

**CTSA
Consortium
Child Health
Oversight Committee**

**April 30 - May 2, 2011
Colorado Convention Center
Denver, CO**

Join us in Denver where the CTSA Consortium Child Health Oversight Committee and the Pediatric Academic Societies (PAS) will host tightly aligned programs. CTSA/PAS joint symposia and original science will be held at the Denver Convention Center.

Registration Information

There will be a single registration fee for the meeting set at the PAS registration fee schedule.

Continuing Education

Continuing Education Credit is available through the PAS. See page 3 for complete information.

Friday, April 29

8:00am–6:00pm

CTSA Consortium Child Health Oversight Committee (CC-CHOC) Members Meeting

Hyatt Regency Downtown, Centennial H

This face-to-face meeting of the CC-CHOC membership will review priorities and deliverables from this past year, strategically plan for next year, engage membership in moving on-going initiatives forward, and present a state-of-the-art workshop on community engaged research. Four clinical and translational child health research fellows selected for their high quality science in this field, will present their work, strengthening peer and mentor networks.

Saturday, April 30

8:00am–10:00am

1140 Community Engaged Research: The Science and Outcomes that Result

Platform Session~Korbel 4D

Chairs: Mary E. Aitken and Karen Dorsey

Refer to PAS Daily Programming for complete details.

10:30am–12:30pm

1310 Community-Engaged Research: The Science and Outcomes that Result

PAS Topic Symposium~Korbel 4D

Target Audience: Scientists and clinicians involved in health services and public health, clinicians interested in partnering with their community to improve wide-scale health outcomes, CTSA and non-CTSA sites interested in the rigorous conduct of community engaged research.

Objective:

- To understand novel methods that can be used in community-engaged research, practical examples of community-engaged research, community level translation of research to improve health outcomes, and how to utilize the CTSA consortium to conduct this type of research

Chairs: Alex R. Kemper, Duke Clinical Research Institute, Durham, NC and James M. Perrin, Harvard Medical School, Boston, MA

Community-engaged research depends on innovative partnerships between researchers and diverse community partners to conduct high quality research that has significant impact on improving the health of the public. The NIH-funded CTSA Consortium has led to the development of enhanced strategies to

conduct community engaged research. This topic symposium will highlight the use of novel methods and their associated health outcomes.

Dr. Aguilar-Gaxiola co-chairs the CTSA consortium committee that promotes community-engaged research. His presentation will provide examples of this work in a variety of different settings and a variety of different methods, and provide practical direction about how the precepts of community-engaged research can be embedded in all aspects of T2 translational research activities.

10:30 Defining Community-Engaged Research

Alex R. Kemper, Duke Clinical Research Institute, Durham, NC

10:40 Study Designs in Community-Engaged Research

Peter G. Szilagyi, University of Rochester School of Medicine and Dentistry, Rochester, NY

11:00 Salud Con La Familia (Health with the Family): The Power of Community Engaged Research Outcomes

Shari L. Barkin, Children's Hospital at Vanderbilt, Nashville, TN

11:20 Pediatric Comparative Effectiveness Research and Community-Engaged Research

Laurel Kristin Leslie, Tufts Medical Center, Floating Hospital for Children, Boston, MA

11:40 Community-Engaged Research Across the CTSA Consortium

Sergio Aguilar-Gaxiola, University of California, Davis, School of Medicine, Sacramento, CA

12:00 Discussion

Jointly sponsored by the Consortium Child Health Oversight Committee and the Pediatric Academic Societies

1:00pm–4:00pm

Commercial Exhibits Open and Posters Available for Viewing

Exhibit Hall A/F

Author Attendance and Opening Reception: 1:15pm–2:45pm

Refer to PAS Daily Programming for complete details.

1:15pm–2:45pm

Poster Session I and Opening Reception

Exhibit Hall F

Refer to PAS Daily Programming for complete details.

