



on The Division of Endocrinology & Metabolism

Henry Fein, MD, Esther Krug, MD, Sally Pinkstaff, MD, & Asha Thomas, MD



Drs Fein, Thomas, Pinkstaff, and Krug

Endocrinology is an ever-evolving field, and the Division of Endocrinology at LifeBridge Health (LBH) is very busy keeping up! However, with the help of the LBH Clinical Research Support Unit based in the Department of Research, this small but dynamic group now has a rapidly expanding clinical research program.

Endocrinology has a diverse and unique group of physicians, each with a keen interest in research. They have a team approach to their clinical research program, and when possible, all faculty participate as co-investigators on each study protocol.

Henry Fein, MD has conducted research in the areas of obesity, diabetes, pituitary disorders and thyroid diseases, and is currently a member of LBH's Administrative Review Board (ARB). Dr. Fein is the Principal Investigator (PI) for the Thyroid Cancer Treatment Registry, and is the PI of a study designed to assess the safety and efficacy of a new treatment for Cushing's syndrome.

Esther Krug, MD directs the Sinai Hospital Center for Bone Health and has a special interest in managing osteoporosis and androgen disorders in women.

Dr. Krug is currently the PI of a clinical trial evaluating the efficacy and safety of a growth hormone-inhibiting implant in patients with acromegaly (extremities enlargement), a study examining osteoporosis in women with high multiple births, and a medical record review of the prevalence of vitamin D deficiency in patients with type 2 diabetes mellitus that are referred to endocrine clinic.

Sally Pinkstaff, MD, PhD directs the Sinai Diabetes Program and has clinical and research interests focused on that disease. She is currently the PI of a clinical study examining exenatide, a drug that enhances insulin secretion, and may help to better regulate glucose metabolism in patients with type 2 diabetes.

Asha Thomas, MD, Division Director, is a clinical research endocrinologist with interests in nutrition, bariatrics, preventive cardiology, lipid management, and the metabolic complications of HIV. In addition to her co-investigator activities within the department, Dr. Thomas serves as a mentor in the Internal Medicine resident research program and serves on the LBH Institutional Review Board (IRB).

Keep your eye on this division's expanding research program which will enable them to offer LBH patients greater access to clinical trials that test promising new therapies for a variety of endocrinological disorders.

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New IRB-Approved Studies @ LBH

✓ Platelet Reactivity and Thrombogenicity in Postmenopausal Women

Paul Gurbel, MD; Mark Antonio; Kevin Bliden; Anand Singla, MD

High platelet reactivity is an important contributing factor in the development of coronary artery disease (CAD). Women have been shown to have higher platelet reactivity than men. Although premenopausal women benefit from the protective effects of estrogen on the heart, this protection is lost after menopause. The purpose of this study is to determine if there is a difference in platelet reactivity and clot strength between premenopausal and postmenopausal women. Results from this study may provide a rationale for optimizing antiplatelet therapy for prevention of CAD in postmenopausal women.

✓ Efficacy and Safety of Drotrecogin Alfa (activated) in Adult Patients with Septic Shock.

Adrian Barbul, MD

There is no pharmacological treatment specifically for septic shock (acute circulatory failure characterized by persistent low arterial pressure and low blood flow due to infection) that has been proven to reduce mortality. The study drug, drotrecogin alfa or XIGRIS, has been shown to be beneficial as a treatment of severe sepsis in adult patients. The purpose of this study is to further evaluate the efficacy and safety of drotrecogin alfa in patients with septic shock and to better identify those patients who would benefit most from this treatment.

✓ Effectiveness of Contraceptive Counseling on Adolescent Postpartum Patients

Julie Jacobstein, MD; Suzanne Jose, MD

This study is designed to evaluate the effectiveness of in-house, pre-discharge counseling on adolescent patients by OB/GYN physicians in Sinai Hospital regarding various postpartum contraceptive options. Particular focus will be on patient understanding and awareness of the different methods of birth control, their efficacy, side-effects and their potential effects on lactation.

Frequently Asked Questions (FAQ)

Q: How do I know if my study requires full IRB review?

A: You don't. Each application must be evaluated by either the IRB coordinator or chairman. In general, if your study is associated with greater than minimal risk, *i.e.*, involving invasive procedures, investigational drugs or devices, multiple blood sample collections, or vulnerable populations including subjects under 18 years of age, pregnant women, or cognitively-disabled subjects, then your study will certainly require full board review.



Q: What determines whether the review of my study can be expedited or not?

A: An expedited review is reserved for studies that pose no more than minimal risk to the participants, and do not utilize minors or other vulnerable participants. Medical record reviews and studies using questionnaires, surveys, and interviews may be eligible for expedited review. Although expedited reviews are typically done by one or two members of the IRB, and usually occur more rapidly than full board review, there are no guarantees that this will be the case.

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Remember:

There are submission deadlines for applications requiring full IRB review. You may find deadline dates for all 2009 IRB meetings at: <http://www.lifebridgehealth.org/body.cfm?id=5089>

Institutional Review Board (IRB)

Community Member: Polly Pugatch Senker

What drives a person to volunteer to serve on not one but two IRB Committees? Polly Senker is a community member who belongs to both IRB (A) and IRB (B) Committees, and each meets once a month. She knows that two large packets of review materials will be arriving at her home approximately every two weeks for her to prepare for each upcoming review meeting. It is not unusual for her to be the first one there, and one of the last members to leave. In between, she provides clear and insightful reviews of each of her assigned studies that clearly reflects the significant amount of time she spends in preparation for each meeting.



