



## MULTI-REGIONAL CLINICAL TRIALS

THE MRCT CENTER of  
BRIGHAM AND WOMEN'S HOSPITAL  
and HARVARD

Advancing International Pediatric Clinical Research:

*Assent and Consent in the Field: Culture, Context & Respect*

28 & 29 June 2022

*The 3<sup>rd</sup> webinar in a 5-part series*

Webinar Participant Biographies



## Conference planning committee members

**Albert J “AJ” Allen, MD, PhD**, Eli Lilly & Co (retired)

**Barbara E. Bierer, MD**, Faculty Director, Multi-Regional Clinical Trials Center (MRCT Center)

**Phaik Yeong Cheah, PhD**, MORU Tropical Health Network, Bangkok, Thailand and University of Oxford, England

**Jonathan M. Davis, MD**, Tufts Medical Center and Tufts University School of Medicine, USA

**Nilza Diniz, MS, PhD**, University of Londrina, Brazil

**Steven Joffe, MD**, University of Pennsylvania Perelman School of Medicine, USA

**Dominik Karres, MD, CPM**, European Medicines Agency

**Elisa Koppelman, MSW, MPH**, The MRCT Center

**Mariana Kruger, MD, PhD**, Stellenbosch University, South Africa

**Susan K. McCune, MD**, PPD

**Walker Morrell, BS, MBe**, The MRCT Center

**Vasantha Muthuswamy, MD**, Forum for Ethics Review Committees in India (FERCI)

**Robert “Skip” Nelson, MD, PhD**, Johnson & Johnson

**Gary Noel, MD**, Institute for Advanced Clinical Trials for Children (iACT)

**Carla Saenz, PhD**, Pan American Health Organization (PAHO)

**Donna Snyder, MD**, U.S. Food and Drug Administration

**Rhian Thomas-Turner, PhD student**, Cardiff and Vale University Health Board, Swansea University, Wales

**Mark Turner, MD, PhD, MRCP, FFPM**, University of Liverpool, England

**Lisine Tuyisenge, MD**, University Teaching Hospital of Kigali, Rwanda

**Leanne West, MS**, Georgia Institute of Technology, USA and International Children’s Advisory Network (iCAN).

**Sarah Alicia White, MPH**, The MRCT Center

**Katharine Wright, MA**, Nuffield Council on Bioethics

## Special Acknowledgements

**Jennifer Ewing & Kristin Bartlett**, The MRCT Center

**Dr. Gianna McMillan**, Loyola Marymount University, Bioethics Institute

**International Children’s Advisory Network (iCAN)**, producer of “Prioritizing Young People’s Voices in Clinical Research” video

All the youth who shared their time, expertise and stories with us from iCAN and Kids Barcelona



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PART THREE

## Advancing International Pediatric Clinical Research

### ASSENT AND CONSENT IN THE FIELD: Culture, Context, and Respect

Session 1 June 28, 2022 From 9am-11am EDT

Session 2 June 29, 2022 From 8pm-10pm EDT

Please register for one or both as each will compliment the other!



This series is supported by an FDA Scientific Conference Grant.



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**Advancing International Pediatric Clinical Research  
Assent and Consent in the Field: Culture, Context & Respect**

**PART THREE: Assent and Consent in the Field: Culture, Context & Respect**

**Session One: 28 June 2022: 9:00 AM – 11:00 AM EDT**

Time	Topic	Speaker
9:00 -9:05 AM EDT	Welcome and introduction	<b>Dr. Barbara E. Bierer</b> Faculty Director, The MRCT Center USA
9:05 -9:10 AM EDT	Video: "Prioritizing Young People's Voices in Clinical Research"	<b>Produced by iCAN and MRCT Center</b>
9:10-9:40 AM EDT	Keynote address: " <i>Lessons learned conducting paediatric clinical research in resource limited settings</i> "	<b>Keynote Speakers:</b> <b>Dr. Dylan Graetz &amp; Dr. Victor Santana</b> St. Jude's Hospital USA
9:40 – 10:55 AM EDT	<b>Panel Discussion:</b>	<b>Moderator:</b> <b>Dr. Martine Dehlinger-Kremer</b> ICON Germany



