

SPHHP Research Activities Newsletter

Inside this issue:

In the News	1
Grant Clinic Reminders & Clarifications OHRP Guidance on Withdrawal of Subjects	1-2 2-3
NIH Funding Opportunities RFA	4
PAR	5
PA	6
National Science Foundation	6
2011-2012 SUNY Chancellor's Award for Internationalization	7
Award Recipients	7-8

In the News

Welcome!

We would like to welcome **Todd C. Rideout, PhD**, Assistant Professor, Department of Exercise and Nutrition Sciences. Todd joined ENS January 3rd. Todd's research incorporates both biomedical animal models and human clinical investigations as tools for identifying how diet and nutraceutical therapies can prevent dyslipidemia and reduce the incidence and progression of cardiovascular diseases.

We also would like to welcome **Pamela Sturtz**, Administrative Assistant, Office of Research Administrative Services. Her first day in the RAS office was Thursday, December 2nd. Pam was an Administrative Assistant for the Research Institute on Addictions (RIA) prior to accepting this position.

Congratulations John!

The UB Council on International Studies and Programs (CISP) presented its 2010 Awards for Outstanding Contributions to International Education to five UB faculty members during its annual awards luncheon held on Dec. 8. Our own **John Stone**, clinical associate professor, Department of Rehabilitation Sciences, and director of the Center for International Rehabilitation Research Information and Exchange was among the recipients. They were honored for exceptional contributions to UB's international studies and programs, including study abroad, area studies, international research and outreach, services and support to international students and scholars and institutional affiliations overseas. For the complete article, please see: http://www.buffalo.edu/ubreporter/2010_12_09/intl_ed_awards

Grant Clinic

REMINDERS AND CLARIFICATIONS:

NIH policy on page limits. The NIH instructs reviewers that they need not consider inappropriate text or materials that have been placed in application sections without page limits (e.g., Protection of Human Subjects), or in the Appendix, as a way to circumvent page limits for the Research Strategy or other page-limited sections. In egregious cases, NIH has the authority to withdraw such an application from review or consideration for funding. <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-077.html>

End of two-day correction window. Beginning with due dates on or after January 25, 2011, NIH will eliminate the error correction window from the application submission process. This applies to electronic and paper-based submissions. <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-123.html>

NIH policy on post-submission application materials. The NIH restricts acceptable post-submission materials to those resulting from unforeseen administrative issues (with exceptions specified for institutional training mechanisms and certain RFAs). Corrections of oversights/errors discovered after submission of the application will not be allowed. <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-091.html>

End of the “grandparent” period for legal A2 applications. The last A2 submission (when the A0 application was assigned to August 2009 Council or before) will be received for the January 7, 2011 AIDS date (May 2011 Council). For October 2012 Council and beyond, no NIH A2 application will be accepted. <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-135.html>

New time limit for NIH resubmission applications. For resubmissions submitted for the January 25, 2011 due date and after, the NIH will not accept a resubmission later than thirty-seven months after the date of receipt of the initial New, Renewal, or Revision application. <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-140.html>

Gentle Reminder: UB’s Annual Disclosure Statements are due

UB’s Investigator Disclosure Policy requires that each year investigators must submit an “Annual Disclosure of Significant Financial Interests and Significant Obligations”. The Annual Disclosure for the current year is available on the SPS website at http://www.research.buffalo.edu/forms/spa/financial_disclosure.pdf.

Any SPHHP faculty member who holds a University at Buffalo appointment and who is a principal investigator, co-investigator or who is responsible for the design, conduct, or reporting of University programs, projects, activities or services described in an application or prospective application for external and/or selected internal support, or in an award made to the University without application must complete the disclosure and submit the document to the RAS office. Thank you to all of those who already have complied with this request.

OHRP Guidance on Withdrawal of Subjects from Research and Retention of Subject Research Data

The federal Office of Human Research Protections (OHRP) issued guidance on September 10, 2010 concerning the withdrawal of research subjects from a study and the impact of subject withdrawal on research data already obtained from the subject. OHRP’s guidance addresses the following questions:

- **What does it mean for a subject to withdraw from a study?**

Subjects have the right to withdraw from (i.e., discontinue participation in) research at anytime. If a subject decides to withdraw from all components of a research study, the investigator must discontinue all of the following research activities involving that subject’s participation in that study.

