LIFEBRIDGE HEALTH

Department of Research
2401 W. Belvedere Avenue
Schapiro Bldg. Suite 203
Baltimore, MD 21215-5271

In the Research Business

February 2008: Volume II, Issue 1
Leslie Wasserman, Editor
lwasserm@lifebridgehealth.org

Phone: 410-601-9021
Fax: 410-601-8282

on Michael Mont, M.D.

Rubin Institute for Advanced Orthopedics (RIAO)

Dr. Michael A. Mont, Director of the Center for Joint Preservation and Replacement at the Rubin Institute for Advanced Orthopedics (RIAO), is one of the nation's most prominent orthopaedic surgeons with extensive experience in total joint replacement and reconstruction. He is a member of the Knee Society, Hip Society, Orthopaedic Research Society, and a co-founder of The National Osteonecrosis Foundation. He serves on the editorial board of numerous research journals, has received many research grants, and has published over 400 articles and book chapters on various aspects of adult joint reconstruction. In addition to being a world expert in preserving joints in patients with osteonecrosis or avascular necrosis as it is also known, Dr. Mont has done over 5,000 joint replacements. He has extensive specialty training in the surgical treatment of complex bone disorders, including revision joint replacement surgery and infected joints, and has been instrumental in bringing hip replacement alternatives such as "resurfacing" to the United States.

Dr. Mont is always looking for opportunities in "cutting- edge" methods/technologies to improve the quality of care for patients with osteoarthritis and osteonecrosis. His highest priority is to preserve knee or hip joints, avoiding the need for joint replacement. A great example of this is TGC-03-01, a human research study recently initiated by Dr. Mont at the RIAO, and sponsored by TissueGene, Inc. TGC-03-01 was five years in the making, originating from the collaborative efforts of Tissuegene, Dr. Mont, and his fellow researchers who guided the development of this study through U.S. Food and Drug Administration and National Institute of Health reviews prior to its final approval by the LBH IRB as a human subjects research Phase I safety study.

TGC-03-01, a first in-human safety study for osteoarthritis, is being conducted at only two institutions world-wide. Sinai Hospital of Baltimore is the only clinical site participating in this study in the western hemisphere. The University of Korea is the other site where subjects are being recruited for this potential "giant-leap for mankind" clinical study.

A Phase I Study to Determine the Safety and Biological Activity of Cell-Mediated Gene Therapy Using Tissue-Gene-C in Patients with Degenerative Joint disease (DJD) Prior to Total Knee Arthroplasty. (TGC-03-01)

Osteoarthritis occurs when cartilage in your joints wear down over time. It gradually worsens, and for now there is no known cure. Current treatments for this disease can only relieve pain in an attempt to keep those suffering from this condition active.

The purpose of this clinical trial is to test the safety of Tissue-Gene-C, a cell-mediated cytokine gene therapy for cartilage regeneration. The study will focus on:

1) The side effects associated with the different doses of Tissue-Gene-C injected into the knee joint, and

2) The ability of Tissue-Gene-C to stimulate new cartilage growth in the joint of subjects scheduled to have knee replacement surgery.

Dr Mont states that Tissue-Gene-C has healed cartilage defects in animals, and if it works as well in humans, will be a monumental breakthrough for many arthritic sufferers.

Inside this Issue:

New IRB-Approved Studies at LifeBridge Health

✓ ***Reamer Irrigation Aspirator (RIA) Effluent Evaluation,*** Janet Conway, M.D.

To evaluate procedural aspects of using RIA for obtaining bone graft and its complications. The second objective is to evaluate the results of bone graft application in terms of bony union.

✓ ***ALT Levels in Crohn's Disease,*** Douglas Jacobstein, M.D., Suchitra Hourigan, M.D.

To investigate whether ALT (alanine transaminase, a liver enzyme that plays a role in protein metabolism) levels are reduced in acute flares of Crohn's disease compared with Ulcerative Colitis.

✓ ***A Randomized Phase III Study Comparing 5-FU, Leucovorin and Oxaliplatin vs 5-FU, Leucovorin, Oxaliplatin and Bevacizumab in Patients with Stage II Colon Cancer at High Risk for Recurrence to Determine Prospectively the Prognostic Value of Molecular Markers. (ECOG E5202),*** Rodrigo Erlich, M.D., Stephen Noga, M.D., Marvin Feldman, M.D., Pallavi Kumar M.D., Cristina Truica, M.D., Nancy VanderVelde, M.D.

