



## Michael A. Williams, MD

**Medical Director, Brain & Spine Institute**  
**Director, Adult Hydrocephalus Center**



Dr. Michael Williams

Dr. Michael A. Williams, Medical Director of the LifeBridge Health (LBH) Sandra and Malcolm Berman Brain & Spine Institute (BSI), is a friendly and approachable kind-of-guy. In addition to being a board-certified neurologist and a leading clinician in adult hydrocephalus, he wears other hats - Researcher, Instructor, and Inventor, to name a few. He currently serves as Secretary-Treasurer of the International Society for Hydrocephalus and CSF Disorders (ISHCSF) and was President of the Hydrocephalus 2009 Conference, which was held September 16 -19, 2009 in Baltimore. This was the first annual conference of the ISHCSF which included the official scientific, educational, and business meetings of this newly formed organization.

On the conference table in his office sits a plaque with a quote from Michelangelo that mirrors Dr. Williams' own personal philosophy: *"I am still learning."* He feels that questions need to be asked and researched. Because of his diverse background, he was approached over three years ago to join the LBH medical staff to help in expanding its research efforts, and it turned out to be an excellent match! His goal is to guide the BSI to a level where it will achieve national and international status not only in clinical care, but also in research. He is quite sure that the BSI faculty, many of whom have academic backgrounds, can achieve this goal.

Of the various approaches toward starting a research project, one way is through an existing sponsored study in which the investigator's facility is one of many sites involved. The challenge is even greater when the investigator initiates an idea for research and designs an original protocol. Obtaining

funds becomes an issue, and writing a grant is an experience on its own! The BSI is fortunate to have a medical editor, Tzipora Sofare, who assists many physicians in completing manuscripts, grants, IRB applications, and books much faster and better than was possible before her arrival. Dr. Williams said that



Dr. Michael Williams and his life partner, Clifton Scott, enjoying their vacation in Hawaii.

"this is a very important part of the infrastructure needed to support and promote investigator-initiated research at LBH".

In collaboration with fellow researchers at the Cleveland Clinic and the University of Umeå in northern Sweden, Dr. Williams has developed a grant application for submission to the NIH that involves the study of hydrocephalus, which is his specialty. His path to becoming known as a specialist among the hydrocephalus patient population, whose ages range from birth to 90 years, is very interesting. Approximately 20 years ago, while in a neurosciences critical care fellowship at Johns Hopkins Hospital, Dr. Williams saw many cases of acute hydrocephalus, which led to his interest and expertise in chronic forms of hydrocephalus in adults. As a result, other neurologists and neurosurgeons started to refer their patients to him. Dr. Williams feels that what makes this specialty so rewarding is that physicians can actually see a significant improvement in patients, even though the extent of recovery can vary, depending on age.

Another of Dr. Williams' primary interests lies in the area of ethics in healthcare, and he is the immediate Past Chair of the Ethics, Law, and Humanities Committee of the American Academy of Neurology, a member of the Med-Chi Ethics Committee and the Sinai Hospital Ethics Committee. In addition, he is a member of the American Neurological Association and has been active on numerous advisory committees and panels that focus on ethics, organ donation, and end-of-life care.

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# New IRB Approved Studies @ LBH

- ✓ **Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety and Tolerability of Oral Lixivaptan Capsules in Subjects with Euvolemic Hyponatremia (The HARMONY Study).**

**This study is taking place in two (2) LBH Facilities with different Principal Investigators:**

**Courtland Gardens Nursing & Rehabilitation Center: Sunil Rajani, M.D.; Jocelyn El-Sayed M.S.**

**Levindale Hebrew Geriatric Center and Hospital: Esther Krug, M.D.; Jocelyn El-Sayed, M.S.**

The purpose of this study is to determine if lixivaptan, an investigational drug that inhibits water reabsorption in the kidney, is safe and effective in increasing plasma sodium in subjects with hyponatremia (low sodium in the blood).

- ✓ **Effects of Smoking on Corneal Thickness**

**Gerami Seitzman, M.D.; Candice Giordano, M.D.; Carl Sloan, M.D.; Shaminder Bhullar, M.D.; and Abram Geisendorfer, M.D.**

This study is designed to determine if smoking is related to increased corneal thickness and to allow clinicians to more fully understand the effect of smoking on ocular health as well as recovery after intraocular surgery.

- ✓ **Implementation of a Program to Improve Inpatient and PICU Nurses' Knowledge of and Attitudes Toward Palliative Care**

**Catherine Haut, R.N., M.S., C.P.N.P., C.C.R.N.**

The purpose of this survey study is to assess inpatient pediatric and pediatric intensive care unit (PICU) nurses' knowledge of and attitudes toward pediatric palliative care before and after completing a formal educational program.

- ✓ **C05013: An Open-Label, Randomized, Phase 2 Study to Assess the Effectiveness of RCHOP With or Without VELCADE in Previously Untreated Patients with Non-Germinal Center B-Cell-Like Diffuse Large B-Cell Lymphoma.**

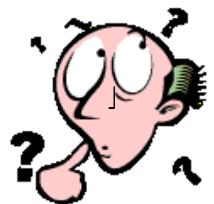
**Stephen Noga, M.D., Ph.D.; Marvin Feldman, M.D.; Cristina Truicia, M.D.; and Pallavi Kumar, M.D.**

This clinical study is designed to determine whether the addition of VELCADE to a commonly used drug combination for patients with diffuse large B-Cell lymphoma called RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone) benefits patients with non-GCB diffuse large B-Cell lymphoma and whether this combination can be given safely.

