RAC NEWS

Volume 8, Issue 11 November 2008

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

REMINDERS

¤»¥«¤»§«¤»¥«¤»§«¤»¥«¤»§«¤»¥«¤»§«¤»¥«¤»§«¤»¥«¤»§

HSC Roundtable Meetings

1329 Bldg., Room 4150

Thurs., Nov. 20, 2008
9:00a.m.-11:00a.m.

Thurs., Dec. 11, 2008
10:30a.m. – 12:00p.m.

CTC Ad Hoc Committee Meetings

Shands Hospital, Room 10-214

Tues., Nov. 18. 2008
10:00a.m.-11:30a.m.

Tues., Dec. 16, 2008
10:00a.m.-11:30a.m.

CTC Class Reminder

The CTC Office routinely offers several role-based classroom trainings to interested investigators and staff. Please visit the CTC website to view detailed descriptions of each class and to sign up for these opportunities!

INSIDE THIS ISSUE

1 Reminders

1-3 What's New

3-4 In the News

5 New Funding Opportunities

5-6 Conferences and Workshops

6 Frequently Asked Questions

WHAT'S NEW

««¤»¥«¤»§«¤»¥«¤»§«¤»¥«¤»§«¤»«¤»§«¤»¥«¤»§«¤»¥

In March 2008 the Clinical Trials Compliance Office merged with the College of Medicine Research Administration and Compliance Office in order to strengthen, unify, and streamline the research administration and various compliance requirements for research. This change is in effort to improve administrative support to the faculty and staff in the College of Medicine and the Health Science Center.

As a result of this realignment, Ms. Yvonne Brinson, Assistant Dean for Research Administration and Compliance, will direct the day to day activities of the new combined office and will continue to report to M. Peter Pevonka, Sr. Associate Dean for Research Administration and Compliance who also serves the campus as Associate Vice President for Research. Ms. Sandra Smith has been promoted to Grant Specialist Supervisor for the pre-award division of the office. See our newly redesigned personnel and contact page on our website. To view, go to http://www.med.ufl.edu/research/rac/other/staff.shtml.

Message from Dr. Good to COM Clinical Research Faculty and Staff

To the COM Research Faculty and Staff:
Our efforts involving Clinical Trials Compliance (CTC) continue to move in a positive direction. Partnerships among our clinical research faculty and staff, research administration, Faculty Group Practice and Shands Hospital are growing stronger as we endeavor to understand and support the complex processes, systems and needed training associated with CTC. Performing safe and valuable clinical research is important to the UF Health Science Center and the College of Medicine. We must also meet regulatory requirements that help to guarantee we are engaging in ethical and compliant business practices.

WHATS NEW – CONTINUED

«¤»¥«¤»§«¤»¥«¤»§«¤»¥«¤»§«¤»¥«¤»§«¤»¥«¤»§«¤»¥«¤»

UF and all of our partners in clinical research share in this responsibility. I am grateful for the dedication of our research teams and clinical service providers to fiscal integrity and protecting our research participants, faculty, staff and environment.

As our commitment and success in clinical research grows, so does the effort needed to ensure we are following sound and efficient CTC processes. The CTC, as part of the Research Administration and Compliance Office, continue to build their support services and I encourage you to review the CTC website for helpful information on processes, tools, forms and to register for essential training.

Soon, CTC will join our required compliance training activities as we carry on this important work. Please contact Yvonne Brinson, Assistant Dean, Research Administration and Compliance or contact her office at 352-273-5946 early in your clinical trial planning for help in navigating the CTC process. Thank you for your continued commitment and support.

Michael L. Good, MD
Interim Dean, College of Medicine

College of Medicine Proposal Submission Requirements via PeopleSoft

http://www.med.ufl.edu/research/rac/proposal/PS_Policy_2008.pdf

If you are not already using Peoplesoft for Grants Submissions through the RAC Office, please begin doing so now for all submissions. The use of PS provides many benefits, a few of which include providing a more consistent business practice in collaboration with other COM Departments and outside Colleges that also use PS, the automation of data entry which increases accuracy while reducing errors, and using Workflow saves time and steps by reducing the time it takes to obtain multiple signatures and fast access to status updates from any computer, just to name a few.

