Putting Kids First:

Facilitating Multisite Pediatric Studies

The 4th Annual Harvard Catalyst Child Health Symposium

April 4, 2017
8:00am–4:30pm

Joseph B. Martin Conference Center
Harvard Medical School

For more information, visit catalyst.harvard.edu/programs/childhealth
or email child.health@catalyst.harvard.edu
2017 Symposium Planning Co-Chairs

Ellen Grant, MD
Christopher Duggan, MD

This event is being photographed. The Child Health Committee and Symposium Working Group gratefully acknowledge the work of Linda Bard and Kate McGroarty for their administrative work in planning this event.

Agenda

Putting Kids First: Facilitating Multisite Pediatric Studies
April 4, 2017

8:20am | Welcome and Opening Remarks
Lee Nadler, MD
Virginia and D.K. Ludwig Professor of Medicine, Harvard Medical School
Dean for Clinical and Translational Research, Harvard Medical School
Senior Vice President for Experimental Medicine, Dana-Farber Cancer Institute

Theme 1 – Pediatric Trials: What is Missing?

8:30am | Is the Paucity of Pediatric Clinical Trials Harming Child Health?
Christopher Duggan, MD, MPH
Professor of Pediatrics, Harvard Medical School
Director, Center for Nutrition, Boston Children’s Hospital
2017 Child Health Symposium Co-Chair

8:55am | Innovating in Clinical Translational Research: Can a Rising Tide Lift All Boats?
Mary Purucker, MD, PhD
Director, CTSA Hubs Program, Division of Clinical Innovation
National Center for Advancing Translational Sciences, National Institutes of Health
Agenda

9:20am | REAL WORLD DATA AND CLINICAL EVIDENCE

Kenneth Mandl, MD, MPH
Professor of Biomedical Informatics and Pediatrics, Harvard Medical School
Director, Computational Health Informatics Program, Boston Children's Hospital

9:45am | SPEAKER DISCUSSION & QUESTIONS

Moderator: David Williams, MD
Senior Vice President and Chief Scientific Officer, Boston Children's Hospital
President, Dana Farber/Boston Children's Cancer & Blood Disorders Center
Leland Fikes Professor of Pediatrics, Harvard Medical School

10:10am | BREAK

10:25am | FDA PERSPECTIVE ON PEDIATRIC CLINICAL TRIALS

Robert “Skip” Nelson, MD, PhD
Deputy Director and Senior Pediatric Ethicist, Food and Drug Administration

10:50am | REGULATORY FRAMEWORK FOR MULTICENTER TRIALS

Bruce Gordon, MD, FAAP
Professor of Pediatric Hematology/Oncology, University of Nebraska Medical Center
Executive Chairman, UNMC Institutional Review Board

11:15am | REGULATORY CHALLENGES OF CLINICAL TRIALS IN OUR HOSPITALS

Susan Kornetsky, MPH
Senior Director of Clinical Research Compliance, Boston Children’s Hospital

11:40am | SPEAKER DISCUSSION & QUESTIONS

Moderator: Ronald Kleinman, MD
Physician in Chief, MassGeneral Hospital for Children
Chair, Department of Pediatrics, Massachusetts General Hospital
Charles Wilder Professor of Pediatrics, Harvard Medical School

12:05pm | LUNCH
**Theme 3 – Success Stories**

**1:15pm** | **BUILDING AN NIH-FUNDED ASTHMA CLINICAL RESEARCH CENTER: A SUCCESS STORY**

Wanda Phipatanakul, MD, MS
Associate Professor of Pediatrics, Harvard Medical School
Director, Asthma Clinical Research Center, Boston Children’s Hospital

**1:40pm** | **HOW TO SET UP A SUCCESSFUL CLINICAL TRIAL NETWORK**

Bonnie W. Ramsey, MD
Director, Center for Clinical and Translational Research, Seattle Children’s Research Institute
Professor & Vice Chair, Research in Pediatrics, University of Washington School of Medicine

**2:05pm** | **SPEAKER DISCUSSION & QUESTIONS**

Moderator: Gary Fleisher, MD
Egan Family Foundation Professor, Department of Pediatrics, Harvard Medical School
Physician in Chief, Pediatrician in Chief
Chairman, Department of Medicine, Boston Children’s Hospital

