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ISSUE 5 | JULY | 2011

LLU

clinical trials

Growing Together

Contributed by Linda Wu, Director — Clinical Trial Center

For the first half of 2011, the Clinical Trial Center continued to facilitate the growth of clinical research activities on campus, with the goal to further mature our established system. We are now able to use our Subject Tracking and Reporting (STAR) system to provide current updates for clinical study reports. The STAR system provides current updates of study activities with minimal paper use. We also use this new system to provide clinical department administrators with financial reports reflecting their research activity. This is a useful tool for assessing study productivity and areas of need for site management. In addition to advancements in our STAR system, the content of the CTC website has expanded as well. It is our goal to provide a comprehensive, interactive Investigator-Initiated Life Cycle Processing Flow prior to the end of the year. To streamline the process in this area, the CTC is actively collaborating with the Institutionôs Research Administration.

The Clinical Trial Center is working in partnership with departments across the institution to improve the clinical study process. Research Billing and Finance training is now available on the OWL Portal (https://myllu.llu.edu/security/newLogin/) through a collaboration between the CTC and Staff Development. This training is the first in-house online research training which incorporates synchronized slides with audio. The Clinical Trial Center has also collaborated with Research Administration in the development of Policies and Procedures, including a Research Records Documentation Policy and a Research Subject Injury Policy that will provide useful guidance to the research community.

The Clinical Trial Center has identified study enrollment as a challenge area for certain studies. To address this challenge, we have begun a project to identify solutions that can be beneficial to all studies i.e., establishing study advertising service and site coordinator recruitment training. The CTC is now providing consultations to the clinical department for site management assessment with the goal to build more efficient and productive clinical research teams. The Clinical Trial Center is delighted to facilitate the initiation of several new trials that meet our researcherôs interests. We look forward to growing our research enterprise with you and to partner with you for better services and success in the future.

TRIAL TRIVIA

Did you know that a Medicare Coverage Analysis (MCA) is required for every clinical research study?
Medicare Coverage Analysis is used to determine the Medicare eligibility of the study based upon Medicare guidelines and a complete review of the protocol to determine which of the clinical ñeventsò mentioned within the protocol can be reimbursed by Medicare. Since clinical research often takes place concurrently with routine care, it is important that billing is handled in accordance with applicable legal requirements. In addition, because most third party payors follow Medicare rules for coverage, institutional policy requires that MCA is performed whether or not the study enrolls Medicare patients (see LLUAHSC policy H40). For more information, please contact the Clinical Trial Center.

finance

Understanding Budgets

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

Dictionary.com defines ñbudgetò as an ñestimate of expected income and expenses,ò and when used as a verb as ñto allot (money, time, etc.).ò However, the definition does not detail the important functions that a properly prepared budget can and will provide. Budgets should not be merely a bunch of meaningless numbers that have been thrown together to prepare the document.

Proactive research study teams will prepare budgets once and update when necessary for such times as amendments and protocol changes. Unfortunately, all too often, the budget process is viewed as more of a formality rather than a useful document or tool. While budgets should be part of a careful and detailed process and analysis of how to reach the needs of a study, it is much more common that the budget is merely thought of as a ñbunch of numbersò that have to be prepared, rather than anything useful. ñLet's just prepare it and pass it throughò or ñIt doesn't really matter, because we'll just change it if we need to anyway,ò are repeated ad nauseums which make the entire process little more than a waste of time and energy.

When either preparing or reviewing a budget, first carefully review the income (or revenue) side. How has each line item been calculated? How does each number compare with the actual amount from previous studies? When a study team prepares a budget, it is important to be very conservative with revenue or income estimates and projections, and very aggressive in calculating expenses.

Expense items need to be reviewed very carefully, item by item. In some instances, a ñprevious budget plus" concept is used during budget formulation. Previous budget plus means it simply takes what was spent (or even worse, projected to be spent) in the previous budget, and a specified amount is simply added across the board to most expense items. When budgets are prepared this way, they are truly the waste of time and effort as mentioned above. When each item is analyzed on a "needs" and "effectiveness" basis, one often realizes that monies are expended in many areas that do not provide the required result, while in other areas; more funds may need to be spent.

