Research Administration Update

June 27, 2016
11:45 am – 12:45 pm
Amphitheater I (S2-102)

Agenda

University of Massachusetts UMASS Medical School

- Research Administration Training Update
- FCOI Retraining Requirements
- Applicability of the eSDFI form
- NIH Update
  - Forms-D: Enrollment Table, Vertebrate Animals Section, PHS Assignment Forms-D: Career Development Applications and the Project Summary/Abstract Attachment
  - NOT-OD-16-105: Revised NIH Parental Leave Policy for Ruth L. Kirschstein National Research Service Awards
  - NOT-OD-16-094: Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research
  - NOT-OD-16-092: Modification of 'No-Cost Extension' and 'Carryover of Funds' Policies for the NIH Pathway to Independence Award (Parent K99/R00)
  - Reviewer Guidance on Rigor & Transparency
- Proposal & Progress Report Statistics

Research Administration Training Update

University of Massachusetts Medical School

- Focus group held 5/20/16
- Discussed new training approach to start in the fall that will focus on UMMS research admin processes.
- Proposed providing this training directly after each Research Administration Update.
- Received feedback from attendees on the types of processes and topics that they would like to see covered by the training.
- We are currently reviewing the feedback and will use it to generate the training sessions that will be offered in the fall.

FCOI Training Requirement

University of Massachusetts Medical School

- Per regulatory requirement each Investigator must complete training at least every four years.
- UMMS Investigators that completed the training over four years ago will need to retake the training again beginning in August 2016 to comply with the retraining requirement.
- Please check the Training Completion Report available on the OSP FCOI page to see when your Investigators will need to retrain.
- The report is available at:
  - http://www.umassmed.edu/globalassets/office-of-research/compliance/fcoi/citi-training-report/coi-training-completion-report.pdf
- OSP is unable to set up awards for those projects where Investigators have not met the training requirement.

Applicability of the eSDFI Form

University of Massachusetts Medical School

- The eSDFI form should only be completed by UMMS employees
- Subrecipient investigators should follow their home institution's FCOI policy and disclosure procedures
- Please notify OSP if a collaborating entity does not have an FCOI policy
- Non-employee investigators should use the Non-UMMS Individual Investigator Disclosure of Financial Interests form available at:
  - http://www.umassmed.edu/contentassets/719e8b06393749f795dfd46b2a45d837/non-umms-individual-investigator-disclosure-form-10-11-12.pdf
  - Sample form is included in the Appendix

PHS Inclusion Enrollment Report

University of Massachusetts Medical School

- Combines Planned Enrollment Report and Cumulative Inclusion Enrollment Report forms into a single form
- Questions used to identify type of report:
  - Delayed onset study? Yes/No
  - Enrollment Type? Planned/Cumulative (Actual)
  - Using an Existing Dataset or Resource? Yes/No
  - Enrollment Location? Domestic/Foreign
  - Clinical Trial? Yes/No
  - NIH-Defined Phase II Clinical Trial? Yes/No
- Affirmative response to delayed onset question does not require the entering of any participant data

PHS Inclusion Enrollment Report

This report format should NOT be used for collecting data from study participants.

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expand all /collapse all (1 study)

Study 1 Title: Barriers to Healthy Eating and physical activity in adults with autism spectrum disorde

Delayed Onset Study: No

If study is not delayed onset, the following selections are required:

Enrollment Type: Planned

Using an Existing Dataset or Resource: No

Participants Location: Domestic

Clinical Trial: No

NIH-Defined Phase III Clinical Trial: No

Comments: n=40

Racial Categories	Ethnic Categories									
	Not Hispanic or Latino			Hispanic or Latino			Unknown/ Not Reported Ethnicity			Total
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/Alaska Native	0	0		0	0					0
Asian	1	2		0	0					3
Native Hawaiian or Other Pacific Islander	0	0		0	0					0
Black or African American	1	1		0	1					3
White	5	25		1	2					33
More than One Race	0	1		0	0					1
Unknown or Not Reported										
Total	7	29		1	3					40

Vertebrate Animals Section

University of Massachusetts Medical School

- Forms-D PHS Cover Page Supplement
  - New Vertebrate Animals Section Added
  - New Questions
    - Are animals euthanized? Yes/No
  - If Yes, is method consistent with AVMA guidelines? Yes/No
  - If No to AVMA guidelines, describe method / provide scientific justification
  - In Cayuse:

2. Vertebrate Animals Section

Are vertebrate animals euthanized? Yes No *(this selection is enabled when the 'Vertebrate Animals Used' question on the Other Project Information page is 'Yes')*

If "Yes" to euthanasia

Is method consistent with American Veterinary Medical Association (AVMA) guidelines? Yes No

If "No" to AVMA guidelines, describe method and provide scientific justification

New PHS Assignment Request Form

- Cayuse now has the optional PHS Assignment Request form that allows Investigators to request a specific study section
- Assignment requests should no longer be included in the cover letter as CSR staff will only be looking for assignment requests via this new form
- The cover letter should still be used for any narrative information you want to relay to our receipt and referral staff, such as:
  - Reason for late application
  - Explanation of why a Subaward isn't active in all periods of the proposed project
  - Statements regarding agency approval documents (e.g., requests over $500,000)

Career Development Applications and the Project Summary / Abstract Attachment

- In Forms-C, the Project Narrative/Abstract attachment on the R&R Other Project Information form used to allow up to a page for career development (K) applications.
- In Forms-D, the attachment can be "no longer than 30 lines of text" for all programs.
- This should roughly work out to the same amount of text, but investigators need to be aware of the line limitation.

NOT-OD-16-105: Revised NIH Parental Leave Policy for Ruth L. Kirschstein National Research Service Awards

University of Massachusetts Medical School

- Current policy allows trainees on institutional research training grants and fellows on individual research training fellowships to receive stipends for up to 60 calendar days (equivalent to 8 work weeks) of parental leave per year for the adoption or the birth of a child when those in comparable training positions at the grantee organization have access to this level of paid leave for this purpose. Either parent is eligible for parental leave. The use of parental leave must be approved by the training Program Director.

- Revised policy:
  - Effective immediately, all NRSA trainees and fellows may receive stipends for up to 60 calendar days (equivalent to 8 work weeks) of parental leave per year for the adoption or the birth of each child.
  - Either parent is eligible for parental leave.
  - NRSA trainees and fellows must provide advanced notification to the grantee institution prior to taking parental leave.
  - Notification of supervisors and others about plans to use leave must be consistent with the organization's policy and must be consistently applied regardless of the source of funds.

NOT-OD-16-094: Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research

University of Massachusetts Medical School

- Released 6/21/16, Final Policy will not take effect until 5/25/17.

- Establishes the expectation that all sites participating in multi-site studies involving nonexempt human subjects research funded by the National Institutes of Health (NIH) will use a single Institutional Review Board (sIRB) to conduct the ethical review required by DHHS.

- This policy is intended to enhance and streamline the process of IRB review and reduce inefficiencies so that research can proceed as expeditiously as possible without compromising ethical principles and protections for human research participants.

