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## **Campus Center to be new home of IMCU, Jagtag**

After 51 years located near or in the Student Union on the IUPUI campus, the Indiana Members Credit Union relocated to the new Campus Center at West Michigan Street and University Boulevard Dec. 3. A grand opening celebration is planned for Friday, Dec. 14.

Campus Card Services, which issues Jagtag, also is moving to the new center. Campus Card Services will permanently close its operation in the Union Building on Tuesday, Dec. 11. A satellite office in University College room 127 will be open until the UC office opens in suite 217 of the Campus Center.

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## **Clinical trials new guidelines and training sessions**

Training sessions to guide investigators and clinical trials personnel on new requirements (Public Law 110-85) for registration will be offered:

- 10 to 11 a.m., Thursday, Dec. 13 – Emerson Hall auditorium
- 3 to 4 p.m. Tuesday, Dec. 18 – ROC Auditorium

Studies of drugs for a serious or life-threatening disease or condition that enrolled the first patient before

Sept. 27, and will still be ongoing on Dec. 26, must submit required information by **Wednesday, Dec. 26**. If the study has previously been registered, additional data elements are required by that date.

Applicable clinical trials that enroll the first patient between Sept. 27 and Dec. 26 must submit required information by Dec. 26. If you have an applicable clinical trial that enrolls the first patient after Dec. 26, you must submit required information no later than 21 days after the first patient is enrolled. Additional data elements must be submitted by Sept. 27, 2008, for studies that have been registered prior to Sept. 27, 2007. These trials include:

- Trials of Drugs and Biologics – controlled, clinical investigations, other than Phase I investigations, of a product subject to FDA regulation (Phase II- IV trials now require registration); and
- Trials of Devices – controlled trials with health outcomes, other than small feasibility studies, and pediatric post-market surveillance.
- NIH encourages registration of ALL trials whether required under the law or not.

Consistent with current FDA and ClinicalTrials.gov guidance, the NIH interprets serious and life-threatening disease or condition to mean: (1) diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted and (2) diseases or conditions with potentially fatal outcomes, where the endpoint of clinical trial analysis is survival.

The seriousness of a disease is a matter of judgment, but generally is based on such factors as survival, day-to-day functioning, and the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one. For example, acquired immunodeficiency syndrome (AIDS), all other stages of human immunodeficiency virus (HIV) infection, Alzheimer's disease, angina pectoris, heart failure, cancer and many other diseases are clearly serious in their full manifestations. Furthermore, many chronic illnesses that are generally well managed by available therapy can have serious outcomes. For example, inflammatory bowel disease, asthma, rheumatoid arthritis, diabetes mellitus, systemic lupus erythematosus, depression, psychoses, and many other diseases can be serious in some or all of their phases or for certain populations.

Any investigational drug that has received fast track designation by the FDA is considered a drug to treat a serious disease or condition.

*Who is responsible for making sure this registration is performed?*

Ultimately, it is the responsibility of the principal investigator. However, sponsors will many times perform the actual registration work for the PIs. Rather than assume that this requirement has been fulfilled by the sponsor, it is best to ask prior to enrollment of any subjects whether the clinical trial fully registered.

NIH-sponsored trials should be registered by the Institute that is funding the research. The PI is responsible for initiating this registration with the agency. Industry-sponsored trials (industry-written protocol) should be registered by the sponsor. Contract language is included to specify that Sponsor will do this registration. Investigator-initiated trials (for which industry has supplied drug or grant funds) should be registered by the PI.

Trials for which PIs hold their own INDs or IDEs should registered by the PI. Multi-site trials should be coordinated among the sites and registered by the “lead sponsor” so that ClinicalTrials.gov does not receive multiple registrations for the same trial.

*What assistance can Indiana University provide?*

The university is in the process of developing a procedure for identifying studies that will meet the registration requirements. More details regarding the procedure will be provided as they become available. In the meantime, if you have questions or are unsure of the applicability of this requirement to your research, please contact the Office of the Vice President of Research Administration at [wecomply@indiana.edu](mailto:wecomply@indiana.edu) email address.

