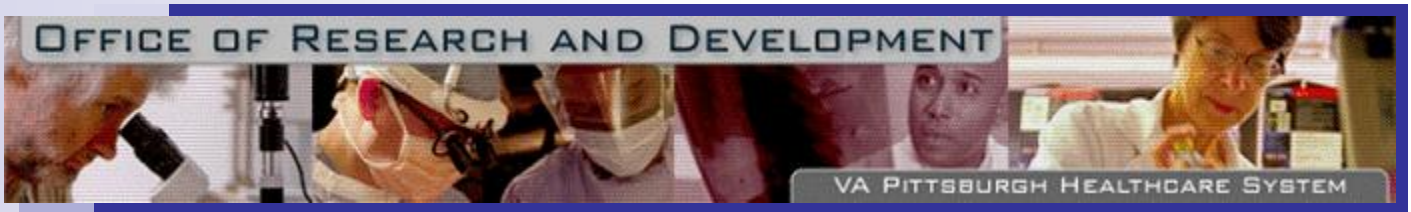
VAPHS
VA Pittsburgh Healthcare System

MAY 2007



Delivering Excellence in Medical Research

Inside this issue:

The Research & Development Newsletter is published quarterly by the VAPHS Office of Research to enhance communication among the research community and increase awareness of local research initiatives. An electronic copy is available on the VAPHS R&D home page.
Please send comments or suggestions for upcoming issues to the editor: Stephanie.Partee@va.gov.

Letter from the ACOS/R&D

Ali F Sonel, MD, FACC, FACP

It is a pleasure for me to reach out to you through our first ever research office newsletter. As you know, VA Pittsburgh Healthcare System is one of the leading research centers in the Veterans Health Administration and is recognized internationally in many fields for delivering excellence in medical research. As Associate Chief of Staff (ACOS) for Research and Development, I am honored to work with such a talented, hard working and productive group of investigators and research staff.

Improving the channels of communication between the research office and our investigators and staff is one of our many strategic goals. The current regulatory climate as well as the rapid expansion of our research enterprise is often associated with new policies and procedures put in place either through national directives and regulations or at the local level. In addition, while all of us are very busy with our own line of research, we often do not realize the progress made in the broader research enterprise at VAPHS. While the former may result in compliance issues, the latter prevents us from reaching our full potential due to missed opportunities in collaborating with world-class researchers who are part of our own team, within our own facilities.

Recent months have also seen some significant administrative changes with me replacing Dr. Steve Graham as Associate Chief of Staff for Research and Development. Dr. Graham has been instrumental in growing our research program, navigating us through some regulatory challenges while fostering our academic affiliation with the University of Pittsburgh. While I am looking forward to the challenges of the future to grow and develop our program, I am also fortunate to be able build upon the solid foundation established by Dr. Graham.

This year we will experience some exciting developments as well as regulatory challenges. As you know, VAPHS was among the first institutions in the nation to have an accredited Human Research Protections Program (HRPP). This year will see us prepare for reaccreditation which involves a new organization, AAHRPP . While many of the processes are similar to the NCQA accreditation that we have experienced in the past, the AAHRPP site visit will focus on the culture and knowledge base of our investigators and research staff through extensive interviews. As such, we will need to approach this accreditation as a team

Continued on page 5

2007 IRB Submission Dates/ Meeting Month

April 30th	May
June 4th	June
August 6th	August
August 31st	September
October 1st	October
November 5th	November
November 26th	December

R&D Committee Meeting

May 8th / May 22nd
June 12th / June 26th
July 10th / July 24th
August 14th / August 28th
September 11th / September 25th
October 9th / October 23rd
November 13th / November 27th
December 11th

IRB Coordinator By Kathleen Parks

Effective immediately, the VAPHS IRB has adopted a new policy regarding multiple enrollment of research subjects. Investigators are prohibited from enrolling research subjects into more than one Greater than Minimal Risk study without an IRB granted waiver. Please review the new policy on the Research Website. Please note: As a result of this new policy, the Informed Consent Template has also been updated. The new version is also available on the Research Website.

