Embracing the full spectrum of translational research

Final Program
Dear Colleagues,

Welcome to the 2011 Clinical and Translational Research and Education Meeting, the annual meeting of the Association for Clinical Research Training (ACRT), the American Federation for Medical Research (AFMR), the Society for Clinical and Translational Science (SCTS), and with active participation from the Association for Patient-Oriented Research (APOR) and the Clinical Research Foundation.

The 2011 Clinical and Translational Research and Education Meeting brings together trainees, educators, and all others engaged in clinical and translational science. You have the opportunity to connect with leaders from government, industry, academia, and philanthropy and add to your perspective on the state of the discipline and its future direction. The meeting focuses on educational sessions designed to provide information on the latest developments.

ACRT and SCTS are pleased to add AFMR as a new partner for the 2011 meeting. The Clinical Research Foundation joins as a new participant in the opening reception and morning plenary session, along with APOR, which has been part of this annual meeting and its predecessors for several years.

We hope that this meeting provides an excellent learning experience for all attendees, providing new information on the latest developments in the techniques and processes vital for the successful conduct of clinical and translational science. The 2011 Meeting Program Committee has worked diligently to bring together stellar speakers and presenters.

Our sincere thanks go to the 2011 Annual Meeting Program Committee for their hard work and time spent in developing this event.

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2011 Annual Meeting Program Committee

Melissa Begg, ScD, Columbia University
Henry Blumberg, MD, Emory University
Beau Bruce, MD, Emory University
Nancy Desmond, PhD, NIMH
Michael Fleming, MD, MPH, University of Wisconsin
Marie Gelato, MD, PhD, Stony Brook University
Lisa Guay-Woodford, MD, University of Alabama at Birmingham
David Kent, MD, Tufts Medical Center

Michael Lichtenstein, MD, MSc, University of Texas Health Science Center at San Antonio
Sharma Prabhakar, MD, MBA, FACP, Texas Tech University
Doris Rubio, PhD, University of Pittsburgh
David Schteingart, MD, Michigan Institute of Clinical and Health Research
Kathryn Schuff, MD, MCR, Oregon Health & Science University
Ellen W. Seely, MD, Brigham and Women’s Hospital

We hope that you enjoy the meeting and look forward to your suggestions to help guide the next Clinical and Translational Research and Education Meeting, which will take place in Washington, DC on April 17 -19, 2012.

Sincerely,

Doris M. Rubio, PhD
University of Pittsburgh
ACRT President

Francis J. Miller, MD
University of Iowa
AFMR President

Harry P. Selker, MD, MSPH
Tufts University
SCTS President
2011 ACRT/AFMR/APOR/SCTS Joint Awards

Distinguished Investigator Awards

Translation from bench research to clinical application – the APOR Edward H. Ahrens, Jr. Award

David Goldstein, MD, PhD, Clinical Neurocardiology Section National Institute of Neurological Disorders and Strokes, NIH

Dr. Goldstein is being recognized as an authority on clinical catecholamine neurochemistry and autonomic function testing and as a founder of the discipline of clinical neurocardiology.

Translation from early clinical use to applicability for widespread clinical practice

William Tamborlane, MD, Yale Center for Clinical Investigation and CTSA Program

Dr. Tamborlane is being recognized for his work on the forefront of clinical research which has provided new delivery methods for physiologic replacement of insulin with prevention of many of the major catastrophic long-term complications of childhood diabetes.

Translation from clinical use into public benefit and policy

William Tierney, MD, MACP, Indiana University School of Medicine

Dr. Tierney is being recognized for his life-long contributions to translational research, as exemplified by his establishment of a translational research program in health informatics studying the effects on healthcare outcomes of computer-based decision support systems for translating evidence-based care guidelines into practice for diagnostic testing and creation of ResNet, the oldest and most productive general internal medicine practice-based translational research network that has hosted more than 100 studies and published more than 300 peer-reviewed medical journal articles.

AFMR Outstanding Investigator Award

Vance Fowler, MD, MHS, Duke University Medical Center

Dr. Fowler’s clinical and translational research in staphylococci has improved the way a generation of physicians diagnoses, treats, and understands S. aureus bacteremia and endocarditis.

Team Science Award

NIH Undiagnosed Diseases Program

Director: William Gahl, MD, PhD, Office of Rare Diseases Research, NIH

Team Members: Thomas C. Markello, MD, PhD; Catherine Groden, NP; Fred Gill, MD; Hannah Carlson-Donohoe, BA; Cynthia Tifft, MD, PhD; David Adams, MD, PhD; Camilo Toro, MD; Grace Park, MD; Neal Boerkoel, MD, PhD; Murat Sincan, MD; Andrea Gropman, MD; Tyler Pierson, MD, PhD; Stephen Groft, PharmD; John Gallin, MD; Gretchen Golas, NP; Lynne Wolfe, NP; Michele Nehrebecky, NP; Colleen Wahl, NP; Rena Godfrey, PA; Chevalia Robinson, RN; Joy Bryant, RN; David Draper, RN; Karin Fuentes, BS; Sandra Yang, MS; Ann Madeo, MS

The recent description of the mutation underlying a rare disorder of vascular calcifications is an outstanding example of the team approach to translational research.

Participating Organizations

Association for Patient-Oriented Research (APOR) Clinical Research Foundation
Meeting Objectives
The goals of the 2011 Clinical and Translational Research and Education Meeting are:

- To inspire the participants by identifying the great successes of clinical and translational research and describing how they have improved the lives of so many people
- To provide exciting and dynamic career development programs for trainees and their mentors
- To provide participants with the most up-to-date and valuable information in clinical and translational science
- To provide scholars an opportunity to present their research to a supportive group of their peers, educators, and senior investigators
- To provide educators a venue to present best practices in clinical and translational research career development.

Attendees Include
Meeting participants should include individuals engaged in clinical and translational science at every stage of their careers including:

Research Scientists, Scientific Administrators, New Investigators, Educators, Scholar/Trainees involved in academia, industry, philanthropy and government to come together and share best practices.

Faculty Disclosure
In accordance with the policies on disclosure of the Accreditation Council for Continuing Medical Education and the University of Pittsburgh Faculty Advisory Committee for Continuing Medical Education in the Health Sciences, presenters for this program have been required to identify all financial interests with pharmaceutical companies, biomedical device manufacturers, and other healthcare-related for-profit entities. *Please refer to enclosed faculty disclosure handout.

CMEs
This activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint sponsorship of the University of Pittsburgh School of Medicine, the Association for Clinical Research Training (ACRT), the Society for Clinical and Translational Science (SCTS), and the American Federation for Medical Research (AFMR). The University of Pittsburgh School of Medicine is accredited by the ACCME to provide continuing medical education for physicians.

The University of Pittsburgh School of Medicine designates this educational activity for a maximum of 9.5 AMA PRA Category 1 Credits™. Each physician should only claim credit commensurate with the extent of their participation in the activity.

Other healthcare professionals are awarded 0.9 continuing education units (CEUs) which are equal to 9.5 contact hours.

The information presented at this CME program represents the views and opinions of the individual presenters, and does not constitute the opinion or endorsement of, or promotion by, the UPMC Center for Continuing Education in the Health Sciences, UPMC/University of Pittsburgh Medical Center or Affiliates, and University of Pittsburgh School of Medicine. Reasonable efforts have been taken intending for educational subject matter to be presented in a balanced, unbiased fashion and in compliance with regulatory requirements. However, each program attendee must always use his/her own personal and professional judgment when considering further application of this information, particularly as it may relate to patient diagnostic or treatment decisions including, without limitation, FDA-approved uses and any off-label uses.

The University of Pittsburgh, as an educational institution and as an employer, values equality of opportunity, human dignity, racial/ethnic, and cultural diversity. Accordingly, the University prohibits and will not engage in discrimination or harassment on the basis of race, color, religion, national origin, ancestry, sex, age, marital status, familial status, sexual orientation, disability, or status as a disabled veteran or a veteran of the Vietnam era. Further, the University will continue to take affirmative steps to support and advance these values consistent with the University’s mission. This policy applies to admissions, employment, access to and treatment in University programs and activities. This is a commitment made by the University and is in accordance with federal, state, and/or local laws and regulations. For information on University equal opportunity and affirmative action programs and complaint/grievance procedures, please contact: William A. Savage, Assistant to the Chancellor and Director of Affirmative Action (and Title IX and 504 Coordinator), Office of Affirmative Action, 901 William Pitt Union, University of Pittsburgh, Pittsburgh, PA 15260, (412) 648-7860.
Barbara M. Alving, MD, MACP
Director, National Center for Research Resources, NIH

Dr. Barbara Alving is the Director of the National Center for Research Resources (NCRR), which funds the development of new technologies for basic and clinical research, supports training for researchers in the biomedical sciences, develops preclinical models, and provides health and biomedical education for the public. The NCRR is responsible for developing the new Clinical and Translational Science Award (CTSA) program that has evolved from the NIH Roadmap initiative to re-engineer clinical research.

Dr. Alving rose to the rank of Colonel in the Army before leaving to become Director of the Medical Oncology/Hematology Section at the Washington Hospital Center in Washington, DC. She has served in various positions at the National Heart, Lung, and Blood Institute and was named director in 2007. She is also a Professor of Medicine at the Uniformed Services University of the Health Sciences and has authored numerous papers in the area of thrombosis and hemostasis.

James M. Anderson, MD, PhD
Director, Division of Program Coordination, Planning, and Strategic Initiatives, NIH

Dr. James Anderson was appointed Deputy Director for Program Coordination, Planning, and Strategic Initiatives, and Director of the Division of Program Coordination, Planning, and Strategic Initiatives at the National Institutes of Health (NIH) in 2010. Prior to joining NIH, Dr. Anderson was Professor and Chair of the Department of Cell and Molecular Physiology in the School of Medicine at the University of North Carolina at Chapel Hill, a position he held since 2002. Before his appointment at Chapel Hill, he was Professor of Medicine and Cell Biology and Chief, Section of Digestive Diseases, at the Yale School of Medicine.

Dr. Anderson received his PhD in Biology from Harvard University in 1979, and his MD from Harvard Medical School in 1983.

Donald Berwick, MD, MPP
Administrator, Centers for Medicare & Medicaid

Donald M. Berwick, MD, MPP, is the Administrator of the Centers for Medicare and Medicaid Services (CMS). As Administrator, Dr. Berwick oversees the Medicare, Medicaid, and Children's Health Insurance Program (CHIP). Together, these programs provide care to nearly one in three Americans.

Before assuming leadership of CMS, Dr. Berwick was President and Chief Executive Officer of the Institute for Healthcare Improvement, Clinical Professor of Pediatrics and Health Care Policy at Harvard Medical School, and Professor of Health Policy and Management at Harvard School of Public Health. He also served as a consultant in pediatrics at Massachusetts General Hospital and adjunct staff in the Department of Medicine at Children's Hospital Boston.

Dr. Berwick has served as Chair of the National Advisory Council of the Agency for Healthcare Research and Quality, and as an elected member of the Institute of Medicine (IOM). He also served on the IOM's governing Council between 2002 and 2007. In 1997 and 1998, Dr. Berwick was appointed by President Clinton to serve on the Advisory Commission on Consumer Protection and Quality in the Health Care Industry.

Dr. Berwick is the recipient of numerous awards and honors for his work, including the 1999 Ernest A. Codman Award, the 2001 Alfred I. DuPont Award for excellence in children's healthcare from Nemours, the 2002 American Hospital Association's Award of Honor, the 2006 John M. Eisenberg Patient Safety and Quality Award for Individual Achievement from the National Quality Forum and The Joint Commission on Accreditation of Healthcare Organizations, the 2007 William B. Graham Prize for Health Services Research, and the 2007 Heinz Award for Public Policy from the Heinz Family Foundation.

Dr. Berwick is a pediatrician and holds a Master in Public Policy degree from the John F. Kennedy School of Government. He received his medical degree from Harvard Medical School, where he graduated cum laude.