- The Office of Research will work with the Center for Clinical & Translational Sciences (CCTS) to implement internal processes that comply with the new policy.

NOT-OD-16-092: Modification of 'No-Cost Extension' and 'Carryover of Funds' Policies for the NIH Pathway to Independence Award (Parent K99/R00)

University of Massachusetts Medical School

- K99 Phase of the Pathway to Independence Award (K99/R00)
  - Generally the K99 phase is for 2 years; however, award recipients may transition earlier than 2 years when the recipient has been offered an acceptable position. It is expected that K99 awardees will receive at least 12 months of career development support from the award before transitioning to the R00 phase. If an applicant achieves independence prior to initiating the K99 phase, **neither the K99 nor the R00 phase will be awarded**. Recipients are advised to contact the awarding Institute or Center (IC) if early transition is being considered. In all cases, early transition is considered a prior approval request and therefore subject to the approval of the NIH awarding IC.
- No-Cost Extension:
  - Since the K99 and R00 phases are awarded independently, a no-cost extension may be allowed should additional time be needed to complete the goals of the K99 phase. However, no-cost extensions for K99 awards are not automatic and require prior approval by the NIH. All terms and conditions of the K99/R00 award (including minimum effort requirements) remain in effect when the grant is in a no-cost extension. In requesting a no-cost extension, K99 awardees wishing to continue to seek a tenure-track or equivalent position should submit a plan for continued career development and a timely transition to an independent position. **If an application for the R00 Phase with a suitable position is not submitted within the one-year period of the no-cost extension, the R00 will not be awarded**. Those not continuing to seek to transition to the R00 will be permitted to extend without additional funds, in order to permit an orderly phase-out of the project.
- Carryover of Funds:
  - Carryover from the K99 phase to the R00 phase may be allowed provided the K99 phase was funded by extramural support. The K99 recipient should consult with the awarding IC as to its practices regarding carryover.

Reviewer Guidance on Rigor & Transparency

University of Massachusetts Medical School

- NIH recently updated their reviewer guidance on rigor and transparency for research project grants (RPGs) and Mentored Career Development Applications.
- Provides reviewers guidance on how to evaluate:
  - Scientific Premise
  - Scientific Rigor
- Please share with your investigators to ensure that their applications align and are responsive with the guidance.
  - The Reviewer Guidance document is attached in the Appendix.

PROPOSAL SUBMISSIONS TO OSP
May 2015 – May 2016

University of Massachusetts Medical School

	May 2015	June 2015	July 2015	August 2015	September 2015	October 2015	November 2015	December 2015	January 2016	February 2016	March 2016	April 2016	May 2016
Count	69	111	90	62	112	129	60	67	107	121	89	72	101
On Time	39%	55%	47%	47%	52%	43%	37%	42%	59%	38%	45%	29%	57%
Late	58%	42%	47%	52%	43%	56%	60%	54%	39%	60%	55%	70%	39%
After the fact	3%	3%	6%	2%	5%	1%	3%	4%	2%	2%	0%	1%	4%
Withdrawn	0%	0%	0%	0%	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)	35%	23%	33%	39%	31%	39%	40%	33%	25%	46%	42%	44%	21%

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
May 2015 to May 2016 Comparison

University of Massachusetts Medical School

PROPOSALS	2015	2016	Change
Count	69	101	+32
On Time	39%	57%	+18
Late	58%	39%	-19
After the fact	3%	4%	+1
Withdrawn	0%	0%	-
Total	**100%**	**100%**	-
Expedited Request (3 days or less)	35%	21%	-14

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

PROGRESS REPORT SUBMISSIONS TO OSP
May 2015 – May 2016

University of Massachusetts Medical School

	May 2015	June 2015	July 2015	August 2015	September 2015	October 2015	November 2015	December 2015	January 2016	February 2016	March 2016	April 2016	May 2016
Count	52	53	32	11	19	30	19	26	36	44	71	58	43
On Time	46%	38%	38%	27%	37%	43%	26%	42%	64%	48%	58%	64%	49%
Late	37%	51%	37%	46%	47%	40%	63%	50%	22%	45%	39%	36%	51%
After the fact	17%	11%	25%	27%	16%	17%	11%	8%	14%	7%	3%	0%	0%
Total	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**
Expedited Request (3 days or less)	19%	38%	31%	36%	26%	20%	58%	42%	19%	30%	27%	26%	37%

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
May 2015 to May 2016 Comparison

University of Massachusetts Medical School

PROGRESS REPORTS	2015	2016	Change
Count	52	43	-9
On Time	46%	49%	+3
Late	37%	51%	+14
After the fact	17%	0%	-17
Withdrawn	0%	0%	-
Total	**100%**	**100%**	-
Expedited Request (3 days or less)	19%	37%	+18

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

APPENDIX

Proposal ID# or Sponsor Award ID:

University of Massachusetts Medical School
Non-UMMS Individual Investigator Disclosure of Financial Interests

*This form is for non-UMMS Consultants, Collaborators or Other Individuals with significant responsibilities who meet the PHS definition of an Investigator. Subrecipients **do not** fill out this form. This information is required to comply with the PHS Regulations on the Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 CFR Part 50, Subpart F) and responsible Prospective Contractors (42 CFR Part 94). Completion of this form is **mandatory**.*

UMMS PHS Supported Project Title:

UMMS Principal Investigator:

The UMMS Principal Investigator responsible for this PHS application has determined that you meet the definition of an "Investigator" for this project.

*For the purposes of this disclosure, **Investigator** is defined as any person, **regardless of title or position**, who is responsible for the design, conduct, or reporting of research, or proposed for such funding, which includes subawardees, consultants and unpaid collaborators.*

Name of Disclosing Individual: E-mail: Tel:

INVESTIGATOR DISCLOSURE

1. Do you (and your spouse and dependent children) have a significant financial interest in a publicly traded entity that when aggregated exceeds $5,000? When determining your response to this question, please add the value of any equity interest as of the date of this disclosure to any remuneration received from the entity in the twelve months preceding this disclosure.

   ☐ Yes ☐ No If yes, provide name of business entity:

2. Do you (or your spouse and dependent children) have the following significant financial interests in a non-publicly traded entity?

   a. Remuneration that when aggregated exceeds $5,000.

   ☐ Yes ☐ No If yes, provide name of business entity:

   b. Any interest equity.

   ☐ Yes ☐ No If yes, provide name of business entity:

3. Have you (and your spouse and dependent children) received income in excess of $5,000 during the twelve months preceding this disclosure that is related to intellectual property rights and interests (e.g., patents, copyrights)?

   ☐ Yes ☐ No If yes, provide name of business entity:

4. Has any organization sponsored or reimbursed you for any travel you have taken that is related to the proposed work on this project? *Note: You are not required to disclose travel that is reimbursed or sponsored by a Federal, state or local government agency, an institution of higher education as defined in 10 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.*

   ☐ Yes ☐ No If yes, provide name of business entity:

5. Is your participation in this application/project being conducted as a consulting or outside activity separate from your primary appointment at an academic institution or hospital?

