

Discoveries

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Notes from the Director,

Dr. Tate Erlinger, MD, MPH

As the Director of the Clinical Research Office, it is a distinct pleasure to introduce you to our newsletter and let you know about some of the changes that have taken place over the last few months. Recently several changes have occurred at the Seton Family of Hospitals that are strengthening and enhancing clinical research. It is tremendously exciting to see these changes and the clear enthusiasm for conducting highquality clinical research. To meet this enthusiasm, we have been working hard to increase educational opportunities around methods, improve general knowledge of regulatory policies and streamline administrative processes. Some exciting changes are highlighted below. The commitment to safe and meaningful clinical research at Seton ultimately reflects the desire to provide the highest quality of care for our patients and the greatest respect for each study volunteer. It is an honor and a privilege to be a part of the Seton Family of Hospitals and to be working with you in this effort.



Dr. Tate Erlinger, MD, MPH

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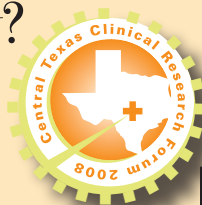
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NOTABLE EVENTS:

Central Texas Clinical
Research Forum 2008
May 9th at the CEC

What's New?

Central Texas Clinical Research Forum 2008



We are currently in the early planning stages for a system-wide research forum. The forum will provide a platform to discuss developments in clinical research. Oral and poster presentations will highlight individual research projects, research groups and novel educational programs. We hope to hold the first forum in the spring of 2008. Stay tuned! More later!

Ken Kirksey, RN, PhD, Director of Nursing Research

Dr. Ken Kirksey recently joined the Seton Family of Hospitals as the Director of Nursing Research. We wish to offer Dr. Kirksey a warm welcome and are very excited to have him here! Yet another example of the excellence of Seton nursing and the commitment to the highest standards.

IRB Member Educational Conference

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Seton Monthly Clinical Research Seminar Series

This monthly series has been created so that Seton staff or individuals conducting research within Seton can better understand research processes. The seminar topics include regulatory issues and an overview of basic research methods. Copies of each presentation will be available on our website.

Topics in Research

Article Title: History of IRB at the Seton Family of Hospitals

Dr. Sharon D. Horner, PhD, RN, Professor of The University of Texas at Austin, School of Nursing, and Chairperson of BHIRB.

In accordance with Federal regulations, an Institutional Review Board (IRB) is responsible for reviewing research protocols to ensure the protection of human research participants. The IRB review of research protocols focuses on three principles: First to minimize risks to human research participants (Beneficence). Second to ensure that all participants are fully informed about the research protocol activities and any risks (Autonomy). Third to promote equity in the selection of human research participants (Justice).

The Brackenridge Hospital Institutional Review Board (BHIRB) was originally established as a free (or no-cost-to-investigator) IRB to oversee oncology clinical trials conducted by physicians affiliated with Brackenridge Hospital and Children's Hospital of Austin. Late in 2004, external and internal factors led the BHIRB to expand its focus beyond oncology clinical trials to provide oversight for research studies conducted within the Seton Network that were either supported with federal funding or were unfunded investigator-initiated studies.

More recently, the affiliation with UTMB-Galveston led to the need for a local IRB that would serve the UTMB faculty, residents, and students. In response, the BHIRB was reconstituted In January 2007 with 11 new and 3 continuing Board members and designed to serve in a collaborative fashion with the local UTMB-IRB#3. In practical terms this means that the BHIRB has the same membership as the UTMB-IRB#3. BHIRB is authorized to oversee federally-funded and unfunded local research conducted in the Seton network by non-UTMB personnel. UTMB-IRB#3 has oversight of all research conducted by UTMB personnel (faculty, residents, students) in Brackenridge Hospital, Dell Children's Medical Center, and the various Seton clinics that are part of the affiliation agreement with UTMB-Galveston.

The new BHIRB provided tremendous service to the Seton Network this year. The BHIRB Policies and Procedures manual was updated with new procedures and policies developed to address emerging research-related issues (http://www.seton.net/medical_services_and_programs/clinical_research/irb/irb_policy_procedures.pdf).

To keep up with the frequent changes in policies and procedures, we recommend that current and future investigators refer to the Clinical Research website (http://www.seton.net/medical_services_and_programs/clinical_research/) for the latest versions of IRB or Steering committee forms, and to find out the most recent policies, or to find summaries of research programs being conducted in the Seton network.

