UN-MEETING 2020

Collaborative Conversations

The Critical Need for Professional Workforce Development at Academic Medical Centers

The Un-Meeting Briefing Book

September 16, 2020 - February 17, 2021

University of Washington
Institute of Translational Health Sciences

Contents

BACKGROUND – The Evolution of CRP Workforce Development

2006 - NIH established the CTSA program to advance inter-institutional research collaboration, identify best practices to support clinical and translational research. The Research Coordinator Taskforce, operating under the Regulatory Knowledge group of the Clinical Research Innovation Key Function Committee was formed to enhance the CTSA's AMCs capabilities to provide support and training for Clinical Research Coordinators (CRCs).

2012 - Published The Critical Need for Academic Health Centers to assess the training, support, and career development requirements of clinical research coordinators: recommendations from the Clinical and Translational Science Award Research Coordinator Taskforce. (Speicher et al, 2012). Concurrently the Joint Task Force for Clinical Trial Competency published on training and harmonizing competencies by developing a single list of standards. Members of our group are active in the JTF (Jones, 2012).

2014 - The Harmonized Core Competency Framework for the Clinical Research Professional was published simultaneously in Center Watch White Papers, Journal of Clinical Research Best Practices, Applied Clinical Trials and most significantly in ACRPs Clinical Researcher (Sonstein et al, 2014).

2014 - NCATS' Enhancing Research Professionals' Training and Qualifications (ERPTQ) project involved all the CTSA Hubs (Calvin-Naylor, et al 2016) building off JTF's Framework. These standards now serve as the framework for defining professional competency across the CTSA clinical research enterprise. The Development, Implementation and Assessment of Novel Training in Domain-based Competencies", or "DIAMOND" project, is a collaboration between University of Michigan, The Ohio State University, University of Rochester and Tufts University (diamondportal.org) continues to extend that work.

2016 - Duke University utilized the work of the Joint Task Force for Clinical Trials Competency (JTFCTC) to create a framework for clinical research jobs at Duke - The Workforce Engagement and Resilience (WE-R) group. ACRP incorporated the JTF Framework into their programming, creating Core Competency Guidelines for Clinical Research Coordinators (CRCs), investigators and other roles. The Research Coordinator Taskforce was recast as The Clinical Research Professional Taskforce (CRPT) to accommodate an enlarged scope of workforce required to manage clinical trials. At the same time, the CRPT was designated as a "Special Interest Group" (SIG) within the Association for Clinical and Translational Science (ACTS).

2018 - JTF updated the Framework to recognize increase in competency as individuals gain experience: Basic, Skilled and Advanced levels. This year they have added relevant competences for Project Management, with possible future plans to incorporate Informatics. Additionally work was completed translating of GCPs to Social and Behavioral Research Good Clinical Practice for Social and Behavioral Research eLearning Course (Murphy et al, 2018), and developing and testing of an assessment tool to measure CRP levels of self- efficacy/confidence in the JTF Core Competencies (Indices of Clinical Research Coordinators' Competence) (Hornung et al 2018 & 2019).

2020 - The University of Washington ITHS (Arti Shah), The Ohio State University CCTS (Carolynn Jones) and The University of Florida CTSI (Bob Kolb) planned these meetings on behalf of this workforce to share perspectives on the challenges and successes in conducting research for NIH with a focus on developing actionable ways to drive improvement. As the role of the CRP continues to evolve well beyond the outmoded models that persist, these "Conversations" remind us through collaboration and sharing of ideas and expertise that we can develop innovative approaches to developing new tools and resources to succeed. Clinical trials are critical for developing and delivering evidence-based care. Trial success depends on clinical research professionals' work as vital members of the research team. Creating opportunities for professional workforce development is indeed critical.

Robert Kolb RN, MS, CCRC, University of Florida CTSI

Carolynn Thomas Jones, DNP, MSPH, RN, FAAN, The Ohio State University CCTS

Welcome Message

Dear Colleagues,

Thank you participating in Collaborative Conversations, addressing the issues and barriers that surround advancing the clinical research professionals (CRPs) working in academic medical centers (AMCs) and their affiliate institutions. We look forward to hearing from everyone on how we expand the pipeline of CRPs, standardize competency-based job titles and roles and identify solutions to staffing attrition and retention. The University of Washington's Institute of Translational Health Sciences (ITHS) welcomes you to this first-ever meeting to address the unique challenges for AMC CRPs. This meeting replaces the April 2020 meeting that was cancelled due to COVID-19. We are sorry that this is no longer in-person in Seattle, but Zoom is expanding our opportunities. This is your meeting. We are using an Un-Meeting approach to make this an interactive, participant-driven opportunity for collaborative conversations. We are hopeful that these conversations will generate new ideas and collaborative projects to improve quality, efficiency and safety of our studies for the public's health. We hope you have a productive Un-Meeting.

