Opportunities for Collaborative Clinical and Translational Science

Natcher Conference Center

National Institutes of Health

Bethesda, MD

September 28, 2010

Meeting Summary

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Summary and Meeting Objectives

The U.S. Department of Veterans Affairs and NIH's Clinical and Translational Awards (CTSA) Consortium have a unique opportunity to combine forces to improve and enhance clinical and translational research. On September 28, 2010, stakeholders from around the country convened a one-day conference at NIH's Natcher auditorium to pursue opportunities for enhanced collaboration between the VA and the CTSA Consortium. Meeting attendees, representing the government, academic health institutions, research organizations, and industry, gathered to discuss topics of interest including electronic health records, genomic and observational research, central IRBs, comparative effectiveness research and research training. The following link provides access to the meeting agenda, speaker bios, and slide presentations: http://www.research.va.gov/CTSA/agenda.cfm.

Summary of Presentations

Keynote Address: Genomics in Clinical Science: Exploiting the Data Tsunami for Lupus

The keynote speaker, John B. Harley, MD, PhD, has been a clinical investigator with the U.S. Department of Veterans Affairs Medical Centers in Oklahoma City, Oklahoma, from 1982 to 2010. He recently joined Cincinnati Children's Hospital Medical Center as the Director of Rheumatology and the founder of the Center of Autoimmunity Genetics and Etiology (CAGE). Before coming to Cincinnati, Dr. Harley led the lupus genetics effort in Oklahoma for over 25 years. He directed the Lupus Family Registry and Repository (LFRR), a collection of 10,000 lupus patients, family members, and controls with 2 billion genotypes and 500,000 specimen aliquots. Despite the administrative barriers that slow scientific progress, he brings extensive expertise in the recruitment of large patient cohorts, implementation of cutting edge genetic technologies, and application of relevant analytical approaches to the identification of genes and environmental etiologies in complex inflammatory diseases.

In his keynote lecture, Dr. Harley commented on the enormous leaps that have been made in research and in particular, genetics research. In the past two years, he said, the maturity of genetic analysis has soared exponentially. Despite the gains in research, challenges and obstacles remain. For instance, subject recruiting is often difficult. There is a wariness and distrust of science in the culture; and compliance with regulation is more important than ever. Moreover, promoting technological security is considerably more complex today than it was just a few years ago. Despite these challenges, he offered the advice: "do your compliance well and complete it once and spend the rest of your time doing the science." He added that investigators must "strive to do the best [they] can given limited resources."

University of Cincinnati: Opportunities for Collaborative Clinical and Translational Science—The Cincinnati CTSA Experience

Funded in April 2009, the University of Cincinnati's Center for Clinical and Translational Science and Training (CCTST) represents a partnership among the University of Cincinnati, Cincinnati Children's Hospital Medical Center, Cincinnati VA Medical Center, the UC Health University Hospital, and the Greater Cincinnati Community. The CTSA grant included funding for the VA General Clinical Research Center (GCRC). The VA Medical Center's Clinical Research Unit (CRU) is a center for clinical research studies in adult subjects (Veterans and non-Veterans). It features 3,000 square feet of dedicated research space including a sleep laboratory, a cardio-pulmonary physiology laboratory, and an investigational drug pharmacy. The VA CRU has supported studies by investigators from Cardiology, Immunology, Infectious Diseases, Pharmacology, Psychology, Neurology, Neurosurgery, and Surgery. The VA Clinical Research Unit is a prominent part of

the Cincinnati CTSA. Substantial support and advocacy from VA leadership, coupled with an entrepreneurial spirit, an ability to attract funds, and designated inpatient and outpatient research space, has helped enhance the role of the CRU and make it attractive to both investigators and companies. The VA CRU has access to all CCTST services, including pilot funds, KL2 awards, and *ResearchMatch* for subject recruitment. Although the relationship between the VA CRU and the overall CCTST is harmonious, challenges can be enumerated. VA regulations, training requirements, IT, privacy, and data security issues are still impediments. However, the opportunities far outweigh the challenges. Some opportunities include mentorship pairing and training, designated VA slots for the KL2 program, intellectual property agreements, and clinical trial recruitment.

University of California Davis Clinical and Translational Science Center (CTSC) and VA Northern California Health Care Systems Collaboration

Spearheaded in the UC Davis School of Medicine, the clinical and translational science center is a broad initiative that draws on the sciences across the broader UC Davis campus, institutional partners, as well as the community. The UC Davis Clinical and Translational Science Center will transform silos of research into new collaborative scientific discoveries. Over the past several decades, the UC Davis School of Medicine and the VA Health Care System have forged efforts to collaborate and integrate clinical research. While efforts to integrate clinical research were steady during this period, barriers to research remained. For instance, the VA System and UC Davis utilize different and independent IRBs. However, the onset of additional NIH-CTSA funding has made it possible to harmonize activities more effectively. There now is a Memorandum of Understanding (MOU) between UC Davis and the VA IRB for oncology and neurology studies, allowing for single consent. The two organizations also leverage shared resources. For example, VA Oncology nurses train UC Davis CTSC nurses in chemotherapy. The VA has established a Task Order to tap UC Davis personnel as needed. There is also an agreement for use of VA clinical labs and nutrition services. Dual investigators have access to CTSC resources such as pilot funding and training support. As a result of this collaboration, mutual benefits have been realized. There has been a significant increase in VA engaged research from 5 to 39 studies, as well as an increased accrual to oncology trials for the UC Davis Cancer Center. Key features that have enabled the effective partnership include an integration of leadership between the two institutions, clear institutional champions and advocates, and a common understanding of a “win-win” scenario. While barriers continue to exist, there is a joint willingness to discuss issues and overcome obstacles.

