Human Subject Protection

I'm Still Standing

October 12-13, 2022 – Virtual

Program Overview

The purpose of this program is to provide information to institutional review board (IRB) members, IRB administrators, clinical investigators, research support staff, research sponsors, contract research organizations (CROs), government regulators, and members of the clinical research community about current issues regarding human subjects protection in research.

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Cincinnati Children's

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Office of Research Integrity

NKU Northern Kentucky University

CCTST Center for Clinical & Translational Science & Training

Center for Clinical and Translational Science

Conference Cost

- $75 registration
- An early-registration rate of $65 is available to all attendees through August 31, 2022.
- Includes material, CME and CEU credits.
- Registration ends October 11, 2022. All payments are non-refundable but transferrable through October 11, 2022.

Virtual Conference

As much as we would like to be able to meet again in person, this conference will be virtual until such time that large group gatherings can be conducted safely. This event will occur via ZOOM. Access details will be included with conference confirmation and reminder messages.

To help keep the event interactive, we will incorporate audience participation with live polling throughout the conference and open Q&A at the end of each talk.

Daily Schedule

To accommodate busy schedules, the conference will be spread over two days, with three talks each day, from 12:00 - 4:00 pm ET.

Register Online

Visit https://cchmc.cloud-cme.com/course/courseoverview?P=0&EID=40958 and click "Register" at the top. Capacity is limited; please register early.

If you have any questions about the conference, please email hspconference@advarra.com or call 513.761.4100 and ask to speak with someone about the conference.

Day 1 Program Overview
Wednesday, October 12, 2022

- **12:00 pm – 12:15 pm**
  Welcome, Opening Remarks, and Introductions

- **12:15 pm – 1:15 pm**
  Beyond the IRB: Downstream Social Impacts of Research
  David Mangus, PhD; Stanford University

  IRBs are prohibited from considering downstream social consequences or impacts on society as risks of research in evaluating their calculation. In AI research, there is widespread recognition of the potential for bias and privacy concerns. But little has been done on potential dual use applications. Potential oversight options to address the limitations of IRB will be discussed.

- **1:15 pm – 1:20 pm Break**

- **1:20 pm – 2:20 pm**
  Applying Health Literacy Principles to Clinical Research Studies: Health Literacy in Action
  Sylvia Baedorf Kassis, MPH, CYT; Brigham and Women's Hospital and Harvard

  In this session, attendees will learn about health literacy and its application to the clinical research life cycle, including specific examples of how health literacy best practices have been integrated into clinical research settings. This session will also identify specific health literacy best practices that attendees can apply to research materials they create and/or review.

- **2:20 pm – 2:25 pm Break**

- **2:25 pm – 3:25 pm**
  Adverse Events: Understanding U.S. Clinical Trial Participation in the Context of Social Inequalities
  Jill Fisher, PhD; UNC Center for Bioethics

  Phase I clinical trials test the safety and tolerability of new pharmaceuticals and typically pay healthy people to enroll as research participants. In addition to the risks of taking investigational drugs, healthy volunteers are confined—and often literally locked in—to residential research facilities for some portion of the clinical trial. Although participants are often assumed to be young, white college students, Phase I clinics actually tend to recruit men of color in their late 20s to early 40s. Motivated by larger social contexts of economic insecurity and racial discrimination, healthy volunteers often enroll serially in Phase I trials to stay afloat or try to get ahead. Drawing on two years of fieldwork in clinics across the U.S. and 268 interviews with research participants and staff, this talk illustrates how decisions to take part in such medical research studies stem from profound racial and economic inequalities in the U.S.

Each session will include time for questions and answers with the presenters/panelists to allow for active learning opportunities.

Please note: Program agenda is subject to change

Day 2 Program Overview
Thursday, October 13, 2022

- **12:00 pm – 12:10 pm**
  Welcome and Introductions

- **12:10 pm – 1:10 pm**
  Ethical Challenges in Research Consent: Nudges, Opt-Out Systems, and Direct-to-Patient Invitations
  Aisha Langford, PhD, MPH; NYU Grossman School of Medicine

  This talk will highlight various approaches to enhancing clinical trial communications and informed decision making about clinical trial opportunities. Attendees will learn about a general conceptual model for clinical trial participation that can be applied to various disease and behavioral contexts. The session will also introduce the ASK (Assume, Seek, Know) approach for enhancing clinical trial participation: (1) assume that all patients will want to know their options, (2) seek the counsel of stakeholders, and (3) know your numbers. Attendees will also hear about the current literature on nudges and choice architecture, and implications for recruitment and retention, and will learn about methods and resources to promote equity and inclusion in research – both from a marketing and patient perspective. The presenter will share lessons learned from serving as a Co-Director of her organization's CTSA's Recruitment and Retention Core.

