From the Director’s Office

Aloha kākou,

We would like to remind everyone on the importance for the PIs, co-PIs, and key personnel to disclose Financial Conflicts of Interest truthfully and accurately when applicable to federal funding and when the disclosure of FCOI is required (e.g., National Institutes of Health). We have seen more news headlines regarding the violation of conflict of interest with federal awards. A criminal complaint was filed against three New York based university researchers for financial conflicts of interest. Please see details in the article below.

To identify whether carryover and/or incremental funding are subject to the new Office of Management and Budget’s (OMB) Uniform Guidance (UG) on and after December 26, 2014, ORS has implemented a new process indicating whether or not UG applies in the award notice. This will help PIs and research administrators to be in compliance with the applicable OMB guidelines. In this month’s issue we also have updates to the university’s subaward process to be in compliance with the new UG. Two new forms have been added for your use in completing the subaward packet.

Also included in this issue we provide information on NIH’s new definition of “clinical trial”, foreign currency exchange rate fluctuations, and a revision to the state budget and finance policies and procedures.

ORS also has a new proposal report available on our website. For details, please see the article below.

Happy Lunar New Year!

Xīn Nián Kuài Lè!

Yaa-Yin Fong
Director
National Institutes of Health (NIH) Issues New Definition of Clinical Trial

In October 2014, National Institutes of Health (NIH) revised its definition of “clinical trial” in order to make the distinction between clinical trials and clinical research studies clearer and to enhance the precision of the information NIH collects, tracks, and reports on clinical trials. The revised definition of “clinical trial” is “A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.” The change is not intended to expand the scope of the category of clinical trials. No changes have been made to the NIH definition of a “Phase III clinical trial.” In addition, because clinical trials are subject to additional oversight, a clearer definition will help investigators ensure that they are meeting all of their obligations, and it will help NIH ensure that the additional oversight is occurring when it is needed. The revised definition will replace the current clinical trial definition in relevant extramural and intramural NIH policies, guidance, and instructional materials. It will apply to competing grant applications that are submitted to NIH for the January 25, 2015, receipt date and subsequent receipt dates and to contract proposals that are submitted to NIH on or after January 25, 2015. Please review the NIH website for further details at this link: http://osp.od.nih.gov/office-clinical-research-and-bioethics-policy/clinical-research-policy/clinical-trials.

For questions or more information, contact Emmitt Ford, Contracts and Grants Manager, Kaka’ako Service Center, at emmitt@hawaii.edu or (808) 356-5764.

Research Compliance: The Importance of Financial Conflicts of Interest Disclosures

Federal financial conflicts of interest disclosure regulations require institutions to review, at the time of proposal submission, all financial disclosures by Investigators/Key Personnel and determine whether any significant financial interest is related to (or could potentially relate to) any research/work proposed for funding.

Violations of federal financial conflict of interest regulations do make headlines and should not be taken lightly.

Summary (from the DOJ Press Release): The Federal Bureau of Investigation (“FBI”) filed charges against three researchers who worked on improving MRI technology at a university in New York, New York, but who also had undisclosed affiliations with a foreign company performing the same type of research. The research at the university was funded by a multi-million dollar federal grant from the National Institutes of Health (NIH). The defendants are each charged with one count of commercial bribery in connection with a conspiracy to receive payments from the foreign company and a foreign government-supported research institution in exchange for providing non-public information about research they conducted at the university.

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Research Compliance: The Importance of Financial Conflicts of Interest Disclosures (continued)

In financial interest disclosure (FCOI) forms that the university required the principal investigator (PI) to complete in connection with the NIH grant, the PI failed to disclose and falsely answered questions regarding the outside affiliations and financial conflicts of interest. The PI is also charged with one count of falsification of records in connection with the NIH grant, which carries a maximum sentence of 20 years in prison.

The full press release can be found at: http://1.usa.gov/1B8jK9I

Please contact Renee Harada, Compliance Specialist, with any COI-related questions at coi@ors.hawaii.edu or (808) 956-9596.

Applicability of the Office of Management and Budget's (OMB) Uniform Guidance - 2 CFR 200 (UG)

As you may be aware, the Office of Management and Budget's (OMB) Uniform Guidance (UG) went into effect on December 26, 2014. For new awards received on or after December 26, 2014, the UG applies to the entire award. For carryovers and incremental funding received on or after December 26, 2014 on awards made prior to the implementation of the UG, applicability is based on whether the federal awarding agency amends the award terms and conditions to make the UG applicable to said funding. Existing federal awards that do not receive incremental funding with revised terms and conditions will be governed by the terms and conditions of the original award.

During this transition period, ORS will indicate whether or not UG applies and the following terms will be included in the myGRANT award notice:


- The carryover and/or incremental funds* covered by this award are subject to the Office of Management and Budget's Uniform Guidance (2 CFR 200). For a summary of changes, please see http://www.ors.hawaii.edu/index.php/omb-new-guidance, and for more information on University of Hawai`i implementation, please see http://www.ors.hawaii.edu/index.php/omb-uniform-guidance-and-uh-implementation. The full text of the guidance can be found here: Electronic Code of Federal Regulations.

  *The award notice will indicate whether carryover and increment, or only carryover or incremental funding is affected.

- This award is not subject to the Office of Management and Budget's Uniform Guidance (2 CFR 200).

