Research Administration Update

Wednesday, November 29, 2017

Lazare Auditorium (S1-607)
1:00 – 3:00 pm

Agenda

University of Massachusetts Medical School
UMASS

- Data Security Issues in Sponsored Research, Brian Coleman, Emily Martins
- Effort Process & Space Overviews, Amy Miarecki
- Office of Research Update
  - Reporting lines
- UMMS PI Eligibility Policy
- NIH Updates
  - NOT-OD-17-121: New Review Criteria for Career Development Award Applications Involving Clinical Trials
  - NOT-OD-17-122: New Review Criteria for Ruth L. Kirschstein National Research Service Award (NRSA) Individual Fellowship Applications Involving Research Experiences in Clinical Trials
  - NOT-OD-17-123: New Review Criteria for Ruth L. Kirschstein National Research Service Award (NRSA) Institutional Research Training Grants Involving Research Experiences in Clinical Trials
  - NOT-OD-17-124: NIH Operates Under a Continuing Resolution Through December 8, 2017
  - NOT-OD-18-003: Guidance on Exceptions to the NIH Single IRB Policy
  - NOT-OD-18-004: Guidance on Implementation of the NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research
  - NOT-OD-18-005: Publication of the Revised NIH Grants Policy Statement (Rev. October 2017) for FY 2018
  - NOT-OD-18-009: FORMS-E Grant Application Forms & Instructions Must be Used for Due Dates On or After January 25, 2018
  - NOT-OD-18-010: NIH Plans for Clinical Trial Specific Parent R01 and Parent R21 Funding Opportunity Announcements
  - NOT-OD-18-103: NIH will Make the Project Outcomes Section of all Interim and Final RPPRs Submitted on or After October 1, 2017 Available via the NIH RePORTER
- Proposal & Progress Report Statistics

SPONSORED RESEARCH GRANT AND CONTRACT REVIEW

COMPLIANCE STANDARDS AND GOVERNING BODIES

WHAT AM I AGREEING TO WHEN SIGNING A GRANT OR CONTRACT?

- Be mindful of what you are agreeing to.
- Security and privacy language within grants and contracts.
- Interpretation of a standards' applicability.
- Privacy Officer's role.

CONTRACT CONSIDERATIONS

- Right to audit clauses
- Data ownership
- Encryption requirements (in transit and at rest)
- State law governing the contract (as a state entity, we can only agree to abide by MA law)
- Indemnification clauses
- Access to UMMS Information or Access to UMMS network

COMPLIANCE STANDARDS AND GOVERNING BODIES – FEDERAL

- FISMA - The Federal Information Security Management Act (**FISMA**) is United States legislation that defines a framework to protect government information, operations and assets against natural or man-made threats.
- FIPS - Federal Information Processing Standard (FIPS) - set of standards that describe document processing, encryption algorithms and other information technology standards for use within non-military government agencies and by government contractors and vendors who work with the agencies.
- NIST - National Institute of Standards and Technology (NIST) promotes and maintains measurement standards. It also has active programs for encouraging and assisting industry and science to develop and use these standards.
- HIPAA - United States legislation that provides data privacy and security provisions for safeguarding medical information.
- FEDRAMP - The Federal Risk and Authorization Management Program (FedRAMP) is a government-wide program that provides a standardized approach to security assessment, authorization, and continuous monitoring for cloud products and services.
- CFR 45 PART 164 (Security and Privacy) - one of fifty titles comprising the United States Code of Federal Regulations (CFR). Title 45 Part 164 is the principle set of rules and regulations issued by federal agencies of the US regarding security and privacy.

COMPLIANCE STANDARDS AND GOVERNING BODIES – MASSACHUSETTS AND INTERNATIONAL

- Massachusetts:
  - MGL 93 (sections H & I) – Security Breaches; Dispositions and Destruction of Records
  - Mass 201 CMR 17 - This regulation establishes minimum standards to be met in connection with the safeguarding of personal information contained in both paper and electronic records.
  - Executive Order 504 - This order recognizes the importance of protecting personal information and specifically outlines how all state agencies in the Executive Branch must address the security and confidentiality of personal information.
- International:
  - GDPR Executive Directive - General Data Protection Regulation (GDPR) effective May 2018. It applies to all organizations that offer goods or services to, or monitor the behavior of, EU data subjects.

Effort Certification Overview

Effort Overview

Effort

- Proportion of time spent on any activity, expressed as a percentage of Total University Effort

Total University Effort

- All professional activity for which an individual is compensated by the University including teaching, research, service.

Effort Reporting

- Verifies that salary charged to sponsored projects is certified as reasonable in relation to the effort expended
- Verifies that commitments and cost sharing requirements are met

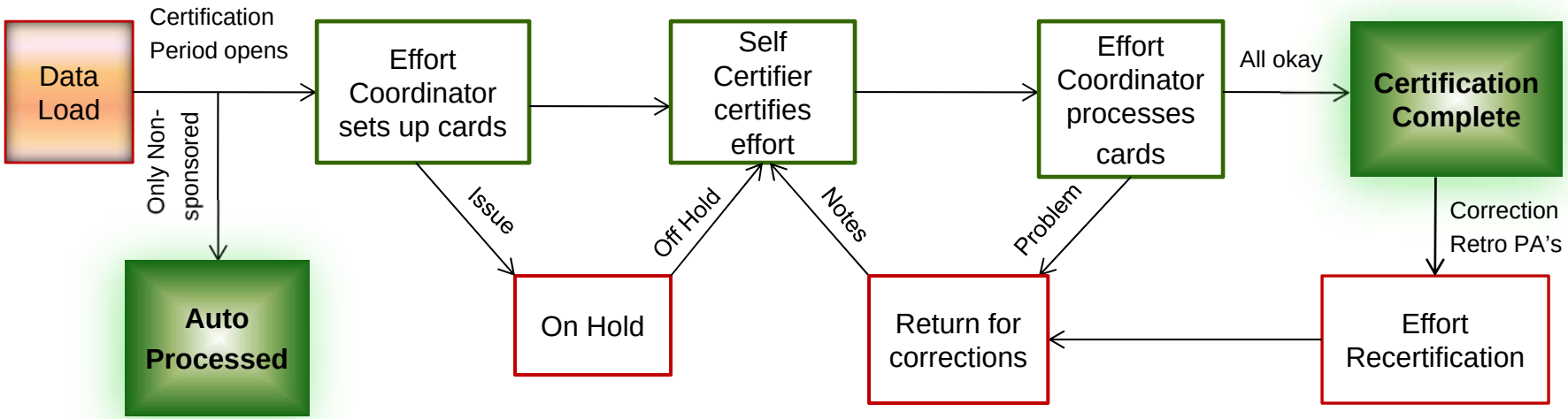
Effort Coordinator Responsibilities

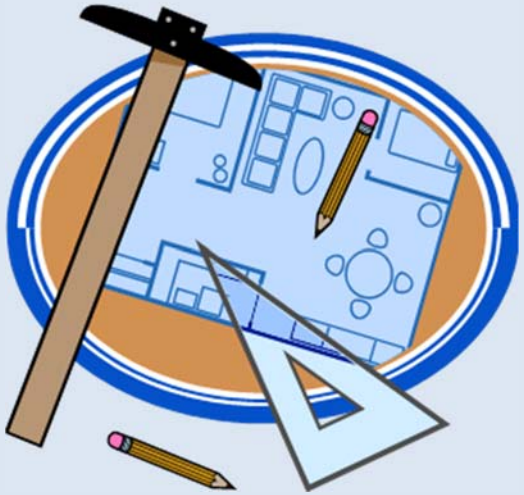
- Support faculty in ongoing monitoring and annually certifying effort
- Determine who needs to certify or be certified and that there are no missing effort cards
- Process salary allocations and cost transfers as applicable using the PA form
- Ensure that any commitment or salary cap cost sharing requirements are met
- Review PI’s over 95% committed or over 95% paid on sponsored projects
- Do manual certification for terminated PI’s before they leave
- Certify the non-sponsored effort for employees who are not Self Certifiers.

Principal Investigator Responsibilities

- Principal Investigators certify themselves entirely.
- Principal investigators are also required to certify the sponsored effort for all personnel on his or her research projects (i.e. graduate students, lab technicians, postdoctoral researchers, and classified staff)