## Frequently Asked Questions

**Q: Is it necessary to submit a copy of an advertisement that I would like to use for my study?**

**A:** Yes. Any information concerning a research study that is seen by the public via flyer, poster, newspaper, radio, or TV must be approved by the IRB. Remember that LifeBridge Health has video screens at various places in each facility and ads appearing on these screens must also be reviewed and approved by this committee. Those wishing to use LBH video screens must submit the ad in PowerPoint to the IRB, and should note the ad's start and end date for viewing. Once approved by the IRB, the research office will make the final arrangements for its display.



**Q: I think that my study can be expedited but I'm not sure how this submission differs from a full board submission.**

**A:** It all comes down to the level of risk a human subject is potentially exposed to. An expedited study has minimal risk. This means that there are no serious adverse events anticipated beyond that which would normally be encountered in daily living. Studies involving observation, behavior, survey/questionnaire and routine psychological testing are usually considered minimal risk, as are studies involving venipuncture, exercise testing, EKG's, and ultrasound scans. However, the subject population studied may affect review status, and studies focusing on potentially vulnerable subjects (*e.g.*, pregnant women, children, or mentally-challenged individuals) may require full board review. To be on the safe side, the IRB chairman or his designee should always make the final determination as to the review status of any human subjects research project.

## IRB (A) Community Member

### Rabbi Avram Israel Reisner

Rabbi Avram Israel Reisner, spiritual leader of Chevrei Tzedek Synagogue, is our community pastoral representative to the LBH IRB. He has a Ph.D. in Talmud and Rabbinics from the Jewish Theological Seminary, and an M.A. in Bioethics from the University of Pennsylvania.

Ten years ago Rabbi Reisner moved to Baltimore from New Jersey because his wife, Rabbi Nina B. Cardin, accepted a local position. He is a long-standing member of the Conservative Movement's Committee on Jewish Law and Standards which make decisions when religious issues arise. His favorite topics usually have to deal with the potential clashes of modern life and technologies with Conservative and Orthodox Jewish law. "There is a need for Jewish law to adapt to features of modernity which are moving really fast. What I love about Judaism is that we have always evolved to fit the needs of the day while maintaining our core values."



Rabbi Avram Reisner

Rabbi Gus Buchdahl, upon retirement from the IRB nearly 5 years ago, highly recommended Rabbi Reisner as his replacement. What makes Rabbi Reisner such a good committee member? Of utmost importance is his interest in bioethics and the protection of human subjects in research.

Whether it is his or another member's review, Rabbi Reisner is known for his thoughtful and insightful comments and suggestions concerning the informed consent of research subjects. He carefully studies the informed consent form making sure that the potential subject understands exactly what will happen if they should decide to participate in a research project. If it seems too clinical or misleading, he is the consummate advocate for the subject requesting specific revisions to help clarify the issue. Together with the other volunteers on the IRB, he is determined that research done at LBH lives up to our high standards.

## Comings & Goings

### Florante A. Santos, M.D, MPA, RA-C

Florante Santos, once a physician specializing in Internal Medicine in the Philippines, was until recently the Orthopedic Research Manager of The Center for Joint Preservation and Replacement in the Rubin Institute for Advanced Orthopedics (RIO) at Sinai Hospital. During his tenure at LBH he vigorously championed the development of clinical research, and was a strong proponent for the development of a Phase 1 clinical



Dr. Florante Santos

research unit. From the "trial and error" evolution of federally-regulated Phase I first-in-human studies to Phase IV clinical trials focusing on agents already proven safe and effective in humans, he believed that a robust clinical trial program provided endless opportunities to offer patients cutting-edge therapies as potential options in lieu of standard medical care. We all wish Florante good luck as he pursues his consulting career!

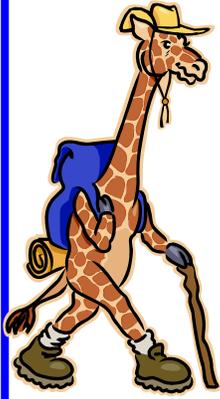
## The "We Do Research Too!" Contest

**Yes Melissa, we do lots of research at LifeBridge Health (LBH)** ...and we want everyone to know it! If you do research, or if you know about those who do research, you can tell everyone in the LBH system about what you (they) do. 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](mailto:lwasserm@lifebridgehealth.org)** Don't be a fool and miss this opportunity for submission! **Deadline: April 1, 2010.**



# Hiking Thru the Web

## Ultra-Tiny 'Bees' Target Tumors

<http://www.cnn.com/2009/HEALTH/08/18/nanotech.cancer.nano.tumors/index.html>

**Nanobees are tiny particles (not insects) designed to destroy cancer cells by delivering a synthesized version of a toxin called melittin that is found in bees. Nanobees are just one of the latest nanotechnologies that may change the way diseases are treated.**

## Eat Late, Put on Weight?

[http://www.webmd.com/diet/news/20090903/eat-late-put-on-weight?src=RSS\\_PUBLIC](http://www.webmd.com/diet/news/20090903/eat-late-put-on-weight?src=RSS_PUBLIC)

**Nighttime eating is contradicting your body's natural circadian rhythm. This is one factor among many contributing to weight gain.**



## Faking the Results (and Fixing the Damage Done)

<http://www.irbforum.org/forum/read/2/216/216?PHPSESSID=32ffa161fe3f627667ae2a6b69aa51a5>

**Misconduct in research, whether it is unintentional wrongdoing or the promising drug had been deemed bogus, is a problem. Two percent of the scientists that took a survey admitted to falsifying, modifying, or fabricating data at least once. Up to one third confessed that they failed to publish data that contradicted their previous conclusions. The solution is better training in ethics and proper research conduct. Have you reviewed your human research subjects training lately?**

# IRB Tips: I Didn't Know That!

## *The IRB Can Stop Research Activity*

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.



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