Sometimes, a subject wants to withdraw from the primary interventional component of a study, but is willing to allow the investigator to continue other research activities described in the IRB-approved protocol and informed consent document that involve participation of the subject.

- **May an investigator retain and analyze already collected data about a subject who withdraws from the research or whose participation is terminated by the investigator?**

OHRP interprets the HHS regulations at 45 CFR part 46 as allowing investigators to retain and analyze data already collected relating to any subject who chooses to withdraw from a research study or whose participation is terminated by an investigator without regard to the subject’s consent, provided such analysis falls within the scope of the analysis described in the IRB-approved protocol. This is the case even if that data includes identifiable private information about the subject.

- **Can investigators honor subjects’ requests to have their data destroyed or excluded from any analysis?**

For research not subject to regulation and review by FDA, investigators, in consultation with the funding agency, can choose to honor a research subject’s request that the investigator destroy the subject’s data or that the investigator exclude the subject’s data from any analysis.

- **Should the withdrawal of a subject from a research study be documented?**

OHRP recommends that investigators and IRBs consider whether and how the withdrawal of a subject for a research study should be documented. While not required, such reporting to the IRB may be most appropriate for biomedical research involving more than minimal risk. On the other hand, for longitudinal social science studies involving serial surveys of large numbers of subjects, attrition of subjects over time is common, and documenting each withdrawal of a subject may not be useful or appropriate.

For research in which it is determined to be appropriate to document the withdrawal of a subject, such documentation could specify:

- Whether the withdrawal of the subject resulted from a decision by the subject or by the investigator, and the reasons for the withdrawal, if known; and
- Whether the withdrawal was from all components of the research study or just the primary interventional component.

- **What is the relationship of this guidance to FDA’s guidance on this issue and to the HIPPA Privacy Rule?**

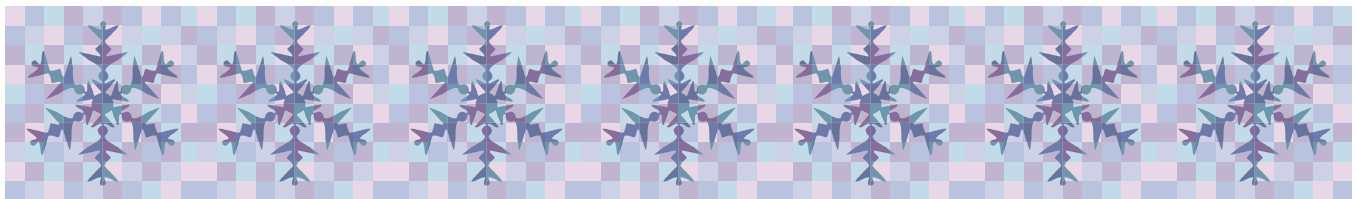
OHRP interprets the federal regulations (45 CFR 46) as “allowing investigators to retain and analyze data already collected relating to any subject who chooses to withdraw from a research study.” On the other hand, OHRP notes that “for research not subject to regulation and review by the FDA, investigators, in consultation with the funding agency, certainly can choose to honor a research subject’s request that the investigator destroy the subject’s data or that the investigator exclude the subject’s data from any analysis.”

Data must be retained for all FDA regulated clinical trials per FDA regulations.

- **When seeking the informed consent of subjects, what should investigators tell subjects about data retention in the event the subjects withdraw?**

OHRP recommends that when seeking the informed consent of subjects, investigators explain whether already collected data about the subjects will be retained and analyzed even if the subjects choose to withdraw from the research. Including this explanation would better inform subjects about what it means that they may “discontinue participation at any time”.

OHRP recommends that investigators be explicit in the consent form concerning the use of research data collected from a subject if the subject decides to withdraw from the study or if the investigator needs to prematurely end the subject’s participation in the study. The guidance document may be found in the Policy and Guidance section of the OHRP website and at www.hhs.gov/ohrp/policy/subjectwithdrawal.html.