Certification Workflow



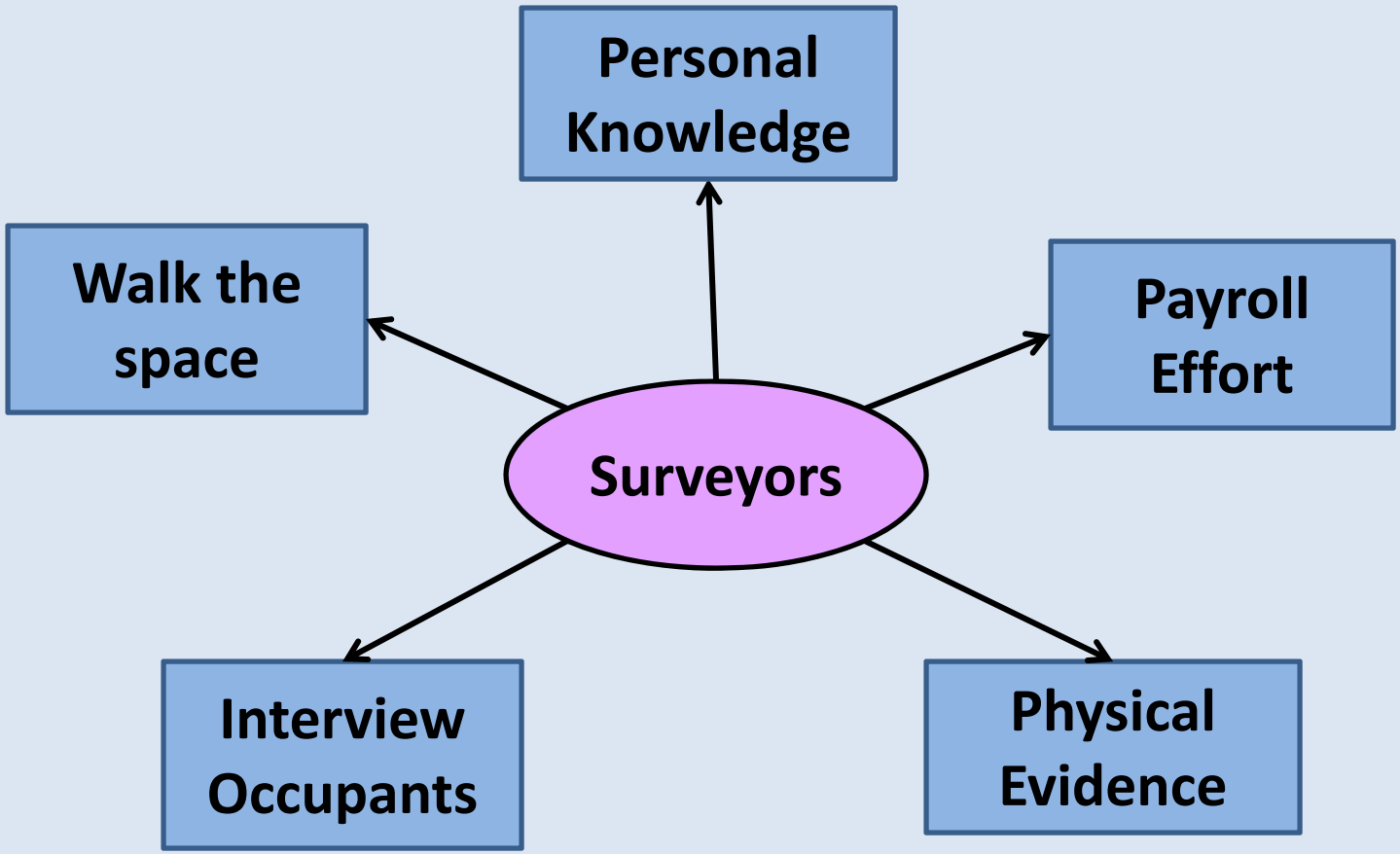


Space Survey Overview

Why a Space Survey

- F&A rate proposal requirement – *critical for FY18*
- Research Space Productivity Report
- Allocation of school space resources
- Various reporting purposes
- Users of the data include Asset Management, Facilities, Financial Services, Dean's Office

Who and How


Personal Knowledge
Walk the space
Payroll Effort
Surveyors
Interview Occupants
Physical Evidence

Tools For Space Survey

Financial Services Home
Forms and Policies
Contact Us
JobAids
Effort Reporting
Online Space Survey
Systems Support
BuyWays Login
PeopleSoft Login
SUMMIT Login
Reporting
Training
University Internal Audit
WCCC

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National distinction in health sciences education, research and public service

Financial Services

Online Space Survey

For FY 2014, a few new enhancements have been added to the Archibus Space Survey:

1. On the Room Details page, there is a new editable field called "Research Core". Please enter only research core names in this field and leave blank if not applicable. This field is captured on the Rooms Survey Status Report and the Room Details Report.

2. There is a new function under Room Listings which is a "room highlight" function. Clicking on the small check box next to the room number will highlight the room in yellow after the user navigates away from the room. This allows the user to quickly identify or return to a room in question among a long list of rooms. Users can use this function at their own discretion, such as to indicate pending review or corrections, as long as the rooms have not been submitted or approved.

Links To The Survey and Training

Click here to access online Space Survey

Training Presentation

Training Calendar

Survey Information

Survey Period:

The FY2014 space survey will be open early July and end on September 19, 2014. Surveyors will be notified by email when the survey is open.

Survey Instructions:

Instructions for coding spaces and explanation of the different function codes can be found here:

Instructions for the Annual Space Survey

Important Considerations

- **Survey entire year** –
  - Take into consideration a person's length of occupancy & activity, e.g. lab tech vs student, terminated employee
- **100% Organized Research space:**
  - This is a red flag to the Feds
  - Should not use formulas either, such as 95:5
- **Space and Base**
  - Coding of space must be consistent with the base costs that support the activities.
- **ECRT Dept Payroll Report**
  - Useful reference
  - Shows funding sources and percentages.

FY17 % Research by Building

UNIVERSITY OF MASS. MEDICAL SCHOOL

JUNE 30, 2017

Percent by Building/Cost Group Report

Building	O&M	G_A	DA	SPA	SSA	LIBRARY	IDR	OR	OSA	OIA	Total ASF
001 - UMass. Medical School	10.82	5.16	6.65	0.38	2.65	9.47	27.08	18.32	3.25	15.51	419,633
010 - Lazare Research Bldg	4.09	0.24	1.93				14.72	66.86	0.13	12.02	226,896
013 - Amb. Care Center (ACC)	7.43		0.16	12.62			24.44	13.09	3.07	36.75	11,291
014 - Biotech I	10.03		5.44		0.26		27.22	25.34	15.85	15.85	9,080
015 - Biotech II	2.28		5.48				16.10	71.36	0.65	4.15	61,687
028 - Brudnick NRI	8.95		5.52		0.06		16.49	54.72	3.11	11.15	20,512
031 - 640 GW Highway	4.90		48.22				30.51	13.56	2.80		5,037
049 - Chang-WF	9.66	0.76	35.75		0.39		5.60	16.93	30.30	0.61	8,783
050 - Fuller-WF	1.93		1.45				4.16	29.69		62.78	4,763
052 - Hoagland-Pincus-WF	2.92		4.75				15.93	26.79	1.07	48.53	18,622
054 - Rose - Gordon-WF	20.46		2.42				25.58	18.55	0.35	32.64	9,244
103 - South Street 1	9.65	10.85	0.21	0.82			0.17	1.14	1.10	75.47	138,698
104 - South Street 2	16.21	35.59						0.11		48.09	80,756
108 - Albert Sherman Center	6.25	1.12	2.72		4.31		27.26	43.81	0.17	14.36	283,057

Office of Research Oversight

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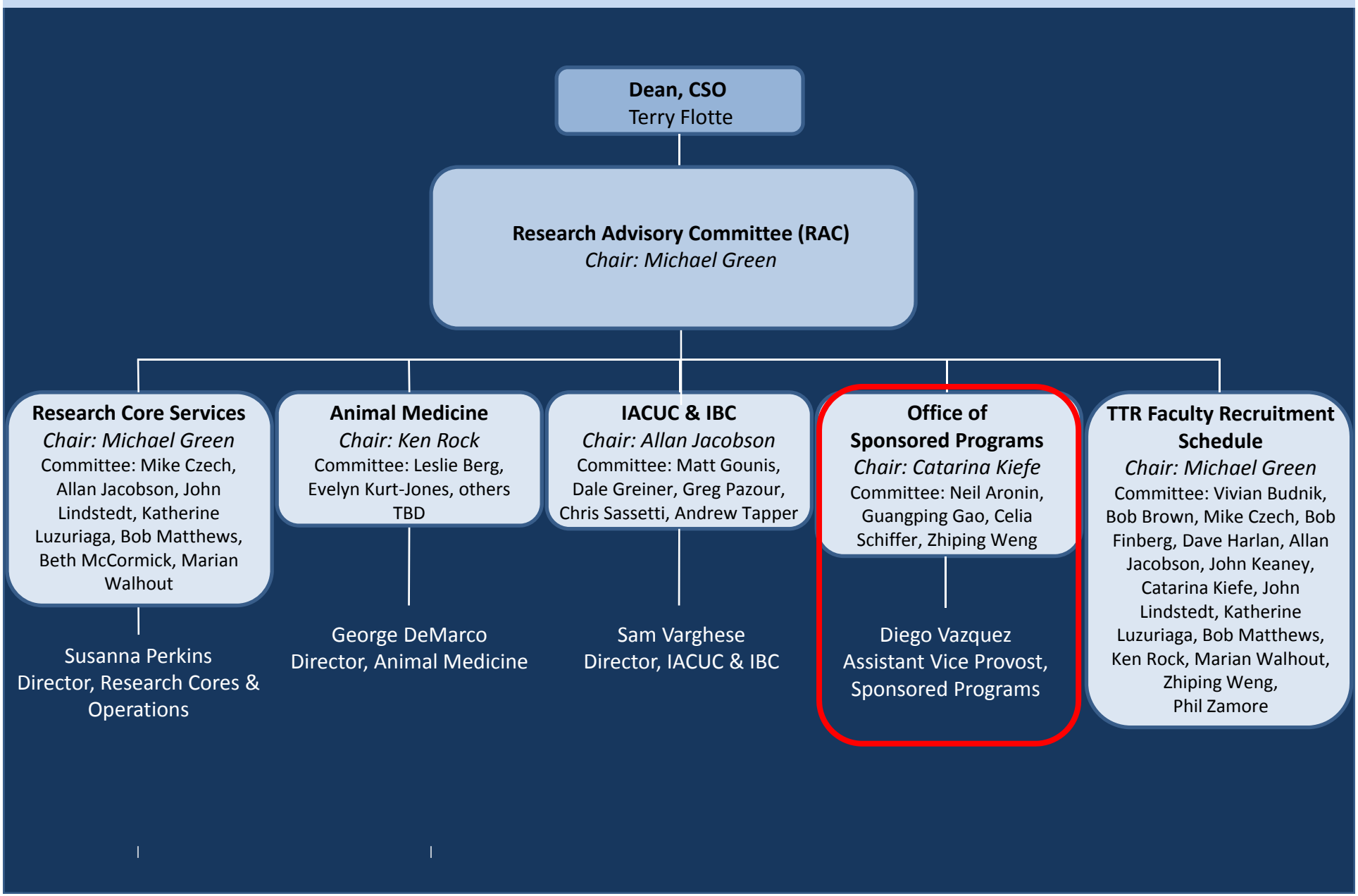

UMMS PI Eligibility Policy

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- Effective September 2017
  - Establishes criteria permitting individuals to fulfill the role of principal investigator, program director or multiple principal investigator on a sponsored project; and to ensure that sponsored projects are conducted by those who have the requisite training, skill, commitment and resources as well as the appropriate relationship to UMMS.
  - The policy also articulates the period of time and privileges available to Principal Investigators when they leave the institution.
  - A copy of the full policy is included in the Appendix

NOT-OD-17-121: New Review Criteria for Career Development Award Applications Involving Clinical Trials

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- Additional review criteria applied to individual career development (K) award applications submitted on or after January 25, 2018.
- Review criteria will differ for individual mentored and independent K award applications, and for K award applications where the PD/PI will lead an independent clinical trial compared with individual K award applications where the PD/PI will undertake clinical trials research experience under the guidance of the mentor or co-mentor. These additional questions will not be used for the evaluation of institutional K12 or KL2 applications.
- Review criteria questions will be effective for the evaluation of individual career development award (K) applications that involve independent clinical trials led by the PD/PI of the K award application or K award applications where the PD/PI will undertake clinical trials research experience under the guidance of the mentor or co-mentor. The questions below will be added to the existing review questions
- For applications involving clinical trials:
- The reviewers will consider that the clinical trial may include study design, methods, and intervention that are not by themselves innovative, but address important questions or unmet needs. Reviewers should also consider the scope of the clinical trial relative to the available resources, including the possibility that research support provided through K awards may be sufficient to support only small feasibility studies.
- Please refer to the full notice in the appendix for treatment on Scored Review Criteria and Additional Review Criteria.