**2:30pm** | **BREAK**

**Theme 4 – Moving Forward**

**2:45pm** | **WHAT IS NEEDED TO BUILD TRIAL NETWORKS?**

Role of the CTSA

James Heubi, MD
Professor of Pediatrics, University of Cincinnati College of Medicine
Director, Center for Clinical and Translational Science and Training, University of Cincinnati

**3:10pm** | **PARTNERING TO CHANGE THE PARADIGM IN PEDIATRIC RESEARCH**

Charles Thompson, MD, FAAP
Global Lead, Pfizer Pediatric Center of Excellence
Founder/Chair, International Children's Advisory Network

**3:35pm** | **COMMUNITY ENGAGEMENT IN PEDIATRIC TRIALS**

Elsie M. Taveras MD, MPH
Chief, Division of General Academic Pediatrics
Director, Pediatric Population Health Management, Massachusetts General Hospital
Professor of Pediatrics, Harvard Medical School
Associate Professor of Nutrition, Harvard T.H. Chan School of Public Health

**2:05pm** | **SPEAKER DISCUSSION & QUESTIONS**

Moderator: Gary Fleisher, MD
Egan Family Foundation Professor, Department of Pediatrics, Harvard Medical School
Physician in Chief, Pediatrician in Chief
Chairman, Department of Medicine, Boston Children’s Hospital

**2:30pm** | **BREAK**
Christopher Duggan, MD, MPH, has been performing clinical trials for 25 years in the fields of pediatric nutrition, gastroenterology, and global health. Duggan and colleagues at Harvard T.H. Chan School of Public Health and Muhimbili University of Health and Allied Sciences in Dar es Salaam, Tanzania, have evaluated the efficacy of micronutrient supplementation in infants and young children born to women with or at risk of HIV infection. These trials have recruited nearly 5,000 infants in urban Dar es Salaam, and achieved excellent rates of follow-up for 18–24 months. Recent studies include the development of new biomarkers of environmental enteric dysfunction, as well as the evaluation of nutritional status on neurodevelopment. Past and present research support has come from the NIH, the Gates Foundation, and the WHO.

Duggan is a professor of pediatrics at Harvard Medical School and a professor in the departments of Nutrition and Global Health and Population at the Harvard T.H. Chan School of Public Health, and a pediatric gastroenterologist and nutrition physician at Boston Children's Hospital where he directs the Center for Nutrition. He is the medical director of the Center for Advanced Intestinal Rehabilitation, one of the largest centers in the US for the care of children with intestinal failure/chronic diarrhea syndromes. He is also the course co-director of the Harvard College course “Nutrition and Global Health,” and mentors undergraduate, graduate, and post-doctoral students.
Gary Fleisher, MD

Egan Family Foundation Professor, Department of Pediatrics, Harvard Medical School
Physician in Chief, Pediatrician in Chief and Chairman, Department of Medicine, Boston Children’s Hospital

Gary Fleisher, MD, is chair of the Department of Medicine and physician in chief at Boston Children’s Hospital (BCH) and the Egan Professor of Pediatrics at Harvard Medical School (HMS). He obtained board certification in four subspecialties, pediatrics, pediatric infectious diseases, emergency medicine, and pediatric emergency medicine (PEM), and continues to practice PEM. Fleisher co-developed the first academic PEM program in 1979 and co-initiated the first fellowship program. He was a founding member of the certification committee for ABP and an examiner for ABEM. Funded by NIH, WHO, and others, he has published more than 150 manuscripts that have elucidated the pathophysiology and improved the diagnosis and treatment for several infectious diseases, particularly bacteremia and meningitis. He has served the academic pediatric community as president of SPR, APS, and on NIH Study Sections. As an educator, Fleisher edits multiple textbooks, including Pediatric Emergency Medicine, a journal of Pediatric Emergency Care, and UpToDate Emergency Medicine (editor in chief) on the web. He received the Janeway Award for Excellence in Teaching at BCH and the Barger Excellence in Mentoring Award at HMS.

Bruce Gordon, MD, FAAP

Professor of Pediatric Hematology/Oncology, University of Nebraska Medical Center
Executive Chairman, UNMC Institutional Review Board

Bruce Gordon, MD, is professor of pediatrics and chief of the Division of Pediatric Hematology/Oncology and Stem Cell Transplantation at the University of Nebraska Medical Center (UNMC) and Children’s Hospital and Medical Center.

