

Office of Research Integrity

N E W S L E T T E R

The *ORI Newsletter* is published quarterly by the Office of Research Integrity, Office of the Secretary of Health and Human Services, and distributed to applicant or awardee institutions and PHS agencies to facilitate pursuit of a common interest in handling allegations of misconduct and promoting integrity in PHS-supported research. Please duplicate and circulate this newsletter freely. An electronic copy is available on the ORI home page.



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Price Retires From Federal Service; Migrates to Texas

Alan R. Price, Ph.D., a pioneer in the development of the PHS approach to handling research misconduct allegations, retired last April from ORI and federal service.

At the time of his retirement, Price had served as Associate Director for Investigative Oversight and Director, Division of Investigative Oversight (DIO), since 2000.

Price joined the PHS effort to combat research misconduct in 1990 as a senior scientist in the Office of Scientific Integrity (OSI). When OSI merged with the Office of Scientific Integrity Review (OSIR) in 1992, he served as chief of an investigative

branch for 7 years before being named Acting Director, DIO, in 1999.

“Alan has been the primary contact the research administrative community has had with ORI on research misconduct allegations for many years,” Chris Pascal, Director, ORI, said. “He worked tirelessly to institutionalize investigative procedures and solve problems that arise in research misconduct investigations.”

Early on, Price realized that research integrity officers (RIOs), the institutional officials who implement federal research misconduct regulations, would require ongoing training because most RIOs are

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ORI Supports Development of 5 More RCR Resources

ORI will make five awards this summer through the RCR Resource Development Program to support the creation of sophisticated hands-on resources with specific applications to data analysis, animal welfare, laboratory management, peer review, and learning assessment.

With these awards, the program has supported 54 projects since its establishment in 2002 to facilitate the creation of RCR resources by the research community for use in the research community. Thirty completed resources are posted on the ORI web site at http://ori.hhs.gov/education/rcr_resources.shtml

“The projects this year are much different than previous projects,” says Loc Nguyen-Khoa, Director, RCR Resource Development Program, . “Instead of educational modules, this year’s projects will create sophisticated hands-on resources with very specific applications.”

A new request for applications (RFP) will be issued in July with a

See New, page 4

**ORI Recruiting
for
Three Positions**

<http://ori.hhs.gov>

Research Misconduct Activity Rebounds in 2005 Reports

A record number of institutions reported a record number of new research misconduct cases in their 2005 Annual Report on Possible Research Misconduct following a downturn in 2004.

Eighty-five institutions reported starting 114 new cases in their 2005 reports. The previous highs were 82 institutions reporting 105 new cases in their 2003 reports. In their 2004 reports, 63 institutions reported opening 81 new cases.

Research misconduct activity is defined as receipt of an allegation or the conduct of an inquiry and/or investigation in the reporting year or carried into the reporting year. Reportable activities are limited to alleged research misconduct involving PHS-supported research, research training, or research-related activities.

Korean Researchers Get Free Copies of ORI Text

Twenty thousand copies of the *ORI Introduction to the Responsible Conduct of Research* were distributed free to researchers in South Korea last March by the Ministry of Education and the Korea Research Foundation in the aftermath of the stem cell research misconduct case.

The Korean translation also includes appendices containing the PHS

The 85 institutions opened new cases upon receipt of 133 allegations that resulted in 79 inquiries and 36 investigations. The allegations included falsification 69, fabrication 31, and plagiarism 33.

Institutions handling new cases included 66 institutions of higher education; 7 research organizations, institutes or laboratories; 6 other health, human resources or environmental organizations; 5 independent hospitals, and 1 small business.

In their 2005 reports, the highest number of institutions (109) reported conducting new or continuing research misconduct activity. Fifty-two cases were carried into 2005 which resulted in the conduct of 26 inquiries and 38 investigations.

Policies on Research Misconduct and the 2004 ORI Annual Report. The ORI publication has also been translated into Chinese and Japanese.

Copies of the English version may be purchased from the U. S. Government Printing Office. See <http://bookstore.gpo.gov>.