NOT-OD-17-122: New Review Criteria for NRSA Individual Fellowship Applications Involving Research Experiences in Clinical Trials

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- Additional review criteria applied to NRSA Individual Fellowships if the applicant fellow is proposing to gain research experience in an ongoing clinical trial led by a sponsor or co-sponsor, submitted to due dates on or after January 25, 2018.
- The review criteria questions below will be effective for the evaluation of NRSA Individual Fellowship applications when the applicant fellow is proposing to gain research experience in an ongoing clinical trial led by a sponsor or co-sponsor. The questions below will be added to the existing review questions which will not change for projects that do not involve clinical trials. Some PAs and RFAs may include additional, FOA-specific questions.
- In addition, for applications involving clinical trials:
  - Reviewers will consider the nature of the research experience proposed by the applicant fellow and the scope of proposal relative to the available resources, including the sponsor's and/or co-sponsor's research support.
- The following are in addition to the standard individual fellowship review questions:
- Sponsors, Collaborators, and Consultants
  - If the applicant is proposing to gain experience in a clinical trial as part of his or her research training, is there evidence of the appropriate expertise, experience, resources, and ability on the part of the sponsor(s) to guide the applicant during the clinical trial research experience?
- Research Training Plan
  - If proposed, will the clinical trial experience contribute to the proposed project and/or the applicant’s research training?

NOT-OD-17-123: New Review Criteria for Ruth L. Kirschstein National Research Service Award (NRSA) Institutional Research Training Grants Involving Research Experiences in Clinical Trials

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- This notice informs the community of additional review criteria that NIH will apply to Ruth L. Kirschstein NRSA Institutional Research Training Grants if one or more appointed trainees will propose to gain research experience in an ongoing clinical trial led by a mentor or co-mentor, submitted to due dates on or after January 25, 2018.
- The review criteria questions below will be effective for the evaluation of Kirschstein-NRSA Institutional applications when the program proposes to offer appointed trainees the opportunity to obtain clinical trial research experience in an ongoing clinical trial led by a mentor or co-mentor. The questions below will be added to the existing review questions, which will not change for projects that do not involve clinical trials. Some PAs and RFAs Applications may include additional, FOA-specific questions.
- In addition, for applications involving clinical trials:
- Reviewers will consider the nature of the research experience proposed by the trainee(s) and the scope of proposal relative to the available resources, including the mentor's and/or co-mentor's research support.
- The following questions are in addition to the standard training review questions:
- Preceptors/Mentors
  - If the program will support clinical trial research experience for the Trainees, do the mentor(s) who will supervise the Trainee(s) have the expertise, experience, resources and ability to provide appropriate guidance and help the Trainee(s) to meet the timelines?

NOT-OD-17-124: NIH Operates Under a Continuing Resolution Through December 8, 2017

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- The Department of Health and Human Services, including NIH, operates under the "Continuing Appropriations Act, 2018 and Supplemental Appropriations for Disaster Relief Requirements Act, 2017," (Public Law 115-56) signed by President Trump on September 8, 2017. This Act (CR) continues government operations through December 8, 2017 at 99.3209 percent of the FY 2017 enacted level.
- Continuing fiscal policies and consistent with NIH practices during the CRs of FY 2006 – 2017, the NIH will issue non-competing research grant awards at a level below that indicated on the most recent Notice of Award (generally up to 90% of the previously committed level).
- Upward adjustments to awarded levels will be considered after FY 2018 appropriations are enacted, but NIH expects institutions to monitor their expenditures carefully during this period.
- All legislative mandates that were in effect in FY 2017 remain in effect under this CR, as well as the salary limitation set at Executive Level II of the Federal Pay Scale).

NOT-OD-18-003: Guidance on Exceptions to the NIH Single IRB Policy

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- This Notice provides additional guidance regarding requests for an exception to the NIH Policy on the Use of a Single Institutional Review Board (sIRB) for Multi-Site Research.
- The sIRB policy applies to domestic sites of NIH-funded multi-site studies where each site will conduct the same protocol involving non-exempt human subjects research.
- The policy does not apply to:
  - Foreign sites; or
  - Career development (K), institutional training (T), or fellowship awards (F).
- Exceptions to the policy will be made where the proposed sIRB would be prohibited by a federal, state, or tribal law, regulation or policy (policy-based exceptions). Policy-based exceptions are automatically granted when identified in the sIRB plan.
- The NIH sIRB policy allows the consideration of requests for other exceptions not based on a legal, regulatory, or policy requirement, if there is a compelling justification for the exception. These other exceptions must be reviewed and approved by NIH.
- Please see full Notice in Appendix for more information on exception requests.

NOT-OD-18-004: Guidance on Implementation of the NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research SLIDE 1/2

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- The goal of the sIRB policy is to reduce the burden of the IRB review process for multi-site research conducting the same protocol, allowing research to proceed effectively and expeditiously without compromising the protections of human subjects.
- The sIRB policy applies to domestic sites of multi-site studies where each site will conduct the same protocol involving non-exempt human subjects research funded wholly or in part by NIH, including grants, cooperative agreements, and Research and Development (R&D) contracts. The policy does not apply to:
  - Foreign sites; or
  - Career development (K), institutional training (T), and fellowship awards (F).
- The policy allows for exceptions in the following instances:
  - Sites for which federal, state, or tribal laws, regulations or policies require local IRB review.
  - Other exceptions to allow for local IRB review may be considered by NIH based on compelling justification. These other exceptions must be reviewed and approved by NIH.
- For grant applications, the sIRB policy will apply to all competing grant applications for due dates on or after January 25, 2018; and for R&D contracts, the policy will apply to all solicitations issued on or after January 25, 2018.

NOT-OD-18-004: Guidance on Implementation of the NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research SLIDE 2/2

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- Single IRB Review Options for Meeting the Policy:
  - Any IRB serving as the sIRB of record for NIH funded research must be registered with the HHS Office for Human Research Protections (OHRP) and must have membership to adequately review the proposed study.
- The following are examples of types of IRBs that could be used:
  - An institutional IRB that is associated with either the awardee or a participating site;
  - An independent, commercial or unaffiliated IRB; or
  - A central IRB organized to review the proposed study.
- When possible, the sIRB should be identified by the applicant in the sIRB plan attachment within the application/proposal. Note that the FOA or RFP may include specific requirements for IRB review, such as the intent to set up a central IRB for specific projects. The applicant is expected to follow the instructions in the specific FOA or RFP.
- Evaluation of sIRB Information
  - The adequacy of the sIRB plan will not factor into the review score or overall rating of the Protection of Human Subjects section, unless the FOA/RFP has specific requirements for the sIRB and associated review criteria. For grant applications, a note may be included in the Summary Statement if the sIRB plan appears to be missing or is incomplete, and this will need to be addressed before an award can be made. For contracts, the RFP will include requirements about what must be provided to NIH regarding the sIRB prior to the time of award and beyond.

NOT-OD-18-005: Publication of the Revised NIH Grants Policy Statement (Rev. October 2017) for FY 2018

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- This revision is applicable to all NIH grants and cooperative agreements with budget periods beginning on or after October 1, 2017. This revision supersedes, in its entirety, the NIHGPS (November 2016) as a standard term and condition of award. Previous versions of the NIHGPS remain applicable as a standard term and condition for all NIH grants and cooperative agreements with budget periods that began prior to October 1, 2017.
- The NIHGPS provides both up-to-date policy guidance that serves as NIH standard terms and conditions of awards for grants and cooperative agreements, and extensive guidance to those who are interested in pursuing NIH grants.
- While this revision does not introduce any new material for the first time, it incorporates new and modified requirements, clarifies certain policies, and implements changes in statutes, regulations, and policies that have been implemented through appropriate legal and/or policy processes since the previous version of the NIHGPS dated November 2016. The document is available in the following electronic formats: HTML and PDF at http://grants.nih.gov/grants/policy/nihgps/index.htm
- NIH will continue to publish interim grants policy changes through the issuance of NIH Guide Notices. Each change will be described, including its applicability and effective date; and the necessary language to implement it as a term or condition of award provided.
- A document is available that summarizes the significant changes that are implemented with the October 2017 NIHGPS: http://grants.nih.gov/grants/policy/nihgps/Significant_Changes_NIHGPS_Oct2017.pdf.

NOT-OD-18-009: FORMS-E Grant Application Forms & Instructions Must be Used for Due Dates On or After 1/25/18

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- This notice reminds the biomedical and health services research communities that applicants must use FORMS-E application packages for due dates on or after 1/25/18 and must use FORMS-D application packages for due dates on or before 1/24/18.
- Applicants are encouraged to submit early to allow time to work through any unforeseen issues.
- FORMS-E application packages are currently being posted to active Funding Opportunity Announcements (FOAs) with due dates on or after 1/25/18. We expect to complete this process by 1/25/17.
- FORMS-E application packages will not be added to Parent announcements since they will be reissued for due dates on or after 1/25/18.
- FORMS-E application packages will not be added to FOAs that will be reissued to allow clinical trials for due dates on or after 1/25/18.
- For a transition period, both FORMS-D and FORMS-E application packages and instructions will be active. Applicants must choose the appropriate application package and associated instructions for their due date when presented with both FORMS-D and FORMS-E application packages on the same FOA.
- Applications submitted using the incorrect application package for their due date may be withdrawn and removed from funding consideration.

