FAQs (from pg. 1)

to www.research@va.gov and click on the VA Research Data Security and Privacy button on the homepage.

Q: What constitutes sensitive information?

A: In VA Directive 6504, "VA sensitive information" is defined as data that require protection due to the risk of harm that could result from inadvertent or deliberate disclosure, alteration, or destruction of the information. The term includes (1) information whose improper use or disclosure could adversely affect the ability of an agency to accomplish its mission, (2) proprietary information, (3) records about individuals requiring protection under various confidentiality provisions such as the Privacy Act and the HIPAA Privacy Rule, and (4) information that can be withheld under the Freedom of Information Act (FOIA). Health information de-identified in accordance with VHA Handbook 1605.1 Appendix B would not be considered sensitive information.

Most results of VA research may be withheld from FOIA responses prior to publication, but not subsequently. Once published, this type of information is not considered "sensitive."

Q: Please clarify whether this is for research pertaining only to VA patient

see FAQs on pg. 3

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Douglas Owens, MD, Palo Alto, received the 2007 Under Secretary's Award for Outstanding Achievement in Health Services Research.

HSR&D (from pg. I)

search and Development (RR&D) Service. In a pre-meeting forum, Center of Excellence directors from the two services discussed plans for joint research aimed at improving the quality, accessibility, and cost-effectiveness of rehabilitation care for veterans. Possible research topics that were discussed included, for example, determining the cost-effectiveness of telemedicine, or addressing the long-term effects of robot-assisted rehabilitation on veterans and healthcare providers.

Hosted by HSR&D's Rehabilitation Outcomes Research Center for Veterans with Central Nervous System Damage, in Gainesville, Fla., the national meeting included an address by VA's Acting Under Secretary for Health, Dr. Michael Kussman, who stressed VA's responsibility to protect veterans' personal information. Kussman also presented the 2007 Under Secretary's Award for Outstanding Achievement in Health Services Research to Douglas Owens, MD, an influential health services investigator and mentor at the VA Palo Alto Health Care System, whose research has focused on HIV, sudden cardiac death, clinical guideline development, and biodefense.

Other speakers included retired Army Capt. Jonathan Pruden, who described his experience as a wounded veteran transitioning from DoD to VA care and his volunteer work with other wounded veterans; Dr. Stephanie Studenski,, director of the Claude D. Pepper Older Americans Independence Center at the University of Pittsburgh, speaking on integrated care for older adults; VA chief research and development officer Dr. Joel Kupersmith; and new HSR&D director Dr. Seth Eisen, who underscored HSR&D's commitment to promoting optimal health care through sustained scientific discovery.

The theme for the 2008 HSR&D national meeting will be "Implementation across the Nation: From Bedside and Clinic to Community and Home." For more information, visit HSR&D's website: www.hsrd.research.va.gov.

FAQs (from pg. 2)

information or does it include basic science protocols, unrelated to VA patients?

A: All studies should complete the checklist and certification forms, indicating "not applicable" where appropriate.

Q: If you have individually identifiable data on your VA office desktop computer, must the computer be encrypted?

A. All stand-alone PCs are required to be encrypted if they contain data that require protection due to the risk of harm that could result from inadvertent or deliberate disclosure, alteration, or destruction of the information. This includes information whose improper use or disclosure could adversely affect the ability of an agency to accomplish its mission, proprietary information, records about individuals requiring protection under various confidentiality provisions, such as the Privacy Act and the HIPAA Privacy Rule, ... and information that can be withheld under the Freedom of Information Act.

Q: Are there any reasons why, or instances where, data on animal experiments should be encrypted?

A: There are at least two reasons: (1) to assure that, when the data are released to the public, they are put into context, and (2) to reinforce good data security practices among investigators. ...

Q: On the conference call it was stated that the protection of sensitive data applies to everyone: PIs, staff assistants, administrative staff, and IRB and R&D Committee members. However, only the PI has to fill out the certification checklist. Will there be forms that others will have to complete for the protection of sensitive data?