Gordon has been a member of the UNMC Institutional Review Board since 1992, served as chairman since 1996, and executive chairman since 2011. Gordon was the first chairman of the National Cancer Institute Pediatric Central IRB, and was a member of the Secretary’s Advisory Committee on Human Research Protections (SACHRP) Subpart A SubCommittee. He has served on the Applied Research Ethics National Association (ARENA) planning committee and the PRIMR Core Conference Planning Committee. He was a member of the Workshops/Didactic Session SubCommittee for five years, and co-chaired the committee in 2008. Gordon was co-chair for the 2009 PRIMR national conference (Advancing Ethical Research). He is currently a board member at PRIMR, has been faculty at every ARENA/PRIMR national meeting since 2002, and is an active participant in PRIMR’s “At Your Doorstep” educational programs, including IRB 101, 200, and 250 programs. Gordon co-developed the “Collaborating for Compliance” workshop, the “IRB Chairs Boot Camp” program, and the “Vulnerable Subjects” workshop for PRIMR AER.
Biographies

Ellen Grant, MD

Professor of Radiology and Pediatrics, Harvard Medical School
Director of Fetal and Neonatal Neuroimaging Research, Boston Children’s Hospital
2017 Child Health Symposium Co-Chair

Ellen Grant, MD, is a professor of radiology and pediatrics at Harvard Medical School, the founding director of the Fetal-Neonatal Neuroimaging and Developmental Science Center (FNNDSC), Boston Children's Hospital (BCH), the first incumbent of BCH Chair in Neonatology, and a practicing pediatric neuroradiologist. At BCH she holds appointments in the Division of Newborn Medicine and the Department of Radiology. She holds an MS degree in physics and an MD from the University of Toronto, completed her radiology residency at Vancouver General Hospital in British Columbia, Canada, and her fellowship in adult and pediatric neuroradiology at the University of California, San Francisco.

Grant headed the Division of Pediatric Radiology at Massachusetts General Hospital for five years before moving to BCH to create the FNNDSC in 2009. The FNNDSC is focused on developing and optimizing tools and analysis streams for better understanding normal and abnormal brain development as well as response to treatments with the ultimate goal of improving cognitive and neurological outcomes. The FNNDSC is developing innovations in three modalities: Magnetic Resonance Imaging (MRI), Magnetoencephalography (MEG), and Near Infrared Spectroscopy (NIRS). The center is also pioneering imaging informatics and machine learning approaches for pediatric neuroimaging. She is a co-author of two popular textbooks for clinical neuroradiology, and has received multiple awards for her research efforts as well as recognition for her clinical excellence.

James Heubi, MD

Professor of Pediatrics, University of Cincinnati College of Medicine
Director, Center for Clinical and Translational Science and Training, University of Cincinnati

James Heubi, MD, is associate dean for Clinical and Translational Research and professor of pediatrics at the University of Cincinnati College of Medicine. He is the director of the Center for Clinical and Translational Science and Training which is the vehicle by which the University of Cincinnati, Cincinnati Children's Hospital, and the Veterans Administration Medical Center administers the NIH-funded Clinical Translational Science Award (CTSA). Heubi has been an active clinical investigator with over 200 peer-reviewed publications and was the long-term program director for the NIH-funded General Clinical Research Center. He is the principal investigator and co-investigator on NIH grants, and participates as a local principal or co-investigator on two rare disease networks supported by the NIH. His research interests include cholestatic liver disease in childhood and its complications, inborn errors of bile acid metabolism, bone disease in gastrointestinal and hepatobiliary disorders, fat absorption, and cholesterol absorption and metabolism.
Ronald E. Kleinman, MD

Physician in Chief, MassGeneral Hospital for Children
Chair, Department of Pediatrics, Massachusetts General Hospital
Charles Wilder Professor of Pediatrics, Harvard Medical School

Ronald E. Kleinman, MD, is physician in chief at the Massachusetts General Hospital for Children, chair of the Department of Pediatrics, and the Charles Wilder Professor of Pediatrics at Harvard Medical School. Kleinman’s major areas of research interest include gastrointestinal immunology, nutrition support of infants and children, and nutrition and public health policy. He was a founder and past president of the International Society of Behavioral Nutrition and Physical Activity. He is the author and editor of multiple textbooks on pediatric nutrition and pediatric gastroenterology and more than 150 peer-reviewed published papers. Currently, he is the chair of the board of Project Bread, a member of the Global Child Nutrition Foundation, the David Ortiz Children’s Fund, and the US Fund for UNICEF New England Regional Board.

