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From the Director's Office

Aloha Kākou,

As the start of the fall semester falls upon us, we'd like to welcome all new faculty and staff who will have joined the University of Hawai'i research community. In this issue of the ORS newsletter, we update you as to recent changes to the National Institutes of Health (NIH) approval requirements for projects involving human subjects.

Of particular importance this month is the implementation of new Financial Conflict of Interest (FCOI) policies relating to grants issued by the United States Public Health Service (PHS). Please take the time to review the changes to the proposal submission and account establishment procedures for PHS-funded awards.

Also, effective as of September 1, 2012, each of the ten university campuses will have its own DUNS number. Notification will be sent out to individual faculty members impacted by this change. To ensure a smooth transition to this new system and prevent proposal submission delays, we encourage principal investigators (PI) who receive this notification to contact the ORS Helpline as soon as possible to make sure PI accounts on sponsor systems are set up correctly.

This issue also contains information on recent myGRANT upgrades, updates on contract and grant invoicing and letter of credit draws for awards, and the upcoming transition from the current cost sharing system to the Kualii Financial System cost sharing process. Please see the articles below.

Welcome back to school!

Yaa-Yin Fong
Director

National Institutes of Health's (NIH) Approval Request Requirements for Changes Involving Human Subjects

The National Institutes of Health (NIH) has announced that the particular changes to human subjects research on an awarded project will necessitate a "prior approval request" to the agency. An addition

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National Institutes of Health's (NIH) Approval Request Requirements for Changes Involving Human Subject (continued)

or change to the human subjects study design or protocol may be defined as:

- Going from non-human subjects research to human subjects research (exempt or non-exempt);
- Going from exempt to non-exempt human subjects research; or
- Going from "no clinical trial" to "includes a clinical trial".

Additionally, if any of the following situations occur during the project, a prior approval request is necessary:

- New inclusion of certain subject populations – pregnant women, human fetuses, and neonates, prisoners or children;
- Any change to the study protocol that would result in an increase in risk to subjects; or
- Any new information that comes to light after a study is underway which indicates a higher risk level to participants than previously recognized.

In order to get agency approval, a formal request endorsed by the University of Hawai'i Office of Research Services to the Grants Management Officer and Program Official at NIH will be required. A prior approval request must include the following documents:

- The principal investigator's (PI) current contact information
- Documentation of the proposed changes
- A new or revised human subjects section, per NIH's competing application instructions
- New or revised Plans for Women, Minorities, and Children, if applicable
- New or revised Targeted Enrollment Table, if applicable
- New or revised Data and Safety Monitoring Plan and Board, if applicable
- Certification of education in human subjects protections; and/or
- The federal-wide Assurance Number and UH IRB approval.

Please note that if the change or addition is deemed to be a change in scope, it will require a peer review process. No changes to human subjects research may occur until the agency has approved the prior approval request.

If you have questions, please contact Jennifer Halaszyn, Kaka'ako Satellite Service Center Manager, at jhalaszy@hawaii.edu or (808) 692-1807.

University of Hawaii Implementation of United States Public Health Services (PHS) Financial Conflict of Interest (FCOI) Regulations

To comply with the United States Department of Health and Human Services (HHS) Final Rule on "Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought (42 C.F.R. § 50, Subpart F) and Responsible Prospective Contractors (45 C.F.R. § 94)" available at <http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>, the University of Hawai'i (UH) has revised Executive Policy E.5.214 entitled "Conflicts of Interest and Commitment" and created APM A5.504 "Procedures for Disclosing and Addressing Conflicts of Interest and Commitment". In order to comply with the PHS specific requirements, ORS developed APM A8.956 "Financial Conflicts of Interest (FCOI) for Public Health Services Grants, Cooperative Agreements and Contracts" and FCOI training for PHS-funded Investigators (including any Key Personnel).

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University of Hawaii Implementation of United States Public Health Services (PHS) Financial Conflict of Interest (FCOI) Regulations (continued)

Beginning **August 24, 2012**, all Investigators who apply for grants, cooperative agreements or contracts will be required to comply with the HHS Final Rule. In order to meet these new requirements, the following changes will be made to the proposal submission and account establishment procedures:

1. The questions in "UH Proposal Person Certification" tab in "Key Personnel" on myGRANT will be revised to capture this information and all Investigators will be required to respond to the following:
 - a. Certify that you have read and understand your responsibilities for disclosing any Significant Financial Interest (SFI) and potential Conflict of Interest (COI) in accordance with the UH Conflict of Interest Policy E.5.214, APM A5.504 and if the project is sponsored by PHS, APM A8.956. For a complete list of PHS Components, see <http://www.hhs.gov/about/orgchart/>.
 - b. Disclose whether you have any SFI or COI as defined above. If "no", attachments are not required. If "yes" and if the SFI or potential COI has been disclosed on the UH Annual Conflict of Interest Disclosure Form (per APM A5.504), you must attach a copy to the myGRANT Proposal Development records "Internal Attachments" tab in "Abstracts and Attachments". If information was not fully disclosed on the annual form, complete FCOI-1 (to be made available on the ORS website on the Forms page) and attach as instructed above.
2. If the proposal is sponsored by PHS, Investigators must acknowledge in the "Key Personnel", "UH Proposal Person Certification" tab in the myGRANT Proposal Development record that they will complete the ORS FCOI Investigator training prior to engaging in any PHS-funded activities. If a proposal is awarded, the PHS-funded Investigators will be reminded of their responsibility for completing the required ORS FCOI training. In addition, ORS Compliance will perform periodic reviews of training logs and may suspend project activity at any time if a PHS-funded Investigator has not completed the required training.
3. Senior Administrators (Deans, Directors, Chancellors) must review the SFI disclosures and determine whether a COI exists. Potential COIs will be forwarded to the Conflict of Interest Committee (COIC) in accordance with APM A5.504 for final determination and development of a Management Plan, if necessary. The review and Management Plan must be completed prior to the establishment of a project or advance account by ORS. For PHS-funded projects, ORS will provide a report to PHS through eRA Commons and disclose required information on the ORS website for each PHS-funded Investigator's FCOI, prior to establishing a project or advance account.

During the award period, the following may be required:

1. If an SFI is identified or obtained after the proposal has been submitted, a "Post Award Action" Proposal Development record must be created in myGRANT with the disclosures attached. ORS Compliance will review these on a weekly basis and forward SFI reports to COIC. COIC will then review the SFI and develop a Management Plan if necessary. For PHS-funded projects, ORS will update the report that was previously provided to PHS and the disclosure on the ORS website.
2. If an FCOI exists on a PHS-funded project, ORS will request an annual FCOI update from the Investigator and submit the information to PHS. This annual report is due at the same time as the annual progress or technical report. ORS will also update the public disclosure on the ORS website.

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University of Hawaii Implementation of United States Public Health Services (PHS) Financial Conflict of Interest (FCOI) Regulations (continued)

The revised E5.514 and new APMs A5.504 and A8.956 will be posted and the required training for PHS-funded Investigators will be available on LauLima on **August 24, 2012**.

For questions regarding the new FCOI requirements and procedures, please contact Dawn Kim, Compliance Manager, at dawnkim@hawaii.edu, or (808) 956-0396.

Campus-Specific DUNS Numbers

Starting September 1, 2012, the University of Hawai'i (UH) system will be moving to campus-specific DUNS numbers and providing each of its ten campuses their own DUNS number for use in proposal submission. This upcoming change will allow each of the campuses to be recognized for the level of extramural funding they bring in. ORS is trying to make this transition as seamless as possible for the UH faculty and has been able to reduce the amount of affected principal investigators (PIs) to a small number. To ensure that everything goes smoothly in the proposal submission process, ORS will notify the PIs impacted by this change and asked them to contact the ORS Helpline **as soon as possible** to ensure that individual accounts are set up to reflect the correct DUNS number in the online sponsor systems and avoid last minute rushes. The ORS Helpline can be contacted at helpline@ors.hawaii.edu.

For reference, here are the campus-specific DUNS numbers.

UH Manoa	UH Hilo	UH West Oahu	UH Maui	UH System
965088057	195738039	195737551	195736207	78495204

Hawaii CC	Honolulu CC	Kapiolani CC	Kauai CC	Leeward CC	Windward CC
195737056	195736801	195736512	195736348	195736272	195306753

myGRANT Upgrades

There have been some recent upgrades to myGRANT which affect the Proposal Development module. Here is a brief summary for your information.

1. Fringe Benefit Rates have been updated for Fiscal Year 2013 and the new rates will appear in the Rates tab within your budget. If your budget was created before the rates were updated, you can click "sync rates" to pull in the updates.
2. myGRANT has been upgraded to comply with new Grants.gov xml rules. This improves validation during Grants.gov system-to-system submissions.
3. myGRANT has been updated to allow for the submission of a National Institutes of Health proposal using the current modular budget form.

For more information, please check the myGRANT FAQ page at <http://www.ors.hawaii.edu/index.php/mygrant-faq>.

Facilities and Administrative (F&A) Cost Rate Update

Although the University of Hawai'i submitted its cost proposal to the federal government in April 2012, we are still waiting for the review to begin. In the meantime, the FY 2012 rates remain in effect as FY 2013 provisional rates from July 1, 2012 until amended, so the FY 2013 provisional rates should be used in proposals and awards until a new rate agreement is issued.

