inquiries

Please direct all inquiries to eRA Commons [Commons@od.nih.gov](mailto:Commons@od.nih.gov).

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[Weekly TOC for this Announcement](#)  
[NIH Funding Opportunities and Notices](#)

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REPLY TO  
ATTENTION OF

**DEPARTMENT OF THE ARMY**  
**US ARMY MEDICAL RESEARCH ACQUISITION ACTIVITY**  
**820 CHANDLER STREET**  
**FORT DETRICK MD 21702-5014**

Date: Aug 22, 2017

MCMR-AAA-A Customer Service Group - Assistance

[REDACTED]  
[REDACTED]  
[REDACTED]research.funding@umassmed.edu  
Subject: CDMRP eBRAP: Application [REDACTED] Deemed Non-Compliant

[REDACTED]  
University of Massachusetts Medical School  
[REDACTED]  
[REDACTED]  
[REDACTED]  
Worcester, Massachusetts 01605-0002  
[REDACTED]

RE: [REDACTED]

STATUS: Non-Compliant

Dear [REDACTED]

I regret to inform you that the Discovery Award Full Application you submitted to the Fiscal Year 2017 Department of Defense Peer Reviewed Medical Research Program (PRMRP) did not comply with the requirements specified in the PRMRP Discovery Award Program Announcement issued by the U.S. Army Medical Research and Materiel Command's Office of the Congressionally Directed Medical Research Programs (CDMRP).

Administrative screening identified the following reason(s) your application was non-compliant:

PI is identified through a reference made to their published work in the Project Narrative, "We have also previously performed [REDACTED] [REDACTED]" (7, 8).

As stated in the Administrative Actions in the FY17 Discovery Award program announcement "Use of I, we, our, this organization, or similar phrases that refer to the PI(s), collaborator(s), or their organization(s) through the references listed,..." will result in administrative rejection of the application.

Your interest in the PRMRP is appreciated. I hope that you will participate in the future. Please direct your question to the CDMRP at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507. A copy of this letter is being sent to the Grants and Contracts Office at your institution.

Sincerely,  
[REDACTED]  
Grants Officer

**ACRONYMS AND TERMS USED TODAY**  
**OSP RA Update - 9/27/2017**

| ACRONYM/TERM             | DESCRIPTION                                                                                                                                                                                                                                                                                |
|--------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Cayuse 424               | Cayuse is a web-based system for submission of applications via <a href="http://grants.gov">grants.gov</a> .                                                                                                                                                                               |
| CDMRP                    | Congressionally Directed Medical Research Programs                                                                                                                                                                                                                                         |
| ClinicalTrials.gov       | ClinicalTrials.gov is a Web-based resource that provides patients, their family members, health care professionals, researchers, and the public with easy access to information on publicly and privately supported clinical studies on a wide range of diseases and conditions.           |
| 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.                          |
| FOA                      | Funding Opportunity Announcement (NIH)                                                                                                                                                                                                                                                     |
| FPR                      | Foreign Project Registration form                                                                                                                                                                                                                                                          |
| GCP                      | Good Clinical Practices                                                                                                                                                                                                                                                                    |
| K Awards                 | Career Development (K) Awards. K awards provide support for senior postdoctoral fellows or faculty-level candidates. K awards are designed to promote the career development of specific groups of individuals based on their past training and career stage.                              |
| NIH                      | National Institutes of Health                                                                                                                                                                                                                                                              |
| NOT                      | A Notice (Guide Notice) is an official NIH announcement relating to a change in policy, procedure, form, or system. Notices are posted on the NIH website and users can be notified via a variety of NIH listservs. You can search for notices and funding opportunities at the NIH Guide. |
| NRSA                     | National Research Service Awards                                                                                                                                                                                                                                                           |
| NRSA                     | National Research Service Awards                                                                                                                                                                                                                                                           |
| OGH                      | Office of Global Health                                                                                                                                                                                                                                                                    |
| OSP                      | Office of Sponsored Programs                                                                                                                                                                                                                                                               |
| OSP                      | Office of Sponsored Programs                                                                                                                                                                                                                                                               |
| PHS                      | Public Health Service                                                                                                                                                                                                                                                                      |
| PI                       | Principal Investigator                                                                                                                                                                                                                                                                     |
| R01                      | Activity Code for NIH Research Projects - Research Project                                                                                                                                                                                                                                 |
| RAU                      | Research Administration Update                                                                                                                                                                                                                                                             |
| sIRB                     | Single Institutional Review Board                                                                                                                                                                                                                                                          |
| Type 1 (NIH Application) | New/Initial request for support of a project that has not yet been funded.                                                                                                                                                                                                                 |
| UMMS                     | University of Massachusetts Medical School                                                                                                                                                                                                                                                 |