RAC NEWS

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www.med.ufl.edu/research/rac ctc.health.ufl.edu

REMINDERS

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HSC Roundtable Meetings

1329 Bldg., Room 4150
9:00a.m.-11:00a.m.

Thurs., Feb. 19, 2009
Thurs., Mar. 19, 2009
Thurs., April 16, 2009

CTC Ad Hoc Committee Meetings

Shands Hospital, Room 10-214
10:00a.m.-11:30a.m.

Tues., Feb. 17, 2009
Tues., Mar. 17, 2009
Tues., Apr. 21, 2009

CTC Class Reminder

The RAC Office routinely offers several role-based classroom trainings to interested investigators and staff on different aspects of clinical trials compliance. Please visit the Clinical Trials Compliance (CTC) website to view detailed descriptions of each class and to sign up for these opportunities!

New Faculty Roundtable Discussions for the Colleges of Medicine, Nursing, Pharmacy, and Vet Medicine

3203 HPNP, 10:00-11:30a.m., Wednesday April 15, 2009

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WHAT'S NEW

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Yale University Settlement

The federal government continues to invest resources in the management and monitoring of federal grant funds. Several articles as recently as December, 2008 highlight the significance of this effort, as Yale University has entered into a $7.6 million settlement with the Federal Government. This included $3.8 million in actual damages for false claims and $3.8 million as penalties for the false claims. No liability was admitted. Specifically, the federal government's allegations focused on salary cost transfers from one federal grant to another and charging 100% of researcher effort for summer salary on federal grants (although a significant portion of researcher effort was spent on unrelated work). Further details may be accessed via the articles at http://opa.yale.edu/news/article.aspx?id=6302 and http://newhaven.fbi.gov/dojpressrel/2008/nh122308.htm.

CTC Document Deferral for Non-Industry, Grant Proposals

The RAC office will now defer all CTC paperwork for grant applications that are submitted to the RAC office only for Non-Industry human subjects with services clinical research. This should decrease the workload and increase accuracy since it is difficult in completing the documentation when all the necessary services are not often known. This documentation will still be required prior to starting the study. Once the award is confirmed, the applicable CTC documents should be completed and submitted to the RAC office allowing adequate time for review and submission of the documents including the Study Registration Form process for obtaining an R99 number. This will assist the research team in obtaining any applicable discounted prices and staying compliant with state and federal regulations. Remember, it may take time to obtain the Confirmation of Services required prior to submission so be sure to begin the process no later than the IRB submission. It is expected that the department will track their submission to avoid any unnecessary delays. This change is effective immediately.

CTC HSC Scope

In January 2009, the Office of the Senior Vice President for Health Affairs has extended the Research Administration and Compliance (RAC)/Clinical Trials Compliance (CTC) Office oversight to all Health Science Center colleges for human subject

Continued on page 3

WHATS NEW – CONTINUED

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and medical services studies. The RAC will work closely with the other College administrative offices. This includes the Colleges of Dentistry, Nursing, Public Health & Health Professions and Pharmacy in addition to the College of Medicine. Stay tuned for further updates and announcements as plans are being developed and implemented. For any questions, please contact CTC at 273-5946.

Invoice Payment Instructions

The HSC College Departments receive invoices for patient care costs (797100 account code) that contain patient health information (PHI). For invoices containing PHI, complete the HSC-PHI Voucher Cover Sheet instead of sending the UB-04 and CMS-1500 to Disbursements/Payables (http://fa.ufl.edu/forms/; Form name: FA-PDS-PHIVC HSC-PHI Voucher Cover Sheet). Disbursements will upload the HSC-PHI Voucher Cover Sheet to the PeopleSoft system in place of the invoices. It is the department's responsibility to keep the original invoices along with other study documentation in the department for audit purposes. The departments may include multiple invoices in one voucher for patient care costs only. Use a sequential numbering system that your department uses and tracks. PeopleSoft will notify the department if a duplicate invoice number is used. This number will be placed on the "Departmental Invoice #" line on the HSC-PHI Voucher Cover Sheet that is faxed to Disbursements/Payables. The "Invoices Referenced" line is where you will list all Invoice/Patient Control Number(s) paid by this Voucher. The list should match what is referenced in Regular Entry, Payments tab, Messages hyperlink (which is being used to list the invoice numbers on the vendor check).