   ☐ Yes ☐ No If yes, provide name of Institution/Hospital:

INVESTIGATOR CERTIFICATION

I certify to the best of my knowledge that the information disclosed herein is complete and accurate. By signing this form I agree to comply with the applicable FCOI regulations set forth in 45 CFR Part 94 and 42 CFR Part 50, Subpart F. Should this project be funded, I understand that I will be required to provide documentation to UMMS that I have completed the required FCOI training at: http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm before I can begin work on the project.

Signature of Individual Investigator Date

PHS FCOI regulations available at: http://grants.nih.gov/grants/policy/coi/.

DEFINITIONS

The 2011 revised PHS regulation defines a “Significant Financial Interest” as it relates to an Investigator's institutional responsibilities. UMMS is applying the SFI definition for non-employees as it relates to the proposed or funded research.

“(1) A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the proposed or funded research:

(i) With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

(ii) With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

(iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

(2) Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i. e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to the proposed or funded research; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education. The Individual will provide the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. UMMS may request additional information in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

(3) The term significant financial interest does not include the following types of financial interests: income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or income from service on advisory committees or review panels for a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.”

Revised NIH Parental Leave Policy for Ruth L. Kirschstein National Research Service Awards

Notice Number: NOT-OD-16-105

Key Dates
Release Date: June 13, 2016

Related Announcements
NOT-OD-08-064

Issued by
National Institutes of Health (NIH)
Agency for Healthcare Research and Quality (AHRQ)
Health Resources and Services Administration (HRSA)

Purpose

This Notice supersedes NOT-OD-08-064 and revises the parental leave policy for Ruth L. Kirschstein National Research Service Awards (Kirschstein-NRSA).

Current policy allows trainees on institutional research training grants (T32, T34, T35, and the NRSA component of T90), and fellows on individual research training fellowships (F30, F31, F32, and F33) to receive stipends for up to 60 calendar days (equivalent to 8 work weeks) of parental leave per year for the adoption or the birth of a child when those in comparable training positions at the grantee organization have access to this level of paid leave for this purpose. Either parent is eligible for parental leave. The use of parental leave must be approved by the training Program Director.

Revised policy: Effective immediately, all Kirschstein-NRSA trainees and fellows may receive stipends for up to *60 calendar days* (equivalent to *8 work weeks*) of parental leave per year for the adoption or the birth of each child. Either parent is eligible for parental leave. Kirschstein-NRSA trainees and fellows must provide advanced notification to the grantee institution prior to taking parental leave. Notification of supervisors and others about plans to use leave must be consistent with the organization's policy and must be consistently applied regardless of the source of funds.

In addition to parental leave, Kirschstein-NRSA trainees and fellows are eligible for other types of leave (vacations and holidays, sick leave, etc.) as described in the NIH Grants Policy Statement.

For a listing of all NIH training grants and fellowships, see: https://researchtraining.nih.gov.

Inquiries

Questions concerning this notice or other policies related to Kirschstein NRSA awards should be directed to:

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

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

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Notice Number: NOT-OD-16-094

Key Dates
Release Date: June 21, 2016
Effective Date: May 25, 2017

Related Announcements
NOT-OD-16-109

Issued by
National Institutes of Health (NIH)

Purpose

The National Institutes of Health (NIH) is issuing this policy on the use of a single Institutional Review Board (IRB) for multi-site research to establish the expectation that a single IRB (sIRB) of record will be used in the ethical review of non-exempt human subjects research protocols funded by the NIH that are carried out at more than one site in the United States. The goal of this policy is to enhance and streamline the IRB review process in the context of multi-site research so that research can proceed as effectively and expeditiously as possible. Eliminating duplicative IRB review is expected to reduce unnecessary administrative burdens and systemic inefficiencies without diminishing human subjects protections. The shift in workload away from conducting redundant reviews is also expected to allow IRBs to concentrate more time and attention on the review of single site protocols, thereby enhancing research oversight.

Background

The NIH published for public comment a proposed draft sIRB policy in a Notice in the NIH Guide for Grants and Contracts on December 3, 2014, (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-026.html) and in the Federal Register on January 6, 2015, (80 FR 511) (https://federalregister.gov/a/2014-30964). The NIH received 167 comments from a range of stakeholders, including individual researchers, academic institutions, IRBs, patient advocacy groups, scientific societies, healthcare organizations, Tribal Nation representatives, and the general public. A compilation of the public comments is available at http://osp.od.nih.gov/sites/default/files/resources/sIRB%2007-21-2015.pdf. The NIH appreciated the public interest in the draft policy and the time and effort stakeholders made to provide comments. The NIH carefully considered those comments in the development of the final policy.

Overview of the Public Comments
In general, most of the comments that were submitted on the draft policy were supportive of NIH's goal of enhancing and streamlining IRB review in multi-site research. Commenters, especially individual researchers, scientific and professional societies, and patient advocacy organizations, generally agreed that the use of a single IRB for multi-site studies involving the same protocol would help streamline IRB review and would not undermine and might even enhance protections for research participants. Most of the comments also favored the approach the NIH proposed to promote the use of single IRBs by making reliance on an sIRB an expectation for all non-exempt multi-site studies carried out at U.S. sites. At the same time, a number of commenters, mainly academic institutions and organizations representing them, did not agree with the scope of the proposed policy or that it should become a term and condition of funding, and suggested the NIH incentivize, not mandate, reliance on an sIRB.

Comments from researchers that supported the draft policy described unnecessary delays and additional costs caused by duplicative IRB reviews. They noted that IRB submission requirements at each site differ and take time to navigate and manage. They also indicated that review of the same protocol by multiple IRBs can sometimes lead to protocol and consent document changes that can introduce inconsistencies in the execution of

the protocol across sites, lead to enrollment imbalances, and skew the analysis of the aggregated data. More often, however, multiple IRB reviews result in changes to consent documents that are merely stylistic and not substantive, or changes that focus on institutional interests (e.g., liability management) rather than human research protections. Commenters raised the concern that the current practice of requiring multiple IRB reviews may actually contribute to some researchers' reluctance to participate in rigorous, multi-site research and may incentivize smaller and simpler study designs.

Scientific and professional societies generally favored the proposed policy. These stakeholders stated that the policy would decrease administrative burdens on clinical research staff, speed up participant recruitment, and streamline the research process and that these changes would result in enhancements to the efficiency of research and acceleration of research progress. They also suggested that the benefits of such a policy include enhanced adverse event monitoring and improvements to the quality and consistency of IRB reviews.

Most of the comments from patient advocacy groups and participant representatives were supportive of the proposed policy. These stakeholders pointed out that greater use of single IRBs will lead to enhanced protections through increased accountability and improved efficiency.

