Collaboration, Community and Connection: Partnering to Advance Research

DAY 1 - Monday, September 9, 2024

Time	Session and Speaker Details
9:45 AM–10 AM	Attendees Joining
10 AM–10:10 AM	Welcome and Opening Remarks • Anantha Shekhar, MD, PhD, serves as senior vice chancellor for the health sciences and John and Gertrude Petersen Dean of the School of Medicine. 3-5 minutes • Rob A. Rutenbar, PhD, is Senior Vice Chancellor for Research at the University of Pittsburgh, where he has responsibility for Pitt's research and innovation infrastructure. 2-3 minutes • OHRP - 2 minutes
10:10 AM–11 AM	OHRP Presents Title: Conducting Cooperative Research Under the Common Rule Research projects in both biomedical and socio-behavioral arenas are now frequently collaborative involving more than one research institution. In this webinar, staff from the HHS Office for Human Research Protections (OHRP) will explain the expectations for multi-site cooperative research under the Common Rule, the concept of institutional engagement in research, and the regulatory requirement for single IRB review for cooperative research. The webinar will discuss how an institution, domestic or international, could determine if it would need to defer review to a single IRB, what this might mean, and which should the single IRB be. Speaker: Dr. Yvonne Lau, Director, Division of Education and Development, OHRP
11 AM–11:15 AM	Break
11:15 AM–12:30 PM (20 minutes per presentation) 15 Minutes for Q&A	Keynote Session: Collaboration, Community and Connection #1. Title: Technological Resolutions for "Digital Divide" Short Description: Information as a determinant of Health. The evolving digital ecosystem has highlighted how much information can impact health. In addition to the many non clinical factors that drive health outcomes much of those captured in the social determinants of health. Information and the technological tools that deliver that can have a distinct impact on the health of communities.

	Learning Aims: 1. Describe the role of information as a determinant of health 2. Describe strategies to improve health outcomes through information delivery. 3. Understand the role of misinformation. Speaker: Dr. Garth Graham – YouTube health (cardiologist); reviews sections for NIH; Penn State has expertise #2. Title: How do we make research inclusive and accessible for all? Learning Objectives: • Identify three critical barriers to research participation by all currently • Discuss possible mechanisms to broad access to research participation and inclusivity • Consider key elements that need to change to achieve broader inclusivity and access • How do historical influences of colonization and structural racism continue to impact research today Speakers: Mylynda B. Massart, MD, PhD Associate Professor Maya Ragavan, MD, MPH, MS Assistant Professor Carmen Guerra, MD, MSCE #3. Title: Engagement in All Areas: Reaching Rural Pennsylvania through Trusted Partnerships Brief Description: Rural communities are less represented in research than their urban counterparts. Engaging rural communities through collaborations between academic medical centers and community partner organizations is an important key to addressing these gaps. Over the past several years, Penn State CTSI has partnered with Primary Health Network (PHN), the largest of FQHC in Pennsylvania and one of the largest in the country. Previously, we met in Mercer County, headquarters for PHN, bringing PHN clinicians and staff, Penn State staff and faculty, and community partnering organizations together to discuss challenges and opportunities in advancing rural health. This spring, we collaborated on an initiative in Schuylkill County, where PHN has two health centers and PSU has a Commonwealth Campus. To move the needle on improving county health rankings in Schuylkill County, we hosted a Community Driven Research Event on May 31, 2024. The vision of this event was to bring community partners collaboratively to the table to address