Susan Kornetsky, MPH

Senior Director of Clinical Research Compliance, Boston Children’s Hospital

Susan Kornetsky, MPH, is senior director of clinical research compliance at Boston Children’s Hospital. She has a master of public health and completed a medical ethics fellowship at Harvard Medical School (HMS). She is currently chair of the board for the organization Public Responsibility in Medicine and Research. Kornetsky is a past member of the Secretary’s Advisory Committee on Human Research Protections (SACHRP) and was co-chair of the Subcommittee on Children, and serves on the Subpart A Subcommittee. She is a past board member of the Association for the Accreditation of Human Research Programs (AAHRP), and past site visitor. She was a member of the Institute of Medicine’s Committee on Clinical Research Involving Children. Kornetsky was on the Council for Certification of IRB Professionals (CCIP) and served as a Council co-chair. She is on the faculty for HMS Office of Global Education, lectures on research ethics and IRB regulations for HMS courses, and lectures at national and international meetings, most recently teaching clinical research ethics in London, Turkey, and Portugal. She is also a consultant for OPRR site visit teams. Topics of interest include pediatric research, boundaries between research and innovation, biobanking, and the obligation to return research results to subjects.
Kenneth Mandl, MD, MPH

Professor of Biomedical Informatics and Pediatrics, Harvard Medical School
Director, Computational Health Informatics Program, Boston Children's Hospital

Kenneth Mandl, MD, MPH, is a professor of biomedical informatics and pediatrics at Harvard Medical School (HMS), and director of the Boston Children’s Hospital Computational Health Informatics Program. Through scholarship intersecting epidemiology and informatics, Mandl pioneered use of IT and big data for population health, discovery, patient engagement, and care redesign. He leads the transformative SMART Health IT initiative to design the “app store for health” and is principal investigator of the Scalable Collaborative Infrastructure for a Learning Health System (SCILHS) across Boston hospitals and nationally. Recognized for research and teaching, Mandl received the Presidential Early Career Award for Scientists and Engineers and the Clifford A. Barger Award for top mentors at HMS. He was advisor to two directors of the CDC, and chaired the Board of Scientific Counselors of the NIH’s National Library of Medicine. His clinical training and experience is in pediatrics and pediatric emergency medicine. Mandl has been elected to multiple honor societies including the American College of Medical Informatics, American Society for Clinical Investigation, Society for Pediatric Research, and American Pediatric Society.

Robert “Skip” Nelson, MD, PhD

Deputy Director and Senior Pediatric Ethicist, Food and Drug Administration

Robert “Skip” Nelson, MD, PhD, is currently the deputy director and senior pediatric ethicist in the Office of Pediatric Therapeutics, Office of the Commissioner at the US Food and Drug Administration (FDA). He provides consultation throughout the FDA on ethical issues arising in the development of FDA-regulated products for children, and serves as a standing member of the FDA Pediatric Review Committee. Prior to joining the FDA full-time in 2009, he was professor of anesthesiology, critical care, and pediatrics at The Children’s Hospital of Philadelphia and University of Pennsylvania School of Medicine. After receiving his MD degree from Yale University, Nelson trained in pediatrics at Massachusetts General Hospital, neonatology and pediatric critical care at University of California, San Francisco, and remains board-certified in all three areas. He received a master of divinity from Yale Divinity School and a PhD in the study of religion from Harvard University, specializing in ethics.
Wanda Phipatanakul, MD, MS, directs the Asthma Clinical Research Center at Boston Children’s Hospital (BCH) and is an associate professor of pediatrics at Harvard Medical School (HMS). Originally from St. Louis, she earned her MD from Loma Linda University and completed her residency in pediatrics at Children’s Hospital Los Angeles, and a fellowship in allergy/immunology at Johns Hopkins University. She joined BCH and HMS in 2000, and as junior faculty received a master of science in epidemiology from the Harvard T.H. Chan School of Public Health.