A budget can be the most important tool used by a successful study team, not simply an exercise. Many like to state that "It's only a small amount. It won't amount to anything- it's not large enough." Nothing could be further from the truth.

Credit Where Credit is Due

Contributed by Terry Merrick, Clinic Manager—Ophthalmology

A sincere congratulations goes out to Ophthalmologyôs Kara Rollins and Cara Davidson for the outstanding results they recently received on their Site Status Report from the DRCRnet study (01/01/10-12/30/2010).

In all major areas where they were previously exceptional, they remained exceptional (3). In other major areas they improved from either below expectation or acceptable to exceptional (2).

Out of sixteen sites scored, they took Second Place. First Place was given to Joslin Diabetic Research Center (Harvard Medical School), which is a site dedicated to research.

Welcoming Carol Evans

Contributed by Carolyn Hurlbut, Project Specialist at the Clinical Trial Center

The Clinical Trial Center is happy to announce their new Administrative Secretary, Ms. Carol Evans.

Ms. Evans provides administrative support to the CTC. She works to facilitate the Clinical Trial process by communicating with investigators, coordinators, clinical trials personnel, and Research Affairs to schedule feasibility meetings and coordinate communication. Carol provides secretarial, data, and clerical support to the CTC in order to facilitate the implementation and management of clinical trials. She also collaborates with departments to coordinate ancillary support for clinical trials. Carol maintains knowledge of institutional research resources and research department contacts and responds to inquiries with accurate and timely information.

Carolôs professional background includes twenty years of administrative/secretarial experience, twelve of which were spent in the insurance field.

Open house



Contributed by Carolyn Hurlbut, Project Specialist at the Clinical Trial Center

Clinical Trial Center Open House!

On May 6, 2011, the Clinical Trial Center Staff was thrilled to find the support of so many colleagues at a very well-attended Open House. Approximately one hundred attendees throughout the entities joined the CTC in celebrating their first permanent location since the departmentôs official inception in 2010.

Linda Wu opened the event by outlining the history of the Clinical Trial Center and explaining the formation of its slogan, operating as ña logistics center for transforming lives through clinical research.ò Ms. Wu continued by stating that the CTC could only transform lives through clinical research by working each day with an important verse in mind. The verse is John 15:5, ñI am the vine, you are the branches. If a man remains in me and I in him, he will bear much fruit; apart from me you can do nothing.ò This message is the key component in the daily operations of the CTC, knowing that with God, their work will be fruitful.

Following this introduction, Chaplain Dilys Brooks gave a blessing upon the office. The celebration continued as guests toured the offices, socialized with colleagues, and enjoyed hors d'oeuvres such as ñfalse claimò cookies, ñdouble-dippedò strawberries, and ñkickbackò punch.



"Thank you so much for the support at the well-attended open house. We are truly blessed to work with such a supportive group of individuals who all strive to work together to transform lives through clinical research." –Linda Wu

laboratory safety

Shipping Dangerous Substances

Contributed by Susan Davey, Laboratory Safety Specialist, Loma Linda University Shared Services

Did you know that the shipping of dangerous goods is highly regulated? The institution could be subject to fines if substances are not packaged and documented correctly. The categories of dangerous goods are as follows:

Class 1	Explosives
Class 2	Gases
Class 3	Flammable liquids
Class 4	Flammable Solids; substances liable to spontaneous combustion; substances which, in contact with water, emit flammable gases
Class 5	Oxidizing substances and organic peroxides
Class 6	Toxic and Infectious substances
Class 7	Radioactive material
Class 8	Corrosives
Class 9	Miscellaneous Dangerous goods

For research studies, shipping of infectious substances (Class 6) and dry ice (Class 9) may be necessary. For shipping materials that have Material Safety Data Sheets, consult section 14 of the MSDS for helpful information. If you need any assistance with shipping or would like to schedule required training (scheduled on an as-needed basis), call Susan Davey at extension 58162.