Francis S. Collins, MD, PhD
Director, National Institutes of Health

Francis S. Collins, MD, PhD became the 16th director of the National Institutes of Health (NIH) on August 17, 2009 after being nominated by President Barack Obama and confirmed by the US Senate.

Dr. Collins, a physician-geneticist noted for his landmark discoveries of disease genes and his leadership of the Human Genome Project, served as director of the National Human Genome Research Institute (NHGRI) at the NIH from 1993 to 2008. The Human Genome Project was a remarkable international collaboration that culminated in April 2003 with the completion of a finished sequence of the human DNA genome.

In addition to his achievements as the NHGRI director, Dr. Collins’ own research laboratory has discovered a number of important genes, including those responsible for cystic fibrosis, neurofibromatosis, Huntington’s disease, a familial endocrine cancer syndrome, and most recently, genes for type 2 diabetes and the gene that causes Hutchinson-Gilford progeria syndrome.

Dr. Collins received a PhD in physical chemistry from Yale University, and an MD with honors from the University of North Carolina at Chapel Hill. Dr. Collins was awarded the Presidential Medal of Freedom in November 2007 and in a White House ceremony on October 7, 2009, Dr. Collins received the National Medal of Science, the highest honor bestowed on scientists by the United States government. On April 22, 2010, Dr. Collins was a co-recipient of the Albany Medical Center Prize in Medicine and Biomedical Research.
Keynote Speakers

John Gallin, MD  
Director, Clinical Center, NIH

Dr. John Gallin was appointed director of the NIH Clinical Center in 1994. The Clinical Center serves the clinical research needs of 17 NIH institutes and is the largest clinical research hospital in the world. During his tenure, Dr. Gallin has overseen the design and construction of a new research hospital for the Clinical Center, the Mark O. Hatfield Clinical Research Center; the establishment of a new curriculum for clinical research training; and development of a new clinical research information system. The new facility opened its doors to patients in 2005.

Dr. Gallin was the 2006 recipient of the Richard and Hinda Rosenthal Foundation Award of the American College of Physicians. Dr. Gallin earned an MD from Cornell University Medical College. Dr. Gallin has published more than 300 articles in scientific journals and edited two textbooks.

Margaret Hamburg, MD  
Commissioner, US Food and Drug Administration

Margaret Hamburg served as health commissioner for New York City from 1991 to 1997, where she developed innovative programs for controlling the spread of tuberculosis and AIDS.

From 1986 to 1988, Dr. Hamburg served in the U.S. Office of Disease Prevention and Health Promotion, and from 1989 to 1990, she was assistant director of the National Institute of Allergy and Infectious Diseases at NIH, where her work focused on AIDS research.

Since 2001, she has been vice president for biological programs at the Nuclear Threat Initiative, a foundation dedicated to reducing the threat to public safety from nuclear, chemical, and biological weapons and she is a leading advocate for changes in the nation’s public health policies and infrastructure. She is a distinguished senior fellow with the Center for Strategic and International Studies.

Dr. Hamburg is a graduate of Radcliffe College. She earned her MD from Harvard Medical School, and completed her training at the New York Hospital/Cornell University Medical Center. She completed research in neuroscience at Rockefeller University in New York from 1985 to 1986 and in neuropharmacology, the study of the action of drugs on the nervous system, at the National Institute of Mental Health in Bethesda, Maryland.

Attend the Clinical and Translational Research and Education Career Expo

The career expo is an exciting addition to the 2011 Clinical and Translational Research and Education Meeting. ACRT, AFMR, and SCTS are pleased to offer you this opportunity to meet with highly regarded institutions to network and discuss career opportunities. Please ask for location and time details at the Registration Desk.
# Program-at-a-Glance

## Wednesday, April 27, 2011

<table>
<thead>
<tr>
<th>Time</th>
<th>Event Description</th>
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<tbody>
<tr>
<td>5:00-6:00</td>
<td>5:00 pm - 7:00 pm Welcome Reception in conjunction with Clinical Research Foundation</td>
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<tr>
<td>6:00-7:00</td>
<td>7:00 pm - 9:00 pm Ancillary Meetings (see page 18)</td>
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<tr>
<td>7:00-8:00</td>
<td>7:00 pm - 9:30 pm Clinical Research Foundation - Awards Dinner (Optional)</td>
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<td>8:00-9:00</td>
<td>Optional for ACRT/SCTS/AFMR Meeting Attendees; Additional Fee Applies</td>
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<td>9:00-10:00</td>
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<tr>
<td>7:00-8:00</td>
<td>7:00 am - 8:00 am – Continental Breakfast</td>
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<tr>
<td>8:00-9:00</td>
<td>8:00 am - 9:30 am – Plenary Session: Translational Research: Innovations and Practical Strategies to Improve Health Margaret Hamburg, M.D., Commissioner, US Food and Drug Administration; Francis S. Collins, M.D., Ph.D., Director, National Institutes of Health; Donald Berwick, M.D., Administrator, Centers for Medicare &amp; Medicaid in conjunction with Clinical Research Foundation</td>
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<tr>
<td>9:00-10:00</td>
<td>9:30 am - 10:30 am – SCTS, ACRT, AFMR and APOR Awards Presentation</td>
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<td>10:00-11:00</td>
<td>10:00 am - 12:00 pm – Plenary Poster Session I and Coffee Break</td>
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<td>11:00-Noon</td>
<td>Noon - 1:15 pm – Concurrent Sessions (see pages 10-11)</td>
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<td>1:00-2:00</td>
<td>1:15 pm - 2:30 pm – Lunch on Own - Ancillary Meetings (see page 18)</td>
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<td>2:00-3:00</td>
<td>2:30 pm - 3:45 pm – Concurrent Sessions (see pages 12-13)</td>
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<td>3:00-4:00</td>
<td>3:45 pm - 4:15 pm – Coffee Break</td>
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<td>4:00-5:00</td>
<td>4:15 pm - 5:45 pm – Plenary Session: The Transformation of NIH: Where Are We and Where Are We Going in Translational Science? John Gallin, MD, Director, Clinical Center, NIH; Barbara M. Alving, M.D., Director, National Center for Research Resources, NIH; James M. Anderson, MD, PhD, Director, NIH Division of Program Coordination, Planning and Strategic Initiatives, NIH</td>
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<tr>
<td>5:00-6:00</td>
<td>5:45 pm - 7:15 pm – Poster Session II and Reception</td>
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<td>6:00-7:00</td>
<td>7:15 pm - 9:00 pm – Ancillary Meetings (see page 18)</td>
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### 2011 Clinical and Translational Research and Education Meeting
**ACRT/SCTS/AFMR Joint Annual Meeting**

**Friday, April 29, 2011**

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<th>Time</th>
<th>Event</th>
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<tr>
<td>7:00-8:00</td>
<td>7:00 am - 8:00 am — Continental Breakfast</td>
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<tr>
<td>8:00-9:00</td>
<td>8:00 am - 9:30 am — Concurrent Sessions (see pages 12-15)</td>
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<tr>
<td>9:00-10:00</td>
<td>9:30 am - 10:00 am — Coffee Break</td>
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<td>10:00-11:00</td>
<td>10:00 am - 11:30 am — Concurrent Sessions (see pages 16-17)</td>
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<tr>
<td>11:00-12:00</td>
<td>11:30 am - Noon — SCTS Annual Business Meeting</td>
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<td>Noon-1:00</td>
<td>Noon - 12:30 pm — ACRT Annual Business Meeting</td>
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<tr>
<td>1:00-2:00</td>
<td>12:30 pm - 2:30 pm Ancillary Meetings (see page 18)</td>
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- **Blue = Scholar/Trainee Sessions**
- **Green = Education/Mentorship Sessions**
- **Orange = Clinical and Translational Science Sessions**
- **Purple = Plenary Session**

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*American Federation for Medical Research*

*Development and improvement of research in medical research*
Schedule of Events

Wednesday, April 27, 2011

Registration Hours: 2:00 pm - 7:00 pm

5:00 pm - 7:00 pm
Welcome Reception
Location: Palladian Ballroom

7:00 pm - 9:30 pm
Clinical Research Foundation - Awards Dinner (Optional)
Ticket Required - See Clinical Research Foundation Registration Desk

Thursday, April 28, 2011

Registration Hours: 6:30 am - 7:00 pm

7:00 am - 8:00 am
Continental Breakfast
Location: Regency Ballroom/Gallery

8:00 am - 9:30 am
Plenary Session: Translational Research: Innovations and Practical Strategies to Improve Health
Location: Regency Ballroom

Keynote Presenters: Margaret Hamburg, MD, Commissioner, US Food and Drug Administration, Francis S. Collins, MD, PhD, Director, National Institutes of Health, Donald Berwick, MD, Administrator, Centers for Medicare & Medicaid

Moderators: Harry P. Selker, MD, MSPH, Dean, Tufts Clinical and Translational Science Institute, Executive Director, Institute for Clinical Research and Health Policy Studies, SCTS President, Garret FitzGerald, MD, Professor of Medicine and Pharmacology, McNeil Professor in Translational Medicine and Therapeutics, Associate Dean for Translational Research Chair Department of Pharmacology, Director, Institute for Translational Medicine

The goal of this opening plenary, jointly hosted by the Clinical Research Foundation, is to delineate the relationships between the NIH, FDA, and CMS and how they may interact to improve health. Each keynote presenter will provide an overview of “The Role of Biomedical Scientific Discovery” followed by a panel discussion.

9:30 am - 10:30 am
ACRT/AFMR/APOR/SCTS Awards Presentation
Location: Regency Ballroom
Join us as we honor leaders from the clinical and translational science community in the areas of research and education.

10:30 am - Noon
Plenary Poster Session I and Coffee Break
Poster Numbers P1-P111 will be presented during this time
Location: Ambassador Ballroom
Scholars will present the methodology, findings, and conclusions of their research. Participants will be exposed to a wide variety of clinical and translational investigations from a broad range of medical disciplines.
Refreshments will be served.

Noon - 1:15 pm
Concurrent Sessions

Understanding How the NIH Works: Guidance from Program Officers
Location: Regency Ballroom
Chair: Eugene Orringer, MD, University of North Carolina at Chapel Hill
Speakers: Nancy Desmond, PhD, National Institute of Mental Health, Judy Podskalny, PhD, National Institute of Diabetes and Digestive and Kidney Diseases, Steve Korn, PhD, National Institute of Neurological Disorders and Stroke, and Walter Schaffer, PhD, National Institutes of Health
A panel of NIH and AHRQ program officers will discuss their institutions, institutes, and the role of program officers in extramural grant support. Panel members will discuss opportunities for trainees to interact with program officers to facilitate career development. The research focus and areas of emphasis for extramural grants, and career development awards will be discussed.