Boston University School of Medicine, Harvard Medical School, VA Boston Healthcare System

The Boston University Clinical and Translational Science (BU CTSI) Institute integrates, connects, and expands research and programs across traditional academic departments and schools. The institute acts as a bridge between disciplines to facilitate interactions that support the university-wide commitment to clinical and translational research. Founded in May 2008, Harvard Clinical and Translational Science Center, Catalyst, is a shared enterprise of Harvard University, its 10 schools and its 18 Academic Healthcare Centers (AHC), as well as the Boston College School of Nursing, MIT, Harvard Pilgrim Health Care, and numerous community partners. The VA Systems are well integrated with both Harvard and Boston University, and the VA system in New England has incredible research strengths. The VA Centers of Excellence draw on experts from Harvard and BU. Examples of joint research successes include Alzheimer’s research located at VA Centers in Boston. The barriers to collaboration and research include geographical barriers as well as IRB harmonization issues. Data sharing barriers and regulatory requirements are also significant among challenges and obstacles. Proposed solutions include common educational initiatives, updated accessible sites and communication channels, and the promotion of collaborative projects. Several initiatives are currently underway to promote greater collaboration

including planned VA retreats, documentation and dissemination of information regarding common interests and concerns, and highlighting VA resources, e.g. electronic health records and research on dental outcomes.

VA Cooperative Studies Program (CSP) Clinical Research Pharmacy Coordinating Center

The Clinical Research Pharmacy Coordinating Center supports investigators by managing drug and device related activities for worldwide multi-center clinical trials conducted for the VA and other federal organizations. The Center's 111 employees have collaborated in planning and conducting more than 200 multi-center clinical trials over its 39-year history. The Center provides customized pharmaceutical services to meet the unique needs of each clinical trial. The Center's mission is "to provide creative and innovative pharmaceutical, scientific, technical, operational, and educational support to clinical studies to improve the health and care of veterans, the nation and mankind." Key services include clinical trials study management design, regulatory support, patient tracking and monitoring, packaging and labeling, etc. The location of sites are distributed around the world in 23 different countries including the United States, Canada, Great Britain, Italy, Mexico, Peru, Spain and Sweden. Patient sample sizes have varied from 70 to 37,546. Partnerships with sponsors span numerous government agencies and offices. Other partners include academic health institutions and the pharmaceutical industry. The facility is located in Albuquerque, New Mexico and boasts 68,000 square feet in office space, warehouse, and laboratories. For more information, please visit:
http://www.research.va.gov/programs/csp/abq.cfm

VA Pharmacogenomics Analysis Laboratory

In 2006, the Department of Veterans Affairs launched the Genomic Medicine Program to: 1) examine the potential of emerging genomic technologies; 2) to optimize medical care for veterans; and 3) enhance the development of tests and treatments for relevant diseases. The Pharmacogenomics Laboratory (PAL) was established in 2007 and aims to support ongoing and future pharmacogenomics observational studies and clinical trials. It also aims to improve the treatment of most illnesses by reducing toxicity and increasing efficacy of drugs by facilitating optimal treatment selection, appropriate dose individualization, and drug discovery. The laboratory hosts top-of-the-line technology supporting applications to support and conduct genomic research.

VA Central IRBs

The primary purpose of the VA's Central IRBs is to improve human research protection in VA multi-site studies by ensuring consistent, expert ethical and scientific review. The secondary purpose is to enhance efficiency of IRB reviews. All new multi-site studies funded by the VA Office of Research & Development must be reviewed by the VA Central IRB by the end of FY 2010. The VA Central IRB is staffed by the VA Office of Research and Development and is comprised of 19 voting members, including four veterans, and five nonvoting members representing ethics, legal affairs, regulatory affairs, privacy & HIPAA, and information security. The initial review process has several steps. After the Principal Investigator (PI) application is approved by the VA Central IRB, or approved contingent upon minor modifications, a copy of the approved PI application packet is sent to each local site while Local Site Investigators (LSIs) prepare applications. The PI reviews the LSI applications; the VA Central IRB will require a justification for any differences among LSI applications. The VA Central IRB is the final arbiter of comments, with global changes affecting all sites and local changes affecting the local sites. A MOU is signed between the VA Central Office and each local VA that wants to use the VA Central IRB as an IRB of record. In its first year of operation, 89 VA facilities have signed up for VA Central IRB review, including 29 studies involving 285 VA facilities. Twenty-one studies have been approved as of September 2010. Numerous benefits and advantages make the VA Central IRB appealing, but there are pros and cons, and stakeholders

should be aware of both. For more information, please visit:
http://www.research.va.gov/programs/pride/cirb/default.cfm

VA Biorepositories and Informatics

The current state of affairs with biorepositories is they are often held in private collections. Each private collection requires different consent forms and upholds different HIPPA rules and regulations. In order to obtain access to data, an investigator must request permission for access, assuming that the investigator is aware of the particular collection. The VA Cooperative Studies Program is supporting biorespositories to overcome this challenge. For instance, it supports the DNA Bank which provides administrative, technical, and scientific coordination and a central repository to enable CSP to collect and store blood, tissue, and other biological specimens. They maintain and analyze data associated with these efforts. Similarly, in 2006, the VA launched the Genomic Medicine Program to optimize medical care for veterans. Under this program, veterans may volunteer to provide blood sample for genetic analysis and their genetic information is linked to their electronic health records.

Vanderbilt University: Extracting Phenotypes from EMRs for genetic association studies—the eMERGE Consortium

The eMERGE Consortium is made up of NIH-funded CTSA awardee institutions with DNA Biobanks linked to EMR data. Consortium members include: Group Health of Puget Sound, Marshfield Clinic, Mayo Clinic, Northwestern University, and Vanderbilt University. The Principal sponsor is NHGRI with additional funding from NIGMS. The Goal of the eMerge network is to assess the utility of electronic medical records as resources for genome science. Each site includes DNA linked to electronic medical records and each project includes community engagement, genome science, natural language processing. Initial proposals included identifying a phenotype of interest in 3,000 subjects and conduct of a genome-wide association study at each center. Supplemental funding was subsequently provided for cross-network phenotypes (now up to 14 done or in progress). Several lessons learned have emerged from the eMerge Consortium to date as follows: 1) Clinically derived phenotypes are a valid source for replicating genome-phenome associations found in research cohorts, and a discovery resource for new associations; 2) Many EMR derived phenotypes have allelic associations that only achieve genome-wide significance when all data sets across the network are pooled; 3) High quality EMR-derived phenotypes require four elements: codes, labs, meds, and Natural Language Processing capability; and 4) Cohort identification logic, once validated to have a high positive predictive value (PPV), at one site, can be transported to other very heterogeneous EMR systems with little degradation of PPV. The eMERGE Phase II RFA is available, and expansion of the consortium is expected. The due date is November 17, 2010. For more information about the Consortium, please visit, **www.gwas.org**.