In general, comments from academic institutions, IRBs, and organizations that represent them cited concerns about the proposed policy, even though many also expressed support for its goal and agreed it could have a positive impact in reducing research review and initiation time to the study. These stakeholders suggested that the scope of the proposed policy is too broad and that the NIH should not make the policy a term and condition of award. They said that decisions about whether to use a single IRB should be voluntary and that the NIH should offer incentives to promote change. For example, they suggested that the NIH encourage investigators and institutions to use single IRBs in grant applications by providing additional funding to those grants that agree to use a single IRB. Some suggested that before issuing a broad policy, the NIH should pilot and evaluate a narrower use of single IRBs and provide appropriate resources to support the participating awardees. Others suggested that the NIH should fund research on existing central IRB models to evaluate potential benefits and costs before mandating single IRB review. A few commenters raised concerns about the timing of the policy in relation to the revisions of the Common Rule, stating their preference that the NIH not adopt a single IRB policy until Common Rule revisions have been finalized. However, other commenters praised the NIH for addressing the single IRB issue in the absence of an updated Common Rule. Finally, a few commenters discussed how the policy could be harmonized with other federal policies. One commenter recommended that the Office for Human Research Protections (OHRP) in the Department of Health and Human Services (HHS) provide guidance to support the policy's stance on duplicative IRB review.

Stakeholders from academic institutions were concerned that the membership of any given sIRB would not be able to achieve the level of local support for a particular research study or its acceptability in terms of all the participating sites' institutional commitments and regulations, applicable laws, and standards of professional conduct and practice. Some commenters contended that only a local IRB is able to understand the specific protections required for a vulnerable population that comprises their research participant base. Some suggested that site-specific practices for recruitment and retention, especially for vulnerable populations, would pose challenges for an sIRB. A number of commenters stated that their institutional IRBs are in the best position to know and understand competencies of and potential conflicts of interest of specific investigators. Others stressed the importance of the relationship between an investigator and the local IRB and noted that IRB members can serve as mentors to investigators whose protocols they oversee.

Some commenters asserted that the proposed policy does not recognize the time and effort needed to identify and establish a single IRB of record, including negotiating and executing authorization agreements and standard operating procedures, conducting study initiation meetings, creating account activities, and modifying information technology (IT) systems. They suggested that the policy would result in the formation of hundreds of different "single IRBs of record" with which institutions and investigators will need to interact. Some questioned whether an sIRB would be equipped to ensure local compliance at a relying institution and expressed the concern that a compliance problem for an sIRB would lead to compliance actions against the sites relying on that sIRB. Several commenters who supported the use of sIRBs recommended that rather than having

participating sites identify a single IRB for each protocol, the NIH should establish a central IRB to review all multi-site research studies, akin to the National Cancer Institute's Central Institutional Review Board (CIRB). They suggested that this approach would create an even "playing field" for every institution, big or small, regardless of whether their own IRB has the resources to act as a single IRB of record.

Many commenters, regardless of whether or not they supported the proposed policy, noted that over the past several decades, the IRB's role has been expanded to include functions that go beyond ethical review of proposed research. For example, IRBs are often responsible for reviewing compliance with institutional policies, such as conflict of interest and investigator training. Commenters in favor of the proposed policy thought that greater use of sIRBs would help to return sIRB review to its primary mission of ensuring appropriate protections for human subjects rather than protecting the institution from legal liability or damage to its reputation. They also suggested that when institutions rely on a single IRB of record for multi-site research studies, IRB responsibilities are clearer, which helps institutions to develop policies and to provide resources beyond IRB review (e.g., human research protections experts) to facilitate compliance with the institutional human research protections program. Some commenters opposed to the proposed Policy suggested that the ancillary responsibilities of IRBs are so intertwined with the research oversight responsibilities that using a sIRB would disrupt the existing system of "checks and balances" at institutions. They also argued that the opportunity for the IRB to recommend protocol changes for reasons unrelated to ethical review (e.g., scientific improvements, changes to study design) would be lost.

Many commenters, regardless of whether they supported or opposed the proposed policy, made a number of specific practical suggestions about implementation. These are summarized below.

Applicability
Most commenters supported a broad application of the policy to all studies involving the same protocol carried out at multiple sites in the U.S. These stakeholders stated that use of a single IRB of record for all types of studies and populations and study arrangements would encourage standardization of clinical research protocols and more effective implementation of protocols and protocol amendments. In contrast, a number of commenters suggested that the NIH should narrow the application of the policy or phase it in over time. Ideas about how the applicability of the policy should be narrowed were wide-ranging. Some stakeholders suggested that the level of risk should be a consideration in whether the policy should apply, with some pointing to minimal risk research and others to research involving more than minimal risk as being more appropriate for single IRB review. Others suggested that the policy should apply only to multi-site studies that involve a large number of sites (e.g., greater than 10); only to research involving clinical trials; only to studies carried out within established cooperative groups; or only to lengthy studies requiring an extended period of IRB oversight, e.g., three years or more. Some commenters suggested that the applicability of the policy remain broad, but that it be phased in over time.

Exceptions
The draft policy proposed exceptions only if the designated single IRB of record is unable to meet the needs of specific populations or where local IRB review is required by federal, tribal, or state laws or regulations. Most commenters agreed that there was a need to allow for exceptions to the ues of a single IRB. There were a number of comments calling for additional exceptions to those proposed in the policy. Commenters who generally supported the proposed policy stated that exceptions should be very limited. Some were concerned that a determination that the sIRB would be unable to meet the needs of specific populations was an overly subjective criterion or that institutions would routinely request exceptions asserting that the needs of specific populations could only be met by local IRBs. Tribal Nation commenters pointed to the importance of firsthand knowledge of local tribal customs, cultural values, and tribal sensitivities and supported exceptions to address those needs and also as a way of respecting tribal sovereignty. Other commenters said that the policy should allow for situational exceptions, depending on the types and complexity of studies and study teams, types and numbers of involved institutions, resources available for the sIRB (including IT resources), available resources for investigators, accreditation status of the human research protection program, or when study sites have concerns regarding the constitution of the designated reviewing IRB, that IRBs' experience reviewing a particular type of research was inadequate, or if relying on the single IRB would affect the institutional IRB's

accreditation status.

Assuring Consideration of Local Context
Commenters were divided about the extent to which individual sites' local contexts would present a challenge for an sIRB. Some commenters suggested that in today's highly interconnected world, local contexts would not be unique or different enough to affect the review of research protocols. Others suggested that local context does vary, not only from state to state and community to community, but even among institutions serving the same community.