NOT-OD-18-010: NIH Plans for Clinical Trial Specific Parent R01 and Parent R21 FOAS SLIDE 1/2

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- NIH published Research Project Grant (Parent R01 Clinical Trial Required) and NIH Exploratory/Developmental Research Grant Program (Parent R21 Clinical Trial Required) FOAs in November 2017 to be used for applications targeting due dates on or after 1/25/18. Some NIH Institutes and Centers will join these parent FOAs and others will jointly or alone publish IC-specific Clinical Trial FOAs using the same definition of trials but will also include additional IC requirements.
- Unless otherwise noted, these Parent Clinical Trial Required FOAs will accept trials of safety and efficacy, as well as mechanistic and other types of trials. Some ICs will accept only mechanistic trials to these Parent Clinical Trial FOAs.
- NIH defines a clinical trial 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.”

NOT-OD-18-010: NIH Plans for Clinical Trial Specific Parent R01 and Parent R21 FOAs SLIDE 2/2

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- NIH not only supports trials of safety and efficacy, it also supports mechanistic exploratory studies that meet the definition of a clinical trial and are designed to explore or understand a biological or behavioral process, the pathophysiology of a disease, or the mechanism of action of an intervention. These studies may focus on basic and/or translational discovery research in healthy human subjects and in human subjects who are affected by the pathophysiology of diseases and disorders.
- By addressing basic questions and concepts in biology, behavior, and pathophysiology, these studies may provide insight into understanding human diseases and disorders along with potential treatments or preventive strategies. NIH also supports biomarker studies that meet the definition of a clinical trial and that may provide information about physiological function, target engagement of novel therapeutics, and/or the impact of therapeutics on treatment response.
- NIH thus supports studies that meet the definition of clinical trials but do not seek to establish safety, clinical efficacy, effectiveness, clinical management, and/or implementation of preventive, therapeutic, and services interventions.
- Examples of mechanistic clinical trials include but are not limited to:
  - Studies that use a manipulation (physiological or behavioral) to answer basic science questions about normal functions.
  - Studies that use an experimental manipulation in order to understand normal functioning or the pathophysiology of a disease or disorder, but do not aim to demonstrate clinical improvement.
  - Studies that involve the prospective use of efficacious interventions where the intent is to obtain and analyze biospecimens to identify genetic risk associations, novel biomarkers, examine the disease process, or characterize mechanisms of therapeutic response.
  - Studies in which an intervention with demonstrated efficacy for a population is being studied to understand mechanisms of response, non-response, or risk of adverse effects of the efficacious intervention.

NOT-OD-18-103: NIH will Make the Project Outcomes Section of all Interim and Final RPPRs Submitted on or After October 1, 2017 Available via the NIH RePORTER

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- NIH intends to publish the Project Outcomes Section of all Final and Interim Research Performance Progress Reports (RPPRs) submitted on or after October 1, 2017 and make them available to the general public via the NIH RePORTER.
- NIH implemented the annual RPPR in 2012, based on a policy memorandum from OMB & OSTP to the heads of executive departments and agencies. The uniform RPPR replaced previous interim performance reporting formats used by NIH and other agencies.
- With NIH's implementation of the Final and Interim RPPR, recipients are required to adhere to the new requirement to report on Project outcomes. This section will be made publicly available via NIH RePORTER, allowing recipients to provide the general public with a concise summary of the cumulative outcomes or findings of the project at the end of each competitive segment.
- The NIH will only publish project outcomes that have been reviewed and approved by NIH staff to ensure the narrative is written for the general public in clear and comprehensible language, without including any proprietary, confidential information or trade secrets. If the description of the project outcomes are found to be unacceptable, recipients will be required upon NIH request to submit revised project outcomes statements using the Additional Material functionality in place for the Final and Interim RPPR.
- The Additional Material functionality for both the Final and Interim RPPR have been enhanced in order to capture revised project outcomes in a web form format that will support NIHs ability to make this information publically available. Please note that the web form data entry field pertains only to the entry of Project Outcomes text. Any other additional materials requested, if applicable, should be uploaded as a file attachment.

PROPOSAL SUBMISSIONS TO OSP

October 2016 – October 2017

University of Massachusetts Medical School
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	October 2016	November 2016	December 2016	January 2017	February 2017	March 2017	April 2017	May 2017	June 2017	July 2017	August 2017	September 2017	October 2017
Count	106	71	48	103	108	90	52	87	98	47	64	102	112
On Time	46%	35%	46%	53%	52%	55%	40%	46%	47%	57%	45%	52%	46%
Late	49%	62%	46%	41%	43%	44%	58%	54%	50%	34%	49%	45%	51%
After the fact	5%	3%	8%	5%	5%	1%	2%	0%	3%	9%	6%	3%	3%
Withdrawn	0%	0%	0%	1%	0%	0%	0%	0%	0%	0%	0%	0%	0%
Total	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
Expedited Request (3 days or less)	32%	35%	33%	22%	28%	33%	44%	28%	36%	21%	34%	27%	36%

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
October 2016 to October 2017 Comparison

University of Massachusetts Medical School
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PROPOSALS	2016	2017	Change
Count	106	112	+6
On Time	46%	46%	-
Late	49%	51%	+2
After the fact	5%	3%	-2
Withdrawn	0%	0%	-
Total	**100%**	**100%**	-
Expedited Request (3 days or less)	32%	36%	+4

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.
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PROGRESS REPORT SUBMISSIONS TO OSP
October 2016 – October 2017

University of Massachusetts Medical School
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	October 2016	November 2016	December 2016	January 2017	February 2017	March 2017	April 2017	May 2017	June 2017	July 2017	August 2017	September 2017	October 2017
Count	34	32	35	43	38	59	50	51	49	30	23	34	23
On Time	62%	59%	63%	68%	58%	54%	62%	59%	63%	37%	52%	47%	61%
Late	35%	38%	37%	30%	39%	42%	32%	35%	29%	50%	39%	29%	26%
After the fact	3%	3%	0%	2%	3%	4%	6%	6%	8%	13%	9%	24%	13%
Total	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
Expedited Request (3 days or less)	29%	19%	23%	21%	32%	25%	26%	22%	22%	40%	26%	24%	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.

SUBMISSIONS TO OSP
October 2016 to October 2017 Comparison

University of Massachusetts Medical School
UMASS

PROGRESS REPORTS	2016	2017	Change
Count	34	23	-9
On Time	62%	61%	-1
Late	35%	26%	-9
After the fact	3%	13%	+10
Withdrawn	0%	0%	-
Total	**100%**	**100%**	-
Expedited Request (3 days or less)	29%	9%	-20

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

Sponsored Research:
Grant and Contract Review

The following terms represent a list of compliance standards and governing bodies. This list is not all encompassing, but can be used as a reference to dictate when Information Security and the Privacy Office should be engaged.

FISMA - The Federal Information Security Management Act (FISMA) is United States legislation that defines a comprehensive framework to protect government information, operations and assets against natural or man-made threats. FISMA was signed into law part of the Electronic Government Act of 2002.

FIPS - Federal Information Processing Standard (FIPS) - set of standards that describe document processing, encryption algorithms and other information technology standards for use within non-military government agencies and by government contractors and vendors who work with the agencies.

NIST - National Institute of Standards and Technology, a unit of the U.S. Commerce Department. Formerly known as the National Bureau of Standards, NIST promotes and maintains measurement standards. It also has active programs for encouraging and assisting industry and science to develop and use these standards.

HIPAA - United States legislation that provides data privacy and security provisions for safeguarding medical information.

CFR 45 PART 164 – Security and Privacy is one of fifty titles comprising the United States Code of Federal Regulations (CFR). Title 45 Part 164 is the principle set of rules and regulations issued by federal agencies of the United States regarding security and privacy.

FedRAMP - The Federal Risk and Authorization Management Program is a government-wide program that provides a standardized approach to security assessment, authorization, and continuous monitoring for cloud products and services.

MGL 93: Part H - The Data Privacy Act; Part I – Dispositions and Destruction of Records

Mass 201 CMR 17 – Standards for the Protection of Personal information of residents of the Commonwealth. This requires companies to employ specific controls to protect the personal information of Massachusetts' residents.

Executive Order 504 - An Order that recognizes the importance of protecting personal information and specifically outlines how all state agencies in the Executive Branch must address the security and confidentiality of personal information.

GDPR Executive Directive – Data Privacy regulation (formerly Data Protection Directive 95/46/EC). It applies to all companies processing the personal data of data subjects residing in the Union, regardless of the company's location. (http://www.eugdpr.org/)

Eligibility to Serve as Principal Investigator on Sponsored Projects

POLICY 10.06.03

Effective Date: 9-01-2017
Date Last Revised: N/A

The following are responsible for the accuracy of the information contained in this document

Responsible Policy Administrators

Diego Vazquez
Assistant Vice Provost, Sponsored Programs
Office of Research

Responsible Departments

Office of Sponsored Programs
Office of Research

Contact (508) 856-2119

Policy Statement

As a condition of its acceptance of sponsored project awards from external sponsors, the UMass Medical School (UMMS) is obligated in its role as the recipient of the awards to ensure that only individuals meeting eligibility requirements may serve as principal investigator, multiple principal investigator, or program director on proposals. The Office of Sponsored Programs is responsible for ensuring that all proposals meet sponsor requirements and are institutionally reviewed and approved prior to submission. The UMMS policy on PI eligibility shall take precedence in instances where the sponsor's requirements are less restrictive.

Reason for Policy

The purpose of this policy is to establish criteria permitting individuals to fulfill the role of principal investigator, program director or multiple principal investigator on a sponsored project; and to ensure that sponsored projects are conducted by those who have the requisite training, skill, commitment and resources as well as the appropriate relationship to UMMS. The policy also articulates the period of time and privileges available to Principal Investigators when they leave the institution.