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		<p><b>Speakers:</b></p> <p><b>Dr. Haleema Saeed</b> Shaukat Khanum Memorial Cancer Hospital and Research Centre Pakistan</p> <p><b>Dr. Ruben Cuttica</b> Hospital General de Niños Pedro de Elizalde Argentina</p> <p><b>Dr. Muhammed Afolabi</b> London School of Hygiene &amp; Tropical Medicine England</p>
10:55 – 11:00 AM EDT	Wrap up	<p><b>Dr. Barbara E. Bierer</b> Faculty Director, The MRCT Center USA</p>



Advancing International Pediatric Clinical Research  
Assent and Consent in the Field: Culture, Context & Respect

**PART THREE: Assent and Consent in the Field: Culture, Context & Respect**

**Session two: 29 June 2022: 8:00 PM – 10:00 PM EDT**

Time	Topic	Speaker
8:00 -8:05 PM EDT	Welcome and introduction	<b>Dr. Barbara E. Bierer</b> Faculty Director, The MRCT Center USA
8:05 -8:10 PM EDT	Video: "Prioritizing Young People's Voices in Clinical Research"	<b>Produced by iCAN and MRCT Center</b>
8:10-8:40 PM EDT	Keynote address: <i>"Consent and assent in paediatric research: challenges in global health research"</i>	<b>Keynote Speaker:</b> <b>Dr. Phaik Yeong Cheah</b> University of Oxford MORU Tropical Health Network Thailand



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8:40 – 9:55 PM EDT	<b>Panel Discussion:</b>	<b>Moderator:</b> <b>Dr. Steven Joffe</b> University of Pennsylvania Perelman School of Medicine USA  <b>Speakers:</b> <b>Dr. Jacinto “Jojo” Blas Mantaring</b> UP College of Medicine Philippines  <b>Dr. Erwin J. Khoo</b> International Medical University Malaysia  <b>Dr. Seung-min Hahn</b> Yonsei University College of Medicine Korea  <b>Dr. Wan-Ting Chou</b> PPD Taiwan/Japan
9:55 – 10:00 PM EDT	Wrap up	<b>Dr. Barbara E. Bierer</b> Faculty Director, The MRCT Center USA

## Webinar speakers



**Muhammed Afolabi, MD, MPH, PhD, FWACP, FHEA, FFPH**, is a Global Health scientist and a Clinical Associate Professor at the London School of Hygiene & Tropical Medicine. He obtained a medical degree from the University of Ibadan and a master's degree in Public Health from Obafemi Awolowo University, both in Nigeria, and a PhD from the London School of Hygiene & Tropical Medicine, UK. Dr. Afolabi underwent specialist training that led to the award of the postgraduate fellowship of the West African College of Physicians in Family Medicine; he is also a Fellow of the Faculty of Public Health and Higher Education Academy.

Dr. Afolabi's research antecedents were in the evaluation of vaccines related to the control and prevention of Ebola, HIV and malaria across several African countries. He led the Ebola paediatric vaccine trials in Sierra Leone, findings of which contributed to the approval of the novel two-dose Ebola vaccine regimen (ZABDENO/MVABEA) by the European Medicines Agency and World Health Organisation for the first time in children. Dr. Afolabi has a track record of developing innovative solutions to address the unmet needs of the populations he works with. For example, to address the perennial challenges faced when communicating essential research information to low-literacy research participants, Dr. Afolabi developed and evaluated a simplified alternative method of delivering consent information using a locally designed multimedia tool which integrated video, animations and audio narrations in local languages. The multimedia consent tool has changed the way informed consent procedure is conducted in many settings in Africa. Additionally, Dr. Afolabi serves on several committees including the WHO Strategic Advisory Group of Experts (SAGE) Working Group on COVID-19 vaccines and Nuffield Council on Bioethics.



**Barbara E. Bierer, MD**, is the Faculty Director of the Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center), a Professor of Medicine, Harvard Medical School and Brigham and Women's Hospital, Boston and a hematologist/oncologist. She is the Director of the Regulatory Foundations, Ethics and the Law Program of the Harvard clinical and translational sciences center. Previously she served as senior vice president, research at the Brigham and Women's Hospital for 11 years, and was the institutional official for human subjects and animal research, for biosafety and for research integrity. She initiated the Brigham Research Institute and the Innovation Hub (iHub), a focus for entrepreneurship and innovation. In addition, she was the Founding Director of the Center for Faculty Development and Diversity at the BWH.