- **1:10 pm – 1:15 pm Break**

- **1:15 pm – 2:25 pm**
  Recognizing and Preventing Fraud in Online Survey Research: Considerations for Researchers and Institutional Review Boards
  Lorraine Reitzel, PhD, FAAHB, FSRNT; University of Houston

  In this session, attendees will learn how to identify signs of online survey compromise and differentiate fake from real participants. They will also learn through real-life case study examples how to modify procedures to protect from further compromise, anticipate research protocols under review that may be vulnerable to fraud, and advise principal investigators regarding how to minimize risk and handle survey compromise (e.g., reporting requirements, compensation provision) if it occurs.

- **2:25 pm – 2:30 pm Break**

- **2:30 pm – 3:30 pm**
  Policy, Regulatory, and Enforcement Updates from the NIH
  Michael Lauer, MD; NIH

  In this session, attendees will learn about the history, requirements, and expectations underlying the NIH Data Management and Sharing Policy and will become familiar with new requirements and resources. Attendees will also hear about the NIH's efforts to address harassment in the biomedical research workspace and the new requirements stemming from FY2022 Congressional legislation.

Each session will include time for questions and answers with the presenters/panelists to allow for active learning opportunities.

Please note: Program agenda is subject to change

Conference Faculty

Jill Fisher, PhD
Dr. Jill A. Fisher is Professor in the Department of Social Medicine and Center for Bioethics at the University of North Carolina at Chapel Hill. She holds a Ph.D. in Science and Technology Studies, and her research primarily focuses on how clinical trials are conducted and who participates in them as researchers and participants. She has published more than 50 articles and book chapters, and she is the author of Medical Research for Hire: The Political Economy of Pharmaceutical Clinical Trials (Rutgers University Press, 2009) and Adverse Events: Race, Inequality, and the Testing of New Pharmaceuticals (New York University Press, 2020). She also edited the collection Gender and the Science of Difference: Cultural Politics of Contemporary Science and Medicine (Rutgers University Press, 2011). More information about Dr. Fisher, as well as many of her publications, can be found at her website: www.jillfisher.net.

Sylvia Baedorf Kassis, MPH, CYT
Sylvia Baedorf Kassis joined the MRCT Center as Program Manager in January of 2018. With 20 years of clinical research-related experience in Canada and the U.S., her expertise includes ethical/regulatory review of research, clinical trial workforce training and capacity building, and study coordination, management, and oversight. In her current role, Kassis is focused predominantly on efforts to make clinical research more understandable and accessible to patients and participants through her work on Health Literacy in Clinical Research, and she provides input on other MRCT Center initiatives through a health literacy lens. Kassis also supports the Individual Return of Results project and capacity-building efforts.

Kassis' clinical research interests include: understanding trial participants' experiences in research and incorporating their insights into study processes; supporting research coordinators through networks and training; and ensuring all research stakeholders are supported in the ethical and compliant conduct of studies involving participants and their data/samples.

Kassis possesses a Master of Public Health degree in Global Health from Boston University School of Public Health (2008) and a Bachelor of Science from the University of Toronto (2001). She is also a Certified Yoga Teacher (2011) and trained in mindfulness techniques.

Aisha Langford, PhD, MPH
Aisha Langford is Assistant Professor in the Department of Population Health, Division of Comparative Effectiveness and Decision Science within NYU Langone Health. She is also an affiliated faculty member in the Division of Medical Ethics. Under NYU Langone Health's Clinical and Translational Science Institute (CTSI), she co-directs the Recruitment and Retention Core (RRC) alongside a pediatrician and geriatrician. In this co-director role, Dr. Langford advises study teams across the medical school on recruitment feasibility and ways to maximize participant retention, covering all stages of clinical trial and health research study design. A large proportion of these consultations include ways to enhance inclusion of women, racial/ethnic minorities, and adults aged 65 and older in clinical research. Dr. Langford advocates that researchers should ensure that all eligible patients are invited to participate in clinical trials and that underrepresented populations in research have equitable access to research opportunities, which often means addressing the logistical and communication barriers that may hinder participation. She earned her BA in English from the University of Virginia, MPH in Behavioral Science from Saint Louis University, and PhD in Health Behavior and Health Education from the University of Michigan.