REDCap: Planning, Collecting, and Managing Data for the Clinical and Translational Research Enterprise
Location: Empire Ballroom
Chair: Paul Harris, PhD, Vanderbilt University
Faculty: John Sharp, MSSA, PMP, FHIMSS, Cleveland Clinic, Michael Lin, Mayo Clinic, and Jihad Obeid, MD, Medical University of South Carolina
Learn all about REDCap (Research Electronic Data Capture) the software program designed to assist research teams with data planning, capture, storage, and dissemination. The program provides researchers an easy way to do the right thing when planning and implementing study data collection strategies. Hear discussion on: REDCap Project Overview – Supporting Data Capture, Management and Dissemination; Supporting Diverse Environments; REDCap Permutations - Supporting Diverse Study Designs; and Real-World Research Projects - Supporting Diverse Research Teams.
Leading causes of death were by infectious diseases. Today, the health, and treatment of infectious diseases. In 1900, the three largely from improvements in prenatal and neonatal care, public Research Institute, and Terri Fox Wetle, PhD, Brown University Faculty: S. Mitchell Harman, MD, PhD, Kronos Longevity San Antonio, South Texas Veterans Health Care System Chairs: Randy Strong, PhD, UT Health Science Center - San Antonio, South Texas Veterans Health Care System Longevity's Impact on Translational Science - The NIA Perspective Marie Bernard, MD, National Institute on Aging Longevity Medicine State of the Art Today and Opportunities for Translation S. Mitchell Harman, MD, PhD, Kronos Longevity Research Institute Implications of Life Extension for Healthcare and Public Policy Terri Fox Wetle, PhD, Brown University Developmental Origins of Adult Health and Disease Location: Senate Room Chairs: William Smoyer, MD, FASN, The Research Institute at Nationwide Children’s Hospital and Julie Inglefinger, MD, Mass General Hospital for Children Nephrology and Hypertension Transplant Center Faculty: Peter W. Nathanielsz, MD, PhD, ScD, FRCOG, The University of Texas Health Science Center at San Antonio, Anne-Monique Nuyt, MD, University of Montreal, Kent L. Thornburg, MD, Oregon Health & Science University, and Janet Rich Edwards, ScD, Brigham and Women’s Hospital This session presents pediatric clinical and translational research that focuses on the fetal origins of major adult diseases, including heart disease, obesity, and diabetes. Research of how early life events, including the prenatal period, can have a major impact on the subsequent health of individuals throughout their lives will be discussed. Three presentations focused on the fetal origins of the three of the most common human diseases (heart disease, obesity, and diabetes) and potential interventions will be discussed.

To What Extent Is the Fetus Fasticicus in Its Optimal Nutrition? (170) Peter W. Nathanielsz, MD, PhD, ScD, FRCOG, The University of Texas Health Science Center at San Antonio Vascular Consequences of Neonatal Oxygen Exposure (180) Anne-Monique Nuyt, MD, University of Montreal Cardiovascular Developmental Origins of Adult Health and Disease (###) Kent L. Thornburg, MD, Oregon Health & Science University Developmental Origins of Health and Disease: A Model of Translational Science (190) Janet Rich Edwards, ScD, Brigham and Women’s Hospital

(continued on next page)
12:30 pm - 2:00 pm
Grab lunch for purchase at our special lunch cart located near the registration desk

1:15 pm - 2:30 pm
Ancillary Meetings

1:30 pm - 2:30 pm
Concurrent Session

Writing a Successful Career Development Award: Tips and Pitfalls
Location: Palladian Ballroom

Chairs: Ellen W. Seely, MD, Brigham and Women’s Hospital and Marie Gelato, MD, PhD, Stony Brook University

Faculty: James Hyde, PhD, National Institute of Diabetes and Digestive and Kidney Diseases and Jonathan Williams, MD, MMSc, Harvard Medical School

Career development awards (also called K awards) provide an important step in the evolution to independent grant funding. This interactive workshop reviews the purpose of K awards, options for K award funding, and provides tips for success in your K application. You will receive advice from senior investigators, current K recipients, as well as from NIH to help you achieve success in your K application.

1:45 pm - 3:45 pm
Mock Study Sections - Pre-registration required
Location: Various, See Registration Desk for Assignments
Chair: David Schteingart, MD, Michigan Institute of Clinical and Health Research

Mentor Training Trial: A National CTSA Study
Location: Palladian Ballroom
Chair: Michael Fleming, MD, MPH, University of Wisconsin

Faculty: Christine Pfund, PhD, University of Wisconsin-Madison, Stephanie House, University of Wisconsin-Madison, Pamela Asquith, PhD, University of Wisconsin-Madison and Karin Silet, PhD, University of Wisconsin-Madison

This seminar presents the initial findings of a 16-site national mentor training trial led by a research team at the University of Wisconsin Madison Institute for Clinical Translational Research. A total of 285 mentor-mentee pairs across the sites were randomized into a control of experimental group. The session presents baseline data and the mentor training experience across the 16 sites. The post intervention interviews of the 285 mentor-mentees will be completed in the summer of 2011.

Creating Networks for Training in Health and Healthcare Disparities Research
Location: Congressional A
Chair: Kirsten Bibbins-Domingo, PhD, MD, San Francisco General Hospital

Faculty: Pamela Asquith, PhD, University of Wisconsin - Madison, Sergio Aguilar-Gaxiola, MD, PhD, University of California Davis, Estela Estape, MT, PhD, University of Puerto Rico, Magda A. Shaheen, MD, PhD, MS, MPH, Charles R. Drew University, Kathryn Pollenz, MPH, Harvard Medical School, Brenda Eakin, MS, University of Michigan, Lourdes Soto de Laurido, EdD, MPHE, University of Puerto Rico, and Alexander Quarshie, MD, Morehouse School of Medicine

Research in health and healthcare disparities is an important component of clinical and translational research. This session brings together leaders from across CTSAs and RCMIs who are actively engaged in developing networks of training programs in health and healthcare disparities. The panel discusses components of successful training programs in disparities research and challenges in the development of such programs, and also highlights current efforts in the development of networks across institutions engaged in training in disparities research.

Work supported by NIH Grants: University of Puerto Rico Medical Sciences Campus S21MD001830, R25 RR17589 and U54RR026139; Meharry Medical College: R25 RR17577; Morehouse School of Medicine: R25 RR17579; Charles Drew School of Medicine: R25 RR19488 and P20 RR022762; University of Hawaii at Manoa: R25 RR19321; University of California, Davis: UL1 RR24146; University of Wisconsin, Madison: UL1 RR25011

2:30 pm - 3:45 pm
Concurrent Sessions

Moving from K to R: Competing Successfully for Your Next Grant
Location: Regency Ballroom

Chairs: Charity Moore, PhD, University of Pittsburgh and Melissa Begg, ScD, Columbia University

Faculty: Jordan Karp, MD, University of Pittsburgh

Scholars will learn how to compete successfully for their next NIH grant application, including K awards or R-series grants and discuss specific strategies and examples and learn to avoid common mistakes. Examples of successful applications will also be shown and audience participation will be encouraged.
Health Care Reform: The Necessity of Translational Science
Location: Diplomat Ballroom
Chair: Eugene Rich, MD, Robert Wood Johnson Foundation
Faculty: Ann Bonham, PhD, UC Davis Center for Neuroscience, Lisa Rubenstein, MD, MSPH, VA Greater Los Angeles Medical Center and Hoangmai (Mai) Pham, MD, MPH, Johns Hopkins Bloomberg School of Public Health

This session summarizes the evidentiary questions posed by current health systems problems, reviews the types of scientific inquiry relevant to answering these questions, outlines the opportunities to support evidence-based approaches to health care reform, and summarizes barriers to success. The session then identifies next steps for evidence-based healthcare reform.

Obesity: What Are the Critical Issues, Where Is the Evidence Base, and How Do We Develop Solutions
Location: Empire Ballroom
Chairs: David Allison, PhD, University of Alabama at Birmingham and Richard L. Atkinson, MD, Virginia Commonwealth University
Faculty: Nikhil Dhurandhar, PhD, Louisiana State University and Giovanni Cizza, MD, PhD, National Institute of Diabetes and Digestive and Kidney Diseases, NIH

Examine the current status of knowledge about the causes of obesity, identify thoughts about new etiologies that have not been considered previously, discuss potential solutions, and identify research areas that will need to be addressed to understand this complex disease. Hear how infectious agents that have been shown to cause obesity and the implications for a portion of obesity being an infectious disease as well as how our environment affects body weight and body fat. Learn how these novel ideas of the causes of obesity fit into the whole picture, and where we should go from here in research and potential treatments.

Introduction: New Thoughts about the Etiology and Treatment of Obesity (200)
Richard L. Atkinson, MD, Virginia Commonwealth University

Microbes and Infectious Influences (210)
Nikhil Dhurandhar, PhD, Louisiana State University

Chronic Sleep Deprivation and Obesity: Two Co-incident Epidemics or Two Faces of the Same Medal? (220)
Giovanni Cizza, MD, PhD, National Institute of Diabetes and Digestive and Kidney Diseases, NIH

Putting It All Together (230)
David Allison, PhD, University of Alabama at Birmingham

Databases for Clinical Translational Research: Repurposing and Designing for Unanticipated Needs
Location: Congressional B
Chairs: Brad Pollock, MPH, PhD, UT Health Science Center San Antonio and Daniel Sullivan, MD, Duke University
Faculty: Eliot Siegel, MD, University of Maryland Medical Center, Christopher J. Lindsell, PhD, University of Cincinnati and Knut M. Wittkowski, PhD, DSc, Rockefeller University

The use of databases for clinical and translational research emphasizing database design considerations will be discussed. Imaging measures and 'imaging biomarkers' development and applications will be highlighted. Administrative healthcare databases for: tracking quality and volume; billing; health services planning; and public health surveillance will all be covered including selection of appropriate administrative databases, their flaws, strengths, and innovative uses.

Repurposing and Designing Imaging Databases for Unanticipated Needs (240)
Eliot Siegel, MD, University of Maryland Medical Center

Linking Healthcare Databases to Simply Answer Complex Questions (250)
Christopher J. Lindsell, PhD, University of Cincinnati

Acquisition, Use, and Reuse of Study Meta Data (260)
Knut M. Wittkowski, PhD, DSc, Rockefeller University

3:45 pm - 4:15 pm
Coffee Break

4:15 pm - 5:45 pm
Plenary Session: The Transformation of NIH: Where Are We and Where Are We Going in Translational Science?
Location: Regency Ballroom
Keynote Speakers: John Gallin, MD, Director, Clinical Center, NIH, Barbara M. Alving, MD, MACP, Director, National Center for Research Resources, NIH and James M. Anderson, MD, PhD, Director, Division of Program Coordination, Planning and Strategic Initiatives, NIH
Moderators: Robert Califf, MD, MACC, Vice Chancellor for Clinical Research and Director, Duke Translational Medicine Institute and Eric Orwoll, MD, Professor of Medicine, Director, Oregon Clinical and Translational Research Institute, Associate Dean for Research, School of Medicine, Associate Vice President for Research, Oregon Health & Science University

The goal of this plenary session is to describe planned changes within the represented NIH components and their efforts to improve health by working with (a) each other, (b) other branches of the Federal Government, and (c) the community. Each keynote speaker will provide an overview on what their Institute or Center envisions as necessary changes to facilitate improving the health of the public followed by a panel discussion.

(continued on next page)
Schedule of Events

5:45 pm - 7:15 pm
Plenary Poster Session II and Reception

Poster Numbers P112-P222 will be presented during this time
Location: Ambassador Ballroom
Scholars will present the methodology, findings, and conclusions of their research. Participants will be exposed to a wide variety of clinical and translational investigations from a broad range of medical disciplines. Refreshments will be served.

7:15 pm - 9:00 pm
Ancillary Meetings

Location: Various
Refer to the ancillary meetings on page 18.

Friday, April 29, 2011

Registration Hours.................................................. 6:30 am - 11:00 am

7:00 am - 8:00 am
Continental Breakfast

Location: Regency Ballroom

7:30 am - 9:30 am
Mock Study Sections - Pre-registration required

Location: Various, See Registration Desk for Assignments
Chair: David Schteingart, MD, Michigan Institute of Clinical and Health Research, University of Michigan
Scholars will review actual K23, R21 and R01 grants with faculty moderators to learn how grants are evaluated and discussed through the NIH peer review process.

8:00 am - 9:30 am
Concurrent Sessions

Tools for Meeting the NIH Responsible Conduct of Research (RCR) Requirements

Location: Regency Ballroom
Chair: Sara Vollmer, PhD, University of Alabama - Birmingham
Faculty: Stephanie Solomon, PhD, Saint Louis University, Catherine Striley, MSW, ACSW, LCSW, PhD, MPE, Washington University, Elizabeth Holmes, CAPT., USN (Ret.), PhD, ABPP, MSC, United States Naval Academy and James DuBois, PhD, DSc, Saint Louis University
Nationally experienced Responsible Conduct of Research (RCR) educators and resource developers will explain the new NIH requirements for teaching RCR, which include face-to-face training. Methods and curricula that have proved successful in meeting these requirements in different contexts are discussed. On-line resources will be presented, which offer useful advice.

