ClinicalTrials.gov (NCT) number mandatory for Device Trials January 1, 2014

CMS recently issued a Manual Instruction - Mandatory Reporting of an 8-Digit Clinical Trial Number on Claims, and an accompanying MLN Article. Effective January 1, 2014, claims for items and services related to Category A and B devices, or under a CED, must include the 8 digit number (always preceded by NCT on each study's page) assigned by the National Library of Medicine on the ClinicalTrials.gov website. Detailed billing instructions are found in the CMS manual which is available at:

The MLN article is at:

New listserv for UFclinicaltrials.gov questions:
This listserv is for anyone who would like information or needs help with ClinicalTrials.gov concerns at UF. Please feel free to use this and pass the information along: protocolregistry-L@LISTS.UFL.EDU

How long does it take to receive the National Clinical Trials (NCT) number from ClinicalTrials.gov?

If you are thinking 2-5 business days, you will be surprised to know that it may take up to 45 days before an NCT number is assigned. The Protocol Record is reviewed by a detailed process called the Quality Assurance (Q&A) Review which ensures that the record is consistent with the ClinicalTrials.gov protocol review criteria before publication on the website. Following successful Q&A Review, the NCT number will be assigned and the Protocol Record will be available on ClinicalTrials.gov within 2-5 business days.
Please start the process early when you know your study requires registration on ClinicalTrials.gov.
RAC Has an Updated Listserv!

We have shortened our listserv to COM-RAC-L@lists.ufl.edu. This will replace the older listserv COM-RESEARCH-ADMIN-COMP-L@lists.ufl.edu. Please be sure to update your email as we will be shutting down the COM-RESEARCH-ADMIN-COMP-L@lists.ufl.edu listserv as of November 1, 2013.

Digital Signatures

RAC will accept digital signatures when the signatures are accompanied with the Adobe validation properties including the name of the signer and date.

Welcome!

Join us in welcoming Tony Parker as our newest Auditor. Tony comes from the Division of Infectious Diseases and Global Medicine where he was an Accountant. He earned his BA from the Baptist College of Florida. Tony started with the RAC office on May 15 and spends his free time enjoying sports and church.

NEW SERVICE OFFERED!!

Let CTSI RKRS help you with your submission. When it is time for an investigator to prepare a RAC Billing Compliance Review submission, it is an ideal opportunity to schedule a free hour of time to discuss RAC documents with a CTSI RAC submission specialist. This specialist has been trained by RAC staff and regularly attends RAC meetings in order to stay up-to-date on all RAC Billing Compliance Review requirements. Additional information is available at https://www.ctsi.ufl.edu/research/study-development/irb-consults/.

UFIRST

Do you know about the University of Florida Integrated Research Support Tool, UFIRST?

In July of 2013, the Office of Research launched a new initiative with the ultimate goal of the creation of a new University of Florida Integrated Research Support Tool (UFIRST). The UFIRST initiative aims to design an integrated, streamlined and intuitive system that will support UF’s research endeavors—from proposal development through award closure.

Over the summer, a team of core research administrators representing various campus units met intensively over a six-week period to methodically examine the university’s current research processes, evaluating what is currently working and where improvements could be made. In addition, the Office of Research hosted two town halls to invite wider campus participation and solicit suggestions that could inform the core team’s discussions. You can read more about this initiative on the official site: http://research.ufl.edu/faculty-and-staff/initiatives/ufirst.html.

RAC News 2
Epic Research Module-FAQs

Almost two years have come and gone since UF “Go Live” for the Epic billing, scheduling, and research modules. Now with the recent Shands “Go Live” for these modules, we have two sides of the same coin to contend with!

To help study teams navigate the details of the Epic Research Module, the RAC office has compiled a “Frequently Asked Questions” handout: Epic FAQs.

Take a look and see if your burning question about the Epic Research Module is answered here. If not, email us your question via ezettler@ufl.edu typing “Epic FAQ” in the subject line and we will do our best to answer - and possibly add to the FAQ handout as well!

Other helpful links and handouts about the Epic Research Module:

- UF Academic Health Center Epic Training – Researchers
- Study Administrative Record in Epic
- Participant Registration in Epic
- RAC Guide to Fields in Epic Research Screens
- Quick Tips for Epic Research Administration Screens

Research Administration Certification Council (RACC) Workshop was a huge success!

UF Office of Sponsored Research & COM Research Administration and Compliance worked to bring the RACC Certified Research Administrator Workshop to UF. Over 80 individuals across campus participated in the sessions designed to familiarize research personnel with the basic body of knowledge covering Project Development and Administration, Legal Requirements and Sponsor Interface, Financial Management and General Management. The College of Medicine proudly sponsored 3 individuals to attend the workshop through a random drawing. Congratulations Belinda Nacionales, Wes Henderson and Christy Dupuis!

Greater Gainesville Area Chapter......is coming!!!

The organizing committee has started efforts to establish that we have 25 interested members to initiate a chapter to serve the Gainesville /Ocala area.

Chapter will:
- Provide Education and CEU’s
- Networking and Social activities
- Mentoring and Certification preparation
- Much more that members will help to develop.

Interested in being a member, we need to know who you are. Please email or contact: Marcia Hodik, RN, BSHS, CCRC, phone 273-9351 or email mhodik@peds.ufl.edu or H. Robert Kolb RN BS CCRC, email kolbhr@ufl.edu.
The Conflict of Interest Program will be holding a series of “Brown Bag” sessions on the Physician Payment Sunshine Act (“OPEN PAYMENTS”) followed by a Q&A session. If you consult with Industry, or believe you may in the future, this is important!