Commenters identified a number of capabilities that the sIRB would need to have in order to be effective, and one comment identified four such capabilities:

- Knowledge of state law and local standards relevant to human subject research, e.g., age of majority and assent laws, mandatory reporting, data security, and awareness of differences in laws that would affect research conducted at sites in multiple states.
- Systems and procedures for collecting information from participating sites in order to ascertain whether the research could feasibly be carried out at the site. The sIRB would need to consider the number of competing studies underway, limits to participant pools, and whether the site had the capabilities and resources to execute research studies. Resources for consideration would include space, equipment, drug/device storage, handling, and dispensing, data storage capacities, and personnel, needed to support the research. Institutional capabilities would include policies on issues such as confidentiality, contraception, compensation for injury, or contacts who can answer research subjects' questions.
- Mechanisms in place to assess the experience and qualifications of site investigators and study staff, including whether they are in good standing with state board and other licensing authorities and have a good record of compliance with all laws and regulations. Other factors to be considered in this assessment would include financial conflicts of interest, research workload, and training in research ethics and the responsible conduct of research.
- Mechanisms for obtaining supplemental information when research would involve sensitive topics or when research would require the participation of discrete and insular communities. In some cases, the sIRB might need community-related information and demographic data including, but not limited to, race/ethnicity, religious affiliation, and language.

Selection of the IRB of Record
A number of commenters called on NIH to establish criteria or a minimum set of requirements to assist in the selection of the sIRB, as well as a need for criteria for an sIRB to use in its evaluation of participating sites. One commenter suggested that NIH's Policy should require the applicant, offeror, or intramural investigator to justify their proposed sIRB. Since the NIH funding Institute or Center (IC) must approve the sIRB, one commenter suggested that NIH describe the criteria to be used in making a determination that the proposed sIRB is acceptable.

Some commenters offered specific suggestions for sIRB evaluation criteria. Suggestions for evaluation criteria included the following:

- Evidence of a commitment to the highest ethical standards and ability to meet rigorous standards for quality and protection of research participants, e.g., through accreditation or assessment of policies, procedures, and practices;
- Ability to meet regulatory requirements;
- Well-established track record of compliance and performing high quality reviews, e.g., no regulatory errors or failures to address Common Rule regulatory requirements or Food and Drug Administration regulations;
- Appropriate expertise and experience to review the proposed research and the capacity to review the study protocol and participating sites;
- Recognition of the importance of building trust across all sites;
- Capacity to develop and maintain the respect and trust of the research participants and the communities in which the research is performed;

- Willingness and ability to serve as a Privacy Board to fulfill the requirements of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule for use or disclosure of protected health information for research;
- Adherence to communication standards and a commitment to transparency through sharing information about the review process, e.g., meeting minutes, approval status;
- Adequate institutional infrastructure and support, and evidence of quality and robustness of the institution's human research protection program;
- Sufficient staff to handle communications between all sites for initial review, continuing review, adverse events, amendments, etc.;
- Available interoperable information technology resources to facilitate communication and exchange of information between the participating institutions;
- Sufficient resources to negotiate and track authorization agreements;
- Ability to account for the IRB costs for review and management and how those costs will be met;
- Adequate processes in place and administrative support to handle additional review responsibilities;
- Adequate processes in place and administrative support to handle additional review responsibilities;

Defining IRB and Institutional Responsibilities
Many commenters pointed out the importance of defining the sIRB's role and scope of responsibility in relation to the responsibilities of the participating research sites. These commenters noted that responsibilities of IRBs defined by the 45 CFR 46 often constitute only one part of institutions' overall human research protections program. Commenters called on the NIH to establish a common approach to the division of responsibilities by providing model authorization agreements or even a uniform agreement that should be used in all cases. In addition to helping ensure a well-functioning review process, clear roles and responsibilities would, some suggested, also help mitigate concerns about added liability that an sIRB might assume.

A range of views were expressed relating to responsibilities that would be assumed by the sIRB and those that would remain with participating sites. Some commenters suggested that in addition to fulfilling the requirements set out in 45 CFR 46, i.e., conducting initial and continuing reviews of protocols, amendments, unanticipated problems, protocol deviations, and required regulatory IRB reporting, sIRBs should adopt some of the responsibilities that are frequently delegated to local IRBs, in particular, acting as a privacy board for all sites. One commenter noted that systems would be required to ensure that duplicative reviews are not conducted by the sIRB and local IRBs, and several commenters expressed concerns about the difficulty of coordinating required sIRB reviews with additional reviews that are not required by regulation, such as reviews for conflict of interest, investigator qualifications, and scientific merit. Some of these commenters questioned how sIRB reviews required by the HHS regulations should be coordinated with other required reviews that may have been delegated to the local IRB. These commenters noted that many institutions have established systems and standard operating procedures for coordinating local IRB review with other required reviews, such as institutional biosafety reviews, radiation safety reviews, pharmacy reviews, reviews required by state or local laws, post-approval monitoring and for-cause auditing purposes, and research billing. One commenter suggested that sIRBs should not be responsible for adverse event reporting. Another commenter suggested that sIRBs should be responsible for maintaining databases of relevant state laws. In addition, a small number of commenters indicated that the regulations of other Common Rule agencies, FDA in particular, may create contradictory requirements, and called for clarification and a more unified approach.

Several commenters stated that coordinating these additional reviews with sIRB reviews would limit the gains in efficiency realized from reliance on an sIRB. One commenter recommended that the NIH develop a template IRB authorization agreement and guidelines to define the institutional obligations that are distinct from the IRB review responsibilities. Another commenter recommended that the NIH publish guidance delineating the specific regulatory requirements for which the sIRB would be responsible, shared responsibilities, and responsibilities that an sIRB could negotiate with IRBs at participating sites.

Resources and Funding
Several commenters described the proposed policy as an unfunded mandate, or stated that it would result in a shifting of expenses from one institution to another. Many commenters expressed the concern that if costs

associated with using a single IRB are taken from a participating institution's indirect costs, there would be insufficient funds for the local Human Research Protection Program (HRPP) that still has institutional oversight responsibilities, even if the IRB of record is external. Most commenters with experience using a single IRB of record for multi-site research studies recommended that indirect costs remain unchanged for relying institutions in order to ensure that the human research protections infrastructure are available for institutional responsibilities, e.g., post-approval compliance monitoring, conflict of interest reviews. Many commenters noted funding sIRBs through indirect costs would divert funds required to conduct research and serve as a disincentive to conducting multisite research. The majority of commenters stated a preference for including the additional costs associated with a single IRB review in the study budget as direct cost, although one commenter stated a preference that sIRB review be included as an indirect cost in order to maximize the amount of funding available for research.
Several commenters stated that the costs and resources needed to establish sIRBs were not addressed by the proposed policy. Infrastructure needs noted by these commenters included additional staff and/or staff time to perform sIRB-related activities, costs to create or adapt electronic managements systems that are interoperable with outside institutions, and the time and cost of developing communication tools to link investigators to IRBs outside their institution. Other commenters familiar with the operations and use of sIRBs noted that while initial financial support from the NIH may be required to establish or expand the capacity of some IRBs to serve as the IRB of record, most sIRBs should be able to become self-supporting eventually.

Commenters had questions about whether plans for single IRB review would be required in grant applications and how plans would be reviewed.

Need for Implementation Guidance
A number of commenters pointed out how important it would be for the NIH to provide practical guidance to facilitate the implementation of the policy, with some commenters stating that, in the absence of such guidance, burden and costs would only shift between institutions rather than adding efficiency to the IRB process. A few commenters noted that this guidance could be developed using the experiences of IRBs that have already implemented centralized IRB review processes.