Phipatanakul is the principal investigator (PI) of her own school- and home-based grants, and Boston Pediatric PI for NIH network consortiums, AsthmaNet, and the Severe Asthma Research Program. She is also the Boston site PI for a multicenter primary asthma prevention study, and the overall PI for a multicenter asthma prevention study evaluating anti-IgE in preventing the allergic asthma march in allergic, wheezing toddlers. She has authored nearly 170 publications in scientific journals, has had continuous NIH funding for 15 years, and was recently elected to the American Society for Clinical Investigation. Phipatanakul is a dedicated mentor and holds multiple mentoring awards from the NIH, HMS, and the Pediatric Academic Society.

Mary Purucker, MD, PhD

As director of the Clinical and Translational Science Awards (CTSA) Hubs Program, Mary Purucker, MD, PhD, oversees the DCI Hubs team to provide oversight and management of more than 60 CTSA Hub award institutions, each of which includes separate but linked UL1 and KL2 awards, and usually an (optional) NRSA TL1 training award. She manages seven CTSA Hub awards in her role as program director, in addition to several large administrative supplement projects, SBIR/STTR (small business grants), R13/U13 conference grants, and is closely involved with other CTSA Program and Network initiatives, including the SMART IRB project, which is working toward a national reliance agreement to enable single IRB review of multisite clinical research studies funded by NIH. Purucker currently serves as the NCATS representative to the national CTSA Program Lifespan Domain Task Force, which promotes collaboration amongst investigators across the more than 60 CTSA Program hubs to ensure that translational science is integrated across its multiple phases and disciplines within complex populations and across the individual lifespan.

Purucker came to NIH in 2008 after a 12-year career with the FDA that included leadership in offices with responsibility for a full spectrum of the agency’s regulatory activities. She is a graduate of the MSTP program of the Albert Einstein College of Medicine, receiving both an MD, and PhD in molecular biology. She is a member of the American Pediatric Society and is board certified in internal medicine, pulmonary diseases, and critical care medicine.
Bonnie W. Ramsey, MD, is the director of the Center for Clinical and Translational Research (CCTR) at Seattle Children’s Research Institute. She is professor and vice chair for research in the Department of Pediatrics, and holds the Endowed Chair in Cystic Fibrosis at the University of Washington School of Medicine. She is also the co-principal investigator of the University of Washington Institute for Translational Health Science, where she has led the Child Health research program for the past decade. She has been active in the NCATS CTSA consortium and has served on several CTSA external advisory committees.

Ramsey received her BA from Stanford University and her MD from Harvard Medical School. Her career has focused on clinical care and research in the field of cystic fibrosis (CF). She is internationally recognized for her work in developing new therapies for patients with CF and is an elected member of the National Academy of Medicine. For nearly the past two decades, Ramsey directed the Coordinating Center for the Cystic Fibrosis Foundation Therapeutics Development Network (CFF TDNCC), a 77-site national clinical trials network that has successfully conducted over 100 therapeutic trials assisting in the development of novel treatments for patients with this disorder. Several FDA approved drugs, such as TOBI®, Kalydeco®, and Orkambi®, have had significant impact on the lives of patients with CF.

Elsie M. Taveras, MD, MPH, is chief of the Division of General Academic Pediatrics and director of Pediatric Population Health Management at Massachusetts General Hospital. She is also associate professor of population medicine and professor of pediatrics at Harvard Medical School and associate professor of nutrition at Harvard T.H. Chan School of Public Health. She received her BS and MD degrees from New York University. Taveras did her internship, residency, and chief residency at the Boston Combined Residency Program at Boston Children’s Hospital and Boston Medical Center in pediatrics. She also holds a MPH from the Harvard T.H. Chan School of Public Health.

Taveras is a pediatrician and a childhood obesity researcher, with a research focus on understanding determinants of obesity in women and children and developing interventions across the lifecourse to prevent obesity and chronic diseases, especially in underserved populations. Her work spans the spectrum of observational studies and interventions—to identify and quantify risk factors—and to modify these risk factors for health promotion and disease prevention. She has published over 150 research studies and served on committees for the National Academy of Medicine to develop recommendations for prevention of obesity in early life and for evaluating the progress of national obesity prevention efforts. Her work in early life origins of childhood obesity was cited by The Robert Wood Johnson Foundation as one of the most influential studies of 2010 and in the White House Task Force Report on Childhood Obesity in May 2010. In 2016, she received the Public Health Leadership in Medicine Award from the Massachusetts Association of Public Health for her extensive work improving health and health care in community-based settings.
Perdita Taylor-Zapata, MD, is a board certified pediatrician from the Washington Metropolitan area. She graduated from Howard University Medical School, and completed her pediatric residency training at the Children’s National Medical Center in Washington, DC. After residency, she started working at the Clinical Center of the National Institutes of Health as a clinic physician in the Pediatric HIV Working Group. There, Taylor-Zapata spent seven years taking care of the outpatient and inpatient medical needs of the HIV-positive pediatric patients enrolled in phase I/II clinical treatment trials. In addition to her role as a staff physician, she was also involved in developing manuscripts and conducting retrospective and prospective research projects. As her career developed, she became interested in the use, side effects, and toxicity profiles of medications used in children and published a paper in Pediatrics in 2004 on Lipodystrophy in HIV-infected Children.