5:00pm–6:30pm

1800 PAS/ASPR Opening General Session

Four Seasons I

Sunday, May 1

10:15am–11:45am

2250 APS Presidential Plenary and Awards

Four Seasons I

10:15 2011 APS Presidential Address

Earthquakes, Tectonic Shifts in Graduate Medical Education, & the Role of the APS in Finding Solid Ground

Gary R. Fleisher, Egan Family Foundation Professor, Department of Pediatrics, Harvard Medical School, Physician-in-Chief, Pediatrician-in-Chief and Chairman, Department of Medicine, Children's Hospital, Boston, MA

10:45 Norman J. Siegel New Member Outstanding Science Award

Genome-wide Association Studies: Early Steps on a Genetic Journey
Joel N. Hirschhorn, Professor of Genetics and Pediatrics, Children's Hospital-Boston/Harvard Medical School, Senior Associate Member, Broad Institute, Boston, MA

11:10 Introduction, John Howland Awardee

Aaron L. Friedman, Vice President for Health Sciences and Dean of the Medical School, University of Minnesota, Minneapolis, MN

Acceptance of the 2011 John Howland Award: Lessons from Models of Disease

Russell W. Chesney, Le Bonheur Professor and Chair, Department of Pediatrics, University of Tennessee Health Science Center, Senior Vice President Medical Affairs, Le Bonheur Children's Hospital, Memphis, TN

1:00pm–3:00pm

2650 Accelerating Research and Product Development for Rare Diseases

PAS State of the Art Plenary~Room 201

Target Audience: Scientists and clinicians working with pediatric disorders, most of which are, by definition, rare.

Objective:

- To understand the broad spectrum of needs of children with rare diseases, as well as emerging opportunities to advantage their medical outcomes through more productive and accelerated research leading to new diagnostics and therapeutics

Chair: Thomas F. Boat, Cincinnati Children's Hospital Medical Center, Cincinnati, OH

Approximately 7000 rare diseases in aggregate represent much of pediatric chronic disease. Most are not readily diagnosed or effectively treated. This session will present highlights of an IOM report focused to enhancing rare disease research and orphan product development by pediatric members of the committee. Topics discussed will include the definition, epidemiology, and current status of medical management and research for rare diseases, the continuum of activities from discovery of biological targets or biomarkers for specific diseases through the identification and testing of products that have potential as diagnostic or therapeutic agents. Recommendations for infrastructure improvements that can overcome barriers and accelerate navigation of the product development pathway, including regulatory (FDA) processes for orphan product approval, will be presented. The symposium will also outline a proposed integrated national policy to promote more certain and timely progress with rare diseases research and more effectively support investigators of rare diseases.

1:00 Rare Diseases: A Growing Pediatric Challenge

Thomas F. Boat, Cincinnati Children's Hospital Medical Center, Cincinnati, OH

1:05 An Overview of Pediatric Rare Diseases

Robert D. Steiner, Oregon Health and Sciences University School of Medicine, Portland, OR

1:35 The Pathway from Scientific Discovery to Creation of Orphan Products

Peter C Adamson, Children's Hospital of Philadelphia, Philadelphia, PA

2:05 Creating Infrastructure for Rare Disease Research and Product Development

Michael R. DeBaun, Washington University School of Medicine, St. Louis, MO

2:35 A National Strategy to Accelerate Rare Disease Research and Product Development

Thomas F. Boat, Cincinnati Children's Hospital Medical Center, Cincinnati, OH

Jointly sponsored by the Consortium Child Health Oversight Committee and the Pediatric Academic Societies

Supported by an unrestricted educational grant from Pediatric Research Foundation

1:00pm–3:00pm

2660 Best Pharmaceutical for Children Act (BPCA) and Opportunities for CTSA Collaboration

PAS Topic Symposium~Korbel 4B

Target Audience: Clinical, translational, basic, behavioral and health services research investigators engaged in implementing studies aimed at short-term outcome measures.

Objectives:

- To advance the understanding of the potential effectiveness of CTSA collaboration in pediatrics as best exemplified by the BPCA Pediatric Administrative Supplements
- To gain knowledge of the CTSA networks and resources in pediatric research in order to facilitate collaborations and future investigations

Chairs: Charlotte A. Hobbs, University of Arkansas, Little Rock, AR and Frederick J. Kaskel, Montefiore Medical Center of AECOM, Bronx, NY

The purpose of the Best Pharmaceuticals this program was to stimulate collaborative, multidisciplinary basic and clinical research to 1) facilitate the development of qualified outcome measures and 2) relate non-clinical to clinical outcome assessments in child health for improving the evaluation of interventions and/or 3) assess and interpret clinical outcomes. Furthermore, a major goal of the announcement was to improve the likelihood of success of pediatric clinical trials, especially drug trials, by identifying more reliable predictors and markers of outcomes. Projects involved multiple CTSA institutions and focused on development of correlations between non-clinical assessments and child health clinical outcomes, harmonization of clinical outcome measures across different age groups, development of predictive biomarkers and/or age appropriate outcome measures in one of the priority areas.