To demonstrate an improvement in 3-year disease-free survival for high-risk stage II colon cancer patients randomly assigned to 5-FU, leucovorin, oxaliplatin versus 5-FU, leucovorin, oxaliplatin and bevacizumab. To compare overall survival between the regimens, to further define the toxicity profiles of the regimens. To prospectively determine the impact of tumor biological characteristics on the survival of patients with stage II colon cancer.

✓ ***Correction of Cubitus Varus After Pediatric Supracondylar Elbow Fracture: Improved Method using The Taylor Spatial Frame.*** Dror Paley, M.D., Mohan Belthur, M.D.

To study the results of this technique in patients who developed cubitus varus, a deformity of the elbow resulting in a decreased carrying angle (so that, with the arm extended at the side and the palm facing forward, the forearm and hand are held at less than 5 degrees).

Frequently Asked Questions

Q: What is the Administrative Review Board (ARB)?

A: ***The ARB is charged with overseeing the financial aspects of all research conducted on LBH properties or patients. ARB responsibilities include: 1) Reviewing financial details of all LBH research activity and ensuring that all research costs are appropriately accounted for and reimbursed, 2) Identifying and evaluating potential conflict of interest scenarios and suggesting appropriate management solutions, 3) Ensuring that ancillary departments required to support research endeavors are aware of demands on personnel, equipment, and supplies, and that these resources are available and accessible when required by the research protocol, and 4) Ensuring that third party payers are not billed for any services provided during a clinical research study over and above the routine care normally provided in the absence of research.***

Q: Can I submit an ARB application for a new study without signatures?

A: ***No! Each new submission must include the signatures of the principal investigator, department chairman., department vice president, and each department director providing support for the project.***

Skiing Thru the Web

A Taste for Alcohol May Come from the Womb

Medical Research News, 12/13/07 @ http://www.news-medical.net/?id=33496

Young people whose mothers drank when pregnant may be more likely to abuse alcohol because in the womb, their developing senses came to prefer its taste and smell!

Researchers with the State University of New York Developmental Ethanol Research Center have found that because the developing nervous system adapts to whatever mothers eat and drink, young rats exposed to alcohol in the womb drank significantly more alcohol than non-exposed rats.

Public Never Warned about Dangerous Device

The Seattle Times, 11/19/2007 @ http://seattletimes.nwsource.com/html/localnews/2004022178_miracle19m2.html

Having the Food and Drug Association (FDA) oversee Institutional Review Boards (IRBs) which then oversee the design and safety of clinical studies from drugs to devices is very important as seen in the following true story. Panos Pappas, a math professor from Athens, Greece, invented the PAP-Ion Magnetic Inductor (PAP-IMI) which is a 260-pound machine that pulses the body with electromagnetic waves. This machine purportedly repairs damaged cells and promises cures for cancer, chronic pain and AIDS. Although the FDA prohibited the use of this machine in 2005 , under the guise of a clinical trial its use in at least five states resulted in numerous injuries and even death. See the above referenced website for more details concerning this story of failed oversight at the Federal, State, and Local levels.

IRB Tips: I Didn't Know That!

- **Any LifeBridge Health (LBH) employee conducting a research study** involving LBH patients or their protected health information **must** apply to the LBH IRB (Institutional Review Board) for review and approval to conduct that study.
- **A physician in private practice**, conducting human research with an FDA-regulated product will likely need to obtain IRB approval. It is always best to have an IRB evaluate any human research project before starting a project in order to determine the degree of IRB oversight required.
- **The LBH IRB defines advertising as** "any outreach effort designed to encourage potential subjects to contact the investigator's site requesting information." Advertisements are viewed by the IRB as an extension of the subject selection and consent processes. Thus, all means of recruiting subjects to participate in a research study, including advertisements *prior to publication* , must be reviewed by the IRB. *Methods commonly used include* advertisements in newspapers, on radio, television, posters on bulletin boards, and office-based flyers.

LIFEBRIDGE HEALTH

Department of Research

Arthur N. Freed, PhD
LifeBridge Director of Research
(410) 601-8742
afreed@lifebridgehealth.org

Patty Lohinski, CIM
Research Coordinator
(410) 601-9272
plohinsk@lifebridgehealth.org

Alan Orpia, RN
Nurse Research Coordinator
(410) 601-0960
aorpia@lifebridgehealth.org

Andrea Kellert
Animal Care Facility Coordinator
410-601-5526
akellert@lifebridgehealth.org