Breakout Session Report: Genomic Research/Biorepository

This breakout group began a discussion regarding VA tissue repository resources and the VA Genomic Medicine Program. The Massachusetts Veterans Epidemiology Research and Information Center (MAVERIC) core laboratory is part of the VA Boston Healthcare System. The Laboratory is a full service repository, from study planning to analysis. The core laboratory has developed standard operating procedures for bio-sample collection, processing, and storage that can be used across studies. It is also the location where the samples for the Cooperative Studies Program (CSP) are held. The CSP is a multi site clinical trial support mechanism which sponsors and conducts large clinical trials in the Veterans Affairs health system. The VA Genomic Medicine Program, called the "Million Veteran Program," will create a national resource for current and future genomic research initiatives to improve health care to Veterans. Up to 1 million

Consenting veterans will be enrolled into an observational cohort where health, genomic, and lifestyle information will be available for analysis to researchers with the appropriate approvals. Recruitment of participants will be coordinated by MAVERIC. As part of the process DNA and plasma will be collected and stored in addition to electronic medical record and other data.

VA policy concerning biological specimens was also discussed. For VA on-site bio repositories there must be a master banking protocol. In addition, an annual compliance audit must be conducted. If samples shared with investigators outside the VA, then a materials transfer agreement (MTA) or MT CRADA must be used. For data (de-identified or limited data set) leaving VA, a data use agreement (DUA)/data transfer agreement (DTA) is required. If a private company is involved clearance must be obtained and a cooperative research and development agreement (CRADA) must be executed. Other requirements are available in VA policy.
http://www.research.va.gov/resources/policies/default.cfm

Breakout Session Report: Informatics/Health Services Research

This breakout group focused on the process to access VA data. The speakers emphasized that the best approach involved collaboration with a VA investigator to help move through the approval process. The VA Information Resource Center (VIReC) provides researchers with detailed and summary information about the data sources most often utilized by VA researchers. The VIReC Toolkit for New Users of VA Data emphasizes orientation to the Medical SAS Datasets, VHA's administrative data on inpatient and outpatient care. This introduction to VA data is intended to suggest the wider world of VHA data and to provide some guidance on searching for data in the VHA.
http://vaww.virec.research.va.gov/

The Austin Information Technology Center (AITC), in Austin, TX, is the VA's centralized computer processing center. The AITC maintains a large library of datasets that researchers may use with proper authorization. VHA facilities and administrative offices provide field data to the AITC for consolidation and storage. AITC, in turn, processes the data for use by researchers. Access to some data at AITC is coordinated by National Data Systems (NDS). NDS is a division of VHA Office of Health Information (OHI), Health Data & Informatics (HDI) and is the data steward for some data at AITC, including the Medical SAS Datasets (MedSAS) and the VA Vital Status Files.

Researchers' access to data requires approval. Each facility has a CUPS POC (Customer User Provisioning System Point of Contact, formerly called the ACRS POC), who provides assistance in completing the required forms. At many facilities, the CUPS POC is the facility ISO. To identify your CUPS POC, contact the AITC Service Desk at (888) 326-6780. In general data access requires approval by the local facility Associate Chief of Staff for Research (ACOS-R), Information Security Officer (ISO), Institutional Review Board (IRB), and Privacy Officer (PO). In addition a Data Use and Data Storage Agreement must be approved.

VA participated in the development of report entitled "Working Group on Information Technology Security and Privacy in VA and NIH-Sponsored Research. This report identifies flow charts which are useful to visualize the process to access VA data for research. The report identifies that "p*atient* consent and authorization have primacy in determinations of when data should be exchanged for research purposes." Questions from the discussion focused on VA data resources and access to these resources.

Breakout Session Report: Technology Transfer in VA

The mission of the VA Technology Transfer Program (TTP) is to promote the translation of the results of worthy discoveries made by employees of VA into practice. TTP receives approximately 160 invention disclosures per year, of which VA asserts an ownership interest in about 100-120 per year. Many of these are early stage technologies. If invention is jointly owned with VA affiliate, then the invention is managed pursuant to the Cooperative Technology Administration Agreement (CTAA) and normally, affiliate takes the lead. If not, the VA Technology Transfer Program patents, markets, and looks for potential licensees. The discussion of the group focused on local and master CRADAs and the role of the VA TTP and the local VA medical center.

Breakout Session Report: Training and Education

This session focused on the current education and career development programs offered by the Veterans Administration (VA) and the Clinical and Translational Science Awards (VA) and sought to identify opportunities for the VA and CTSAs to collaborate on supporting individuals with dual appointments. The session was chaired by Holly Birdsall, M.D., PhD, Office of Research & Development, VA. The panelists included:

- Theresa Gleason, PhD, Office of Research & Development, VA,
- Tshaka Cunningham, PhD, Office of Research & Development, VA, and
- Michael Lichtenstein, MD, Professor, University of Texas Health Science Center at San Antonio CTSA.

Dr. Gleason provided an overview of the Career Development Award (CDA) program. The Career Development Program was established to provide mentoring for junior researchers so they can learn from renowned, experienced VA researchers. Awards are provided in all areas of VA's research enterprise: biomedical laboratory, clinical science, health services, and rehabilitation research. The link is provided for reference: http://www.research.va.gov/funding/cdp.cfm

Dr. Cunningham provided an overview of the Rehabilitation Research and Development Service training opportunities. He also raised the idea of reaching out to the NIH Clinical Center's Bench to Bedside award as a way of leveraging intramural training opportunities between the NIH and the VA. The audience commented on their experiences as mentors and scholars of the CDA program.