In addition to general requests for implementation guidance, a number of commenters made specific guidance suggestions. These suggestions included the need for guidance covering:

- The specific criteria to use for evaluation of IRBs of record when selecting a single IRB for a multisite study;
- The process for determining roles and responsibilities of the sIRB versus IRBs of participating research sites and a standard authorization agreement template that specifies these roles and responsibilities. One commenter recommended that this guidance clearly define who is responsible for ensuring investigator compliance, while another recommended that this guidance cover review of modifications to approved research, addition of research sites, and other post- approval monitoring issues including the relationship between the IRB and a data monitoring committee (such as a data and safety monitoring board). A number of commenters asked the NIH to provide guidance about liability as part of this guidance;
- Processes for local IRBs working with an sIRB, including what types of reviews will be performed by the local IRB (radiation safety review, pharmacy review, conflicts of interest) and best practices for maintaining oversight of research reviewed and approved by a non-institutional IRB. Additionally, one commenter requested that NIH encourage and provide guidance for institutional review of the impact the sIRB will have on the institution's HRPP business goals, policies, accreditation status, tracking and management processes;
- Consent forms, including the process of consent approval by the sIRB and participating sites, and whether and how local institutions could alter an sIRB informed consent document to fit local needs;
- Plans to ensure quality and processes for institutions relying on an sIRB to question or appeal sIRB decisions, and to address and resolve issues arising from duplicate reviews.

In addition, commenters requested:

- Guidance and tools to enable sIRBs to consider local context issues. Specific guidance was requested on

the process by which sIRBs would collect local information (e.g., through a standard form or through an ad hoc member or consultant with local context knowledge), and what types of information should be provided to sIRBs (e.g., how to apply state and local laws). One commenter also recommended that the NIH develop a set of guidelines for how the sIRB would apply local standards, knowledge of institutional policies, institutional capacity issues, investigator and study staff qualifications, and local community and subject considerations to their reviews;
- An explanation of costs associated with development and maintenance of sIRBs and guidance on how the use of an sIRB should be proposed at the grant level, including a fee structure to help investigators incorporate sIRB review into their budgets;
- A more detailed description of the standards for permitting exceptions for sIRB review;
- A description of what resources, if any, NIH would make available to assist in training IRBs and researchers regarding single IRB review.
- Some of the commenters who requested guidance recommended that any NIH guidance on sIRBs be released along with or prior to the issuance of the final Policy.

Implementation of the Policy

In developing the final policy set out below, the NIH carefully considered the many thoughtful comments we received on the Draft NIH Policy on the Use of a Single Institutional Review Board (IRB) for Multi-Site Research (NOT-OD-15-026). While we found no compelling reason to narrow the essential scope of the final policy—it will cover all domestic sites of NIH-funded non-exempt multi-site studies as was proposed—we have clarified the policy intent and modified several provisions. The final policy is intended to apply only to studies where the same research protocol is being conducted at more than one site; it does not apply to studies that involve more than one site but the sites have different roles in carrying out the research. Applicants/offerors will be expected to submit a plan identifying the sIRB that will serve as the IRB of record for all study sites. It will be the responsibility of the applicant/offeror to assure that the sIRB is qualified to serve; the applicant's plan will not be evaluated in peer review. The additional costs associated with sIRB review may be charged to grants or contracts as direct costs, provided that such costs are well-justified and consistently treated as either direct or indirect costs according to applicable cost principles in the NIH Grants Policy Statement and the FAR 31.202 (Direct Costs) and FAR 31.203 (Indirect Costs). Exceptions to the policy will be granted, as was proposed, if the use of an sIRB is prohibited by federal, state, or tribal laws or regulations. We will also grant exceptions where the federal, state, or tribal prohibition on the use of an sIRB is established by policy, and we will consider granting an exception if a request is made and a compelling justification provided for why an exception is needed. Such justifications could be for reasons other than that the sIRB is unable to meet the needs of a specific population, as was proposed in the draft policy. The final policy also clarifies that multi-site studies within ongoing, non-competing awards will not be expected to comply with the policy until a competing renewal application is submitted.

The NIH recognizes that the policy will begin a paradigm shift in IRB review. As such, the final policy will not take effect until May 25, 2017. In the interim, the NIH will issue guidance and provide resources to assist awardees in adapting to the shift.

Guidance on how costs associated with sIRBs may be charged as direct versus indirect costs can be found in Guide Notice NOT-OD-16-109 Other guidance materials will be issued before the policy's effective date and posted along with the policy on the following site: http://osp.od.nih.gov/office-clinical-research-and-bioethics-policy/clinical-research-policy/models-irb-review. Among other topics, the guidance will address:

- How costs associated with sIRBs may be charged as direct versus indirect costs;
- Considerations in the selection of the sIRB;
- The content of the sIRB plan that must be submitted with applications and proposals;
- Process for applicants/offerors to submit a request for an exception and process for NIH review of the request for exception;
- Roles and responsibilities of the sIRB and participating sites;
- Model authorization agreement that lays out the roles and responsibilities of each signatory;
- Models for gathering and evaluating information from all the reliant sites about community attitudes and

the acceptability of proposed research;
- A model communication plan that identifies when and which documents are to be completed and shared with those involved so each may fulfill their responsibilities.

Finally, while the NIH anticipates that that there will be challenges associated with implementation, we expect these to be short-lived. Once the transition to the new way of operating is made, the benefits of widespread use of sIRBs will outweigh any costs and, ultimately, reduce burdens to the research process. At the same time, the NIH will also closely monitor the implementation of the policy, consider its impact on research such as improvements in time to initiation of research and reduction of unnecessary burden, and be vigilant about any diminution in the protection of human subjects.
National Institutes of Health Policy on the Use of a Single Institutional Review Board for Multi-Site Research

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

Purpose
The National Institutes of Health (NIH) Policy on the Use of a Single Institutional Review Board of Record for Multi-Site Research establishes the expectation that all sites participating in multi-site studies involving non-exempt human subjects research funded by the National Institutes of Health (NIH) will use a single Institutional Review Board (sIRB) to conduct the ethical review required by the Department of Health and Human Services regulations for the Protection of Human Subjects at 45 CFR Part 46. This policy, which is consistent with 45 CFR Part 46.114, is intended to enhance and streamline the process of IRB review and reduce inefficiencies so that research can proceed as expeditiously as possible without compromising ethical principles and protections for human research participants.

Scope and Applicability
This policy applies to the domestic sites of NIH-funded multi-site studies where each site will conduct the same protocol involving non-exempt human subjects research, whether supported through grants, cooperative agreements, contracts, or the NIH Intramural Research Program. It does not apply to career development, research training or fellowship awards.

This policy applies to domestic awardees and participating domestic sites. Foreign sites participating in NIH-funded, multi-site studies will not be expected to follow this policy.

Consistent with the Roles and Responsibilities section, applicants/offerors will be expected to include a plan for the use of an sIRB in the applications/proposals they submit to the NIH. The NIH's acceptance of the submitted plan will be incorporated as a term and condition in the Notice of Award or in the Contract Award. This policy also applies to the NIH Intramural Research Program.