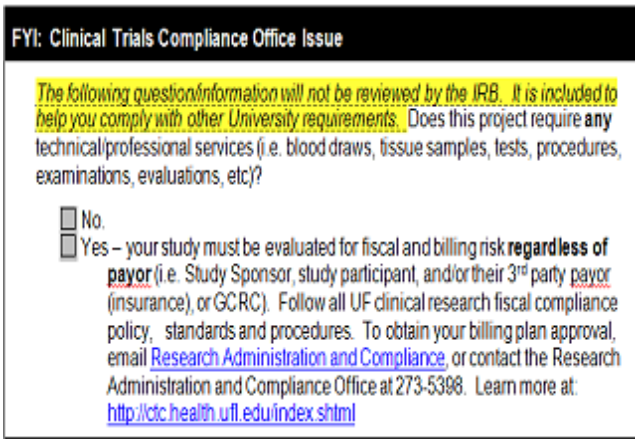
CMS Clarification MLN SE0822 Revision

On January 7, 2009, CMS released a revised version of the MLN MattersSE0822. They removed the prior Q&A #1 which referred to clinical trials. Upon insurance denials, if study participants were not billed for the denial, then Medicare could not be billed either. See http://www.cms.hhs.gov/MLNMattersArticles/downloads/SE0822.pdf. UF will no longer accept sponsor Clinical Trial Agreement contingency language in payment considerations, deductibles and co-pays or subject injury language.

New CTC Item on Introductory Questionnaire

The Health Science Center Institutional Review Board (IRB) has revised its Introductory Questionnaire (IQ) to include an alert box (see below) which will assist researchers in determining when their studies should be evaluated for fiscal and billing risk. You may view the updated IQ at http://irb.ufl.edu/docs/frm-iq.doc. This box will be a reminder if you have a study with human subjects and services and have not yet submitted your CTC paperwork to the RAC.

Use the handy link provided to contact the RAC.



FYI: Clinical Trials Compliance Office Issue

The following question/information will not be reviewed by the IRB. It is included to help you comply with other University requirements. Does this project require **any** technical/professional services (i.e. blood draws, tissue samples, tests, procedures, examinations, evaluations, etc)?

☐ No.
☐ Yes – your study must be evaluated for fiscal and billing risk **regardless of payor** (i.e. Study Sponsor, study participant, and/or their 3rd party payor (insurance), or GCRC). Follow all UF clinical research fiscal compliance policy, standards and procedures. To obtain your billing plan approval, email Research Administration and Compliance, or contact the Research Administration and Compliance Office at 273-5398. Learn more at: http://ctc.health.ufl.edu/index.shtml

CTC Information Management Project Updates

The goal of the Clinical Trials Compliance Information Management (CTC IM) Project is to investigate, develop and implement a CTC Information Management Solution to support the fiscal compliance requirements associated with risk management of UF Clinical Trials Research.
Highlights of project activities are listed below. http://www.health.ufl.edu/aiss/projects/ctc/reports/Annual-Report-CTC-IM-Project-2008-2009.pdf Visit the CTC IM Project website: (http://www.health.ufl.edu/aiss/projects/ctc/index.php) for more information including the CTC IM Project Annual Report at: http://www.health.ufl.edu/aiss/projects/ctc/reports/Annual-Report-CTC-IM-Project-2008-2009.pdf

- **CTC As-Is Process Evaluation and To-Be Process Design:** Process interviews are underway to determine the current CTC process. A detailed level 'As-Is' process map is being developed from the information collected and will provide a starting point for process improvement work and the 'To-Be' process redesign.
- **Assessment of Current Information Systems**: A data collection methodology is being developed to assess current information systems associated with the CTC process. The assessment will catalog functionality, interfaces, data/information flows and relationships to organizations and functions.
- **UFHSC Research Directory**
  The research directory will serve as a source of information for the UFHSC clinical research community and clinical care affiliates and initially support targeted training and communications. Contact information, primary role, and major functions performed by investigators and research staff will be included. Data collection has begun for the College of Medicine Clinical Departments and will continue for all UFHSC Colleges including Clinical and Basic Science Departments, UF Research Administration, Shands HealthCare, and University of Florida Physicians.