In addition to her academic responsibilities, Dr. Bierer serves on the Board of Directors of Vivli, Inc., a non-profit organization founded by the MRCT Center dedicated to global clinical trial sharing; North Star Research Board; Clinithink, Inc., and the Edward P Evans Foundation. Previously she has served on the Board of Directors of Public Responsibility in Medicine and Research (PRIM&R) and the Association for Accreditation of Human Research Protection Programs (AAHRPP) and as chair of the Secretary's Advisory Committee on Human Research Protections, HHS, among others. She has authored or co-authored over 270 publications and is on the editorial boards of a number of journals including *Ethics and Human Research*. Dr. Bierer received a B.S. from Yale University and an M.D. from Harvard Medical School.



**Phaik Yeong Cheah** is a Professor of Global Health and bioethicist at University of Oxford. She is the founder and current head of the Department of Bioethics & Engagement at the Bangkok based Mahidol Oxford Tropical Medicine Research Unit (MORU). Dr. Cheah's research focuses on ethical issues arising in conducting research with underserved populations, in particular how to ethically involve children, migrants, refugees and other marginalized groups in health research. She currently manages MORU's community and public engagement programme that aims to embed community and public voices in research, and health programmes to ensure that they are ethical, responsive and that their potential health impact is maximized.



**Wan-Ting Chou, MD, PhD**, joined PPD in August 2019 as an associate medical director. Her responsibilities include providing consultation to clients and project team members for clinical trial program development, training, safety monitoring and other medical issues. She also serves as a medical reviewer for clinical trial documents and provides medical oversight on clinical trials. Dr. Chou is a certificated medical doctor both in Japan and Taiwan. She received her M.D. degree in 2003 from National Yang-Ming University in Taiwan and thereafter was fully trained in Kaohsiung Veterans General Hospital as a pediatrician. After working as an experienced pediatrician in hospital, she obtained her PhD in Medicine degree (Epidemiology) in Japan and was an Assistant Professor in Tohoku University Graduate School of Medicine in Japan.

Dr. Chou's clinical experiences in pediatrics range from neonatology, rare diseases, hematology, oncology, nephrology, cardiology, pulmonology, immunology, endocrinology, rheumatology, neurology, gastroenterology, infectious diseases and vaccination. Dr. Chou is fluent in Mandarin Chinese, Japanese and English.



**Rubén J. Cuttica, MD, Prof** received his Medical Doctor degree from the University of Buenos Aires, School of Medicine, and is a member of the Pediatrician Argentine Pediatric Association and Rheumatologist Argentine Rheumatology Association. After completing his residency in Pediatrics in Elizalde Children's Hospital of Buenos Aires he founded and developed Pediatric Rheumatology in Argentina in 1974.

In 1980 Dr. Cuttica was a fellow of Pediatric Rheumatology with Dr. Barbara Ansell in The Clinical Research Centre, Harrow, London. He was Professor of Pediatrics at the University of Buenos Aires School of Medicine, and Director of the Carrere of Pediatric Rheumatology. In 1990 Dr. Cuttica was appointed as Medical Advisor in Clinical Research at Ciba Geigy company, later Novartis, until 1998. Since that time, he has been a Principal Investigator in more than 20 clinical trials for development of biologic drugs for children with rheumatic diseases. A member of PRINTO (Pediatric Rheumatology International Trials Organization), Dr. Cuttica has participated in several consensus meetings for the development of scales of evaluation of disease activity and damage in several rheumatic diseases in children. He is the Founder and President of the Pediatric Rheumatology Foundation and currently is a Pediatric Rheumatology Consultant at Elizalde Children's Hospital of Buenos Aires and Principal Investigator in Clinical Trials.



**Martine Dehlinger-Kremer, MD** expertise spans more than 30 years in the research industry, including 30 years of experience in global regulatory affairs, medical affairs, and pediatric leadership. Prior to joining ICON, she served in several executive leadership roles at global CROs, and has experience in global drug development in more than 40 countries. She has contributed to the global development of numerous products, including medicines for children, drugs for orphan diseases and biosimilars. Her vision and leadership extend to service with a number of professional organizations: she is an observer member of the Coordinating Group of the European Network of Pediatric Research (Enpr-EMA) at the European Medicines Agency, chair of the Pediatric Working Group and also President of the

European CRO Federation (EUCROF), serves as chair of the European Forum for Good Clinical Practice (EFGCP) Children Medicines Working Party and Board Member of the association, and is active in the International Children's Advisory Network (iCAN).