NIH Funding Opportunities: RFAs

RFA-DC-11-002

Identification of Immune-Mediated Causes of Sensorineural Hearing Loss (R21/R33)

The purpose of this FOA is to encourage submission of milestone-driven interdisciplinary Exploratory/Developmental Phased Innovation (R21/R33) research proposals designed to further our understanding of the mechanism, etiology, and pathophysiology of immune mediated sensorineural hearing loss (IMSNHL). Applications considered responsive include studies of 1) ear organ-specific autoimmune sensorineural hearing loss - i.e. autoimmune inner ear disease (AIED), 2) sudden sensorineural hearing loss attributable to AIED, as well as 3) sensorineural hearing loss associated with systemic autoimmune disease. Proposals primarily involving human subjects/tissues will be given highest priority. The human health goal of this FOA is the ultimate translation of the research findings into clinical biomarkers, new diagnostic tests with high sensitivity, specificity and positive predictive value, and the development of therapies that preserve natural hearing.

Application Due Date: February 8, 2011, June 8, 2011

<http://grants.nih.gov/grants/guide/rfa-files/RFA-DC-11-002.html>

RFA-DC-12-001

Improving Access to Hearing Health Care (SBIR) (R43/R44)

The purpose of this funding opportunity is to improve hearing health care outcomes and reduce health disparities through the development and commercialization of improved devices for hearing health care (HHC). For the purposes of this FOA, "hearing health care" is defined as assessment and access to hearing aids and nonmedical treatment, including hearing screening and hearing assessment as well as acquiring an appropriate device and services for the individual's hearing loss and communication needs. Appropriate technologies must have the following basic characteristics: easily affordable, effective, culturally acceptable, and accessible to those who need them.

Application Receipt Date(s): March 18, 2011; November 18, 2011; and July 18, 2012

<http://grants.nih.gov/grants/guide/rfa-files/RFA-DC-12-001.html>

RFA-DC-12-002

Improving Access to Hearing Health Care (STTR) (R41/R42)

The purpose of this funding opportunity (FOA) is to improve hearing health care outcomes and reduce health disparities through the development and commercialization of improved devices for hearing health care (HHC). For the purposes of this FOA, "hearing health care" is defined as assessment and access to hearing aids and nonmedical treatment, including hearing screening and hearing assessment as well as acquiring an appropriate device and services for the individual's hearing loss and communication needs. 1 Appropriate technologies must have the following basic characteristics: easily affordable, effective, culturally acceptable, and accessible to those who need them.

Application Receipt Date(s): March 18, 2011; November 18, 2011; and July 18, 2012

<http://grants.nih.gov/grants/guide/rfa-files/RFA-DC-12-002.html>

RFA-ES-11-001

Environmental Health Sciences Core Center Grants (P30)

The National Institute of Environmental Health Sciences (NIEHS) invites applications from qualified institutions for support of Environmental Health Sciences (EHS) Core Centers. These Centers are designed to establish innovative programs of excellence in the field of environmental health sciences by providing scientific and programmatic support for promising investigators and areas of research. A Core Center Grant is an institutional award to support centralized scientific resources and facilities shared by investigators with existing research projects. By providing a Center structure and Core resources this support is intended to enhance the ability of scientists working in the field of environmental health sciences to identify and capitalize on current and emerging opportunities that will lead to outstanding research advances to improve our understanding of the relationship between environmental exposures and both human biology and human disease.

Application Receipt Date(s): February 24, 2011

<http://grants.nih.gov/grants/guide/rfa-files/RFA-ES-11-001.html>

RFA-HD-11-081

Rehabilitation Medicine Scientist Training (RMST) Program (K12)

UB may submit one application to the Rehabilitation Medicine Scientist Training (RMST) Program [K12] sponsored by the National Institutes of Health. This Funding Opportunity Announcement (FOA) solicits applications for institutional research career development (K12) programs from applicant organizations that propose to support a national network of researchers to mentor clinically trained individuals from the field of physical medicine and rehabilitation (PM&R). The program is responsible for identifying and recruiting clinically trained individuals with research potential and matching them with established mentors who have a strong record of research productivity. The program will be responsible for developing guidelines for mentoring, didactic interactions, and career development in order to promote the successful transition of the candidates into independent research careers in appropriate academic settings.

Application Receipt Date(s): February 28, 2011

<http://grants.nih.gov/grants/guide/rfa-files/RFA-HD-11-081.html>

Due to the limited number of applications, if you or your colleagues are interested in applying, please submit a letter of intent to Dr. Kenneth Tramosch at kmt1@buffalo.edu by January 14, 2011.