Entities Affected By This Policy

This policy is applicable to all UMMS employees that seek to submit proposals and serve as Principal Investigator/Project Director on sponsored projects.

Related Documents

- Participation Agreement

Scope

This document applies to all individuals submitting proposals to external sponsors through the Office of Sponsored Programs seeking monetary or non-monetary support of a sponsored project which, if awarded to UMMS will be governed by a contract, grant, cooperative agreement or other binding agreement.

This policy does not apply to consultant agreements or the procurement of goods or services from vendors.

UMass Medical School Faculty & UMass Memorial Health Care Physicians with Medical School Faculty Appointments

Faculty within the academic ranks listed below must have 50% FTE or greater employment to be eligible to serve as PI/PD on sponsored projects:

Professor
Associate Professor
Assistant Professor
Instructor

PI Eligibility for Incoming (New) Faculty

Incoming faculty in the above categories with signed offer letters are considered PI/PD eligible and are allowed proposal submission privileges prior to their start date.

Departing Faculty

Departing faculty may receive an adjunct appointment to assist in their transition to a new institution, allowing them to retain PI/PD status on sponsored projects remaining at UMMS for a period of 12 months or less. No new sponsored project applications may be submitted through UMMS by these individuals.

UMass Medical Faculty with Veterans Administration (VA) Appointments

The type of UMMS faculty appointment a VA employee has will determine their PI eligibility.

UMass Medical School & UMass Memorial Health Care Affiliate Faculty and Volunteers

Affiliate faculty and volunteers are ineligible to serve as PI/PD on Medical School sponsored projects.

UMass Amherst, Boston, Dartmouth and Lowell Faculty

Faculty at the other UMass campuses may sometimes be allowed to serve as PI/PD of a UMMS proposal. Please reach out to the Office of Research if you encounter this situation.

Retired Faculty

Retired faculty are ineligible to serve as PI/PD on sponsored projects unless they receive an exception.

Adjunct Faculty

The term “Adjunct” shall precede the academic title of any non-UMMS, non-UMMHC salaried member of the faculty holding a primary appointment at another academic institution. Adjunct faculty are ineligible to serve as PI/PD on Medical School sponsored projects unless the individual has a less than 1.0 FTE appointment at their primary academic institution which allows them to provide effort on UMMS grants. In no instance can the combined faculty member’s FTE at the primary academic institution and Adjunct appointment at UMMS exceed 1.0 FTE.

Departing faculty that have been given adjunct appointments at UMMS as part of their transition to a new institution are allowed to retain PI status on grants remaining at UMMS for a period of 12 months or less in order to facilitate their departure. No new sponsored project applications may be submitted by departing faculty.

Visiting Faculty

Visiting faculty are ineligible to serve as PI/PD on UMMS sponsored projects.

Non-Faculty/Staff

For non-academic grant seeking units, employees with the title/rank listed below must have a 50% FTE greater employment to be eligible to serve as PI/PD on sponsored projects:

Department Head
Director
Manager

Postdoctoral Associates (Postdocs) & Students/Trainees

Students & Trainees are not allowed to serve as PI/PD on sponsored projects, but may serve as PI/PD on projects specifically targeting Postdoctoral Associates & Students/Trainees including individual fellowships and career development grants for which holding PI/PD status is a requirement.

Exceptions Requests

Department Chairs, Program Directors, Department Heads may request an exception to the PI eligibility policy for otherwise ineligible individuals. Exception request procedures are identified in the Principal Investigator Eligibility Matrix on page 5 of the policy.

Responsibilities

Department Chair, Chief, Unit Head

1. Ensure that all proposal submissions contain an eligible individual as a principal investigator, multiple -principal investigator or program director and the eligible individual(s) has a signed participation agreement in place, and have the requisite training, resources and effort to devote to the proposed sponsored project.

2. Review and approve departmental proposal submissions.

3. Submit exception requests to this policy.

Office of Research

1. Review all proposal submissions to confirm eligible individuals are being proposed as principal investigator, multiple principal investigator or program director and have received the appropriate prior approvals.

2. Review exception requests to this policy and make determination to approve or reject requests.

Definitions

Participation Agreement: Agreement required for all Principal Investigators and any other covered individuals engaging in sponsored project activity that confirms and documents acceptance of the University of Massachusetts Intellectual Property Policy and assigns to the University all rights in any Intellectual Property in which the University asserts ownership.

Principal Investigator/Program Director/Multiple Principal Investigator: The individual designated by the UMass Medical School and approved by the sponsor to direct a project funded by an external sponsor. S/he is directly responsible and accountable to the Medical School and sponsor for the proper programmatic, scientific or technical conduct of the project, and its financial and day-to-day management.

The principal investigator is a critical member of the sponsored project team responsible for ensuring compliance with the financial and administrative aspects of the award. The principal investigator works closely with appropriate administrators within the Medical School to create and maintain necessary documentation, including both technical and administrative reports; prepare budget justifications; appropriately acknowledge external support of research findings in publications, announcements, news programs, and other media; and ensure compliance with other Federal and organizational requirements. It is expected that the principal investigator will maintain contact with the appropriate sponsor representative with respect to the scientific aspects of the project and the business and administrative aspects of the award.

Adjunct Faculty: An appointment for faculty who hold a primary academic appointment at another institution other than UMMS.

Affiliate Faculty: Voluntary members of the faculty who are not employed by UMMS or UMMHC.

Visiting Faculty: Faculty that hold an academic appointment at another institution and are at UMMS for a limited period.

Postdoctoral Associate (Postdoctoral Trainee): Individual employed by UMMS holding a doctoral degree engaged in a temporary period of mentored research and/or scholarly training for the purpose of acquiring the professional skills needed to pursue a career path.

Approvals

Chief Research Officer — Date: 8/25/17

Executive Vice Chancellor for Administration & Finance — Date: 9.6.17

UMass Medical School & UMass Memorial Health Care – Principal Investigator Eligibility Matrix

	UMMS Faculty	UMMS &UMMHC Affiliate Faculty	Retired & Volunteer Faculty	Adjunct Faculty	Visiting Faculty	Non-Faculty/Staff	Postdocs, Residents & Students/Trainees
Rank / Category	Professor Associate Professor Assistant Professor Instructor		Refer to ranks in UMMS Faculty column.	The term "Adjunct" shall precede the academic title of any non-UMMS, non-UMMHC salaried member of the faculty holding a primary appointment at another academic institution.	The term "Visiting" shall precede the academic title of any member of the faculty who continues to hold a primary appointment at another institution and whose appointment at UMMS is for a limited time.	For non-academic grant seeking units: Department Head Director Manager	N/A
Eligibility	Eligible if faculty with 50% FTE employment or greater. Incoming faculty in the above categories with signed offer letters are PI eligible and can submit proposals prior to their start date.	Not eligible to serve as UMMS PI.	Not eligible to serve as UMMS PI.	Not eligible to serve as UMMS PI unless individual has a less than 1.0 FTE appointment at primary academic institution.	Not eligible to serve as PI, Co-I or Multi-I.	50% FTE employment or greater to be eligible to serve as PI.	Postdocs, Students & Trainees are not allowed to serve as PI on research grants, but can serve as PI on projects specifically targeting these areas including on individual fellowships and career development grants for which holding PI status is a requirement.
Transition / Departure	12 month or less transitional period. PI effort during transitional period limited to no more than 20% for all projects. Longer transitional periods will require approval of the Chief Research Officer or their designee.		N/A	UMMS & UMMHC faculty given adjunct appointments as part of their transition to a new institution can retain PI status on grants remaining at UMMS for a period of 12 months or less.	N/A	N/A	N/A
Exception Process	IF < 50% FTE employment, approval needs to be requested through the Office of Research by Department Chair or Program Director.	Approval needs to be requested by Department Chair or Program Director through the Office of Research.	Approval needs to be requested by Department Chair or Program Director through the Office of Research.	Approval needs to be requested by Department Chair or Program Director through the Office of Research.	N/A	Approval needs to be requested by Department Head / Program Director through the Office of Research.	Approval needs to be requested by Department Chair or Program Director through the Office of Research.
Approvals Required	Chief Research Officer or designee	Chief Research Officer or designee	Chief Research Officer and Executive Vice Chancellor, Administration & Finance	Chief Research Officer or designee	N/A	Chief Research Officer or designee	Chief Research Officer or designee

UMass Amherst, Boston, Dartmouth and Lowell Faculty may sometimes be allowed to serve as PI/PD of a UMMS proposal. Please reach out to the Office of Research if you encounter this situation.

The NIH Announces New Review Criteria for Career Development Award Applications Involving Clinical Trials

Notice Number: NOT-OD-17-121

Key Dates
Release Date: October 6, 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 individual career development (K) award applications submitted to due dates on or after January 25, 2018.

Important Note: Review criteria will differ for individual mentored and independent K award applications, and for K award applications where the PD/PI will lead an independent clinical trial compared with individual K award applications where the PD/PI will undertake clinical trials research experience under the guidance of the mentor or co-mentor.

Note that these additional questions will not be used for the evaluation of institutional K12 or KL2 applications.

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 criteria questions below will be effective for the evaluation of individual career development award (K) applications that involve independent clinical trials led by the PD/PI of the K award application or K award applications where the PD/PI will undertake clinical trials research experience under the guidance of the mentor or co-mentor, and are submitted for funding consideration for due dates on or after January 25, 2018. The questions below will be *added* to the existing review questions (see https://grants.nih.gov/grants/peer/critiques/k.htm). Some Program Announcements and Requests for Applications may include additional, FOA-specific questions.

Criteria

In addition, for applications involving clinical trials:

The reviewers will consider that the clinical trial may include study design, methods, and intervention that are not by themselves innovative, but address important questions or unmet needs. Reviewers should also consider the scope of the clinical trial relative to the available resources, including the

possibility that research support provided through K awards may be sufficient to support only small feasibility studies.

Scored Review Criteria

The following questions are in *addition* to the standard individual K award review questions:

Candidate

- Does the candidate have the potential to organize, manage, and implement the proposed clinical trial, feasibility or ancillary study?
- Does the candidate have training (or plans to receive training) in data management and statistics including those relevant to clinical trials?

Career Development Plan/Career Goals and Objectives

- No additional questions.