ORI Conferences 2006

July 24-25, 2006

Mentoring and Supervision for the Responsible Conduct of Research
St. Louis, MO
Co-sponsor: Washington University School of Medicine

September 14-15, 2006

Research Bias and Misconduct: Statistics, Images and Perceptions of Truth
Birmingham, AL
Co-sponsor: UA - Birmingham

September 28-29, 2006

New Capabilities, Emerging Issues and Responsible Conduct in Data Management
Baltimore, MD
Co-sponsor: UMD - Baltimore

December 1-3, 2006

Research Conference on Research Integrity
Tampa, FL
Co-sponsors: AAMC, AAAS

New RRI Pubs

DeVries R, Anderson MS, Martinson BC. "Normal Misbehavior: Scientists Talk about the Ethics of Research." *Journal of Empirical Research on Human Research Ethics* 2006, 1(1):43-50.

Martinson BC, Anderson MS, Crain AL, DeVries R. "Scientists' Perceptions of Organizational Justice and Self-Reported Misbehaviors." *Journal of Empirical Research on Human Research Ethics* 2006, 1(1):51-66.

Keith-Spiegel P, Koocher GP, Tabachnick B. "What Scientists Want from Their Research Ethics Committees." *Journal of Empirical Research on Human Research Ethics* 2006, 1(1):67-82.

Research on Research Integrity Program

Submission Deadline: 9/14/06

Request for Applications

<http://ori.hhs.gov>

Dahlberg, Davidian Named to Head ORI Investigative Oversight Division

Two highly experienced, veteran ORI investigators were named last April to manage the office's investigative oversight functions by Chris Pascal, Director, ORI, following the retirement of Alan Price.

John E. Dahlberg, Ph.D., Expert Advisor in Microbiology since January 1996, was named Associate Director for Investigative Oversight and Director, Division of Investigative Oversight (DIO). Nancy McConnell Davidian, Ph.D., Clinical Case Expert who joined ORI as a Senior Scientist in August 1991, was named Deputy Director, DIO, a position that has been vacant for several years.

"John and Nancy have handled most of the major research misconduct cases reported to ORI over the last 15 years," Pascal said. "I am sure they will continue to provide the quality professional service that the research commu-

nity has come to expect from ORI."

Dahlberg joined the ORI in 1992 as a Senior Scientist. Previously, he worked for biotechnology firms as a research director and the National Cancer Institute as a microbiologist and senior staff fellow. Earlier in his career, he was an assistant research professor at Rutgers University and a postdoctoral fellow at the Public Health Research Institute of the City of New York.

Dahlberg received his doctorate in virology from Purdue University in 1968 and his bachelor's degree from Brandeis University in 1963. Among the journals that have published his scientific work are *Nature*, *Virology*, *Journal of Virology*, and the *Proceedings of the National Academy of Sciences*.

Davidian joined the Office of Scientific Integrity (OSI), a prede-

cessor of ORI, in 1991 as a Senior Scientist. Previously, she held various research administrative positions at NIH including grant appeals, project clearance, peer review activities, staff development, and special programs over a 14 year period. Earlier in her career, she served as a research associate and instructor at the University of North Carolina-Chapel Hill and as a research assistant at the Sterling-Winthrop Research Institute, Rensselaer, NY.

Davidian received her doctorate in biochemistry from the University of North Carolina-Chapel Hill in 1969 and her bachelor's degree in chemistry from Cornell University in 1962. Her scientific work has been published in such journals as the *Archives of Biochemistry and Biophysics*, *the Journal of Biological Chemistry*, and *Experimental and Molecular Pathology*.

Price Created Working Relationship With Research Institutions (from page 1)

inexperienced when appointed and receipt of a research misconduct allegation is a low probability event with potentially high impact.

Price organized some conferences focused on plagiarism and advanced investigative techniques. In 2000, he created the Rapid Response Technical Assistance Program to permit RIOs to seek advice from ORI early in a case, even hypothetical ones. More recently, he has supported the development of a training program for RIOs.

"Alan has made a considerable contribution to improving relations between ORI and research institutions," Pascal said. "His even-

handed approach has won the trust of most whistleblowers, respondents, and RIOs. And for that we thank him."

Price and his wife, Katherine, have relocated to Lago Vista, TX, a suburb of Austin, where several of their high school friends reside. His youngest daughter lives in Austin. Price will continue with his barber-shop harmonizing and begin golf and country dancing. He may be contacted at alankathprice@earthlink.net.