Data Safety Monitoring Board reports for multicenter studies are to be included with continuing review submissions even if previously submitted to the IRB.

When submitting consent forms for approval, please update the version date on the last page of the form.

Research and Development By Dawn Fuhrer

VAPHS Research and Development Committee (R&D) approval is required prior to submission for all grants submitted to VA central office. R&D review is required by central office prior to submission to ensure appropriate and helpful scientific review of the proposal content as well as for administrative review of all required forms.

Be sure to check with Dawn Fuhrer for local submission deadlines.

A Submission Calendar for All R&D Services can found at the following link:

http://www1.va.gov/resdev/funding/process/submission-calendar.cfm.

Animal Use and Biosafety By Elizabeth Toth

Both subcommittees meet on the third Thursday of the month. The committee members review projects which have been submitted to the Research Office as Requests to Conduct Research. These studies are approved based on the project's applicability to the VA mission.

All investigators wishing to conduct research at the VA should access the Office of Research and Development website at http://www.vaphs.research.med.va.gov/ for more information. Excellent references are the VA Handbook 1200.7, Use of Animals in Research and VA Handbook 1200.6, Control of Hazardous Agents in VA Research Laboratories. Researchers should also refer to the link for the VAPHS IACUC: Description, Policies and Procedures for guidance before submitting their projects.

Research Compliance Office

By Krissa Caroff

As many of you are aware, the past few months have been a whirlwind of activity in response to the February 6th Memorandum from William F. Feely, Deputy Under Secretary for Health Operations and Management (DUSHOM) and Joel Kupersmith, MD, Chief Research and Development Officer (CRADO) regarding VA Data Security and Privacy Requirements for Research and the locally instituted Research Stand Down that took place from March 12th -16th. On behalf of the Research Office, I would like to thank each and every one of you for your cooperation and patience with our various requests. As a result of everyone's hard work we were able to achieve 100% compliance with the February 6th Memorandum. The fruits of our collective labor have also resulted in a stronger relationship between the VAPHS Research Community and the Privacy Officer, Barbara Becker and Information Security Officer, Judith Buccini. Additionally, both Ms. Becker and Ms. Buccini have been appointed as members of our Institutional Review Board (IRB). It is our hope that by having the expertise of these two individuals on our board, we will be able to more efficiently review submissions for issues related to data security and privacy.

Recently, we have added a "Frequently Asked Questions" section to the Research Website (http://www.vaphs.research.med.va.gov/). This new addition to our website will allow us to address some of the more common questions related to data security and privacy in one centralized location. We are also expecting that within the next week, we will have a dedicated email address that you can send questions regarding data security or any other research compliance issue to. This new address will allow you to be in touch with each staff member of the Compliance Office by sending only one message. The Compliance staff can then effectively triage your concerns and the appropriate staff member will get back to you.

Over the next few months, you will continue to see a flurry of activity from the Research Office, as we work to ensure that local policies and procedures related to VA Data Security and Privacy are in place to help you understand what the new requirements mean for you and your research activities. If you are a member of our list serve, email updates will be sent directly to you regarding any changes being implemented. You should also be sure to visit the VAPHS Research Website frequently so that you can keep abreast of any revisions to forms, checklists, templates, etc. Instructions on how to subscribe to the list serve are also available on the "Resources" tab on the Website.

In closing, I want to say again, how much we appreciate all of the work each of you has done to help VAPHS affirm the VA's commitment to protecting veterans' sensitive research information. If there is anything we can do to help you move forward with the new requirements, please let us know.

Veterans Research Foundation

By Nicholas Squeglia

VRFP 101

What is the VRFP?

The Veterans Research Foundation of Pittsburgh is a not-for-profit corporation established in 1991 to provide support to the VA research mission. The foundation administers research projects funded from non-VA sources.

How many studies and employees does the VRFP have?

Currently, there are 160 projects under the direction of 61 principal investigators. The foundation employs 51 employees, 25 of which are full-time. The total assets are $3.125 million dollars.

What other ways does the VRFP support research at the VAPHS?

In addition to supporting the various projects mentioned above, Veterans Research Foundation of Pittsburgh provides monetary support to the Human Research Protection Program to support the training and educational activities of the Research Compliance Office and the Institutional Review Board.

