▶ Clinical Research Coordinator Networking Group 2

▶ Department Highlights: Emergency Medicine....5

▶ Finance: Simple Ways to Eliminate Delayed Sponsor Payments 7

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LLU

clinical trials

Looking At the Road Ahead: 2011

January 2011 marks the first anniversary of the establishment of the Clinical Trial Center. In the past year, the CTC has worked with several research stakeholders, such as the PBO, FPBO, clinical departments, Research Affairs, and LLUHC Central Administration to set up effective systems for clinical trials. All parties involved have provided a tremendous amount of support for the CTC's endeavors.

The process of enrolling departments into the CTC initially began with two pilot groups, Pediatrics and Ophthalmology. The CTC would like to extend a special thank-you to these groups for their constant support and collaboration. Subsequent departments who enrolled in CTC services during 2010 included Emergency Medicine, Neurology, Cardiology, Internal Medicine and Cardiovascular & Thoracic Surgery.

As commissioned by the Dean of the School of Medicine, the institution will continue to enroll all remaining departments into the CTC during the first quarter of 2011. In order to help with the integration of CTC services in each department, the director of CTC first met with department chairs and group administrators, and then facilitated open meetings between the departmental research team and the CTC team. During these meetings, CTC services and the financial management process have been explained and discussed. The goal is to help implement the institutional vision for clinical research development via centralized services as transparently and as collaboratively as possible.

On the educational and networking fronts, there are a couple of exciting and noteworthy items. Firstly, the Clinical Research Coordinator Networking Group has a new planning committee that has prepared the agenda for the 2011 sessions. The meeting topics and formats have been carefully designed to build upon feedback received from coordinators via the August 2010 survey. Secondly, the Clinical Research Finance & Billing Compliance Workshop has been scheduled for February 24 and 25. Please see related articles in this newsletter for additional details.

Also in 2011, the CTC will strive to improve efficiency within clinical trial systems. The CTC has an open-door policy for study teams, and questions and feedback are always welcome.

As we move forward together into a new year, it is our hope that we can achieve great success in clinical research through mutual cooperation and collaboration. It is only when we partner together that our common goals in building a better clinical research environment can be achieved.

Sincerely,

Linda Wu
Director, Clinical Trial Center

TRIAL TRIVIA

Did you know that Confidential Disclosure Agreements/Non-Disclosure Agreements for clinical trials need to be reviewed by the Clinical Trial Center before the PI and Institutional Official sign?

All CDAs/NDAs must be reviewed by the CTC to make certain the Institution is not assuming unreasonable liability, to verify appropriateness of legal terms, and to ensure that the document is compliant with Institution policies. Please be aware that CDAs/NDAs can appear in many different ways, such as in a letter form or even as an initial site questionnaire. When in doubt, contact Amy Casey at acasey@llu.edu or Ext. 87539.

Clinical Research Coordinator Networking Group

Contributed by Sarah Roper Schrag, Project Specialist at the Clinical Trial Center

The Clinical Research Coordinator Networking Group serves as a forum for networking and information sharing amongst clinical research coordinators at Loma Linda University. Meetings are held on a monthly basis with a new "hot topic" discussed at each meeting.

In November 2010, several regular networking group attendees convened to form the CRC Networking Group Planning Committee. The purpose of the committee is to give coordinators the opportunity to be actively involved in planning the CRC Networking Group, and thus far their efforts have produced a highly promising agenda for 2011.

A three-part series on Informed Consent has been scheduled for the first quarter of 2011. At January's meeting, there will be a general Informed Consent overview as well as an explanation for IRB "bounce-backs," and a look at some useful templates. In February, the group will meet at the Simulation Lab in the Centennial Complex for a hands-on Informed Consent role play experience. March's meeting will address Informed Consent Advanced Concepts. Individuals who attend both the January and February sessions or the March session will receive Renewal IRB Credit.

One important idea stemming from the committee is the Anonymous Question Forum. This will encourage coordinators to submit their questions to the networking group without the concern of having their name attached to it.

Each networking group meeting will include a five-minute Coordinator Concerns Corner, which is intended to allow coordinators to describe any needed improvements they have identified within the system. These concerns will be documented and presented to the Office of Sponsored Research by the Clinical Trial Center.

The IRB will be invited to facilitate a regulations segment after several meeting discussions throughout the year. This will help familiarize coordinators with the pertinent laws and guidelines associated with the topics being addressed.

