



# VAPHS Quarterly Research Review

WINTER/SPRING EDITION

Volume 2, Issue 1

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## AAHRPP IS COMING!!!



VAPHS is seeking accreditation from the Association for the Accreditation of Human Research Protection Program (AAHRPP). The VA has mandated that all VA medical centers that participate in human research receive accreditation by AAHRPP. AAHRPP is a nonprofit organization that works to protect the rights and welfare of research participants and promote scientifically meritorious and ethically sound research. AAHRPP achieves its mission by using an accreditation process based on self assessment, peer review and education.

VAPHS Office of Research has already performed a self-evaluation of the institution's human research protection program (HRPP) and has taken the first step to accreditation by submitting an application to AAHRPP. The second step is an AAHRPP site visit which is scheduled on February 14<sup>th</sup> and 15<sup>th</sup>. In addition to reviewing research records, AAHRPP site visitors will be interviewing VAPHS senior management and research staff (including IRB members, investigators, study coordinators and pharmacists). Investigators are often asked about questions regarding the research including study design, risk, recruitment and the consent process. Investigators and coordinators may need to elaborate on resources, personnel training and how problems that arise during research are handled.

In anticipation of the February AAHRPP visits, the VAPHS Office of Research will be preparing review materials that will be shared with all staff involved in human research.

## Special points of interest:

- \* Article on Data Security & Privacy (Page 5)
- \* Publications and Awards (Page 6 through 8)

## IRB Submissions and Meeting Dates

### FEBRUARY

Submission Date: 2-01-2008

Meeting Date: 2-25-2008

### MARCH

Submission Date: 2-27-2008

Meeting Date: 3-24-2008

### APRIL

Submission Date: 04-01-2008

Meeting Date: 04-28-2008

## TIPS FROM THE IRB COORDINATOR



- ◆ FYI - **Linda Calgaro** is the new IRB Assistant. Linda will be receiving IRB submissions and corresponding with investigators and their staff. Linda's contact information is:

**Telephone:** 412-365-4315      **Fax:** 412-365-4263      **Email:** linda.calgaro@va.gov

- ◆ If VA research data is being transmitted, transferred, or stored outside of the VA entity, the *VA Protocol*, *VA Consent Form*, *Data Security Checklist* (Appendix C), and the *Request for Off-Site Storage/Transfer of Research Data* must all consistently reflect this.
- ◆ **All** submissions to the IRB are to include an original plus 5 copies, with the exception of *Serious Adverse Event Reports* and *Unanticipated Problem Reports*.
- ◆ Be sure to include a *Data Security Checklist* (Appendix C) and *Principal Investigator Certification* (Appendix D) with all initial review, continuing review, and amendment submissions.
- ◆ *Consent Forms* must be submitted using the most recent version (July 2007) of the Consent Form template.



## EDUCATIONAL SEMINARS

**Please see the list below for upcoming HRPP educational seminars for investigators and coordinators.**

**February 11th** Review of the IRB SOP changes

**March 10th** The VAPHS Data Security & Privacy Policy

**April 14th** Adverse Events and Unanticipated Problems



## RESEARCH NEWS

- ◆ The Financial report on Research Expenditures for Fiscal Year 2007 has been completed. The VAPHS Research Program has grown to 107 investigators performing 333 active projects with a budget of 24.3 million in FY 2007. That is a growth of \$1,955,755.00 from FY 2006.
- ◆ The VAPHS Research and Development Office will begin to perform semi-annual biosafety and biosecurity inspections of all research laboratories in 2008 in conjunction with Facilities Management Services.
- ◆ The CHERP Competitive Pilot Award Program FY 2008 which is supported by the VA Stars & Stripes Healthcare Network has funded 4 proposals, 2 from Pittsburgh and 2 from Philadelphia
- ◆ The VISN-4 Competitive Pilot Project Fund awards will fund two protocols by VAPHS investigators for the fall cycle. A request for proposals for a spring/summer cycle is also likely.