Dr. Lichtenstein raised the issue of CTSA-VA collaborations and the challenges he has experienced as director of the KL2 program in securing funding for scholars. He outlined the figure that illustrates the issues from the perspective of effort, work appointments, and salary source. Currently, most KL2 awards require that awardees devote 75% of their effort to research and education. However, there are circumstances where the work appointment may be split between the VA and the University – in the figure the example is 4/8 VA, 4/8 University. There are a variety of reasons why an awardee may or may not want to reduce their VA effort to meet the K-requirements (e.g., eligibility for VA grants). Local VA Medical Centers would have the flexibility, with support from Central Office to allow 2/8 of VA time to be devoted to research and education. For a hypothetical salary of $150,000, the K award, administered through the university, would cover $75,000 of salary, the VA would cover $37,500 for the 25% other time (2/8), and $37,500 to cover 25% effort (2/8) to for research and education. It should be noted, that current K-award funding limits frequently do not cover the full 75% effort required to be eligible for the

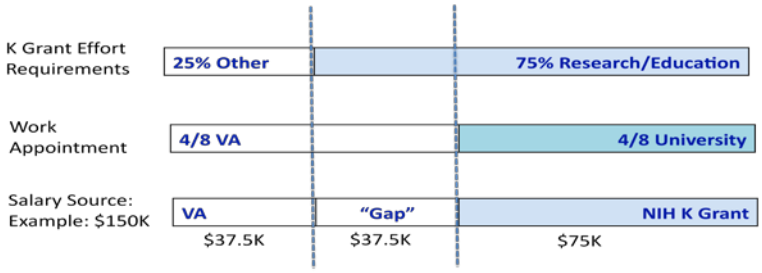

Figure: K-Grant appointments from 3 perspectives – Effort, Work, and Salary

grant, thereby leaving Divisions, Departments, Schools, and Academic Health Centers to come up with ways to cover the shortfall. There would be advantages to the NIH, VA, Academic Health Centers, and trainees to have more flexibility in putting together non-duplicative funding that supported research education and career development.

Academic Health Centers and KL2 administrators are willing to be transparent and accountable with reporting practices that clearly document on an annual basis that co-funding will be non-duplicative. However, current NIH policies do not permit the use of funds from other federal sources to share support for K-grant trainees. This presents a gap in funding to get to the 75% effort required for research and education on a K-award. Funds from clinical revenues and/or private sources may be used to 'supplement' the K-award, but not Federal Funds.

The action items that emerged from the session were to:

1. Know the policies – obtain copies of the relevant NIH policies - study and review them;
2. Determine the underlying rationale for the policies; and
3. Determine who has the authority to act and change the policies if necessary.

The NIH policy guideline does not permit supplementing scholar salaries using federal funds. The group discussed ways of addressing the issue in a memorandum of understanding, providing additional support through VA non-profit entities, and entertained the idea of forming a smaller group to change the NIH policy. There were those who supported maintaining separate lines of funding for VA and CTSA scholars where the VA scholars could still take advantage of the CTSA resources.

Conclusions

The research enterprise has undergone revolutionary transformations over the last decade given technological advances and other factors. Despite the gains in research, challenges and obstacles remain. In the context of VA/CTSA research, regulations, training requirements, subject recruitment, IT, privacy, and data security issues are still impediments to both research and collaboration. However, the opportunities far outweigh the challenges, and despite the challenges, it is imperative to identify solutions to address barriers. This meeting highlighted synergies and opportunities to improve the processes, approaches, and practices in the interest of improved outcomes and high-value impact.

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Opportunities for Collaborative Clinical and Translational Science

Meeting Co-Chairs

Barbara M. Alving, MD directs the National Center for Research Resources (NCRR) at the National Institutes of Health. NCRR provides laboratory scientists and clinical researchers with the environments and tools they need to understand, detect, treat, and prevent a wide range of common and rare diseases.

Dr. Alving earned her medical degree *cum laude* from Georgetown University School of Medicine, where she also completed an internship in internal medicine. She received her residency training in internal medicine at the Johns Hopkins University Hospital, followed by a fellowship in hematology. Dr. Alving then became a research investigator in the Division of Blood and Blood Products at the Food and Drug Administration. In 1980, she joined the Department of Hematology at the Walter Reed Army Institute of Research and became Chief of the Department in 1992. She left the Army at the rank of Colonel in 1996 to become the Director of the Medical Oncology/Hematology section at Washington Hospital Center in Washington, D.C. In 1999, she joined the National Heart, Lung, and Blood Institute (NHLBI), serving as the Director of the extramural Division of Blood Diseases and Resources until becoming the Deputy Director of the Institute in September 2001. From September 2003 until February 1, 2005, she served as the Acting Director of NHLBI. In March 2005 she became the Acting Director of NCRR and was named Director in April 2007.

Dr. Alving is a Professor of Medicine at the Uniformed Services University of the Health Sciences in Bethesda, a Master in the American College of Physicians, a former member of the subcommittee on Hematology of the American Board of Internal Medicine, and a previous member of the FDA Blood Products Advisory Committee. She is a co-inventor on two patents, has edited three books, and has published more than 100 papers in the areas of thrombosis and hemostasis.

Joel Kupersmith, M.D, is the **Chief Research and Development Officer for the Department of Veterans Affairs. He** is a graduate of New York Medical College where he also completed his clinical residency in internal medicine. Subsequently, he completed a cardiology fellowship at Beth Israel Medical Center/Harvard Medical School. After research training in the Department of Pharmacology, Columbia College of Physicians and Surgeons, he joined the faculty of the Mt. Sinai School of Medicine where he rose to the rank of Professor and was Director of the Clinical Pharmacology section. After this he became Chief of Cardiology and V.V. Cooke Professor of Medicine at the University of Louisville and then Professor and Chairperson, Department of Medicine at the College of Human Medicine at Michigan State University. Dr. Kupersmith then became Dean, School of Medicine and Graduate School of Biomedical Sciences, Vice President for Clinical Affairs at Texas Tech University as well as CEO of the Faculty Practice. Subsequently, Dr. Kupersmith was a Scholar-in-Residence at both the Institute of Medicine and the Association of American Medical Colleges before assuming duties as Chief Research and Development Officer of the VA. In these roles he completed projects and published papers on a number of health and research policy projects including how to fund, oversee and promote comparative effectiveness research, how Academic Medical Centers should be accountable, quality of care in teaching hospitals, regional IRBs, medical manpower and other issues.

Dr. Kupersmith has 150 publications and two books. His earlier research interests were in the area of electrophysiology, the causes and treatment of heart rhythm abnormalities and implantable cardioverter defibrillators. His work included delineation of conduction system characteristics in the human heart, unique effects of antiarrhythmic drugs in ischemic tissue as a basis for their antiarrhythmic actions and classification and electrophysiologic consequences of the sodium/potassium pump. Subsequently, he published in the area of cost effectiveness of heart disease treatments and

outcomes following heart attacks. Most recently his work has been on health policy issues. Dr. Kupersmith has been on many national and international committees involved in heart disease and on editorial boards of the American Journal of Medicine and two heart disease journals. He is a member of numerous professional organizations including the American Society for Clinical Investigation. Dr. Kupersmith is a winner of an Affirmative Action Award from the University of Louisville and an Alumni Association distinguished achievement award from New York Medical College. Dr. Kupersmith has also been a Visiting Scholar at the Hastings Center for ethics. He is listed in Who's Who in America and several others.

