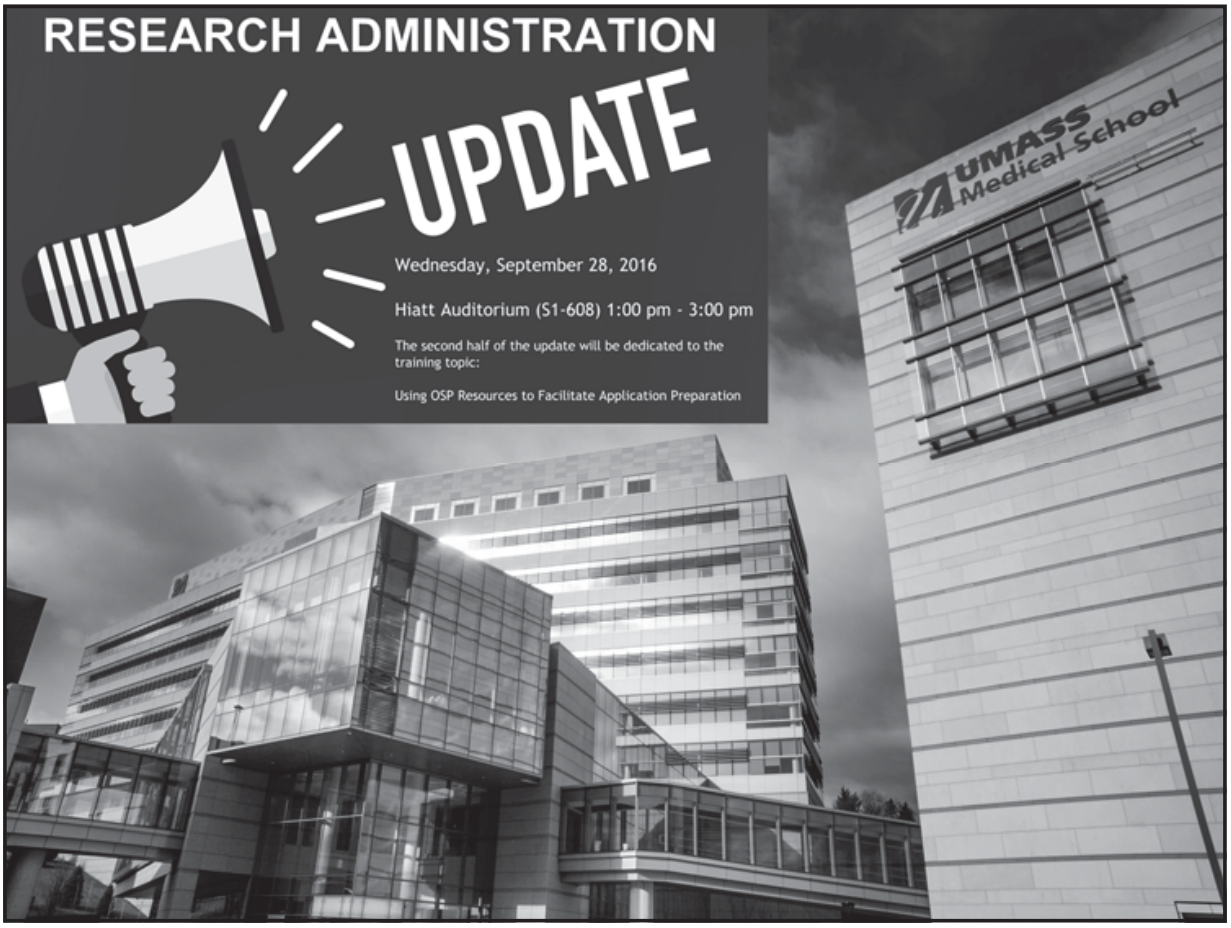

Agenda

University of Massachusetts UMASS Medical School

- HHS Final Rule on Clinical Trials.gov – Terry Sousa, CCTS
- FCOI Retraining Requirement
- eSDFI Form Update
- NIH Update
  - NIH Loan Repayment Program (LRP)
  - Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research NOT-OD-16-094
  - Change of Eligibility Period in the NIH Continuous Submission Policy for Reviewers with Recent Substantial Service NOT-OD-16-121
  - New Policy Eliminates Most Appendix Material for NIH/AHRQ/NIOSH Applications Submitted for Due Dates On or After January 25, 2017 NOT-OD-16-129
  - Changes to the NIH/AHRQ Policy on Post-Submission Materials for Applications Submitted for Due Dates On or After January 25, 2017 NOT-OD-16-130
  - Projected FY 2017 Stipend Levels for Postdoctoral Trainees and Fellows on Ruth L. Kirschstein National Research Service Awards (NRSA) NOT-OD-16-134 & NOT-OD-16-134
  - Optional Electronic Method to Request Withdrawal of Applications from Consideration for Funding NOT-OD-16-143
- Proposal & Progress Report Statistics

HHS Final Rule Clinicaltrials.gov

Terry Sousa
UMass Medical School
PRS Administrator for Clinicaltrials.gov

What is ClinicalTrials.gov?

