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NEWS TO USE

New Clinical Trials Process Office Created

A new Clinical Trials Process Office (CTPO) was recently created to integrate functions of the Institutional Review Board Office, the Sponsored Projects Office and the Clinical Trials Office. CTPO will coordinate the billing analysis for all clinical trials and will design and implement a consistent institution-wide process of identifying, for billing purposes, services that are a part of a clinical trial.

Ultimately, the CTPO will be the exclusive central office for all aspects of clinical trials, including grants at Rush. However, effective November, 2004, principal investigators should forward all proposed clinical trial documents to the CTPO for billing analysis for those studies that have not yet had signed sponsor agreements. This will begin the process of ensuring that all of our clinical trials have consistent billing processes.

Lisa Pitler, RN, MS, JD, will head the Clinical Trials Process Office as its senior director. The CTPO is located in the Professional Building, Suite 439 and can be reached at (312) 942-5498.

Introducing a Rush Speakers Bureau

The marketing communications department is developing a speakers bureau of physicians and other health professionals to speak on health topics of interest to consumers. This speakers bureau will be promoted to community groups in the Rush service area, and speaker requests will be fielded by the community marketing manager in the marketing communications department. Physicians who are interested in participating should call Lori Allen, (312) 942-8708, or Laura Pellikan, (312) 942-8757, for more information.

RUSH Programs and Services Spotlight

The Department of Otolaryngology

The Department of Otolaryngology provides state-of-the-art care for patients with diseases of the ear, nose, sinuses, larynx and upper respiratory tract as well as diseases of the head and neck, tracheobronchial tree and esophagus. They also provide cochlear implants for people who are severely-to-profoundly hard of hearing.

The department's national reputation, strong patient outcomes and solid structure (measuring RN to patient ratio, Magnet status and available technology and services) led to a ranking of 30th in the nation according to *U.S. News & World Report*. Department chairperson, David Caldarelli, MD, holds the Stanton A. Friedberg, MD, Endowed Professorship of Otolaryngology.

The department's greatest volume is in the following treatments:

- Endoscopic sinus surgery
- Skull-base surgery; performed with neurosurgery
- Neurotology
- Head and neck cancer
- Laryngology and care of the professional voice
- Pediatric otolaryngology

In addition to routine otolaryngology cases involving any of the above, patients should be referred to the department when:

- An otherwise healthy person experiences sudden hearing loss. This could mean an inner ear loss that doesn't present with any physical findings, and must be tested immediately to increase the probability of restoring hearing.
- A sore throat doesn't respond to a course of antibiotics or patients have a hoarse voice for more than two weeks. These could be warnings of cancer and should be investigated by an otolaryngologist as soon as possible.

Physicians

Joseph Allergretti, MD
1725 W. Harrison,
Suite 340

Larry L. Bailey, MD
3340 S. Oak Park Ave.
Berwyn, Ill.

David D. Caldarelli, MD
1725 W. Harrison,
Suite 308

Steven J. Charous
3633 W. Lake Avenue
Glenview, Ill.

Angelique Cohen, MD
3340 S. Oak Park Avenue
Berwyn, Ill.

Jay Dutton, MD
1725 W. Harrison,
Suite 340

Michael Friedman, MD
30 N. Michigan,
Suite 1107

Thomas J. Haberkamp, MD
1725 W. Harrison,
Suite 938

Ashok A. Jagasia, MD
1221 N. Highland Ave.
Aurora, Ill.

Paul J. Jones, MD
1725 W. Harrison,
Suite 938

Daniel M. Kurtzman, MD
3340 S. Oak Park Avenue
Berwyn, Ill.

Andrew J. Lerrick, MD
1400 Golf Road,
Suite 121
Des Plaines, Ill.