## FUNDING OPPORTUNITIES



◆ The Department of Defense Breast Cancer Research Program has released \$10 million in funding opportunities in Concept Awards that will fund approximately 85-95 awards, and \$10 million in Predoctoral Awards that will fund approximately 110 awards.

- ◆ The VA Stars & Stripes Healthcare Network (VISN 4) invites you to submit an application for research support from the Geriatric Research, Education and Clinical Center (GRECC) Pilot Project Fund. The purpose of the GRECC Pilot Project Fund is to promote research that focuses on basic or applied problems relevant to geriatric healthcare and health services delivery. A total of \$50,000 will be awarded in FY 2008 to support pilot projects consistent with the program's mission. The highest priorities for funding are for proposals that support 1) new investigators for projects conducted at the VA, and 2) novel and innovative pilot work conducted at the VA by established VA investigators. The amount of the GRECC Pilot awards will be limited to \$25,000. It is expected that GRECC Pilot Projects awarded in FY08 will be completed NLT September, 30, 2009.

### CLINICAL TRIALS CENTER



The CTC currently has 16 active studies with 267 subjects enrolled. Additionally, there are 5 clinical research studies being prepared for IRB submission.

The CTC also offers the use of 4 experienced clinical research coordinators.

## ANIMAL RESEARCH

### **AAALAC IS COMING!!!**

The VAPHS Animal Care and Use program will be undergoing a site visit from AAALAC on February 19, 2008. This visit is due to our 3 year accreditation cycle, the VAPHS has been fully accredited by AAALAC and has been since 1993. As such, AAALAC performs a routine site visit every 3 years.



### VAPHS POLICY ON REPORTING ANIMAL ABUSE

The VAPHS is strongly committed to the humane care and treatment of all animals used for research and teaching. Our animal care and use program is governed by Federal Guidelines for the care and use of animals. The Animal Care and Use Committee oversees the entire program and reviews and approves all animal related studies. If you observe or have knowledge of activities that you believe constitute inappropriate animal care or use, you are encouraged to report these activities so that they can be investigated. The VAPHS has policies and procedures in place in compliance with the VA Policy, the Animal Welfare Act, NIH and PHS guidelines to investigate and remediate any animal care or use issues. The Animal Welfare Act specifically states that

*“no facility employee, committee member, or laboratory personnel shall be subject to any reprisal for reporting violations of any regulation or standards under the Act”*

The best way to address an animal care or use concern is directly. Sometimes unfamiliar research activities may be misinterpreted as painful or distressful. Frank discussion may clear up misunderstandings. If you do not wish to speak to the people involved directly (investigator, technicians, students), please call any of the following numbers to discuss your concerns. Your confidentiality will be respected to the best of our abilities.

**Research Compliance Office 412-365-4294**

**IACUC Chair 412-365-4290**

**Research Integrity Officer 412-365-4274**



## Research Contacts

### Research & Development

**Ali F. Sonel**, 365-4274

ACOS, R&D

**Nicholas Squeglia**, 365-4273

AO- R&D

VRFP, Executive Director CTC

### Committees

**Elizabeth Toth**, 365-4263

IBC and IACUC Subcommittees,

Grant Submissions

**Kathleen Parks**, 365-4295

IRB Coordinator

**Chris Brining**, 365-4275

Orders

**Charlene Simmons**, 365-4275

Contracts, Orders, and

Research Accounts

### Research Compliance Staff

**Krissa Caroff**, 365-4310

Compliance Officer

**Tammy Capozzoli**, 365-4266

Compliance Officer

**Stephanie Partee**, 365-4294

Education and Compliance  
Assistant

**Mark Pagano**, 365-4292

VRFP and CTC

Financial Compliance Officer

Contracting Officer CTC



**REMEMBER!!!!**

**VA Form 10-3203,**

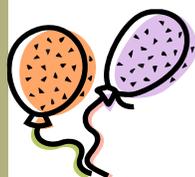
**Consent to Picture or Voice**

This form is required to be completed and submitted with the initial IRB application when appropriate. The Principal Investigator must obtain consent using the VA Form 10-3203 from a subject prior to capturing any image or the voice of the subject, or any other persons, including VA employees. Please make sure all sections of the form are complete.