What Core Competencies Should Every Translational Scientist Have?

Location: Empire Ballroom
Chair: Mary Anne McDonald, DrPH, MA, Duke University Medical Center
Faculty: Syed Ahmed, MD, MPH, DrPH, FAAFP, Medical College of Wisconsin, Beatrice Golov, MD, Albert Einstein College of Medicine and Wishwa N. Kapoor, MD, MPH, University of Pittsburgh
A key component of the Clinical and Translational Science Awards (CTSA) is the development of training and educational programs for translational scientists. The Education and Career Development Key Function Committee (KFC) of the National CTSA developed core competencies for 14 thematic areas. What are the core shared competencies that anyone who identifies themselves as a translational scientist should have? This session will address this question and serves as a forum for discussion with participation from those attending.

Best Practices in Community Engaged Research

Location: Congressional A
Chair: Charles Vukotich, MS, University of Pittsburgh
Faculty: Cynthia Morris, PhD, MPH, Oregon Health and Science University, Paul Targonski, MD, PhD, Mayo Clinic, Carolyn Jenkins, DrPH, APRN-BC, MS, RD, MSN, Medical University of South Carolina, Sam Stubbins, MD, MPH, Center for Public Health Practice
Schedule of Events

Community Engaged Research (CEnR) includes the community as an equal partner in the research process and provides for different methods for research that the community wants, and benefits the community. This panel provides a practice-based look at CEnR. It will inform on why CEnR is important, provide examples of success with lessons learned on how to be successful, how to do community engaged research, and provide insight on how their research may engage the community.

Research in Primary Care: The Oregon Rural Practice Based Research Network (270)
Cynthia Morris, PhD, MPH, Oregon Health and Science University

Coordinating Care at the Community/Clinic Interface: Community-Engaged Practice Based Research (280)
Paul Targonski, MD, PhD, Mayo Clinic

REACH U.S. South Eastern African American Center of Excellence and its Efforts to Decrease Diabetes-Related Health Disparities (290)
Carolyn Jenkins, DrPH, APRN-BC, MS, RD, MSN, Medical University of South Carolina

School Based Research and Practice Network (300)
Sam Stebbins, MD, MPH, Center for Public Health Practice

Efforts to Promote Translational Science Training for PhDs: An Initiative of the Howard Hughes Medical Institute

Location: Diplomat Ballroom
Chair: William Galey, PhD, Howard Hughes Medical Institute
Faculty: Fred Meyers, MD, MACP, University of California-Davis, Martha Cathcart, PhD, Case Western Reserve University and Anh-Chi Le, PhD, Howard Hughes Medical Office

The Howard Hughes Medical Institute (HHMI) established an institutional grant program in 2006 to help graduate programs create and implement curricula to train PhD scientists with an understanding of both medicine and pathobiology. This initiative, known as “Med into Grad,” provides institutional funds to integrate the learning of medicine and pathobiology into new or existing PhD graduate programs. The unique features and common elements of the programs supported over the years will be discussed by program directors and HHMI administrators.

Insert Title and Abstract # from ACRT
William Galey, PhD, Howard Hughes Medical Institute

Insert Title and Abstract # from ACRT
Fred Meyers, MD, MACP, University of California-Davis

Insert Title and Abstract # from ACRT
Martha Cathcart, PhD, Case Western Reserve University

Insert Title and Abstract # from ACRT
Anh-Chi Le, PhD, Howard Hughes Medical Office

Translational Development of Specimen and Imaging Biomarkers: Early Diagnosis vs. Over Diagnosis

Location: Palladian Ballroom
Chairs: Daniel Sullivan, MD, Duke University and Don McClain, MD, PhD, University of Utah Health Sciences Center
Faculty: Arun Rajan, MD, NCI/Medical Oncology Branch, NIH, Norman Foster, MD, University of Utah Health Sciences Center, Christine Berg, MD, National Cancer Institute and Brad Dickerson, MD, Massachusetts General Hospital

This session uses lung cancer and Alzheimer's disease as examples to illustrate how specimen and imaging biomarkers are developed, evaluated, and validated for use in either therapy development or clinical practice. Speakers will address the issues associated with testing biomarkers of risk (screening tests) for lung cancer, and the research questions that follow from the recently identified benefit of CT screening. Additionally, speakers will address the current status of Alzheimer's biomarkers research as a paradigm for biomarker work in other chronic diseases.

Specimen Biomarkers in Lung Cancer (310)
Arun Rajan, MD, NCI/Medical Oncology Branch, NIH

Molecular Brain Imaging in Clinical Research (311)
Norman Foster, MD, University of Utah Health Sciences Center

CT Screenings as a Biomarker of Risk for Lung Cancer (###)
Christine Berg, MD, National Cancer Institute

Imaging Biomarkers of Age-Related Neurodegenerative Diseases (315)
Brad Dickerson, MD, Massachusetts General Hospital

New Models for Drug Development

Location: Congressional B
Chairs: Kenneth Kaitin, PhD, Tufts Medical Center and Richard Whitley, MD, University of Alabama at Birmingham
Faculty: Leonard Sacks, MD, Office of Critical Path Programs

This session discusses the emergence of tomorrow's life-saving and life-extending drugs. New models of drug development are needed to ensure that newer and better medicines continue to be developed to treat a host of diseases for which inadequate or no treatments currently exist. This session explores current restructuring efforts within the commercial sector, the growth and impact of academic-industry partnerships, and the role of the Food and Drug Administration, through the Critical Path Initiative, in supporting new drug development.

Innovation Networks: A New Paradigm for Pharmaceutical Development (320)
Kenneth Kaitin, PhD, Tufts Medical Center

Public and Private Partnerships with Academic Medical Centers (330)
Richard Whitely, MD, University of Alabama at Birmingham

FDA’s Critical Path Initiative (340)
Leonard Sacks, MD, Office of Critical Path Programs

(continued on next page)
Foundation Opportunities in Basic, Translational, and Clinical Research Training

Location: Congressional A
Chair: Betsy Myers, PhD, Doris Duke Charitable Foundation
Faculty: Desmond Runyan, MD, DrPH, MPH, Social Medicine & Pediatrics and Nancy Sung, PhD, Community Engaged Research

This session examines three foundations that have programs for physician-scientists in early career stages with a focus on basic, translational, clinical, and health services research. The Career Award for Medical Scientists from the Burroughs Wellcome Fund supports physician-scientists who are in advanced postdoctoral/fellowship training, and the award extends into the early years of faculty service. The Clinical Scientist Development Award from the Doris Duke Charitable Foundation is an award for Instructors or Assistant Professors to facilitate the transition to independent clinical research careers. The Robert Wood Johnson Foundation Clinical Scholars program has fostered the development of physicians to be leaders in research areas such as problems of healthcare delivery and financing, clinical decision-making, biomedical ethics, medical history, and healthcare policy. During the session, the three programs will be described, including programmatic goals, eligibility, and selection criteria.

Opportunities for Research Career Development through the VA

Location: Congressional B
Chair: Theresa Gleason, PhD, United States of Department of Veteran Affairs
Faculty: Shira Maguen, PhD, University of California - San Francisco Medical School

The Department of Veterans Affairs (VA) Office of Research and Development has a rich research training history of clinician and non-clinician scientists interested in advancing knowledge for issues related to Veterans’ health. This session provides an opportunity to hear about the VA research career development and career path, especially for those interested in pursuing clinical research. Funding opportunities and real life examples will be presented.

VA Career Development Award: Transforming Clinical Care through Research (359)
Shira Maguen, PhD, University of California - San Francisco Medical School
**Comparative Effectiveness Research**

*Location: Palladian Ballroom*

*Chair:* Mark Helfand, MD, MPH, MS, Portland VA Medical Center

*Faculty:* Christopher Schmid, PhD, Tufts University School of Medicine; David Kent, MD, MSc, Tufts Medical Center; and Sean Tunis, MD, MSc, John Hopkins and Stanford University School of Medicine

A CTSA CER Methods Workgroup consisting of 10 members recently identified a set of 10 methodological research and development issues that were considered of highest priority to CTSA. The speakers participated in creating a paper entitled “A CTSA Agenda to Advance Methods for Comparative Effectiveness Research” that was endorsed by CTSA leadership in December 2010. In this session, they will highlight and discuss more details about this report and suggest collaborative approaches to meet these methodological needs.

**Can Pharmacogenetics Deliver on Personalized Health Care? Lessons Learned**

*Location: Empire Ballroom*

*Chairs:* Muin J. Khoury, MD, PhD, Centers for Disease Control and Tom Trikalinos, MD, Tufts Medical Center

*Faculty:* David Veenstra, PharmD, PhD, UW School of Pharmacy and Andrew Freedman, PhD, National Cancer Institute

Technological advances have allowed the rapid generation of genetic and genomic data, thereby presenting the opportunity to improve patient care and public health through numerous genomic applications. At the same time, translation of these data into knowledge and evidence-based action is severely lagging. Realizing the promise of genomics in treating and preventing disease, improving health, and reducing health disparities is the major challenge faced by comparative effectiveness researchers. Hear an introduction to translational research in genomic applications in practice and prevention, and outline what expectations are realistic. Then discuss current thinking on science- and infrastructure-based recommendations toward facilitating the discovery and validation of pharmacogenetic markers, and speeding their thoughtful translation and integration into clinical practice. Summarize approaches to evaluating and interpreting evidence on pharmacogenetic tests by virtue of applied example and use lessons learned from studying pharmacogenetic tests in non-cancer conditions using a wide spectrum of methodologies.

**The Promise, the Pitfalls, and the Policy Implications of Whole Genome Sequencing**

*Location: Diplomat Ballroom*

*Chair:* Brian D. Athey, PhD, University of Michigan Medical School

*Faculty:* Bruce R. Korf, MD, PhD, University of Alabama at Birmingham and Leslie Biesecker, MD, National Institutes of Health

Even with more than 100 genome-wide association studies on over than 40 common diseases and the identification of hundreds of risk-related genetic variants, identification of specific disease-risk genes has proven to be a daunting challenge. Learn how comprehensive analysis of well-characterized patients at the DNA sequence level using third-generation DNA sequencing machines holds the promise of reducing costs of sequencing a single human genome to less than $3,000. Learn the pitfalls of this “personalized medicine” paradigm. Reduction of costs, Medicare, and private insurers’ reimbursement of costs of pharmacogenetic testing; encouraging pharmaceutical companies to integrate “genetic biomarker” information into the design of early-stage clinical trials; and facilitating the development and implementation of diagnostics based on genetic information will be covered.