Research Plan

- If proposed, will the clinical trial experience contribute to the research project and/or the applicant's research career development?
- Are the scientific rationale and need for a clinical trial, feasibility or ancillary study well supported by preliminary data, clinical and/or preclinical studies, or information in the literature or knowledge of biological mechanisms?
- If proposing a small feasibility study, is the study warranted and will it contribute to planning and preliminary data needed for design of future larger scale clinical trials?
- Is the clinical trial or ancillary study necessary for testing the safety, efficacy or effectiveness of an intervention, or in the case of a feasibility study necessary to establish feasibility of future clinical trial?
- Is the study design justified and relevant to the clinical, biological, and statistical hypothesis(es) being tested?
- Are the plans to standardize, assure quality of, and monitor adherence to, the protocol and data collection or distribution guidelines appropriate?
- Are planned analyses and statistical approach appropriate for the proposed study design and methods used to assign participants and deliver interventions?

Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s)

- If the applicant is proposing to gain experience in a clinical trial as part of his or her research career development, is there evidence of the appropriate expertise, experience, and ability on the part of the mentor(s) to guide the applicant during participation in the clinical trial?
- Does the mentor or mentoring team have the expertise, experience, and ability to guide the applicant in the organization, management and implementation of the proposed clinical trial, ancillary, or feasibility study and help him/her to meet the timelines?

Environment & Institutional Commitment to the Candidate

- 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 feasibility or ancillary study at the proposed site(s) or centers? If applicable, are there 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?

Additional Review Criteria

Study Timeline for Clinical Trials

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:

Division of Biomedical Research Workforce
Office of Extramural Programs
Office of Extramural Research
Email: NIHTrain@mail.nih.gov

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices

The NIH Announces New Review Criteria for Ruth L. Kirschstein National Research Service Award (NRSA) Individual Fellowship Applications Involving Research Experiences in Clinical Trials

Notice Number: NOT-OD-17-122

Key Dates
Release Date: October 6, 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 Ruth L. Kirschstein National Research Service Award (NRSA) Individual Fellowships if the applicant fellow is proposing to gain research experience in an ongoing clinical trial led by a sponsor or co-sponsor, 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 criteria questions below will be effective for the evaluation of Kirschstein-NRSA Individual Fellowship applications when the applicant fellow is proposing to gain research experience in an ongoing clinical trial led by a sponsor or co-sponsor. The questions below will be *added* to the existing review questions (see https://grants.nih.gov/grants/policy/review_templates.htm), which will not change for projects that do not involve clinical trials. Some Program Announcements and Requests for Applications may include additional, FOA-specific questions.

Criteria

In addition, for applications involving clinical trials:
Reviewers will consider the nature of the research experience proposed by the applicant fellow and the scope of proposal relative to the available resources, including the sponsor's and/or co-sponsor's research support.

Scored Review Criteria

The following questions are in *addition* to the standard individual fellowship review questions:

Fellowship Applicant

- No additional questions.

Sponsors, Collaborators, and Consultants

- *If the applicant is proposing to gain experience in a clinical trial as part of his or her research training*, is there evidence of the appropriate expertise, experience, resources, and ability on the part of the sponsor(s) to guide the applicant during the clinical trial research experience?

Research Training Plan

- *If proposed, will the clinical trial experience contribute to the proposed project and/or the applicant's research training*?

Training Potential

- No additional questions.

Institutional Environment & Commitment to Training

- No additional questions.

Inquiries

Please direct all inquiries to:

Division of Biomedical Research Workforce
Office of Extramural Programs
Office of Extramural Research
Email: NIHTrain@mail.nih.gov

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices

The NIH Announces New Review Criteria for Ruth L. Kirschstein National Research Service Award (NRSA) Institutional Research Training Grants Involving Research Experiences in Clinical Trials

Notice Number: NOT-OD-17-123

Key Dates
Release Date: October 6, 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 Ruth L. Kirschstein National Research Service Award (NRSA) Institutional Research Training Grants if one or more appointed trainees will propose to gain research experience in an ongoing clinical trial led by a mentor or co-mentor, 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 criteria questions below will be effective for the evaluation of Kirschstein-NRSA Institutional applications when the program proposes to offer appointed trainees the opportunity to obtain clinical trial research experience in an ongoing clinical trial led by a mentor or co-mentor. The questions below will be *added* to the existing review questions (see https://grants.nih.gov/grants/policy/review_templates.htm), which will not change for projects that do not involve clinical trials. Some Program Announcements and Requests for Applications may include additional, FOA-specific questions.

Criteria

In addition, for applications involving clinical trials:
Reviewers will consider the nature of the research experience proposed by the trainee(s) and the scope of proposal relative to the available resources, including the mentor's and/or co-mentor's research support.

Scored Review Criteria

The following questions are in *addition* to the standard training review questions:

Training Program and Environment

- No additional questions.

Training Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)

- No additional questions.

Preceptors/Mentors

- *If the program will support clinical trial research experience for the Trainees,* do the mentor(s) who will supervise the Trainee(s) have the expertise, experience, resources and ability to provide appropriate guidance and help the Trainee(s) to meet the timelines?

Trainees

- No additional questions.

Training Record

- No additional questions.

Inquiries

Please direct all inquiries to:

Division of Biomedical Research Workforce
Office of Extramural Programs
Office of Extramural Research
Email: NIHTrain@mail.nih.gov

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices

NIH Operates Under a Continuing Resolution Through December 8, 2017

Notice Number: NOT-OD-17-124

Key Dates
Release Date: October 2, 2017

Related Announcements

NOT-OD-17-087
NOT-OD-17-086
NOT-OD-17-084
NOT-OD-17-075
NOT-OD-17-048
NOT-OD-17-003

Issued by
National Institutes of Health (NIH)

Purpose

The Department of Health and Human Services (HHS), including NIH, operates under the "Continuing Appropriations Act, 2018 and Supplemental Appropriations for Disaster Relief Requirements Act, 2017," (Public Law 115-56) signed by President Trump on September 8, 2017. This Act (CR) continues government operations through December 8, 2017 at 99.3209 percent of the FY 2017 enacted level.

Continuing the fiscal policies under NOT-OD-17-086 and consistent with NIH practices during the CRs of FY 2006 – 2017, the NIH will issue non-competing research grant awards at a level below that indicated on the most recent Notice of Award (generally up to 90% of the previously committed level). Upward adjustments to awarded levels will be considered after FY 2018 appropriations are enacted, but NIH expects institutions to monitor their expenditures carefully during this period. All legislative mandates that were in effect in FY 2017 (see NOT-OD-17-075) remain in effect under this CR, as well as the salary limitation set at Executive Level II of the Federal Pay Scale (see NOT-OD-17-087). The Ruth L. Kirschstein National Research Service Award predoctoral and postdoctoral stipend levels and tuition/fees are described in NOT-OD-17-084 and NOT-OD-17-003.

Inquiries

Please direct all inquiries to:

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

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices

Guidance on Exceptions to the NIH Single IRB Policy

Notice Number: NOT-OD-18-003

Key Dates
Release Date: October 11, 2017

Related Announcements
NOT-OD-16-094
NOT-OD-18-004
NOT-OD-17-119
NOT-OD-17-076
NOT-OD-16-109

Issued by
National Institutes of Health (NIH)

Purpose

The purpose of this Notice is to provide additional guidance to the extramural research applicant and offeror community regarding requests for an exception to the NIH Policy on the Use of a Single Institutional Review Board (sIRB) for Multi-Site Research.

Exceptions to the NIH sIRB Policy

The sIRB policy applies to domestic sites of NIH-funded multi-site studies where each site will conduct the same protocol involving non-exempt human subjects research.

The policy does not apply to:

- Foreign sites; or
- Career development (K), institutional training (T), or fellowship awards (F).

Exceptions to the policy will be made where the proposed sIRB would be prohibited by a federal, state, or tribal law, regulation or policy (policy-based exceptions). Policy-based exceptions are automatically granted when identified in the sIRB plan (see Application Guide for grants; or Document Generation System for R&D contracts).

The NIH sIRB policy allows the consideration of requests for *other exceptions* not based on a legal, regulatory, or policy requirement, if there is a compelling justification for the exception. These *other exceptions* must be reviewed and approved by NIH.

Who Should Request an Exception to the NIH sIRB Policy?
Applicants/offerors should identify any policy-based exceptions in the sIRB plan.

If the applicant, offeror, or awardee believes that one or more research sites should be exempt from the use of the single IRB of record to conduct local IRB review due to compelling reasons, they must request an *other exception* and provide compelling justification in the sIRB plan.

Identification of NIH sIRB Policy Exceptions

If review by the sIRB will not be possible because local IRB review is required by an existing federal, state, or tribal law, regulation or policy, indicate which site(s) require local review and include a specific citation to the

relevant law, regulation, or policy. Policy-based exceptions are approved without review by the NIH sIRB Exceptions Review Committee (ERC).

Steps to Request an Other Exception to the NIH sIRB Policy

Exception requests not based on a federal/state/tribal law, regulation, or policy require the review and approval of the NIH ERC. Applicants/offerors who wish to seek an *other exception* should contact the Program Officer (PO) or Contracting Officer (CO) to discuss potential exception requests, and then follow the steps below:

- Applicants must include justification for an *other exception* in the sIRB plan attachment within the grant application (section 3.2 in the Study Record: PHS Human Subjects and Clinical Trials Information form, see Application Guide).
- Offerors shall follow the instructions that are contained in the Request for Proposal (RFP) for submitting an exception request.
- Applicants/offerors must include the name of the site(s) for which an IRB other than the sIRB of record is proposed to review the study for the site(s).
- Applicants/offerors must substantiate their exception request with sufficient information that demonstrates a compelling justification for *other exceptions* to the sIRB policy. The rationale should include why the single IRB of record cannot serve as the reviewing IRB for the site(s), and why the local IRB is uniquely qualified to be the reviewing IRB for the specific site(s).
    - For instance, the justification may consider ethical or human subjects protections issues, population needs, or other compelling reasons that IRB review for the site(s) cannot be provided by the single IRB of record.
- Note that the proposed budget in the application/proposal must reflect all necessary sIRB costs without an approved other exception. Applicants/offerors should not assume that an other exception will be granted when considering what sIRB costs to include in the budget.