Need dry ice for shipping?

The CTC may be able to help with ordering. Please contact Carol Evans at ext. 15002.

contracts

Playing the Match Game: Consistency between ICD, Contract and Protocol

Contributed by Amy Casey, Assistant Director of Clinical Trial Contracts at the Clinical Trial Center

With any industry sponsored clinical trial, there are three key documents provided by the sponsor no matter what the focus of the study: the clinical trial agreement (CTA), the study protocol and the informed consent document (ICD). The key to starting any study is making sure these three documents are consistent with one another. If they do not match, confusion and trouble may lie ahead for the sponsor, the Institution and Principal Investigator, or the study subject and maybe even all four!

There are numerous instances where it is important that consistency between the aforementioned documents is confirmed. For example, responsibility for paying for research subject injury is often mentioned in both the ICD and CTA and even the study protocol. It is essential that what is being communicated to the subject in the ICD is what is actually agreed to in the CTA. Many Institutions have run into trouble when their approved ICD states that the sponsor will pay for research subject injury; however, the contract states that research subject injury will not be paid by the sponsor. In this situation, the subject does not know that their insurance company or they themselves could be billed for any injury they may receive as a result of the trial. If a subject was to be injured and these two documents are not consistent, who would pay for a research subject injury?

It is essential that there is a check for consistency between all documents in order to avoid complications and inconsistencies as the study progresses. Many of these inconsistencies, when gone unchecked at the time of pre-approval, are usually not discovered until there is a problem, which is the worst time to encounter this issue. To avoid problems, open communication between the contracting parties and the IRB, as well as making sure that someone is ñplaying the match gameò with all documents before a contract is executed and IRB approval is released, creates a win-win situation for all.

clinical lab update

Research Lab Requests are now Streamlined

Contributed by the Clinical Trial Center staff

In an effort to simplify the ordering of outpatient clinical laboratory testing, a research specific requisition has been created. The Clinical Trial Center has collaborated with the Clinical Lab, Patient Care Services & Nursing Informatics, Patient Billing Offices, and Clinical Informatics to create a standard Research Test Requisition and Research Clinical Lab Testing workflow. Both the requisition and workflows are now accessible on the Clinical Trial Center Website.

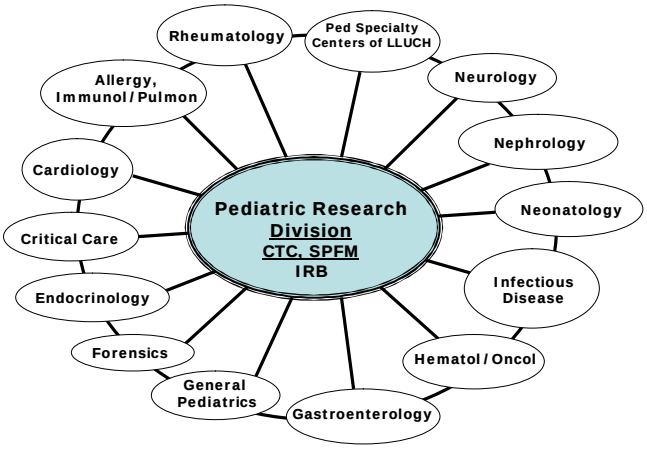
To access these documents, visit www.llu.edu/clinical-trials and select ñUseful Guides and Formsò on the drop-down menu under ñFor Clinical Researchers.ò Next, select the ñClinical Laboratoryò icon. The requisition and workflow are the last two links listed. To order the Research Requisition form, please submit a requisition to Printing Services.