- National registry of federally and privately supported research studies

Why register and report results?

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- Because it's the law
- Federally mandated
- Required by FDA for IND/IDE trials
- Promotes transparency to the public about clinical trials
- Beneficial to the research community
  - Assists in enrollment
  - Upholds research integrity by tracking protocol changes
- The NIH has approved a policy to ensure that every clinical trial that receives NIH dollars is registered on ClinicalTrials.gov.
- CMS requires registration in order to cover claims from qualifying clinical trials.

And another reason…

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- **The International Committee of Medical Journal Editors (ICMJE)**
  - Established a requirement that all clinical trials be entered in a public registry as a condition of consideration for publication in a journal.

US Department HHS Issues Final Rule

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- Announced September 16, 2016
- Effective date: January 18, 2017
- Purpose:
  - increase the availability of information to the public about clinical trials via ClinicalTrials.gov
  - aim to help ensure that information about clinical trials and their results are made publicly available in a timely manner.

When do I register?

University of Massachusetts Medical School

- When to register
  - FDAAA 801: No later than 21 days after the first participant is enrolled
  - NIH: same as above
  - ICMJE: before the first participant is enrolled

Which studies do I register? Final Rule

University of Massachusetts Medical School

- FDAAA 801
- Applicable Clinical Trials
  - Interventional studies of drugs, biologics & devices
  - Not Phase 1 (drugs/biologics), not small feasibility (devices)
  - US FDA jurisdiction (e.g., IND/IDE or US site)
  - Applicable clinical trials initiated on or after 9/27/07 or if initiated after 09/27/07, "ongoing" as of 12/26/07

What should be registered?: Final Rule NIH Policy

University of Massachusetts Medical School

- What should be registered?:
  - Applies to *all* clinical trials funded in whole or in part by NIH, regardless of study phase, or type of intervention,
  - Applies to all other trials funded by NIH, including phase 1 trials of drug and biological products and small feasibility studies of device products.
  - Includes trials that do not involve any FDA regulated product such as trials involving only behavioral interventions.
- Although the policy does not apply to NIH-funded clinical trials initiated before the effective date, the NIH *encourages* all ongoing NIH-funded clinical trials to follow it.

Who is required to register and submit results?

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- Responsible Party
  - Sponsor [Industry, agency or investigator initiated]
  - Sponsor may designate the Principal Investigator (PI) [only one per trial]
  - Principal Investigator may designate a staff member to do the data entry

Applying for an account

University of Massachusetts Medical School

- Send an email to: teresa.sousa@umassmed.edu
- Organizational account for UMass Medical School. An account must be created in order to access PRS
  - Individual accounts are linked to the "*UMass*" account
  - Only PRS Administrators can create user accounts
  - Applicant must provide current email address and phone
- Accounts can be modified and deactivated
  - Contact information should be updated on a regular basis
  - Passwords can be reset by the PRS Administrators
  - If PI's leave, I need to know.

When to report results?

University of Massachusetts Medical School

- When to Report Results? Within 12 months of Primary Completion Date (final data collection for primary outcome(s)).
  - the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the pre-specified protocol or was terminated.

When to report results? Cont'd

University of Massachusetts Medical School

- What's new?
  - Results must be submitted regardless of whether the drug, biological, or device products under study have been approved, licensed or cleared for marketing by the FDA.
- Publishing? If you think you can publish within the timeframe, best to prepare both at the same time. Otherwise, post results first, then publish, then update the results in CT.gov so they align.
  - Delays are possible under limited circumstances. **Pending publication is NOT considered a good cause for delay**

Non applicable trials results reporting

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- Trials not subject to FDAAA are not required to report results. In order to clarify in the database that the trial is not subject to FDAAA, go to the trial's registration record and answer "No" to the data element (field) "Section 801 Clinical Trial?". Answering "no" documents that the trial is not subject to FDAAA and not out of compliance.

NIH Results Reporting

University of Massachusetts Medical School

- What's new?
- NIH now *requires* results reporting for all NIH supported clinical trials registered in ClinicalTrials.gov, regardless of whether or not they are required to do so under FDAAA.