Did you know that VRFP participates in the CFC Campaign?

As a not–for–profit organization, the Veterans Research Foundation of Pittsburgh has been a participant in the Combined Federal Campaign raising $1,979.00 in the 2005 campaign and $5460.48 in 2006.

Research Education

By Stephanie Partee

May 31st marks the end of the VA IRB education year. As the Principal Investigator of an active human subjects research study, you are required to complete three educational sessions by the end of May 2007. The Coordinator identified on the staff form is required to complete six sessions.

We have scheduled several video replays of core sessions in May to give everyone the opportunity to complete their education requirement.

Q. How many sessions do I currently have?

A. Please send an e-mail to Stephanie Partee (Stephanie.Partee@va.gov).

Letter from the ACOS/ R&D *(continued)*

and we will need your help in the coming months as we prepare for this important visit in March of 2008.

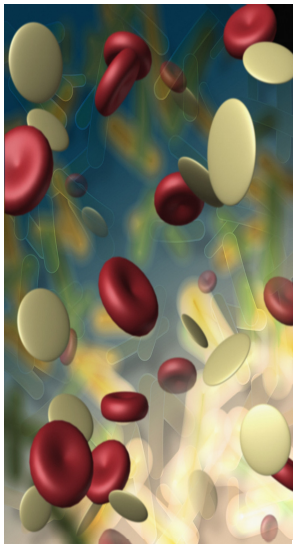
As you know, data security and privacy, particularly in research has been high on the priority list for VAPHS as well as the Office of Research and Development at the Central Office. During our Research Stand Down between March 12-16, we took a proactive approach to identifying our vulnerabilities in terms of data security processes and while we did not find any significant deficiencies, we were able to identify significant opportunities for not only meeting the current regulatory standards in data security but perhaps to be a leader in ensuring the highest level of data security standards for our subjects and our research enterprise. I would like to take this opportunity to thank all of you for the diligence, patience and commitment you have all displayed during an admittedly challenging time for our investigators and staff. In the coming months, with your support, we will be able to implement many of the action plans developed as a result of the findings obtained during the stand down. Our number one priority remains the safety, security and privacy of the veterans who provide us with the most important gift by participating in our research activities.

An exciting new development that is one of my strategic goals is the development of our new Clinical Trials Center. We currently have a cadre of investigators working on cutting-edge clinical research including several national multi-center clinical trials being coordinated through VAPHS. However, many of the specialties that provide clinical services to our veterans do not participate in clinical trials creating areas of unmet needs in terms of cutting-edge research. In addition, many of our junior investigators are unable to get involved in clinical trials, due to the lack of staff support available to them. Utilization of existing coordinators is often inefficient as coordinators are usually limited to working with one investigator and perform some functions that could be centralized, thereby allowing them to focus on patient selection, recruitment and study procedures. Over the next few months, we will be introducing various pieces of the VAPHS Clinical Trials Center with several clinical coordinators, a regulatory coordinator, and the creation of an Investigational Drug Service. Longer term plans include creation of a data core to support clinical trials as well.

We are also working to improve our review processes in order to reduce the delays associated with IRB and R&D Committee approvals. While our R&D Committee meeting frequency has been increased, we will also soon have an IRB Review Specialist in place to work with our investigators to ensure that submissions are appropriately prepared for IRB review in order to expedite the review process.

I am also pleased to report that the design of the new Research Building at the Oakland facility is well under way with construction expected to start within the next 6-12 months. While this will cause some inconveniences with many of our investigators being temporarily displaced, the resulting product will be a state of the art facility that will serve our needs for many years to come.

Stay up-to-date with all of the most recent developments in the research office. Register your e-mail address on: www.vaphs.research.med.va.gov/pages/general_information/subscribe.htm



Research Coordinators

By Lin Hough

This forum for research coordinators at VAPHS will include reports of experiences and novel approaches to problem-solving, in addition to informing the research community about our activities. Initial suggestions for "coordinating the coordinators" involve scheduling periodic group meetings, possibly with invited speakers, for continuing education and discussions of policies and procedures. An e-mail distribution list of research coordinators has been developed to facilitate those gatherings and promote effective communication. If you are a research coordinator and have not received a message as part of that list, please send your name and information about your research studies to Lin Hough (linda.hough@va.gov), coordinator for the Diabetes Telemonitoring (Dia Tel) Study.