Neal M. Lofchy, MD
1725 W. Harrison,
Suite 340

George T. Moynihan, MD
60 E. Delaware,
Suite 1400

Thomas J. Nielsen, MD
1725 W. Harrison,
Suite 938

William R. Panje, MD
1725 W. Harrison,
Suite 340

TK Venkatesan, MD
3000 N. Halsted,
Suite 401

David L. Walner, MD
8780 Golf Road,
Suite 200
Niles, Ill.

focus on CONTINUING AND GRADUATE MEDICAL EDUCATION

Upcoming CME Courses at RUSH

5th Annual Rush Review

January 29, 2005

5 credit hours

Sponsoring department: Department of Internal Medicine

Location: The Westin Michigan Avenue, 909 North Michigan, Chicago

Cost: \$25

Contact: Maureen Moore, Helix

E-mail: Maureen.moore@helix-medcom.com

13th Annual Rush Medical College Ophthalmology Clinical Review Course

February 11 - 13, 2005

February 18 - 20, 2005

37.5 credit hours

Sponsoring department: Department of Ophthalmology

Location: Rush University Medical Center

Armour Academic Center

600 South Paulina, Room 976

Cost: Call for information

Contact: Judy Linquist

Phone: (312) 563-2302

Fax: (312) 942-2140

E-mail: eye_ctr@rush.edu

Preimplantation Genetic Diagnosis: A Medical Marvel and an Ethical Dilemma

February 16, 2005, 6:30 - 9:00 p.m.

2 credit hours

Sponsoring department: Patient Care Services, Rush North Shore Medical Center

Location: Rush North Shore Medical Center, Sharfstein Academic Center

Cost: \$40

From the RUSH Clinical Trials Office

Angina Pectoris Study Using Recombinant DNA Gene Therapy

The Section of Cardiology is conducting a study to determine the optimum effective dose of a recombinant DNA gene therapy administered using an experimental cardiac direct injection catheter system compared to placebo for patients with severe angina pectoris. Subjects must have moderate to severe chest pain unresponsive to medication, experience signs or symptoms of chest pain during the exercise tolerance test (ETT), have had an angiogram within 90 days prior to screening and be willing to undergo cardiac catheterization or nuclear (SPECT image) procedure. Exclusion criteria include exercise-limited noncardiac chest discomfort; candidacy for conventional revascularization procedures; other disease severe enough to limit exercise test or place patient at risk; uncontrolled atrial fibrillation, atrial flutter and/or significant arrhythmias; unstable chest pain or an acute non-Q-wave heart attack within 14 days; documented stroke or transient ischemic attack within 60 days; or pacemaker dependency. For more information contact Jason Daily, RN, BSN, at (312) 942-8144.

Treatment of Bone Loss in Prostate Cancer Patients

The Department of Urology is conducting a randomized, double-blind, placebo-controlled study to evaluate an investigational product in the treatment of bone loss caused by treatment for prostate cancer (androgen deprivation therapy) for nonmetastatic prostate cancer. The total duration of the study is 24 months. Patients will receive either the study drug or placebo every six months. The dose of study medication will be given by subcutaneous injections. Patients will be provided calcium and vitamin D tablets and will receive a bone scan to rule out bone metastasis and DXA (bone density) scan for the spine, hips, arms and total body. For more information contact Nahla Hasabou, MD, at (312) 942-3027.

Osteoarthritis Study

The Department of Rheumatology is conducting an osteoarthritis study for patients who suffer from hip or knee soreness and pain with movement or have swelling or decreased mobility in the hips or knees. Subjects must be at least 40, have had pain for at least three months and be able to walk without assistance. For more information contact Rita Tharp, RN, at (312) 942-2167.

INTRODUCTIONS The following is a list of physicians who joined the RUSH medical staff between September 1, 2004 and October 31, 2004. The Medical Staff Office and the Office of Marketing Communications have made every effort to publish accurate information that is as complete as possible; however, if the information below is incorrect or we have omitted information, we apologize and ask that you contact Muriel Coleman in the Medical Staff Office at (312) 942-5496.

