



## RESEARCH ENTERPRISE

May 15, 2006

Welcome to the *RESEARCH ENTERPRISE*, a new mode of communication from the IUPUI Office of Research and Sponsored Programs (R&SP) that replaces the *R&SP Communicator*. The *RESEARCH ENTERPRISE* will be published monthly, distributed by email, and will contain time sensitive research information as well as links to several research-related sites. The appearance of the R&SP Web page has changed with this issue of the *RESEARCH ENTERPRISE*. The information contained in the navigation bars on this Web page is in the process of being reorganized and will be updated monthly. This is the maiden voyage of the *RESEARCH ENTERPRISE*. We consider it a "work in progress" and we would appreciate your feedback.

### **NOTE FROM THE INTERIM VICE CHANCELLOR FOR RESEARCH**

I assumed the position of Interim Vice Chancellor for Research and Director of the IUPUI Office of Research and Sponsored Programs (R&SP) in November of 2006. During the past six months many changes have been made in the R&SP Office in order to better serve the research community and to strengthen and expand the research enterprise on the IUPUI campus. Everyone in the R&SP Office has been working diligently to make the office more responsive to the needs of investigators, to comply with regulations that govern research operations, and to increase research opportunities on the IUPUI campus. Please let us know if we are meeting your needs.

-Janice Froehlich-

### **CHANGES IN THE IUPUI OFFICE OF RESEARCH AND SPONSORED PROGRAMS**

#### **FROEHLICH LEADS RESEARCH AT IUPUI**

Janice Froehlich was appointed Interim Vice Chancellor for Research at Indiana University-Purdue University Indianapolis (IUPUI) and Associate Vice President for Research at Indiana University in November 2005. She provides leadership in the areas of research development, research compliance, research centers and institutes, grant and contract submission, and pre-award negotiation for all schools on the IUPUI campus. She is the authorized institutional official signing

grant and contract proposals submitted from the IUPUI campus and from the Centers on Medical Education system-wide. She coordinates research efforts, promotes interdisciplinary collaboration, and fosters partnerships with other institutions and the business community.

Dr. Froehlich is a Chancellor's Professor in the Department of Medicine, Division of Endocrinology and Metabolism, in the School of Medicine, with joint appointments in the Departments of Cellular and Integrative Physiology and in Medical Neurobiology. She serves as a Scientific Co-Director of the Indiana Alcohol Research Center. Her research program focuses on the hormonal, neurochemical, behavioral, and genetic factors that contribute to alcohol abuse and the development of alcoholism. She has served on the editorial board of national journals and as a member of a study section for the National Institutes of Health. She has authored numerous papers, book chapters, and review articles, has supervised more than forty graduate students and postdoctoral fellows, and serves as Scientific Program Director for the biennial pre- and postdoctoral trainee workshop of the National Institute of Alcohol Abuse and Alcoholism (NIAAA).

## **BIZILA OVERSEES RESEARCH COMPLIANCE**

Shelley Bizila, Director of Research Compliance Administration in the IUPUI Office of Research and Sponsored Programs (R&SP), was appointed Research Integrity Officer for the IUPUI campus in February 2006 and campus-wide compliance activities have been reorganized. As the Director of Research Compliance Administration, Shelley is responsible for assuring that research on the IUPUI campus is conducted in full compliance with federal regulations governing all research with human subjects, recombinant DNA, biohazardous materials, and laboratory animals. Shelley also oversees the Institutional Review Boards that review and approve all human research studies for IUPUI/Clarian and the Centers of Medical Education. As IUPUI Research Integrity Officer, Shelley oversees campus committees that identify, assess, develop, and implement management plans for conflict of interest, conflict of commitment, research misconduct and financial compliance.

## **JOHNSON DIRECTS GRANTS AND CONTRACTS**

Sponsored Research Services (SRS) in the IUPUI Office of Research and Sponsored Programs (R&SP) has undergone reorganization in order to be more responsive to the needs of IUPUI investigators. W.S. (Sid) Johnson, JD, has been reappointed as the Executive Director of Sponsored Research Services. Sid continues to oversee submission and pre-award negotiation of grants, contracts, subcontracts, and other research agreements and provides guidance on research related policies for the IUPUI campus. Prior to his appointment as

Executive Director of SRS, Sid was the Director of Corporate Contracts Administration in the IUPUI R&SP Office.

## **RESEARCH DEVELOPMENT**

Campus-wide internal grant funding mechanisms have been expanded and adjusted to reflect changes in the IUPUI research mission and to increase the competitiveness of proposals for external funding. Experienced investigators from every school on the IUPUI campus, representing more than 50 disciplines, have been recruited to serve as reviewers for campus-wide internal grant funding mechanisms. The Office of Research and Sponsored Programs is committed to fostering research and scholarship in all disciplines and to creating new opportunities for IUPUI faculty.

## **IRB SUBMISSIONS STREAMLINED**

In January, the IUPUI Research Compliance Administration (RCA) began requiring that all human subject research study applications be submitted electronically to streamline the review and approval process. Along with the electronic submission requirement, an electronic review and approval pilot program was initiated with one IUPUI IRB (IRB-04). Studies submitted to IRB-04 receive a pre-review from an RCA staff member and from Dr. C. Conrad Johnston, Jr. (Chair of IRB-04), in order to answer scientific questions and resolve potential protocol problems. The Principal Investigator of the study is given an opportunity to revise and clarify the protocol prior to formal submission to the IRB. The goal of this program is to reduce the time for IRB approval. If successful, this pilot program will be expanded to include additional IRBs.