	leading county health concerns in partnership with Penn State strengths. We are developing partnerships in Schuylkill County to better understand and help address these outcomes. One avenue we are looking to explore is replicating efforts of a task force in Mercer County, whose focus is on social problems (housing, food, isolation, loneliness), and connecting the social service agencies in the communities to work collaboratively. Our goal is to make the Community-Driven Rural Health Initiatives a collaborative model founded in community partnerships and community-driven change, that can be replicated in other communities with Penn State campuses across the Commonwealth. The CTSI's goal is to serve as the hub, providing training, technical assistance, and facilitation of collaborations and workforce development opportunities to guide rural communities in evidence-based health interventions in their identified health priority areas. This also facilitates collaborations between CTSI and Commonwealth campus faculty, provides seed funding, and supports interdisciplinary teams in the implementation of community-led health interventions and workforce development opportunities. Learning Objectives: • Learn best practices in academic medical center and community partner collaborations. • Understand the impact of community partners to ensuring engagement in research, particularly in populations who are underrepresented in research. • Reflect on opportunities in your institution to partner with community organizations to engage in all areas. Speakers: Jennifer Kraschnewski George Garrow, MD (Penn State)
12:30 PM–1 PM	Break
1 PM–1:45 PM	Concurrent Presentations During this Time Frame Session #1 Title: Decentralized by Design – Lessons on Building and Deploying Studies for Patients Everywhere Learning Objectives • We will discuss lessons learned in deploying hundreds of decentralized clinical trials including success and failure • Review practical strategies to approach the integration of technology and services using Human-Centered Design to reach patients everywhere.

	• Determining the right level of "decentralization" from digitally enabled, to hybrid, to fully decentralized trials – what's right for your study Speaker: Noah Goodson (THREAD with CTSI background) Title: Enhancing Community Engagement through lay health workers and technology connections in Decentralized Clinical Trials Short Description: This presentation will briefly describe the methods for two recent NIH-funded and registered trials that enhance Community Engagement and participation of hard to reach populations in Decentralized Trials. In a study of a Cambodian diaspora population in the Northeast that has faced genocidal trauma and subsequent high risk of the combination of diabetes and severe mental illness, the use of a multi-site and multi-layered community engagement approach included community Lay Health Workers connecting community member participants with health care providers, as well as with both group and individual-level behavioral interventions informed by individual participant data. A separate trial recruited community-dwelling older adults in PA with insomnia in a Cognitive Behavioral Therapy for Insomnia (CBT-I) intervention. Therapy was delivered remotely by out-of-state specialists via Telehealth, data were collected via phone-based redcap surveys, wearables and other devices, and one arm included a data-enhanced clinician dashboard leveraging device data as well as Internet of Things (IoT) behavioral and environmental intervention elements. Learning objectives: At the conclusion of the presentation and discussion, participants will be able to describe how to involve community members in data collection and or intervention delivery, and how robust new technologies can be integrated in a behavioral trial and intervention delivery for broader community engagement and participant engagement in multi-level interventions. Speaker: Orfeu Buxton (Penn State) ---------- Session #2 Title: Advancing Research with Minoritized Populations: Innovative Approaches to e-Consent and Decentralized Behavioral Trials Brief Description: Dr. Jonassaint will present his work on engaging hard-to-reach populations in research. Drawing from three multisite trials, he will discuss the challenges and successes of conducting decentralized behavioral trials with minoritized communities. A key focus of the talk will be the innovative use of e-consent

	technologies to enhance participation and trust among these underrepresented groups. Dr. Jonassaint will share insights on how to effectively design and implement e-consent processes that prioritize clarity, accessibility, and cultural sensitivity. Through real-world examples, attendees will learn practical strategies for collaborating with community partners, building trust, and ensuring the ethical conduct of research with vulnerable populations. The talk will emphasize the importance of community engagement, shared decision-making, and the responsible use of technology in advancing health equity. Learning Objectives: 1. To share innovative approaches for engaging minoritized populations in research through decentralized behavioral trials and e-consent technologies. 2. To discuss the challenges and successes of conducting multisite trials with hard-to-reach communities. 3. To provide practical strategies for collaborating with community partners, building trust, and ensuring the ethical conduct of research with vulnerable populations. 4. To emphasize the importance of community engagement, shared decision-making, and the responsible use of technology in advancing health equity. Aims: 1. Increased understanding of the barriers and facilitators to engaging minoritized populations in research, particularly in the context of sickle cell disease and other health disparities. 2. Enhanced knowledge of e-consent best practices, including the design and implementation of culturally sensitive, accessible, and clear consent processes. 3. Improved ability to conduct decentralized behavioral trials with hard-to-reach communities, drawing from the experiences of three multisite studies. 4. Greater appreciation for the role of community partnerships, shared decision-making, and the ethical use of technology in promoting research participation and trust among underrepresented groups. 5. Identification of actionable steps for advancing health equity through collaborative, community-engaged research practices. Speaker: Charles Jonassaint Jonassaint
1:45–2:30 PM	Ethics: Thoughtfully Partnering with AI and Technology Brief Description: A panel discussion exploring ethical considerations from philosophical, medical ethics and provider perspectives. Learning Objectives:

