ISSUE 4 | APRIL | 2011

LLU

clinical trials

Research Billing Workshop: An Educational Triumph!

Contributed by Sarah Roper Schrag, Project Specialist — Clinical Trial Center

More than one-hundred twenty research personnel attended the Clinical Research Finance & Billing Compliance Workshop at Wong Kerlee Conference Center on February 24 and 25. Amongst the attendees were Principal Investigators, Administrators, Coordinators, Nurses, Technicians, and other research-related staff.

So why all the fuss? With the government intensifying regulations around medical billing, it was time to provide an opportunity for research personnel to learn the most current finance and billing guidelines as they pertain to human study research at Loma Linda University. The workshop was initiated by the Compliance department and developed in cooperation with the Clinical Trial Center, General Legal Counsel, Staff Development and other Loma Linda University research stakeholders.

Day One of the workshop was designed to provide high-level information particularly relevant to Principal Investigators in addition to their supportive staff. Alternatively, Day Two was geared specifically toward the supportive staff with a practical application context.

Dr. Roger Hadley, Linda Wu (Director of the CTC), and Dr. Daniel Giang opened the workshop with some valuable insights into the importance of billing and finance compliance as well as the PI's role and responsibilities.

Kerry Heinrich (Legal Counsel) and Beth Elwell (Director of Compliance Operations) gave an in-depth look into current regulations as well as Medicaid/Medicare/CMS guidelines.

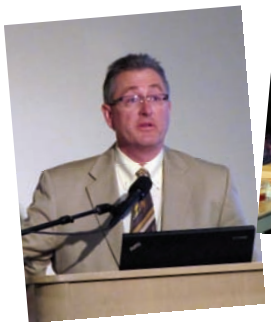
Linda Wu acted as a guide to workshop participants, walking them through a Medicare Coverage Analysis, Budget Development, and Feasibility Meeting. *...(Story continued on the following page)*

TRIAL TRIVIA

Contributed by Michael Wilson, Jr., Senior Financial Analyst — Clinical Trial Center

Did you know that patient stipends are a taxable income for the patient/recipient?

All research-related patient stipends that exceed the current year's non-taxable limit must be reported to the IRS and are subject to be taxed as an additional income. The patient (or other recipient) will receive a 1099 from LLUHC Finance for the total amount of stipends received within a given calendar year, only if it exceeds the non-taxable limit. Based on IRS guidelines, research stipends are considered to be "Non-Employee Compensation" and could be a taxable income.



"The program hit key points people need"

"Outstanding program overall"

"Great job CTC"

"Excellent program with helpful information"

To make the connection between billing and medical records, Jennifer Miller (Director of LLUMC Medical Records) teamed up with Karen Koehn (Program Manager, Compliance), Patti Radovich (Manager-Nursing Research at Patient Care Services Administration), and Beth Elwell.

Representatives from the FPBO, PBO, LLUHC Finance, Sponsored Projects Financial Management, and the Clinical Trial Center were able to help workshop participants understand the varying roles of research personnel within the billing process, and how to take advantage of recent system developments to increase efficiency and accuracy.

Serving as Master of Ceremonies for the event was Lila Dalton (Associate Director of the CTC). She kept the two-day program on target, provided workshop participants opportunities to network, and ensured that all participants could be comfortable asking questions either verbally or via anonymous notes.

Attendees were asked to complete a Post-Test at the end of both days. Each test was followed up with a review to ensure that any unanswered questions were addressed.

All workshop sessions were recorded and will be available as an online training in the near future. Research personnel can expect to receive an email announcement as soon as this feature is prepared for use.

To the following individuals, a special thank-you for your valuable contributions to this successful event:

Beverly Beck
Shayne Bigelow-Price
Amy Casey
Lila Dalton
Beth Elwell
Dr. Daniel Giang
Rick Grable
Dr. Roger Hadley
Kent Hansen
Kerry Heinrich
Andrew Holland
Carolyn Hurlbut
Karen Koehn
JR Krausz
Jennifer Miller
Patti Radovich
Sarah Roper Schrag
Barry Stimmel
Arlin Tueller
Michael Wilson, Jr.
Linda Wu

irb corner

Updated IRB Tools for Investigators/Staff

Contributed by Anuradha Diekmann, Sponsored Research Analyst, Sr.—Office of Sponsored Research

As part of the IRB's on-going quality improvement effort for human studies, "IRB Tools for Investigators and Their Staff" on the Research Website (http://research.llu.edu/IRBinvestigator.asp) are periodically updated and simplified. Recent improvements include:

Under Preparing your informed consent document

- Clinical Trial Consent Template (updated on 2/3/11)
- Anonymous Survey Consent Template (new, model consent language when study procedures are limited to anonymous surveys)

Under Applying to LLU's IRB

- Applicant Checklists (updated on 3/11/2011)
- IRB Application Form (updated on 1/24/2011)
- Humanitarian Use Device Application (updated on 1/27/2011)
- Protocol Outline (new, specific guidance on preparing a research protocol)

Also, remember that the schedule of IRB deadlines and meetings is maintained and available for your convenience at http://research.llu.edu/CalendarInternal.asp.