Dr. Kupersmith was elected to the Governing Council, Medical School Section of the American Medical Association, is a member of the Association of American Medical Colleges Task Force on Fraud and Abuse, and has been a Site Visit Chair for the Liaison Committee on Medical Education. He is a member of the NIH National Advisory Research Resources Council and the American Society for Clinical Investigation.

KEYNOTE SPEAKER

John B. Harley, MD, PhD has been a clinical investigator with the U.S. Department of Veterans Affairs Medical Centers in Oklahoma City, Oklahoma, from 1982 to 2010 and now with Cincinnati, Ohio, since July 2010. He recently came to Cincinnati Children's Hospital Medical Center as the Director of Rheumatology and the founder of the Center of Autoimmunity Genetics and Etiology (CAGE). Before coming to Cincinnati, Dr. Harley led the lupus genetics effort in Oklahoma for over 25 years. He directed the Lupus Family Registry and Repository (LFRR), a collection of 10,000 lupus patients, family members, and controls with 2 billion genotypes and 500,000 specimen aliquots. He has authored more than 300 publications identifying or confirming over 20 SLE genetic effects and proposing Epstein-Barr virus as the environmental cause of lupus. Despite the administrative barriers that slow scientific progress, he brings extensive expertise in the recruitment of large patient cohorts, implementation of cutting edge genetic technologies, and application of relevant analytical approaches to the identification of genes and environmental etiologies in complex inflammatory diseases. He has held various positions at the University of Oklahoma Health Sciences Center, including Chief of Rheumatology, Allergy and Immunology Section, James R. McEldowney Chair in Immunology and Professor of Medicine, and Vice Chair for Research.

SPEAKERS

Lars Berglund, MD, PhD is Professor of Medicine, Associate Dean for Research, and Director of the NIH-funded Clinical and Translational Science Center at UC Davis, and also serves as a physician at the Sacramento VA Medical Center. He received his Ph.D. in 1977 and his M.D. in 1981, both from Uppsala University, Sweden. His internship and residency in Internal Medicine and Clinical Chemistry were completed at the Karolinska Institute, Stockholm Sweden, where he served as a faculty member in the Department of Clinical Chemistry (1986-1993). Dr. Berglund was recruited to Columbia University as a Florence Irving Associate Professor of Medicine in 1993, and became Professor of Medicine in 2000. He served as Associate Director for the Columbia University GCRC from 1997. In 2002, he was recruited to UC Davis and in 2004 he became the first Program Director of the UC Davis GCRC. Dr. Berglund became the first Assistant Dean of Clinical Research at UC Davis in 2004, and Associate Dean of Clinical and Translational Research in 2006. The same year he became the first Director of the NIH-funded UC Davis CTSC. In 2009, Dr. Berglund assumed the position as Associate Dean for Research in the UC Davis School of Medicine.

As CTSC Director, Dr. Berglund ensures that administrative, patient care and research reporting procedures are carried out in conformity with NIH, UC Davis, and Department of Veterans Affairs policies. In addition, he sets goals and standards for the CTSC, encourages investigators to utilize the CTSC and fosters collaborations between clinical and basic science investigators. He serves in several CTSA consortium committees and was co-Chair for the CTSA Consortium Oversight Committee 2006-2008. Dr. Berglund's research focus is in the area of lipoprotein metabolism and cardiovascular disease and his research is funded by NHLBI. He has published more than 190 peer-reviewed papers and is a member of the Editorial Board of seven journals, including Arteriosclerosis, Thrombosis and Vascular Biology, the Journal of Clinical Endocrinology and Metabolism, and Clinical and Translational Science. He serves on multiple Advisory Boards and is a member of the American Heart Association Peer Review Committee, the Clinical Guidelines subcommittee of the Endocrine Society, and serves as Chair of the NIH AIDS, Clinical Research and Epidemiology (ACE) study section.

Holly H Birdsall MD, PhD joined the VA Office of Research and Development in October 2009 as the Acting Deputy Chief Research and Development Officer. Prior to that, she was the Associate Chief of Staff for Research and Development at the Michael E. DeBakey Veterans Affairs Medical Center in Houston, Texas. She is a Professor of Otolaryngology, Immunology and Psychiatry at Baylor College of Medicine and was the Assistant Dean of Research Education. She has also served as the Assistant Director to the BCM Clinical Scientist Training Program, Chair of the IACUC, and Interim Director of the Center for Comparative Medicine. Her research, funded by both the NIH and VA Merit Review programs, has been both basic and translational in the areas of autoimmunity and inflammation, particularly in the context of HIV disease.

Mary T. Brophy, MD, MPH serves as the Director of the VA Central Biorepository and Acting Director of the Cooperative Studies Program's Clinical Trials Coordinating Center located at the Massachusetts Veterans Research and Information Center in Boston, MA. Mary received her MD from Tufts University School of Medicine and MPH from Harvard School of Public Health. She is an Assistant Professor of Medicine at the Boston University Schools of Medicine and a staff hematologist/oncologist at the VA Boston.

K. Lynn Cates, MD is Assistant Chief Research & Development Officer in VA's Office of Research & Development, and Director of the Program for Research Integrity Development & Education (PRIDE). She is responsible for policy development and training in human research protection for the 108 VA facilities that perform human research; ensuring that all VA facilities' human research protection programs are accredited by AAHRPP; and creating and implementing the VA Central IRB to review multi-site VA research projects. Before joining the VA, Dr. Cates was in academic medicine specializing in pediatric infectious diseases for 20 years. She served as president of the Pediatric Infectious Diseases Society, and as a member of Institute of Medicine advisory committees on vaccines. Dr. Cates was a Robert Wood Johnson Health Policy Fellow, assigned to Senator James M. Jeffords, Chair of the Committee on Labor and Human Resources, and she was a Senior Medical Advisor in the Department of Health and Human Services, Washington, D.C. She was elected to the Committee that created the international eHealth Code of Ethics for how health information and services are provided over the Internet, and she was Vice President for Health of the Dr. Spock Company.