Department Highlights

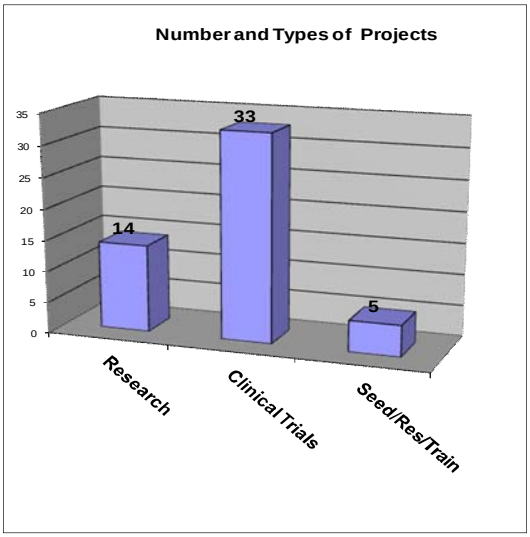
pediatrics

Contributed by the Department of Pediatrics Research

The Pediatric Research Division, created in 2002, is a multi-disciplinary research support team within the Department of Pediatrics located in Coleman Pavilion. The Pediatric Research Division operates on the mission *To Provide Support for Research Investigators within the Department of Pediatrics*. This 23-member team, directed by Mike Kirby, PhD, and managed by Ricardo Parker, PhD, provides increasing research support for both the pediatrics faculty carrying out clinical research as well as basic research studies.



The division also provides education to assure compliance with institutional and federal regulations. For Fiscal Year 2010/2011, the pediatric research division supported faculty researchers engaged in over 40 open and active research projects, including 33 Clinical Trials and 14 Basic Science Projects. The CTC currently manages the logistics for 10 active clinical trials, and SPFM manages 44 active projects, with an average annual income for the most recent academic year of $1.9 million. Research projects encompass 14 different pediatric disciplines (see Figure above). Projects are predominately funded by federal grants and private contracts. The department was just awarded its fourth NIH R01 grant. Our ongoing objective is to expand our research support capabilities and establish further collaborations in pediatric research.



As of 2009, LLUCH is the second busiest childrenôs hospital in California. The department of Pediatrics is the only full-service department serving nearly 1.2 million over a 4-county region. Resources include 270 beds; the nationôs largest IC nurseries (84 beds); 25 pediatric critical care beds; 14 cardiac ICU; and 19 intermediate ICU beds; Unit 4200 converted for care of adolescent patients; Out-patient Services; General & Sub-specialty Clinics; Hospital-based Multi-disciplinary Team Clinics; and an Integrative ñWholisticò Pediatric Health Care Clinic.

The Pediatric Research Division created the Pediatric Research Oversight Committee to facilitate future growth and expansion. Goals include:

- Support an environment of inquiry with the department
- Foster development of research skills and results amongst the faculty
- Develop department research policy
- Oversight of fiscal implications of department research endeavors
- Oversight of performance of support functions of the research division
- Support philanthropy for research in the department

Pediatric Research Team

Chairman: Richard Chinnock, MD
Chief of Pediatric Research and Associate Director of Research Affairs: Michael Kirby, PhD
Senior Administrator: Joy Iwakoshi

Investigators:
Dr. Richard Chinnock
Dr. Harry Opsimos, Allergy/Pulmonary
Dr. Kimberly Otsuka, Allergy/Pulmonary
Dr. William Kennedy, Infectious Diseases
Dr. Soo Kim, Infectious Diseases
Dr. Antranik Bedros, Hematology/Oncology
Dr. Albert Kheradpour, Hematology/ Oncology
Dr. Christopher Morris, Hematology/ Oncology
Dr. Shamel Abd-Allah, Critical Care
Dr. Jim Eguchi, Critical Care
Dr. Chiaka Ejike, Critical Care
Dr. Mudit Mathur, Critical Care
Dr. Cynthia Tinsley, Critical Care
Dr. Ravindra Rao, General Pediatrics
Dr. Valarie Wong, General Pediatrics
Dr. Arlin Blood, Neonatology
Dr. Mitchell Goldstein, Neonatology
Dr. Andrew Hopper, Neonatology
Dr. Kristen Hougland, Neonatology
Dr. Yomna Ibrahim, Neonatology
Dr. Thurman Merritt, Neonatology
Dr. Stephen Ashwal, Neurology
Dr. Shobha Sahney, Nephrology
Dr. David Michelson, Neurology
Dr. Peter Przekop, Neurology
Dr. Marti Baum, Pediatric Teaching Office
Dr. Kiti Freier, Psychology
Dr. Eba Hathout, Endocrinology
Dr. Manoj Shah, Gastroenterology