Before entering federal service, Price worked at the University of Michigan for 17 years as a member of the faculty, an assistant dean, and

associate vice president for research. He worked at NIH from 1987-1989 as a genetics program officer and an AIDS Unit Assurance Coordinator. He earned his doctorate in biochemistry from the University of Minnesota in 1968 and his bachelor's degree in chemistry from Florida State University in 1964.

CGS/NSF RCR Program

Request for Applications

Deadline: 8/11/06

<http://www.cgsnet.org/>

Default.aspx?tabid=123

New RFP Expected To Be Posted on ORI Web Site This Summer *(from page 1)*

submission date in late February 2007. Maximum funding per project will remain at \$50,000. Projects start in September each year and are expected to be completed in one year. The RFP will be posted on the ORI home page when available. For more information contact the program director at LNguyen-Khoa@osophs.dhhs.gov.

Project titles, project directors, awardee institutions, and a brief description of the proposed resources follow:

RCR Instructional Assessment Project

James Dubois, St Louis University

An extensive list of learning objectives for seven RCR core instructional areas and a battery of test items categorized by RCR topic and learning objectives.

Teaching Research Integrity in Analysis and Reporting: A Web Site with Case-Based Vignettes

Harold Kincaid and Sara Vollmer, University of Alabama-Birmingham

A multimedia course to address questionable practices in power analysis, microarray analysis, handling of outliers, and image processing.

IACUC Animal Facility Inspections Training Modules: "Virtual Walk-Through"

David Lyons, Wake Forest University

A virtual walk-through of an animal laboratory that will enable trainees to use their computers to navigate through the laboratory to inspect for violations.

Multimedia Software to Ensure Responsible Laboratory Management Skills

Derina Samuel, Syracuse University

A computer-based tool to help new and experienced laboratory directors with the following tasks—hiring personnel, working with administrators, maintaining budgets, time management, and mentoring junior scientists or graduate students.

Peer Review Tool

Min Qi Wang, University of Maryland

A complete "Peer Review Tool" package that covers hypothesis formation, methodology, data analysis, and interpretation. The software will produce a report which will include possible errors found in the paper along with explanations.

Fourth RCR Expo: Exhibitors Wanted

Show the research community the educational materials your institution or organization has created to promote the responsible conduct of research (RCR) at the fourth annual RCR Expo.

The RCR Expo will be held in the Quebec City (Canada) Convention Center on October 16-17, 2006 in conjunction with the annual meeting of the Society of Research Administrators (SRA) International.

"We want to display the full range of materials that have been produced by universities, academic societies, professional associations, and commercial firms," Loc Nguyen-Khoa, Director, RCR Resource Development Program, said. "We

are interested in web-based applications or modules, videos, games, DVDs, CD-ROMs, courses, newsletters, books, pamphlets, assessment tools, pedagogical techniques and so on."

ORI will provide the exhibit space, a table, two chairs, and electricity for free. Internet access to the exhibit space will be provided as needed for free. Exhibitors will be responsible for furnishing their own computers, projectors, and other display technology.

Exhibitors should contact Loc Nguyen-Khoa at 240-453-8400 or via email to LNguyen-Khoa@osophs.dhhs.gov.

Fourth Biennial ORI Research Conference on Research Integrity

Safety Harbor Resort and Spa

Tampa, FL

December 1-3, 2006

http://www.cme.hsc.usf.edu/research_integrity/

Case Summaries

Susan M. Aronica, PhD, Indiana University-Purdue University Indianapolis: Based on the evidence and findings of an investigation report by Indiana University-Purdue University Indianapolis (IUPUI) and additional analysis conducted by the Office of Research Integrity (ORI) in its oversight review, ORI found that Susan M. Aronica, Ph.D., former Postdoctoral Student/Fellow, IUPUI, committed 21 acts of scientific misconduct by knowingly and intentionally falsifying and fabricating data in her notebooks, in 17 figures and figure panels, in two tables published in the *Journal of Biological Chemistry* (J. Biol. Chem. 270:21998-22007, 1995) and *Blood* (Blood 89:3582-3595, 1997), and in two figures in a manuscript submitted for publication to *Blood* in August 1997.