Penalties for not registering

- NIH Enforcement Provisions
  - Public notices of noncompliance
  - Withholding NIH and other federal grant funds for current and future studies
- FDAAA Enforcement Provisions
  - Public notices of noncompliance
  - Civil monetary penalties (up to $10,000 per day)

FAQ

- My study is not yet approved by a human subjects review board (ethics review committee, institutional review board). Can I register it on ClinicalTrials.gov?
  - Yes
  - Register the study as “Not Yet Recruiting”
  - When IRB approval is obtained, change status to “Recruiting”

FAQ

University of Massachusetts Medical School

- Why can't I find my study on ClinicalTrials.gov?
  - Did you “release” it?
  - The study might also be undergoing review
  - Updates to record take a few days to review
  - Results can take up to 30 days to review

FAQ

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- When will the NCT identifier for my study be assigned?
  - Assigned after the protocol information has been Released (submitted) by the Responsible Party and passed review by ClinicalTrials.gov staff
  - The record and NCT identifier will available on ClinicalTrials.gov within 2–5 business days after it is Released

FAQ

University of Massachusetts Medical School

- Can I register a study after it has started, has closed to recruitment, or has been completed?
  - Yes, you can register a study on ClinicalTrials.gov at any time.
  - Remember, to be compliant with FDAAA, the study must be registered 21 days after first subject has been enrolled and…
  - ICMJE required registration prior to enrollment of first subject

FAQ

University of Massachusetts Medical School

- How do I contact ClinicalTrials.gov if I have a question about my study record?
  - register@clinicaltrials.gov
  - Provide them with the NCT identifier or unique protocol ID if the NCT has not been assigned yet

Links

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- Final Rule Summary: https://www.nih.gov/news-events/summary-hhs-nih-initiatives-enhance-availability-clinical-trial-information
- Definitions of a Applicable Clinical Trial: https://prsinfo.clinicaltrials.gov/ElaborationsOnDefinitions.pdf
- Clinical trial registration and results submission requirements: Information for NIH Grantees: https://grants.nih.gov/ClinicalTrials_fdaaa/index.htm
- Information about registering a study at UMass Medical School http://www.umassmed.edu/ccts/human-research/clinical-research-resources/guidance-for-investigators/

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Questions?

FCOI Training Requirement

- Per regulatory requirement each Investigator must complete training at least every four years.
- UMMS Investigators that completed the training in 2012 will need to retake the training again 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.

eSDFI Form Update

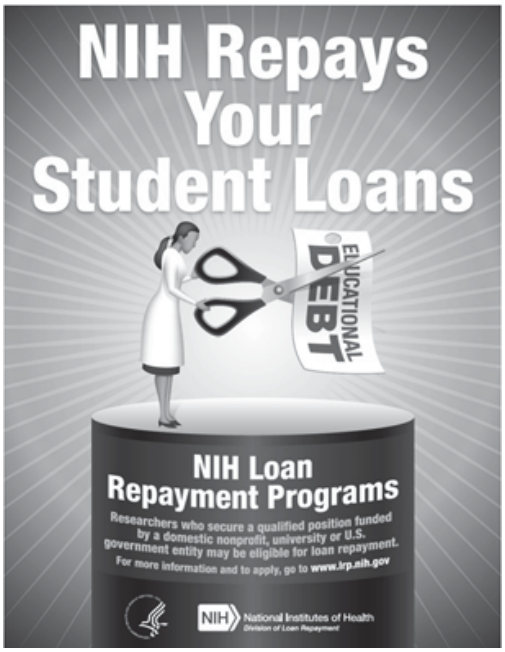
- The Adobe Sign software built into the eSDFI form has a total limit of 25 signatures per form.
- In the rare instance where a project has more than 25 disclosing individuals we recommend they be split between two separate eSDFI forms and that the PeopleSoft Project ID field note that there are multiple forms for the project (e.g., “Form 1/2”).

NIH Loan Repayment Programs (LRPs)

University of Massachusetts Medical School

Summary

- **Up to $35k/year in educational loan repayment**
  - **Depending on debt level**
- **Coverage of most Federal taxes resulting from the NIH LRP**
- **2 year initial contracts**
  - **1 or 2 year competitive renewal**
- **Approximately 1,600 researchers funded yearly**
- **50% application success rate**



NIH LRP email sent out to UMMS community on 9/16/16. Application cycle closes 11/15/16.

https://www.lrp.nih.gov/apply

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 is working with the UMMS IRB and Center for Clinical & Translational Sciences (CCTS) to implement internal processes that comply with the new policy.

NOT-OD-16-121: Change of Eligibility Period in the NIH Continuous Submission Policy for Reviewers with Recent Substantial Service

University of Massachusetts Medical School

- This Notice announces the lengthening of the window of time during which peer reviewers who have served six times in eighteen months can submit their applications under the NIH Continuous Submission Policy.
- Eligibility now begins on August 1 following the eighteen month service window and continues through September 30 of the next year.