Manager, Research & Grants: Ricardo Parker, PhD
Lead Research Nurse Coordinator: Anne Keough, RN
Division Secretary: Zeresh King

Clinical Research Coordinators: Leon Smith, LVN; Betty Voltz, LVN; Genevieve Gradilla, LVN; Melissa Rundquist, LVN
Research Associates: Nirmalya Ghosh, PhD; Christine Turenious-Bell, PhD; Viorela Pop, PhD; Taiming Liu, PhD; Jaime Pivonka-Jones, PhD, Beatriz Tone

Research Technicians: Jesica Kanady, Kamlesh Joshi

Research Assistants: Kamlesh Joshi; Jesica Kanady; Tian "Tina" Huirou; Dane Sorensen; Kurt Vrancken

irb corner

Contributed by Anu Diekmann, Sponsored Research Analyst at Sponsored Research

Ask the IRB

What are the most frequent reasons IRB application packets are returned without being reviewed?

1. An outdated IRB application form was submitted. *ALWAYS* go to our website (http://research.llu.edu/ApplyingToIRB.asp) and download the current application form! We frequently update and improve our forms to make them more user-friendly and to keep up with changing regulations, policies, and guidance.

2. The application form was incomplete (i.e. was lacking necessary signatures and/or required responses to certain sections).

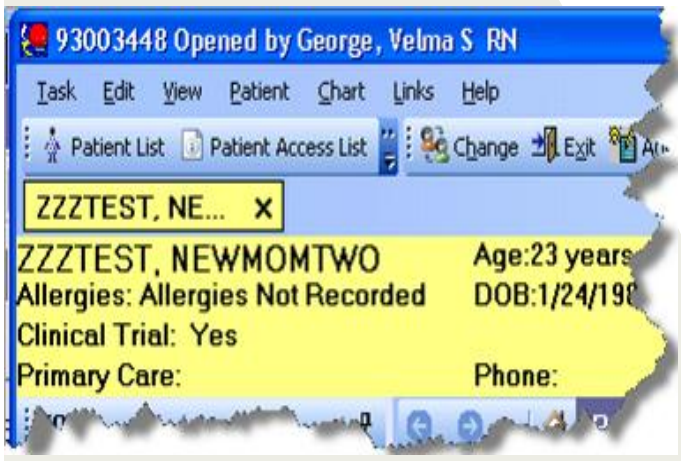
3. Items from the applicable IRB checklist (available at http://research.llu.edu/ApplyingToIRB.asp) and supporting appendices were not submitted. Remember to organize your IRB packet in the following order:

   a. One copy of the applicable IRB Checklist
   b. One copy of the Clinical Trial Center Feasibility Checklist (for clinical trials)
   c. Current IRB Application Form
   d. Abstract
   e. California Experimental Subjectôs Bill of Rights (if applicable)
   f. Informed Consent/Assent Documents (if applicable)
   g. Authorization for Use of Protected Health Information form (if applicable)
   h. Protocol
   i. Appendices (Survey tools, advertising material, investigatorôs brochures, any other supporting documentation)
   j. Clinical Trial Center Billing Grid (for Clinical Trials)

Feel free to e-mail us at IRB@llu.edu if you have any other questions.

announcement

The CLT Flag is now live!



We are pleased to announce that phase one of the Clinical Trial flag project is completed! Patients who are enrolled and are active in Clinical Studies are now flagged on the Cerner demographic banner. The flag contributes to patient safety as well as billing compliance. The CTC collaborated with numerous departments on campus and was well-supported to complete this project. Thank you to all for your assistance in this project!

policy particulars

Policy & Procedure Updates

Contributed by Lorraine Sarmiento, Accreditation Coordinator at Research Affairs

The following new policies have been approved this year: Clinical Trial Medicare Coverage Analysis (H-40) and Freedom of Information Act Requests (H-41). A new procedure has also been added: Institutional Review of Research (H-22.A). Summaries of these documents are below:

Clinical Trial Medicare Coverage Analysis (H-40)
All clinical trials will receive a Medicare Coverage Analysis to determine eligibility for reimbursement of routine care costs incurred during a clinical trial. The Center for Medicare and Medicaid Services has established criteria that ñdeemò clinical trials eligible to have approved costs reimbursed. This policy and procedure describes which clinical trials meet the CMS eligibility requirements and who is responsible for conducting and submitting the coverage analysis.