PAR-11-043

NIDDK Program Project Applications (P01)

National Institute of Diabetes and Digestive and Kidney Diseases

Application due date(s): Standard dates apply

Expiration Date: January 8, 2014

The research of the program projects should advance the mission of the NIDDK to develop new knowledge relevant to understanding diabetes, endocrine and metabolic diseases, digestive diseases and nutrition, and kidney, urologic and hematologic diseases, and to develop new approaches to prevent, treat and cure these diseases. Investigators, who are considering pursuing a collaborative approach to their research problem, are strongly encouraged to contact NIDDK program staff at least 9 months prior to the projected receipt date to discuss a potential application.

<http://grants.nih.gov/grants/guide/pa-files/PAR-11-043.html>

PAR-11-084

NLM Grants for Scholarly Works in Biomedicine and Health (G13)

National Library of Medicine

Application Receipt/Submission Date(s): February 23, 2011, February 23, 2012

Expiration Date: February 24, 2012

The National Library of Medicine (NLM) awards Grants for Scholarly Works in Biomedicine and Health for the preparation of book-length manuscripts and other scholarly works of value to U.S. health professionals, public health officials, biomedical researchers, and historians of the health sciences. Grants are awarded for major critical reviews, state-of-the-art summaries, historical studies, and other useful organizations of knowledge in clinical medicine, public health, biomedical research, and the informatics/information sciences relating to them. The scholarly work may be prepared for publication in print or non-print media, or both.

<http://grants.nih.gov/grants/guide/pa-files/PAR-11-084.html>

PAR-08-213

Methodology and Measurement in the Behavioral and Social Sciences (R21)

Application Due Date(s): Standard dates apply

Expiration Date: September 8, 2011

The goal of this FOA is to encourage research that will improve the quality and scientific power of data collected in the behavioral and social sciences, relevant to the missions of the participating NIH Institutes and Centers.

<http://grants.nih.gov/grants/guide/pa-files/PAR-08-213.html>

PAR-09-224 (R01) and PAR-09-225 (R21)

Improving Diet and Physical Activity Assessment

Application Due Date(s): February 5, 2011, October 5, 2011, June 5, 2012 (R01)
February 16, 2011, October 16, 2011, June 16, 2012 (R21)

Expiration Date: July 6, 2012 (R01) and July 17, 2012 (R21)

This FOA encourages innovative research to enhance the quality of measurements of dietary intake and physical activity.

<http://grants.nih.gov/grants/guide/pa-files/PAR-09-224.html>

<http://grants.nih.gov/grants/guide/pa-files/PAR-09-225.html>

PAR-10-282

Pilot and Feasibility Clinical Research Grants in Arthritis and Musculoskeletal and Skin Diseases (R21)

Application Due Date(s): March 1, 2011, July 1, 2011; Nov 1, 2011, March 1, 2012, July 2, 2012; Nov 1, 2012, March 1, 2013, July 1, 2013

Expiration date: July 2, 2013

This FOA, issued by National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) of the National Institutes of Health, encourages exploratory/developmental clinical research related to the prevention or treatment of arthritis and musculoskeletal and skin diseases, conditions, and/or injuries.

<http://grants.nih.gov/grants/guide/pa-files/PAR-10-282.html>

PAR-10-145

Social Network Analysis and Health (R01)

Application Due Date(s): May 11, 2011; May 11, 2012

Expiration date: May 12, 2012

Purpose: This FOA encourages research that aims to accomplish one or more specific goals: (1) generate new theories that would enhance the capabilities and value of Social Network Analysis (SNA); (2) address fundamental questions about social interactions and processes in social networks; (3) address fundamental questions about social networks in relation to health and health-related behaviors; (4) develop innovative methodologies and technologies to facilitate, improve, and expand the capabilities of SNA.

<http://grants.nih.gov/grants/guide/pa-files/PAR-10-145.html>

NIH Funding Opportunities: PAs

PA-09-216

Mechanisms Underlying the Links Between Psychosocial Stress, Aging, the Brain and the Body (R01)

Application Due Date(s): Standard dates apply

Expiration Date: September 8, 2012<http://grants.nih.gov/grants/guide/pa-files/PA-09-216.html>

PA-09-235

Diet, Epigenetic Events, and Cancer Prevention (R21)

Application Due Date(s): Standard dates apply

Expiration Date: September 8, 2012<http://grants.nih.gov/grants/guide/pa-files/PA-09-235.html>