NOT-OD-16-129: New Policy Eliminates Most Appendix Material for NIH/AHRQ/NIOSH Applications Submitted for Due Dates On or After January 25, 2017

University of Massachusetts Medical School

- This Notice alerts the scientific research community of plans to eliminate most appendix materials for applications submitted to the NIH, AHRQ or NIOSH for due dates on or after January 25, 2017.
- Application instructions will be updated by November 25, 2016 to reflect this change.
- The Notice also clarifies:
  - Status of appendix materials in peer review, allowable appendix materials and consequences for submitting disallowed appendix materials
- Please review the full Notice in the Appendix to this presentation to ensure you are aware of the allowed and disallowed appendix materials.
- Consequences for submitting disallowed appendix materials:
  - Applications submitted for due dates on or after January 25, 2017 will be withdrawn and not reviewed if they are submitted with appendix materials that are not specifically listed in this Notice or the FOA as allowed or required.

NOT-OD-16-130: Changes to the NIH/AHRQ/NIOSH Policy on Post-Submission Materials for Applications Submitted for Due Dates On or After January 25, 2017

University of Massachusetts Medical School

- This Notice simplifies and consolidates current NIH and AHRQ policy concerning post-submission materials, and extends this policy to NIOSH.
- Post-submission application materials are those submitted after submission of the grant application but prior to the initial peer review. The policy is based on the principle that, for the majority of applications, the only post-submission materials that these agencies will accept are those resulting from an unforeseen event.
- The policy on post-submission application materials is not intended to correct oversights/errors discovered after submission of the application.
- Please refer to the attached Notice in the Appendix to this presentation for the full list of allowable post-submission materials and requirements for how to submit the materials.

NOT-OD-16-134: Projected FY 2017 Stipend Levels for Postdoctoral Trainees and Fellows on Ruth L. Kirschstein National Research Service Awards (NRSA)

University of Massachusetts Medical School

- The purpose of this Notice is to announce projected stipend levels for postdoctoral trainees and fellows supported by Kirschstein-NRSA awards in Fiscal Year (FY) 2017.
- These projected new stipend levels are planned to be effective December 1, 2016. The projected new stipend levels reflect recognition of the significant contributions of postdoctoral researchers to the NIH, AHRQ, and HRSA missions, and also align with the spirit of the U.S. Department of Labor's (DOL) recently issued revisions to the rules on paid overtime under the Fair Labor Standards Act (FLSA).
- The exact stipend levels and the actual date of implementation are subject to the availability of FY 2017 appropriations and implementation of the new FLSA threshold for professional workers to be eligible for paid overtime.

Projected Postdoctoral Stipend levels for FY2017

Career Level	Years of Experience	Actual Stipend for FY 2016	Projected Stipend for FY 2017	Monthly Stipend
Postdoctoral	0	$43,692	$47,484	$3,957
	1	$45,444	$47,844	$3,987
	2	$47,268	$48,216	$4,018
	3	$49,152	$50,316	$4,193
	4	$51,120	$52,140	$4,345
	5	$53,160	$54,228	$4,519
	6	$55,296	$56,400	$4,700
	7 or More	$57,504	$58,560	$4,880

NOT-OD-16-143: Optional Electronic Method to Request Withdrawal of Applications from Consideration for Funding

University of Massachusetts Medical School

- Applications submitted to the NIH can be rejected by the Authorized Organization Representative (AOR), usually the Signing Official (SO), during the two business day viewing window that follows application submission. After that time, the submission process is complete, and an application must be withdrawn in order to remove it from review and consideration for funding.
- Applicant organizations are now able to submit requests to withdraw a processed application after the two day viewing window has passed using the eRA Commons Prior Approval module. The request can be submitted electronically by an AOR/SO from within the Electronic Research Administration's (eRA) Commons, navigating from the Prior Approval tab on the landing page.
- The Center for Scientific Review's Division of Receipt and Referral (DRR) will review and act on all withdrawal requests. Applicants can follow the status of their application in the eRA Commons. Applicants will see a status of "Withdrawn" if DRR approves the withdrawal request. In addition, the AOR/SO will be able to track all requests for their organization in the "Search for Request" screen.
- Submission of application withdrawal requests through the eRA Commons is optional. Applicant organizations may still withdraw applications by contacting DRR directly: a letter with ink signature from the AOR/SO may be sent via e-mail attachment to the e-mail address listed below.

PROPOSAL SUBMISSIONS TO OSP
August 2015 – August 2016

University of Massachusetts Medical School

	August 2015	September 2015	October 2015	November 2015	December 2015	January 2016	February 2016	March 2016	April 2016	May 2016	June 2016	July 2016	August 2016
Count	62	112	129	60	67	107	121	89	72	101	106	78	86
On Time	47%	52%	43%	37%	42%	59%	38%	45%	29%	57%	40%	44%	44%
Late	52%	43%	56%	60%	54%	39%	60%	55%	70%	39%	59%	56%	50%
After the fact	2%	5%	1%	3%	4%	2%	2%	0%	1%	4%	1%	0%	6%
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)	39%	31%	39%	40%	33%	25%	46%	42%	44%	21%	36%	42%	35%

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

SUBMISSIONS TO OSP
August 2015 to August 2016 Comparison

University of Massachusetts Medical School

PROPOSALS	2015	2016	Change
Count	62	86	+14
On Time	47%	44%	-3
Late	52%	50%	-2
After the fact	2%	6%	-4
Withdrawn	0%	0%	-
Total	**100%**	**100%**	-
Expedited Request (3 days or less)	39%	35%	-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.
Expedited Request: Received by OSP with 3 business days or less to review before requested return date.