## **UPDATES**

### **CHANGE IN POLICY FOR ESTABLISHING HUMAN BIOLOGICAL MATERIAL REPOSITORIES**

Based on recent guidance from the Department of Health and Human Services (DHHS), the IUPUI Institutional Review Boards (IRBs) will no longer require that informed consent to store human biological materials specify future potential use of the materials. In the past, the IRBs have required that subjects give informed consent for a specific future use of human biological materials at the time of material collection. While informed consent is still required for collection and storage of human biological materials, the future potential use of the materials no longer has to be specified. This change will become effective immediately in the IUPUI/CLARIAN IRB system. More information regarding IUPUI/CLARIAN Standard Operating Procedures will follow.

## **OFF-SITE IRB APPROVED**

In April, the IUPUI Research Compliance Administration (RCA) established an agreement with the National Cancer Institute (NCI) to use a central, off-site, IRB (CIRB), composed of cancer research experts from all over the country, to review human subject cancer protocols from the IUPUI campus. This agreement should reduce the administrative burden on IUPUI IRBs and campus investigators while continuing to provide a high level of protection for participants in human research studies. Off-site IRB reviews should also shorten the total time required for study review thereby allowing for more rapid subject recruitment and faster completion of studies. This new program will be initiated in the summer of 2006.

## **HUMAN SUBJECTS PROTECTION**

The IUPUI Human Research Protection Program (HRPP) received full accreditation from the Association for the Accreditation of Human Research Protection Programs (AAHRPP) in September 2005. In the most recent audit (November 2005) by the U.S. Food and Drug Administration, the IUPUI/Clarian Institutional Review Board (IRB) system was given very high marks.

## **NON-COMPETING PROGRESS REPORTS**

Principal investigators may submit National Institutes of Health (NIH) non-competing progress reports electronically through the NIH eRA Commons (<https://commons.era.nih.gov/commons/>) for projects designated to use the Streamlined Non-competing Application Process. This designation is contained in the "Terms and Conditions" of the NIH Notice of Grant Award.

Principal investigators may delegate authority to another individual to enter the progress report into the system. After a report is completed and verified by the principal investigator, copies should be routed to Sponsored Research Services (SRS) in the IUPUI Office of Research and Sponsored Programs using a paper or ERA route sheet. SRS will review and submit the report on behalf of the institution. An email from the NIH eRA Commons will be sent to the principal investigator and to SRS indicating receipt of the progress report.

Non-competing progress reports submitted electronically are due at the NIH 45 days prior to the next budget period start date instead of the 60 days required for submission of paper copies of the reports. If the principal investigator elects to submit the non-competing progress report in paper format, the face page must include an authorized institutional signature and is due 60 days prior to the next budget period start date.

## **JUST-IN-TIME APPLICATION PROCESS**

Just-In-Time information may now be submitted electronically through the National Institutes of Health (NIH) eRA Commons. Just-In-Time, the application process requiring applicants to send documentation to the NIH if an award is probable, should only be submitted when formally requested by NIH staff. The principal investigator must initiate the Just-In-Time submission by entering the documents requested in the NIH eRA Commons. Copies of the information should then be routed to Sponsored Research Services (SRS) in the IUPUI Office of Research and Sponsored Programs using a paper or ERA route sheet. Once reviewed and submitted by SRS on behalf of the institution, an email from the NIH eRA Commons will be automatically sent to the principal investigator and to SRS indicating receipt of the Just-In-Time information.

## **eRA COMMONS**

If you need a National Institutes of Health (NIH) eRA Commons account, please contact Sponsored Research Services (SRS) in the IUPUI Office of Research and Sponsored Programs at 317.278.3473. If you would like to request an individual or departmental training session on these topics, or have comments or questions, please contact Michelle Artmeier, Director of Proposal Services at 317.278.8644. SRS is committed to assisting faculty in all matters related to grant submission.

## **HUMAN SUBJECT RESEARCH**

New principal investigators involved in research with human subjects are required to complete the Investigator 101 Course and pass the test, which was developed by the Office of Human Research Protections on the appropriate conduct of clinical and non-clinical research. This requirement, as established by the IUPUI Institutional Review Board (IRB) Executive Committee in 2004, applies to new principal investigators that submit protocols to the IUPUI IRB. This includes both behavioral and medical protocols and all levels of submission (exempt, expedited, and full review). The three-hour course may be completed in multiple sessions. To obtain a copy of the Investigator 101 Course on a compact disc (CD) free of charge, contact Research Compliance Administration at 317.274.8289 or [resrisk@iupui.edu](mailto:resrisk@iupui.edu).

## **MONTHLY REMINDER: LIMITED SUBMISSION GRANT OPPORTUNITIES**

Check the IU Research Web site at <http://www.srs.indiana.edu/LimSub/LimSub.asp> for upcoming limited submission program opportunities. Click on the program name for a summary with links to the agency guidelines and instructions for applying. If you have questions contact Etta Ward at 317.278.8427 or [emward@iupui.edu](mailto:emward@iupui.edu).

**NSF: INTERNATIONAL VISIT AND WORKSHOP GRANTS**

NSF grants are available to support the early phases of developing research and education activities with a foreign partner. Visit proposals are accepted at any time. Workshop proposal deadlines are May 20, September 20, and February 20. For additional information, visit [http://www.nsf.gov/funding/pgm\\_summ.jsp?pims\\_id=12815](http://www.nsf.gov/funding/pgm_summ.jsp?pims_id=12815).