	• Introduce philosophical and conceptual factors with regard to AI and Technology in medicine. • Discuss proposed standards of practice and how these suggestions apply to navigating dilemmas in health care ethics. • Examine current considerations of health care professionals with regard to AI and Technology • Introduce policy considerations moving forward with AI and Technology Moderator: Cindy McCarthy Panelists: Michael Deem John Maier Chaton Turner
2:30 PM–2:45 PM	Break
2:45 PM–3:45 PM	Concurrent Presentations During this Time Frame: Break out Sessions Session #1 Title: Application of Implementation Science to Advance Clinical and Translational Science Learning Objectives: 1) Define implementations science and its role advancing translational science, 2) Define key steps involved in identifying and reporting effective implementation strategies, and 3) Apply a model/framework to facilitate the design, implementation, and evaluation of interventions in clinical and community settings. Presenter: William Calo ---------- Session#2 Title: Using Human-Centered Design to Enhance Collaboration and Connection in Research Brief Description: Human-centered design is a participatory problem-solving approach that puts the people most likely to benefit from a solution at the center of the design process. In this session, we will provide an overview of HCD as a discipline and highlight use cases in health research that showcase how it can enhance collaboration among researchers, research participants, and community

	partners during the co-creation of health interventions. We will also outline considerations and tips for integrating HCD into regulatory and ethics protocols. Learning Objectives: • Define the key elements of HCD as a discipline composed of frameworks, methods, and mindsets. • Describe the ways in which HCD can support connection and collaboration in health research. • Identify regulatory considerations for integrating HCD into research protocols. Speakers: Chelsea Proulx Will Hierholzer
3:45 PM–4:00 PM	Wrap-up for Day 1 Reminders for those who may have missed the morning introduction. Overall questions?

DAY 2 - Tuesday, September 10, 2024

Time	Session and Speaker Details
9:45 AM–10 AM	Welcome, Networking, and Reminders
10 AM–10:45 AM	Office of Research Integrity (ORI) Welcome/introduction of The Office Of Research Integrity (ORI) Susan Sesack Title: Identifying Research Misconduct in Diverse Research Environments Short Description: Research misconduct threatens public health and safety, undermines research integrity, and misuses public funds. The U.S. Department of Health and Human Services (HHS) and institutions that apply for or receive Public Health Service (PHS) support for biomedical and behavioral research share the responsibility for ensuring the integrity of the research processes and the research itself. To protect PHS-supported research and the human research subjects enrolled in clinical trials, the HHS Office of Research Integrity (ORI) oversees institutional inquiries and investigations into allegations of research misconduct and makes federal determinations when warranted. In this presentation, we will examine

	case studies of research misconduct involving individuals at different levels of the research spectrum and performing research in different areas of clinical and translational research. Our aim is to discuss the circumstances under which it may be appropriate to involve other institutional officials and federal agencies, including ORI and the NIH Office of Extramural Research, when addressing protocol deviations and noncompliance in research supported by the PHS Presenters: Office of Research Integrity Yvette M. Carter, M.D., Scientist-Investigator, Division of Investigative Oversight Ning Du, M.D., Ph.D., Scientist-Investigator, Division of Investigative Oversight LaToya Lewis, M.S., MT (ASCP), CCEP, CCRP, Compliance Officer, Division of Education and Integrity
10:45 AM–11 AM	Break
Speaker 11 AM–11:45 AM . Panel. 11:45 AM–12:30 PM	Title: Generating Synthetic Electronic Health Record Data Short Description: Concerns about patient privacy limit the broad sharing of electronic health records (EHRs) for research. We developed an open-source plugin for the Integrating Biology and the Bedside (i2b2) platform that creates synthetic patient records that retain sufficient clinical detail and temporal realism to support exploratory research. Preliminary results demonstrate the utility and efficacy of the plugin by showing the same pattern of age-related medication usage in both actual patient records and their synthetic equivalents. The plugin will be deployed on the Evolve to Next-Gen ACT (ENACT) network. Objectives / Aims: After the session, attendees will understand the capabilities and functioning of the synthetic patient generator tool, which integrates with the Integrating Biology and the Bedside (i2b2) platform. In addition, they will understand how it can be used with electronic health records (EHRs) in their institution to generate synthetic patient cohorts that can be freely shared outside the institution for research. Speaker: Shyam Visweswaran
12:30PM–1:15PM	Break/Lunch
1:15 PM–2:00 PM	Title: AI Fairness and Explainability in Medical Image Analysis: Insights from Multi-Modal Data in Orthopedics Brief Description:

	The AI-powered segmentation to hip and knee bony anatomy has demonstrated very successful application in orthopedics, significantly impacting pre-operative planning and post-operative assessment. Despite the impressive progress in deep learning medical image segmentation, a crucial aspect remains largely overlooked: the presence of biases inherent within these AI-powered models. This talk addresses this critical concern by conducting a thorough re-examination of deep learning-driven segmentation of hip and knee bony anatomy using plain radiographs combined with demographic-based data, with a specific emphasis on identifying and mitigating potential biases related to sex and race. Through extensive evaluation, it introduces targeted mitigation strategies aimed at alleviating biases associated with sex and race, thus promoting the generation of segmentation results that are fair, impartial, and conducive to patient safety using AI. The findings from this research are invaluable for advancing AI in healthcare, guiding the development of deep learning models that prioritize inclusivity, ethical standards, equity, and a bias-free healthcare environment. This, in turn, has the potential to improve clinical outcomes, promoting both clinical decision-making and research on osteoarthritis (OA). Learning Objectives: • Understand the significance of AI-powered segmentation in orthopedics, particularly its impact on pre-operative planning and post-operative assessment. • Recognize the existing biases within AI-powered medical image segmentation, especially concerning sex and race. • Evaluate bias mitigation strategies associated with sex and race in AI-powered segmentation. Speaker: Ahmad Tafti leading Pitt HexAI Research Laboratory. Title: Ethical Pitfalls in AI-Assisted Clinical Research The presentation will highlight key problems in incorporating AI into clinical research, including data biases, demographic representation, research integrity, privacy concerns, and the need for (and deficits in) training in ethical applications of AI. Specific topics to be discussed include how AI models perpetuate biases in future research and transmit these biases to research staff, problems in information access and control, overreliance on AI tools for grant writing, literature searches, and statistical analysis, and the success and failures of efforts to train students and staff in the ethical use of AI. The aims of the presentation will be to educate attendees on current ethical quandaries in using AI in research settings and provide them with some potential mechanisms of engaging with AI tools appropriately.

	Speaker: Dr. Matt Butkus, PhD, HEC-C Professor of Philosophy at McNeese State University
2:00 PM–3:00 PM	Title: Clinical Natural Language Processing to Accelerate Research on People with Disabilities Short Description: The advent of electronic health records (EHRs) in significant healthcare systems has markedly improved the resources available for conducting observational research on people with disabilities. The majority of EHR data are in structured format, however, detailed disability and patient functioning information are usually documented in unstructured EHR notes. Clinical natural language processing (NLP) technologies have played a crucial role to extract such important information from notes. Clinical NLP systems leverage techniques ranging from rule-based algorithms to advanced deep learning neural networks. Recent advancement in large language models (LLMs) has brought new excitement to the NLP field, particularly due to the use of generative artificial intelligence (AI) and the success launch of ChatGPT. These LLMs are fundamentally changing the way we are doing for biomedical and clinical NLP tasks, providing a new paradigm to these tasks with zero/few-shot learning approaches. This talk will walk through traditional biomedical and clinical NLP techniques that have been successful in the medical domain and the new promise brought by generative AI with recent research outcomes from Dr. Wang's team for biomedical and clinical NLP. Learning Objectives: 1. Learn how clinical natural language processing is used to extract information from unstructured electronic health records 2. Learn the infrastructure development to develop clinical NLP algorithms 3. Learn recent advances in large language models for clinical NLP tasks Speaker: Yanshan Wang
3:00 PM–3:15 PM	Break
3:15 PM–3:45 PM	OHRP Presents: Conversation with the FEDS
3:45 PM–4:00 PM	Thank You