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Invoice Reconciliation Model!
Shands PFS invoices routinely drop on the 7th of each month. A department sent their tracking log to Shands PFS on November 3, 2008 and received their outstanding invoices on November 21, 2008 (15 business days). Sending your tracking log with outstanding invoices highlighted to Shands before the 7th of the month will help you to receive your invoices in a timely manner!

Staff Changes
Carrie Saites has joined the RAC office as a new Senior Grants Specialist. Carrie comes to us from the Orthopaedics and Rehabilitation Research Department, where she was a program assistant responsible for preparing the NIH grant applications for Gene Therapy and Ortho Oncology, an IRB coordinator for the department, and an assistant on various other projects within the research department. Welcome Carrie!

Leslie McElvey, CTC Document Coordinator has left the RAC office to join the Division of Internal Medicine in the Department of Medicine as their new Administrative Coordinator. Leslie, we will miss you and wish you the best of luck!

Edy Zettler has joined the RAC office as CTC Document Coordinator. For the past 2 years, Edy has led the main Contracts & Grants team for non-federal clinical trials, foundation, and industry awards. Welcome Edy!

IN THE NEWS

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NIH Updates-

Transition of Individual Career Development (K) Applications to Electronic Submission (Grants.gov) New Business Processes and Other Information
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-029.html
Effective with the February 12, 2009 submission date, all Research Career Development Award Programs ("K"s) with the exception of K12s are transitioning to electronic submission. Funding Opportunity Announcements (FOAs) for individual "K" programs have been updated and will also be announced in the NIH Guide for Grants and Contracts. Historically "K" applications have required limited budget information to be included with the application at the time of submission. With the transition to electronic submission, applicants will be required to include the SF424(R&R) Detailed Budget Component with their application submission.

However, only the Senior/Key Person costs for the candidate (base salary, person months, requested salary and fringe benefits); and the Other Direct Costs/Materials and Supplies reported under section F.1 will be entered.

A budget justification is also required. The F&A costs for Ks will continue at a rate of 8% of modified total direct costs. Reference letters are still an integral part of the application and they will be joined with the electronic application within the eRA system once an application completes the submission process. Reference letters required for mentored "K" programs must be submitted directly by the referee through the eRA Commons and not as part of the electronic application that goes through Grants.gov. The applicant's biosketch has been revised to include the same "Research Support" section used in the biosketch for all researchers. Applicants are also required to include descriptions of ongoing and completed research projects that are relevant to the research proposed in the application, and employment information from both the current and the projected positions must be included.

PHS 416-9 Progress Reports and Prior Approval Requests for Individual Fellowships
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-007.html
Effective immediately, the NIH has eliminated signatures of the Individual Fellow and Sponsor (Faculty Advisor) as a part of a NRSA Fellowship application or NRSA Progress Report. The NIH has updated the Fellowship Application Face Page (Form 416-1) and the Progress Report Face Page (Form 416-9) by removing those signature blocks. The only required signature remaining on those Face Pages is that of the official signing for the applicant organization, which for UF will be officers in the Division of Sponsored Research (DSR). NIH as part of this change also issued a new compliance requirement whereby the applicant organization (UF) agrees to secure and retain at the organization level a written assurance from the Fellow and Sponsor prior to submitting an application to the NIH. This assurance must be available to the NIH or other Federal official upon request. To comply, UF's Division of Sponsored Research will make available an internal UF Fellow and Sponsor Assurance Form which will need to be signed and submitted to DSR with the NRSA application or the progress report submitted to the NIH. The UF Fellow and Sponsor Assurance Form is available on the
DSR Forms web page.
http://rgp.ufl.edu/research/pdf/NRSA_FASA.pdf

Reminder and Clarification on NIH/AHRQ/CDC/FDA Transition to Adobe-based forms for SF424 Research and Related (R&R) Electronic Submissions through Grants.gov
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-020.html
Electronic Submissions after January 1, 2009 must use the new Adobe-base application forms for electronic submissions. Adobe-based application packages became available the first week of December 2008**.** Applicants should download the new application from the FOA for which they are applying for. The new Adobe-based forms require Adobe Reader version 8.1.3 or later. Non-compatible versions of Adobe Reader will prevent successful submission to Grants.gov. Remember: Although the software has changed, the electronic submission process has NOT. The new Adobe forms will have the same look and feel as PureEdge forms.