Michail N. Avramov, MD
Anesthesiology
(312) 942-6504
mavramov@rush.edu

Joseph B. Garber, MD
General ophthalmology
(773) 525-8700
leslieandjoe@comcast.net

Teresa J. Lynch, MD
General internist
(312) 942-8000
lynchtjv@home.com

Theophilus T. Sai, MD
General internist
(312) 942-6600
theosai@hotmail.com

David A. Barthwell, MD
Psychiatry
(708) 383-2700
Dbarthmd@aol.com

Tarek S. Husayni, MD
Pediatric cardiovascular-
thoracic surgery
(708) 346-5580

Luis A. Manrique, MD
General internist
(312) 942-6600
lmanrique@sbcglobal.net

Arati A. Wagh, MD
Endocrinology
(312) 942-8231
Arati_Wagh@rush.edu

Bettina F. Cuneo, MD
Pediatric cardiology
(312) 942-2094
bettina_f_cuneo@rush.edu

Michel Ilbawi, MD
Pediatric cardiovascular-
thoracic surgery
(708) 346-3029
nancy@thic.com

Ira J. Miller, MD, PhD
Pathology
(312) 942-6128
Ira_Miller@rush.edu

COMPLIANCE CENTRAL

What Are the New Recruiting Rules for Clinical Trials Post-HIPAA?

Along with other changes brought on by HIPAA, recruitment techniques for clinical trials must now meet HIPAA Privacy Rule standards for privacy and confidentiality. Under the Privacy Rule, providers who have a direct treatment relationship with a patient may contact their own patients for the purposes of recruiting them into a clinical trial without patient authorization.

All other nontreating physicians or staff, however, may not discuss study participation with other patients. In addition, they may not look for, obtain or receive patient names and contact information without a) written authorization from the patient or b) a waiver of authorization from the Institutional Review Board (IRB).

Can faculty review their own patient records to identify possible enrollees in clinical trials and speak with the patients about the clinical trials without a patient's authorization?

Yes, if the faculty member has a direct treatment relationship with the patient, no authorization is necessary.

How can I identify patients eligible for a study if I do not have a direct treatment relationship with them?

If you do not have a direct treatment relationship with potential study participants, you have four options:

1. *Solicit the participation of direct treatment providers.* In this instance, direct treatment providers may contact their patients and a) tell them how to

contact the researcher; b) solicit an authorization for the entire study on the research team's behalf or c) solicit authorization to pass on the patient's contact information and eligibility for the study to the research team (the IRB-approved "recruitment only authorization" should be used).

2. *Apply to the IRB for permission to advertise the study in the public media.*
3. *Apply to the IRB for a "recruitment only waiver of authorization."* This allows the research team to access protected health information for the purposes of determining recruitment eligibility only. This authorization waiver would apply to recruitment only and is not a waiver of informed consent or individual authorization for the study itself.
4. *Submit a "recruitment repository" proposal to the IRB, proposing that specified providers or clinical departments routinely solicit from their patients "authorization to discuss the possibility of research study participation" for a variety of future uses.* Even after the IRB approves the creation of a recruitment repository, however, investigators must still apply for IRB "recruitment waiver of authorization" each time the investigator proposes to access the limited screening information for a new study.

For more information, please see the Research Compliance policy "Recruitment for Clinical Trials and Other Research" or call David Clark, PhD, Director of Research Compliance at (312) 942-3351.

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Contact: Karen Litwack, Chicago Center for Jewish Genetic Disorders
Phone: (312) 357-4717
Fax: (312) 855-3295
E-mail: KarenLitwack@juf.org

Grand Rounds

"Are Some Joints Programmed to Self-Destruct?"

February 3, 2005

Noon – 1:00 p.m.

Cohn Research Building conference room

Ada Cole, Director of Medical Education Programs,
Associate Professor in Biochemistry