Should you have any questions, please contact Dawn Kim, Compliance Manager, at dawnkim@hawaii.edu or (808) 956-0396.
The Office of Management and Budget's (OMB) Uniform Guidance (UG): Updates to the University's Subaward Process

The Federal Demonstration Partnership (FDP) Subaward Agreement templates, Subrecipient Commitment Form (S-1) and the Federal Subrecipient Questionnaire (S-2) have been updated to reflect the Office of Management and Budget’s (OMB) Uniform Guidance (UG) requirements. Two new forms: Federal Subrecipient or Contractor (Vendor) (S-5) and Subaward Information Checklist (S-6) have been added for your use in completing the subaward packet. To ensure that the most current versions are being used, please access the Subrecipient Forms and Agreement Templates through the ORS Forms page at http://www.ors.hawaii.edu/index.php/apply/forms.

The university's Subaward Notice provided to the principal investigator /fiscal administrator upon execution of a subaward has also been revised to reflect the subrecipient's risk level in order to determine the appropriate subrecipient monitoring activities. Reminders for subrecipients to comply with all subaward terms and conditions and requirements to provide performance and financial information with each invoice have also been added.

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

Foreign Currency Exchange Rate Fluctuations

Sponsored agreements with foreign entities that have award terms in foreign currencies pose a risk that the amount ultimately received from the sponsor may not equal the U.S. dollar budget at the time proposal is submitted due to fluctuations in currency exchange rates. Often, there is a difference in the amount that is received as compared to the budget. Generally, payments for awards in foreign currencies are wired to the university’s bank account and may also be reduced by a bank service charge related to the wire transfer. If amounts received differ from what was expected, either based on the proposal budget or invoiced amount, the Projects Financial Services section will notify the fiscal administrator and ORS accountant assigned to the award so that any budget adjustments can be made accordingly to the project account. In order to avoid the risk related to exchange rate fluctuations, agreements should be stated in U.S. dollars whenever possible.

The Office of Management and Budget’s (OMB) Uniform Guidance (UG) provides regulations related to exchange rate fluctuations for federal awards in projects abroad. Section 200.440 of the UG allows for “cost increases for fluctuations in exchange rates” subject to availability of funding and prior approval from the sponsor. The Council of Financial Assistance Reform (COFAR) clarified that prior approval is not required each time the exchange rate changes and a federal award is charged. Approval would only be required when the change results in the need for additional funding or the increased cost results in a significant change to the scope of the project.

Should you have any questions, please contact Joanne Yama, Projects Financial Services Manager, at jyama@hawaii.edu or (808) 956-8163.
State Budget and Finance Policies and Procedures Revision – Funding Lapse

We have recently been informed that the State Budget and Finance office has revised their policies and procedures relating to use of prior year General Funds, limiting carry-over to twelve (12) months after the project end date. If you have any State of Hawaii awards consisting of general funds, please plan accordingly as funding will lapse after this time period and any requests for project period extensions after the twelve (12) month carry-over period will likely not be approved. If you have any questions or need clarification, please contact your assigned ORS Specialist (http://www.ors.hawaii.edu/index.php/ors-assignments).

New Proposal Report Available

As you may know Up-to-Date Award Reports are available on the ORS website http://www.ors.hawaii.edu/index.php/reports. What you may not have known is that we have recently added a proposal report for UH community use. The proposals provided in the report are ones that have been submitted to sponsor, not ones that are currently under developed or pending approval. Please remember that the project title is public information and provided in this report. If there are concerns about proprietary information, make sure that you do not include anything confidential as a part of the project title in myGRANT record.

The proposal report can focused down in three tiers (Campus, School, and Department) but it is not necessary to select down to the department level. If you want to see the proposals submitted by a school, select the campus, then the school and run the report. The proposals for the report are based only on the principal investigator’s (PI’s) primary unit for the proposal. Proposal reports by PI will be coming soon. We hope that this new tool becomes a valuable resource for the UH community.

For questions or more information, contact Michael Morimoto, ISS Manager, at mcmorimo@hawaii.edu or (808) 956-4908.

ORS Helpline Frequently Asked Questions

For myGRANT routing, do I need to add my Co-Investigators/Key Personnel’s department approvers on as ad-hoc approvers?

You do not to add on these extra ad-hoc approvers. The system will automatically add on the necessary approvers for Co-Investigators and they will be in parallel with the routing for the principal investigator. For Key Personnel, you have the option to add their department to the approval workflow. This is based on if the Key Person has a unit added under the “Key Personnel” tab.

You will still need to add ad-hoc approvers for financial/time commitments from other UH departments that are not already included in the routing.

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ORS Helpline Frequently Asked Questions (continued)

Can I set my own delegations for myGRANT workflow approvals?

You have the ability to set your own delegations for workflow approvals. Please note that these delegations will only apply to workflow approvals, not other tasks such as creating proposals.

To set up a delegation go to the “Help” tab in myGRANT and click on the “Delegation” icon:

Once you log in, click on the “Add a new delegation” button:

Add a new delegation

Enter the UH username, or use the “Lookup” tool to find the UH username of the person you want to add as a delegate. If this is a temporary delegation (for example, if you are going on vacation or sabbatical) you can enter the date range of when this delegation will be active, or you can leave it blank for an indefinite range. Check the box “I want to still be able to approve and get notifications” if you would still like to be included on the workflow and receive notification emails from myGRANT. If unchecked, your delegate will replace you in the workflow and you will no longer receive notifications from myGRANT.

Do you have a Question or Comment for ORS?

Please feel free to contact us at the ORS Helpline:

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