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Research FAQs

Q. What exactly is de-identified data?

A. For data to be considered truly de-identified it must meet both of the following definitions:

HIPAA definition of de-identified:

- Removal of all 18 identifiers that could be used to identify the individual, individual's relatives, employers or household members

Common Rule definition of de-identified:

- Removal of all information that would identify the individual or would be used to readily ascertain the identity of the individual

Q. What are the 18 HIPAA identifiers?

A. The 18 HIPAA identifiers are:

- Names
- All geographic subdivisions smaller than a state, except for the initial three digits of the zip code if the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people
- All elements of dates except year and all ages over 89
- Telephone numbers
- FAX numbers
- E-mail addresses
- Social security numbers
- Medical record numbers
- Health plan beneficiary numbers
- Account numbers
- Certificate or license numbers
- Vehicle identifiers and license plate numbers
- Device identifiers and serial numbers
- URLs
- IP addresses
- Biometric identifiers (Finger prints / Voice prints)
- Full-face photographs and any comparable image
- Any other unique identifying number, characteristic or code, unless otherwise permitted by the privacy Rule for re-identification (scrambled SSNs, initials, last four of SSN, employee numbers)

HRPP News

By Timothy Carlos, MD

This year the VAPHS IRB is preparing for accreditation by the Association for the Accreditation of Human Research Protection Programs (AAHRPP), which is the new organization for the certification of human research programs within the VHA.

AAHRPP was founded in 2001 and is recognized nationally and internationally as an organization that works to protect the rights and welfare of research participants and to promote scientifically meritorious and ethically sound research. In addition to ensuring adequate human research protections, AAHRPP accreditation builds public trust, attracts high-quality investigators and improves the overall quality of the research operation.

There are four steps in the AAHRPP accreditation process:

1. Rigorous self-assessment by VAPHS Research Community
2. On-site evaluation by a panel of compliance experts
3. AAHRPP Council review of inspection findings
4. Notification of accreditation status

The VAPHS Office of Research has initiated the self-assessment process and will submit the application on November 30, 2007 with the site visit to follow in March 2008. In the upcoming months the HRPP staff will be working diligently on the AAHRPP application. Policies and procedures will be revised to ensure compliance with the AAHRPP elements. The research staff requests patience and cooperation from the investigators and research coordinators at VAPHS while this work is accomplished.

In a 2004 address to the VA IRB Chairs, Bernard A Schwetz, DVM, PhD, Director of the Office for Human Research Protections, challenged the VA research community to become the model for human subject protection. It is the goal of the VAPHS Office of Research and Development to rise to this challenge and achieve full AAHRPP accreditation in June 2008.

Information on the progress of the application process will be disseminated to the research community via e-mail , the regularly scheduled monthly education sessions and this newsletter. Please refer to the AAHRPP website at www.aahrpp.org for more information.

"The VA fully intends not only to be a leader in research, but also the way research is conducted—with heavy emphasis on the ethics of human research and protection of participant's right and welfare."

K. Lynn Cates, MD
VA Assistant Chief R&D Officer

Announcements and Upcoming Events

Welcome

Krissa Caroff, Research Compliance Officer, comes to us from the University of Pittsburgh Cancer Institute where she worked as a Regulatory Affairs Coordinator. She has extensive experience with both psychological intervention and cancer trials. She is excited to be a part of the research program here at VAPHS.

VA Research Education—May 21st

The topic for this monthly education seminar is Reporting Unanticipated Problems. Please note that this is a new policy developed in compliance with recent OHRP guidelines. Please plan to attend this seminar to be held on May 21st at 12:00 PM in Conference Room B, UD.