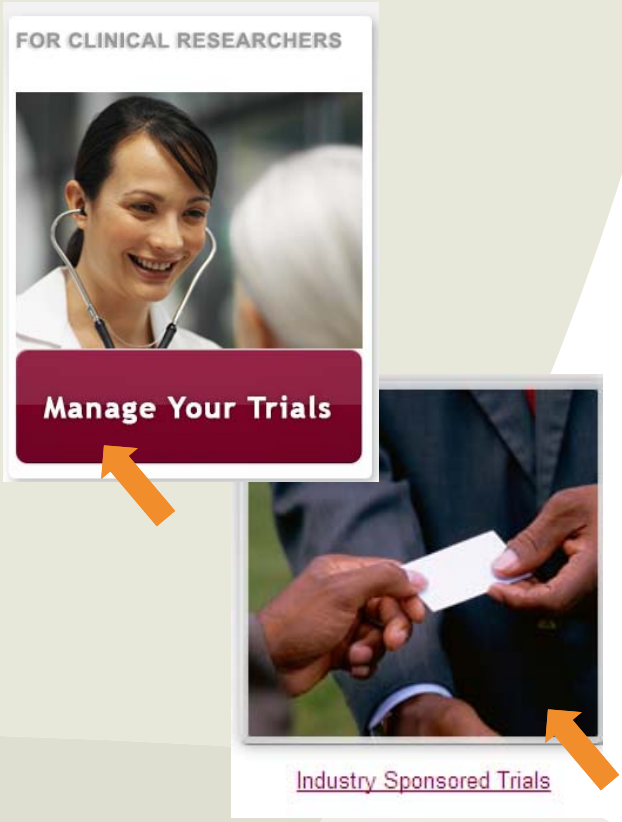
To give coordinators a better opportunity to share and address real-life workplace issues, the format of the meetings will be designed so that more time is dedicated to discussion as well as question and answer sessions.

Because of the problem with loud background noise at the Medical Center Cafeteria meeting location, it has been arranged that 2011 meetings will be held at the Children's Hospital, Room 1832.

If you have never attended the Networking Group or if it has been a while since the last time you stopped by, this is a great time for you to show up and see what is new. We'll save you a seat!

For questions or comments regarding the Clinical Research Coordinator Networking Group, please contact the Clinical Trial Center at clinicaltrials@llu.edu or Ext. 15002. For information regarding IRB Credit, please contact JR Krausz (Research Education Coordinator) at jrkrausz@llu.edu or Ext. 87463.

ctc updates



Now Available Online

Based upon feedback received from users across campus, improvements have been made to the Clinical Trial Center submission e-forms to make them easier to use.

One significant upgrade provides users the ability to save partially-completed e-forms. In order to access each e-form, users are asked to log in with their normal computer log-in username and password. Users can save their partially completed e-form by clicking "Save Form" on any page. They will then receive an email including a link where they can re-open their e-form later.

Remember, you can easily find all the forms you need for industry-sponsored clinical trials by utilizing the interactive processing flow-chart located under Manage Your Trials on the Clinical Trial Center Website (www.llu.edu/clinical-trials).

You will find that the following forms have also been updated to reflect current processes and include all necessary information:

- Billing & Reimbursement Information (BRI) Form
- LLU Feasibility Checklist
- LLUMC Clinical Lab Research Support Request Form

Welcoming Michael Wilson, Jr.

In September 2010, the Clinical Trial Center welcomed their new Senior Financial Analyst, Mr. Michael Wilson, Jr., to the team.

Mr. Wilson works in conjunction with Clinical Trial Center staff as well as university faculty and administration to manage clinical trial financials from commencement to close-out. His areas of responsibility include preparing financial documents, tracking and monitoring financials, responding to inquiries regarding study accounts, invoicing study sponsors, and distributing study compensations.

Mr. Wilson graduated in 2004 from California State University, Northridge with a Bachelor of Science degree in Systems and Operations Management. His professional repertoire incorporates over eight years of experience in project financial management, business and personal finance management, as well as commercial insurance billing administration.

