ISSUE 6 | OCTOBER | 2011

LLU clinical trials

Moving Forward

Contributed by Linda Wu, Director — Clinical Trial Center

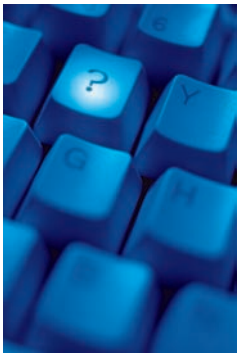
The Clinical Trial Center's (CTC) focus this past year has been maturing our operational systems and services. Our Subject Tracking and Reporting System (STAR) is near completion, with action plans in place to begin reporting via a business intelligence tool, and converting our system to a web-based format. These added features will enable us to analyze operational data as well as enhance our services to you.

We have added many helpful features to the CTC website to assist you in the clinical study process. One of these features is the "Open and Recruiting Trials" page, which lists studies that are currently open for enrollment at LLU, along with a link to an IRB-approved flyer containing study contact information. Information regarding student or volunteer assistance in clinical research is also listed under "Tools and References." All links on the CTC website to the Research Administration website have now been updated so you can access the most up-to-date information for your research needs. An IND Decision Worksheet is now available to assist you when deciding whether your study requires an IND submission to the FDA. If you need assistance finding an industry grant for a PI-Initiated study, visit our Investigator-Initiated Trial Grant Resources link. In addition, the instructional and interactive PI-Initiated Clinical Trial Life Cycle will be made available by the end of this year.

The CTC is currently developing a Research Coordinator Toolbox training, which is targeted to be held in the first quarter of 2012. The training will be a hands-on four-hour course focused on regulatory document management and study and patient management. More information will follow soon. The CTC has also collaborated with other departments to develop standard forms for research use. One of these forms is the LLU Clinical Engineering Inspection Request Form, which can be found on the CTC website under "Tools and References." The second form is the LLU Device Study Worksheet, which was developed with the Office of Sponsored Research and Research Integrity. This worksheet will be used in conjunction with the Feasibility Checklist when determining whether an IDE needs to be submitted for your study.

We are pleased to introduce our newest member of the CTC in this issue, our Regulatory Affairs Coordinator, Mary Ann Nyc. Our office will soon be able to provide regulatory support for your studies as needed. This will be a fee-for-service for those research teams that need regulatory support. In response to the identified need for study enrollment support, we have assisted PIs with study advertising to increase patient recruitment. A subject recruitment service is also currently in development, this service can provide you with pre-screening and subject referral services.

As always, we are here to serve you. If you have any questions, comments, or suggestions, please do not hesitate to contact our office.



TRIAL TRIVIA

Q: When do I need to notify the billing offices that I am screening a patient for a specific study?

A: It's very important that the billing offices receive notification within 1 business day of you consenting a patient. This step assures that the patient will not be billed for any research related activity that may occur as part of the screening process. It also assures that the study records will accurately reflect the number of patients consented to a study.

Q:If the patient screen fails, do I still need to notify the CTC?

A: Yes; It is important that the CTC be notified when a patient screen fails. Screen failure may be reimbursable item. Your notification is the trigger for such reimbursement as well as the removal of research flag in medical record.

finance

Understanding Audits

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

Audits come in many forms, shapes and sizes and are usually viewed by most with a negative appeal. On the contrary, an audit can prove to be beneficial and enlightening. Administrators and department personnel often spend copious amounts of time managing their processes and financial information. Administrators can use an external audit to review their process flows and financial information. Usually a certified auditor will interview key employees, discuss processes, and test the accounting information. External audits offer several benefits: validity, error discovery, process voids, mitigates liability, and education.

Provides Validity
External audits provide an objective opinion of an institution's processes. Some administrators or department heads may not have an in-depth understanding of departmental processes. Unbiased professional auditors can review this information and provide administration with insight on the accuracy and validity of the institution's processes. Validated processes can provide administration assurance on compliant operations within the institution.

Discovers Errors
Hospital Administration can use external audits to discover errors in their process flows. With these process errors, proper analysis could be hindered and prohibit department heads and administration from making the best decisions. Administration can also find it difficult to review historical financial information and discover trends if errors are in place. Trends allow for planning future production output and estimates for the upcoming months.

Educates Business Owner
External audits can help educate department heads on the importance of the process flows within their department. Department heads will often work closely with external auditors to further improve their current processes. External auditors may provide administration with information on current healthcare issues and recommend how to adopt the new procedures. After an audit, the auditing staff may provide the institution with free educational seminars to increase employee knowledge and ensure compliance. Creating a personal relationship with an auditing firm provides an institution with professional insight for future questions or concerns.