Michael Lauer, MD
Dr. Michael Lauer is the Deputy Director for Extramural Research at the National Institutes of Health (NIH), where he serves as the principal scientific leader and advisor to the Director of the NIH on all matters relating to the substance, quality, and effectiveness of the NIH extramural research program and administration. He received education and training at Rensselaer Polytechnic Institute, Albany Medical College, Harvard Medical School, Harvard School of Public Health, and the NHLBI's Framingham Heart Study. He spent 14 years at Cleveland

Clinic as Professor of Medicine, Epidemiology, and Biostatistics. During his tenure at the Clinic, he led a federally funded, internationally renowned clinical epidemiology program that applied big data from large-scale electronic health platforms to questions regarding the diagnosis and management of cardiovascular disease. From 2007 to 2015 he served as a Division Director at the National Heart, Lung, and Blood Institute (NHLBI), where he promoted efforts to leverage big data infrastructure to enable high-efficiency population and clinical research and efforts to adopt a research funding culture that reflected data-driven policy. He has received numerous awards including the NIH Equal Employment Opportunity Award of the Year and the Arthur S. Flemming Award for Exceptional Federal Service in recognition of his efforts to grow a culture of learning and accountability.

David Mangus, PhD
David Magnus is Thomas A. Raffin Professor of Medicine and Biomedical Ethics and Professor of Pediatrics and Medicine and by Courtesy of Bioengineering at Stanford University, where he is Director of the Stanford Center for Biomedical Ethics and Associate Dean of Research. Magnus is a member of the Ethics Committee for the Stanford Hospital and is currently the Vice-Chair of the IRB for the NIH Precision Medicine Initiative ("All of Us"). He is the former President of the Association of Bioethics Program Directors and is the Editor in Chief of the American Journal of Bioethics. He has published articles on a wide range of topics in bioethics, including research ethics, genetics, stem cell research, organ transplantation, end of life, and patient communication. He was a member of the Secretary of Agriculture's Advisory Committee on Biotechnology in the 21st Century and currently serves on the California Human Stem Cell Research Advisory Committee. He is the principal editor of a collection of essays entitled "Who Owns Life?" (2002) and his publications have appeared in New England Journal of Medicine, Science, Nature Biotechnology, and the British Medical Journal. He has appeared on many radio and television shows including 60 Minutes, Good Morning America, The Today Show, CBS This Morning, FOX news Sunday, and ABC World News and NPR. In addition to his scholarly work, he has published opinion pieces in the Philadelphia Inquirer, the Chicago Tribune, the San Jose Mercury News, and the New Jersey Star Ledger.

Lorraine R. Reitzel, PhD, FAAHB, FSRNT
Lorraine R. Reitzel is a licensed clinical psychologist and a Distinguished Professor of Education in the Department of Psychological, Health, & Learning Sciences at the University of Houston. Her research focuses on the social determinants of cancer and cancer risk behaviors - and the specific biopsychosocial mechanisms that account for associated disparities among minoritized and marginalized groups - with an emphasis on generating highly translational results that inform policy and intervention. She has been instrumental in securing >$40 million in interdisciplinary sponsored research as a principal investigator (PI) or co-investigator, with ~$10 million as PI. This work has been funded by the Centers for Disease Control and Prevention; the Cancer Prevention & Research Institute of Texas; the National Cancer Institute; the National Institute on Drug Abuse; the National Institute on Minority Health and Health Disparities; the National Heart, Lung, and Blood Institute; and the American Cancer Society. She has authored over 170 empirical research publications and has served as a member and chair of IRB committees at two institutions over the last 12 years (Psychosocial, Behavioral, and Health Services Research Committee at the University of Texas MD Anderson Cancer Center, 2010-2013; Committee for the Protection of Human Subjects/Institutional Review Board #1 at the University of Houston, 2013-present).

Continuing Education Information

In support of improving patient care, this activity has been planned and implemented by Cincinnati Children's, Northern Kentucky University, and Advarra. Cincinnati Children's is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC), to provide continuing education for the healthcare team.

JOINTLY ACCREDITED PROVIDER™
INTERPROFESSIONAL CONTINUING EDUCATION

CME: Cincinnati Children's designates this live activity for a maximum of 6.25 (3.0W, 3.25Th) *AMA PRA Category 1 Credit(s)*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

CNE: This activity is approved for a maximum 6.25 (3.0W, 3.25Th) continuing nursing education (CNE) contact hours.

IPCE CREDIT™

IPCE: This activity was planned by and for the healthcare team, and learners will receive a maximum of 6.25 (3.0W, 3.25Th) Interprofessional Continuing Education (IPCE) credits for learning and change.

CIP: Conference sessions that meet the criteria in the Certified IRB Professional (CIP) recertification guidelines are eligible as accredited continuing education units. Conference participants who hold the CIP® credential who wish to apply the 6.25 credits from this program toward CIP recertification may submit their Certificate of Attendance as documentation of their participation. Additional information about CIP recertification can be found here: primr.org/cip/recertification

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