Amy Centanni, JD is the Director of the Technology Transfer Program in the Office of Research and Development. Amy began her career with VA in 1995 at the Board of Veterans Appeals. In 1998 she transferred to the Office of General Counsel where she served as a Staff Attorney specializing in Freedom of Information Act and Privacy Act appeals. In April 2000, she assumed primary responsibility for matters relating to intellectual property and technology transfer.

Amy has been actively involved in helping redefine and reshape VA intellectual property policies, to include invention disclosures, licensing and marketing of VA owned technologies. She has also led the way in establishing Cooperative Technology Administration Agreements with more than 65 academic affiliates. As Director of the Technology Transfer Program office she continued to address these issues as well as redefining the clinical trials process conducted within VA via the Cooperative Research and Development Agreements. Amy has been instrumental in the development of the new model agreements VA has developed and in identifying the role of the VA nonprofit corporations.

David Center, MD is the Gordon and Ruth Snider Professor of Pulmonary Medicine, Chief of Pulmonary, Allergy and Critical Care Medicine, Associate Provost for Translational Research and Director of Boston University's Clinical and Translational Science Institute. His basic science research interests are in T cell trafficking, regulatory functions and the T cell cycle. Much of that work revolves around functions of Interleukin 16 which I discovered with Bill Cruikshank in 1982. His translational science interests are vested in intellectual property owned by BU describing therapeutic uses of IL-16 mimetics and antagonists in immune mediated inflammatory processes; in particular asthma and multiple sclerosis.

Tshaka Cunningham, PhD is the Scientific Program Manager for Aging and Neurodegenerative Diseases for the Rehabilitation Research and Development Service within the Office of Research and Development at the Department of Veterans Affairs. He is a graduate of Princeton University, where he earned a BA degree in molecular biology. He then worked as a research scientist at Bristol-Myers Squibb Pharmaceuticals Inc, where he developed biological screening assays to identify drugs for the treatment of cardiovascular diseases. He holds a Ph.D. in molecular biology from Rockefeller University in New York. Dr. Cunningham has served as a technology development consultant to small biotechnology companies and has been an invited columnist on scientific and social issues for Nature magazine and The Scientist. In addition, he is an adjunct assistant professor in the Microbiology Department at Howard University School of Medicine where he lectures in the medical virology course for medical and dental students. He completed his postdoctoral training at the Pasteur Institute in Paris, France, and at the National Institutes of Health in Bethesda, MD.

Leonard D'Avolio, PhD is the Associate Center Director of Biomedical Informatics for the VA's Massachusetts Veterans Epidemiology Research and Information Center (MAVERIC) and faculty at Harvard Medical School. MAVERIC is a national coordinating center for multi-site clinical trials, a VA epidemiology research center, and a biospecimen repository with over 400k blood and tissue samples. In his role as Associate Center Director, Dr. D'Avolio is responsible for several initiatives to expand the biomedical informatics capabilities of the Veterans Health Administration, including the development of the Genomic Information System for Integrative Science (GenISIS), a national VA resource for conducting genomic analysis combining clinical and biological data. Dr. D'Avolio's research interests include natural language processing, data quality assessment, and machine learning techniques applied to improve the quality of healthcare.

Seth Eisen, MD, MSc, an internist and epidemiologist, was a Staff Physician at the St. Louis Veterans Affairs Medical Center for nearly 30 years, and a Professor of Internal Medicine and Psychiatry at Washington University School of Medicine in St. Louis. He was a developer of the Vietnam Era Twin (VET) Registry, a national cohort of 7400 male-male veteran twin pairs, which has been used to investigate genetic and environmental influences on a wide variety of physical and psychiatric health issues, and aging. Dr. Eisen has extensive experience with complex issues relating to research design and quality data collection, and the construction, maintenance & management of large research cohorts and computer databases. He has over 120 peer reviewed publications.

Dr. Eisen was appointed Director, Health Services Research and Development Service, Office of Research and Development, Department of Veterans Affairs in December, 2006. In this role, he has developed major initiatives in

healthcare informatics, health care genomics, traumatic brain injury research, health systems research, transformation of clinical research into practice, comparative effectiveness research, and research that focuses on methods of improving provider education to improve patient outcomes.

Louis Fiore, MD, MPH is the Director of the VA Cooperative Studies Program Coordinating Center at the VA Boston Healthcare System. He is a practicing hematologist/oncologist and has been with the VA since 1981 where his research roles have included Co-Director of the Massachusetts Veterans Epidemiology Research and Information Center (MAVERIC), Director of the Veterans Affairs Biorepository and Director of the Cooperative Studies Program Informatics Group. His current interest is in the development of the Genomic Information System for Integrated Science (GenISIS), a research platform that will host phenotype, genotype and public reference data in a secure analytical environment. GenISIS will be the primary research platform for the VA genomic medicine program and will host the data from the VA Million Veteran Program.

J. Michael Gaziano, MD, MPH, received his MD from Yale Medical School and his MPH from Harvard School of Public Health. He is an internationally recognized chronic disease epidemiologist and trialist. His research interests include the epidemiology of chronic diseases, with a particular interest in lifestyle, biochemical and genetic determinants of vascular disease and its risk factors and the adverse impact of vascular disease on other organ systems. Based at the VA Boston Healthcare System, he serves as one of the Directors the Massachusetts Veterans Epidemiology Research and Information Center (MAVERIC), a national epidemiology and trial center funded by CSR&D where he directs the epidemiology research center. He also serves as the Director of the Boston Geriatric Research and Education Center (GRECC). At VA Boston he runs a preventive cardiology program with an associated fellowship. He is Chief of the Division of Aging at the Brigham and Women's Hospital and serves as principal investigator for the Physicians' Health Study, a trial-based cohort of over 29,000 physicians who have been followed for up to 28 years. He is a Professor of Medicine at Harvard Medical School. He has published over 350 original reports, reviews, book chapters, and books. He teaches advanced epidemiology and has mentored over 50 trainees. He is a contributing editor for *JAMA*.