Coming Soon: Clinical Research Finance & Billing Compliance Workshop

Contributed by Sarah Roper Schrag, Project Specialist at the Clinical Trial Center

Pictured L—R: Barry Stimmel (PBO), Lila Dalton (CTC), Amy Casey (CTC), Jennifer Miller (Medical Records), Andrew Holland (Finance), Karen Koehn (Medical Records), Michael Wilson, Jr. (CTC), Beverly Beck (FPBO), Rick Grable (LLUHC Administration), Linda Wu (CTC), Dr. Daniel Giang (Medical Affairs), Sarah Roper Schrag (CTC), Kerry Heinrich (Legal), Shayne Bigelow-Price (Staff Development), JR Krausz (Research Integrity)

The Clinical Research Finance & Billing Compliance Workshop has been rescheduled to be held February 24 and 25, 2011 at the Wong Kerle Conference Center.

This institutionally required workshop is designed to provide clinical research investigators and related clinical trials personnel with a comprehensive overview of current regulations and policies that govern the finance and billing of clinical research.

Attendees will receive training on specific tools, systems, forms, people, and channels of communication needed to implement and ensure correct billing from initial planning through delivery of service, billing, payment receipt, and clinical research study closure.
Principal Investigators will benefit most from sessions the first day, while administrators, coordinators, and other support staff will attend both days.

The workshop was initiated by the Compliance department and developed in cooperation with Clinical Trial Center, Staff Development and other Loma Linda University research stakeholders.

If you have questions or comments, contact the Clinical Trial Center at clinicaltrials@llu.edu or Ext. 15002.

Rebecca Fuentes
Clinical Research Billing Coordinator—FPBO

introducing...

Contributed by Rebecca Fuentes, Clinical Research Billing Coordinator at the FPBO
Edited by Sarah Roper Schrag, Project Specialist at the Clinical Trial Center

"As an FPBO Coordinator I am charged with coordinating all billing activity within the FPBO related to Clinical Research Trials and Medicare Recovery Auditor Contract (RAC) accounts in various UHC departments. I also have to work along side A/R mangers, Client Service Representatives and Clinical Research Coordinators to ensure clear lines of communication are established. It's also imperative I maintain an ongoing relationship with the Clinical Coordinator through regular meetings, and observation. I am further responsible to provide clear and concise billing protocols' for research studies and RAC claims billed through the FPBO under the direction of the Director of Quality Assurance.

The position of FPBO Coordinator is specific and requires direct attention when a Clinical Trial is started but it continues to be challenging. I will continue to develop as the FPBO Coordinator and hopefully help streamline this process."

Department Highlights

emergency medicine

Contributed by Emergency Medicine
Edited by Sarah Roper Schrag, Project Specialist at the Clinical Trial Center

Emergency Medicine Research Staff

Department Chair: Dr. Kathleen Clem
Director of Research: Dr. Ellen Reibling

Principal Investigators: Besh Barcega, Sean Bush, Stephen Corbett, Tommy Kim, Timothy McNaughton, H. Bryant Nguyen, James Rhee, Dustin Smith, Robert Steele, Tamara Thomas, Andrea Thorp, Lea Walters

Research Coordinator: Sarah Pearl

Lead Research RN: Susie Smith

Sepsis Research Technicians: Michael Batech, Tammy Phan

The Department of Emergency Medicine has an impressive Research staff of thirteen PIs, a Director, a Coordinator, eighteen volunteer students, a Lead Research RN, and two Sepsis Research Technicians. The department is involved in three clinical trials focusing on anti-venom for rattlesnake bites and black widow bites as well as acetaminophen overdose poisoning antidote treatment. Two PIs (Dr. Nguyen and Dr. Barcega) are working on investigator-initiated trials.

Sponsors providing support to Emergency Medicine include Cumberland, National Medical Test Bed, Hutchinson, University of Massachusetts, Instituto Bioclon, and Rocky Mountain Poison and Drug.

The Emergency Medicine department has a few areas of special interest. As one of three pediatric emergency centers in California, the department enjoys special opportunities to investigate potential solutions pertinent to children. The department also gives emphasis to sepsis and envenomation.

Dr. Nguyen continues to be a nationally recognized researcher in the field of sepsis, and partners with the Department of Internal Medicine as Director of Research. His work this past year on early goal directed therapy in severe sepsis and septic shock patients has shown to have positive effects on this populations mortality rates. He was recognized and featured at this year's ACEP Scientific Assembly for his global work titled, "Implementation of Sepsis Bundle in Asia: A Multi National Study." The study compiled data from eight centers in five countries including China, Taiwan, Singapore, India, and Korea. His study showed a 17% decrease in mortality when the bundle was implemented. His current study efforts are focusing on finding a non-invasive hemodynamic monitoring technology for resuscitation of septic shock patients and identifying biomarkers and prognostics for severe sepsis patients.