A: Under this initiative, the research *education* requirement will be for all research staff. The *certification* process is the responsibility of the PI for each research project.

Q: We are concerned that the security and privacy review may adversely affect key

research efforts with our affiliates.

A: We realize that VA research is highly collaborative and that the new requirements ... could potentially impact those collaborations. We need to work together to keep the research mission going, but it's also critical to emphasize that securing sensitive research data is the principal objective. VA leadership has already initiated dialogue with the academic community and other federal sponsors of research so that our respective efforts are aligned and synchronized. [On March 9, the National Institutes of Health issued a statement expressing its commitment to data security: See http:// grants.nih.gov/grants/guide/notice-files/ NOT-OD-07-054.html.] We also want to highlight that the Federal Information Protection Standards that form the basis of VA policy apply to all federal contractors and may be part of the Terms and Conditions for specific federal grants. We urge you to engage in dialogue with your university partners to ascertain whether specific shared data repositories are covered by the definition of sensitive data, and whether their current IT infrastructure is compliant with applicable VA standards. Some VA facilities have found it useful to establish a joint VA-affiliate "Research Information Security Workgroup" to address these issues on an ongoing basis. Your local Information Security Officer and Chief Information Officer are the "go-to" persons for any concerns and questions concerning information security.

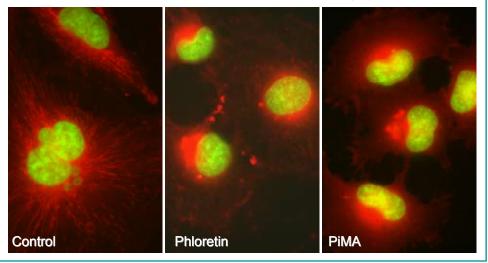
Q: In a multicenter research study, who is responsible for cybersecurity?

A: In a multicenter research study, the PI is responsible for cybersecurity, along with the staff of the data coordinating center and the site PI at any location where study data is collected. The Cooperative Studies Program Coordinating Centers are working with Office of Information Technology staff to assure that these systems are compliant with VA Directive 6504.

The 'art' of science

Insights into dying tumor cells may lead to anti-cancer vaccine

A team at the Long Beach (Calif.) VA lab of Martin R. Jadus, PhD, has been studying a type of programmed cell death called "paraptosis," as distinct from the better-known form of cell death known as apoptosis. Based on their studies in rat models of glioma, the most common type of brain cancer, Jadus and his colleagues believe paraptotic cells can form the basis of a vaccine to immunize an organism against its own tumor. The images below illustrate how Jadus' team induced paraptosis in glioma cells by treating them with phloretin (center) or pimaric acid (right). The mitochondria, in red, are thin and well-defined in control cells but swollen in the paraptotic cells.



Recent publications and presentations by VA investigators

Below is a brief sampling of recent publications and presentations by VA investigators, based on notifications received by R&D Communications (see reporting requirements at www.research. va.gov/resources/policies/pub_notice.cfm.) Only VA-affiliated authors are listed here, due to space constraints.

"Active Absorption is Required for Glucose-Induced Vasodilation in Rat Intestine." Richard N. Garrison, MD. **Louisville.** Academic Surgical Congress, Feb. 6-9.

"Alteration of NPY and Y(1) Receptor in Dorsomedial and Ventromedial Areas of Hypothalamus in Anorectic Tumor-Bearing Rats." William T. Chance, PhD; Ramesh Dayal. Cincinnati. Peptides, Feb. 2007.

"The Effectiveness of a Primer to Help People Understand Risk: Two Randomized Trials in Distinct Populations." Steven Woloshin, MD, MS; Lisa M. Schwartz, MD, MS; H. Gilbert Welch, MD, MPH. **White River Junction.** *Annals of Internal Medicine*, Feb. 20, 2007.