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IN THE NEWS-CONTINUED

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The Adobe based application forms will be updated again in March/April 2009. Applicants will need to access their respective FOAs at that time to download the latest version of the application forms for receipt dates in May 2009 and beyond**.**

NIH increases the Salary Cap Limitation on Grants, Cooperative Agreements and Contracts Under the Current Continuing Resolution
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-037.html
Effective January 1, 2009, the Executive Level I salary level increased to $196,700. The Consolidated Appropriations Act, 2008, Public Law 110-161, restricts the amount of direct salary of an individual under an NIH grant to Executive Level I of the Federal Executive Pay scale. Previously, the Executive Level I annual salary rate was $191,300 for the period January 1 through December 31, 2008. Applicants should use the new Executive Level I salary level of $196,700 now on all current and pending submissions for personnel who's current or prorated Institutional Base Salary exceeds the NIH salary cap.

Eligible PIs urged to establish Early Stage Investigator status; Update Personal Profile in eRA Commons
http://era.nih.gov/news_and_events/early_stage_investigator_01-09-09.cfm
Principal Investigators who have attained their terminal research degree or completed their medical residency with in the past ten years, and have not previously received a substantial NIH research grant, may be eligible to qualify as an Early Stage Investigator (ESI) for the purposes of an NIH R01 research grant application. An ESI is a subset of the New Investigator category. Early Stage Investigators benefit from this status by having their R01 grant application flagged as an Early Stage Investigator application beginning with the February 2009 R01 submissions. In reviewing this application, reviewers will be instructed to focus more on the research portion of the application and less on the ESI's track record. Beginning in May 2009, Early Stage Investigator applications will be clustered for review. The goal behind this new policy is to encourage scientists to seek NIH funding for their research early on in their career.

To ensure that NIH recognizes your eligibility as an Early Stage Investigator, PIs are urged to log into eRA Commons (https://commons.era.nih.gov/commons/) and update their Personal Profile immediately. Note that PIs need to update their degree/residency data *before* they submit their R01 application. Once the PI enters the information, the system will calculate ESI eligibility and display the eligibility end date to the user if he is eligible. The PI will be notified if his or her ESI eligibility status changes. Please note that a Multiple-PI application is only considered ESI-eligible if **all PIs** listed on the application are ESI-eligible.

NEW FUNDING OPPORTUNITIES

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Dept. of Defense Congressionally Directed Medical Research Program
http://cdmrp.army.mil/funding/reftable.htm

DOD CDMRP FY09 Breast Cancer Research Program (BCRP)
https://cdmrp.org/Program_Announcements_and_Forms/index.cfm?prg=BCRP&prg_fy=2009

- **Predoctoral Traineeship Award:** Maximum funding of $120K (up to $40K per year) for direct costs for a maximum period of 3 years (Pre-application due 2/25/09, Application due 3/11/09)
- **Postdoctoral Fellowship Award:** Maximum funding of $300K, up to $100K per year, for direct costs for a maximum period of 3 years (Pre-application due 2/25/09, Application due 3/11/09)
- **Impact Award:** Maximum funding of $2M for direct costs for a maximum period of 5 years (Pre-application due 3/12/09, Application due 6/17/09)
- **Integrated Multi-Team Research Award:** Maximum funding of 4.5M for direct costs for a maximum period of 4 years (Pre-application due 3/12/2009, Application due 6/17/09)

DOD CDMRP FY09 Tuberous Sclerosis Complex Research Program (TSCRP)

- **Clinical and Translational Research Award:** Maximum funding of $750K in direct costs ($900K in direct if requesting an Optional Qualified Collaborator), for a maximum period of 3 years (Pre-application due 3/24/09, Application due 4/14/09)
- **Idea Development Award:** Maximum funding of $450K in direct costs for a maximum of 3 years (Pre-application due 3/24/09, Application due 4/14/09)