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## **New diversity director at IU Simon Cancer Center**

Rivienne Shedd-Steele, a veteran cancer educator and advocate for minority health care, has been named outreach and diversity coordinator at the Indiana University Melvin and Bren Simon Cancer Center, effective Dec. 1.

In this role she will develop and implement cancer education programs and leverage resources to assist the IUSCC in increasing cancer awareness in the community, with a focus on underserved populations. Shedd-Steele will work with diverse community groups and build collaborative relationships with the purpose of increasing participation in cancer clinical trials.

Shedd-Steele most recently was the partnership program coordinator for the National Cancer Institute's Cancer Information Service Midwest Region. In that role, she collaborated state-wide with partner organizations to deliver cancer control and education programs to help improve the health of underserved populations.

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## **IUSCC Combined Seminar Series for December**

The IU Simon Cancer Center Combined Seminar Series is from 4 to 5 p.m. on the first and third Wednesday of each month in the auditorium of the IU Cancer Research Institute. For December:

### Special Seminar

2-3 p.m., Wednesday, Dec. 12

Van Nuys Medical Science Building, room 326

Alan Rickinson, PhD

Professor of Cancer Studies

University of Birmingham

“Immune Responses to Epstein-Barr Virus Infection”

4-5 p.m. Wednesday, Dec. 19

James D. Yager, PhD

Senior Associate Dean

Department of Environmental Health Sciences

Johns Hopkins University

“Mechanisms of Estrogen Carcinogenesis in Breast Cancer –

The Roles of Metabolism and Receptor-Mediated Signaling Processes”

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## **Zurlo to address ethics of animal use in research**

On Wednesday Dec. 19, Joanne Zurlo, PhD, director of the Institute for Laboratory Animal Research, The National Academies, Washington, D.C., will present a seminar entitled "Ethics of Animal Care and Use in Research - Why It's Important to Science and Society" from 2 p.m. to 3 p.m. in Van Nuys Medical Science Building, room 326.

This is a career development seminar for the postdoctoral fellows and graduate students of the IUSM but IUSM faculty and staff are also welcome to attend. Contact the Graduate Division at 274-3441 if there are questions.

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## **Weather or not, city and campus are prepared**

Helpful information and tips on dealing with winter weather are provided by IUPUI Campus Facilities and Parking Services at [www.iupui.edu/~cfs/Documents/snow/Let%20it%20Snow.pdf](http://www.iupui.edu/~cfs/Documents/snow/Let%20it%20Snow.pdf) .

The city of Indianapolis has information on snow routes, up-to-date road conditions and other tidbits to make navigating your way to work easier at [www.IndyGov.org/Snow](http://www.IndyGov.org/Snow) .

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## **Medical Library needs your help**

The Medical Library is in need of a few insightful medical faculty, residents and medical students for input on the redesign of the library's website.

Volunteers will be asked to participate in a card sorting exercise, which will take about an hour. The exercise will be Dec. 17-21 at the Medical Library. If you are willing to participate, contact Kellie Kaneshiro, AMLS, at [kkaneshi@iupui.edu](mailto:kkaneshi@iupui.edu), or Beth Whipple, MLS at [ewhipple@iupui.edu](mailto:ewhipple@iupui.edu).

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## **Health statistics online**

The Health-Related Statistics web page, hosted by the IUSM Medical Library, is available to all at [www.medicine.iu.edu/body.cfm?id=6834](http://www.medicine.iu.edu/body.cfm?id=6834). The site lists annotated online and print sources of statistics on health and health-care topics, hospital data, etc.

In addition to targeting the U.S. and world health, Indiana-specific data sources are listed as well. Popular print reference sources available at the Medical Library are listed with their call number for easy access. Feel free to link to this page as a handy starting point for statistical research.

For additional information, contact Elaine Skopelja at [eskopelj@iupui.edu](mailto:eskopelj@iupui.edu)

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## Scope schedule for the holidays

The final edition of *Scope* for 2007 will be published Friday, Dec. 14. The deadline for submitting copy is 8:30 a.m. Thursday, Dec. 13.

*Scope* will resume publication Jan. 4. Stories for that issue can be submitted in December. (Hint.)