Post-Award Exception Requests

For any post-award changes that necessitate an exception request, such as the addition of a new domestic site that may be unable to use the sIRB, awardees must contact their PO or CO. For policy-based exceptions, the awardee will need to provide the appropriate citation to verify the requirement for local IRB review for the newly added site(s) to the PO or CO. For other exceptions, the awardee must provide compelling justification to the PO or CO to be reviewed by the NIH ERC (*see* **Steps to Request *an Other* Exception to the NIH sIRB Policy** above).

Notice of Approval or Disapproval of *Other Exception* Requests

For grant applications, after peer review has been completed, the exception request may be submitted to the NIH ERC at the IC's discretion based on the justification provided. Only the NIH ERC may approve *other exception* requests. Applicants will be notified of the final decision by their IC's PO prior to award. Approved exceptions will be incorporated in the terms and conditions in the Notice of Award.

For contracts, single IRB exception requests will be considered after peer review for those proposals in the competitive range. All requests for exceptions must be reviewed by the NIH ERC. Offerors will be notified of the final decision by the CO prior to award. Approved exceptions will be incorporated in the term and conditions in the contract award. Also, any exception requests submitted after award must be submitted to the CO and reviewed by the NIH ERC. The decision of the NIH ERC is final. No further revisions of the exception request will be accepted.

For both grant applications and contracts, the award budget will likely need to be adjusted if an exception is granted.

Time Limited Exception: Ancillary Studies to Ongoing Research without a Single IRB

NIH funds many awards that are ancillary to other ongoing studies, or parent studies. During this transitional time, new multi-site non-exempt human subjects ancillary studies, both grants and contracts, that would otherwise be expected to comply with the sIRB policy, but are associated with ongoing multi-site parent studies, will not be required to use a sIRB of record until the parent study is expected to comply with the sIRB policy. This is a standing exception until the associated parent study is submitted for competitive renewal after the effective date of the sIRB policy.

The need for this time limited exception for these ancillary studies should be documented in the sIRB plan by identifying the associated parent study and will not require review and approval of the NIH ERC.

Resources

- NIH sIRB Policy for Multi-Site Research (Policy WebPage)
- NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research (NIH Guide Notice)
- Clinical Research Policy – IRB Review
- FAQs on NIH Policy on the Use of a Single IRB for Multi-Site Research Costs
- FAQs on Implementation of the sIRB Policy
- NIH Office of Extramural (OER) Webinars

Inquiries

Please direct all inquiries to:

NIH Office of Extramural Research
Email: SingleIRBPolicy@mail.nih.gov

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices

Guidance on Implementation of the NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research

Notice Number: NOT-OD-18-004

Key Dates
Release Date: October 11, 2017

Related Announcements
NOT-OD-16-094
NOT-OD-18-003
NOT-OD-17-076
NOT-OD-16-109
NOT-OD-17-062
NOT-OD-17-119

Issued by
National Institutes of Health (NIH)

Purpose

The purpose of this Notice is to provide additional guidance to the extramural research community for the implementation of the Final NIH Policy on the Use of a Single Institutional Review Board (sIRB) for Multi-Site Research.

Background

On June 21, 2016, the NIH issued the Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research. The goal of the sIRB policy is to reduce the burden of the IRB review process for multi-site research conducting the same protocol, allowing research to proceed effectively and expeditiously without compromising the protections of human subjects.

The sIRB policy applies to domestic sites of multi-site studies where each site will conduct the same protocol involving non-exempt human subjects research funded wholly or in part by NIH, including grants, cooperative agreements, and Research and Development (R&D) contracts. The policy does not apply to:

- Foreign sites; or
- Career development (K), institutional training (T), and fellowship awards (F).

The policy allows for exceptions in the following instances:

- Sites for which federal, state, or tribal laws, regulations or policies require local IRB review.
- Other exceptions to allow for local IRB review may be considered by NIH based on compelling justification. These other exceptions must be reviewed and approved by NIH. Please see NOT-OD-18-003 for more information about exceptions to the policy.

As announced on June 16, 2017 (NOT-OD-17-076), the effective date of the policy has been extended to January 25, 2018. For grant applications, the sIRB policy will apply to all competing grant applications for due dates on or after January 25, 2018; and for R&D contracts, the policy will apply to all solicitations issued on or after January 25, 2018.

Implementation Guidelines

Single IRB Review Options for Meeting the Policy:
As required by the federal regulations at 45 CFR 46, any IRB serving as the sIRB of record for NIH funded research must be registered with the HHS Office for Human Research Protections (OHRP) and must have membership to adequately review the proposed study.

The following are examples of types of IRBs that could be used:

- An institutional IRB that is associated with either the awardee or a participating site;
- An independent, commercial or unaffiliated IRB; or
- A central IRB organized to review the proposed study.

Expectations for Applications/Proposals:
When possible, the sIRB should be identified by the applicant/offeror in the sIRB plan attachment within the application/proposal. Note that the Funding Opportunity Announcement (FOA) or Request for Proposal (RFP) may include specific requirements for IRB review, such as the intent to set up a central IRB for specific projects. The applicant/offeror is expected to follow the instructions in the specific FOA or RFP.

The following resources provide additional information about the sIRB plan:

- Instructions for writing a sIRB plan and providing the justification for exceptions to the sIRB policy within Section 3.2 of the Study Record in the grant application are provided in the PHS Human Subjects and Clinical Trials Information Form Application Guide.
- For studies considered delayed onset, instructions for documenting the applicant's intention to comply with the single IRB policy within the justification for delayed onset of multi-site human subjects research are provided in the PHS Human Subjects and Clinical Trials Information Form Application Guide.
- Instructions about sIRB costs are provided in the G.300 - R&R Budget Form.
- For R&D contracts, instructions for writing a sIRB plan and documenting exceptions to the sIRB policy within a proposal are provided in the solicitation.
- The approved sIRB plan will be a term and condition in the Notice of Award or in the Contract Award.

Note: Effective for due dates on or after January 25, 2018, applicants will be required to use the new PHS Human Subjects and Clinical Trials Information Form in the application package. To learn more about the implementation of the new PHS Human Subjects and Clinical Trials Information Form and the attachment upload for the sIRB plan, see NOT-OD-17-062 or NOT-OD-17-119.

Evaluation of sIRB Information

The adequacy of the sIRB plan will not factor into the review score or overall rating of the Protection of Human Subjects section, unless the FOA/RFP has specific requirements for the sIRB and associated review criteria. For grant applications, a note may be included in the Summary Statement if the sIRB plan appears to be missing or is incomplete, and this will need to be addressed before an award can be made. For contracts, the RFP will include requirements about what must be provided to NIH regarding the sIRB prior to the time of award and beyond.

Resources

- NIH sIRB Policy for Multi-Site Research (Policy WebPage)
- NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research(NIH Guide Notice)
- Clinical Research Policy – IRB Review
- FAQs on NIH Policy on the Use of a Single IRB for Multi-Site Research Costs
- FAQs on Implementation of the sIRB Policy
- NIH Office of Extramural (OER) Webinars

Inquiries

Please direct all inquiries to:

NIH Office of Extramural Research
Email: SingleIRBPolicy@mail.nih.gov

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices

Publication of the Revised NIH Grants Policy Statement (Rev. October 2017) for FY 2018

Notice Number: NOT-OD-18-005

Key Dates
Release Date: October 12, 2017

Related Announcements
None

Issued by
National Institutes of Health (NIH)

Purpose

The National Institutes of Health (NIH) announces the publication of the revised NIH Grants Policy Statement (NIHGPS, rev. October 2017). This revision is applicable to all NIH grants and cooperative agreements with budget periods beginning on or after October 1, 2017. This revision supersedes, in its entirety, the NIH Grants Policy Statement (November 2016) as a standard term and condition of award. Previous versions of the NIHGPS remain applicable as a standard term and condition for all NIH grants and cooperative agreements with budget periods that began prior to October 1, 2017.

The NIHGPS provides both up-to-date policy guidance that serves as NIH standard terms and conditions of awards for grants and cooperative agreements, and extensive guidance to those who are interested in pursuing NIH grants.

While this revision does not introduce any new material for the first time, it incorporates new and modified requirements, clarifies certain policies, and implements changes in statutes, regulations, and policies that have been implemented through appropriate legal and/or policy processes since the previous version of the NIHGPS dated November 2016. The document is available in the following electronic formats: HTML and PDF (http://grants.nih.gov/grants/policy/nihgps/index.htm).

Prior versions of the NIHGPS are accessible at http://grants.nih.gov/grants/policy/policy.htm#gps.

NIH will continue to publish interim grants policy changes through the issuance of NIH Guide Notices found at http://grants.nih.gov/grants/guide/index.html. Each change will be described, including its applicability and effective date; and the necessary language to implement it as a term or condition of award provided.

A document is available that summarizes the significant changes that are implemented with the October 2017 NIHGPS: http://grants.nih.gov/grants/policy/nihgps/Significant_Changes_NIHGPS_Oct2017.pdf.

Inquiries

Please direct all inquiries to:

Division of Grants Policy
Office of Policy for Extramural Research Administration (OPERA)
Telephone: 301-435-0949
Email: GrantsPolicy@od.nih.gov

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices

Reminder: FORMS-E Grant Application Forms & Instructions Must be Used for Due Dates On or After January 25, 2018

Notice Number: NOT-OD-18-009

Key Dates
Release Date: October 24, 2017

Related Announcements
NOT-OD-17-119
NOT-OD-17-062
NOT-OD-17-043

Issued by
National Institutes of Health (NIH)

Purpose

This notice reminds the biomedical and health services research communities that 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 (see NOT-OD-17-062 for details).

Applicants are encouraged to submit early to allow time to work through any unforeseen issues.

Additional Updates:

- FORMS-E Grant Application Instructions are now posted on the How to Apply - Application Guide page (NOT-OD-17-119).
- FORMS-E application packages are currently being posted to active Funding Opportunity Announcements (FOAs) with due dates on or after January 25, 2018. We expect to complete this process by November 25, 2017.
    - FORMS-E application packages will not be added to Parent announcements since they will be reissued for due dates on or after January 25, 2018.
    - FORMS-E application packages will not be added to FOAs that will be reissued to allow clinical trials for due dates on or after January 25, 2018.