**Establishing the Data Infrastructures for “Omics” and Other Systems Biology Technologies (395)**

Brian D. Athey, PhD, University of Michigan Medical School

**Whole Genome Sequencing in Clinical Practice: Hopes and Challenge (400)**

Bruce R. Korf, MD, PhD, University of Alabama at Birmingham

**Massively Parallel Sequencing in Clinical Research: Hypothesis-Testing and Hypothesis-Generating Research Approaches (410)**

Leslie Biesecker, MD, National Institutes of Health

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**Schedule of Events**

11:30 am - Noon

SCTS Annual Business Meeting

*Location: Regency Ballroom*

Noon - 12:30 pm

ACRT Annual Business Meeting

*Location: Regency Ballroom*
Ancillary Meetings

Wednesday, April 27

2011 Biostatistics/Epidemiology/Research Design

Key Function Committee Face-to-Face Meeting – Closed, Separate Registration Required
8:00 am - 5:00 pm
Location: Empire Ballroom

Hill Day Training – Open, Pre-registration required
9:00 am - 1:00 pm
Location: Congressional A & B

Bringing Science to Life: The Interdisciplinary Advantage – Open
1:00 pm - 5:00 pm
Location: Congressional A & B

Key Function Committee Mentor Meeting – Open
6:30 pm - 8:30 pm
Location: Sales Conference Room

For Education Program Coordinators: Networking with your Peers – Open
7:00 pm - 9:00 pm
Location: Congressional B

Open Roundtable Discussion: Healthcare Reform & Clinical Effectiveness Research - Unintended Consequences – Open
7:00 pm - 9:00 pm
Location: Cabinet Room

NAB Welcome Reception – Closed
7:00 pm - 9:00 pm
Location: Congressional A

Association of Clinical and Translational Statisticians (ACTS) Dinner – Closed
7:30 pm - 10:00 pm
Location: Meet at the Registration Desk

Thursday, April 28

Bionutrition Educational Sessions in Translational Science – Open
12:45 pm - 1:45 pm
Location: Executive Room

ACRT Communications Committee – Closed
12:45 pm - 1:45 pm
Location: Sales Conference Room

Friday, April 29

Joint Advocacy Coalition Meeting – Open
7:00 am - 8:00 am
Location: Calvert Room

SCTS Business Meeting – Open
11:30 am - Noon
Location: Regency Ballroom

ACRT Business Meeting – Open
Noon - 12:30 pm
Location: Regency Ballroom

Getting Blood from a Turnip: Cost Recovery in the 21st Century – Open
12:30 pm - 2:30 pm
Location: Congressional A
Speaker Abstracts

BALANCE IN EXPERTISE: BUILDING NEW MODELS IN CLINICAL AND TRANSLATIONAL RESEARCH

100
NINR Funded Study and Health Disparities
Jemmott L 1
University of Pennsylvania, Philadelphia, PA, USA
Women of color, particularly African American women, are drastically affected by HIV/AIDS. To date, few STI/HIV prevention interventions have been designed for use with African American women in primary care settings. In a NINR funded nurse-led randomized controlled trial, "Sister to Sister," a 20-minute, one-on-one, skill-based HIV risk reduction intervention, demonstrated efficacy in reducing HIV risk-associated sexual behavior and the incidence of STDs among inner-city African American women in primary care settings at 12-months post intervention. Recently, CDC selected "Sister to Sister" to be replicated and evaluated for feasibility to integrate it as part of the routine care at three women’s health clinics in their Replication of Effective Projects. CDC also selected it to be translated into practice in their Dissemination of Evidence-Based Projects. The results demonstrated the feasibility of implementing the intervention in primary care clinical settings that provide services to women. Challenges and approaches for successfully integrating and translating this evidence-based project into clinical settings will be discussed.

INTEGRATING GENETICS INTO CLINICAL RESEARCH

110
Lyon DE 1
Virginia Commonwealth University, Richmond, VA, USA
OBJECTIVES/SPECIFIC AIMS: Integrating bench science into nursing research has the potential for promoting innovative translational research. METH- ODS/STUDY POPULATION: Our collaboration of nurse scientists and human geneticists resulted in a 5-year multiple PI, NIH-funded R01 designed to examine epigenetic and genetic factors related to symptom development and persistence in women receiving chemotherapy for breast cancer. This study will recruit 75 women with early-stage breast cancer prior to chemotherapy and follow them at 5 time points across a 2 year period to examine relationships among circulating markers of inflammation, epigenetic, and genetic measures, and symptom measures (cognitive impairment, depression, anxiety, pain, and sleep disturbances). RESULTS/ANTICIPATED RESULTS: This study will expand biobehavioral theory and research by integrating epigenetic measures (frequency and genome-wide location of methylation; expression of a histone methyltransferase, EZH2; and telomere attrition) with measures of inflammation and symptoms. Although this project was described by reviewers as potentially "transformational," differences in disciplinary perspective, expectations, and the costs of integrating genetic measures into clinical research present challenges in the development and implementation of this inter-disciplinary research. DISCUSSION/SIGNIFICANCE OF IMPACT: Challenges and approaches for successfully navigating the challenges of integrating basic science with nursing research will be discussed.

BUILDING COLLABORATIONS IN CHALLENGING SITES

120
Larson EL 1
Columbia University, New York, NY, USA
OBJECTIVES/SPECIFIC AIMS: 1. Discuss challenges of conducting research in a setting designed primarily to maintain security and in which research is not supported (maximum security prisons). 2. Describe difficulties in translating results of studies in relevant and meaningful ways to prison staff and inmates.

METHODS/STUDY POPULATION: A 5-year NIH-funded R01 designed to determine the prevalence and transmission dynamics of methicillin-resistant Staphylococcus aureus in New York State maximum-security prisons.

RESULTS/ANTICIPATED RESULTS: Several major challenges include conducting research in a setting designed primarily to maintain security and in which research is not supported, developing research collaborators within the correctional system and supporting a highly interdisciplinary team, clarifying roles and responsibilities within the research team and correctional staff, supporting rights and confidentiality of prisoners who volunteer (or not) for research, and translating results of studies in relevant and meaningful ways to prison staff and inmates.

DISCUSSION/SIGNIFICANCE OF IMPACT: Approaches for successfully dealing with these challenges will be discussed.

LONGEVITY’S IMPACT ON TRANSLATIONAL SCIENCE

130
PHARMACOLOGICAL INTERVENTION IN THE AGING PROCESS
Strong R 1
University of Texas Health Science Center at San Antonio, San Antonio, TX, USA
Numerous preclinical studies have been reported showing that extending lifespan and slowing aging retards and/or prevents many age-related diseases. Thus, a consensus is developing around the concept of aging as a therapeutic target. The National Institute on Aging Interventions Testing Program (NIA-ITP) is a multi-institutional study investigating treatments with the potential to extend lifespan and healthspan in mice. Successful interventions may then be proposed for clinical evaluation. We reported in the journal Nature in July 2009 that rapamycin (Sirolimus; Rapamune), an inhibitor of the mTORC1 signaling pathway, extends median and maximal lifespan of genetically heterogeneous mice chosen to avoid genotype-specific effects on disease susceptibility. This is the first treatment other than dietary restriction or genetic manipulation to reproducibly increase both median and maximal survival in mammals. Microencapsulated rapamycin at a concentration of 14 ppm (≈2 mg/kg/day) was fed to both male and female mice in their chow beginning at 60 days of age, equivalent to 60 years of age in humans (Nature, 2009). On the basis of the expected lifespan remaining, rapamycin treatment led to a 28% increase in male maximal lifespan and a 38% increase in female maximal lifespan. The effect was replicated at the three NIA Interventions Testing Centers. In a separate study, rapamycin fed to mice beginning at 270 days of age also increased longevity (J. Gerontol., 2011). Significant increases in median and maximum lifespan were observed in the data pooled from the three sites for both males and females. A secondary analysis revealed significant increases in median and maximum survival at each test site. The overall pattern of end-of-life pathology was not significantly different between rapamycin treated and control mice. However, the rapamycin fed mice died later of the same diseases. In two separate studies, the same dose of rapamycin that increased lifespan also prevented the decline in cognitive function and reduced pathology in two different transgenic models of Alzheimer’s disease. These findings have implications for the further development of interventions that are aimed at extending lifespan and slowing or preventing age-related diseases in humans.

LONGEVITY’S IMPACT ON TRANSLATIONAL SCIENCE: THE NIA PERSPECTIVE

140
Bernard M
National Institute on Aging, NIH, Bethesda, MD, USA
During this decade, for the first time in global history, there will be more individuals older than 65 than younger than 5. This is due to growing longevity world-wide. The National Institute on Aging is the lead federal agency supporting research in aging and longevity. It was established in 1974 to support and conduct genetic, biological, clinical, behavioral, social, and economic research related to the aging process, diseases and conditions associated with aging, and other special problems and needs of older Americans. Dr Bernard, NIA’s Deputy Director, will highlight emerging basic, neuroscience, behavioral, and clinical research that contributes to a better understanding of longevity. Discoveries that have been translated or are on the verge of translation will be featured.

(continued on next page)
that “You are what your mother ate.” Developmental programming is defined as a universal process in metazoa, characterized by progressive deterioration in structure and function with decreases in fecundity, impaired ability to repair cell and tissue damage and restore homeostasis, and eventually disease and death of the organism. Slowing the aging process would be a potent strategy for reducing human disease and disability. Although biological aging has been viewed as a concomitant of entropy, with inevitable gradual disorganization of vital cellular components, evidence has accumulated over the last 30 years that lifespan is genetically determined, varies tremendously between species, and is plastic even within species. Investigations suggest a variety of processes contribute to the aging process including: oxidative stress, telomere shortening, stem cell depletion and/or inactivation, accumulation of advanced glycation end products and protein crosslinks, impaired protein degradation (proteosome dysfunction), chronic inflammation, altered levels of various hormones (IGF-1, growth hormone, insulin, sex steroids) cytokines (IL-6, TGF, PDGF, VEGFs), chronic inflammation/immune senescence, and insulin resistance. These factors interact with one another on a number of levels. Recent evidence regarding the roles of selected factors will be reviewed. Each presents a potential opportunity for translational intervention.

Recent evidence regarding the roles of selected factors will be reviewed. Each presents a potential opportunity for translational intervention.

**150 LONGEVITY MEDICINE STATE OF THE ART TODAY AND OPPORTUNITIES FOR TRANSLATION**

**Harman SM**

1Kronos Longevity Research Institute, Phoenix, AZ, USA; 2University of Arizona College of Medicine, Phoenix, AZ, USA

Aging is a universal process in metazoa, characterized by progressive deterioration in structure and function with decreases in fecundity, impaired ability to repair cell and tissue damage and restore homeostasis, and eventually disease and death of the organism. Slowing the aging process would be a potent strategy for reducing human disease and disability. Although biological aging has been viewed as a concomitant of entropy, with inevitable gradual disorganization of vital cellular components, evidence has accumulated over the last 30 years that lifespan is genetically determined, varies tremendously between species, and is plastic even within species. Investigations suggest a variety of processes contribute to the aging process including: oxidative stress, telomere shortening, stem cell depletion and/or inactivation, accumulation of advanced glycation end products and protein crosslinks, impaired protein degradation (proteosome dysfunction), chronic inflammation, altered levels of various hormones (IGF-1, growth hormone, insulin, sex steroids) cytokines (IL-6, TGF, PDGF, VEGFs), chronic inflammation/immune senescence, and insulin resistance. These factors interact with one another on a number of levels. Recent evidence regarding the roles of selected factors will be reviewed. Each presents a potential opportunity for translational intervention.

**160 IMPLICATIONS OF LIFE EXTENSION FOR HEALTH CARE AND PUBLIC POLICY**

**Wetle TF**

1Brown University, Providence, RI, USA

During the last century, Americans gained 30 years in average life expectancy. While this sea change in population demographics has been described as a “silver tsunami,” it has resulted in longer and healthier lives for millions of individuals. It also has had substantial impact on healthcare utilization and costs of care, as well as on social institutions. It is estimated that 25 years of that 30-year gain is attributable to public health advances including: assurance of clean water, prevention of foodborne illnesses, vaccination against infectious diseases and reduction of smoking. More recently, efforts to prevent and improve management of chronic disease have had some success. While these efforts have increased average life expectancy, attention has now turned to efforts to actually extend the life span, through unlocking the secrets of the biology of aging. The genes associated with 30 to 200% increases in life span in animal models, ally extend the life span, through unlocking the secrets of the biology of aging.