**Time for you to renew!!**

Appendices C & D will soon be due. New copies of appendices C & D are required for **all** VA approved research studies. The Research Office will be issuing a reminder with the exact deadlines soon. If you have any questions, please contact the Research Education and Compliance Office at 412-365-4294.



**WELCOME !!!!!**

**Dr. Chanrashekhar Gandhi:** We would like to welcome Dr. Chandrashekar Gandhi has been appointed as Deputy ACOS/R&D and will be assuming the full responsibility of this role on February 1, 2008. Dr. Gandhi is an experienced VA and University of Pittsburgh researcher. His background is primarily in biochemistry and pharmacology. Dr. Gandhi has authored many original papers, reviews and book chapters on liver cell function and liver transplantation. Dr. Gandhi will be assisting Dr. Sonel in all aspects of his duties, with a particular focus on the animal research program, institutional biosafety program, assisting junior investigators in terms of grant submissions and the scientific review process and in enhancing our academic ties with the University of Pittsburgh.

**Linda Calgaro:** We would like to take the opportunity to welcome Linda Calgaro as the new IRB assistant. Linda comes to us from the University of Pittsburgh and has 2 years experience in conducting clinical research studies. Linda will be the IRB Assistant, helping process new and renewal submissions at the VAPHS IRB Office.



## Data Security & Privacy

### VAPHS Research Data and Security Policy- Data Security and Privacy Risk Level Assignments for Human Subjects Protocols

Krissa Caroff, Research Compliance Officer

Since November 2007, all human subjects research protocols reviewed by the VAPHS IRB have been getting an additional risk level assigned to them. This particular risk level is specific to the degree of risk to subjects' privacy and security of the data collected from them. Here is a brief review of the three new risk levels:

#### Level I Protocols:

Level I protocols represent the greatest risk to privacy and include those protocols in which VA Sensitive Information will be used/collected and the subjects are unaware of the use and disclosure of the research data. Level I protocols typically propose to use an IRB approved Waiver of Informed Consent and a Waiver of HIPAA Authorization in order to collect sensitive information.

#### Level II protocols:

Level II Protocols are those protocols which represent an intermediate privacy risk to human subjects and include those protocols in which VA Sensitive Information is collected and used and the subjects have been informed of the risks to privacy and have given permission for the use and disclosure of the research data (i.e., an Informed Consent and HIPAA Authorization have been obtained).

#### Level III Protocols:

Level III protocols represent a low privacy risk to human subjects and typically refer to those protocols in which only de-identified data or limited data sets are being collected and used.

Please note that the requirements for approval to store, transfer, and/or transmit VA research data outside of the VA entity will vary depending upon the risk level assigned to your protocol. Please refer to the VAPHS Research Data Security and Privacy Policy, Chapter 7 (available on the Research Office Website) for additional information.

If you have any comments, concerns or complaints regarding research conducted within the VAPHS please contact the Office of Research.

Telephone: 412-365-4274

E-mail address: **VHAPTHResearchCompliance@va.gov**.

Postal address: 7180 Highland Drive (151U-H) Pittsburgh, PA 15206

Your communication will be acknowledged and handled as confidential.