This past year, Dr. Sean Bush (international envenomation expert) focused on expanding his work in envenomation medicine to include global efforts to increase education and training of snakebite patients. He traveled to Swaziland, Africa with members of the ED research team, and spent time training hospital personnel on proper administration of anti-venom and treatment of patients.

During 2010, Dr. Rhee (Loma Linda's only board certified toxicologist) has been greatly involved with the academic training of medical students and residents here at Loma Linda. He is actively pursuing a clinical trial focus on testing a new IV formulation of acetylcysteine in patients with acetaminophen overdoses.

Emergency Medicine recently hired a new Director of Research, Dr. Ellen Reibling. She comes to Loma Linda from UCI and brings with her a wealth of experience in mentoring and institutional navigation. She has already made tremendous strides in helping the Department to have an increased focus on research.

Recent Emergency Medicine accomplishments include:

- Dr. Nguyen—featured presentation at ACEP
- Dr. Clem—featured poster presentation at AAMC 2010 Annual meeting in Washington D.C.
- Dr. Bush—recent TV appearances
- Susie Smith—Kaiser presentations on envenomation treatment and clinical trial protocols
- Andrea Thorp—Kiwanis presentation featured online
- Dr. Clem—episode of Untold Stories of the ER
- Collectively from 2009 through 2010—more than 50 publications and 29 grants

Emergency Medicine has a number of goals:

- Further develop collaborative research. Fifty-three percent of LLU admissions come from the ED, so logically the ED wants to partner with PIs in departments admitting ED patients.
- Continue innovative work in disaster preparedness and emergency response.
- Encourage nursing directed research in conjunction with Patti Radovich, Manager Nursing Research and Janis Palaganas, CEO from the Simulation Center.
- Increase focus on injury prevention, especially distracted driving among young drivers.
- Strive to acquire a mix of grants and clinical trials to enhance opportunities for resident and medical student research.

policy particulars

Research Conflict of Interest

Contributed by Lorraine Sarmiento, Accreditation Coordinator at Research Affairs
Edited by Sarah Roper Schrag, Project Specialist at the Clinical Trial Center

Got a Conflict? Not the end of the world!
A conflict of interest is commonly misconstrued as something to be avoided by members of the research community, but just the opposite is true. In fact, having a conflict of interest shows that you are actively contributing to the development of a field of science or clinical care. Conflicts of interest are not bad; they just require disclosure and management.

What is Research Conflict of Interest?
Situations in which significant financial or non-financial interests may influence an investigator's professional judgment in the design, conduct, or reporting of research. You may have good reasons for believing that your personal interests would not contaminate your science, but the public must be reassured. Even the appearance of undue influence must be considered.

Why is it important to disclose potential conflicts of interest?
Government regulations require that all potential conflicts of interest be disclosed and, if necessary, managed. This is meant to assure the public that connections between investigators and companies are positive associations beneficial to research participants. Disclosing these relationships to your institution is intended to provide reassurance that research personnel will give the public's welfare the highest priority.

Do I need to Submit a Research Conflict of Interest Disclosure?
Anyone involved in the design, conduct, or reporting of any portion of a research project, must submit a disclosure form. This includes, but is not limited to: Principal Investigators (PI's), Co-Investigators, Research Coordinators, Research Assistants, Technical Staff, Administrative Staff, Collaborators, and Students.
*Remember, interests of family members must also be reported.

PLEASE NOTE: It is the PI's responsibility to ensure that ALL personnel are identified on the project and that they submit a disclosure of their interests. Incomplete forms will result in processing delays. Each person listed must submit his/her own form. To expedite this process, make sure all disclosures are submitted in a timely manner.