Definitions
The **Authorization Agreement**, which is also called a reliance agreement, is the agreement that documents respective authorities, roles, responsibilities, and communication between an institution/organization providing the ethical review and a participating site relying on the sIRB.

A **multi-site study** uses the same protocol to conduct non-exempt human subjects research at more than one site.

Participating site in a multi-site study is a domestic entity that will rely on the sIRB to carry out the site's IRB review of human subjects research for the multi-site study.

sIRB is the selected IRB of record that conducts the ethical review for participating sites of the multi-site study.

Roles and Responsibilities
Applicant/Offeror. In the application/proposal for research funding, the applicant/offeror is expected to submit a plan describing the use of an sIRB that will be selected to serve as the IRB of record for all study sites. The plan should include a statement confirming that participating sites will adhere to the sIRB Policy and describe

how communications between sites and sIRB will be handled. If, in delayed-onset research, an sIRB has not yet been identified, applications/proposals should include a statement that awardees will follow this Policy and communicate plans to use a registered IRB of record to the funding NIH Institute/Center prior to initiating a multi-site study. The applicant/offeror may request direct cost funding for the additional costs associated with the establishment and review of the multi-site study by the sIRB, with appropriate justification; all such costs must be reasonable and consistent with cost principles, as described in the NIH Grants Policy Statement and the Federal Acquisition Regulation (FAR) 31.302 (Direct Costs) and FAR 31.203 (Indirect Costs).

Awardees. Awardees are responsible for ensuring that authorization agreements are in place; copies of authorization agreements and other necessary documentation should be maintained in order to document compliance with this policy, as needed. As appropriate, awardees are responsible for ensuring that a mechanism for communication between the sIRB and participating sites is established. Awardees may delegate the tasks associated with these responsibilities.

Funding Institute or Center (IC). Funding ICs are responsible for management and oversight of the award, including communicating with the awardee regarding the implementation of its proposed plan to comply with the sIRB Policy. In the event that questions arise about the awardee's plan, including the IRB that has been selected to serve as the sIRB, the funding IC will work with the awardee to resolve them.

sIRB. The sIRB is responsible for conducting the ethical review of NIH-funded multi-site studies for participating sites. The sIRB will be expected to carry out the regulatory requirements as specified under the HHS regulations at 45 CFR Part 46. In reviewing multi-site research protocols, the sIRB may serve as a Privacy Board, as applicable, to fulfill the requirements of the HIPAA Privacy Rule for use or disclosure of protected health information for research purposes. The sIRB will collaborate with the awardee to establish a mechanism for communication between the sIRB and the participating sites.

Participating Site. All sites participating in a multi-site study are expected to rely on an sIRB to carry out the functions that are required for institutional compliance with IRB review set forth in the HHS regulations at 45 CFR 46. Participating sites are responsible for meeting other regulatory obligations, such as obtaining informed consent, overseeing the implementation of the approved protocol, and reporting unanticipated problems and study progress to the sIRB. Participating sites must communicate relevant information necessary for the sIRB to consider local context issues and state/local regulatory requirements during its deliberations. Participating sites are expected to rely on the sIRB to satisfy the regulatory requirements relevant to the ethical review. Although IRB ethical review at a participating site would be counter to the intent and goal of this policy, the policy does not prohibit any participating site from duplicating the sIRB. However, if this approach is taken, NIH funds may not be used to pay for the cost of the duplicate review.

Exceptions

Exceptions to this policy will be made where review by the proposed sIRB would be prohibited by a federal, tribal, or state law, regulation, or policy. Requests for exceptions that are not based on a legal, regulatory, or policy requirement will be considered if there is a compelling justification for the exception. The NIH will determine whether to grant an exception following an assessment of the need.

Effective Date

This policy applies to all competing grant applications (new, renewal, revision, or resubmission) with receipt dates on or after May 25, 2017. Ongoing, non-competing awards will not be expected to comply with this policy until the grantee submits a competing renewal application. For contracts, the policy applies to all solicitations issued on or after May 25,, 2017. For the intramural program, the policy applies to intramural multi-site studies submitted for initial review after May 25, 2017.

Inquiries

Please direct all inquiries to:

NIH Office of Science Policy

Telephone: 301-496-9838
Email: SingleIRBPolicy@mail.nih.gov

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices

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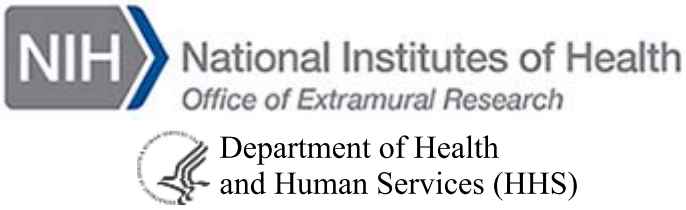

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Note: For help accessing PDF, RTF, MS Word, Excel, PowerPoint, Audio or Video files, see Help Downloading Files.

Modification of 'No-Cost Extension' and 'Carryover of Funds' Policies for the NIH Pathway to Independence Award (Parent K99/R00)

Notice Number: NOT-OD-16-092

Key Dates
Release Date: June 21, 2016

Related Announcements
PA-16-193

Issued by
National Institutes of Health (NIH)

Purpose

The purpose of this Notice is to modify policies for "No-cost Extensions" and "Carryover of Funds" under the NIH Pathway to Independence Award (Parent K99/R00).

K99 Phase of the Pathway to Independence Award (K99/R00)
Generally the K99 phase is for 2 years; however, award recipients may transition earlier than 2 years when the recipient has been offered an acceptable position. It is expected that K99 awardees will receive at least 12 months of career development support from the award before transitioning to the R00 phase. If an applicant achieves independence prior to initiating the K99 phase, neither the K99 nor the R00 phase will be awarded. Recipients are advised to contact the awarding Institute or Center if early transition is being considered. In all cases, early transition is considered a prior approval request and therefore subject to the approval of the NIH awarding Institute or Center.

No-Cost Extension: Since the K99 and R00 phases are awarded independently, a no-cost extension may be allowed should additional time be needed to complete the goals of the K99 phase. However, no-cost extensions for K99 awards are not automatic and require prior approval by the NIH. All terms and conditions of the K99/R00 award (including minimum effort requirements) remain in effect when the grant is in a no-cost extension. In requesting a no-cost extension, K99 awardees wishing to continue to seek a tenure-track or equivalent position should submit a plan for continued career development and a timely transition to an independent position. If an application for the R00 Phase with a suitable position is not submitted within the one-year period of the no-cost extension, the R00 will not be awarded. Those not continuing to seek to transition to the R00 will be permitted to extend without additional funds, in order to permit an orderly phase-out of the project.

Carryover of Funds: Carryover from the K99 phase to the R00 phase may be allowed provided the K99 phase was funded by extramural support. The K99 recipient should consult with the awarding IC as to its practices regarding carryover.