The new year will begin with several exciting events, including Diversity Week speakers during the week of Jan. 21, and the second annual IUSM Day at the Statehouse is Jan. 24.

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## IUSM, IUSCC gifts online

*IUSCC holiday shopping:* Looking for some fresh ideas to finish your holiday shopping list? In response to employee demand, a special holiday shopping web page featuring IU Simon Cancer Center apparel and gifts is now available at <http://www.tcamarketing.com/> through Wednesday, Dec. 12. All orders will be available for pick-up in the Indiana Cancer Pavilion, room 102, on Thursday, Dec. 20, from noon to 4 p.m. Orders not picked up that day will be shipped to your home and shipping charges will be billed to you.

*IUSM gifts and apparel:* For gifts and apparel with IUSM appeal, see the IUSM Alumni web site at [alumni.iupui.edu/medicine/merchandise.htm](http://alumni.iupui.edu/medicine/merchandise.htm). IUSM sweatshirts, microfiber fleece jackets, T-shirts, hats and other items, are available online.

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## Honors

IU Distinguished Professor **Hal Broxmeyer**, PhD, a pioneer in the field of umbilical cord blood transplantation, will be honored Dec. 10 at the American Society of Hematology's annual meeting in Atlanta. Dr. Broxmeyer is the recipient of the 2007 E. Donnall Thomas Prize. The award is named in honor of Dr. Thomas, who in 1990 was awarded a Nobel Prize in Medicine.

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## This week on *Sound Medicine*

Tune in at 2 p.m. Sunday, Dec. 9, to *Sound Medicine*, the award-winning weekly radio program co-produced by IUSM and WFYI Public Radio (90.1 FM) in Indianapolis. The program is hosted by Barb Lewis.

This week's program will focus on sexual health issues. A newly devised comfort scale to make observing safe sex practices more practical will be discussed, as well as a special report by Jeremy Shere on Sexual Health in Indiana. Darron Brown, MD, an infectious diseases researcher who helped develop vaccines for the human papillomavirus will discuss the role of Gardasil in protecting women from

cervical cancer.

Geriatrician Malaz Boustani, MD, MPH, will offer his insights on dementia testing for America's aging population.

In this month's issue of *Sound Ethics*, Eric M. Meslin, PhD, and medical student Patrick Barrett, will discuss the time-honored Hippocratic oath.

Archived editions of *Sound Medicine* as well as other helpful information can be found at <http://www.soundmedicine.iu.edu/>. *Sound Medicine* is underwritten by the Lilly Clinic, Clarian Health, and IU Medical Group; Jeremy Shere's "Check-Up" is underwritten by IUPUI.

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## Continuing Medical Education at your fingertips

Online registration and a list of grand rounds, conferences and courses are available on the Continuing Medical Education website at [cme.medicine.iu.edu](http://cme.medicine.iu.edu).

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## Scientific Calendar online

A comprehensive listing on IUSM seminars, lectures and Grand Rounds can be accessed at [the new Scientific Calendar website](#). To place items on the Scientific Calendar, please forward them to Iona Sewell at [imsewell@iupui.edu](mailto:imsewell@iupui.edu).

To access calendars and information prior to 2003, visit the old site [at www.medlib.iupui.edu/calendar](http://www.medlib.iupui.edu/calendar).

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## Scope submission guidelines

*Scope* wants your news items.

The deadline for submission is 8:30 a.m. on Thursdays. *Scope* is published electronically and sent to faculty, staff, students, and residents.

There are three easy ways to submit story ideas or information to *Scope*:

- e-mail the information to [mhardin@iupui.edu](mailto:mhardin@iupui.edu)
- mail the information to Mary Hardin, Z-7, Ste. 306, IUPUI
- fax your information to (317) 278-8722

Contributions submitted by e-mail should be forwarded in 12 point, plain text format.

In the interest of accuracy, please do NOT use:

- acronyms
- abbreviations
- campus building codes (use full, proper name of building and include the room number)
- Dr. as a preface before names (designate MD or PhD)

To keep the electronic version of *Scope* as streamlined as possible, only seminars and lectures of general or multidisciplinary interest will be included.

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