Personnel are available both in the RAC Office as well as in the Division of Sponsored Research to assist you in training new staff as well as retraining existing staff either in groups or providing one-on-one training. If you or your staff require training, refresher training or individual assistance please contact our office at 273-5398. In addition, step-by-step instructions and other resource information that may assist you in this process is also available via the RAC website under the Proposal Preparation section.

http://www.med.ufl.edu/research/rac/proposal/peoplesoft.shtml

Once trained, all COM departments should be using PS and Workflow by December 1, 2008.

UF Grant Summary Pages Now Available in myUFL

http://apps.research.ufl.edu/research/fyi/article.cfm?id=15688

The Grant Summary Pages feature was recently added to the Grants Module in Peoplesoft. This feature makes it easier to access proposal, project, and award information with a few clicks of the mouse. A few of the benefits these summary pages offer are the ability to quickly access information on the entire life cycle of a grant, from proposal to project including the ability to view a grant's KK available balance, F&A rate, HR Account Codes, IACUC and IRB expiration dates, and related subprojects. You can access the Grant Summary Page by navigation to myUFL>Grants>Grant Summary Pages.

Study Registration Form Exemption Clarification

The Research Administration & Compliance (RAC) Office issued an announcement last month regarding a Study Registration Form (SRF) Exemption for studies with no IND/IDE AND all services are Standard of Care (SOC). The clarification below addresses concerns while continuing to decrease billing risk.

Research teams will no longer need to submit a Study Registration Form for studies that do not include a **drug, device, or treatment** AND **for which all services in the trial will be billed to Medicare/insurance/patient** (all M's on the Study Registration Form billing grid). For example, patients consent to a study while they are seen for a liver biopsy procedure that is considered standard of care. The study requires the study coordinator to draw blood samples after the procedure that will be sent to a core lab. All participant services in the trial are routine costs that will be billed by FGP and/or PFS to a patient and/or their 3rd party payor and would therefore not require a Study Registration Form to be submitted to the Research Administration & Compliance (RAC) Office. For any questions, contact Debbie Vergara.

CMS "Free of Charge" Rule

SE0822 – Clarification of Medicare Payment for Routine Costs in a Clinical Trial

http://www.cms.hhs.gov/MLNMattersArticles/downloads/SE0822.pdf

On September 30, 2008, the Centers for Medicare & Medicaid Services (CMS) issued a clarification to an existing rule regarding payment for routine costs in a clinical trial. As a result of this new clarification, the University of Florida will no longer allow clinical trial sponsors to include contingency payment clauses (i.e. where sponsor agrees to pay claims that are denied by 3rd party payors) in clinical trials contracts. This applies to routine costs, offering to pay for co-pays and/or deductibles, and subject injury provisions. This option has also been removed from the Clinical Trial Agreement Checklist, which was previously Option #4, as well as the Study Registration Form Shands & FGP Payment Grid.

The changes to existing studies with such contingency clauses will require that **either** the Sponsor pays for the specified service(s) **or** the patients and/or their insurance pay. Both contracts and Informed Consent Forms may be affected. A process to update these documents is in development. **Further communication will be forthcoming.**

Continued on page 3

Two Open Forums were held to discuss this new clarification was held on Thursday, October 16, 2008 and Wednesday, October 29, 2008in the McKnight Brain Institute. Representatives from the Division of Sponsored Research (DSR), RAC, IRB-01 and General Counsel attended this session to address questions.

IN THE NEWS

«¤»¥«¤»§«¤»¥«¤»§«¤»¥«¤»§«¤»¥«¤»§«¤»¥«¤»§«¤»¥«¤»

New NIH Policy Limits the Number of Resubmissions

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-003.html

The NIH plans to phase out second amendments for new applications submitted after January 25, 2009. Over the past several years, as the availability of funding from the NIH has decreased, fewer and fewer applications were awarded on their first submission. In 2002, an investigator had a 17 percent chance of a first submission being funded as compared to a 7 percent chance in 2006. As a result, investigators are spending more time rewriting applications for resubmissions. Thus, the number of applications submitted each year to NIH has doubled and the number of investigators applying for grants has increased by over 75 percent, increasing stress on the system. After careful analysis, NIH found that eliminating the second amended application is the best way to help ensure they fund the best science earlier and reduce administrative burden on meritorious scientists and their projects. This policy intends to fund high quality applications earlier with fewer resubmissions.