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HOW TO REACH US:

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[www.seton.net/
medical_services_and_
programs/](http://www.seton.net/medical_services_and_programs/)



“The IRB review of research protocols focuses on three principles: First to minimize risks to human research participants (Beneficence). Second to ensure that all participants are fully informed about the research protocol activities and any risks (Autonomy). Third to promote equity in the selection of human research participants (Justice)”.

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In addition, the BHIRB has certainly performed its primary function of reviewing new protocols – several of which were submitted by first-time investigators and provided continuing review of current studies. Currently the BHIRB is overseeing more than 135 research studies. Board members represent various disciplines (e.g. pharmacy, nursing, medicine), specialties (e.g. cardiology, internal medicine, obstetrics, oncology, pediatrics, psychiatry and psychology), and non-scientific members both within Seton (e.g. patient representatives) and from the greater Austin community (i.e., community member). The Board meets monthly (2nd Thursday, 7am – 9am) to provide this service and we wish to thank all of our BHIRB members.



Questions & Answers: This section will be useful to anyone who wants to know more about clinical research.

Do you have any questions for us?
Ask questions and find answers in this section.

Q: Who can I contact about getting a research study approved?

A: For information about clinical research administration, IRB, and Seton Clinical Research Steering Committee (CRSC), or to speak with someone by telephone, please call clinical research office at: 512-324.7991. Also see clinical research website: www.seton.net/medical_services_and_programs/clinical_research/

Q: What is Clinical Research?

A: Clinical research may be defined as “the elucidation of human biology and disease, and its control.” A three-part definition was adopted by the National Institutes of Health Director’s Panel on Clinical Research (CRP) as follow:

- Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which the investigator (or colleague) directly interacts with human subjects. This area includes: mechanisms of human disease, therapeutics interventions, clinical trials, development of new techniques.
- Epidemiologic and behavioral studies
- Outcomes research and health services research

Q: What is Good Clinical Practice (GCP)?

A: Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve human subjects. Compliance with GCP assures that the rights, safety, and well-being of trial subjects are protected and that the clinical trial data are credible.

Q: What is a Protocol?

A: A research protocol is a document that describes the objective(s) / study aims, background / rationale, design, methodology, statistical considerations, and the organization and timeline of a study. A Protocol template is available on the Seton Clinical Research Website.

Q: What is Informed Consent?

A: Informed consent is the process by which people learn the key facts about a clinical study to help them decide whether or not to participate. This information includes details about what is involved, such as the purpose of the study, duration, required procedures used in the study, the possible risks and benefits, and key contacts. People who agree to take part in the study are asked to sign the informed consent form. Informed consent is not a contract, and the participant may withdraw from the study at any time. The informed consent process continues throughout the study to provide information for participants.

Q: What is the Patient Load Form (PLF)?

A: It is a brief form that identifies research participants who are also patients within the Seton system. This identification allows hospital and clinic administrators to follow proper billing and accounting. The PI and/or the study coordinator must ensure that a patient load form is completed for each study patient at each visit who will be receiving clinical care or study related procedures or services at Seton facilities at the time of contact or enrollment (whichever comes first). An online version of this form can be found on the Seton Sharepoint site, or you can find a printable version of the form on the Clinical Research website: www.seton.net/medical_services_and_programs/clinical_research/

Q: What is the role of the Clinical Research Steering Committee (CRSC)?

A: The role of the CRSC is to ensure alignment of research projects with the mission and resources of the institution. The feasibility, legal and financial implications are some aspects analyzed at the CRSC. Approval by the CRSC does not constitute IRB approval. Therefore, approval by both entities is necessary before any study can begin. The CRSC submission process can begin in parallel to the IRB submission process. The CRSC must approve all research projects being conducted at Seton facilities prior to implementation.



Quick Talk

Interview with Lauren Brandt, RN, MSN, CNS, Director, Neurosciences, Brain & Spine Center.



1- Q: What are the areas of research interest of your department?

A: Primarily Neurosciences. Stroke and spinal cord injury are two of the most exciting areas as there are many different studies coming up.

2- Q: Who are the research team members?

A: Michele Ajsaonkar is our Research Coordinator for the Brain & Spine Center. She deals with all studies from site initiation, IRB, implementation, monitors data collection, and everything else associated with our studies. Lynne Andrus and Lisa Houy are our study coordinators who actually perform the studies. We have the good fortune to work with multiple physicians as our principle investigators.

