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University of Hawaii System
Office of Research Services



Aloha from *Insight*:
The monthly news letter for the UH Office of Research Services for 2016.

National Institutes of Health (NIH) Policy on the Use of a Single Institutional Review Board (sIRB) for Multi-Site Research

The National Institutes of Health (NIH) has issued a new policy to streamline the review process for NIH-funded, multi-site clinical research studies in the United States. The [NIH Policy on the Use of a Single Institutional Review Board \(IRB\) for Multi-Site Research](#) sets the expectation that multi-site studies conducting the same protocol use a single IRB to carry out the ethical review of the proposed research.

What types of studies are expected to use a single IRB (sIRB) under the new NIH Policy?

The sIRB 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. Under the policy, "multi-site" is defined as two or more sites. Foreign sites participating in NIH-funded, multi-site studies will not be expected to follow this policy. The policy recognizes that it may not always be possible to use an sIRB, and it provides for exceptions.

When does the sIRB policy take effect?

The sIRB policy applies to all competing grant applications (new, renewal, revision, or resubmission) with receipt dates on or after May 25, 2017, all contract solicitation issued on or after May 25, 2017, and all NIH Intramural studies submitted for initial IRB review after May 25, 2017.

Who is responsible for selecting the sIRB and when must this be done?

In the application/proposal for research funding, the applicant/offeror is expected to submit a plan describing the use of an sIRB that would be selected to serve as the IRB of record for all study sites. Where possible, the plan would include the registration number issued to the IRB by the HHS Office for Human Research Protections. For delayed-onset research, where the IRB cannot be identified, applications/proposals should include a statement that awardees will follow the sIRB policy and communicate plans to use a registered IRB of record to the funding NIH Institute/Center prior to initiating a multi-site protocol.

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What is the role of the human subjects protections programs at a site that is part of a multi-site trial but not the site of the sIRB?

Except for the IRB review described in HHS regulations (45 CFR 46), human subjects protections programs at participating sites will be responsible for meeting all of their current responsibilities. Participating sites are also 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.

Where can I find more information on the NIH sIRB policy?

More information about the NIH sIRB policy may be found on the OSP Website. NIH will continue to provide additional resources and guidance to this page prior to the implementation date. Additionally, questions about the sIRB policy may be sent to SingleIRBPolicy@mail.nih.gov.

On July 25, 2016, the National Science Foundation (NSF) will release updates to FASTLANE that may impact how you prepare your NSF proposal.

As part of NSF's efforts to reduce the workload associated with manually compliance checking proposals, NSF continues to focus on implementing automated proposal compliance checks. The next series of automated proposal compliance checks will be released in FASTLANE on July 25, 2016 to ensure that proposals submitted in response to the **Grant Proposal Guide** (GPG), Program Descriptions, Program Solicitations, or Program Announcements, comply with requirements specified in the **Proposal & Award Policies & Procedures Guide** (Chapter II.C.2 of the GPG). The goals outlined in this release are to increase competitive fairness in the proposal process by ensuring that all required proposal elements are compliance checked in the same manner, and at the same time reduce burden on both NSF programs and the research community.

The new set of automated compliance checks will trigger warning or error messages depending on the funding opportunity type for each of the following rules:

- Biographical Sketch(es) and Current and Pending Support files are required for each Senior Personnel associated with a proposal.
- Biographical Sketch(es) can only be uploaded as a file, must not exceed two pages and can no longer be entered as text.

Note About Proposal File Update (PFU): Proposers should be aware that if a proposal was previously submitted successfully with only one Biographical Sketch and/or Current & Pending Support file (rather than individual files for each senior personnel), a PFU performed on such proposals will be prevented from submission if it does not comply with the new compliance checks.

National Science Foundation (NSF) Upgrades to FASTLANE (Continued)

The automated compliance checks apply when a PFU is performed on a proposal. The checks will be run on all sections of the proposal regardless of which section was updated during the PFU.

Warning Messages vs. Error Messages: Warning messages will not prevent a proposal from being submitted. However, proposals that receive error messages will not be able to be submitted.

Note About Grants.gov: Proposers submitting through Grants.gov should be aware that Grants.gov will allow a proposal to be submitted, even if it does not comply with these proposal preparation requirements. Should NSF receive a proposal from Grants.gov that is not compliant, it may be returned without review.

Please note that the new set of compliance checks are in addition to the compliance checks that currently exist in FASTLANE. You can view a complete list of FASTLANE auto-compliance checks, including these checks at http://www.nsf.gov/bfa/dias/policy/autocheckcompliancechecks_july16.pdf. The list specifies which checks are run depending on funding opportunity type (GPG, Program Description, Program Announcement, or Program Solicitation) and type of proposal (Research, RAPID, EAGER, Ideas Lab, Conference, Equipment, International Travel, Facility/Center, or Fellowship). It also specifies whether the check triggers a “warning” or “error” message for noncompliant proposals.

For system-related questions, you can contact the NSF Help Desk at 1-800-381-1532 or Rgov@nsf.gov.