Inquiries

Please direct all inquiries to:

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

Reviewer Guidance on Rigor and Transparency: Research Project Grant and Mentored Career Development Applications

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The goal of this initiative is enhancing reproducibility of research through rigor and transparency in the four areas below. Assessment of these factors has always been implicit in peer review but now is formalized in the stated review criteria. NIH recently updated instructions and review criteria for research grant (NOT-OD-16-011) and mentored career development award (NOT-OD-16-012) applications submitted for due dates of January 25, 2016 and beyond. Implementation of rigor and transparency has been postponed for individual fellowship, institutional career development, and institutional training grant applications.

- **Scientific Premise:** The key data introduced by the applicant to justify the project.
  - The applicant should supply a sufficient evaluation of the strengths and weaknesses of the data or other justification used to support the application, and should describe how the proposed research will address any weaknesses or gaps. NIH will not prescribe a "formula" for addressing scientific premise, although it may involve assessing the other three elements below.
  - Scientific premise will be addressed in peer review as part of the Significance criterion for research grant applications and as part of the Research Plan criterion for mentored career development award applications. This extends the existing review criteria to include a retrospective assessment of the foundation for the project.
  - You should factor a weak premise or the failure to address scientific premise adequately, into your criterion score and overall impact score. The page limit is not an acceptable excuse for an applicant to not address scientific premise.

- **Scientific Rigor:** The strict application of the scientific method to ensure robust and unbiased experimental design, methodology, analysis, interpretation and reporting of results.
  - Whereas scientific premise pertains to supporting data, scientific rigor pertains to the proposed research (statistical procedures, data analysis, precision, subject inclusions and exclusion criteria, etc.). Different research fields may have different standards or best practices for scientific rigor.
  - Rigor will be assessed in peer review as part of the Approach criterion for research grant applications and as part of the Research Plan criterion for mentored career development award applications.

	Scientific Premise	Scientific Rigor
Pertains to:	Supporting data	Proposed research
Review Criterion – Research Grants	Significance	Approach
Review Criterion – Mentored Career Development Grants	Research Plan	Research Plan

- **Consideration of Relevant Biological Variables:** critical factors affecting health or disease in vertebrate animals or human subjects
  - The NIH Policy applies broadly to all relevant biological variables, for example sex, age, source, weight, and genetic strain.
  - Consideration of sex as a biological variable (SABV) is required for studies involving human subjects or vertebrate animals. Both SABV and inclusion need to be addressed in the respective sections of the application, and can affect the Approach (or Research Plan) criterion score and the overall impact score. Reviewers will assess information according to the section where it is included in the application.
    - Justification should be provided if the application proposes to study one sex, for example in the case of a sex-specific condition of phenomenon (e.g., ovarian or prostate cancer), acutely scare resources (e.g., non-human primates), or sex-specific hypotheses possible due to known differences between males and females.
    - Cost and absence of known sex differences are inadequate justifications for not addressing SABV.
  - Other biological variables deemed to be relevant by the applicant will be considered in the application and reviewers will comment on the adequacy of plans to address them.

- **Plan for Resource Authentication:** key biological and/or chemical resources are those that may differ from lab to lab or over time, could influence the research data, and are integral to the proposed research.
  - Examples include cell lines, specialty chemicals, antibodies, and other biologics, not standard laboratory reagents.
  - The plan should be brief (one page or less for the entire plan), and should not include authentication data. The plan may reflect existing guidelines for some resources or the need for a community to develop a plan for other resources.
  - Review of this attachment will occur after scoring; comments on key resource authentication should not affect scores. Reviewers will comment on the adequacy of the plan for key resource authentication; comments can be addressed by the applicant prior to award for meritorious applications.

Not all activity codes are included in the rigor and transparency initiative. Therefore, reviewers need to follow the correct review criteria and use the appropriate and current critique template for each application. Your Scientific Review Officer (SRO) should provide or direct you to the appropriate templates and guidance.

Page limits have not changed. SROs and reviewers will need to be alert for over-stuffed applications.

You may submit your comments/questions about the NIH policy to reproducibility@nih.gov.

OVERVIEW: RESEARCH PROJECT GRANT (RPG) APPLICATIONS

Element of Rigor and Transparency	Section of Application	Criterion Score	Additional Review Consideration	Contribute to Overall Impact Score?
Scientific Premise	Research Strategy	Significance	NA	Yes
Scientific Rigor	Research Strategy	Approach	NA	Yes
Consideration of Relevant Biological Variables, such as Sex	Research Strategy	Approach	NA	Yes
Authentication of Key Biological and/or Chemical Resources	New Attachment	NA	Yes	No

OVERVIEW: MENTORED CAREER DEVELOPMENT AWARD (K) APPLICATIONS

Element of Rigor and Transparency	Section of Application	Criterion Score	Additional Review Consideration	Contribute to Overall Impact Score?
Scientific Premise	Research Strategy	Research Plan	NA	Yes
Scientific Rigor	Research Strategy	Research Plan	NA	Yes
Consideration of Relevant Biological Variables, such as Sex	Research Strategy	Research Plan	NA	Yes
Authentication of Key Biological and/or Chemical Resources	New Attachment	NA	Yes	No

References

- Nature Perspectives: "A call for transparent reporting to optimize the predictive value of preclinical research" Landis, et al., 10/10/2012
- Nature Commentary: "Policy: NIH plans to enhance reproducibility" Collins & Tabak, 01/27/2014
- Nature Commentary: "Policy: NIH to balance sex in cell and animal studies" Clayton & Collins, 05/14/2014
- Science Editorial: "Journals Unite for Reproducibility" 11/07/2014
- Science Perspectives: "Fixing problems with cell lines" Lorsch, Collins & Lippincott-Schwartz, 12/19/2014
- FASEB Journal Life Sciences Forums: "Studying both sexes: a guiding principle for biomedicine" Clayton 10/29/2015

ACRONYMS AND TERMS USED TODAY
OSP RA Update - 06/27/2016

ACRONYM/TERM	DESCRIPTION
CCTS	Center for Clinical & Translational Sciences
CSR	Center for Scientific Review
DHHS	Department of Health & Human Services
eSDFI	Electronic Summary Disclosure of Financial Interests form
FCOI	Financial Conflict of Interest
IRB	Institutional Review Board
K99	NIH Career Transition Award
NIH	National Institutes of Health
NOT	A Notice (Guide Notice) is an official NIH announcement relating to a change in policy, procedure, form, or system. Notices are posted on the NIH website and users can be notified via a variety of NIH listservs. You can search for notices and funding opportunities at the NIH Guide.
NRSA	National Research Service Awards
OSP	Office of Sponsored Programs
PHS	Public Health Service
R00	NIH Research Transition Award
RPG	Research Project Grants
SDFI	Summary Disclosure of Financial Interests (SDFI) form. Used by UMMS to disclose signficant financial interests on a proposal/project basis.
sIRB	Single Institutional Review Board
VAS	Vertebrate Animals Section