Patient Recruitment Service now Available

The Clinical Trial Center is pleased to announce a new service to assist with patient recruitment. On the Clinical Trial Center website, there is now a link to "Open and Recruiting Trials" under the "For Research Volunteers and their Families" drop-down menu. This link includes information for potential study participants, including who can participate in the study and the goal of the study. When the text within "who can participate" is selected, a link to an IRB-approved flyer opens with the study contact information.

You are highly encouraged to take the advantage of this new advertising portal as our website is visited by the public and our center has received inquiries from the public about open recruitment trials. Please contact Carolyn Hurlbut at the Clinical Trial Center at churlbut@llu.edu or extension 15002 to explore how to use this service.

Thank you for your continued dedication to transform lives through clinical research.

Welcoming Mary Ann Nyc

Ms. Mary Ann Nyc coordinates study regulatory submissions for clinical research projects managed by the Clinical Trial Center. She is responsible for assisting the PI in the creation and maintenance of all regulatory documentation, assists with study-related analysis, and maintains communication among the Office of Research Affairs, the Office of Sponsored Projects, research investigators, clinical research staff, and project sponsors. Her job ensures quality management of regulatory documents by continuing review and submissions of required documents in compliance with Federal, State, and local standards.

Ms. Nyc received a Bachelor of Science in Biology and a Bachelor of Science in Biological Anthropology & Anatomy from Duke University. She is currently completing her Masters in Public Health at Loma Linda University. She has over 12 years of experience in clinical research, working on pharmaceutical industry, investigator-initiated, non-profit, and federal research projects.

New Coordinators on the Block

Cindy Kronbeck, Department of Medicine Research Nurse

In July 2011, the Department of Medicine welcomed Cindy Kronbeck as their newest Research LVN. One of her responsibilities is working on networking within the department. Under the direction of Dr. H. Bryant Nguyen, Chair of Research, they are beginning the process by constructing a research database. This database will be a tool for faculty and residents to make them aware of new and on-going studies within the department.

Ms. Kronbeck has worked for Loma Linda University for 18 years as a pediatric neurology nurse. Most recently, she worked with Pediatric Research for the last 2 ½ years. She is very happy to be a part of this growth in the Department of Medicine.

Brandi Perez, Department of Ophthalmology Research Coordina-

The Department of Ophthalmology welcomes Brandi Perez as their newest Research Coordinator. Ms. Perez is currently the head coordinator for both the Diabetic Retinopathy Clinical Research (DRCR) Network, as well as a study with GlaxoSmith-Kline. Brandi is also a backup coordinator for other current and upcoming studies. She worked as an Ophthalmic Assistant/ Medical Assistant for two years with Loma Linda Ophthalmology before moving to research. In that time, she gained experience in most subspecialties within Ophthalmology, such as Cornea, Glaucoma, Retina, Oculoplastics and Neuro-Ophthalmology. Before joining the Loma Linda team, Ms. Perez worked many years in the field of optometry as a Licensed Optician.

Tammy Phan, Emergency Medicine Clinical Research Coordinator

The Department of Emergency Medicine welcomes Tammy Phan as their newest Research Coordinator. Tammy was born in San Bernardino and raised in Orange County. She is the younger of two twins and one of five children. In 1998, she moved to Moreno Valley and graduated Moreno Valley High School in 2000. In 2004, she received her Bachelor's of Science from the University of California, San Diego. In June 2010, Tammy completed medical school at the American University of Antigua, College of Medicine. Tammy married her husband in 2008 and they welcomed their baby girl, Kourtney Ly Phan, to the family this year. Recently, she has worked with Dr. H. Bryant Nguyen in his severe sepsis research and RCRMC as a scribe. In her spare time, Tammy enjoys bowling, watching TV, trying different foods, frozen yogurt, and cycling, to name a few.

Megan Russell, Cardiothoracic Clinical Research Coordinator

In July 2011, the Department of Cardiovascular and Thoracic Surgery welcomed a new Research Coordinator, Megan Russell, to their team. Megan works to coordinate the research efforts of the Cardiovascular and Thoracic Surgery Department. She is involved in preparing and submitting IRB applications, working with study subjects, interfacing with study sponsors, and providing general research support to the department wherever needed.

Megan graduated from Brigham Young University in 2007 with a BS in Neuroscience and from the Medical College of Wisconsin in 2011 with a MA in Bioethics. Megan comes to us from the Medical College of Wisconsin where she worked as a Clinical Research Coordinator and Quality Improvement Specialist for the IRB. Her areas of expertise include research coordination, research ethics, and research compliance.