Preparing for Annual Kuali System (KFS) Effort Certifications and Cost Sharing Effort Certifications

To comply with the requirements of the U.S. Office of Management and Budget's Uniform Guidance at 2 CFR 200.430 and support the university's system of internal controls which provides a reasonable assurance that compensation charges are accurate, allowable and properly allocated to an award, the annual KFS Effort Certifications and Cost Sharing Effort Certifications will be generated in early August 2016. The principal investigator (PI) must certify to the reasonableness of compensation that have been charged or cost shared to their projects. The fiscal administrator should assist the PIs with completing the certifications in accordance with the established deadline.

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Preparing for Annual Kualii System (KFS) Effort Certifications and Cost Sharing Effort Certifications (Continued)

Please note that separate certification processes have been developed for compensation charged to or cost shared on your award.

- For compensation charged to your award, "**KFS Effort Certifications**" will be generated from payroll recorded in the KFS Labor Ledger. EC eDocs will be created and saved in your KFS action list.
- For compensation cost shared on your award, "Cost Sharing Effort Certifications" will be generated from the cost shared payroll recorded in the KFS cost share sub-account. **However, the Cost Sharing Effort Certifications are NOT in KFS but will be accessible online with your UH username and password.**

In preparation for the creation of the annual KFS Effort Certifications and Cost Sharing Effort Certifications, please process all adjustments that impact prior year balances by **July 31, 2016**. After July 31, 2016, adjustments to prior year balances will not be accepted. For prior year Labor Ledger adjustments, Salary Transfers should be prepared and routed for approval through KFS. For prior year Cost Sharing adjustments, please refer to the accompanying newsletter article entitled "**Prior Year Cost Sharing Entry Adjustments.**"

Detailed instructions for certifying both KFS Effort Certifications and Cost Sharing Effort Certifications will be provided in August along with the release of the certifications.

For questions, please contact Dawn Kim, Compliance Manager, at dawnkim@hawaii.edu or (808) 956-0396.

Prior Fiscal Year Cost Sharing Entry Adjustment

As noted in the above newsletter article, "**Preparing for Annual Kualii Financial System (KFS) Effort Certifications and Cost Sharing Effort Certifications,**" in order for the Cost Sharing Effort Certification Report that will be generated in August 2016 to properly reflect the cost sharing for University of Hawaii (UH) employees, any cost sharing adjustments related to fiscal year (FY) 2016 UH personnel salaries and wages must be submitted to ORS by July 29, 2016.

For audit purposes, all cost sharing entries should be recorded in a timely manner. Therefore, it is requested that any other cost sharing adjustments for FY 2016 and prior are also submitted by July 29, 2016.

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Prior Fiscal Year Cost Sharing Entry Adjustment (Continued)

Please submit the following information for cost sharing adjustments for UH personnel salaries and fringe and other direct costs for FY 2016 and prior in an Excel spreadsheet:

Chart	Account	Sub-Account	Object Code	UH ID	Source Account (Chart/Account)	Cost Sharing Period (Do not combine fiscal years)	Adjustment Amount (rounded to the nearest dollar)	
							DR	CR
		CS001	7810 Salaries & Wages (7820 contra account)	Required for adjustments to 7810	Required	Required		
		CS001	7811 Fringe Benefits (7821 contra account)	Required for adjustments to 7811	Required	Required		
		CS001	7812 (Direct Costs (7822 contra account)	N/A	Required	Required		

Submit the Excel file via e-mail to Karen Matsunaga, Projects Financial Services Specialist, at klmatsu@hawaii.edu. Please use the email subject line **“Prior Year Cost Sharing Adjustments.”**

For cost sharing of external support, unrecovered indirect costs and tuition waivers, please continue to submit any adjustments via the Kualii Financial System (KFS) DI (“Distribution of Income and Expense”) e-Doc.

As described in APM A8. 947, Accounting for Cost Sharing, proper supporting documentation must be maintained for all cost sharing amounts reported. The principal investigator and project staff are responsible for providing any supporting documentation requested by sponsors and/or auditors.

For questions, please contact Suzanne Efan, Projects Financial Services Manager, at efhans@hawaii.edu or (808) 956-8163.

What is unrecovered F&A?

Unrecovered Facilities & Administrative (F&A) cost is the difference between the amount awarded and the amount which could have been awarded under the recipient's approved negotiated indirect cost rate (F&A rate).

According to OMB Circular A-110 the unrecovered indirect cost may be included as a part of cost sharing or matching only with the prior approval of the federal awarding agency.

When would I have unrecovered F&A?

Unrecovered F&A applies where any of the following apply:

- The award or sponsor's F&A rate is less than the university's standard F&A rate, which is the federally negotiated rate.
- The PI obtains a F&A cost reduction or waiver in writing from the appropriate campus chancellor or chancellor's designee.

Do you have any questions or comments for ORS?

Please contact us at the ORS Helpline:

Email: helpline@ors.hawaii.edu or Phone: (808) 956-5198