1:00 Targets and Barriers for Hydroxyurea Therapy in Sickle Cell Hemoglobinathies

Nancy S. Green, Columbia University Medical Center, New York, NY

1:20 Outcome Measures for Trials in Children with Autism

Randi J. Hagerman, M.I.N.D. Institute, University of California at Davis Medical Center, Sacramento, CA

1:40 Improving Management of the Neonatal Abstinence Syndrome

Robert M. Ward, University Medical Center, Salt Lake City, UT

2:00 Improving BPD Predictors and Outcomes for Clinical Trials

Jonathan M. Davis, The Floating Hospital for Children at Tufts Medical Center, Boston, MA

2:20 Pediatric Hypertension Outcome Measures Study

Robert Piotr Woroniecki, Montefiore Medical Center of AECOM, Bronx, NY

2:40 The BPCA and Pediatric Administrative Supplements

Steven Hirschfeld, Interim Director, National Children's Study, NICHD, Bethesda, MD

Jointly sponsored by the Consortium Child Health Oversight Committee and the Pediatric Academic Societies

1:00pm–3:00pm

2675 Longitudinal Children's Studies: A Global Perspective

PAS Topic Symposium~Korbel 4A

Target Audience: Clinicians, researchers, policymakers.

Objectives:

- To describe and compare the objectives and methods of the Danish National Birth Cohort study, the Japanese Environment and Children's Study, and the United States' National Children's Study
- To highlight the similarities and differences as well as the strengths and limitations of these population-based studies of child health

Chairs: Elena Fuentes-Afflick, University of California, San Francisco, CA and Shumpei Yokota, Yokohama City University School of Medicine, Yokohama, Japan

There is a growing interest in population-based studies of child health and the determinants of child health and human development. This special symposium

will provide a global perspective on three longitudinal studies of child health: the Danish, Japanese, and United States studies. The Danish National Birth Cohort study, the Japanese Environment & Children's Study, and the US National Children's Study are all large-scale, population-based studies with long-term follow-up, yet the focus of each study is unique. The Danish study is a well-established study which focuses on gene-environment relationships; the Japanese and American studies focus on the impact of environmental factors on child health and development. In this session we will compare the purpose and methodologic approaches of the studies and discuss their strengths and limitations.

- 1:00 Welcome**
Elena Fuentes-Afflick, University of California, San Francisco, San Francisco, CA
- 1:10 The Japanese Environment and Children's Study**
Shumpei Yokota, Yokohama City University School of Medicine, Yokohama, Japan
- 1:30 The US National Children's Study**
Elena Fuentes-Afflick, University of California, San Francisco, San Francisco, CA
- 1:50 The Danish National Birth Cohort**
Mads Melbye, Statens Serum Institut, Copenhagen, Denmark
- 2:10 Is There a "Best" Approach to Population-based Studies of Child Health?**
Elena Fuentes-Afflick, University of California, San Francisco, San Francisco, CA
- 2:25 Questions and Discussion**
Elena Fuentes-Afflick, University of California, San Francisco, San Francisco, CA

Jointly sponsored by the Asian Society for Pediatric Research, Consortium Child Health Oversight Committee and the Pediatric Academic Societies

1:00pm–3:00pm

- 2690 Treatment of Pediatric Diseases Using Gene Therapy**
PAS Topic Symposium~Korbel 4D

Target Audience: Scientists and clinicians involved in the care of patients with genetic diseases including general pediatricians, immunologists, neurologists, geneticists, and hematologists.