In August of 2004, Taylor-Zapata joined the Obstetric and Pediatric Pharmacology branch of the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), where she is now a medical officer working with a team of experts responsible for the implementation of the Best Pharmaceuticals for Children Act (BPCA). Taylor-Zapata oversees the prioritization process of the BPCA Program and is the project officer for the Data Coordinating Center.

Charles Thompson, MD, FAAP, is a board-certified pediatrician who earned his MD at the University of Connecticut School of Medicine and completed his pediatric residency at Connecticut Children’s Medical Center in Hartford. He is a clinical instructor of pediatrics at the University of Connecticut School of Medicine and is a member of the medical staff at Connecticut Children’s Medical Center.

Currently, Thompson is the global lead for the Pfizer Pediatric Center of Excellence. Throughout his 20-year career at Pfizer, he has taken on diverse roles in clinical development, clinical safety/risk management, and field medical affairs. He is also the past chair of the Executive Committee for the American Academy of Pediatrics Section on Advances in Therapeutics and Technology, a member of the board for the Hezekiah Beardsley Connecticut Chapter of the American Academy of Pediatrics, the founder and chair of iCAN (International Children’s Advisory Network), and a steering committee member for the Global Alliance for Pediatric Therapeutics, a pre-competitive public/private partnership to advance the development of medicines for children. He is serving his second term as a governor-appointed member of the Connecticut Pharmaceutical and Therapeutics committee, and has served on the State of Connecticut Immunization Task Force following an appointment by the speaker of the House.
David Williams, MD is chief scientific officer and senior vice president for research at Boston Children’s Hospital and president of the Dana-Farber/Boston Children’s Cancer and Blood Disorders Center. His laboratory has been continuously NIH funded since 1986, and has trained over 45 fellows and post-doctoral fellows, as well as numerous residents and medical students in his laboratory. Williams is a member of the National Academy of Medicine (formerly Institute of Medicine). He has published over 250 peer-reviewed manuscripts, over 100 invited reviews, and multiple textbook chapters. He is actively involved in gene therapy trials for blood, immunodeficiency, and neurological genetic diseases and has been the investigator, co-investigator, or sponsor (IND holder) of four previous gene therapy trials and is sponsor, investigator, or co-investigator of four current trials. Williams was ASH councilor for four years, served three years in succession as an officer, and president of ASH in 2014-2015, and a past president of the International Society of Hematology. He served as the editor-in-chief of Molecular Therapy from 2004-2009. He is co-founder of the Transatlantic Gene Therapy Consortium and the North American Pediatric Aplastic Anemia Consortium. His basic research has focused on hematopoietic stem cell biology, including genetic diseases of the blood and specifically molecular and biochemical analysis of the interaction between hematopoietic stem cells and the bone marrow supporting environment. He has multiple-issued patents, several of which have been licensed including IL-11 (NeumegaTM) and the use of fibronectin in gene transfer (RetronectinTM).
Founded in 2008, Harvard Catalyst | The Harvard Clinical and Translational Science Center is dedicated to improving human health by enabling collaboration and providing tools, training, and technologies to clinical and translational investigators. As a shared enterprise of Harvard University, Harvard Catalyst resources are available to all Harvard faculty and trainees, regardless of institutional affiliation or academic degree.

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Harvard Catalyst is one of three collaborators on the NCATS-funded SMART IRB platform, designed to ease common challenges and burdens associated with initiating multisite research and to provide a roadmap for institutions to implement the NIH Single IRB Review policy.

Over 150 institutions across the US have already signed on.

smartirb.org

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