Beginning with applications intended for the January 25, 2009 due date, all original new applications (i.e., never submitted) and competing renewal applications will be permitted only a single amendment (A1). Any second amendment (A2) will be administratively withdrawn and not accepted for review. Applicants who fail to receive funding after two submissions may resubmit but only if the application is fundamentally revised to qualify as new. A new application is expected to be substantially different in content and scope with more significant differences than are normally encountered in an amended application. Note that there is no time limit for the submission of the original and subsequent A1. Original new and competing renewal applications that were submitted prior to January 25, 2009 will be considered “grandfathered” and thus permitted two amendments (A1 and A2), so long as the A2 is submitted no later than January 7, 2011.

Announcing Transition Schedule for NIH/AHRQ/CDC/NIOSH/FDA 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-08-117.html

NIH has announced their schedule to transition from PureEdge to Adobe-based grant application forms for electronic submissions of SF424 Research and Related (R&R) applications. With some exceptions, most electronic submissions to NIH on or after January 1, 2009, must use Adobe application forms. After the transition dates Grants.gov will not accept PureEdge applications.

Although the new Adobe forms have a slightly different look and feel from the PureEdge forms, the changes are mainly cosmetic. The overall electronic submission process of finding opportunities, downloading application packages, preparing forms, preparing attachments, and submitting applications remains the same.

Applicants should make sure they are using the recommended versions of Adobe Reader. Version of Adobe Reader earlier than version 8.1.2 will not be accepted by the system.

Applicants currently working on a PureEdge grant application to be submitted in January 2009 are advised to continue to develop their research plan components and other parts of the application that will be uploaded as attachments, but wait to complete the application forms until the Adobe forms become available in December.

Reviewing WIRB Consents

If you are having WIRB write your informed consent for you, please be aware that the final approved consent must include UF's specific template language for the HIPAA authorization, study costs and subject injury sections. As part of the contract that WIRB has with UF, they are required to only accept the UF template language unless separate permission has been obtained from the UF IRB Office. The UF WIRB templates are available at http://irb.ufl.edu/wirb/icftemplate.htm.

Recently, we have noticed several newly approved WIRB consent forms that do not contain the UF template language. The appropriate UF template language for the cost and subject injury sections should be derived from the CTA and this language must be included in the submission. Unfortunately, the language that was used was not acceptable in many cases and revisions have been necessary. We are asking that you carefully review your final approved consent from WIRB and ensure that the appropriate language has been inserted. If changes are needed due to non-template language being used, WIRB should not charge a fee for that correction.

Device Trial Reminder

In order to ensure that all ancillary departments are notified and aware of the use of an investigational device in their respective service areas, it is imperative that research teams obtain a completed Confirmation of Services (COS) form from that particular ancillary department (such as OR, Cath Lab, and Interventional Radiology). Please see the Getting Help: Contact: Who Can Help? section of the CTC website for a complete listing of ancillary department contacts.

Brown Bag Meetings

The CTC Office holds Brown Bag meetings every other month for interested study coordinators and fiscal personnel. Topics related to clinical trials fiscal compliance are discussed and suggestions for future topics are welcomed. For further information on the CTC Brown Bag Meetings or to suggest a topic, please contact Deborah Vergara via email or phone at 273-7818.

Continued on page 4

IN THE NEWS-CONTINUED

«¤»¥«¤»§«¤»¥«¤»§«¤»¥«¤»§«¤»¥«¤»§«¤»¥«¤»§«¤»¥«¤»

Clarification of NIH Policy on Late Submission of Grant Applications

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-111.html

On September 2, 2008, the NIH released clarification on its policy for Late Submission of Grant Applications. Specifically, the noticed addressed a chance in text from the previous notice for the reasons it will consider a late submission:

From the previous notice:
"Late applications have been accepted for reasons such as: death of an immediate family member of the Principal Investigator, sudden acute severe illness of the Principal Investigator or immediate family member, temporary or ad hoc service on a NIH extramural peer review group, service on a NIH Board of Scientific Counselors or Advisory Board/Council, or large scale natural disasters."