### DEVELOPMENTAL ORIGINS OF ADULT HEALTH AND DISEASE

**170 TO WHAT EXTENT IS THE FETUS FASTIDIOUS IN ITS ORIGINAL NUTRITION?**

**Nathanielsz P**

1The University of Texas Health Science Center at San Antonio, San Antonio, TX, USA

Good maternal nutrition is central to optimal fetal development. It is a truism that “You are what your mother ate.” Developmental programming is defined as the response to a specific challenge during a critical developmental time window that alters development with persistent effects on phenotype. The post-natal mammalian organism has great homeostatic capability. For example, renal function is adjusted to respond to intake within a broad range. Whether the fetus has the same adaptive capabilities is a question that greatly impacts the health of the individual in particular and society in general that adjusts the developing fetus can face either the challenge of restricted or over-nutrition. The first occurs in the setting of teenage pregnancy, poor socioeconomic conditions, maternal, and placental vascular disease. The second is now a major problem associated with the increase in obesity in women of reproductive age. This presentation will consider both sub-optimal macro- and micronutrient delivery. The fetus must integrate availability with need and respond to competing requirements such as gluconeogenesis and protein breakdown in a setting where its ultimate goal is optimal growth. The example in this research is of the methionine cycle which requires several vitamins - folate, and B12 as well as substrates such as amino acids and choline. The methionine cycle supports synthesis of key elements of all tissues as well as regulating DNA at several points such as methylation. Some deficits faced are primarily intake deficits. Others are the consequence of associated pathologies such as poor placental transport.

**180 VASCULAR CONSEQUENCES OF NEONATAL OXYGEN EXPOSURE**

**Nuyt A**

1University of Montreal, Montreal, QC, Canada

Preterm infants, who represent 8% of newborns, have diminished antioxidant defences and are exposed to high oxygen (O2) levels both in the intensive care and as compared to the intrauterine environment leading to short vascular complications such as retinopathy of prematurity and bronchopulmonary dysplasia. However, the long-term vascular consequences of neonatal hyperoxic stress are not well known. Sprague-Dawley pups were kept with their mother in 80% O2 or room air (RA) from day 3 to 10 (P10) of life. At P10, tibialis anterior muscles were sampled to study microvascular density. At 4 weeks and in adults, blood pressure (tail cuff), vascular reactivity (ex vivo), and microvascular density were studied. Elastin fibers and collagen density in relation to media area were evaluated (aorta) at 4 weeks and arterial rigidity (aorta pulse wave velocity) in adults. At 4 weeks of age, no difference was observed in blood pressure and vascular reactivity but microvascular rarefaction and decreased aorta elastin-collagen ratio were present in O2 vs. RA. Adult O2 vs. RA rats presented increased systolic and diastolic blood pressures; increased pulse wave velocity; vascular dysfunction (increased reactivity to AngII, impaired endothelium-mediated vasodilatation); increased vascular reactive oxygen species production; decreased microvascular density. Neonatal hyperoxic stress leads to microvascular rarefaction at a major site of peripheral resistance and a lower percentage of elastin fibers in media of aorta. These processes are established before elevation of blood pressure and vascular dysfunction observed in adult animals and could therefore participate in the increased blood pressure and arterial stiffness observed later in life. These results support the hypothesis of developmental programming of adult cardiovascular diseases by neonatal/perinatal oxidative stress.

**190 DEVELOPMENTAL ORIGINS OF HEALTH AND DISEASE: A MODEL OF TRANSLATIONAL SCIENCE**

**Rich Edwards J**

1Brigham and Women’s Hospital, Boston, MA, USA

The past decades have seen an explosion in research on the ‘fetal origins’ or ‘developmental origins’ of health and disease, also known as ‘the Barker hypothesis’. Early observations that geographic regions with low mean birth weight also suffered from high adult mortality have inspired a myriad of epidemiologic study designs and preclinical experiments. The cross-talk between disciplines has fostered innovative approaches, and the field has developed into a mutual exercise of ‘triangulation’ on the puzzling question of whether early life environment can ‘program’ human disease risk several decades later. The case of utero influences on the risk of type 2 diabetes will be explored as a model of translational science.
OBESITY: WHAT ARE THE CRITICAL ISSUES, WHERE IS THE EVIDENCE BASE AND HOW DO WE DEVELOP SOLUTIONS

200 INTRODUCTION: NEW THOUGHTS ABOUT THE ETIOLOGY AND TREATMENT OF OBESITY

Atkinson R1
1Virginia Commonwealth University, Richmond, VA, USA

Obesity has dramatically increased since 1980 in most countries of the world. Previously it was thought by behavioral scientists that most obesity could be explained by poor choices by obese people, specifically in selecting an inappropriate diet and by failing to perform sufficient physical activity. Physiological scientists felt most obesity could be explained by genetic differences in obese people. The rapid increase of obesity in countries highly diverse in amount and types of food and physical activity belie both previously accepted explanations for obesity and suggest that other factors, by necessity mainly environmental, must be involved. In recent years there have been a number of novel studies that illustrate that obesity is a highly complex disease that has multiple etiologies. Unfortunately the treatment of obesity continues to be focused on outdated concepts that adjustments in the “Big Two” of diet and exercise will be effective in producing weight loss, or failing that, in improving health. The long-term success rate of diet, exercise, and behavior modification for weight loss is less than 5%. Since obesity is a lifelong, chronic disease, it is apparent that new thinking about the etiology and treatment of obesity must occur. This symposium will discuss some of the more novel potential etiologies of obesity, including obesity as an infectious disease and obesity due to changes in sleep patterns and exposure to light. Dr. Allison will summarize these explanations and cover some of the other etiologies of obesity that require closer examination. Treatment is not a focus of this symposium, but the discussion will illustrate that markedly different types of treatment are likely to be needed in the future.

210 MICROBES AND INFECTIOUS INFLUENCES

Dhurandhar N1
1Louisiana State University, Baton Rouge, LA, USA

OBJECTIVES/SPECIFIC AIMS: Obesity has a multifactorial etiology. Yet, conventionally, its treatment is focused on lifestyle modification, which tends to treat the symptom, and not necessarily the cause. At the population level, conventional approaches are inadequate to effectively reduce obesity and sustain weight loss. METHODS/STUDY POPULATION: Instead, cause-specific treatment approaches may be more effective, which would require a comprehensive understanding of various endogenous and exogenous factors that contribute to obesity. Studies over the past three decades have reported several microbes including bacteria, viruses, parasites and prions, which increase adiposity in various animal models. Some of these microbes also show significant association with human obesity. Among the adipogenic microbes, human adenovirus Ad36 is extensively studied in animal models, humans and cells and tissues. RESULTS/ANTICIPATED RESULTS: While the crucial question - whether microbes contribute to human obesity is not yet resolved, Ad36 research does provide a template to determine the role of other candidate microbes in human obesity. DISCUSSION/SIGNIFICANCE OF IMPACT: A long-term goal of this research would be to identify adipogenic microbes relevant to human obesity and to develop vaccines to prevent the sub-type of obesity induced by such microbes.

220 CHRONIC SLEEP DEPRIVATION AND OBESITY: TWO CO-INCIDENTAL EPIDEMICS OR TWO FACES OF THE SAME MEDAL?

Caiza G1
1National Institute of Diabetes and Digestive and Kidney Diseases/CEB/NIH, Bethesda, MD, USA

In parallel with the obesity epidemic a secular trend towards chronic sleep deprivation has been reported. Self-reported sleep duration has fallen from 9-10 hours in early 1900s to 6-7 hours today. In children and teen-agers, who notoriously need more sleep the sleep deprivation is more severe. Epidemiological studies have reported, mostly in a cross-sectional fashion an association between sleeping less and gaining weight over time. Well-controlled studies of acute and severe sleep deprivation conducted in controlled experimental conditions have demonstrated that a few days of sleep deprivation may induce insulin resistance in lean, healthy individuals. Other endocrine changes induced by acute sleep deprivation include hypercortisolism, decreased GH secretion, cytokine release, and as most recently reported, increases in ghrelin and decrease in leptin that together may induce increased appetite. A direct causal link has not been demonstrated yet. At the NIH Clinical Center we are conducting a controlled, randomized study of sleep extension in obese men and women chronically sleep deprived (sleeping on average less than 6 ½ hours as assessed by actigraphy over a 2 week time period. The main goals of the studies are to see: a) whether sleep extension can be achieved in a population of obese individuals in a non-pharmacological fashion; b) to see whether sleep extension may induce weight loss. Preliminary results from this study will be presented.

230 PUTTING IT ALL TOGETHER

Allison D1
1University of Alabama at Birmingham, Birmingham, AL, USA

This talk will comment on the prior talks and draw connections among them. In addition, connections between the factors of sleep and microbial influences on obesity will be discussed as they relate to other putative causes and the evidence for these other causes briefly mentioned. Issues of evidence will be brought forth. Finally, ways in which mindfulness of these putative causes may be brought to bear on developing and evaluating treatment and prevention strategies will be discussed.

DATABASES FOR CLINICAL TRANSLATIONAL RESEARCH: REPURPOSING AND DESIGNING FOR UNANTICIPATED NEEDS

Siegel E1
1University of Maryland Medical Center, Baltimore, MD, USA

OBJECTIVES/SPECIFIC AIMS: 1. The various ways in which image databases can be repurposed for stakeholders such as the research, vendor, educational, and clinical communities. 2. Challenges associated with the design of imaging databases for unanticipated needs including discovery of the data, adherence to standards, variability in acquisition parameters and ways of specifying those parameters. 3. Currently available databases. 4. The National Biomedical Imaging Archive METHODS/STUDY POPULATION: The presentation will present multiple imaging databases that are available to the public and will focus on the NBIA, which represents a combination of free and open source software and a Federated group of databases with non-oncology images as well as those related to cancer. RESULTS/ANTICIPATED RESULTS: The NBIA has been utilized as a repository for multiple databases that have been repurposed such as a subset of the glioblastoma MRI examinations used in the Cancer Genome Project, the LIDC and RIDER studies of variability in defining and measuring lung nodules on CT, a Virtual Colonoscopy database for software development and education, and many others. We have learned many lessons, including the critical importance of curation, of making the data easy to discover and download, and of the creation of standards for defining the contents of the database and its elements, security, and performance of the database. DISCUSSION/SIGNIFICANCE OF IMPACT: Our experience has demonstrated tremendous value and potential associated with the sharing and repurposing of imaging databases and very high utilization and impact. Challenges include the lack of a general library of these databases, lack of use of a general standard for Annotation and Image Mark-up, and issues related to curation and security. Based on our experience, these can be successfully addressed resulting in high relevance and value for the various stakeholders.

Speaker Abstracts (continued on next page)
WEB-BASED USER INTERFACE FOR CLINICAL RESEARCH ON DATABASE ACQUISITION, USE, AND REUSE OF STUDY META DATA
Witkowski KM
1Rockefeller University, New York, NY, USA

OBJECTIVES/SPECIFIC AIMS: As more clinical/translation data is being collected and stored, the potential reuse increases. To turn data into information, however, knowledge about the data (meta data) is needed. What are the characteristics of the subjects (or patients) involved? What happened to the subjects before the data was collected? How are the variables to be interpreted? Hence, for stored data to be useful when the original investigators are not directly available, the meta data required for anticipated uses needs to be defined and then entered. METHODS/STUDY POPULATION: As in the Open Systems Interconnection (OSI) model, meta data for (re)analysis of clinical or epidemiological studies can be organized as layers. Each layer describes layers below it. The bottom layer is the Access Layer. The Access Layer describes how to access programs and data. DESIGN knowledge specifies the study design, the MANNELD knowledge the types of variables. The DOMAINT knowledge allows variables to be imported from ontologies such as OCRE (Ontology for Clinical Research). RESULTS/ANTICIPATED RESULTS: We present a Web-based user interface, where a study description can be "pulled together" from ontologies or existing descriptions of similar studies. The proposed scheme suffices for all conceivable studies and a wide range of statistical methods, yet the graphical user interface minimizes the time required to enter meta data. DISCUSSION/SIGNIFICANCE OF IMPACT: As with all "knowledge based" systems, knowledge acquisition is the bottle neck. As an alternative approach for estimating undiagnosed disease prevalence would be to implement some form of prospective screening program, which would likely be time and resource intensive. Despite the strengths, however, there are weaknesses that can limit the interpretation of results. How to select appropriate administrative databases, how to review their flaws and strengths, and other innovative uses will be discussed.