PA-10-026

Development, Application and Evaluation of Prediction Models for Cancer Risk and Prognosis (R21)

Application Due Date(s): Standard dates apply

Expiration Date: January 8, 2013<http://grants.nih.gov/grants/guide/pa-files/PA-10-026.html>

PA-10-236 (R01) and PA-10-237 (R21)

Health Promotion Among Racial and Ethnic Minority Males

Application Due Date(s): Standard dates apply

Expiration Date: September 8, 2013<http://grants.nih.gov/grants/guide/pa-files/PA-10-236.html><http://grants.nih.gov/grants/guide/pa-files/PA-10-237.html>

PA-10-042

Critical Illness and Injury in Aging (R01)

Application Due Date(s): Standard dates apply

Expiration Date: January 8, 2012<http://grants.nih.gov/grants/guide/pa-files/PA-10-042.html>

PA-10-052

School Nutrition and Physical Activity Policies, Obesogenic Behaviors and Weight Outcomes (R01)

Application Due Date(s): Standard dates apply

Expiration Date: January 8, 2013<http://grants.nih.gov/grants/guide/pa-files/PA-10-052.html>

PA-11-047 (R01) and PA-11-048 (R21)

Women and Sex/Gender Differences in Drug and Alcohol Abuse/Dependence

Application Due Date(s): Standard dates apply

Expiration Date: January 8, 2014<http://grants.nih.gov/grants/guide/pa-files/PA-11-047.html><http://grants.nih.gov/grants/guide/pa-files/PA-11-048.html>

PA-11-053 (R01) and PA-11-055 (R21)

Studies in Neonatal Hypoglycemia

Application Due Date(s): Standard dates apply

Expiration Date: May 8, 2014<http://grants.nih.gov/grants/guide/pa-files/PA-11-053.html><http://grants.nih.gov/grants/guide/pa-files/PA-11-055.html>

PA-11-061 (R01) and PA-11-062 (R21)

Research Into The Impact Of Economic Fluctuations On Alcohol Consumption, Drinking Patterns, And Prevention And Treatment Of Problem Drinking And Related Problems

Application Due Date(s): Standard dates apply

Expiration Date: January 8, 2014<http://grants.nih.gov/grants/guide/pa-files/PA-11-061.html><http://grants.nih.gov/grants/guide/pa-files/PA-11-062.html>

National Science Foundation

MMS Program Applications (NSF 08-561)

National Science Foundation

Methodology, Measurement and Statistics (MMS)

Application Due Date(s): Annually, January 16th and August 16th

Synopsis: The Methodology, Measurement, and Statistics (MMS) Program is an interdisciplinary program in the Social, Behavioral, and Economic Sciences that supports the development of innovative analytical and statistical methods and models for those sciences. MMS seeks proposals that are methodologically innovative, grounded in theory, and have potential utility for multiple fields within the social and behavioral sciences. As part of its larger portfolio, the MMS Program partners with a consortium of federal statistical agencies to support research proposals that further the development of new and innovative approaches to surveys and to the analysis of survey data.

<http://www.nsf.gov/pubs/2008/nsf08561/nsf08561.htm#dates>

The CAFI Program was originally developed in 2003 by the Office of International Programs (OIP) in collaboration with the SUNY Council for International Education (SUNY/CIE) to encourage the development of new and different study abroad opportunities. Among the things SUNY can be very proud of is the large array of study abroad offerings available to any SUNY student through the SUNY/CIE study abroad network of programs, which includes at present more than 550 programs in over 50 countries on all seven continents. SUNY's Strategic Plan for 2010 and beyond, The Power of SUNY, states that we will seek to, "create a globally competent student body...[and] increase the opportunities for international exposure throughout all courses and degrees," while we, "send more students abroad." The Chancellor's Award for Internationalization encourages program development in new areas and in less common destinations while utilizing the ample regional, cultural and linguistic expertise of SUNY faculty for the benefit of students throughout the SUNY System.

Please note that the DEADLINE FOR SUBMISSION IS FEBRUARY 14, 2011. More information and the application packet is available at: www.suny.edu/global/strategicinitiatives/CAFI.cfm. Interested faculty may contact Melissa Rybarczyk, Assistant Vice Provost for Study Abroad Programs, at 645-3912 or mpolasik@buffalo.edu to consult about their application.

