Dr. John Herzenberg, Chief of Pediatric Orthopedics in the Rubin Institute for Advanced Orthopedics and Co-Director of the International Center for Limb Lengthening at Sinai Hospital of Baltimore, has more than 20 years experience in the field of limb lengthening and the treatment of clubfoot. He graduated from Boston University Medical School and trained in orthopedics at Duke University, and in pediatric orthopaedics at Toronto’s Hospital for Sick Children. Here at Sinai Dr. Herzenberg specializes in the diagnosis and treatment of adult and pediatric patients with congenital abnormalities, joint contractures, neuromuscular disorders, non-healing fractures, malunited fractures, and bone loss due to tumor, trauma, or infection. When not actively practicing medicine, he participates in community service projects, the mentoring of students and clinical fellows, and visiting professor activities. He is in demand worldwide as a speaker, has received numerous grants and awards, written many book chapters and journal articles, and was listed as one of the top 15 pediatric orthopaedic doctors in the United States in *American Health* (March 1996).

In 1997, Dr. Herzenberg came to champion the Ponseti method, which is a manipulative technique that corrects congenital clubfoot without invasive surgery. It was developed by Dr. Ignacio V. Ponseti at the University of Iowa in the 1950’s, but until recently was largely ignored by the orthopedic community. Dr. Herzenberg enthusiastically embraced this method, wrote an impressive review of Ponseti’s book (that describes this procedure in detail) on Amazon.com (6/1999), and through his teaching efforts has helped shift the accepted standard treatment for babies with clubfoot from surgery to non-invasive casting.

Idiopathic clubfoot is the most common congenital deformity of the foot. This deformity is very apparent at birth, and can have a devastating effect on parents when they see their newborn with a foot that is essentially turned upside down. This deformity occurs during the 2nd trimester of pregnancy. One of the chief advantages of using the Ponseti method is the decreased cost. This method consists of gently manipulating the foot and placing it in a new cast every week during a 4-to-8-week period. Some patients also require a quick office procedure while under local anesthesia.

Current research focuses on humeral limb lengthening, the recurrence of idiopathic clubfoot after use of the Ponseti Method, and inherited musculo-skeletal disorders that may contribute to the development of idiopathic clubfoot. The latter study is a collaborative effort with the Washington University Medical Center.

John Herzenberg is married to Merrill Chaus, RN, and they have three daughters. Since 1998, he and his family have volunteered yearly with Operation Rainbow, providing free orthopaedic surgery to underprivileged children in Central and South America. In his spare time he enjoys weight lifting and biking.
√ A Randomized, Multicenter, Placebo-Controlled and Active Reference (Glatiramer Acetate) Comparison Study to Evaluate the Efficacy and Safety of BG00012 in Subjects with Relapsing-Remitting Multiple Sclerosis. (109MS302).

Braeme Glaun, M.D.

To determine if treatment with BG00012 [dimethyl fumarate (DMF)] can decrease the number of multiple sclerosis relapses that occur over time. DMF may have anti inflammatory as well as neuroprotective effects.

√ The ANSWER Program - American Norditropin Studies: Web Enabled Research.

Judith McLaughlin, M.D., Karen Armour, M.D.

Data collected will be used to learn more about the long term use of Norditropin (a man-made growth hormone) in children with growth failure due to deficiency of natural growth hormone and other growth related medical disorders. This information will be used to determine the most effective dosing patterns for future treatment.

√ COG ACCL0631: Impact of Obesity on the Pharmacokinetics of Anticancer Therapy in Children with High Risk Acute Lymphoblastic Leukemia (ALL).

Joseph Wiley, M.D.; Jason Fixler, M.D.; Kristen Britton, D.O.; Revonda Mosher, MSN, PNP; Yoram Unquru, M.D.; Stephanie Entrup, RN

To compare the pharmacokinetics (i.e., the characteristic interactions of a drug and the body in terms of its absorption, distribution, metabolism, and excretion) of four induction chemotherapy drugs between obese, middle weight and underweight children who are between 10 and 20 years old and who have been diagnosed with high risk ALL.