This has been changed to: "Late applications have been accepted for reasons such as: death of an immediate family member of the Principal Investigator, sudden acute severe illness of the Principal Investigator or immediate family member, or large scale natural disasters. Recent service by the Principal Investigator **only** (this does **not** include other participants in the application) on an NIH extramural review group, NIH Board of Scientific Counselors or Advisory Board/Council that could reasonably be expected to require a time commitment that could have been used to prepare an application is also an allowable reason"

The change emphasizes that this consideration applies only to those with the PD/PI role who have ***recent*** service, not past service.

New Study Registration Process

The process has been redesigned for obtaining 'Confirmation of Services' from Shands Ancillary Departments and Faculty Group Practice (FGP) Liaisons, 'Discounted Research Prices' from Shands Financial Planning &Analysis (FP&A) and FGP, and new R99 assignments. The purposes of this business process redesign effort are as follows:

- Reduces the time required to obtain research prices and R99 numbers
- Eliminates redundancies in tasks, which increase time and potential for errors
- Supports improved version control of documents
- Creates greater transparency and improved lines of communications
- Establishes one point of contact to inquire regarding the status of submissions.

Changes to the current process include:

Research Teams will obtain written confirmation of feasibility for sponsor paid services from Shands Ancillary Departments and/or FGP. For all requests from Laboratory/Pathology, Radiology, Surgery/Anesthesia, and Investigational Drug Services, please utilize their existing procedures and request forms. For all other services, use the new 'Confirmation of Services' (COS) Form (also available on the Frequently Used Forms and Resources Section of the Clinical Trials Compliance website). Be sure to include any email correspondence as backup for the COS.

Researchers will communicate directly with the Ancillary Departments and FGP in determining correct study services and codes before submitting a study proposal packet to RAC.

The 'Discounted Pricing Request (R99) for Shands & FGP Clinical Services' page of the 'Study Registration Form' has been eliminated. Research Teams will no longer need to transcribe study tests or procedures onto this page. Instead, Research Administration & Compliance (RAC), Shands & FGP staff will use the information on the COS Forms to produce Discounted Price Lists and assign an R99 number for the study. The goal will be 10 business days from the time Researchers receive RAC approval of the study proposal packet/documents to receive the discounted pricelist and R99 number.

Please review the Study Registration Process Instructions for further details and contact us if you have any questions about this redesigned process (COM-RESEARCH-ADMIN-COMP-L@LISTS.UFL.EDU). For all other questions or assistance related to obtaining/completing/submitting a Confirmation of Services (COS) Form, please contact Deborah Vergara at dverga@ufl.edu or 273-7818.

Reminder! Please complete an Amended Study Registration Form and submit to the RAC office as soon as possible upon the change of Principal Investigator in a study.

Medicare Rate Quotes

When a clinical trial is sponsored by multiple funding agencies and one of those agencies is a federal entity (such as NIH), please note in #6 of the Study Registration Form exactly what items/services/procedures are being funded by that particular sponsor. This clarification will assist Shands & Faculty Group Practice with determining which items/services/procedures should be quoted with Medicare rates.

NEW FUNDING OPPORTUNITIES

«¤»¥«¤»§«¤»¥«¤»§«¤»¥«¤»§«¤»¥«¤»§«¤»¥

Internal Deadlines:

UFSCC Junior Investigator Pilot Project Grants, Applications due 11/15/08
http://www.medicine.ufl.edu/ACS_dimarco.asp

2009 Research Opportunity Incentive Fund Competition, Selected Applications due to RGP on 01/12/09
http://research.ufl.edu/researchsupport/research_support_docs/2009_Opp_Fund_Guidelines_FINAL.pdf

External Deadlines:

Alzheimer's Association

- New Investigator Research Grant - Letters of Intent due 12/01/08, Applications due 1/08/09 http://www.alz.org/professionals_and_researchers_new_investigator_research_grants.asp
- Investigator Initiated Research Grant - Letters of Intent due 12/01/08, Applications due 1/08/09 http://www.alz.org/professionals_and_researchers_investigatorinitiated.asp
- Zenith Fellows Award - Letters of Intent due 12/01/08, Applications due 1/08/09 http://www.alz.org/professionals_and_researchers_zenith.asp

American Federation for Aging Research (AFAR)
Applications due 12/16/08
http://www.afar.org/afar99.html

DOD CDMRP Research Funding for 2009 Announced
http://cdmrp.army.mil/pubs/press/2008/08fundingann.htm

Florida Department of Health Bankhead-Coley Cancer Research Grant – Preannouncement (solicitation will be released in mid December)
http://www.floridabiomed.com/index.html

Florida Department of Health James & Esther King Biomedical Research Program Grant – Preannouncement (solicitation will be released in mid December)
http://www.floridabiomed.com/index.html

Juvenile Diabetes Research Foundation
http://www.jdrf.org/files/General_Files/For_Scientists/FS_2008/Applicant_Guidelines_2008.pdf

- Scholar Award - Applications due 12/01/08
- Career Development Award - Applications due 1/15/09
- Regular Research Grant - Applications due 1/15/09

Muscular Dystrophy Association (MDA) – Letters of Intent due 12/15/08, Applications due 1/15/09
http://www.mda.org/research/guidelines.html

Susan G. Komen Postdoctoral Fellowships - Pre-applications due 10/17/08, Full Applications due 11/20/08
http://cms.komen.org/komen/GrantsProgram/ResearchGrants/index.htm

CONFERENCES AND WORKSHOPS

«¤»¥«¤»§«¤»¥«¤»§«¤»¥«¤»§«¤»¥«¤»§«¤»¥«¤»§«¤

Research Administration Training (RATS) Series - Cost Sharing and CAS Compliance Workshop
http://apps.research.ufl.edu/research/training/index.cfm
Date\Time: November 20, 2008\1:00 - 2:30 pm
Location: G-005 McCarty Hall

Presented by Brian Prindle, Associate Director, Sponsored Research (CAS Compliance portion), and a Curtis Ball from the Contracts and Grants Office. Topic 1: Appropriate for those responsible for departmental post-award contract and grant administration or for those who are Principal Investigators. This practical workshop includes a discussion on what cost sharing is and how to report it. Participants will learn how to recognize, monitor, and report cost sharing in a variety of ways. This workshop cuts through the confusing aspects of cost sharing, making compliance with agency rules, Cost Accounting Standards, OMB A-21, and university policies much easier.

Topic 2: Educational institutions with major federal contracts and grants are now required to comply with certain Cost Accounting Standards and to submit a Disclosure Statement which describes the institution's cost accounting practices as they relate to direct and indirect charges to Federally sponsored programs. This includes the practices followed by the institution's major service centers to develop and apply recharge rates for external and internal users of their services. For questions cgtraining@admin.ufl.edu

Research Administration Training (RATS) Series - Contract Negotiation
http://apps.research.ufl.edu/research/training/index.cfm
Date\Time: December 4, 2008\1:00 -2:00 pm
Location: G-005 McCarty Hall

Presented by Dr. Thomas Walsh, Director, Sponsored Research. Many issues exist when a proposal is funded by a sponsoring agency. After a comprehensive review of the terms of an agreement, DSR coordinates with the PI, the college research offices, the accounting office, general counsel and the technology transfer office to ensure that the terms of the agreement will legally allow the institution to accept the agreement, allow the PI to carry out the work as planned, and minimize the financial and legal risks associated with conducting externally sponsored activities. This class will introduce key issues routinely seen in university contract negotiations. - Presented by Thomas Walsh, Ph.D. For questions browncl@ufl.edu

NCURA'S Fundamentals of Sponsored Project Administration Workshop
http://www.ncura.edu/content/educational_programs/workshops/fundamentals/
When: December 3-5, 2008
Where: The Westin San Diego, San Diego, CA

Who Should Attend: This program is intended primarily for

Continued on page 6

CONFERENCES AND WORKSHOPS-CONTINUED

«¤»¥«¤»§«¤»¥«¤»§«¤»¥«¤»§«¤»¥«¤»§«¤»¥

the newcomer (less than 2 years experience) involved in sponsored projects administration at higher education institutions and affiliates, or for the individual who has worked primarily in only one area of sponsored projects administration and is seeking a broader view of the field. This session is targeted specifically to: proposal development personnel, sponsored projects administrators, grant and contract accountants, departmental administrators, research compliance administrators and others with newly acquired responsibilities in sponsored projects administration.