Awards Received with Start Dates between 7/1/10 and 12/31/10

At 6-month intervals, we acknowledge and celebrate the success of faculty within the SPHHP who have garnered external funding. Listed below are the SPHHP faculty (alphabetized by department) who received new or renewal awards, as UB principal investigators, between 7/1/10 and 12/31/10:

PI	Department	Title	Sponsor
Randolph Carter	Biostatistics	Prospective Evaluation of Lower Extremity Lymphedema in Women Undergoing Radical Surgery for Gynecological Cancer	Health Research, Inc.
Randolph Carter	Biostatistics	GOG Statistical and Data Center	Nat'l Cancer Inst.
Randolph Carter	Biostatistics	Evaluating the Impact of EI Services on Children with ASD and Their Families	NYS Dept. of Health Bureau of Early Intervention
Alan Hutson	Biostatistics	Gynecologic Oncology Group Statistical and Data Center	Health Research, Inc.
Gregory Wilding	Biostatistics	Role of Androgen Axis in Racial Differences in Prostate Cancer Mortality	Health Research, Inc.
Gregory Wilding	Biostatistics	RPCI CCSG Biostatistics Resource	Health Research, Inc.
Gregory Wilding	Biostatistics	Prostate Cancer Transition to Androgen Independence	Health Research, Inc.
Christine Oddo	Center for Assistive Technology	Technology-Related Assistance for Advocate for Individuals with Disabilities (TRAID)	NYS Office of Persons with Disabilities Program
Elizabeth Gage	Community Health and Health Behavior	SES, Race, and Patterns of Health Care Navigation of Parent of Pediatric Cancer Patients	Nat'l Cancer Inst.
Heather Orom	Community Health and Health Behavior	Race, Prostate Cancer Treatment and Treatment Decision Difficulty and Regret	Health Research, Inc.

Awards Received with Start Dates between 7/1/10 and 12/31/10 con't

PI	Department	Title	Sponsor
John Stone	Dean's Office	Center for International Rehabilitation Research Information and Exchange (CIRRIE-3)	U.S. Dept of Education, NIDRR
Robert Burkard	Rehabilitation Sciences	A comparison of reference equivalent threshold sound pressure levels of TDH-39 and inter-acoustics earphones	Diagnostic Group LLC
James Lenker	Rehabilitation Sciences	RERC on Universal Design in the Built Environment	U.S. Dept of Education, NIDRR
Kathleen Mc Nerney	Rehabilitation Sciences	Caffeine and Vestibular Function Doubt: Is it really necessary to go without?	American Academy of Audiology
Jo Freudenheim	Social and Preventative Medicine	Risk Factors for MiRNA Expression and Differentiation in Normal Breast Tissues Proposal 1	Georgetown University
Pavani Ram	Social and Preventative Medicine	Prevention of Secondary Transmission of Human Influenza by Promoting Hand Washing with Soap/Bangladesh Interruption of Secondary Transmission of FLU	Int'l Center for Diarrhoeal Disease Research
Carol Rudra	Social and Preventative Medicine	Use of cellphone-based time-activity data for air pollutant exposure estimation	Nat'l Inst. Of Environmental Health Issues
William Scheider	Social and Preventative Medicine	WNED Anti-Obesity Initiative Evaluation	WNED
John Violanti	Social and Preventative Medicine	Long-Term Psychosocial Impact on Police Officers: Post-Hurricane Katrina	Nat'l Inst. For Occupational Safety and Health
John Violanti	Social and Preventative Medicine	Stress and Subclinical Cardio-Metabolic Disease in Police: A Longitudinal Study	Nat'l Inst. For Occupational Safety and Health
Jean Wactawski-Wende	Social and Preventative Medicine	Women's Health Initiative Extension 2010-2015	Nat'l Heart, Lung & Blood Institute
Jean Wactawski-Wende	Social and Preventative Medicine	Breast Tumor Tissue Pilot (BTTP) Study (An ancillary study to the Women's Health Initiative)	Kaiser Foundation Research Institute

Congratulations to all of our award recipients!

Words to Live by:

"Don't be afraid to go out on a limb. That's where the fruit is."

H. Jackson Browne, author



HAPPY NEW YEAR

Please submit your comments/suggestions to Traci Jackson, jacksont@buffalo.edu or Pam Sturtz, pjsturtz@buffalo.edu, 106 Kimball Tower