**OPEN PAYMENTS** requires pharmaceutical and medical device companies (and others) to report payments to physicians and teaching hospitals to CMS for inclusion in a publicly-accessible database.

These sessions will be presented by Gary Wimsett, Jr., JD on September 24<sup>th</sup>, October 24<sup>th</sup>, November 26<sup>th</sup>, and December 10<sup>th</sup> from 12 to 1 pm in the Shepard Broad Building - conference room 104.

Points of interest will include:

- What the new law does
- Who is required to do what under the new law
- How to dispute payments reported by Industry to CMS
- How the data might be used

Please reserve your seat through Crystal Sutherland as space will be limited. Please list your name and department in the email and “COI Brown Bag” in the subject line.

If you cannot attend a Brown Bag session but would like to learn more about the new OPEN PAYMENTS law, please do not hesitate to contact the COI Program to make an appointment. Mr. Wimsett is also available to present this information at department meetings.

Please call 273-7508 with any questions.
**From Ad Hoc**

**STUDY CLOSEOUT PROCESS**

We often talk about the closure of a study as a final review of the accounts to ensure that all services completed were paid for per the contractual agreement and/or budget. This final review is used as final verification that there are no outstanding invoices for patient services so Contracts & Grants (C&G) can move forward with closing the projects in PeopleSoft and residual monies may be moved to other accounts. C&G cannot completely close a study until Research Administration & Compliance (RAC) has completed their final review.

**Please be aware, the study cannot be closed and is considered active even if they are only collecting data and paying salaries. For purposes of Epic we cannot close anything without the W/IRB Closure letter.** The reason for this requirement is once a study is marked completed in Epic there is no way to reverse the process.

The most important elements of the closeout process that RAC requires are:

- The completed tracking log
- W/IRB Closure letter
- Department Closeout Form,
- Shands & UFP Confirmation that there are no balances on the R99.

After initial review, additional documents may be necessary for the closure of your study and will be requested via the department closeout form. Studies are closed in the order in which they were received.

We recommend you email both C&G and RAC to initiate the closeout processes at the same time.

**Investigational Drug Ordering in Epic**

With the implementation of Epic II on July 19, 2013, all medication orders (including chemotherapy and investigational drugs) will be submitted electronically through Epic. This is a practice consistent with all other medication orders throughout University of Florida Health.

Recognizing that some research teams do not have a nurse coordinator to assist with pending Epic medication orders for physician investigator signature, the Investigational Drug Service (IDS) will continue to accept paper orders via fax transmission if investigator entry presents a significant hardship. The goal is not to create a barrier to investigational medication management, but rather align with the standard practice of medication processing through UF Health.

Susan Beltz from IDS has created a detailed guide for ordering IDS medications, which has been posted on the RAC website [http://media.news.health.ufl.edu/misc/rac/forms/RAC_Handouts/Investigational_Drug_Ordering.pdf](http://media.news.health.ufl.edu/misc/rac/forms/RAC_Handouts/Investigational_Drug_Ordering.pdf).

If you have questions or need assistance with placing an investigational medication order, please contact:

- IDS Main Pharmacy: 265-0680 extension 4-4237 or 4-4716
- CTSI IDS Pharmacy: 294-5894
- IDS On-Call Pager: 413-2086
Upcoming Proposal Deadlines [http://apps.research.ufl.edu/research/fyi/deadlines.cfm]

**NIH FUNDING OPPORTUNITIES AND NOTICES – Guide for Grants and Contracts**

[All NIH Funding Opportunities and Notices]

**TRAINING OPPORTUNITIES**

**UPCOMING MEETINGS/CONFERENCES**

**NCURA:**
- **PRA Conference**
  - March 18-20, 2014
  - San Francisco, CA

**MAGI:**
- **Clinical Research Conference – 2013 West**
  - October 27-30, 2013
  - Las Vegas, NV
  - [http://magiworld.org/events/]

**NIH 2014 Regional Seminar:**
- **Program Funding and Grants Admin.**
  - Spring 2014
  - Baltimore (Tentative)
  - [http://grants.nih.gov/grants/seminars.htm]

**CTSI:**
- **Good Clinical Practice Guidelines**
  - Individualized Training for Small or Large Groups - Ongoing
  - Contact: Wajeeh Bajwa
  - Email: bajwa@ufl.edu
  - Phone: 273-8702
Northwestern University to Pay Nearly $3 Million to the United States to Settle Cancer Research Grant Fraud Claims
http://www.justice.gov/usao/iln/pr/chicago/2013/pr0730_01.html

Study Finds Underreporting of Cancer Trial Results
Despite the FDAAA, results for nearly half the trials of cancer drugs in the United States were not publicly available 3 years after completion of the trials.
http://jco.ascopubs.org/content/early/2013/07/22/JCO.2012.46.9577

OHRP to Develop Guidance on Research Involving 'Standard of Care'; NIH Disputes Findings of Consent Violations in SUPPORT Trial

Epic Systems' Tough Billionaire
http://www.forbes.com/sites/zinamoukheiber/2012/04/18/epic-systems-tough-billionaire/

Emory U. Will Pay $1.5-Million to Settle Claims of Medical Overbilling

We are always interested in your comments and suggestions for improvements. Would you like to participate? Join the UF Research Administrator’s Roundtable or Clinical Research Improvement Campaign Ad Hoc Committee. Be a part of the solution! Contact our office for more information.

---------Yvonne Brinson, RN MHSc, Assistant Dean