In 2015, Dr. Dehlinger-Kremer was named one of PharmaVOICE's 100 Most Inspiring People in Life Sciences.

Dr. Dehlinger-Kremer earned a Doctorate in Sciences from the J. W. Goethe University in Frankfurt on the Main, Germany; a Degree of Advanced Study in Neurophysiology from the University Louis-Pasteur, Strasbourg, France, and a Master of Sciences degree from University Moulin de la Housse in Reims, France.



**Dylan Graetz, MD, MPH**, is a pediatric oncologist and Assistant Professor at St. Jude Children's Research Hospital where she directs the Culture and Communication program within the department of Global Pediatric Medicine. Dr. Graetz's research focuses on how cultural context impacts interactions between pediatric cancer patients and families and their healthcare teams. Through her work, Dr. Graetz aims to understand and enhance communication practices and patient-centered care of pediatric oncology patients in global settings, as well as interdisciplinary communication of healthcare teams. Dr. Graetz's work spans the globe including ongoing studies in the United States, Guatemala, Pakistan, Jordan, Zimbabwe, and the Philippines. Clinically, Dr.

Graetz treats children with solid tumors with a specific focus in renal cancers.



**Seung-min Hahn, MD**, graduated from Yonsei University College of Medicine in 2009, completing her pediatric residency and pediatric hematology/oncology subspecialty training in Yonsei Cancer Center, Severance hospital. Dr. Hahn works as a pediatric hematologist/oncologist and participates in international multicenter clinical trials of new oncologic drugs and hemophilia therapies. She is also working as a member of the Korean society of hematology (KSH), the Korean society of pediatric hematology-oncology (KSPHO), the Korean society of Blood and Marrow Transplantation (KSBMT), and Severance Hospital, Yonsei University Health System Institutional Review Board.



**Erwin J Khoo, MBBS, FRCPC, AM** is a Fellow in the Centre for Bioethics, Harvard Medical School (US) for the upcoming academic year of 2022-2023 and Head of Paediatrics Department at International Medical University, Malaysia. He is a Consultant Paediatrician and Fellow of the Royal College of Paediatrics and Child Health (UK), as well as a Former Deputy Director of Centre for Bioethics and Humanities at International Medical University. He has been involved in the governance of several public and private initiatives, and currently serves as an Executive Council Member for the College of Paediatrics, Academy of Medicine of Malaysia and an editorial board member for *BMC Pediatrics*. Dr Khoo is actively involved in both undergraduate and postgraduate medical education and has over 50 publications in peer-reviewed journals and the media. He has received many honors in recognition of his accomplishments and has been awarded various grants from national and international organisations for his work. Dr. Khoo's research includes all aspects of child health and assent seeking from children on the ground in multi-cultural Malaysia.



**Steven Joffe, MD, MPH**, is a pediatric oncologist and bioethicist who is currently the Art and Ilene Penn Professor of Medical Ethics and Health Policy and Professor of Pediatrics at the University of Pennsylvania Perelman School of Medicine, where he serves as Acting Chair of the Department of Medical Ethics and Health Policy and Chief of the Division of Medical Ethics. He is also the Director of the Penn Postdoctoral Training Program in the Ethical, Legal and Social Implications (ELSI) of Genetics and Genomics. Dr. Joffe's research addresses the many ethical challenges that arise in the conduct of clinical and translational investigation and in genomic medicine and science. He has led NIH and foundation grants to study the roles and responsibilities of principal investigators in multicenter randomized trials, accountability in the clinical research enterprise, children's capacity to engage in research decisions, return of individual genetic results to participants in epidemiologic cohort studies, and the integration of whole-exome sequencing technologies into the clinical care of cancer patients. He has coauthored over 200 articles addressing these topics. He serves as a member the NIH's COVID19 Vaccine Trials Data and Safety Monitoring Board, recently completed a term as a member of the US FDA's Pediatrics Ethics Subcommittee, and is immediate past chair of the National Human Genome Research Institute's Genomics and Society Working Group, NIH, USA. He attended Harvard College, received his medical degree from the University of California at San Francisco, and received his public health degree from UC Berkeley. He trained in pediatrics at UCSF and undertook fellowship training in pediatric hematology/oncology at the Dana-Farber Cancer Institute and Boston Children's Hospital.