VAPHS RESEARCH PUBLICATIONS **(From 11/13/2007 to January 22, 2007)**

**"The Veterans Health Administration: A Domestic Model for a National Healthcare System?"** Submitted by Said A. Ibrahim, MD, MPH  
The journal or meeting title: American Journal of Public Health

**"Adherence to the Medical Regimen During the First Two Years After Lung Transplantation.** Submitted by Mary Amanda Dew Ph.D.; Andrea F. DiMartini, M.D.; Annette De Vito Dabbs, Ph.D.; Rachele Zomak, MS, RN, CCTC; Sabina De Geest, Ph.D., RN; Fabienne Dobbels, Ph.D.; Larissa Myaskovsky, Ph.D.; Galen E. Switzer, Ph.D.; Mark Unruh, M.D.; Jennifer L. Steel, Ph.D.; Robert L. Kormos, M.D.; Kenneth R. McCurry, M.D. The journal or meeting title: Transplantation

**"Thirty-day Mortality for Patients Hospitalized with Acute Pulmonary Embolism is Lower for Women than for Men"** Submitted by Sonya Borrero, M.D; Drahomir Aujesky, M.D., MSc; Roslyn A. Stone, Ph.D.; Ming Geng, MS; Michael J. Fine, M.D. MSc; Said A. Ibrahim, M.D., MPH. The journal or meeting title: Journal of Women's Health

**"A Preliminary Classification System for Homeless Veterans with Mental Illness"** Submitted by Gerald Goldstein; James F. Luther; Aaron Jacoby; Gretchen L. Haas; Adam J. Gordon. The journal or meeting title: Psychological Services

**"Confirmatory factor analytic studies of the Wechsler scales in autism".** Submitted by Gerald Goldstein, Ph.D.; NJ Minshew; DL Williams; DN Allen. The journal or meeting title: Poster presented at The 36th Annual Meeting of the International Neuropsychological Society, Waikoloa, HI.

**"Neurocognitive heterogeneity in traumatic brain injury".** Submitted by Gerald Goldstein, Ph.D.; DN Allen. The journal or meeting title: Poster presented at The 36th Annual Meeting of the International Neuropsychological Society, Waikoloa, HI.

**"The effects of alcoholism comorbidity on neurocognitive function following traumatic brain injury (TBI)".** Submitted by Gerald Goldstein, Ph.D.; DN Allen. The journal or meeting title: Poster presented at The 36th Annual Meeting of the International Neuropsychological Society, Waikoloa, HI.

**"Organic disorder"** Submitted by Gerald Goldstein, Ph.D. The journal or meeting title: M Hersen & J Rosqvist (Eds.) Handbook of psychological assessment, case conceptualization, and treatment, Volume 1 Adults

**"The Burden of Stroke Scale (BOSS) provided valid, reliable, and responsive score estimates of functioning and well-being during the first year of recovery from stroke".** Submitted by Patrick J. Doyle; Malcolm R. McNeil; James E. Bost; Katharine B. Ross; Julie L. Wambaugh; William D. Hula; Joseph M. Mikilic. The journal or meeting title: Quality Life Res (2007)

**"The Veterans Health Administration: A Domestic Model for a National Health Care System?"** Submitted by Said A. Ibrahim, M.D., MPH. The journal or meeting title: American Journal of Public Health

**"Factors Associated with Patients Who Leave Acute-Care Hospitals Against Medical Advice".** Submitted by Said A. Ibrahim, M.D., MPH; C. Kent Kwok, M.D. and Eswar Krishnan, M.D., MPH. The journal or meeting title: American Journal of Public Health

**"Distribution and cost of wheelchairs and scooters provided by Veterans Health Administration".** Submitted by Sandra L. Hubbard, Ph.D., OTR/L, ATP; Shirley G. Fitzgerald, Ph.D.; Bruce Vogel, Ph.D.; Dean M. Reker, Ph.D., R.N.; Rory A. Cooper, Ph.D.; Michael L. Boninger, M.D. The journal or meeting title: Journal of Rehabilitation Research & Development



**"Assessing mobility characteristics and activity levels of manual wheelchair users"**. Submitted by Michelle L. Tolerico, M.S.; Dan Ding, Ph.D.; Rory A. Cooper, Ph.D.; Donald M. Spaeth, Ph.D., RET; Shirley G. Fitzgerald, Ph.D.; Rosemarie Cooper, MPT, ATP; Annmarie Kelleher, M.S., OTR/L, ATP; Michael L. Boninger, M.D. The journal or meeting title: Journal of Rehabilitation Research & Development.

