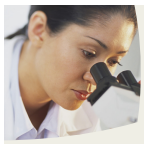
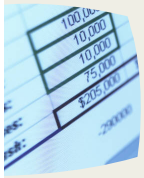




ISSUE 2 | SEPT | 2010

LLU clinical trials

From the Director's Desk

As we approach the brink of autumn, I would like to take a moment to share with you some exciting progress from the Clinical Trial Center.

On the Financial Management front, beta testing on new research-geared billing and accounting mechanisms has begun. The first Clinical Trial IDX Training is scheduled for September for Pediatrics, Cardiothoracic, Ophthalmology, and Emergency Medicine.

We continue to work to establish research subject flagging in Medical Record (Cerner) so clinicians are alerted when they are treating someone who is involved in a clinical trial. This alert mechanism will provide contact information to the research team without disclosing protected research information. Flagging will also facilitate accurate research billing and coding.

In an effort to build career development for clinical research professionals on campus, Human Resource Management and the CTC have worked together to identify research personnel and job titles and create master contact lists. We look forward to working with HRM on the next phase of the project: standardizing titles and job descriptions.

Our next large educational event, the "Research Billing Compliance Workshop," is scheduled for December, and will involve regulations and hands-on skill building geared toward Loma Linda systems. Invitations will be coming soon.

As of August 3, the total number of this year's new clinical trials was forty-three (consisting of twenty-six industry-sponsored, ten cooperative group, and seven investigator-initiated). The CTC has provided a total of sixty-seven ad hoc requests in the areas of ancillary support, trial consultation, site management issues, etc. this year. As the result of the CTC's new trial recruitment effort, four LLU principal investigators have been selected for five new trials in the area of Diabetes Treatment, Emergency Care and Pediatric Pain Management. We look forward to providing quality clinical trial support upon your request.

We are also pleased to announce that two CTC staff have been invited to speak at this year's MAGI's Clinical Research Conference West in October.

Please contact us with questions or comments!

Blessings,
Linda Wu— Director of Operations, Clinical Trial Center

TRIAL TRIVIA

Did you know you can receive a general IRB submission orientation with Susan Fajardo (OSR Coordinator)?

Learn more by sending an email to irb@llu.edu or by calling ext. 44531.

Informed Consent Copies: The Essentials

A research subject (or their legally authorized representative) has just signed an Informed Consent Form. Now what? In compliance with ICH Good Clinical Practice Guidelines, the subject must receive a signed and dated copy of the Informed Consent Form, as described in either of the scenarios below.

Scenario A
Provide the subject with a copy of the Informed Consent Form they signed (along with all other required signatures).

Scenario B
If the subject signs the Informed Consent Form but the other signatures are not obtained until later, be sure to provide the subject:

1. A copy of the Informed Consent Form the subject signed (even without the other signatures)
2. A new copy once all other signatures have been obtained

Research activity cannot proceed until all signatures are obtained.

lab updates

Please take notice of these important Clinical Lab Research Support Updates, which took effect June 15, 2010:

Departments must make their own arrangements to pick and store research samples outside of the Clinical Lab within four days of collection. The four day window gives the department sufficient time to 1) have the processing completed by the clinical lab and then 2) transfer the sample(s) to the department's designated storage location.

The lab will provide dry ice as part of a requested, approved, and billing shipping service to be performed by the Clinical Lab. Otherwise, dry ice may be obtained from Smart and Final in Redlands.

Requests for letters of support and prices for tests not included on the approved research price list should be forwarded to the Clinical Lab two weeks prior to the requested deadline. The Clinical Lab may respond sooner if time and resourced are available to do so.

Now Available Online

Need a one-stop-shop for Clinical Laboratory forms? Check out the CTC Website's Clinical Laboratory page, which includes:

- Laboratory Director's Curriculum Vitae
- LLUMC Clinical Laboratory Research Support Request Form
- Clinical Laboratory Reference Range for Normal Laboratory Values
- Current Licensures

Come across an unfamiliar clinical trial term? See if you can find it on the Glossary page.

Both of these new features can be found under "Useful Guides & Forms" located within the "For Researchers" section of the CTC Website: www.llu.edu/clinical-trials.

Glossary

Clinical Laboratory

Image courtesy of James Ponder, Office of University Relations

Pictured L to R:

Dr. Khashayar Dashtipour,

Dr. Bryan Tsao (Department Chair),

Julie Calleros-Lacanlale (MA),

Dr. David Swope (Director of Research),

Kathy Asher (Clinic Manager),

Dr. Travis Losey,

Sheba Baroya (Research Assistant),

Dr. A. Dean Sherzai (Director of Research)

Not Pictured:

Dr. Judy Chang,

Dr. Natasha Demattos,

Dr. Rodolfo Escutin,

Dr. Daniel Giang,

Rajesh Krishnamurthy (Research Assistant)

Dharmaseeli "Dee" Moses (Research Coordinator),

Dr. Laura Nist,

Dr. Gordon Peterson,

Dr. Sarah Uffindell

Department Highlights

Neurology

Dementia. Movement Disorders. Multiple Sclerosis (MS). Amyotrophic Lateral Sclerosis (ALS). Epilepsy. Headache. Sleep. Each of these is a primary clinical trial focus area at Loma Linda University's Department of Neurology, headed up by its team of eleven principal investigators. Neurology Research is co-directed by Dr. A. Dean Sherzai and Dr. David Swope.