PROGRESS REPORT SUBMISSIONS TO OSP
August 2015 – August 2016

University of Massachusetts Medical School

	August 2015	September 2015	October 2015	November 2015	December 2015	January 2016	February 2016	March 2016	April 2016	May 2016	June 2016	July 2016	August 2016
Count	11	19	30	19	26	36	44	71	58	43	50	25	17
On Time	27%	37%	43%	26%	42%	64%	48%	58%	64%	49%	52%	60%	41%
Late	46%	47%	40%	63%	50%	22%	45%	39%	36%	51%	42%	28%	41%
After the fact	27%	16%	17%	11%	8%	14%	7%	3%	0%	0%	6%	12%	18%
Total	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
Expedited Request (3 days or less)	36%	26%	20%	58%	42%	19%	30%	27%	26%	37%	36%	16%	35%

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

SUBMISSIONS TO OSP
August 2015 to August 2016 Comparison

University of Massachusetts Medical School

PROGRESS REPORTS	2015	2016	Change
Count	11	17	+6
On Time	27%	41%	+14
Late	46%	41%	-5
After the fact	27%	18%	-9
Withdrawn	0%	0%	-
Total	**100%**	**100%**	-
Expedited Request (3 days or less)	36%	35%	-1

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

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.
- Today we are presenting the first training topic:
  - Using OSP Resources to Facilitate Application Preparation

APPENDIX

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

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, (https://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

National Institutes of Health
Office of Extramural Research

Department of Health
and Human Services (HHS)

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

Change of Eligibility Period in the NIH Continuous Submission Policy for Reviewers with Recent Substantial Service

Notice Number: NOT-OD-16-121

Key Dates
Release Date: July 26, 2016

Related Announcements
NOT-OD-09-155
NOT-OD-11-093

Issued by
National Institutes of Health (NIH)

Purpose

This Notice announces the lengthening of the window of time during which peer reviewers who have served six times in eighteen months ("Recent Substantial Service" as defined in NOT-OD-09-155) can submit their applications under the NIH Continuous Submission Policy: Eligibility now begins on August 1 following the eighteen month service window and continues through September 30 of the next year.

Inquiries

Frequently Asked Questions and answers have been prepared (see https://grants.nih.gov/grants/peer/faq_continuous_submission.htm). Any remaining issues/appeals may be directed to a NIH Continuous Submission Committee by emailing CSR.cont.sub.comm@csr.nih.gov

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices

New Policy Eliminates Most Appendix Material for NIH/AHRQ/NIOSH Applications Submitted for Due Dates On or After January 25, 2017

Notice Number: NOT-OD-16-129

Key Dates
Release Date: August 12, 2016

Related Announcements
NOT-OD-16-130
NOT-OD-11-064
NOT-OD-11-080

Issued by
National Institutes of Health (NIH))
Agency for Healthcare Research and Quality (AHRQ)
National Institute for Occupational Safety and Health (NIOSH)

Purpose

This Notice alerts the scientific research community of plans to eliminate most appendix materials for applications submitted to the NIH, AHRQ or NIOSH for due dates on or after January 25, 2017. Application instructions will be updated by November 25, 2016 to reflect this change.

The Notice also clarifies:

- Status of appendix materials in peer review
- Allowable appendix materials
- Consequences for submitting disallowed appendix materials

The NIH, AHRQ, and NIOSH strive to ensure fairness in peer review for all grant applicants by specifying the types and amount of application material that are accepted for peer review. At the same time, these agencies appreciate both the need for applications to provide sufficient information to allow for an informed, expert review process and the importance of limiting the burden on peer reviewers.

Elimination of most appendix materials is intended to rectify inequities in the peer review process that can arise from submission of inappropriate or excessive appendix materials by some applicants and consideration of appendix materials in peer review by some, but not all reviewers.

Policy

Appendix materials in peer review
All information submitted with an application except the cover letter, assignment request form and appendix information are assembled into a single application image for funding consideration. The different sections within the application image are specified in the application instructions and correspond to the standard review criteria.

Therefore:

- All information required for the peer review process must be contained within those designated sections of the application image, unless the Funding Opportunity Announcement (FOA) specifies otherwise.
- Information that expands upon or complements information provided in any section of the application -- even if it is not required for the review -- is not allowed in the appendix unless it is listed in the allowed appendix materials (below). (NOT-OD-11-080)

- Unless the FOA *requires* that certain information be included in the appendix, failure of reviewers to address appendix materials in their reviews is not an acceptable basis for an appeal of initial peer review (NOT-OD-11-064).