Freedom of Information Act (FOIA) Requests (H-41)
The Freedom of Information Act (FOIA) is a federal law that allows for full or partial disclosure of previously unreleased information or documents controlled by the United States government. The Act defines the types of records subject to disclosure, outlines mandatory procedures, and grants nine exemptions to disclosure requirements. Requests for information are initiated with a government agency, who will then contact specific non-governmental organizations prior to release of information pertaining to them. This policy/procedure outlines how Research Affairs in collaboration with appropriate departments or individuals will work with the government agencies to complete these requests.

Institutional Review of Research (H-22.A)
Federal regulations allow the institution to disapprove human studies research that has been previously approved by the IRB. This procedure identifies the process for institutional review of research, when there is a question about whether or not it is in alignment with the vision/mission/interests of the institution. Anyone can raise concerns about a research project. The determination as to whether the institution will allow the research to be conducted will be made by the President/IO (VPRA) in consultation with the Research Oversight Committee.

For additional information on LLUAHSC Policies H-40, H-41 and LLUAHSC Procedure H-22.A, please visit www.llu.edu/pages/handbook/lluahsc_policies/H-Research Affairs/ Table of Contents.

training opportunities

Upcoming IDX Training Dates

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

Did you know you can view IDX training dates on the VIP page?

Go to the following link and select the UHC Training Calendar.
Two IDX trainings are available: one for established IDX Users and another for New IDX Users.

To schedule, cancel, or reschedule a class, please call the UHC Education Line at Ext. 15017.

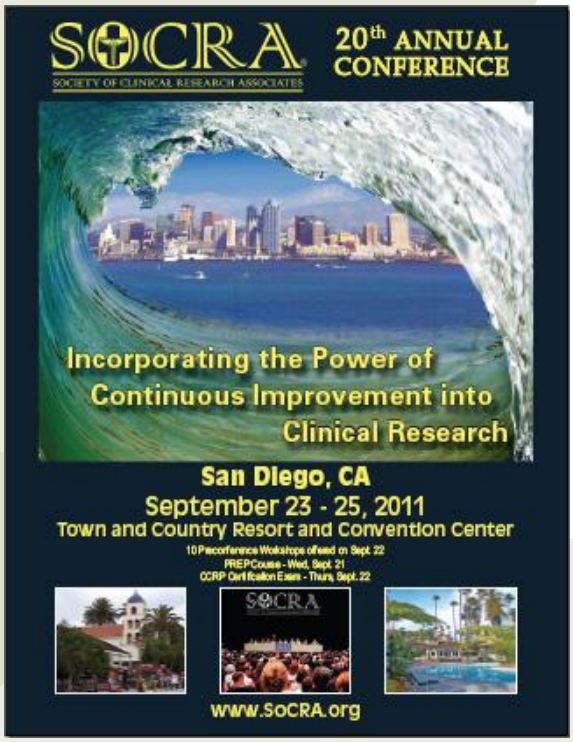
http://vip.mc.llumc.edu/vip/Departments/LLUHC-Departments/Front-Office-Services/Front-Office-Education/Index.page

July IDX Training dates are as follows at the FMO, Room B150:

- July 18 9:00-11:30 Established Users
- July 25 1:00-4:00 New Users

Researcherâs Resources

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



SOCRA 20th Annual Conference:
Incorporating the Power of Continuous Improvement Into Clinical Research

September 23-25, 2011
San Diego, CA

http://www.socra.org/html/SoCRA_Annual_Conference.htm

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