Objectives:

- To understand the current uses of vector technology and their role in pediatric clinical trials
- To understand the strengths and weaknesses of current vector systems
- To learn about research that seeks to develop additional novel gene therapy approaches in the future

Chair: David Williams, Children's Hospital Boston and Dana-Farber Cancer Institute, Boston, MA

Over the past 25 years, gene therapy methodology has surmounted multiple technological problems and clinical setbacks and has now shown promise in several serious pediatric diseases including severe combined immunodeficiency, chronic granulomatous disease and adrenoleukodystrophy. This session will provide a summary of the field relevant to current applications in pediatric diseases and a view to future applications.

- 1:00 Clinical Applications of Gene Therapy**
David A. Williams, The Children's Hospital of Boston, Harvard Medical School, Boston, MA
- 1:10 Gene Therapy for Primary Immune Deficiencies: Promise, Pitfalls and Progress**
Donald B. Kohn, University of California, Los Angeles
- 1:45 Gene Therapy for Hematologic Diseases**
Mary C. Dinauer, University of Indiana School of Medicine, Indianapolis, IN

- 2:20 Innovations in Cell and Gene Therapy**
David A. Williams, The Children's Hospital of Boston, Harvard Medical School, Boston, MA

- 2:55 Discussion**

Jointly sponsored by the Consortium Child Health Oversight Committee and the Pediatric Academic Societies

1:00pm–3:00pm

- 2700 Clinical & Translational Research: Putting Science to Work**
Platform Session~Korbel 2A/3A

Chairs: Dan M. Cooper and William W. Hay

Refer to PAS Daily Programming for complete details.

3:30pm–5:30pm

- 2785 Ethical Controversies in Pediatric Biobanks**
PAS Topic Symposium~Room 207

Target Audience: Scientists who collect and store pediatric tissues for research; scientists who engage in genetic/genomic research; and colleagues who serve on institutional review boards or research ethics consultation services.

Objectives:

- To encourage researchers and members of institutional review boards to understand the controversies raised by the policies that surround population-based biobanks with a particular emphasis on biobanks that enroll children and store pediatric samples
- To provide guidance regarding the range of ethical solutions

Chair: Steven Leuthner, Medical College of Wisconsin, Milwaukee, WI

New technologies are increasing the types of research that can be conducted on stored tissue and blood samples, and multiplex approaches permit the detection of millions of genetic variations simultaneously. Advances in computer technologies make it possible to link genomic data with an enormous amount of clinical and other data about individuals, at times uncovering potentially significant genetic risk factors; but often uncovering genetic variations of unknown significance. These issues take on immediacy given the extensive number of biobanks that exist and that are being developed. In this symposia, the various research ethics questions raised by pediatric biobanks will be addressed. Speakers will examine: 1) consent issues including broad consent, re-consent and the evolving role of the minor; 2) the use of residual newborn blood spots for research; 3) policies regarding when and when to return individual genetic results; and 4) biobank governance issues.

- 3:30 The National Children Study as a Paradigm Case of Pediatric Biobanks**
Steven R. Leuthner, Medical College of Wisconsin, Milwaukee, WI
- 3:40 What Does It Mean To Get 'Assent' from Children for Biobank Genomic Research?**
Benjamin S. Wilfond, University of Washington School of Medicine, Seattle, WA
- 4:05 The Return of Individual Research Results in Pediatric Biobanks**
Lainie F. Ross, MacLean Center for Clinical Medical Ethics, University of Chicago, Chicago IL
- 4:30 Use of Residual NBS Samples for Research**
Jeffrey Robert Botkin, University of Utah, Salt Lake City, UT
- 4:55 Governance of Pediatric Biobanks**
Kyle Bertram Brothers, Vanderbilt University School of Medicine, Nashville, TN
- 5:20 Discussion**

Jointly sponsored by the Consortium Child Health Oversight Committee and the Pediatric Academic Societies

3:30pm–5:30pm

2795 Transgenerational Inheritance of Human Diseases: Impact and Consequences of Epigenetic Alterations

PAS State of the Art Plenary–Korbel 2A/3A

Target Audience: Basic and translational scientists as well as practicing clinicians who wish to understand the impact of transient exposure to environmental toxins on transgenerational epigenetic errors leading to developmental defects and heritable human diseases.