Leon Smith, Cancer Center Clinical Research Coordinator

The Loma Linda University Cancer Center welcomes their newest Clinical Research Coordinator, Leon Smith. Leon is originally from Philadelphia, PA. He moved to Southern California in 2004 and has worked as a LVN for Loma Linda since that time. He began work in research for the department of Pediatrics in 2008. In 2010, he received his certification in Clinical Research. Leon is inspired by two lifelong friends who are cancer survivors.

ctc website updates

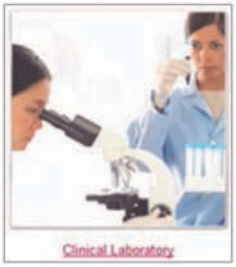
Now available online

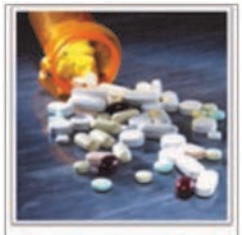
Contributed by Carolyn Hurlbut, Project Specialist at the Clinical Trial Center

Looking to increase patient recruitment? Try the new "Open and Recruiting Trials" Feature, which includes a list of open and recruiting studies for potential participants. Pertinent information such as who can participate, the goal of the study and an IRB-Approved flyer is included on the webpage.

Just how "useful" are the Useful Guides and Forms?

- Clinical Lab confusion? Check out the Clinical Lab Workflows and Research Test Requisition.
- Looking for volunteer assistance with your studies? Go to "Student/ Volunteer Assistance in Clinical Research."
- Need more information on Investigational Drug Services? See the Investigational Drug Services Useful Guides and Forms.
- Quick! How do I get to the new Research Affairs Forms?
- Do I really need to submit an IND to the FDA? Find out by using our IND Decision Checklist.


Clinical Laboratory


Investigational Drug and Device


Research Affairs Forms

ctc website updates

IDX Posting Training Update

Contributed by Rick Grable, Director of Front Office Services for UHC

IDX Training Videos are now available on the VIP website at: http://vip.mc.llumc.edu/vip/Departments/LLUHC-Departments/Front-Office-Services/Front-Office-Education/Index.page. There are five videos available at this link, which you may view at your own pace. These videos include:

Registering a New Clinical Trials Patient
Generating a Research Case
Scheduling a Clinical Trials Appointment
Posting Charges to a Research Appointment
Posting Research Charges with No Appointment or Inpatient Charges

**Prerequisite: Regulatory scheduled TES Check Out training should be attended prior to posting research charges.*

These videos are recommended for users already trained in IDX (Registration, Scheduling and TES Check-Out). They contain information specific to Clinical Trials and general IDX knowledge is assumed. By watching these videos, an experienced IDX user will be provided the necessary instruction in how to process a clinical trial encounter.

General IDX classes are available by calling ext 15017.

irb corner

Contributed by Anu Diekmann, Sponsored Research Analyst at Sponsored Research

Ask the IRB

1. How do I find out the status of my IRB review?

For *ALL* status inquiries, call x44531 and refer to the study by IRB number (if available) or the PI's name and study title. Co-investigators (i.e., medical students, residents, fellows) are urged to check with their PIs before calling Sponsored Research.

2. What affects study status?

When a new study is received, an acknowledgement e-mail is sent to the PI/coordinator to alert them that their approval documents will be held until:

- Current CVs for investigators are on file
- Human Subject Education requirements are met for all study personnel
- Sponsor contract/agreement is signed by an officer of the appropriate LLUAHSC entity
- IRB fee has been paid
- Research conflict of interest disclosure forms have been submitted and/or conditions from the research conflict of interest committee have been satisfied

The study may also be held for:

- Radiation Safety Committee approval
- Institutional Biosafety Committee approval
- Satisfaction of IRB conditions of approval (as indicated in an interim letter/communication)
- Letters of agreement from collaborating departments (if applicable)
- Clinicaltrials.gov registration (if applicable)

In addition, incomplete submissions or failure to provide requested documents such as clean consents and HIPAA authorizations delay the investigator's receipt of IRB approval.

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

announcements

Did you know that an Informed Consent Template is available on the Research Affairs website? It is highly recommended that investigators thoughtfully revise the content provided by sponsors and follow the Research Affairs template as a guide to include the appropriate text and information required by LLU.