Polly Senker

When Mrs. Senker is not immersed in IRB business, she runs the Immediate Care Medical Centers in Reisterstown and Glen Burnie. Not surprisingly, as an owner/operator of such a business, she is very interested in health care, clinical trials, and the protection of human subjects, which is the primary charge of this committee.

"Dr. David Cooper, a past Chairman of the IRB, invited me to join the committee approximately nine years ago. Since then, my association with this group had enabled me to use my educational and professional knowledge to ensure that the rights and welfare of human subjects who participate in research are adequately protected."

Being active in the community is in Mrs. Senker's blood. In the past, she has served as President of the Sinai Hospital Auxiliary, Vice President of the Children's Guild, member of the Sinai Hospital Board of Directors, and member of the Baltimore County Board of Education Northwest Advisory Council.

Resident Research: the Road to Success

Research is a required activity for most Sinai Hospital residency training programs. All research activity requires IRB evaluation, and may need IRB approval (see p. 2, FAQ).

In order to do research, residents must first identify a faculty sponsor or mentor whose role is to provide guidance and training. Faculty sponsors should have either clinical or research experience in the topic of interest. Although expertise in both areas is desirable, it is not mandatory because residents can enlist co-mentors that can provide the appropriate blend of clinical and research guidance.

After finding a mentor or mentors and identifying a project, the resident must complete the Collaborative Institutional Training Initiative (CITI) course, which is a web-based training program focusing on the protection of human subjects participating in clinical research.

Since *In the Research Business* last visited with **Dr. Miruais Hamed** he has completed his research study, and has had the pleasure of seeing his work examining the cardio-protective properties of dark chocolate published in the *Southern Medical Journal*.



Dr. Hamed

Dr. Hamed states that "not everyone has this chance, and I think having had Drs. Steven Gambert and Paul Gurbel as my mentors helped me tremendously to succeed in my research. I now know what is important when initiating a study and also what to look for when reviewing other studies. I have become more confident and mature due to the opportunity of presenting posters at major international meetings in cardiovascular

health". Dr. Hamed was selected as one of the Chief Residents in Internal Medicine for 2009-2010, and is in the process of interviewing for a cardiology fellowship.

Resident **Dr. Oscar Bailon** is also very interested in research. "My passion for cardiology and research drove me to join Dr. Paul Gurbel's lab at the Sinai Center for Thrombosis Research. One of my main goals as a physician was to get into a cardiology fellowship program. Dr. Gurbel's crew was very supportive, and allowed me to learn while challenging me to think and work independently within the group. This environment provided a strong mentoring and research experience, and played a key role in helping me to reach my goal of being accepted into the cardiology fellowship program at the University of Texas Health Sciences Center at San Antonio."



Drs. Singla and Bailon

Similarly, **Dr. Anand Singla** envisioned his residency at Sinai Hospital as one of the steps leading towards his realized dream of becoming a cardiology fellow under the mentorship of Dr. Gurbel at the Sinai Center for Thrombosis Research. The training and support from Kevin Bliden, Udaya Tantry, and Mark Antonino has not only taught me a tremendous amount about thrombosis and antiplatelet therapy, but also about undertaking experimental endeavors. After completing my residency I intend to continue as a Heart Failure and Cardiac Transplant Fellow in the Texas Heart Institute at the Baylor College of Medicine."



Keeping Warm while Browsing the Web

Effects of Flowering and Foliage Plants in Hospital Rooms on Patients Recovering from Abdominal Surgery

<http://horttech.ashspublications.org/cgi/content/abstract/18/4/563?maxtoshow=&HITS=10&hits=10&RESULTFORMAT=&fulltext=hospital%2C+flowers&searchid=1&FIRSTINDEX=0&sortspec=relevance&resourcetype=HWCIT>

Using various medical and psychological measurements, this study was initiated to see if plants and flowers for patients in hospital rooms have therapeutic differences for a speedy recovery. The results of this research suggested that plants in a hospital environment could be noninvasive, inexpensive, and an effective complementary medicine for patients recovering from surgery.



Use of the Transcendental Meditation Technique to Reduce Symptoms of Attention Deficit Hyperactivity Disorder (ADHD) by Reducing Stress and Anxiety: An Exploratory Study

<http://cie.asu.edu/volume10/number2/>



Transcendental meditation (TM) is becoming common as a means of coping with stress and improving psychosocial factors. Researchers are just beginning to explore the use of meditation for ADHD symptoms. Participation in the study was restricted to students, ages 11-14, with pre-existing diagnoses of ADHD made by a physician or psychologist. The current findings suggest that TM may be a beneficial intervention for students with ADHD, and that it can be practiced comfortably within the typical school day.

IRB Tips: I Didn't Know That! *Research or Not ?*

IRBs review all research that involves human subjects. Some of the types of research that are covered include anthropological, behavioral, educational, epidemiological, international health, and psychological studies; oral histories and clinical trials. Research can range from laboratory studies using the latest molecular biology techniques to observational studies of human behavior in the field. IRB oversight is always required when investigators do research involving either a living human subject or their protected health information. Because research is defined as a process that is designed to disseminate new knowledge, activities whose results are not intended to be seen outside of

LifeBridge Health may not be considered research. Because of this, quality assurance programs may be exempt from IRB review. However, this is a gray area and the final determination concerning the research status of any activity must be made by the IRB.



Research or not? Future Sinai Scientists?



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