Allowable appendix materials
Beginning with applications submitted to the NIH, AHRQ, or NIOSH for due dates on or after January 25, 2017, the only allowable appendix materials are:

- *For applications proposing clinical trials (unless the FOA provides other instructions for these materials)*:
- Clinical trial protocols
- Investigator's brochure from Investigational New Drug (IND), as appropriate

- *For all applications:*
- Blank informed consent/assent forms
- Blank surveys, questionnaires, data collection instruments
- FOA-specified items.
    - If appendix materials are *required* in the FOA, review criteria for that FOA will address those materials, and applications submitted without those appendix materials will be considered incomplete and will not be reviewed.

Consequences for submitting disallowed appendix materials
Applications submitted for due dates on or after January 25, 2017 will be withdrawn and not reviewed if they are submitted with appendix materials that are not specifically listed in this Notice or the FOA as allowed or required.

Inquiries

Please direct all inquiries to:

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

Sally A. Amero, Ph.D.
NIH Review Policy Officer
Email: ReviewPolicyOfficer@mail.nih.gov

Francis D. Chesley, Jr., M.D.
Director, Office of Extramural Research, Education, and Priority Populations
Agency for Healthcare Research and Quality
Telephone: 301-427-1521
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Viji Potula, Ph.D.
Office of Extramural Programs
National Institute for Occupational Safety and Health
Centers for Disease Control and Prevention
Telephone: 404-498-2551
Email: VPotula@cdc.gov

Changes to the NIH/AHRQ/NIOSH Policy on Post-Submission Materials for Applications Submitted for Due Dates On or After January 25, 2017

Notice Number: NOT-OD-16-130

Key Dates
Release Date: August 12, 2016
Implementation Date: Applications submitted for the January 25, 2017 due date and thereafter.

Related Announcements
NOT-OD-16-129
NOT-OD-12-111
NOT-OD-12-141

Issued by
National Institutes of Health (NIH)
Agency for Healthcare Research and Quality (AHRQ)
National Institute for Occupational Safety and Health (NIOSH)

Purpose

This Notice simplifies and consolidates current NIH and AHRQ policy concerning post-submission materials, and extends this policy to NIOSH. Post-submission application materials are those submitted after submission of the grant application but prior to the initial peer review. The policy is based on the principle that, for the majority of applications, the only post-submission materials that these agencies will accept are those resulting from an unforeseen event. The policy on post-submission application materials is not intended to correct oversights/errors discovered after submission of the application.

Policy

Allowable Post-Submission Materials for All Applications

- Revised budget page(s) (e.g., due to new funding or institutional acquisition of equipment)
- Biographical sketches (e.g., due to the hiring, replacement, or loss of an investigator)
- Letters of support or collaboration due to the hiring, replacement or loss of an investigator
- Adjustments resulting from natural disasters (e.g., loss of an animal colony)
- Adjustments resulting from change of institution [e.g., Program Director/Principal Investigator (PD/PI) moves to another university]
- News of professional promotion or positive tenure decision for any PD/PI or Senior/Key Personnel
- Approval by the NIH Stem Cell Registry of a human embryonic cell line(s) after submission of the application (see NOT-OD-12-111)
- Videos, within defined limits, that demonstrate devices and experimental data with a temporal element, which refers to the need to show how something functions or occurs over time, or demonstrates movement or change. Applicants must follow the directions in NOT-OD-12-141 for submitting videos to accompany grant applications
- Other post-submission materials specified in the FOA for which the application was submitted or in a special Guide Notice.
- **News of an article accepted for publication since submission of the application,** which must include *only*:
    - List of authors and institutional affiliations
    - Title of the article
    - Journal or citation (if available)

Copies of articles, links to articles, or any other materials related to an article accepted for publication will not be accepted as post-submission materials, unless specified in the Funding Opportunity Announcement (FOA) for which the application was submitted or a special Guide Notice.

Additional Materials for Certain Applications

Institutional Training and Training-related Grants (e.g., T32, T34, T35, T90, TU2, T15, D43, K12, KM1, UR2): in addition to the materials for All Applications above, news - since the training grant application was submitted - of:

- a trainee's or former trainee's graduation, employment, promotion, funding, or publications;
- a faculty member's promotion, funding, or publications; and
- the addition or removal of any faculty member who will be involved in the training program (mentors or senior/key persons).

Individual Fellowship (F-Series) and Individual Career Development Award (K-series) Applications: in addition to the materials for All Applications listed above:

- New information on the Sponsor/Mentor funding, limited to the project title, funding source (e.g., NIH/AHRQ/NIOSH grant number), a brief description of specific aims, and relevance to the fellowship or career development application under review.
- News of change in Mentor(s) or other Senior/Key Persons specified in the original application.