COORDINATING CARE AT THE COMMUNITY/CLINIC INTERFACE: COMMUNITY-ENGAGED PRACTICE BASED RESEARCH
Targonski P, Lawson C, Gunderson J, Caldwell C, Schrader L
1Mayo Clinic, Rochester, MN, USA; 2Intercultural Mutual Assistance Association, Rochester, MN, USA

METHODS/STUDY POPULATION: Practice-based research is an inquiry into healthcare practice to improve care to patients, populations, and communities. We present a collaboration on the integration of community health workers (CHWs) in the care of inpatients as an example of community-engaged practice based research. The impetus for the project came through a request to the clinic for evaluative assistance from a community organization (CBO) employing CHWs, and recognition by the clinic of disparities in the delivery of care to clients served by that CBO. A shared vision and agreement on project responsibilities was established. Extramural funding was obtained for a community-based trial of a transcultural medical home aligning needs of the CBO, its clients, existing standards of care, and conventional study design. Substantial effort was made to ensure human subject protection, regulatory compliance, and the use of collaborative community engagement methods. The impact of CHW intervention on preventive service receipt and chronic disease management among diverse populations was examined. RESULTS/ANTICIPATED RESULTS: Early results suggest the mechanism by which referrals are made and how the CHW is engaged as a healthcare team member dramatically impact the ability for the CHW to effect change in preventive service receipt and chronic care management. Indirect benefits of the research include capacity building for collaboration, evaluation and community engagement, program support, advancement of models consistent with medical home expectations, and facilitation of self-efficacy in diverse patients/clients. DISCUSSION/SIGNIFICANCE OF IMPACT: Practice-based research, with its placement in the community and emphasis on directly improving care, provides a fertile environment to conduct community-engaged research.

REACH US SOUTHEASTERN AFRICAN AMERICAN CENTER OF EXCELLENCE AND ITS EFFORTS TO DECREASE DIABETES-RELATED HEALTH DISPARITIES
Jenkins C
1Medical University of South Carolina, Charleston, SC, USA

In response to the Centers for Disease Control and Prevention's (CDC) effort to decrease health-related disparities in racial and ethnic groups across the U.S., the Medical University of South Carolina College of Nursing and the Diabetes Initiative of South Carolina formed a Coalition composed of diabetes researchers, community interventionists, public health leaders, community organizations, and grassroots neighborhood leadership. The Coalition focused on assessing disparities, developing, implementing, evaluating, and continuing sustained community outreach (rural and one urban) for African Americans at risk and with diabetes. The Coalition received the designation of Center of Excellence (CEED) in 2007 and has since spread delivery and to reduce rural health disparities. It is one of only six practice-based research networks in the U.S. with a rural focus, and is the only all-rural network. The core, located at Oregon Health & Science University, includes an administrative and research staff, which includes practice enhancement research coordinators (PERCs), regional research associates who travel to clinics and maintain relationships with member clinics. ORPRN membership includes a statewide network of 161 clinicians and 49 primary care practices located in 37 rural communities throughout Oregon serving > 235,000 patients. The network is primarily comprised of family physicians with a 66%/34% mix of physician and non-physician clinicians (e.g. nurse practitioners and physician assistants). The practice sites reflect the geographic, demographic, and practice organization diversity in rural Oregon and are also representative of health access factors faced by organizations providing healthcare in rural settings. ORPRNs research and quality improvement projects in clinics and their surrounding communities has included studies of practice management and change; screening and management of common problems in primary care; patient safety; and assessment and improvement of practice quality. Working with a practice-based research network can provide a valuable resource for trainees interested in community-based research, implementation and dissemination research, practice change, as well as in facilitating recruiting patients not usually accessible in an academic medical center.
across the southeastern U.S. with 12 active coalitions. Diabetes is the leading cause of amputation of the lower limbs. Yet, half of these amputations might be prevented through simple but effective foot care practices. This presenta-
tion will describe the progress made across approximately 10 years, as well as discuss the county-wide reductions of lower extremity amputations (LEAs), and other diabetes-related challenges in African Americans. The Coalition’s community action plan, interventions, and outcomes are based on an expanded Chronic Care Model that spawned changes in policies, health and education systems, and other community systems for people with diabetes and their sup-
port systems. This will focus on lessons learned and application of principles.

300 SCHOOL BASED RESEARCH AND PRACTICE NETWORK
Stebbins S1
1Center for Public Health Practice, Pittsburgh, PA, USA
The University of Pittsburgh School Based Research and Practice Network (“Network”) was established in July 2008 and brings together research inves-
tigators and public, private, and parochial schools for grades K-12, with the purpose of creating more community-based research in schools and to improve the school environment through outreach and education. Initially, the Network met with 42 of 44 school districts in Allegheny County, PA (1.2 million people) to establish communication and identify research interests and priorities. Next, the Network created training for academic researchers so they could better understand the advantages and pitfalls of doing research with schools, and more than 100 have completed the seminar. Subsequently, the Network facilitated the placement of research activities in interested schools, which now include 23 investigators and 7 research projects in over 100 public and private schools. This presentation will detail the formation of the Network, the results of the school research inventory in Allegheny County, and process by which investigators and schools are “matched” and the process facilitated, and discuss ways in which research results can be returned to the schools to allow for improvements in practice.

310 SPECIMEN BIOMARKERS IN LUNG CANCER
Rajan A1
1National Cancer Institute, Medical Oncology Branch, NIH, Bethesda, MD, USA
Lung cancer is responsible for the largest number of deaths related to cancer in men and women in the United States. The majority of patients present with metastatic disease at diagnosis. In light of the poor prognosis associated with advanced lung cancer and with the advent of targeted therapy, it is imperative to develop prognostic and predictive biomarkers that can help in early diagno-
sis and for choosing appropriate therapy. Gene expression profiling using tissue microarrays or quantitative reverse-transcriptase polymerase chain reaction-based techniques is being developed to aid in diagnosis and to provide
prognostic information. Validation of these genomic models is a major issue that needs to be resolved before these gene signatures can be widely adopted in clinical practice. Lung cancer demonstrates a significant degree of molecular heterogeneity. Activating mutations in the epidermal growth factor receptor (EGFR), PI3K, BRAF, and KRAS genes are identifiable in approximately 40% of non-small-cell lung cancers (NSCLCs). Rarer oncogene mutations reported in less than 5% of lung cancers include mutations in ERBB2, ERBB4, MET, MEK, AKT, FGFR1-4, and PTEN, among others. A fusion gene, EML4/ALK has been reported in about 6% to 13% of patients with NSCLC. Mutations in RB1, TP53, PTEN, EGFR, PIK3CA, and BCL-2 have been reported in small cell lung cancer. Some of these genetic aberrations can be targeted with newly developed drugs and can thus influence patient management and hopefully improve outcomes. This is illustrated by the impressive response rates to treatment with erlotinib and crizotinib in patients with EGFR-sensitizing mutations and ALK translocations respectively. Based on this knowledge, efforts to conduct molecular profiling of lung tumors and treat patients with appropriate targeted therapy are currently ongoing.

311 MOLECULAR BRAIN IMAGING IN CLINICAL RESEARCH
Foster NL1
1University of Utah, Health Sciences Center, Salt Lake City, UT, USA
Molecular imaging is used to probe the anatomy of brain biochemistry. Scans reflect the distribution of a tracer that participates in a biochemical reaction, interacts with an enzyme or transporter, occupies a cellular receptor, or binds a cellular or extracellular protein. Single photon emission computed tomography (SPECT) is based upon gamma-emitters with relatively long half-life. Positron emission tomography (PET) uses positron-emitting isotopes that are more biologically relevant and has inherently better resolution. These techniques are technically challenging and good quality control is essential. On the other hand, these techniques can be very specific and sensitive. Although many tracers have been developed, only a few are adequately validated for use in research, and fewer still have routine clinical application. Nevertheless, significant advances have occurred recently and there is great future promise. 18F-FDG provides a quantitative measure of synaptic function that are useful for explanatory research and in clinical trials. Innovative image analysis method-
ods allow statistical comparison of groups and individual subject analyses that can be used in personalized medical care. PET imaging in dementing diseases illustrates how molecular imaging can provide unique insights into the relation-
ship between clinical symptoms and pathology and drug therapeutics. Tracers examining the integrity of dopaminergic neurons and the presence of abeta amyloid fibrillary plaques illustrate how new methods provide more precise answers to old problems but also raise new questions. Validating diagnostic imaging biomarkers requires pragmatic clinical trials, which are only now getting underway. Innovative study designs can allow molecular imaging to aid in the investigation of normal brain function and neurological diseases and hasten the development of new drug treatments.

315 IMAGING BIOMARKERS OF AGE-RELATED NEURODEGENERATIVE DISEASES
Dickerson B1
1Massachusetts General Hospital, Boston, MA, USA
Imaging biomarkers are attaining growing prominence in a variety of diseases as measures that are useful in diagnosis, prognostication, monitoring, or as outcome measures in clinical research and trials of novel therapeutics. In this session, MRI biomarkers in Alzheimer’s disease and related disorders will be reviewed. New imaging techniques and computational tools are making these measures more efficient to obtain in a standardized fashion, and also are providing the promise of a variety of novel types of measures. Despite the fact that such measures have become well-established in the research community, many challenges are still faced in considering how they should be used in clinical practice, clinical trials, and as surrogate outcome measures in trials of new treatments.

NEW MODELS FOR DRUG DEVELOPMENT
320 INNOVATION NETWORKS: A NEW PARADIGM FOR PHARMACEUTICAL DEVELOPMENT
Kaitin K1
1Tufts Medical Center, Boston, MA, USA
The research-based drug industry is the source of many of the pharmaceutical and biopharmaceutical medicines in use today. However, the industry is cur-
rently being buffeted by a host of economic, regulatory, legal, and competitive pressures that are forcing many companies to re-evaluate and restructure their R&D processes. A major shift within the commercial sector is the transforma-
tion from fully-integrated pharmaceutical companies (HiPCos) to a network model that encompasses all the major stakeholders in drug development, including large and small pharmaceutical and biotechnology companies, academic research institutions, patient groups, public-private-partnerships, and contract research organizations. This presentation will examine the current landscape for pharmaceutical development; review new drug development metrics, and assess the shift to innovation networks.

(continued on next page)
Speaker Abstracts

**PUBLIC AND PRIVATE PARTNERSHIPS WITH ACADEMIC MEDICAL CENTERS**  
Whitley R¹, Everts M¹

¹University of Alabama at Birmingham, Birmingham, AL, USA

**OBJECTIVES/SPECIFIC AIMS:** Historically, drug discovery at academic institutions has been limited. More recently, universities have recognized that drug discovery can be an integral part of their mission. However, many academic institutions do not have the full complement of requisite programs that allow for the success of drug discovery and development. Herein, public/private partnerships in drug discovery can play a meaningful role. This review will focus on the Alabama Drug Discovery Alliance (ADDA), a collaboration between the University of Alabama at Birmingham (UAB) and Southern Research Institute (SR). METHODS/STUDY POPULATION: The alliance is designed to support the discovery and development of therapeutic molecules that address unmet medical needs. The ADDA builds on the expertise present at both institutions and has the dedicated commitment of their intellectual property offices. Following a financial commitment from UAB, solicitation of molecular targets for the development of high-throughput screens (HTS) that would ultimately lead to targeted molecules for medicinal chemistry was established. Two RFAs are issued annually with the award of funding to 4-6 investigators. RESULTS/ANTICIPATED RESULTS: The ADDA project manager establishes teams with multidisciplinary expertise to facilitate the development of the molecular target for HTS, consisting of representation from molecular biology, pharmacology, toxicology, HTS, biology, and intellectual property. The project team defines timelines in order to target goals, assist in the development of assays, evaluate leads through HTS, and assists in interpretation of medicinal chemistry derivatives. DISCUSSION/SIGNIFICANCE OF IMPACT: Benchmarks of success include grants awarded to either of the institutions, manuscripts, patents obtained, and, ultimately, the advancement of molecules into, first, animal and, then subsequently, human investigations.