Where do I Submit the Disclosure?
The Office of the Vice President for Research Affairs

Who do I Call if I have Questions or to Schedule RCOI Training?
RCOI Coordinator
(909) 558-4000 Ext. 85794 or researchcoi@llu.edu
LLUAHSC Policy H-35 and additional information can be found at http://research.llu.edu/RCOI.asp.

irb corner

Revised IRB Application & Updated Website

Contributed by Anu Diekmann, Sponsored Research Analyst at Sponsored Research
Edited by Sarah Roper Schrag, Project Specialist at the Clinical Trial Center

As an interim measure until the Research website is redesigned, sections of relevant IRB guidance and tools at http://research.llu.edu have been updated and simplified. The following new or revised documents are now available under IRB Tools for Investigators:

- IRB Application Form (Please use the version on the website since the form is updated frequently.)
- Protocol Outline (Applying to LLU's IRB: specific guidance on preparing a research protocol)
- Anonymous Survey Consent Template (Preparing Your Informed Consent Document: model consent language when study procedures are limited to anonymous surveys)

Please contact IRB@llu.edu if you have any comments or feedback.

finance

Simple Ways to Eliminate Delayed Sponsor Payments

Contributed by Michael Wilson, Jr., Senior Financial Analyst at the Clinical Trial Center
Edited by Sarah Roper Schrag, Project Specialist at the Clinical Trial Center

With today's economy, striving for profitable clinical studies goes beyond just effective time and effort management. In addition to time and effort management, attention must also be given to processes which affect collection periods from the sponsor. In a survey conducted by CenterWatch, "…on average collection periods often exceed 120 days, even in a good economy."[1] With consideration by the site to certain processes, the collection period can be shortened. Thus, while study budgets are being negotiated, the promptness of payments must also be considered.

As the Industry-Sponsored study framework is based upon Government-Sponsored studies, payment periods used to be a non-negotiable item.[2] Sponsors are legally able to stretch or withhold their dollar in many ways, resulting from the site's action or lack thereof. One way is through the Case Report Form (CRF). Leaving one field empty on a CRF gives the Sponsor ample reason to withhold a payment to a site. A second way is delaying a monitor visit. Many sponsors wait to approve payments until after a monitor visit. A way to avoid this delay is by utilizing electronic CRFs and by conducting monitor visits remotely. Also, submitting payments without payment remittance information makes it difficult for the site to recognize revenue. This is an item that many sites overlook and can be made a contractual requirement for any payment. Even with today's market and the fact that pharmaceutical companies are not as profitable as before, but they are still willing to make prompt payments to trustworthy sites.

1. CenterWatch 2007 Survey of 522 Investigative Sites, in "State of the Clinical Trials Industry: A Sourcebook of Charts and Statistics," 2009.
2. Journal of Clinical Research Best Practices, "Solving the Revenue Collection Problem for Clinical Research Sites," Goldfarb, Narman M., September 2009.

Researcher's Resources

Contributed by Sarah Roper Schrag, Project Specialist at the Clinical Trial Center

ClinicalTrials.gov

A service of the U.S. National Institutes of Health
Developed by the National Library of Medicine

ClinicalTrials.gov is a registry containing the profiles of privately and federally sponsored clinical trials. As of December 2010, the site was inclusive of more than 100,000 trials from 174 different countries and all 50 states.

The site was built by the NIH in cooperation with the FDA pursuant to the FDA Modernization Act (1997). The intended purpose of the registry was (and is) to give the public and medical personnel convenient and readily understood information about available clinical trials. Contents of ClinicalTrials.gov were first published online for public viewing in 2000.

By law, all clinical trials conducted in the United States of America are required to register on ClinicalTrials.gov via the Protocol Registration System. Together, the investigator and the sponsor hold the responsibility for ensuring that the trial is registered. Subject enrollment may not begin until registration has been completed, and each ClinicalTrials.gov study profile must be updated every six months.

"Clinical Trials.gov provides researchers with another medium to recruit subjects."
- Sabrina Velez, Research Integrity

LLUAHSC Policy H-29 and H-29A provide information about ClinicalTrials.gov registration as it pertains to research at LLU. For additional information about ClinicalTrials.gov registration, contact Sabrina Velez (Research Integrity) at svelez@llu.edu or Ext. 49408.

*ClinicalTrials.gov facts provided by ClinicalTrials.gov.

SCT
SOCIETY FOR CLINICAL TRIALS

The "Society for Clinical Trials" is an international professional organization whose focus is the creation and distribution of information about industry and government-sponsored clinical trials.

On their website, www.sctweb.org, you will find specifics regarding the Society's annual scientific meetings, publications (including the "Clinical Trials" journal), as well as semi-annual newsletters bursting with hot topics from the research field.

LOMA LINDA UNIVERSITY
HEALTH CARE

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