**"Longitudinal assessment of vibrations during manual and power wheelchair driving over select sidewalk surfaces"**. Submitted by Erik Wolf, Ph.D.; Rory Cooper, Ph.D.; Jonathan Pearlman, Ph.D.; Shirley G. Fitzgerald, Ph.D.; Annmarie Kelleher, M.S., OTR/L, ATP. The journal or meeting title: Journal of Rehabilitation Research & Development

**"Multisite comparison of wheelchair propulsion kinetics in persons with paraplegia"**. Submitted by Alicia M. Koontz, Ph.D., RET; Yusheng Yang, Ph.D.; Robert Price, MSME; Michelle L. Tolerico, M.S.; Carmen P. DiGiovine, Ph.D., RET; Sue Ann Sisto, Ph.D.; Rory A. Cooper, Ph.D.; Michael L. Boninger, M.D. The journal or meeting title: Journal of Rehabilitation Research & Development

**"Comparison of mobility device delivery within Department of Veterans Affairs for individuals with multiple sclerosis versus spinal cord injury"**. Submitted by Fabrisia Ambrosio, Ph.D., MPT; Michael L. Boninger, M.D.; Shirley G. Fitzgerald, Ph.D.; Sandra L. Hubbard, Ph.D.; Steven R. Schwid, M.D.; Rory A. Cooper, Ph.D. The journal or meeting title: Journal of Rehabilitation Research & Development

**"Estimates of the Prevalence of Arthritis and Other Rheumatic Conditions in the United States"**. Submitted by Charles G. Helmick, M.D.; David T. Felson, M.D., MPH; Reva C. Lawrence, MPH; Sherine Gabriel, M.D., MSc; Rosemarie Hirsch, M.D., MPH; C. Kent Kwoh, M.D.; Matthew H. Liang, M.D., MPH; Hilal Maradit Dremers, M.D., MSc; Maureen D. Mayes, M.D., MPH; Stanley R. Pillemer, M.D.; John D. Reveille, M.D.; John H. Stone, M.D., MPH. The journal or meeting title: Arthritis and Rheumatism

**"Pituitary adenylate cyclase-activating polypeptide stimulates corticotropin-releasing factor, vasopressin and interleukin-6 gene transcription in hypothalamic 4B cells"**. Submitted by Kazunori Kageyama, Komaki Hanada, Yasumasa Iwasaki, Satoru Sakihara, Takeshi Nigrawara, John Daschow and Toshihiro Suda. The journal or meeting title: Journal of Endocrinology

**"Design, feasibility, and acceptability of an intervention using personal digital assistant-based self-monitoring in managing type 2 diabetes"**. Submitted by Mary Ann Sevick, ScD, RN; Susan Zickmund, Ph.D.; Mary Korytkowski, M.D.; Beth Piraino, M.D.; Susan Sereika, Ph.D.; Shannon Mihalko, Ph.D.; Linda Snetselaar, Ph.D., RD; Phyllis Stumbo, Ph.D., RD; Leslie Hausmann, Ph.D.; Dianxu Ren, M.D. Ph.D.; Rita Marsh, MSN, RN; Teresa Sakraida, DSNc, RN; Jolynn Gibson, MSN, RN, CDE; Mehry Safaian, MS, RD, CDE, BC-ADM; Terry J. Starrett, MSN, RN; Lora E. Burke, Ph.D., MPH, FAAN. The journal or meeting title: Contemporary Clinical Trials

