Stephen J. Noga, MD, PhD originally majored in Zoology at the University of Florida, but soon switched to Medical Technology, and eventually earned a PhD in Experimental Pathology. Dr. Noga continued his education at Johns Hopkins University where he attended medical school, completed a residency in Internal Medicine, and then a Fellowship in Oncology. He then joined the faculty at the Johns Hopkins Oncology Center as an attending physician on the Bone Marrow Transplant Unit and the Director of the Cellular Engineering laboratory. In 2001 he moved to LifeBridge Health (LBH) to become the Director of the Division of Hematology and Medical Oncology/Cellular Therapeutics in the Alvin & Lois Lapidus Cancer Institute.

Since Dr. Noga’s arrival at LBH research activity in oncology has more than doubled, and continues to grow. He is very proud of the fact that 23% of the department’s patients are enrolled on clinical trials, as compared to a national average of only 3%. Dr. Noga attributes this success to the clinical trial team-approach used in the Cancer Institute. The team consists of nurses, pharmacists, doctors, social workers, nutritionists, and occupational/physical therapists. Their integrated efforts to expedite and improve medical care are key to the successful treatment of cancer patients. In the outpatient setting, many patients, especially on their first visit to the Cancer Institute, are seen by this professional team, which provides a coordinated approach to their disease. This eliminates the need to make separate appointments, and assures the patient that everyone involved in their treatment is talking to each other. Dr. Noga is quick to note that “Patient care and supportive care are linked. When treating patients requiring chemotherapy or radiation one must take into account many factors, such as age, mobility, diabetes, and heart disease to ensure the best quality of life during their battle against disease progression.”

Dr. Noga’s vision for future cancer research at LBH involves the growth and development of an oncology Phase I clinical trial program. In Phase I studies biomedical researchers test an experimental drug or treatment for the first time in a small group (20-80) of healthy volunteers to evaluate its safety, to determine a safe dosage range, and to identify unwanted side effects. After that, research moves to Phase II trials, which are designed to see if the drug is safe and effective in a larger group (100-300) of ill volunteers. Finally, Phase III trials expand the focus on efficacy from 100’s to 1000’s of subjects, and is the final phase leading to a potential new treatment for a specific disease. There are a number of positive aspects resulting from participation in a clinical trial: 1) You play a more active role in your own health care, 2) you gain access to experimental treatments when alternative therapies are no longer available, 3) the monitoring of your health typically exceeds standard of care, and 4) you may help others by contributing to medical research.

Among the numerous professional organizations that Dr. Noga belongs to, he is a founding member and past-President of the International Society for Cellular Therapy. He’s also served as a member of numerous LBH committees including IRB (A) and the Administrative Review Board (ARB), which oversees the financial aspects of all research done within the LBH system.

Dr. Noga has always wanted to establish a hematologic malignancy program, which would provide multidisciplinary care for patients with leukemia, lymphoma, myeloma, and other neoplastic diseases. In October, he will assume a new position as Director of Hematologic Malignancies at Franklin Square Hospital (FSH), which should bring him one step closer to achieving this goal. We thank him for his contributions to LBH research, and wish him all the best in his new role at FSH.
CALGB 30610: Phase III Comparison of Thoracic Radiotherapy Regimens in Patients with Limited Small Cell Lung Cancer also Receiving Cisplatin and Etoposide

Stephen Noga, MD, PhD; Marvin Feldman, MD; Cristina Truica, MD; Pallavi Kumar, MD

The purpose of this study is to compare the effects of three different ways to give radiation therapy. Two experimental methods will be compared to the standard of care methodology.

An Open Label Extension Study of the Efficacy and Safety of CORLUX® (mifepristone) in the Treatment of the Signs and Symptoms of Endogenous Cushing’s Syndrome

Henry Fein, MD; Asha Thomas, MD

This study was designed to assess the long term safety and effectiveness of CORLUX® in treating Cushing’s syndrome. CORLUX® blocks the effects of cortisol, which may reduce the symptoms and signs of the disease.

Angiogenesis in Osteonecrosis of the Femoral Head

Michael Mont, MD; Ronald Delanois, MD; Harpal Khanuja, MD; Aaron Johnson, MD; Michael Zywiel, MD

The purpose of this clinical trial is to analyze and characterize potential angiogenic growth factors in mesenchymal stem cells obtained from the bone marrow of patients undergoing treatment for osteonecrosis of the femoral head.

A Phase 3, Randomized, Double-Blind, Double-Dummy, Parallel-Group, Multi-Center, Multi-National Study for the Evaluation of Efficacy and Safety of (LMW) Heparin/Edoxaban Versus (LMW) Heparin/Warfarin in Subjects With Symptomatic Deep-Vein Thrombosis and/or Pulmonary Embolism.