Gary Gilbert, MD is Deputy Associate Chief of Staff for Research and Development at the Boston VA and Associate Professor of Medicine at Harvard Medical School. For 21 years his laboratory has studied membrane interaction of factor VIII, particularly using biophysical studies. His lab developed an equilibrium membrane binding assay using fluorescence energy transfer and the quasi-equilibrium assay using lipospheres. With our studies we discovered that membrane binding is mediated by stereoselective interaction with phosphatidyl-L-serine rather than via an electrostatic interaction. Eight years ago we began to study lactadherin, a protein that has phosphatidyl-L-serine binding lectin domains homologous with those of factor VIII. We have ongoing studies to understand the details of the membrane-binding mechanisms and biology of both factor VIII and lactadherin. Dr Gilbert received his MD degree from Loma Linda University.

Theresa C. Gleason, Ph.D. currently serves as Psychiatric and Behavioral Disorders Research Portfolio Manager for both Biomedical Laboratory and Clinical Sciences R&D Services at the Department of Veterans Affairs, Washington DC. She received her Ph.D. at George Washington University in Cognitive Neuropsychology, and afterwards was an NIH Senior Fellow in the Experimental Therapeutics Branch, National Institute of Mental Health, Bethesda, Maryland. Responsibilities include managing all mental health and behavioral sciences studies, including scientific peer review. Additionally, she serves as Program Manager for Collaborative Clinical Trials Awards Program (supporting small, early phase clinical trials) as well as Central Data Monitoring Committee. She managed the VA Career Development Program

(mentored training awards) for five years. Dr. Gleason serves as scientific advisor to the VA National Center for PTSD, Department of Defense InTRUST Clinical Trial Consortium, and Senior International Forum of Veterans Administrations.

Terence M. Keane, Ph.D. is Associate Chief of Staff for Research & Development, Director of the National Center for PTSD-Behavioral Sciences Division at VA Boston Healthcare System, and Professor and Vice Chairman in the Division of Psychiatry at Boston University. The Past President of the International Society for Traumatic Stress Studies (ISTSS), Dr. Keane has published eleven edited volumes and over 230 articles on the assessment and treatment of PTSD. For the past 30 years the VA, the National Institutes of Health, Department of Defense, and Substance Abuse Mental Health Services Administration (SAMHSA) have continuously supported his program of research on psychological trauma. His contributions to the field have been recognized by many honors including the Lifetime Achievement Award (2004) and the Robert Laufer Award for Outstanding Scientific Achievement (1996) from the ISTSS, a Fulbright Senior Scholar Award (1993-4), an Outstanding Researcher Award from the Association for Advancement of Behavior Therapy (2004), an Outstanding Research Contributions Award (2000) and the Distinguished Service Award (2002) from the American Psychological Association, and the Weisband Distinguished Alumnus Award (1998) from Binghamton University (SUNY). Dr. Keane is a Fellow of the American Psychological Association and the Association for Psychological Science. He has presented Congressional testimony on numerous occasions and consulted, lectured, and conducted workshops internationally on topics related to psychological trauma.

Michael Lichtenstein, MD, MSc is the co-Principal Investigator for the Research Education, Training, and Career Development Programs of the Institute for the Integration of Medicine and Science (IIMS). The IIMS is the academic home for the San Antonio Clinical and Translational Science Award. Dr. Lichtenstein serves as the Chief of the Division of Geriatrics, Gerontology, and Palliative Medicine in the Department of Medicine at the UT Health Science Center at San Antonio. Over the past 15 years, he has worked closely with colleagues from multiple disciplines to develop research and science education curricula and courses at the public school and graduate levels. Dr. Lichtenstein is the founding director for San Antonio's Masters of Science in Clinical Investigation Degree Program that has graduated more than 70 students in the past 10 years. He is currently the Principal Investigator on two NIH grants focused on science education, one from the National Institute for Drug Abuse ("Critical Appraisal to Improve Science Education") and a Science Education Partnership Award from the National Center for Research Resources ("Positively Aging: Maximizing the Healthspan").

Daniel R. Masys, M.D. is Professor and Chair of the Department of Biomedical Informatics. An honors graduate of Princeton University and the Ohio State University College of Medicine, he completed postgraduate training in Internal Medicine, Hematology and Medical Oncology at the University of California, San Diego, and the Naval Regional Medical Center, San Diego. He served as Chief of the International Cancer Research Data Bank at NIH-NCI, and was also Director of the Lister Hill National Center for Biomedical Communications, National Library of Medicine. In this capacity he was the principal architect of the National Center for Biotechnology Information (NCBI), which hosts the data from the Human Genome Project. Dr. Masys serves as Principal Investigator of the eMERGE (electronic MEdical Records and GEnomics) network coordination office, which is engaged in cross site pooling and meta-analysis of EMR-derived genome association studies from five CTSA partner institutions. He is an elected member of the Institute of Medicine of the National Academy of Sciences, and a member of the VA Genomic Medicine Program Advisory Committee.

Jeff Moore, PhD currently works as a Technology Transfer Specialist in the Veterans Affairs Office of Research and Development (ORD), Technology Transfer Program (TTP) where he has been since 2003. Jeff is active in negotiating

single-site Cooperative Research and Development Agreements (CRADAs) and was instrumental in negotiating master template CRADAs that are designed to streamline clinical trials, saving tremendous time and resources at VA medical centers nationwide. He also negotiates and manages Cooperative Technology Administration Agreements (CTAA) and their amendments; the CTAAs are agreements that are used to manage co-owned inventions with respective academic affiliates around the country. Lastly, Jeff's duties include managing part of a portfolio that oversees patenting, marketing, and licensing of VA-owned inventions stemming from a VA research program. This intramural research program has an appropriated budget of $585 million and supports research at over 100 VA medical centers nationwide. Prior to joining VA, Jeff earned his Bachelor of Arts from Hanover College and a Ph.D. in Chemistry from Purdue University. His research at Purdue focused on developing derivatives of the anti-cancer drug cis-platin to better understand how platinum complexes interacted with DNA. His interdisciplinary training spanned inorganic, organic, analytical, and biochemical fields of chemistry. Jeff's family includes a wife, a 3 year old daughter, and an old black Lab named Maverick.