Applications submitted to Requests for Applications (RFAs): the same post-submission materials as other applications (see "All Applications" above), for all due dates in the RFA.

Conference Grant Applications (R13, U13): a one-page explanation of all speakers who accepted invitations to participate in the proposed conference after the application was submitted, plus a one-page explanation of all speakers who declined such invitations after the application was submitted. Alternatively the PD/PI may consider submitting a one-page explanation for each plenary slot on the agenda.

Any other types of post-submission materials are not likely to be accepted.

Requirements for Submitting Post-Submission Materials

All post-submission materials must conform to NIH/AHRQ/NIOSH policies on font size, margins, and paper size as referenced in the applicable application instructions.

- Any specified formats (e.g., budgets, biographical sketches) and page limits referenced in the applicable application instructions apply.
- If post-submission material is not required on a specific format page and does not have a specified page limit, each explanation or letter is limited to one page.
- If the application has multiple components (subprojects or cores), each subproject or core is allowed explanations or letters, but each explanation or letter is limited to one page.

Post-submission materials must be received by the NIH, AHRQ, or NIOSH Scientific Review Officer (SRO) no later than 30 calendar days prior to the peer review meeting. Post-submission materials will not be accepted if fewer than 30 calendar days remain before the peer review meeting, unless specifically stated otherwise in the FOA for which the application was submitted or in a special Guide Notice.

Concurrence from the Authorized Organization Representative (AOR) of the applicant organization is required. Although the post-submission materials may originate from the PD/PI, Contact PD/PI, or organizational officials, the AOR must send the materials directly to the SRO or must send his/her concurrence to the PD/PI

who will forward the materials and concurrence to the SRO. A communication from the PD/PI only or with a "cc" to the AOR will not be accepted.

Post-submission materials **can only** be submitted as a PDF attachment. The SRO is responsible for uploading acceptable materials into the official electronic grant file maintained in the eRA Commons. The PD/PI can check his/her application via the Commons to see these materials in the section titled "Additions for Review". This procedure provides the information to reviewers in a secure manner.

Inquiries

Please direct all inquiries to:

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

Sally A. Amero, Ph.D.
NIH Review Policy Officer
ReviewPolicyOfficer@mail.nih.gov

Francis D. Chesley, Jr., M.D.
Director, Office of Extramural Research, Education, and Priority Populations
Agency for Healthcare Research and Quality
Telephone: 301-427-1521
Email: Francis.Chesley@ahrq.hhs.gov

Viji Potula, Ph.D.
Office of Extramural Programs
National Institute for Occupational Safety and Health
Centers for Disease Control and Prevention
Telephone: 404-498-2551
Email: VPotula@cdc.gov

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices

Revised: Projected FY 2017 Stipend Levels for Postdoctoral Trainees and Fellows on Ruth L. Kirschstein National Research Service Awards (NRSA)

Notice Number: NOT-OD-16-134

Key Dates
Release Date: August 10, 2016

Related Announcements
NOT-OD-16-131 - Rescinded
NOT-OD-16-062

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

Purpose

This Notice revises NOT-OD-16-131 to correct an error in the effective date. The purpose of this Notice is to announce projected stipend levels for *postdoctoral trainees and fellows* supported by Kirschstein-NRSA awards in Fiscal Year (FY) 2017.

These projected new stipend levels are planned to be effective December 1, 2016. The projected new stipend levels reflect recognition of the significant contributions of postdoctoral researchers to the NIH, AHRQ, and HRSA missions, and also align with the spirit of the U.S. Department of Labor's (DOL) recently issued revisions to the rules on paid overtime under the Fair Labor Standards Act (FLSA).

The exact stipend levels and the actual date of implementation are subject to the availability of FY 2017 appropriations and implementation of the new FLSA threshold for professional workers to be eligible for paid overtime.

Projected Postdoctoral Stipend levels for FY2017

Career Level	Years of Experience	Actual Stipend for FY 2016	Projected Stipend for FY 2017	Monthly Stipend
Postdoctoral	0	$43,692	$47,484	$3,957
	1	$45,444	$47,844	$3,987
	2	$47,268	$48,216	$4,018
	3	$49,152	$50,316	$4,193
	4	$51,120	$52,140	$4,345
	5	$53,160	$54,228	$4,519
	6	$55,296	$56,400	$4,700
	7 or More	$57,504	$58,560	$4,880

Background
The new FLSA paid overtime rule sets a salary level of $47,476 for professional employees to be exempt from paid overtime.

Current NRSA stipend levels at years 0, 1 and 2 years of postdoctoral experience are below $47,476.
Many universities, teaching hospitals, and other institutions that employ postdoctoral researchers use the NRSA

stipend levels as a guide to set the salary or compensation levels for postdoctoral researchers funded on research project grants and grants other than the NRSA.