"Evaluating Palliative Care Programs: Let's Do it Right." Melissa D.A. Carlson, PhD; R. Sean Morrison, MD. **Bronx.** *Journal of Palliative Medicine*, Feb. 2007.

"Evaluation of Prospectively Collected Presenting Signs/Symptoms of Biopsy-Proven Melanoma, Basal Cell Carcinoma, Squamous Cell Carcinoma, and Seborrheic Keratosis in an Elderly Male Population. Erin Warshaw, MD. **Minneapolis.** *Journal of American Academy of Dermatology.* Jan. 25, 2007.

"Health Values of Patients With Systemic Sclerosis." Dinesh Khanna, MD, MS; Joel Tsevat, MD, MPH; Mansoor Ahmed, MD; Shaari S. Ginsburg, BA. Cincinnati. *Arthritis & Rheumatism*, Feb. 15, 2007.

"How are Substance Use Disorders Addressed in VA Psychiatric and Primary Care Settings? Results of a National Survey." Jodie Trafton, PhD; Kenneth Weingardt, PhD; Keith Humphreys, PhD. **Palo Alto.** *Psychiatric Services*, Feb. 2007.

"Hyaluronan Accumulation in Thyroid Tissue: Evidence for Contributions from Epithelial Cells and Fibroblasts." Andrew G. Gianoukakis, MD; Terry J. Smith, MD. **Albany, Long Beach.** *Endocrinology,* Jan. 2007.

"Impact of Self-Reported Patient Characteristics Upon Assessment of Glycemic Control in the Veterans Health Administration." Miriam Maney, MA, CPHQ; Chin-Lin Tseng DrPh; Leonard Pogach, MD, MBA. **East Orange.** Journal of the American Medical Association, Feb. 2007.

"Informatics Systems to Promote Improved Care for Chronic Illness: A Literature Review." Laura M. Bonner, PhD; Amy N. Cohen, PhD; Rebecca S. Shoal, MPH, MSW; Ruth Perrin, MA; Edmund Chaney, PhD; Alexander S. Young, MD, MSHS. **Seattle, Los Angeles, Hines.** *Journal of the American Medical Informatics Association,* Jan. 9, 2007.

"Insulin-like Growth Factor-1 (IGF-1) Induces WISP-2/CCN5 via Multiple Molecular Cross-talks and Is Essential for Mitogenic Switch by IGF-1Axis in Estrogen Receptor-Positive Breast Tumor Cells." Kakali Dhar, PhD; Snigdha Banerjee, PhD; Gopal Dhar, PhD; Krishanu Sengupta, PhD; Sushanta K. Banerjee, PhD. Kansas City. Cancer Research, Feb. 15, 2007.

"Obesity Increases the Risk of UV Radiation-Induced Oxidative Stress and Activation of MAPK and NF-kB Signaling." Santosh K. Katiyar, PhD, Syed M. Meeran, PhD. **Birmingham.** Free Radical Biology and Medicine, Jan. 15, 2007.

"Physiologic Responses to Loud Tones in Individuals with Obsessive Compulsive Disorder." Scott P. Orr, PhD. **Manchester** (NH). *Psychosomatic Medicine*, March-April 2007.

"A Practical Screening Toll for Anxiety and Depression in Patients with Chronic Breathing Disorders." Mark E. Kunik, MD, MPH: Jeffrey A. Cully, PhD; Nelda P. Wray, MD, MPH; Melinda A. Stanley, PhD. **Houston, Bedford.** *Psychosomatics*. Jan. – Feb. 2007.

"Second-Generation Antipsychotic Exposure and Metabolic-Related Disorders in Patients with Schizophrenia." Christopher Reist, MD, MBA; Lawrence J. Albers, MD; M. Mazen Jamal, MD, MPH; Sandor Szabo, MD, PhD, MPH; Vural Ozdemir, MD, PhD. **Long Beach.** *Journal of Clinical Psychopharmacology*, Feb. 2007.