"Advancing Human Subject Protection: Here and Now"

The VAPHS Office of Research & Development is proud to co-sponsor a one day conference that will be held at the Sheraton Station Square on Friday, June 22, 2007. Nationally recognized experts from OHRP, FDA, VA, and the Department of Education, will discuss a wide range of topics related to both psychosocial and biomedical research, IRB membership and research administration. VA speakers include Marisue Cody, PhD, RN and Ben Gao, PhD. The title of their presentation is "Data Security in the Electronic Era," a very timely topic for all VA research staff.

Those investigators and coordinators who attend the full day session will receive one full year of VAPHS research education credit. This credit will be granted upon presentation of the conference attendance certificate .

For more information regarding this event please visit http://ccehs.upmc.edu/courses/brochure_825.pdf. If you would like to register for this event please contact Stephanie Partee in the Education and Compliance Office. (Stephanie.partee@va.gov)

Newly Funded VA Cooperative Study

CSP #565 - Combination Angiotensin Receptor Blocker and Angiotensin Converting Enzyme Inhibitor for Treatment of Diabetic Nephropathy

Study Chairs: Linda Fried, MD, MPH - Pittsburgh VAMC; William Duckworth, MD - Carl T. Hayden (Phoenix) VAMC

CSP Coordinating Center:

West Haven

Contact:
linda.fried@va.gov

VAPHS Office of Research & Development

Research Publications and Funding

The following publications, authored by VAPHS research investigators, have been accepted by peer-reviewed journals. (Nov 2006 - March 2007) Congratulations!

1. "Patency Outcomes of Aortic Connectors,"
   Submitted by: Marco A Zenati, MD, Ali Sonel, MD, Jennifer Gabany

2. "Comparison of Outcomes for Low-Risk Outpatients and Inpatients with Pneumonia. A Propensity Adjusted Analysis."
   Submitted by Michael J. Fine, MD, MSc

3. "Engineering Better Wheelchairs to Enhance Community Participation"
   Submitted by Rory A. Cooper, Ph.D.

4. "Initial Outcomes of Laparoscopic Roux-en-Y Gastric Bypass in Morbidly Obese Adolescents"
   Submitted by George Eid, MD

5. "Skill Representation in the Primary Motor Cortex After Long-Term Practice"
   Submitted by Peter L. Strick, Ph.D.

6. "Upper Limb Joint Power and its Distribution in SCI Wheelchair Users: Steady State Self Selected Speed vs. Maximal Acceleration Trials"
   Submitted by Michael L. Boninger, MD

7. "Mutation of the sequestosome 1 (p62) gene increases osteoclastogenesis but does not induce Paget disease"
   Submitted by G. David Roodman, MD, Ph.D.

8. "Vasculitic Neuropathy: Electrodiagnostic Features and Association with Malignancies"
   Submitted by Sasa Zivkovic, MD

9. "Myasthenia gravis and scleroderma: two cases and a review of the literature"
   Submitted by Sasa Zivkovic, MD

10. "Cost-Effectiveness of Alternative Approaches for Motivating Activity in Sedentary Adults: Results of Project STRIDE"
    Submitted by Mary Ann Sevick, ScD

Congratulations to the following investigators who have been awarded either new VA funding or a renewal of an existing grant in this fiscal year!

Biomedical Laboratory R&D:

Harry Blair, MD
Regulation of Bone Turnover by TNF-family Receptors
New - 4 Years

Jie F. Fan, MD
Role of TLR Crosstalk in Alveolar Macrophage Priming
New - 3 Years

Garson D. Roodman, MD, Ph.D.
Osteoblast Dysfunction in Multiple Myeloma
Renewal - 4 Years

Rehabilitation R&D:

Alicia Koontz, Ph.D.
Investigation of Transfer Techniques to Minimize Shoulder Joint Loading
New - 3 Years

Malcolm R. McNeil, Ph.D.
Research Career Scientist Award

Health Services R&D:

Sherrie L. Aspinall, PharmD.
Implementation of Practices to Improve Efficiency of Care for Pneumonia
New- 1 Year

Richard J. Bjerke, MD
lntra-Operative Predictors of Adverse Outcomes
New - 2 Years

Chester B. Good, MD
Implementation of Real-Time ADE Surveillance and Decision Support
New - 2 Years