ORI issued a charge letter enumerating the above findings of scientific misconduct. However, Dr. Aronica requested a hearing to dispute these findings to the Departmental Appeals Board. Based upon the insufficiency of Dr. Aronica's hearing request, ORI filed a Motion to Dismiss. On February 10, 2006, the Administrative Law Judge (ALJ) ruled in ORI's favor by dismissing Dr. Aronica's request for a hearing. ORI's research misconduct regulation specifically delineates the requisite content for an acceptable hearing request. A sustainable hearing request must admit or deny each finding of research misconduct, and each denial must be detailed and substantive. 42 C.F.R. 93.501(c). Dr. Aronica's hearing request contained only a general denial of the proposed findings. The regulation states that a general denial is not sufficient to establish a genuine dispute. 42 C.F.R.

93.503. The regulation also states that the ALJ must dismiss a hearing request if the respondent does not raise a genuine dispute over facts or law material to the research misconduct findings. 42 C.F.R.

93.504(a)(2). The ALJ concluded that the determination of whether the hearing request raises a genuine dispute is a threshold jurisdictional determination. Thus, the ALJ decided that Dr. Aronica's request did not show a genuine dispute, because it did not specifically deny any allegation. As a result, the ALJ concluded that Dr. Aronica's hearing request could not be granted, but was required to be dismissed pursuant to 42 C.F.R. 93.504(a)(2).

Specifically, ORI found that Dr. Aronica falsified and fabricated data in: Figures 1, 2, 3, 4, 5A, 5B, 5C, 6A, and 6B, and Tables III and IV in: Aronica, S.M., Mantel, C., Gonin, R., Marshall, M.S., Sarris, A., Cooper, S., Hague, N., Zhang, X., & Broxmeyer, H.E. "Interferon-inducible Protein 10 and Macrophage Inflammatory Protein-1 [alpha] Inhibit Growth Factor Stimulation of Raf-1 Kinase Activity and Protein Synthesis in a Human Growth Factor-dependent Hematopoietic Cell Line." *JBC* 270:21998-22007, 1995 (September 15) ("JBC paper"). Figures 1 (both panels), 3A, 3B, 3D, 3E, 4A, and 8A in: Aronica, S.M., Gingras, A.C., Sonenberg, N., Cooper, S., Hague, N., & Broxmeyer, H.E. "Macrophage Inflammatory Protein-1 [alpha] and Interferon-inducible Protein 10 Inhibit Synergistically Induced Growth Factor Stimulation of MAP Kinase Activity and Suppress Phosphorylation of Eukaryotic Initiation Factor 4E and 4E Binding Protein 1." *Blood* 89:3582-3595, 1997 (May 15)

("Blood paper"). Figures 1B and 2B in: Aronica, S.M., Reid, S.L., & Broxmeyer, H.E. "Chemokine Inhibition of Stress-Activated Kinase Activity in a Human Hematopoietic Cell Line." *Blood*, submitted August 4, 1997 ("Blood manuscript"). The research was supported by or reported in the following U.S. Public Health Service (PHS) grants from the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health:

- RO1 HL49202, "Myeloid Regulation by Growth-Suppressing Cytokines."
- R01 HL54037, "Stem Cell Transduction of SLF/FLT-3-Ligand Genes by AAV."
- R01 HL56416, "Mechanisms of Synergistic Regulation of Stem/Progenitors."
- T32 DK07519, "Regulation of Hematopoietic Cell Production."

The following administrative actions have been implemented: (1) Dr. Aronica has been debarred from any contracting or subcontracting with any agency of the U. S. Government and from eligibility or involvement in nonprocurement programs of the U.S. Government referred to as "covered transactions" as defined in the debarment regulations at 45 C.F.R. part 76 for a period of five (5) years, beginning on February 10, 2006; (2) Dr. Aronica is prohibited from serving in any advisory capacity to PHS including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as consultant for a period of five (5) years, beginning on February 10, 2006; and (3) Within 60