NCURA'S Financial Research Administration Workshop
http://www.ncura.edu/content/educational_programs/workshops/financial_research_admin/
When: December 3-5, 2008
Where: The Westin San Diego, San Diego, CA

Whether you are a research administrator in a department, a post-award office, a combined sponsored programs office that supports pre- and post-award functions, or a pre-award office that wants to understand how their functions support the post-award functions, this program will help you help you, your institution, and your faculty. Attendees are encouraged to have a minimum of two years of sponsored projects administration experience.

NCURA Financial Research Administration X (Post Award)
http://www.ncura.edu/content/educational_programs/conferences/fra.php
When: February 9-11, 2009
Where: La Quinta Resort and Club, La Quinta, CA

Who Should Attend: For those engaged in the financial administration of research, this conference offers special topics on post-award issues. This in depth and targeted training and professional development includes offerings for those new to the profession through to our most senior level members.

NIH Regional Seminar
http://www.osp.gatech.edu/NIH_Seminar.html
When: April 16-17, 2009
Where: Hyatt Regency Atlanta, Atlanta, GA.

Who Should Attend: The regional seminar is intended to help demystify the application and review process, clarify federal regulations and policies, and highlight current areas of special interest or concern. The sessions are appropriate for grants administrators, new and experienced researchers, and graduate students.

FREQUENTLY ASKED QUESTIONS

«¤»¥«¤»§«¤»¥«¤»§«¤»¥«¤»§«¤»¥«¤»§«¤»¥«¤»

Q: How do I pay for patient services from my study-funded account?

A: Shands-PFS
For invoices for study funded services, Shands PFS has requested that, for correct payment posting to occur **be sure** to include the patient control number (box #3a on the UB-04) that is provided to you on the invoice as the invoice number to be printed on the check. To voucher multiple participants or invoices in PeopleSoft, UF Purchasing and Disbursements has suggested utilizing the Message hyperlink under the Payment tab that will allow 70 characters that will print on the check.

You will be able to enter up to 6 patient control numbers into this box (including commas and spaces) which in turn will allow 6 line items to print on the check. You may also pay for patient services with your P-Card. **Do not** use the R99# any longer on the voucher. Contact the PFS billing department for questions or error correction.

Faculty Group Practice (FGP)
For FGP invoices, follow the same procedure above. Note that instead of a Patient Control Number that Shands PFS uses, there is a Patient Account Number (also called the Invoice Number) that you would insert into the same fields.

Q: What should I do once my sponsor-funded participant services have ended in my study?

A: Once all of the study participants have completed all sponsor-funded services in your study (services billed to a Shands and/or FGP BAR K account), be sure to settle all charges and send your completed tracking log to the Research Administration & Compliance (RAC) office in order to deactivate the R99 number assigned to that study.

Q: Is there a central email address where I can send all of my auditing questions?

A: Yes, you may send all auditing questions and tracking logs to CTC-AUDITORS@UFL.EDU.

UFCOLLEGE OF MEDICINE

RAC News is a quarterly publication of the College of Medicine Research Administration and Compliance in the Health Science Center at the University of Florida,
JHMHSC M134, PO Box 100215,
Gainesville, Florida 32611-0215.
Tel: (352) 273-5398 - Fax: (352) 273-5387

Send suggestions and/or comments regarding this publication to Idella Philman with "Suggestions/Comments" in the subject line.

¤»¥«¤»§«¤»¥«¤»§«¤»¥«¤»§«¤»¥«¤»§«¤»¥«¤»§«¤»