



## Albert J Aboulafia, MD Orthopaedic Oncologist and Vice Chair of the IRB (A)



Dr. Albert J. Aboulafia is an extravert and a well recognized member of Sinai's Alvin and Lois Lapidus Cancer Institute. He is known throughout the hospital as a jovial guy who is never without a smile or a kind word for others. People know him as someone who enjoys conversation, but few are aware that he speaks Hebrew and Spanish fluently. There are other aspects about Dr. Aboulafia that many people at Sinai are unaware of. While most of us are familiar with his sense of humor and fun spirit, his serious side lurks just beneath the surface when it comes to his professional life.

Dr. Aboulafia specializes in Orthopaedic Oncology, caring for children and adults with benign and malignant conditions that affect the musculoskeletal system. There are only about 100 doctors in the United States specializing in this field. "I was attracted to this subspecialty for several reasons. Orthopaedic Oncology is an especially intellectual field that allows me to interact with physicians from other specialties. I also felt that I could contribute to the emotional and personal needs of patients who faced extraordinary challenges. There is so much more to being a cancer surgeon than just being able to perform technically competent surgery." After completing his fellowship, he worked at The National Institute of Health and later Emory University. He's been at Sinai for eight years and is able to provide outstanding care to his patients while continuing academic and research interests. He is committed to research and recognizes the potential it offers for the future. "We do research for the same reason we chose to be

doctors in the first place: To help alleviate the pain and suffering of others and to provide hope. It also ensures that I stay at the forefront of my profession." People at Sinai won't be surprised to hear that Dr. Aboulafia is recognized nationally and internationally as a leader in his field. His patient referrals are not only from Maryland, but also from across the country and around the world. He has been an invited speaker throughout the U.S. and as far away as Turkey and South America. He had published more than 50 peer reviewed articles, numerous book chapters, and also teaches multiple courses including board reviews. He was chosen for The American Academy of Orthopaedic Surgeons Leadership Development Program and further developed his leadership interests by getting his MBA in 2006. Currently he is president elect of The Musculoskeletal Tumor Society, which is the premier society committed to the advancement of musculoskeletal oncology.

Outside of the hospital, Dr. Aboulafia is an active volunteer and was awarded the Governor's Citation for the State of Maryland for his tireless efforts. He works with the FDA Orthopaedic and Rehabilitation Devices Panel, serves on several committees, reviews for seven journals, is section editor of Orthopaedic Knowledge Online, is on the board of the Baltimore City Medical Society and is an active fundraiser and board member for charitable organizations. Last but not least, Dr. Aboulafia is the Principal Investigator of several bone cancer clinical trials here at Sinai and proudly serves as the Vice-Chair of IRB A.



Enjoying the football game is proud Dad with daughters Alanna (11), and Arielle (13)

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# New IRB Approved Studies @ LBH

- ✓ **Multicenter, rAndomized, parallel Group Efficacy superiority study in hospitalized medically ill patients comparing rivaroxaban with enoxaparin. (The MAGELLAN Study)**

*Charles Albrecht, MD; Chaitanya Ravi, MD; Ledys DiMarsico, MD; Marianne Cunanan-Bush, MD*

The purpose of this study is to determine if rivaroxaban (the study drug), taken once a day as a tablet is safe and can help prevent blood clots in patients who have been hospitalized for a medical illness. The study drug plays a critical role in blood clotting by inhibiting factor Xa, and will be compared to enoxaparin.

- ✓ **A Prospective Study Assessing the Value of Stride Length and Base of Support change, as Measured by GAITRite After Temporary Cerebrospinal Fluid (CSF) Drainage, to Predict Expert Recommendation for Shunt Surgery and Response to Shunt Surgery in Patients with Probable Adult Hydrocephalus.**

*Robin Wilson, MD*

Adult hydrocephalus (AH) results from an accumulation of cerebrospinal fluid that causes cavities in the brain to swell. AH is treated surgically via placement of a shunt that improves symptoms of imbalance, gait impairment, thinking, and loss of bladder control. The purpose of this study is to determine whether objective gait analysis via the GAITRite electronic walkway can substitute for expert clinical judgment in the diagnostic workup for uncomplicated cases of probable AH, thus allowing the probability of successful shunt surgery to be predicted by physicians with limited exposure to AH.