**"Development of a Wheelchair Virtual Driving Environment - Trials with Individuals with Traumatic Brain Injury"**. Submitted by Donald Spaeth, Ph.D.; Harshal Mahajan, MS; Amol Karmarkar, MS; Diane Collins, Ph.D.; Rory A. Cooper, Ph.D. and Michael L. Boninger, M.D. The journal or meeting title: Archives of Physical Medicine and Rehabilitation (Special TBI Issue)

**"Access to affordable medications: The VA pharmacy plan as a national model"**. Submitted by Chester B. Good, M.D., MPH; Michael Valentino, RPh, MHSA. The journal or meeting title: American Journal of Public Health

**"The coordination of swallowing and breathing in Parkinson's Disease"**. Submitted by Roxanne D. Gross, Ph.D.; Charles W. Atwood Jr., M.D.; Sheryl B. Ross, MA; Kinberly A. Eichhorn, MS; Joan W. Olszewski, MA; Patrick J. Doyle, Ph.D. The journal or meeting title: Dysphagia

**"Clinical Correlates and Treatment of Bone/Joint Pain and Difficulty with Sexual Arousal in Patients on Maintenance Hemodialysis"**. Submitted by Myra Carreon, M.D.; Linda F. Fried, M.D., MPH; Paul M. Palevsky, M.D.; Paul L. Kimmel, M.D.; Robert M. Arnold, M.D.; Steven D. Weisbord, M.D., MSc. The journal or meeting title: Hemodialysis International



PUBLICATIONS (Continued)

**"Health-related quality of life in the era of erythropoietin"**. Submitted by Steven D. Weisbord, M.D., MSc; Paul L. Kimmel, M.D. The journal or meeting title: Hemodialysis International.

**"Acute Mountain Sickness in Disability and Adaptive Sports: Preliminary Data"**. Submitted by Brad E. Dicianno, MD; Eric D. Aguila, MD; Rory A. Cooper, PhD; Paul R. Pasquina, MD; Mary J. Clark, DO; Diane M. Collins, PhD, OTR/L; Shirley G. Fitzgerald, PhD; Todd A. Wichman, MD. The journal or meeting title: Journal of Rehabilitation Research and Development

**"A Preliminary Classification System for Homeless Veterans with Mental Illness"**. Submitted by Gerald Goldstein; James F. Luther; Aaron M. Jacoby; Gretchen L. Haas; Adam J. Gordon. The journal or meeting title: Psychological Services 2007, Vol. 5, No. 1, 000-000

**"A Dynamic Seating Intervention for Wheelchair Seating Discomfort"**. Submitted by Barbara A. Crane, PhD, PT, ATP; Margo B. Holm, PhD, OTR/L; Douglas Hobson, PhD; Rory A. Cooper, PhD; Matthew P. Reed, PhD. The journal or meeting title: American Journal of Physical Medicine & Rehabilitation

**"Interest in the Use of Computerized Patient Portals: Role of the Provider-Patient Relationship"**. Submitted by Susan L. Zickmund, PhD; Rachel Hess, MD, MSc; Cindy L. Bryce, PhD; Kathleen McTigue, MD, MS, MPH; Ellen Olshansky, DNSc, RNC, FAAN; Katharine Fitzgerald, MID; Gary S. Fischer, MD. The journal or meeting title: J Gen Intern Med 23(Suppl 1):20-6 (January 7, 2008)

**"Hospital volume and patient outcomes in pulmonary embolism"**. Submitted by Drahomir Aujesky, MD, MSc; Maria K. Mor, PhD; Ming Geng MS; Michael J. Fine, MD, MSc; Bertrand Renaud, MD; Said A. Ibrahim, MD, MPH. The journal or meeting title: Canadian Medical Association Journal (published 1/1/08)

**"Hitting the target: Why existing measures of 'religiousness' are really reverse-scored measures of 'secularism'."** Submitted by Daniel E. Hall, MD, MDiv, MHSc. The journal or meeting title: EXPLORE: The Journal of Science & Healing