**FDA’S CRITICAL PATH INITIATIVE**  
Sacks L¹

¹Office of Critical Path Programs, Silver Spring, MD, USA

FDA’s Critical Path Initiative was launched in 2004 to tackle the steep decline in the number of medical products submitted for approval despite increasing expenditure in research and development. Dr. Sacks will discuss the Initiative’s history and the program’s structure within FDA. Focusing on facilitating new medical product development, Dr. Sacks will review some of the reasons why products have failed to gain approval in the past. He will stress the major areas where new science, technology, and strategies are being applied, specifically, biomarkers, models and modeling efforts, manufacturing programs, development strategies and clinical study designs, bioinformatics, and communication programs. Dr. Sacks will review approaches to public-private partnerships that have enabled FDA to collaborate with healthcare and academic communities to address areas of need. Existing Critical Path programs will be reviewed that target medical product development in general and specific areas of unmet public health needs, such as neglected tropical diseases and tuberculosis. Dr. Sacks will also highlight some of the Critical Path projects led by each of the FDA centers.

**TRAJECTORIES FOR SUCCESS IN CLINICAL RESEARCH: NO ONE PATH FITS ALL**

**CLINICAL/TRANSLATIONAL RESEARCH TRAINING FOR SURGEON-SCIENTISTS AND OTHER TIME-CONSUMING CLINICAL SPECIALTIES: LESSONS FROM THE TRENCHES**  
Einstein M¹

¹Albert Einstein College of Medicine, Bronx, NY, USA

Clinicians in time-engulfing specialties like the surgical subspecialties or procedure-focused specialties have long been a challenge to train in clinical-translational research, despite the considerable need. While career-development awards often allow different effort in surgical trainees, there are still numerous challenges to overcome; amplified by the faculty member’s need to maintain surgical skills with volume in order to maintain expertise. During this session, some of these issues will be discussed, in addition to suggestions from the trenches as to how to achieve balance and success.

**BEDSIDE TO REAL WORLD: PERSPECTIVES ON ACADEMIA FROM A VASCULAR INTEREST**  
Collins T¹

¹University of Minnesota, Minneapolis, MN, USA

Dr. Collins, board certified in internal and vascular medicine, is an Associate Professor in the Department of Medicine at the University of Minnesota. She will discuss being a physician and researcher, juggling clinical care, and her experiences practicing both general and vascular medicine, the latter being a relatively new specialty, transitioning from a VA to a non-VA setting; relocating to a new institution as a late assistant professor; and establishing mentor/mentee relationships in a new academic setting.

**CLINICAL RESEARCH, LEADERSHIP, AND GIVING UP CLINICAL MEDICINE**  
Ahuwalia J¹

¹University of Minnesota, Minneapolis, MN, USA

Jasjit S Ahuwalia, MD, MPH, MS will discuss researching health of high risk populations, such as the underserved and ethnic minorities and how he juggles being a clinician, administrator, educator, and investigator, and will use his career story to discuss issues, and answer questions, such as giving up clinical medicine, taking on administrative roles, chairing a department with few physicians, benefits of an endowed professorship, chairing a NIH study section, taking on a significant mentoring role, and running a center.

**OPPORTUNITIES FOR RESEARCH CAREER DEVELOPMENT THROUGH THE VA**

**VA CAREER DEVELOPMENT AWARD: TRANSFORMING CLINICAL CARE THROUGH RESEARCH**  
Maguen S¹

¹University of California- San Francisco Medical School

Dr. Maguen will present comments about her pathway through several levels of career development awards entitled, “VA Career Development Award: Transforming Clinical Care Through Research” and serve as an example of a success story that others might benefit from. Following presentations about the program and experience, we will answer questions and hope to address the audience’s need for information.

**CAN PHARMACOGENETICS DELIVER ON PERSONALIZED HEALTHCARE? LESSONS LEARNED**

**GENOMIC MEDICINE MEETS EVIDENCE-BASE MEDICINE**  
Khoury M¹

¹Centers for Disease Control, Atlanta, GA, USA

Genomics promises profound changes in medicine and public health by providing new tools for risk assessment, early detection, and targeted therapy. However, the promise of field is currently not matched by the evidence that supports its use in clinical practice. The mismatch between expectations and reality can be addressed by placing greater emphasis on multidisciplinary translation research and rapid evidence synthesis and by stakeholder-driven collaboration that uses such research to address various and occasionally competing factors affecting the integration of genomic discoveries into clinical practice.

**EVIDENCE-BASED PHARMACOGENOMICS: PROMISE AND PITFALLS**  
Trikalinos T¹

¹Tufts Medical Center, Boston, MA, USA

Evidence-based medicine methodologies, systematic reviews, and meta-analyses in particular are instrumental in addressing clinical and health policy questions and present a natural framework for assessing the utility of pharmacogenetic testing. By considering the totality of knowledge on a research question they can provide a snapshot of the state of the science,
quantify and explore between-study heterogeneity, identify research gaps, and inform on the likelihood of systematic errors or biases. At the same time they inherit all the limitations of their building blocks (the primary studies), and add several of their own. We will discuss cross-cutting methodological issues for evidence-based approaches to evaluating pharmacogenetic testing drawing from 3 examples, namely CYP2D6 and tamoxifen for breast cancer, KRAS and anti-EGFR antibodies for colorectal cancer, and BCR-ABL1 variations for chronic myelogenous leukemia.

380
TRANSLATIONAL RESEARCH IN CARDIOVASCULAR PHARMACOGENOMICS: WHAT HAVE WE LEARNED?
Veenstra D

1University of Washington, School of Pharmacy, Seattle, WA, USA

OBJECTIVES/SPECIFIC AIMS: Cardiovascular pharmacogenomics has been an area of intensive research over the past decade, yet the clinical success stories have been limited. METHODS/STUDY POPULATION: The variety of translational research methodologies that have been employed will be reviewed and critiqued, with a focus on warfarin pharmacogenomics. Translational research opportunities in pharmacogenomics will be discussed using clopidogrel pharmacogenomics as an example. RESULTS/ANTICIPATED RESULTS: Participants will gain an understanding of translational research approaches in cardiovascular pharmacogenomics, and strategies for identifying areas of interest to focus career development in pharmacogenomics. DISCUSSION/SIGNIFICANCE OF IMPACT: The challenges encountered in the past decade in cardiovascular pharmacogenomics offer a learning opportunity for young investigators.

390
INTEGRATING PHARMACOGENOMIC DISCOVERIES IN BASIC, CLINICAL AND POPULATION SCIENCES TO ADVANCE PREDICTIVE CANCER CARE
Freedman AN

1National Cancer Institute, NIH, Bethesda, MD, USA

To fully realize the potential of personalized cancer treatment it will be essential to connect and integrate basic discoveries in drug development and pharmacogenomic variability, patient outcomes, and genomic data from randomized clinical treatment trials, and data on the effects of drugs and their interactions, with genomic variants in large heterogeneous patient populations. In this talk we will present recent research findings that illustrate how pharmacogenomic marker discoveries from clinical trials and population-based studies can lead to both clinical utility and novel insights into the underlying biology of drug response phenotypes.

THE PROMISES, THE PITFALLS, AND THE POLICY IMPLICATIONS OF WHOLE GENOME SEQUENCING

395
ESTABLISHING THE DATA INFRASTRUCTURES FOR ‘OMICS AND OTHER SYSTEMS BIOLOGY TECHNOLOGIES
Athey B

1University of Michigan Medical School, Ann Arbor, MI, USA

The Next Generation Sequencing (NGS) revolution has brought with it the reality that the data infrastructures to support this activity need to be addressed. Indeed, it is widely accepted that the biomedical research community is struggling to manage the growth of computational and data infrastructures to analyze, store, and retrieve data from a diverse set of other Systems Biology technologies, such as Epigenomics and transcriptomics data, 1,000 genome-like and HapMap-like studies, miRNA and siRNAs databases, Proteomics, and alternative splicing isoforms, protein folding predictions, Metabolomics measurements, system pathways, Simulations of cells, tissues and organs, and digital imaging at all scales. In addition to be useful for clinical and translation-al research, these data will need to integrate with the following data types: Clinical research and trials data, Pharmacogenomics; Toxicogenomics, Cognitive and Behavioral measures, Electronic Health Record (EHR)-based phenotype data, Environmental measures, and Healthcare Quality Metric (HQM) data to allow for Patient-Centered Outcomes Research (PCOR). Establishing integrated data infrastructures for discovery and hypothesis testing at the enterprise-level at an Academic Health Center (AHC) is not a trivial undertaking. Commitment to use of standard terminologies, lexicons, and ontologies (e.g. GO, SNOMED) are not only a must for internal integration efforts, but data would indicate of data services from other AHCs and information repositories. Other steps to success involve the commitment to inventory core and major laboratory data, and centralize key services by establishing partnerships between Research Administration and major information technology providers, under the guidance of the academic informatics unit. Deployment of data mining and machine learning algorithms to enhance expert analysts is an obvious next step.

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WHOLE GENOME SEQUENCING IN CLINICAL PRACTICE: HOPES AND CHALLENGES
Korf BR

1University of Alabama at Birmingham, Birmingham, AL, USA

OBJECTIVES/SPECIFIC AIMS: Describe the prospects for incorporation of whole genome sequencing into routine medical practice and some of the challenges in managing and interpreting the data. DISCUSSION/SIGNIFICANCE OF IMPACT: The cost of genome sequencing is falling rapidly and this trend is likely to continue in the next several years. Already the cost of exome sequencing is becoming price competitive with sequencing some large single genes for diagnostic purposes and the approach is being used to elucidate the genetic basis of several rare disorders. Exome sequencing is likely to become a mainstream diagnostic approach in the relatively near future. Integration of exome or genome sequencing into routine medical care could be transformative, but also raises many provocative questions. Once sequence data indicate an individual’s carrier status for recessive disorders, would “diagnose” those with Mendelian conditions, would identify pharmacogenetic genotypes, and might be helpful in risk assessment or differential diagnosis for rare disorders. The informatics challenges to curate the information would be formidable, as would the need to provide counseling and education to patients. Intellectual property issues regarding patented genes will need to be addressed. Questions will have to be answered regarding when an individual would have sequencing, where sequence data would be stored, and who would have access to it. Now is the time to begin to address these issues, as they are likely to be more difficult to answer than solving the technical challenges in doing the sequencing itself.

410
MASSIVELY PARALLEL SEQUENCING IN CLINICAL RESEARCH: HYPOTHESIS-TESTING AND HYPOTHESIS-GENERATING RESEARCH APPROACHES
Biesecker L

1National Institutes of Health, Bethesda, MD, USA

OBJECTIVES/SPECIFIC AIMS: 1. Orient participants to technical capabilities of sequencing 2. Differentiate sequencing from genotyping 3. Address challenges in so called secondary or incidental results METHODS/STUDY POPULATION: Describe the ClinSeq project; a cohort of 1,000 patients who are fully consented to whole genome interrogation with return of results. Describe a rare disease whole genome sequencing study to elucidate the etiology of mendelian disorders. RESULTS/ANTICIPATED RESULTS: Whole exome sequencing results of >400 patients will be described. These data demonstrate the capacity of sequencing to identify patients who are at risk for, or actually have high penetration mutations (point mutations and copy number changes) that relate to medically important disease. As well, these data identify many secondary results: for example, essentially all participants have multiple mutations as they are carriers for several recessive traits. DISCUSSION/SIGNIFICANCE OF IMPACT: Massively parallel sequencing has the potential to elucidate the complete heritable component of disease. The acquisition, analysis, and storage of this scale of data in clinical research poses many challenges and opportunities. The successful translational investigator will need to master the necessary skills to use these powerful data sets.
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