- ✓ **A Phase II Single Arm Study of Carboplatin and DOXIL Plus Bevacizumab in Subjects with Platinum Sensitive Recurrent Ovarian, Fallopian Tube and Primary Peritoneal Cancers. (DOXILOVC2007)**

*Fouad Abbas, MD; Pallavi Kumar, MD*

The purpose of this study is to evaluate the combined use of Doxil, Carboplatin, and Bevacizumab for the treatment of patients with reoccurring ovarian, fallopian tube, or peritoneal cancer, and to ultimately determine this investigational combination's safety and effectiveness.

## Frequently Asked Questions



**Q: I'm confused as to how many *paper copies* are needed for submission to the LBH IRB for either an IRB(A) or IRB(B) full board review.**

**A: The LBH IRB prefers electronic submissions due to ecological and economic reasons. Please note, if applicable, that only the original and reviewer copies include the Investigational Brochure (IB). Let the numbers decide!**

	<i>Electronic</i>	<i>Paper</i>
<b><i>Initial Review</i></b>	1 - Original 3 - Reviewer Copies 7 - IRB (A) or 6 - IRB (B) <b>11 or 10 Total</b>	1 - Original 3 - Reviewer Copies 15 - IRB (A) or 12 - IRB (B) <b>19 or 16 Total</b>
<b><i>Continuing Review</i></b>	1 - Original 2 - Reviewer Copies 7 - IRB (A) or 6 - IRB (B) <b>10 or 9 Total</b>	1 - Original 2 - Reviewer Copies 16 - IRB (A) or 13 - IRB (B) <b>19 or 16 Total</b>

## IRB (B) Community Member Dave Durfee



**Dave Durfee** has been on the IRB (B) for approximately 8 years. Prior to that, for over 40 years, Mr. Durfee was a commercial insurance agent.

In 1979, while living in Buffalo NY, there was a blizzard with over four feet of snow that fell within 24 hours. Soon after that he and his wife were happy to move to Baltimore for better weather. They have never regretted that decision and the IRB has benefited from this. Once retired, while serving on a committee of the Children's Guild, he was recruited by Polly Senker, another community member of the LBH IRB. Back then, there was only one IRB in contrast to the two (A & B) that are currently in operation. Dr. David Cooper was the chairman and Rabbi Gus Buchdahl served as another community member.

Mr. Durfee spends anywhere from 25-45 minutes reviewing each new submission. Over the years, he has found that there have been fewer typographical errors and the consent forms are more concise. As a layperson, when looking for ways to improve a study, he tries to find ways to reword the consent forms in order to make the protocol easier for a layperson to understand. Mr. Durfee is a graduate of Brown University and lives in Greenspring East. His wife Sandra taught at St. Paul's School for Girls where she became Chairman of the English Department and then Dean of Faculty. Mrs. Durfee knows that he looks forward to these meetings and is very supportive of her husband's involvement in the protection of human subjects involved in research.



*IRB (B) Board in Action*

## Department of Research News

### We are Growing!

We welcome Chi Tran, BSN, RN to the Department of Research's Nurse Research Program. Working with Alan Orpia, she has quickly become very busy recruiting and managing subjects for new clinical trials.



Chi loves her new position as a research coordinator. She has found that it is very different from being a unit nurse, involving more paper work, less patient contact, and requiring highly developed multi-tasking skills. Monitoring blood pressure, recording EKGs, drawing blood, and performing physical assessments are

the nursing skills that Chi combines with her compassion and respect for her subjects that result in success.