"Use of a Computer-Based Reminder to Improve Sedative-Hypnotic Prescribing in Older Hospitalized Patients." Joseph V. Agostini, MD. **West Haven.** *Journal of the American Geriatrics Society*, Jan. 2007.

"The Validity of Using Patient Self-Report to Assess Psychotic Symptoms in Schizophrenia." Noosha Niv, PhD; Amy N. Cohen, PhD; Alexander S. Young, MD. **West Los Angeles.** *Schizophrenia Research*, Feb. 2007.

Correction—The Jan. 2007 issue of VA Research Currents reported that Vidya Jayawardena, MD, Richmond, had presented a poster at the International Congress of Behavioral Medicine. Dr. Jayawardena presented his research at a meeting of the American Academy of Physical Medicine and Rehabilitation.

Review study links marijuana use to breathing difficulties

Long-term marijuana is associated with increased symptoms suggestive of emphysema or other obstructive lung disease, according to a review of 34 studies by researchers with VA, Yale University School of Medicine, and Case Western University School of Medicine. The findings appeared in the Feb. 12 *Archives of Internal Medicine*.

"We found that long-term marijuana smoking is associated with increased respiratory complaints such as cough, phlegm and wheeze, and this association seemed to persist even after adjusting for tobacco smoking," said lead author Jeanette Tetrault, MD, of the West Haven VA Medical Center and Yale.

An earlier study by one of Tetrault's coauthors, Brent Moore, PhD, of Yale, based on national surveys of 6,728 adults in 1988 and 1994, found significant similarities between the respiratory effects of marijuana and those of tobacco.

In addition, a review study published last year in *Archives*, involving Moore and Tetrault, suggested a link between marijuana use and lung cancer. "Although there was no direct association between marijuana exposure and lung cancer, the literature seemed to suggest an association between marijuana smoking and premalignant changes in the lung," said Tetrault of that earlier research.

Given that an estimated two million Americans use marijuana regularly, Tetrault said it is

important for doctors to be aware of the drug's possible role in respiratory problems. "We should consider marijuana smoking in our patients who present with respiratory complaints and we should be counseling on the potential effects that marijuana has on overall lung health."



Rhode Island grant to VA-Brown prosthetics team

Roy K. Aaron, MD, and Deborah McK. Ciombor, PhD, of VA's Providence-based Center for Restorative and Regenerative Medicine and Brown University, have received funding from the Rhode Island Science and Technology Advisory Council for their project "Virtual Immersive Environments and Motion Analysis for Advanced Rehabilitation," aimed at promoting the design of artificial limbs that react to a person's natural musculoskeletal movements.



Mark Garzotto, MD, says PSA density may be the single most important factor in determining when a second prostate biopsy is appropriate.

Research identifies key measure for justifying repeat prostate biopsies

Mark Garzotto, MD, a urologist and researcher at the Portland VA and Oregon Health and Science University Cancer Institute, says a study by his group shows that a measure called PSA density is a "simple marker" for identifying men who are likely to have fast-growing prostate tumors and may benefit from a second biopsy, even if their first was negative.

"It's that 1-in-10 men that do have a life-threatening cancer that we wanted to identify," said Garzotto, who reported his findings at a prostate cancer symposium in Orlando, Fla., last month.

Garzotto's team studied 511 VA patients who had been referred to urology clinics for suspicion of prostate cancer and had at least one negative biopsy. They analyzed a host of clinical indicators to see which could have reliably predicted which men had aggressive cancers. The most meaningful factor, said Garzotto, was PSA density—the level of prostate-specific antigen (PSA) adjusted for the size of the prostate gland. The PSA test is a common initial screening method for prostate cancer, and prostate size can be measured by ultrasound during a first biopsy.

"PSA density, by itself, was the best discriminator between guys in the high-risk group and the guys in the low-risk group," said Garzotto.