For a transition period, both FORMS-D and FORMS-E application packages and instructions will be active. Applicants must choose the appropriate application package and associated instructions for their due date when presented with both FORMS-D and FORMS-E application packages on the same FOA.

Applications submitted using the incorrect application package for their due date may be withdrawn and removed from funding consideration.

Resources:

- How to Apply - Application Guide
- High-level Summary of Form Changes in FORMS-E Application Packages
- Annotated Form Set for NIH Grant Applications
- New Human Subjects and Clinical Trial Information Form
- 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 (preferred method of contact)
Telephone: 301-945-7573

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices

NIH Plans for Clinical Trial Specific Parent R01 and Parent R21 Funding Opportunity Announcements

Notice Number: NOT-OD-18-010

Key Dates
Release Date: October 25, 2017

Related Announcements
None

Issued by
National Institutes of Health (NIH)

Purpose

The purpose of this Notice is to announce NIH's plan to publish NIH Research Project Grant (Parent R01 Clinical Trial Required) and NIH Exploratory/Developmental Research Grant Program (Parent R21 Clinical Trial Required) Funding Opportunity Announcements (FOAs) in November 2017 to be used for applications targeting due dates on or after January 25, 2018. Some NIH Institutes and Centers will join these parent FOAs and others will jointly or alone publish IC-specific Clinical Trial FOAs using the same definition of trials described below but will also include additional IC requirements.

Unless otherwise noted, these Parent Clinical Trial Required FOAs will accept trials of safety and efficacy, as well as mechanistic and other types of trials. Some ICs will accept only mechanistic trials to these Parent Clinical Trial FOAs.

NIH defines a clinical trial 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." (NOT-OD-15-015)

NIH not only supports trials of safety and efficacy, it also supports mechanistic exploratory studies that meet the definition of a clinical trial and are designed to explore or understand a biological or behavioral process, the pathophysiology of a disease, or the mechanism of action of an intervention. These studies may focus on basic and/or translational discovery research in healthy human subjects and in human subjects who are affected by the pathophysiology of diseases and disorders. By addressing basic questions and concepts in biology, behavior, and pathophysiology, these studies may provide insight into understanding human diseases and disorders along with potential treatments or preventive strategies. NIH also supports biomarker studies that meet the definition of a clinical trial and that may provide information about physiological function, target engagement of novel therapeutics, and/or the impact of therapeutics on treatment response. NIH thus supports studies that meet the definition of clinical trials (as noted above) but do not seek to establish safety, clinical efficacy, effectiveness, clinical management, and/or implementation of preventive, therapeutic, and services interventions.

Examples of mechanistic clinical trials include but are not limited to:

- Studies that use a manipulation (physiological or behavioral) to answer basic science questions about normal functions.
- Studies that use an experimental manipulation in order to understand normal functioning or the pathophysiology of a disease or disorder, but do not aim to demonstrate clinical improvement.
- Studies that involve the prospective use of efficacious interventions where the intent is to obtain and analyze biospecimens to identify genetic risk associations, novel biomarkers, examine the disease process, or characterize mechanisms of therapeutic response.
- Studies in which an intervention with demonstrated efficacy for a population is being studied to understand mechanisms of response, non-response, or risk of adverse effects of the efficacious intervention.

Inquiries

Please direct all inquiries to:

NIH Grants Information
Email: grantsinfo@od.nih.gov (preferred method of contact)
Telephone: 301-945-7573

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices

NIH will Make the Project Outcomes Section of all Interim and Final RPPRs Submitted on or After October 1, 2017 Available via the NIH RePORTER

Notice Number: NOT-OD-18-103

Key Dates
Release Date: November 16, 2017

Related Announcements

NOT-OD-17-085
NOT-OD-17-022
NOT-OD-17-037
NOT-OD-15-111
NOT-OD-15-014
NOT-OD-14-092
NOT-OD-14-084
NOT-OD-14-079
NOT-OD-14-026
NOT-OD-13-113
NOT-OD-13-035
NOT-OD-13-061
NOT-OD-12-083

Issued by
National Institutes of Health (NIH)

Purpose

The National Institutes of Health (NIH) intends to publish the Project Outcomes Section of all Final and Interim Research Performance Progress Reports (RPPRs) submitted on or after October 1, 2017 and make them available to the general public via the NIH RePORTER.

Background

NIH implemented the annual RPPR in 2012, based on a policy memorandum from the Office of Management and Budget and Office of Science and Technology Policy (OSTP) to the heads of executive departments and agencies. The uniform RPPR replaced previous interim performance reporting formats used by NIH and other agencies.

The Research Business Models (RBM), an Interagency Working Group of the Social, Behavioral & Economic Research Subcommittee of the Committee on Science (CoS), charged NSF and NIH to serve as the co-chairs of an interagency workgroup. The RBM asked the Working Group to consider lessons learned from the development of the annual RPPR and to develop a standard format for use in reporting final progress on Federally-funded research projects and research-related activities. On November 16, 2016, the Working Group published a Federal Register notice announcing the updated standardized RPPR.

NIH Implementation

With NIH's implementation of the Final and Interim RPPR, recipients are required to adhere to the new requirement to report on Project outcomes. *This section will be made publicly available via the NIH RePORTER*, thus allowing recipients to provide the general public with a concise summary of the cumulative outcomes or

findings of the project (analogous to the Project Summary/Abstract section of the competing application) at the end of each competitive segment.

The NIH will only publish project outcomes that have been reviewed and approved by NIH staff to ensure the narrative is written for the general public in clear and comprehensible language, without including any proprietary, confidential information or trade secrets. If the description of the project outcomes are found to be unacceptable, recipients will be required upon NIH request to submit revised project outcomes statements using the Additional Material functionality in place for the Final and Interim RPPR (i.e., Final Report Additional Materials (FRAM) for Final RPPR). The Additional Material functionality for both the Final and Interim RPPR have been enhanced in order to capture revised project outcomes in a web form format that will support NIHs ability to make this information publically available. *Please note that the web form data entry field pertains only to the entry of Project Outcomes text. Any other additional materials requested, if applicable, should be uploaded as a file attachment.* In order to assist recipients, NIH has posted sample descriptions for project outcomes that may assist recipients in submitting acceptable project outcomes. *See the Sample Project Outcomes description available at:* https://grants.nih.gov/grants/rppr/sample_project_outcomes_RPPR.htm.

See steps on how to submit revised project outcomes for interim RPPRs (IRAM) and for final RPPRs (FRAM) in the eRA Commons online help.]

Reminders

NIH has successfully transitioned to the Interim and Final RPPR. For details concerning the requirements please refer to NOT-OD-17-085 and NOT-OD-17-022.

NIH requires that organizations submit an "Interim-RPPR" while their renewal application (Type 2) is under consideration. In the event that the Type 2 is funded, NIH will treat the Interim-RPPR as the annual performance report for the final year of the previous competitive segment. If the Type 2 is not funded, the Interim-RPPR will be treated by NIH staff as the institution's Final-RPPR.

The RPPR web page provides related resources and the FAQs were updated based on NIH's implementation of the Final and Interim RPPR.

Inquiries

Please direct all inquiries to:

Division of Grants Policy
Office of Policy for Extramural Research Administration
Office of Extramural Research
Email: grantspolicy@od.nih.gov

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices

ACRONYMS AND TERMS USED TODAY
OSP RA Update - 11/29/2017

ACRONYM/TERM	DESCRIPTION
45 CFR 164	Security and Privacy is one of fifty titles comprising the United States Code of Federal Regulations (CFR). Title 45 Part 164 is the principle set of rules and regulations issued by federal agencies of the United States regarding security and privacy.
CR	Continuing Resolution
ECRT	Effort Certification and Reporting Technology (UMMS Effort Reporting System)
eRA Commons	The eRA Commons is NIH's online interface where signing officials, principal investigators, trainees and post-docs at institutions/organizations can access and share administrative information relating to research grants and process prior approval requests.
FedRAMP	The Federal Risk and Authorization Management Program is a government-wide program that provides a standardized approach to security assessment, authorization, and continuous monitoring for cloud products and services.
FIPS	Federal Information Processing Standard (FIPS) - set of standards that describe document processing, encryption algorithms and other information technology standards for use within non-military government agencies and by government contractors and vendors who work with the agencies.
FISMA	Federal Information Security Management Act (FISMA) is United States legislation that defines a comprehensive framework to protect government information, operations and assets against natural or man-made threats. FISMA was signed into law part of the Electronic Government Act of 2002.
FOA	Funding Opportunity Announcement (NIH)
HIPAA	United States legislation that provides data privacy and security provisions for safeguarding medical information.
IRB	Institutional Review Board
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.
K12	Physician Scientist Award - Research Career Programs (NIH)
KL2	Mentored Career Development Award - Research Career Programs (NIH)
NIH	National Institutes of Health
NIHGPS	NIH Grant Policy Statement
NIST	National Institute of Standards and Technology, a unit of the U.S. Commerce Department. Formerly known as the National Bureau of Standards, NIST promotes and maintains measurement standards. It also has active programs for encouraging and assisting industry and science to develop and use these standards.
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
OMB	Office of Management and Budget
OSP	Office of Sponsored Programs
OSTP	Office of Science & Technology Policy
PA	Program Announcement (NIH)
Parent R01 & R21	Parent announcements are broad funding opportunity announcements allowing applicants to submit investigator-initiated applications for specific activity codes. They are open for up to 3 years and use standard due dates.
PI	Principal Investigator
R01	Activity Code for NIH Research Projects - Research Project
R21	Activity Code for NIH Exploratory/Developmental Grants - Research Project
RAC	Research Advisory Committee (UMMS)
RAU	Research Administration Update
RePORTER	RePORTER is an electronic tool that allows users to search a repository of NIH-funded research projects and access publications and patents resulting from NIH funding.
RFA	Request for Application (NIH)
RPPR	Research Performance Progress Report
sIRB	Single Institutional Review Board
UMMS	University of Massachusetts Medical School