Objectives:

- To understand, the interplay of environmental susceptibility, epigenetic alteration and phenotype impacting human health and diseases
- To understand epigenetic memory, transgenerational heritable disorders / diseases resulting from transient exposure to environmental agents, nutrients, hormones and medications
- To understand epigenetic profiling techniques, and possible reversal of the disease through removal of the stressor using targeted epigenetic therapeutics

Chairs: Mala R. Chinoy, Tufts University School of Medicine, Boston, MA and Thomas P. Shanley, C.S. Mott Children's Hospital, University of Michigan, Ann Arbor, MI

Developmental origins of pediatric or adult diseases and their transgenerational impact have enormous implications on human health and well-being. Environmental toxicants entering a human system of an individual, community or society today can lead to disease susceptibility in future generations. Scientific attention on early life / in utero transient exposure to environmental agents – external or internal – such as pollutants including smoke and toxic industrial chemicals, plastics and pesticides, dietary preferences of mother, hormonal supplements and medications, can reprogram Epigenome through DNA methylation. The epigenetic changes result in chronic lung and heart diseases; autoimmune diseases such as lupus and arthritis; neurological disorders such as autism and bipolar disorder; cancers; diabetes; obesity; metabolic diseases; infertility. This session is intended to better understanding of transgenerational impact and consequences of environmental exposure in early life, identify epigenetically labile targets and develop epigenetic therapeutics to reverse the disease condition / improve human health.

- 3:30 Developmental Origins of Diseases and Transgenerational Susceptibility**
Mala R. Chinoy, Tufts University School of Medicine, Boston, MA
- 3:40 Fetal Basis of Adult Diseases: Environmental Exposure, Susceptibility and Transgenerational Effect**
Retha Newbold, National Institute of Environmental Health Sciences, Research Triangle Park, NC
- 4:05 Epigenetic Effects of Fetal and Post-natal Environmental and Nutritional Exposures on Later Outcomes in Life**
Dana Dolinoy Cipolla, University of Michigan School of Public Health, Ann Arbor, MI
- 4:30 Developmental Origins of Diabetes and Underlying Epigenetic Mechanisms**
Rebecca A. Simmons, University of Pennsylvania School of Medicine, Philadelphia, PA
- 4:55 Epigenetic Transgenerational Actions of Endocrine Disruptors**
Michael K. Skinner, Washington State University, Pullman, WA
- 5:20 Conclusion**
Thomas P. Shanley, C.S. Mott Children's Hospital, University of Michigan School of Medicine, Ann Arbor, MI

Jointly sponsored by the Consortium Child Health Oversight Committee, Pediatric Endocrine Society and the Pediatric Academic Societies

4:15pm–7:30pm

Commercial Exhibits Open and Posters Available for Viewing

Exhibit Hall A/F

Posters Available for Viewing: 4:15pm–7:30pm

Author Attendance: 5:45pm–7:30pm

Refer to PAS Daily Programming for complete details.

5:45pm–7:30pm

Poster Session II

Exhibit Hall F

Refer to PAS Daily Programming for complete details.

7:30pm–9:30pm

Bridging Pediatric and Adult Clinical Pharmacology and Therapeutics

Hyatt Regency Downtown, Agate A/C

Monday, May 2

8:00am–10:00am

3085 Health Information Technology Platforms for Research and Discovery: From Healthcare to Home to the Genome

PAS State of the Art Plenary–Room 203

Target Audience: Clinical and translational researchers, as well as practitioners who participate in or follow research.

Objectives:

- To understand how electronic health information technology can support clinical and translational discovery research.
- To become familiar with emerging and available open source toolkits to support new approaches to discovery research, including the i2b2 platform (www.i2b2.org), personally controlled health records (www.indivohealth.org), the Gene Partnership (informedcohort.org) and the SMARt platform (www.smartplatforms.org)

Chair: Kenneth D. Mandl, Children's Hospital Boston, Harvard Medical School, Boston, MA

The Obama Administration is investing \$48 billion in health information technology to support an agile, learning healthcare system. This plenary will show how radically different approaches to electronic health records can produce a flexible information infrastructure that supports and facilitate innovation not only in health care but also scientific discovery. The speakers will demonstrate leading edge approaches, strongly grounded on clinical and translational investigation (of autism, inflammatory bowel disease and diabetes), to assembling, phenotyping, and studying large populations over time—approaches that repurpose the informational byproducts of routine clinical care and that engage patients themselves in the research enterprise.