These institutions may choose to carefully track their employed postdoctoral researchers' hours and pay overtime, or raise their salaries to levels above the new FLSA threshold and thereby qualify them for exemption from paid overtime.

NIH is fully supportive of increased pay for postdoctoral researchers and has proposed to increase the NRSA postdoctoral stipends to levels above the threshold: http://www.huffingtonpost.com/francis-s-collins-md-phd/fair-pay-for-postdocs-why_b_10011066.html.

Stakeholders at many extramural institutions have requested information about projected NRSA stipends for FY 2017 to assist with planning for future postdoctoral researcher payscales.

This Notice is therefore provided to assist the extramural community in their planning.

It is important to note that the projected FY 2017 stipends listed here and the implementation date are still to be finalized.

Relevant NIH Policies
For institutional training grants (T32, T90, TL1) and individual fellowships (F32), the stipend level for the entire first year of support is determined by the number of full years of relevant postdoctoral experience when the award is issued. Relevant experience may include research experience (including industrial), teaching, internship, residency, clinical duties, or other time spent in a health-related field beyond that of the qualifying doctoral degree.

Kirschstein-NRSA support for postdoctoral research training is limited to three years. The presence of eight discrete levels of experience does not constitute an endorsement of extended periods of postdoctoral research training. The NIH, HRSA and AHRQ provide eight postdoctoral stipend levels to accommodate individuals who complete other forms of health-related training prior to accepting a Kirschstein-NRSA supported position for research training.

Additional guidance on NRSA stipend levels and implementation dates will be communicated in the coming months.

Inquiries

Please direct all inquiries to:

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

Additional Information
Note that the interpretation and implementation of the FLSA and the DOL overtime regulations are under the authority of the DOL and the courts. While NIH plans to raise its NRSA stipends for consistency with spirit of the DOL's support for increased pay, as reflected in its recent revisions to the overtime regulations, the NIH takes no position on the applicability of the overtime regulations to a particular worker supported by NIH grants. Institutions should consult their own counsel and/or local Department of Labor office about the applicability of the overtime regulations and for information on overtime obligations.

Optional Electronic Method to Request Withdrawal of Applications from Consideration for Funding

Notice Number: NOT-OD-16-143

Key Dates
Release Date: September 8, 2016

Related Announcements
None

Issued by
National Institutes of Health (NIH)

Purpose

Applications submitted to the NIH can be rejected by the Authorized Organization Representative (AOR), usually the Signing Official (SO), during the two business day viewing window that follows application submission. After that time, the submission process is complete, and an application must be withdrawn in order to remove it from review and consideration for funding.

Applicant organizations are now able to submit requests to withdraw a processed application after the two day viewing window has passed using the eRA Commons Prior Approval module. The request can be submitted electronically by an AOR/SO from within the Electronic Research Administration's (eRA) Commons, navigating from the Prior Approval tab on the landing page.

The Center for Scientific Review's Division of Receipt and Referral (DRR) will review and act on all withdrawal requests. Applicants can follow the status of their application in the eRA Commons. Applicants will see a status of "Withdrawn" if DRR approves the withdrawal request. In addition, the AOR/SO will be able to track all requests for their organization in the "Search for Request" screen.

Submission of application withdrawal requests through the eRA Commons is optional. Applicant organizations may still withdraw applications by contacting DRR directly: a letter with ink signature from the AOR/SO may be sent via e-mail attachment to the e-mail address listed below.

Instructions for how to use this new system can be found in the Prior Approval User Guide.

Inquiries

Please direct all process-related inquiries to:

Division of Receipt and Referral
Center for Scientific Review
Telephone: 301-435-0715
Email: CSRDRR@mail.nih.gov

Please direct all technical-related inquiries to:

eRA Service Desk
Telephone: 1-866-504-9552

ACRONYMS AND TERMS USED TODAY
OSP RA Update - 09/28/2016

ACRONYM/TERM	DESCRIPTION
AHRQ	Agency for Health Care Research & Quality
AOR	Authorized Organizational Representative (in eRA Commons)
CCTS	Center for Clinical & Translational Sciences
DHHS (aka HHS & USDHHS)	Department of Health & Human Services
DRR	Division of Receipt and Referral (NIH)
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.
eSDFI	Electronic Summary Disclosure of Financial Interests form
FCOI	Financial Conflict of Interest
FDA	Food & Drug Administration
FDAAA	Food & Drug Administration Amendments Act
ICMJE	International Committee of Medical Journal Editors
IDE	investigational device exemption
IND	Investigational New Drug Application
IRB	Institutional Review Board
LRP	NIH's Loan Repayment Program
NCT	National Clinical Trial (identifier)
NIH	National Institutes of Health
NIOSH	National Institute for Occupational Safety and 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
sIRB	Single Institutional Review Board
SO	Signing Official (in eRA Commons)
SUMMIT	SUMMIT is the UMass Medical School's web based reporting tool.