VIRTUAL (from pg. 1)

this type of therapy, with its videogame-like qualities, will resonate well with the current generation of warfighters."

Jeffrey Pyne, MD, of the Little Rock VA and University of Arkansas, is participating in two of the Naval grants—one aimed at developing new virtual environments to help active-duty military members, and the other focused on using VR therapy to help non-combat personnel, such as medics and truck drivers. He is also leading a new VA-funded study that will integrate VR therapy in a larger effort to better understand the pathology and physiology of PTSD.

Hawaii VA teams with DoD on trial of active-duty troops

Sarah Miyahira, PhD, director of intramural research at the Pacific Telehealth and Technology Hui, part of the Honolulu-based VA Pacific Islands Health Care System, is co-principal investigator on the third Naval grant.

She and partner Hunter Hoffman, PhD, of the University of Washington have launched a study that will involve 60 Army soldiers who have come back from operations OIF and OEF and are seeking treatment for PTSD. Participants will receive therapy twice a week for five weeks, and be followed up at six months and a year.

According to Miyahira, the goal of the therapy is to expose patients to gradually increasing levels of stimuli that trigger memories of their traumas, while using cognitive behavioral techniques to help them modify the thoughts, feelings and behaviors linked to those events.

"We use graded exposure to the scenarios to prevent the soldier from becoming emotionally overwhelmed during treatment," she says. "We begin at the lowest level of intensity—driving through a Mideast town with no incidents. We want to get a baseline of how sensitive they are to being in an environment that reminds them of Iraq.

"Over the course of treatment, we gradually increase the intensity as the soldier's response to each level of anxiety-producing events decreases. You gauge how much the person can tolerate, and then you work through that till they're comfortable with the memory. Our goal is to help them overcome their trauma memories, not revitalize them."

Miyahira emphasizes that administering the therapy properly requires extensive training.

"It's not like you have a 'cookbook' and can just follow the directions. Even mental health providers who have solid training in treating PTSD still require extensive preparation for doing this therapy. We train our therapists in our protocol for several weeks and then have them practice for months before we actually let them go ahead and perform it on their own."

Exposure therapy surpasses supportive intervention in trial of women veterans with PTSD

In the first randomized clinical trial to assess treatments for active-duty and veteran women with posttraumatic stress disorder, VA researchers found prolonged-exposure therapy more effective than present-centered therapy. The results appeared in the Feb. 28 *Journal of the American Medical Association*.

The study, funded by VA's Cooperative Studies Program and led by Paula Schnurr, PhD, deputy executive director of VA's National Center for PTSD in White River Junction, Vt., included 284 women—277 veterans and 7 active duty. About 90 percent of the women had experienced sexual trauma, and 25 percent had experienced combat.

The women were randomly assigned to one of two therapies: prolonged exposure, a type of cognitive behavioral therapy in which the therapist helps the patient recall and work through the frightening experience, in a safe, controlled manner; and present-centered therapy, a supportive intervention in which the therapist mainly provides emotional support centered on current problems. The latter therapy is the one used most often by VA counselors to treat PTSD.

After 10 weekly 90-minute sessions, 41 percent of women in the prolonged-exposure group no longer PTSD diagnostic criteria, compared with nearly 28 percent in the present-centered group. About 15 percent in the prolonged-exposure group achieved total remission, versus 7 percent in the other group.

"Although treatment as usual [present-centered therapy] is quite effective, the study holds out promise that even better results might be achievable for some veterans with the prolonged exposure approach," said Schnurr.

Coauthor Matthew J. Friedman, executive director of the NCPTSD, added: "The challenge will be to customize PTSD treatment for each veteran, because different approaches might be best for different individuals—one size doesn't fit all. Future research will be needed to determine who might benefit most from current treatment, and who from prolonged exposure treatment, so that clinicians can offer the best evidence-based treatment options to each veteran with PTSD."