**Jacinto Blas V. Mantaring III, MD, MSc**, or "Jojo" as he is fondly called, graduated from the University of the Philippines, College of Medicine in 1984. He underwent specialty training in Pediatrics in the Philippine General Hospital from 1986-1988 and served an extra year as the chief resident in 1989. He then pursued post-residency fellowship training in Neonatal-Perinatal Medicine in the Wayne State University, Detroit Medical Center in Detroit Michigan from 1992 to 1997. Upon his return to the Philippines, he pursued a Masters' degree in Epidemiology (Clinical Epidemiology) in the University of the Philippines, and was eventually absorbed as a faculty member in the Department of Clinical Epidemiology, which he serves as the current chair. Because of his mastery of clinical epidemiology, he was exposed to the world of research ethics. He has been involved in research ethics since 2004 and has been the chair of the University of the Philippines Research Ethics Board since 2011. He now also serves the country as the chair of the Department of Health - Single Joint Research Ethics Board and a member of the Health Technology Assessment Council. Recently, he has been tapped to introduce research integrity to the University of the Philippines as one of the founding members of the Committee on Research Integrity. In his capacity as either the chair or a member of the above-mentioned committees, Dr. Mantaring combines

his knowledge of Pediatrics, Neonatology, Epidemiology and Research Ethics in creating policies, guidelines and operating procedures. He has been a favorite and important resource speaker in lectures, seminars, workshops, conferences and conventions.



**Haleema Saeed, MD** is a pediatric hematologist and oncologist with a special interest in pediatric oncology in resource limited settings. She completed her medical degree from The Aga Khan University Medical College in Karachi, Pakistan. After that she travelled to USA to complete her residency in Pediatrics at MetroHealth Medical Center and later fellowship training in Pediatric Hematology/Oncology at Children's Hospital Medical Center, Akron, Ohio. For the last eight years, she has been practicing as a consultant Pediatric Oncologist at Shaukat Khanum Memorial Cancer Hospital and Research Center (SKM) in Lahore, Pakistan. SKM is a tertiary care referral Center for Cancer care in the region. This has been a time of significant growth in this specialty in Pakistan and Dr. Saeed has had an opportunity to be a part of development of local fellowship training in pediatric oncology and development of national guidelines for treatment of common pediatric malignancies like retinoblastoma. She is now actively involved in initiation of the first multi-institutional national prospective clinical trials in pediatric oncology in Pakistan under the umbrella of Pakistan society of Pediatric Oncology.



**Victor M. Santana, MD** is a full member in the Department of Oncology and the Department of Global Pediatric Medicine at St. Jude Children's Research Hospital (SJCRH) and holds the Charles B. Pratt Endowed Chair in Solid Tumor Research. His professional career as a pediatric oncologist and clinical investigator has been devoted to developing new experimental treatment approaches for children with high-risk cancers and applying knowledge and expertise in clinical trial design and regulatory aspects of pediatric clinical research. His research aims to identify promising new therapies for children with cancer and understanding how they can be best implemented globally. As a clinical investigator for more than 35 years, Dr. Santana has been a principal investigator and collaborator in numerous clinical trials. Dr. Santana is a past member of the U.S. Food and Drug Administration's Pediatric Advisory Committee, and presently serves on the NCI's Central Pediatric Institutional Review Board (CIRB) and the NCI Clinical Trials and Translational Research Advisory Committee (CTAC). Dr. Santana is a past Chair of the Children's Oncology Group Phase I-II Data Safety Monitoring Board, as well as past chair of the NCI Pediatric Central IRB. Dr. Santana's interest in teaching the next generation of clinical investigators and staff is evidenced in his active participation as lecturer in the SoCRA Clinical Science course, and as a recipient of the organization's President's Award for Distinguished Service. Within the St. Jude Graduate School in Biomedical Sciences, he co-leads the master's degree program in clinical investigations. To this webinar he brings expertise in understanding conceptual development, implementation strategies and solutions to challenges inherent in clinical research in international settings.