3- Q: What are your latest research projects?

A: We have a new stroke study coming that occludes the aorta by 70% of someone with a stroke. They are looking to see if this affects outcome because of the way it changes perfusion to the ischemic area.

4- Q: Are there new department initiatives or programs that you would like to tell readers about?

A: We are looking at expanding our studies, including a Traumatic Brain Injury database.

5- Q: Has the Brain and Spine department collaborated work with UTMB or another facility or organization?

A: We've been able to collaborate with UT Austin on some of our spinal cord injury research and most of our stroke study PI's are UTMB faculty.

6- Q: Is there anything else you would like to say?

A: We've been able to successfully implement studies which impact multiple hospitals with multiple people and departments. Everyone we have worked with has been supportive and helpful; it's how we've been able to continue to grow!

Thank you!

Upcoming Events

CLINICAL RESEARCH SEMINARS SERIES

The seminars will be held at the Annex classroom from 2:00 pm to 3:00 pm.

All the meetings are open to the public.

Parking will be validated.

CME and CNE credits for seminar participation will be available soon!

Seminars Agenda:

Topic: Good Clinical Practice (GCP) - Part II

Date: February 4, 2008 - from 2:00 pm to 3:00 pm

Place: Annex Classroom, Brackenridge Hospital

Speaker: Pam Kiani, LVN, CCRC

Topic: Bioethics

Date: March 5, 2008 - from 2:00 pm to 3:00 pm

Place: Annex Classroom Brackenridge Hospital

Speaker: Dr. Wayne Patterson or
Harold Vanderpool, PhD

Topic: Study Design I

Date: April 09, 2008 - from 2:00 pm to 3:00 pm

Place: Annex Classroom, Brackenridge Hospital

Speaker: Dr. Erlinger, MD, MPH

Topic: Study Design II

Date: June 2, 2008 - from 2:00 pm to 3:00 pm

Place: Annex Classroom, Brackenridge Hospital

Speaker: Dr. Erlinger, MD, MPH

Topic: Sample Size Calculation

Date: August 4, 2008 - from 2:00 pm to 3:00 pm

Place: Annex Classroom, Brackenridge Hospital

Speaker: Karla A. Lawson, PhD, MPH

Topic: Protocol Development

Date: September 8, 2008 - from 2:00 pm to 3:00 pm

Place: Annex Classroom, Brackenridge Hospital

Speaker: Dr. Erlinger, MD, MPH



Topic: Clinical Research Office Resource

Date: October 6, 2008- from 2:00 pm to 3:00 pm

Place: Annex Classroom, Brackenridge Hospital

Speaker: Dr. Erlinger, MD, MPH

Topic: Adverse Event, Protocol Changes and
Other Reporting Requirement

Date: November 3, 2008 - from 2:00 pm to 3:00 pm

Place: Annex Classroom, Brackenridge Hospital

Speaker: TBD

Topic: Benefits of Internal Monitoring

Date: December 1, 2008 - from 2:00 pm to 3:00 pm

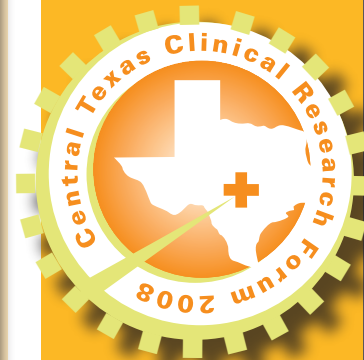
Place: Annex Classroom, Brackenridge Hospital

Speaker: Joni Koenig

 **Seton Family of Hospitals**

SAVE THE DATE

The Central Texas Clinical Research Forum 2008 is coming!



The event will be on
May 9th, 2008, at the CEC,
Brackenridge Hospital.

Free Registration.

Free Parking.

Soon online registration
and online abstract
submission!

CME and CNE will be
available for participants!

This forum will provide
excellent opportunities for
you to present your work,
and to learn about your
colleagues' work!

Please consider
contributing to this
very important meeting
through the poster session.

Come talk with colleagues
and identify research
partnerships you might
want to pursue.

Plan to join the forum!
More information will
come soon!

For comments, questions,
or additional information,
please contact clinical
research administration
office at 512-324.7991, or
via e-mail to Ilana Torban:
itorban@seton.org