Frequently Asked Questions

Q: Are sponsors allowed access to IRB written procedures, minutes and membership rosters?
A: FDA regulations do not require public or sponsor access to IRB records. However, FDA does not prohibit the sponsor from requesting IRB records. The IRB and the institution may establish a policy on whether minutes or a pertinent portion of the minutes are provided to sponsors.

Q: Are there any regulations that require clinical investigators to report to the IRB when a study has been completed?
A: IRBs are required to function under written procedures. One of these procedural requirements [21 CFR 56.108(a)(3)] requires ensuring "prompt reporting to the IRB of changes in a research activity." The completion of the study is a change in activity and should be reported to the IRB. Although subjects will no longer be "at risk" under the study, a final report to the IRB allows it to close its files.
LifeBridge Health (LBH) has been making its mark in the Research World. Here are some questions presented to Neil Meltzer from inquiring minds as to where do we go from here?

**What is your vision for the future of LBH research?**

“I would like to see research developed into its own center of excellence over time. My goal would be to continue to increase both the number of researchers and protocols as well as the dollar volume of research activity. I see research as one of the cornerstones of Sinai Hospital and LifeBridge Health, adding to the strength we already have in both clinical care and depth and breadth of medical expertise.

Several goals include:
- Enhance collaboration across departments and become regionally recognized for several multidisciplinary research programs,
- Make excellence in research an integral part of our clinical and educational programs, and
- Expand research collaboration with outside organizations.”

**Research is growing at LBH, and space is very limited. Are there any plans for expansion to accommodate this increasing activity?**

“Yes, as we continue to expand space on the Sinai Hospital campus, our goal is to find additional space for our research offices. Additionally, we would like to take advantage of some of the underutilized clinical laboratory space and create a situation where multiple researchers can share the existing lab space.”

**What does LBH have to gain by supporting research? Wouldn’t that support be better used for hiring more doctors and nurses?**

“Research, and the resulting publication of results, has the effect of increasing the profile of a health care organization both among physicians from across the country as well as among the general public to the extent that the results are picked up by the media.”
IRB Tips: I Didn’t Know That!

Using surveys or questionnaires for research can be a tricky business. Administration of questionnaires by telephone or by mail for research purposes requires IRB exemption or approval. IRB policy differs according to whether 1) the questionnaire is for identification of potential subjects or for data to be used in a research project, 2) the questionnaire is administered verbally by telephone or in writing by mail, and 3) the informed consent and authorization are verbal, written, or implied.

Researchers must be prepared to deal with a myriad of unexpected problems associated with the subject interview process. For example, if a subject ends the interview early or simply hangs up the phone, what happens to the information collected up to that point? When an interview ends because the potential subject is found to be ineligible, are their names kept for contact for future studies? Is this information kept or disposed of? If it is kept, what measures will be taken to maintain confidentiality? If the records are disposed of, are they shredded or simply put out as trash? The procedures used to protect the rights and welfare of the prospective subjects would depend on the sensitivity of the data gathered, which may include personal, medical, or financial information. Further details concerning these protective measures can be reviewed at: http://www.lifebridgehealth.org/workfiles/IRB/IRB_Guide_17.doc

IRB Days Boon For Medical Research


Twins are helping to advance medical science. Every year in Twinsburg, Ohio thousands of twins meet for a special festival. Researchers often need to collect data that will answer questions to see whether it’s genetic or environmental reasons for the prevention of anything from Crohn’s Disease to wrinkles. Having this many identical twins together in one place is a plus for researchers looking to consent new subjects!

A Video Game Improves Behavioral Outcomes in Adolescents and Young Adults With Cancer: A Randomized Trial

http://pediatrics.aappublications.org/cgi/content/full/122/2/e305

This study shows that a strategically designed video game can be a powerful new tool to enhance the impact of medical treatment by motivating healthy behavior in the patient.