Should you have any questions, please e-mail Kevin Hanaoka, Cost Studies Manager at hanaokak@hawaii.edu.

Revised Effort Certification Process and New Cost Transfer / Cost Overrun APM

Our current monthly FTE Certifications (CBMR289) will be replaced by an electronic Effort Certification document (eDoc) in KFS. The KFS Effort Report will be generated annually and certified online. The first KFS Effort Reporting cycle will be for FY 2013 and will be generated in August 2013. Effort Reports will be routed to the principal investigator for approval, then to the appropriate fiscal authority for administrative approval. As a result of this change, it is very important to reconcile accounts and process cost transfers on a regular and timely basis. By doing this, all payroll cost transfers should be processed prior to the annual certification. Training and related APM for certifying Effort Reports in KFS will be provided post-go live.

In addition, a new APM to process cost transfers and cost overruns is being drafted. In general, accounts should be reviewed and reconciled on a regular and timely basis. Reporting tools will be developed through eThorty for use in reconciling accounts.

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

Contract and Grant Invoicing and Letter of Credit Draws

In the Kualii Financial System (KFS), billing for contract and grants utilizes the organization code entered on the account and the corresponding object code entered for the "organization income account defaults" under the menu option Maintenance/Organizational Accounting Default. The object code for contract and grant revenue is 0270, "Sponsored Grants/Contracts Revenue." KFS records the general ledger entry based on this object code and does not allow any change to the coding for the general ledger entry. Therefore, we ask that organization codes that reflect the 0270 object code under Organization Accounting Default not be revised to any other code in order to ensure that the contract and grant revenue is recorded to the proper object code.

ORS will be invoicing and requesting funds via the letter of credit draw based on the information recorded in KFS. We understand that information on salary transfer entries are forthcoming and any transfer adjustments will most likely not be completed until the end of August. Until then, if there are any significant expense adjustments necessary related to the salary expense recorded or any other expense type for your extramural account, please inform your ORS Projects Fiscal Accountant to ensure that ORS only requests reimbursement for proper expenses for the project account.

Cost Sharing Transition

We are in the process of transitioning from the current cost sharing system to the Kualii Financial System (KFS) cost sharing process. Information on the new process and training schedule are forthcoming.

In the meantime, these are the interim procedures for reporting cost sharing for awards terminating or requiring interim reporting in July or August 2012.

Fiscal authorities will be asked to annotate the June 30th report and submit to ORS Accounting as the final cost sharing report for terminating awards or as the interim report in the case of continuing awards. July or August reports do not need to be certified, however, the annotated form must be submitted to ORS Accounting section prior to the due date of any final financial reporting due to the sponsor.

If the July or August reports contain cost shared salaries for the month of July through August, these cost shared salaries and related fringe benefits are required to be entered into the KFS cost sharing account for KFS effort reporting purposes. For terminating awards only, none of the other data needs to be entered.

For your information, salary data entered into KFS cost sharing (a.k.a. cost shared effort) will be certified in conjunction with paid effort for FY 2013. Thus, we anticipate a separate certification of cost shared effort will no longer be needed going forward.

Should you have any questions, please contact Kevin Hanaoka, Cost Studies Manager, at hanaokak@hawaii.edu or at (808) 956-9242.

ORS Helpline Frequently Asked Questions

How do I register for National Science Foundation's (NSF) Fastlane?

You can register through our helpline portal:

<http://www.ors.hawaii.edu/helpline/>

I want to add more than four co-principal investigators to my cover sheet, can I do this?

NSF policy permits only one principal investigator (PI) and a maximum of four co-PIs on a proposal. However, you can add more individuals as non-co-PI Senior Personnel to a proposal.

How do I submit my proposal to ORS once I have completed it in Fastlane?

Once you log in, access the "Proposal Actions" screen. From there, select your proposal number in the list, and click the "Allow SRO Access" button. If there are any errors or missing components in your proposal, you should receive a proposal errors screen. When all errors have been corrected, you will get to the "Sponsored Research Office (SRO) Access Control" screen. Click the "GO" button next to "Allow SRO to view, edit and submit proposal." The appropriate Pre-Award specialist will be notified that your proposal is ready to submit.

Please note that you will also need to submit a *myGRANT* Proposal Development record. In the *myGRANT* record, you are required to attach the full NSF Fastlane proposal. To do this, on the "Proposal Actions" screen, click the "Print" button, then the "GO" button next to "Print Entire Proposal." This will generate a full PDF copy of your proposal, which you can then attach to the *myGRANT* record under the "Abstracts and Attachments" tab.