Case Summaries (*continued*)

days of February 10, 2006, the authors of the following papers will be requested to submit a letter to the editors of *Journal of Biological Chemistry* and *Blood*, requesting their retraction of: Aronica, S.M., Mantel, C., Gonin, R., Marshall, M., Sarris, A., Cooper, S., Hague, N., Zhang, X-f., & Broxmeyer, H.E. "Interferon-Inducible Protein 10 and Macrophage Inflammatory Protein-1 [alpha] inhibit Growth Factor Stimulation of Raf-1 Kinase Activity and Protein Synthesis in a Human Growth Factor-Dependent Hematopoietic Cell Line." *J. Biol. Chem.* 270:21998-22007, 1995. Aronica, S.M., Gingras, A.-C., Sonenberg, N., Cooper, S., Hague, N., and Broxmeyer, H.E. "Macrophage Inflammatory Protein-1 [alpha] and Interferon-Inducible Protein 10 Inhibit Synergistically Induced Growth Factor Stimulation of MAP Kinase Activity and Suppress Phosphorylation of Eukaryotic Initiation Factor 4E and 4 Binding Protein 1." *Blood* 89:3582-3595, 1997.

Hiwot A. Woreta, Duke University Medical Center: Based on the report of an inquiry into admitted fabrication of data conducted by the Duke University Medical Center (DUMC) and additional analysis conducted by ORI in its oversight review, the U.S. Public Health Service (PHS) found that Hiwot A. Woreta, former medical student, DUMC, engaged in research misconduct while supported by National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institutes of Health (NIH), grant P30 DK034987. Specifically, PHS found that Ms. Woreta engaged in research misconduct by fabricating data included in Figure 2 of her third year medical school thesis at DUMC. These data

were also included in a poster presented during the Alpha Omega Alpha Honor Society symposium in May 2004.

Ms. Woreta has entered into a Voluntary Exclusion Agreement in which she has voluntarily agreed, for a period of three (3) years, beginning on February 24, 2006: (1) to exclude herself from serving in any advisory capacity to PHS including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as consultant; and (2) that any institution that submits an application for PHS support for a research project on which the Respondent's participation is proposed or which uses the Respondent in any capacity on PHS supported research, or that submits a report of PHS-funded research in which the Respondent is involved, must concurrently submit a plan for supervision of the Respondent's duties to the funding agency for approval. The supervisory plan must be designed to ensure the scientific integrity of the Respondent's research contribution. Respondent agreed to ensure that a copy of the supervisory plan is also submitted to ORI by the institution. Respondent agreed that she will not participate in any PHS-supported research until such a supervisory plan is submitted to ORI.

Paul H. Kornak, Stratton VA Medical Center, Albany, New York: Upon recommendations from the Office of Research Integrity (ORI), Acting Assistant Secretary for Health for the Department of Health and Human Services (HHS), the Office of Research Oversight (ORO), and the Under Secretary for Health, Department of Veterans Affairs (VA), that

were based on criminal convictions of making and using a materially false statement, in violation of 18 USC § 1001(a)(3); mail fraud, in violation of 18 USC §§ 1341 and 1346; and criminally negligent homicide, in violation of 18 USC § 13 and New York Penal Law § 125.10, the HHS debarbing official has permanently debarred Mr. Paul Kornak, former research coordinator at the Stratton VA Medical Center. This action is taken pursuant to the government-wide non-procurement debarment and suspension regulation at 45 C.F.R. Part 76. As such, Mr. Kornak is excluded for life from participating in any and all federal agency transactions, both procurement and nonprocurement, as set forth in Part 76.

Of the 48 criminal charges contained in his Indictment, Paul Kornak pled guilty to the three criminal charges listed above. See *United States of America v. Paul H. Kornak*, Criminal Action No. 03-CR-436 (FJS), US District Court (N.D.N.Y.) (January 18, 2005). In addition to the 71-month term of imprisonment imposed, Mr. Kornak was directed to pay restitution to two pharmaceutical companies and the VA in the amount of approximately \$639,000.

As part of his guilty plea, Mr. Kornak admitted to the following facts:

- In August 2000, Mr. Kornak applied for employment to the VA, submitting a false "Declaration for Federal Employment" form. Mr. Kornak denied that he had been convicted or on probation in the preceding 10 years, whereas in fact, he had been convicted of mail fraud in 1992 and placed on probation for 3 years.