Contact IRB@llu.edu if you have any comments/feedback.

a word from the pharmacy

Contributed by Desiree Wallace, Rph., Pharm D.—
Investigational Drug Service, Department of Pharmacy

Destruction of Used or Partially Used Medications

The Pharmacy wishes to draw your attention to the following memorandum, which was put into effect by Desiree Wallace, Pharm D. (LLUMC Investigational Drug Pharmacist) on February 9, 2011:

"This memo is to further clarify the disposal and destruction of pharmaceutical waste per SOP T-9, for Loma Linda University Medical Center. Used or partially used pharmaceutical waste generated by a investigational study, specifically the used/partially used study medications will be placed in the white pharmaceutical waste containers for incineration at periodic monitoring visits and/or closeout of a study. Documentation of destruction on drug accountability records/destruction records or as documents provided by a sponsor will be maintained. A waste management company as coordinated by LLUMC Environmental Health and Safety Management, Donna Gurule [(909) 558-4000, x47270], will pickup and destroy the pharmaceutical waste. Currently it is Stericycle.

Stericycle collects medical waste daily from LLUMC. The waste is then consolidated and the incinerable waste (e.g., pharmaceutical, pathological and chemotherapeutic) is hauled to Salt Lake City, Utah and incinerated there. Stericycle does not supply destruction records of this waste to the pharmacy."

For additional details, please refer to the Loma Linda University Medical Center & Children's Hospital Operating Policy T-9, "Management of Waste and Hazardous Materials."

Important Location Update

Desiree Wallace now has a new off-campus office location, across from the Emergency Department. Stephanie Starr, Rx Research Technician for the Cancer Center, is also located in this office. Please note that shipping of drugs should still be made to the same place, emphasizing Dock B, M-F 7-3:30pm. After hours or weekend deliveries must be made directly to the 2nd floor pharmacy in the hospital.

Office:

Desiree Wallace, Rph., PharmD.
Investigational Drug Service
Department of Pharmacy

LLU School of Pharmacy
11262 Campus Street, West Hall Rm 1313
Loma Linda, CA 92350

Phone: (909) 558-4500, x83773
Fax: (909) 558-0323
Pager : (909) 558-1717, 1505 or dwallace@my2way.com
Email : dwallace@llu.edu

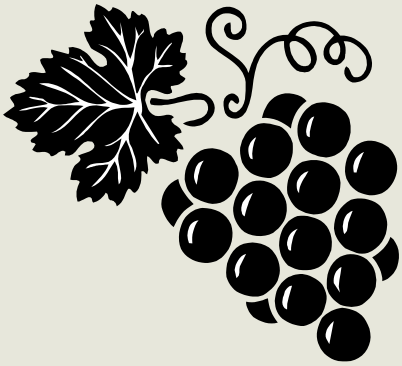
Shipping:

Attn: IDS Research Pharmacy LLUMC
11223 Campus Street, Dock B
Loma Linda, CA 92354

(909) 558-4500
Fax: (909) 558-4145

ctc updates

Contributed by Sarah Roper Schrag, Project Specialist — Clinical Trial Center



Save the Date!

The Clinical Trial Center has moved to their permanent office location! You're invited to...

An Open House Celebration

Friday, May 6, 2011

1:00–3:00 p.m.

Clinical Trial Center - Coleman Pavilion 11113

Refreshments and Hors d' oeuvres will be provided

Welcoming Carolyn Hurlbut

Ms. Carolyn Hurlbut is the newest addition to the Clinical Trial Center team, filling the role of Administrative Secretary as of January 24, 2011.

Carolyn provides secretarial, data, and clerical support to the CTC in order to facilitate the implementation and management of clinical trials. She communicates regularly with investigators, clinical trials personnel, and Research Affairs to schedule study-related meetings and to maintain the open exchange of study information. In addition, Carolyn maintains knowledge of institutional research resources and research department contacts in addition to responding to inquiries with accurate and timely information.

In 2010, Carolyn graduated from the University of Redlands with a Master's of Arts Degree in Counseling. Her professional background includes education, Family Law, and over six years of customer service experience. Carolyn also holds a current Notary Public commission.

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HEALTH CARE

Clinical Trial Center

909.651.5002

www.llu.edu/clinical-trials

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