DOD CDMRP FY09 Neurofibromatosis Research Program (NFRP)

- **Clinical Trial Award:** Maximum funding is $750K in direct costs for a maximum of 4 years (Pre-application due 3/24/09, Application due 4/14/09)
- **Investigator-Initiated Research Award:** Maximum funding is $525K in direct costs, $675K in direct if requesting an Optional Qualified Collaborator, for a maximum of 3 years (Pre-application due 3/24/09, Application due 4/14/09)

DOD CDMRP FY09 Ovarian Cancer Research Program (OCRP)

- **Idea Development Award:** A maximum of $375K in direct costs for a period of 3 years (Pre-Application due 3/02/09, Application due 06/02/09)
- **Collaborative Translational Research Award:** A maximum of $1.125M for 3 PIs and 1.5M for 4 PIs in direct costs for a period of 3 years (Pre-Application due 3/02/09, Application due 06/02/09)

CONFERENCES AND WORKSHOPS

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NIH Regional Seminars on Program Funding and Grants Administration
http://grants.nih.gov/grants/seminars.htm
When: April 16-17, 2009, April 15, 2009 Optional eRA Workshop
June 25-26, 2009, June 24, 2009 Optional eRA Workshop
Where: Georgia Tech, Georgia State University, Atlanta, GA (April)
University of Nevada, Las Vegas Nevada

Who Should Attend: These seminars are intended to help demystify the application and review process, clarify Federal regulations and policies, and highlight current areas of special interest or concern. The seminars serve the NIH mission of providing education and training for the next generation of biomedical and behavioral scientist. NIH policy, grants management, reviews and program staff provides a broad array of expertise and encourage personal interaction between themselves and seminar participants. The seminars are appropriate for grants administrators, researchers new to NIH, and graduate students.

NCURA Fundamentals of Sponsored Project Administration Workshop
http://www.ncura.edu/conferences/fundamentals/

When/Where:
March 4-6, 2009, Albuquerque, NM
May 27-29, 2009, Chicago, IL

Who Should Attend: This workshop is intended primarily for newcomers but also serves as an excellent refresher for all the pieces of the sponsored programs puzzle. This workshop provides an overview on all aspects of award administration including Regulatory issues, Proposal development, Proposal preparation and review, Compliance issues, Award negotiation and acceptance, Post-award administration, and Closeout and audit.

NCURA Financial Research Administration Workshop
http://www.ncura.edu/conferences/financial/

When/Where:
May 27-29, 2009, Chicago, IL
August 3-5, 2009, Philadelphia, PA

Who Should Attend: This workshop, geared for those with a minimum two years experience, will focus on critical topics such as a more in-depth look at A-21, A-110, sub-recipient monitoring, billing and invoicing, service centers, and close-outs and audit. This workshop includes interactive case studies and lessons learned from Federal audits. Space is limited to encourage active participation of attendees.

NCURA-Region III: Southeastern Conference
http://www.ncuraregioniii.com/
When: May 3-6, 2009
Where Marriott Bay Point Resort, Panama City, FL

Who Should Attend: Region III of the National Council of University Research Administrators (NCURA) serves the members of NCURA who work or live in the Southeast Region of the United States and Puerto Rico. It advances the field of research administration through professional development, through the sharing of knowledge, and by fostering a sense of community in the region.

FREQUENTLY ASKED QUESTIONS

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Q: Upon receiving an invoice from Shands Patient Financial Services (PFS), which dollar amount on the UB-04 am I to pay?

A: When looking at the UB-04, you will see the study discounted price in column #48 (Non-Covered Charges). At the bottom of this column, there will be a total that is to be paid to Shands PFS. The total will be in box #55 (Est. Amount Due). If you have any questions about what to pay please contact Desheba Rutledge at davdes@shands.ufl.edu or 265-0680, x42135 or Heather Cavin at cavinhm@shands.ufl.edu or 265-0680, x42126.

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Send suggestions and/or comments regarding this publication to Idella Philman with "Suggestions/Comments" in the subject line. If you do not wish to receive any more issues, please reply to dphilman@ufl.edu with "Unsubscribe" in the subject line.

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