There are currently fourteen clinical trials taking place in Neurology. Present sponsors include (but are not limited to) Advanced Neuromodulation Systems, Inc.; Genzyme; Biogen; Sanofi Aventis; ACADIA; ANS; Allergan, Sepracor; Novartis; UCB; Schwarz; Teva; Massachusetts General Hospital; and H. Lundbeck. Neurology would also like to recognize a few sponsors from prior projects: Cangene, Pfizer, Esai, PramiBid, Pharmacia, Cognition, Merck, Kyowa, Ikano, and Ovation.

In addition to the principal investigators, support for Neurology's clinical trials is provided by one coordinator, two research assistants, and one MA.

The Neurology Department's excellence in research has been recently commended through a number of awards and public recognitions:

- 2009—Dr. A. Dean Sherzai was selected to attend the highly competitive National Institute on Aging (NIA) Summer Institute on Aging Research in Washington, D.C.
- 2009—Cangene (sponsor) recognized Dr. Gordon Peterson as a very outstanding Principal Investigator.
- 2010— The Association of Clinical Research Professionals (ACRP) recognized Dharmaseeli (Dee) Moses, RN for maintaining her CCRC for more than ten years.
- 2010—Dr. Khashayar Dashtipour, Dr. Rodolfo Escutin, Dr. Daniel Giang, Dr. Travis Losey, Dr. Laura Nist, and Dr. David Swope were congratulated for having active subjects in the Pharmaceutical Trials.

irb corner

Continuing Review Fees

Industrial sponsors will now be required to pay a fee for continuing review by the IRB as follows:

Full Board Renewal Fee: $750 Expedited Renewal Fee: $500

There is no change to the fee structure for initial review of industry-sponsored clinical trials: Full Board, $2,500; Expedited, $1,500; Exempt, $750.

LLU investigators are asked to incorporate the appropriate fees in their contract budgets, taking into consideration the possibility that the study may require more than one year to accomplish.

It is the IRB's experience that most sponsors will acknowledge this fee whether or not it was stipulated in the original budget. Some industry sponsors may request a contract amendment to accommodate this expense. For assistance with an amendment, please contact Amy Casey (Assistant Director of Clinical Trial Contracts) at acasey@llu.edu or at ext. 87539.

Support from the research community in pursuing this reimbursement with sponsors is greatly appreciated by the IRB. To receive help in resolving any problems that may arise, please contact the Office of Sponsored Research at irb@llu.edu or ext. 44531.

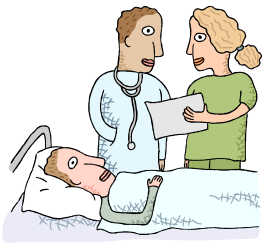
policy particulars

Are You Qualified to Perform Clinical Procedures on Research Subjects?

The Principal Investigator (PI) is directly responsible for all aspects of the research investigation. (21 CFR 312.60) Where appropriate, the PI may delegate task performance to other people qualified by licensure, training, and/or experience to perform such tasks. Any such delegations must be recorded in writing on the Delegation of Authority and Responsibility Log.

If the IRB has limited the possible activities that may be delegated (whether generally or for the specific project), any delegation must be within that scope. Ultimate responsibility for all study activities remain with the PI, regardless of any delegations made. In addition, the laws pertaining to license requirements for the practice of medicine extend to research. Any medical or medically-related procedures that are performed as part of research require the person doing the procedure to hold a valid California license or certificate, if such procedures would require a license or certificate outside of research.

Clinical Research Coordinators should refer to Loma Linda University Health Care (LLUHC) Operating Policy PC-61 for specific certification /license requirements for LLUHC clinical staff that will be performing any patient care procedures (e.g. blood draws, EGK, vital signs on research subjects).



Any inquiries can be directed to Linda Wu, Director of the Clinical Trial Center (ext. 15001); Maxine Ullery, Director of Nursing Resources (ext. 22035); or Kim Skousen, Associate Director of Nursing Resources (ext. 22118).

Researcher's Resources

Your toolbox is only useful if you fill it with the right things. Here are some ideas…

MAGI's Clinical Research Conference—2010 West will be held October 24-27 in San Francisco.

The conference is set up to be an educational treasure-trove of 92 sessions and workshops facilitated by more than 150 speakers, including Linda Wu (Director of the LLUHC Clinical Trial Center) and Lila Dalton (Associate Director of the LLUHC Clinical Trial Center).

The conference has been structured into six different tracks, including Sponsor Operations, Site Operations, Regulatory and Ethics, Contracts, Budgets and Billing, and Special Topics. Attendees may choose to attend any sessions and/or workshops from any track.

"It is a valuable resource for anyone in the clinical research arena."

- Amy Casey, Assistant Director of Clinical Trial Contracts, CTC

In addition to providing an excellent learning environment, the conference will be an ideal setting for networking. More than five hundred professionals are expected to attend, primarily those from clinical trial sites, clinical trial sponsors, CROs, and other service providers. The majority of attendees have several years of experience in clinical research.

MAGI's Clinical Research Conference—2010 West is worth twenty or more continuing education contact hours. Early-bird registration rates end September 17.

For details about the conference schedule and registration, please visit http://www.magiworld.org/events/2010W/.

Clinical Trial Networks (CTN) Best Practices

The CTN Best Practices website, operated by Duke Clinical Research Institute, is a hub for clinical trial information. Main features include Education, Resources, and Collaborations.

If you are looking for templates, new clinical ideas and perspectives, networking opportunities, or just an answer to a burning question… you just might find it here.

CTN Best Practices

https://www.ctnbestpractices.org/

LOMA LINDA UNIVERSITY
HEALTH CARE

Clinical Trial Center

909.651.5002
www.llu.edu/clinical-trials