This study is taking place at two (2) LBH Facilities with different Principal Investigators and Co-Investigators:

Marianne Cunanan-Bush, MD; Celian Valero, MD (Sinai Hospital)
Chaitanya Ravi, MD; Deborah Fitzpatrick, MD (Northwest Hospital)

This clinical trial was designed to determine if the investigational drug Edoxaban is at least as safe and effective as the well known anticoagulant Warfarin in the treatment of deep vein thrombosis and/or pulmonary embolism.

To find out more about clinical research at LifeBridge Health go to: http://www.lifebridgehealth.org/body.cfm?id=3842

Frequently Asked Questions

Q: Recruiting subjects for my study seems to be difficult at times. Any suggestions?
A: Recruitment may be done using: newspapers, radio, TV, websites, bulletin boards, posters, flyers, and sometimes through the participant’s grapevine. Information should be limited to the prospective subject’s need to determine their interest and eligibility and may include:

1. The name and address of the clinical investigator and/or research facility.
2. The condition under study and/or the purpose of the research.
3. A brief description of the criteria that will be used to determine eligibility for the study.
4. A brief list of participation benefits, e.g., a no-cost health exam.
5. The time or other commitment required of the subjects.
6. The location of the research and contact information.

Please don’t forget to obtain IRB approval before using any type of recruitment tool.

Q: How can I speed up the approval process once I submit an Initial Application to the IRB and ARB?
A: Making sure you have all the required signatures is one sure-fired way of speeding things along! If your study requires Full Board Review, make sure you take into consideration all submission deadlines. Rapid response to reviewer queries will significantly reduce the turn-around time!
Bruce Fellerman, the LBH ARB chairman has a personal history with Sinai Hospital. It all started when he was born here during the first year it opened (his Mom still reminds him that she gave birth to him in an un-air-conditioned room!). While working at Sinai, he met his wife Donna, a co-worker, and their daughter Sarah was born here. No wonder he has loved working here for over 20 years now. He passed the CPA exam in 1991, has been working in auditing and financial analysis for 30 years, and is currently the Operations Analyst for the Departments of Medicine and Anesthesia at Sinai.

Bruce had expressed an interest in joining the ARB and began serving on the Board in 2005. In 2009, after “being groomed” for the vacant ARB Chair position, he “dived” right in. His new role allows him to serve as an advocate for LBH, provides an opportunity for growth, and also reinforces his tremendous admiration and respect for the doctors conducting research at LBH. He indicated that another factor for wanting to assume a leadership role in the ARB was his sincere respect for the ARB Committee members.

Bruce is also involved with Sinai’s Red Cross Blood Drive. Knowing how important it is to make sure that it is successful, he not only works it, he is also a blood donor. How about participating and saving someone’s life? Check out the dates for the next Blood Drive at: http://lbhweb/lifebridgebody.cfm?id=226

Kenneth Rempher: IRB and ARB Member Reflects on Nursing Research

As quoted on the American Association of Critical-Care Nurses website “Dr. Rempher is a dedicated, visionary and inspirational leader who has transformed nursing practice within our critical care arena and throughout our organization”, and pretty much sums up Dr. Rempher’s contributions at LBH as well. In addition to his role as Director of Professional Nursing Practice, Patient Care Services, and the Magnet program, he serves on IRB-A, IRB-B, and the ARB. Of the many activities Dr. Rempher has been involved in at Sinai Hospital, one of the toughest and most rewarding was the Magnet Hospital certification process, in which he played the major role of a tireless champion. Now that we have attained Magnet status, Dr. Rempher is confident that the growing nursing research program will help Sinai continue to meet the highest standards. Research is one of the many ways that Sinai nurses can have a greater impact on the clinical environment. He points out that patient care studies have increased because nurses are being encouraged to “jump aboard the research frenzy”. Flexible time for nursing research is provided on patient care units so that those involved with projects can collect data and ensure that high quality research can be done. Since 2004, a Nursing Research Council was established, and Dr. Rempher chairs that committee. Currently there are 4 completed, 4 active, and 7 studies in preparation. They are sponsored by the Department of Patient Care Services, and principal investigators are encouraged to apply for outside funding. He is very proud that many of these studies were presented at the Nursing National Conference and at the Women’s Health Conference over the past year.

Being a Research Coordinator Has Its Perks!