MODEL CONSENT FOR RESEARCH IN CLINICAL SETTINGS

INSTRUCTIONS (Delete this box)

INFORMED CONSENT

TITLE:
SPONSOR:
PRINCIPAL INVESTIGATOR:

Did you know if you use non-Loma Linda equipment, it needs to be inspected?

See the LLU Equipment Inspection Form on the CTC Website for more information.

policy particulars

Policy & Procedure Updates

Contributed by Lorraine Sarmiento, Accreditation Coordinator at Research Affairs

The following new procedure and chart has been approved. Summaries of these documents are below:

Policy H-42: Research Records, Documentation, Retention, Storage, and Access for Human Subject Research

Clinical Research Records Documentation (procedure)

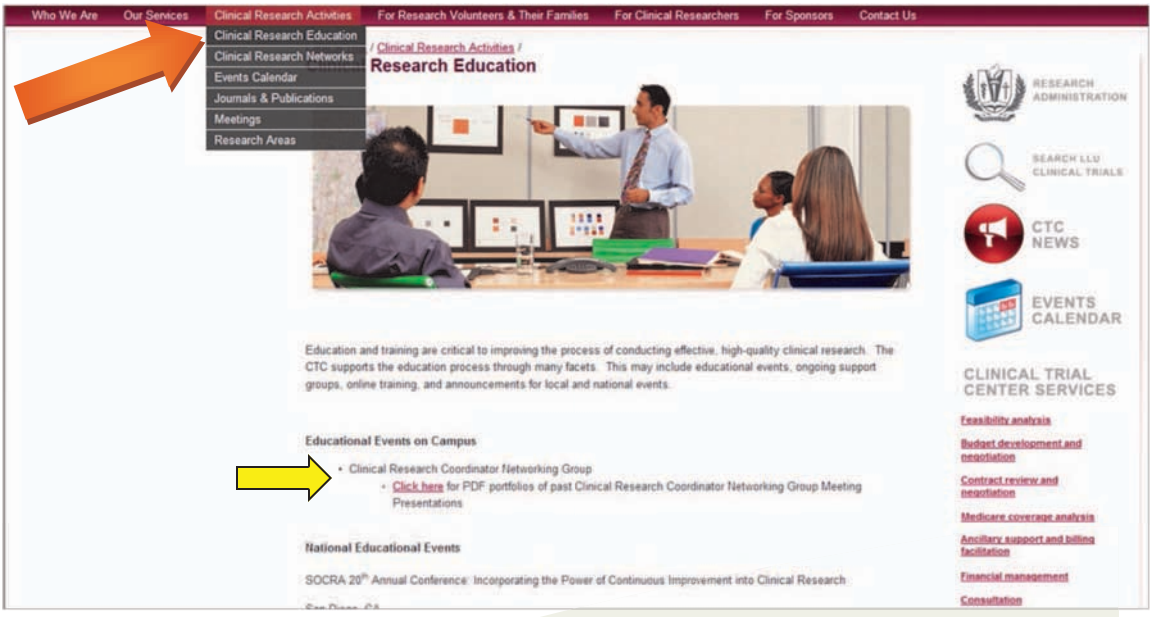
Human Subject Research Records (charts)

Research records must be prepared and maintained, and kept, stored, and accessed as allowed by federal regulation and in accord with institutional policy. Procedures will address each of the areas pertaining to research records. Currently, Research Affairs has developed a procedure for Clinical Research Records Documentation identifying specific requirements that must be followed in setting up and maintaining research records when they have the potential to impact current or future care of the patient. In addition, three charts have been created, outlining which research records belong in the Medical Record, Investigational File for Clinical Research, and in the Investigator's Research files (administrative). Subsequent procedures addressing retention, storage, and access to research records are currently under development.

For additional information, please visit www.llu.edu/pages/handbook/lluahsc_policies/H-Research Affairs/ Table of Contents.

for your convenience...

Presentations and handouts from the Clinical Research Coordinator Networking Group Meetings are now posted on the CTC Website under "Clinical Research Education."



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: 2011 West

October 23-26, 2011
Las Vegas, NV

http://www.magiworld.org/events/2011W

PRIM&R
PUBLIC RESPONSIBILITY IN MEDICINE AND RESEARCH

PRIM&R 2011 Advancing Ethical Research Conference
Harmonizing Ethics, Regulations, & Research
December 2-4 | Pre-Conference Programs December 1
National Harbor, Maryland

PRIM&R's Advancing Ethical Research Conference: Harmonizing Ethics, Regulations, and Research

December 2-4, 2011
National Harbor, Maryland

http://www.primr.org/Conferences.aspx?id=11065

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