Sumitra Muralidhar, PhD obtained her degree in Microbiology from the University of Maryland at College Park. Following post-doctoral training at NIAID and NCI, she served on the faculty at the Department of Microbiology at Georgetown University Medical Center. She joined ORD's program management team in 2001. In 2006, she served as Health and Science Advisor on the Senate Veterans Affairs Committee . Since 2007, she has been the Scientific Program Manager for VA's Genomic Medicine Program , leading the efforts on several initiatives including the Veterans' Focus Group and Survey, and currently the Million Veteran Program. She is also the Designated Federal Officer for VA's Genomic Medicine Program Advisory Committee.

Mike R. Sather, Ph.D., FASHP, Veterans Affairs Cooperative Studies Program Clinical Research Pharmacy Coordinating Center. Dr. Mike Sather joined the Cooperative Studies Program in 1976 as the Director of the VACSP Clinical Research Pharmacy Coordinating Center. He has led the Pharmacy Coordinating Center to the ZIA Award from Quality New Mexico, the State's highest quality award. The Center also has been the recipient of the VA Secretary's Robert W. Carey Trophy Award for Organizational Excellence and three VA Circle of Excellence Awards. The Center is registered in ISO 9001 and 15378 by the National Standards Authority of Ireland. In addition, the Center has been the recipient of the 2009 National Malcolm Baldrige Program Quality Award in the nonprofit category, which is a Presidential Award sponsored by the National Institute of Standards and Technology, U.S. Department of Commerce. Moreover, Mike has developed multiple clinical trial collaborations with several Institutes of the National Institutes of Health, university based medical and biostatistical groups and industry throughout the United States, Canada, and parts of Europe and South America.

Mike earned his BS degree in Pharmacy in 1968 and MS Degree in Pharmaceutical Sciences in 1970 from North Dakota State University. He was inducted as a fellow of the American Society of Health Systems Pharmacists in 1993. He also received his Ph.D. Degree in Pharmaceutical Sciences with emphasis in the ethics of clinical trials from the University of New Mexico in 2001. Mike has held Pharmacy faculty positions at North Dakota State University and the University of Florida, and is currently a faculty member at the University of New Mexico.

Steven A. Schichman, MD, PhD is the Director of Hematopathology and Molecular Diagnostics at the Central Arkansas Veterans Healthcare System in Little Rock, Arkansas, where he directs a state-of-the-art Genomics Laboratory (designated the Pharmacogenomics Analysis Laboratory) within the Little Rock VA Research Service. Dr. Schichman is Associate Professor of Pathology at the VA-affiliated University of Arkansas for Medical Sciences. A graduate of the University of Chicago Pritzker School of Medicine (1982), Dr. Schichman performed his PhD Thesis work at the California

Institute of Technology. After completing Residency training in Pathology and post-doctoral work in molecular genetics at the University of North Carolina, Chapel Hill, Dr. Schichman completed Hematopathology Fellowship training at the University of Pennsylvania. Dr. Schichman is board certified in Clinical Pathology, Hematology, and Molecular Genetic Pathology. He has published important papers in the molecular genetics of acute and chronic leukemia.

Joel Tsevat, MD, MPH is a general internist and Professor of Medicine; Associate Dean for Clinical and Translational Research; Co-Director of the Center for Clinical and Translational Science and Training; Director of Outcomes Research in the Department of Internal Medicine; Research Director in the Center for Clinical Effectiveness in the University of Cincinnati College of Medicine; and Director of Health Services Research and Development (HSR&D) for the Veterans Healthcare System of Ohio (Veterans Integrated Service Network [VISN] 10). He received a BA in Plan II from the University of Texas, an MD from the University of Texas School of Medicine in San Antonio, and an MPH from the Harvard School of Public Health. A past-president of the Society for Medical Decision Making, Dr. Tsevat's research interests include health-related quality of life, in particular health status vs. utility assessment; HIV/AIDS; spirituality/religion; cost-effectiveness analysis; and decision analysis. He is multi-PI (with James Heubi, MD) on the University of Cincinnati's NIH Institutional Clinical and Translational Science Award (CTSA). He has served as principal investigator on multiple other federally-funded grants and has published over 140 peer-reviewed papers, reviews, book chapters, and editorials. In 2007, he received the Distinguished Alumnus Award from his medical school.

Peter D. Walzer, MD, Msc, graduated from Albany Medical College in 1968, and completed part of his Internal Medicine residency at the Mary Imogene Bassett Hospital. He then served on active duty in the USPHS as an Epidemic Intelligence Service (EIS) Officer in the Parasitic Disease Branch of CDC. It was here that he developed an interest in infectious diseases. Following immunology training at Rockefeller University and infectious diseases training at Memorial Sloan Kettering Cancer Center, Dr. Walzer joined the faculty at the University of Kentucky and the Lexington VA Medical Center in 1976. He moved to the University of Cincinnati (UC) and the Cincinnati VAMC in 1981 where he has remained ever since. In 1994, he was appointed Associate Chair for Research in the Department of Medicine at UC and the Associate Chief of Staff for Research at the VA. In 2005, Dr. Walzer obtained a VA and NIH funding for a one year sabbatical at the London School of Tropical Medicine and Hygiene where he obtained an MSc Epidemiology.

Dr. Walzer's research involves the opportunistic fungal pathogen, Pneumocystis, which is an important cause of Pneumonia in HIV patients and other immunocompromised hosts. He has been funded by VA and/or NIH since 1977 and has more than 200 publications. He has developed an interdisciplinary research group based in Cincinnati which has gained international recognition for its research contributions. Dr. Walzer has a long record of involvement in the VA. Nationally, he has served as Program Specialist in Infectious Diseases, Member of the Merit Review Council, Chair of the Advisory Group in Infectious and Immune Disorders, and recently was appointed to the Field Research Advisory Committee. Locally, he revitalized an ailing Research Service, and restored good relations with UC. When VA inpatient units were closed, he played a leadership role first in getting the space designated for clinical research and then developing the space into a General Clinical Research Center (GCRC). There was a GCRC at Cincinnati Children's Hospital and UC that focused on studies in children and healthy young adults. The VA GCRC, which was intended to be a satellite of the Children's GCRC, focused on veteran and non-veteran adults with complex medical problems. It took some time for these goals to be achieved, but today the VA GCRC (or as it is currently called the VA "Clinical Research Unit") is fully integrated into the Cincinnati CTSA and receives NIH funding. Dr. Walzer has long believed that VA, NIH and medical schools would benefit by more involvement of the VA in CTSAs and Clinical Research Units.

Opportunities for Collaborative Clinical and Translational Science

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