She is excited and grateful to be a part of this new and developing Nurse Research Coordinator Program (NRCP) in the Department of Research. "To be able to learn and grow with the program is wonderful and challenging at times, yet very rewarding. Everyone has been supportive and great to work with."

Born in Vietnam and then immigrating to the United States at the age of 11 with her parents and three brothers, she is the first in her family to graduate college: B. S. in Biology from The College of Notre Dame of Maryland and a B.S. in Nursing from the University of Maryland.

Since joining LBH last winter she has had the opportunity to work on clinical trials in Endocrinology, Neurology,

Neurosurgery, and Pediatric Gastroenterology. If you want to know more about the NRCP, please contact Chi at 410-601-1915 or e-mail her at: [ctran@lifebridgehealth.org](mailto:ctran@lifebridgehealth.org)

### The Bottle-Neck Starts Here

Wow, have we been busy! The number of active studies at LBH is pushing 300! If you have a deadline and need an approval in a timely manner, please allow yourself and the IRB enough time to process your application. Reasons for delayed approval range from not having the required signatures on documents to investigators not completing their CITI Training. If your study submission requires a full board review, plan ahead and check the deadlines at:

<http://www.lifebridgehealth.org/body.cfm?id=5089>



*Dr. Freed's Desk - out to lunch?*

### Resident Research



Are you a resident? Feeling totally confused about submitting all that paperwork for IRB review of your new research project? Do you have a deadline to meet? Well, help is just a phone call away. Make sure you give yourself plenty of time! Contact the Department of Research now at 410-601-9021.



# Biking Thru the Web



## Fun Express Water-based Face Paints for Children Recalled

<http://www.fda.gov/bbs/topics/NEWS/2009/NEW02015.html>

A recall has been issued for the cosmetic "Face Paint" item distributed by Oriental Trading Co. due to adverse event reports of skin reactions in children.

## Many Seniors at Risk of Malnutrition

<http://www.news-medical.net/?id=49266>

As many as one in six people who live at home were undernourished and are at risk of malnutrition. This was especially true of those that knew that they were in poor health and/or were suffering from depression. Women were more likely to be at risk than men especially if they were depressed.

## Numerous Patients In Intensive Care Are Deficient in Vitamin D

<http://www.news-medical.net/?id=49070>

Being Vitamin D deficient can be due to a poor diet or lack of sunlight. This causes our bones to become thin and brittle which can play a role in adverse health outcomes. It is also involved in controlling blood sugar and calcium levels, heart function, gastrointestinal health and in defending against infection. Tissue demand for Vitamin D is increased during infection, metabolic disturbance, and inflammation, which could be depleted during critical illness.



# IRB Tips: I Didn't Know That!

## Data Retention

FDA regulations require the collection and maintenance of complete clinical trial data. This includes information on subjects who withdraw from a clinical investigation regardless of whether the subject decides to halt participation in the clinical trial him or herself, or is removed by the investigator because the subject no longer qualifies under the protocol. Although a subject may withdraw from a study, the withdrawal does not extend to the data already obtained during the time the subject was enrolled. In order to maintain the scientific integrity of the study, all data collected on study subjects up to the time of withdrawal must remain in the trial database. Doing otherwise could possibly negatively affect subject safety and place future users of marketed products at an unreasonable risk.

## ALCOA

The FDA requires that all study data and documents pass what it calls the ALCOA test. That means that all data should be **A**ccurate, **L**egible, **C**ontemporaneous, **O**riginal, and **A**tributable. Even if the FDA does not oversee your study, the ALCOA test is a good one to keep in mind during the collection of all research data. Be sure that all study activities are fully documented, and that study documents and notes to file are appropriately signed and dated, regardless of the kind of human subject research you do.

## Avoid Delays

When submitting an application, please fill in every appropriate area and do not reply with: "Please see attachment". Lost attachments create unnecessary questions during the review process and can ultimately delay approval of your study.



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