Case Summaries *(continued)*

- By October of 2000, Mr. Kornak was responsible for organizing, coordinating, implementing, and directing all research elements in the Stratton VA Medical Center oncology research program. Specifically, Mr. Kornak was the site coordinator at the Stratton VA Medical Center for the “Iron (Fe) and Atherosclerosis Study” (FeAST), cancer studies known as Tax 325 and Tax 327, and a bladder cancer study. The FeAST study was a clinical trial that tested a novel procedure for controlling atherosclerosis, also known as hardening of the arteries, by reducing the iron in the body through blood drawing. The Tax 325 cancer treatment study involved the administration of pharmaceutical products to patients with metastatic or locally recurrent gastric cancer previously untreated with chemotherapy for advanced disease. The Tax 327 study involved the administration of pharmaceutical products to patients with metastatic hormone refractory prostate cancer. The purpose of the bladder cancer study, which was co-sponsored by the National Cancer Institute, National Institutes of Health.
- From May 14, 1999, to July 10, 2002, in connection with the above protocols, Mr. Kornak participated in a scheme to defraud the sponsors of the clinical studies in that “he would and repeatedly did submit false documentation regarding patients and study subjects and enroll and cause to be enrolled persons as study subjects who did not qualify under the particular study protocol.”
- Mr. Kornak caused the death of a study subject when he “failed to

perceive a substantial and unjustifiable risk that death would occur when he knowingly and willfully made and used . . . documents falsely stating and representing the results of [the study subject’s] blood chemistry analysis . . . , which false documents purported that [the study subject] met the inclusion and exclusion criteria for participation in Tax 325 when the actual results did not meet the inclusion and exclusion criteria and showed impaired kidney and liver function, and [the study subject] thus was administered the chemotherapeutic drugs docetaxel, cisplatin, and 5-FU in connection with Tax 325 on or about May 31, 2001, and died as a result thereof on or about June 11, 2001.”

Based on the criminal conviction and the facts admitted above, HHS and VA believe that a debarment period longer than the standard length of debarment is warranted in this case. Mr. Kornak admitted to dishonest handling of the research records and demonstrated a complete disregard for the well-being of vulnerable human subjects under his care. In pleading guilty to criminally negligent homicide, Mr. Kornak admitted that a reasonable person would have perceived a substantial and unjustifiable risk of death if an ineligible subject were enrolled in the cancer study in question and that his failure to perceive such a risk in enrolling the ineligible subject constituted a gross deviation from the standard of care.

Moreover, a longer debarment period is warranted in this case because of an established pattern of misconduct and criminal behavior on the part of

Mr. Kornak. As stated above, Mr. Kornak has a prior conviction of mail fraud. In addition, the Office of Personnel Management excluded Mr. Kornak from all federal nonprocurement transactions for an indefinite period, effective July 22, 1993. Nonetheless, beginning in 1999, Mr. Kornak actively participated in federally sponsored research protocols in violation of the imposed exclusion. A lifetime debarment of Mr. Kornak is necessary to protect the public interest overall. Given the scope of his criminal conviction, his longstanding pattern of criminal behavior, and his total disregard for the safety and well-being of human subjects, Mr. Kornak’s responsibility to engage in transactions with the Federal Government cannot be assured at any time in the future.

ORI Model Policy Being Revised

ORI expects to publish its revised model policy for responding to allegations of research misconduct for public comment this summer. The revised policy will offer a model that institutions may use to implement the PHS Policies on Research Misconduct (42 C.F.R. Part 93) that became effective June 16, 2005.

Following the comment period, the model policy will be further revised to incorporate appropriate comments.

After the final model policy is published, ORI will begin to review institutional policies for compliance with the new regulation.

Conference, Workshop, and Meeting Proposals Due October 1, 2006.

ORI is seeking proposals from institutions, scientific societies, and professional associations that wish to collaborate with ORI in developing conferences, workshops, symposia, colloquiums, seminars, and annual meeting sessions that address the responsible conduct of research, research integrity, or research misconduct. ORI will provide up to \$20,000, depending on the event proposed.

The next target date for receipt of applications is October 1, 2006. Proposal instructions and an application form are available on the ORI web site at <http://ori.hhs.gov/html/programs/confworkshops.asp>. Please submit your proposal electronically to stitus@osophs.dhhs.gov. Call Dr. Sandra Titus at 240-453-8400.

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