- 8:00 An "iPhone-Like" App Store for Health and Discovery**
Kenneth D. Mandl, Children's Hospital Boston and Harvard Medical School, Boston, MA
- 8:10 High Throughput Phenotyping and Genotyping: Instrumenting the Health System for Discovery**
Isaac S. Kohane, Children's Hospital and Harvard Medical School, Boston, MA
- 8:45 Practice Networks, Registries, and Primary Investigation of the Comparative Effectiveness of Therapeutics**
Peter A. Margolis, Cincinnati Children's Hospital Medical Center, Cincinnati, OH
- 9:20 Personally Controlled Health Records and Online Social Networks: A Patient Centered Health Information Economy**
Kenneth D. Mandl, Children's Hospital Boston and Harvard Medical School, Boston, MA

Jointly sponsored by the Consortium Child Health Oversight Committee and the Pediatric Academic Societies

10:15am–12:15pm

3260 SPR Presidential Plenary and Awards

Four Seasons 4

Refer to PAS Daily Programming for complete details.

4:15pm–7:30pm

Commercial Exhibits Open and Posters Available for Viewing

Exhibit Hall A/F

Posters Available for Viewing: 4:15pm–7:30pm

Author Attendance: 5:45pm–7:30pm

Refer to PAS Daily Programming for complete details.

5:45pm–7:30pm

Poster Session III

Exhibit Hall F

Refer to PAS Daily Programming for complete details.

Tuesday, May 3

8:00am–10:00am

4112 Comparative Effectiveness Research and Child Health Policy: Where are We Now, and Where Should We Go from Here?

PAS Topic Symposium~Room 205

Target Audience: This session will appeal to health services researchers, academic general pediatricians, health administrators, students and individuals interested in health policy as well as care delivery models, clinical organization and improvement.

Objectives:

- To gain new knowledge of current Comparative Effectiveness Research (CER) priorities for children
- To appreciate methodological challenges with CER for the pediatric population
- To determine how to successfully translating CER into clinical decision-making and evidence-informed policy

Chair: Lisa Simpson, Cincinnati Children's Hospital Medical Center, Cincinnati, OH

Comparative Effectiveness Research (CER) is an area of interest to scientists, clinicians and decision-makers and is seen as a method for accelerating improvements in clinical care, administration, and population health. Recent funding represents a major opportunity to improve child health and health delivery. This session will offer an overview of Comparative Effectiveness Research (CER), and will detail current priority areas. Cutting-edge child health CER will be profiled, including research related to children with special health care needs (CSHCN) and other priority areas. US and Canadian models will be discussed, highlighting differences in available data and support. Innovative thinking around methodological issues specific to CER for children will be shared, highlighting the use of pragmatic trials and observational research. This session will detail how CER is enabling decision-makers to craft evidence-informed policy, and will offer strategies for making research questions germane, and effectively communicating research findings for maximal impact.

8:00 Comparative Effectiveness Research: An Overview

Lisa Simpson, Cincinnati Children's Hospital Medical Center, Cincinnati, OH

8:15 Comparative Effectiveness Research: An Overview

Patrick Conway, Cincinnati Children's Hospital Medical Center, Cincinnati, OH

8:35 Comparative Effectiveness: An Overview of Current Medical and Political Developments

James M. Perrin, Harvard Medical School, Boston, MA

8:55 Comparative Effectiveness Research: The Children with Special Health Care Needs Population

Astrid Guttman, The Hospital for Sick Children, Toronto, Ontario, Canada

9:15 What is Next?: Effectively Translating Comparative Effectiveness Research into the Policy Environment

Charlotte Moore, The Hospital for Sick Children, Toronto, Ontario, Canada

9:35 Discussion

Jointly sponsored by the Consortium Child Health Oversight Committee and the Pediatric Academic Societies

12:30pm–2:00pm

Poster Session IV

Exhibit Hall F

Visit the CTSA Consortium Child Health Oversight Committee

at www.ctsaweb.org

Contact for CTSA information:

Chair, CTSA Consortium Child Health Oversight Committee (through May 2011)

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Chair-Elect, CTSA Consortium Child Health Oversight Committee (through May 2011, then becomes Chair of the Committee)

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