Many people are unaware that being a Research Coordinator can be a very interesting job. As we all know, the most important duty of a clinical investigator and research coordinator is to insure to the best of their ability that the research subjects are protected from harm. Training is one way sponsors of clinical research can minimize the risks to research subjects, and provide all expense paid trips for investigators and coordinators to attend trial-specific training conferences around the world. Dr. Chaitanya Ravi (Principal Investigator), Alan Orpia RN, BSN, and Chi Tran, RN, BSN (Research Coordinators) have traveled to Amsterdam for one such meeting and found that they had some free time, so they decided to spend it in Paris, France! As you can see in the pictures, they are wearing very big smiles. On a related note, we want to offer a belated welcome to MaryLou Mullen, RN, MS, and Sharmaine McAdoo, BA, our newest members of the Department of Research’s Research Coordinator Program.
Well, here’s the good news: we’re extending the “We do research too!” contest until November 1st! The BAD news is: based on the previous response to this announcement we’ve determined that only 2 (that’s two) people actually read this newsletter! We’re hoping that our comprehensive statistical analysis is wrong and that we have many more smart, dedicated, and good-looking readers than indicated by the response rate. However, just in case we don’t, the ad will also be distributed via the All-User e-mail system. In the mean time, read the ad (below) and consider the possibilities. Get the whole family involved, particularly if you have a talented kid or spouse who can make your vision a PowerPoint reality!

The “We Do Research Too!” Contest

Yes Melissa, we do lots of research at LifeBridge Health (LBH) …and we want everyone to know it! Be as general or as specific as you like. If you do research, or you know about research, you can help educate everyone in the LBH system about this activity. In order to make our research activity more visible, the Department of Research is sponsoring a contest for creating the best video screen advertisement designed specifically to bring this little known fact to the attention of the LBH community.

Just create one (or more) PowerPoint slide(s) suitable for display on the LBH video screen system designed to deliver the message that your favorite LBH group does research too. You can be as general or as specific as you like.

Be creative! Make it pretty, witty, and fine! But most of all, PLEASE submit on time!

First, second, and third place prizes (20,000, 10,000, and 5,000 LB points, respectively) will be awarded for the most eye-catching, insightful, and witty ads. Winners will be determined by a panel of judges. Winners and honorable mentions will be highlighted in this newsletter, as well as displayed on the LBH video screens. Submit your PowerPoint slide via e-mail to lwasserm@lifebridgehealth.org  Deadline: 11/1/2010.
The IRB has the authority to suspend or terminate research that is not carried out in accordance with federal, state, and local regulations, or has been associated with unexpected serious harm to the subjects. Principal investigators are notified in writing of any suspension or termination of approval, and this action is reported promptly to the department head, and if applicable, the sponsor, the Food and Drug Administration, and the Office for Human Research Protections.

**Keeping IRB Forms After A Study Is Closed**

Signed forms must be kept on file for at least three (3) to six (6) years after the completion of the study, depending on the area of research.

**Consenting a Minor/Cognitively Impaired Person**

Assent is an agreement by a “vulnerable” individual who is not competent to give legally valid informed consent to participate in a research project. Federal regulations require that if a child is cognitively capable of assenting, he/she must be given the opportunity to do so. Although exceptions may arise, the child’s wishes must be followed. In addition to the assent process, parents/guardians must always sign a consent form. If the IRB determines the study to be high risk or it deals with a sensitive issue, the consent form must be signed by both parents/guardians unless one has legal responsibility for, and care of, the minor/cognitively-impaired subject.

**Hiking Thru the Web**

**ADHD: Disconnect Between Brain Regions**
http://medicinenewworld.org/stories/lead/1-2010/disconnect-between-brain-regions.html

There is direct evidence that two brain areas fail to connect when children with Attention Deficit Hyperactivity Disorder (ADHD) attempt a task that measures attention.

**Study Linking Autism to Vaccine Retracted**
http://toledoblade.com/apps/pbcs.dll/article?AID=/20100206/OPINION02/2060323

Dr. Andrew Wakefield’s research results in 1998 showed that by mixing the vaccines for measles, mumps, and rubella (MMR) into a single shot, weakened the immune system of children, damaged the gut and could lead to the development of autism. Since then, years of subsequent medical research disproved this.

**Henrietta lacks: Immortality In A Test Tube**

Nearly 60 years ago, Henrietta Lack died of aggressive cervical cancer. Her cells were preserved without her family’s knowledge, and have been used by many scientists all over the world. They have become a major role in biomedical research. A book entitled, “The Immortal Life of Henrietta Lacks” by Rebecca Skloot describes the importance of these HeLa cells: To help develop Jonas Salk’s polio vaccine, used during the Cold War to test radiation exposure on human cells, and were fired into orbit to examine the effect of weightlessness on biological processes. For more information including the ethical issues raised by the existence of theses cells, see:
http://www.jhu.edu/jhumag/0400web/01.html

**IRB Tips: I Didn’t Know That!**

**The IRB Can Stop Research Activity**

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