Nora Disis, MD, ITHS Principal Investigator

Tong Sun, MS, MBA, ITHS Executive Director

Arti Shah, MPH, CHES, ITHS Director of Education

Aric Lane, MPA, ITHS Research Education Specialist

Milu Worku, ITHS Training Education Specialist

Purpose

The purpose of this meeting is to use an Un-Meeting format to enhance focused discussions on topics related to workforce development for clinical research professionals (CRPs) working in academic medical centers (AMCs), especially those that are working on federally funded clinical research. Originally planned as a face-to-face event, we are now converting these "collaborative conversations" into a series of virtual sessions, continuing to use Un-Meeting principles.

Key Goal(s)

The goal is to share perspectives on the challenges and successes in developing the Clinical Research Professional (CRP) workforce within federally-funded institutions with a focus on developing actionable ways to drive improvement. The focus would be on workforce development initiatives and the generation of new ideas and collaborative teams.

Our Un-Meeting Planning Team

This project has been a collaborative effort of several CTSA hubs, through support by the National Center for Advancing Translational Sciences (NCATS) of the National Institutes of Health (see grant numbers below), including Un-Meeting technical assistance from Center for Leading Innovation & Collaboration (CLIC) and meeting support and collaboration from the Association of Clinical Research Professionals.

University of Washington Institute of Translational Health Sciences (ITHS): Arti Shah, Milu Worku, Aric Lane, Pavel Kruchek, Amy Good (PI: Mary L. "Nora" Disis, MD; UL1TR002319)

University of Florida Clinical and Translational Science Institute (CTSI): Bob Kolb, Holly Morris (PI: Duane Mitchell, MD, Phd, UL1TR001427)

The Ohio State University Center for Clinical and Translational Science (CCTS): Carolynn Jones, Karen Carter, Penny Jester (PI: Rebecca Jackson, MD, UL1TR002733)

University of Rochester Clinical & Translational Science Institute (CTSI): Alfred Vitale, Russell Lackey (PIs: Martin Zand, PhD & Nancy Bennett, MD, UL1TR002001)

Association of Clinical Research Professionals (ACRP): Beth Harper, Jim Kremidas

The Un-Meeting Concept

The Un-Meeting is different from a traditional passive conference. Rather, this is a highly interactive meeting whereby attendees create and drive the topic discussions surrounding a common theme. This enables attendees to discuss their experiences, identify areas of potential research, innovation, & collaboration. This will cultivate connections across the clinical research professionals and CTSA hubs. It further enhances "team science" through the collaborative nature of the format.

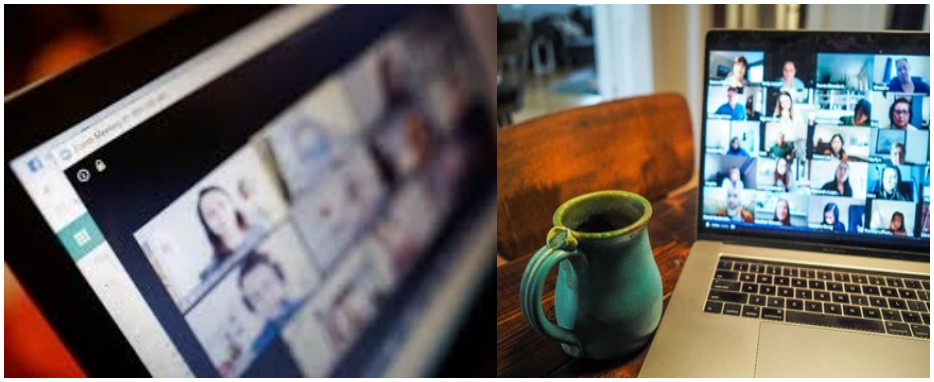
For additional information on the Un-Meeting process, the Center for Leading Innovation & Collaboration (CLIC) has prepared an Un-Meeting planning guide. The aim of this Un-Meeting will be to enhance clinical research professional workforce development through the creation of sustainable, collaborative relationships and initiatives. Outputs from this Un-Meeting may range from: White Papers, Collaborations, Initiatives, and connections. This VIDEO illustrates the Un-Meeting process.

What have people said about their experiences at other Un-Meetings?

"I loved the organizational (self-organizing) strategy of the Un-Meeting. The 4x4 presentations were great. The multidisciplinary characteristics of the event were outstanding. The participants were exciting and interesting to meet.

"[I] met a number of great new contacts and gained insight for a new project."

"It was enjoyable and engaging."
"I'm hoping to stay in touch with at least a few of the folks I met." "Each of us knows some [aspects] but not the other. Together we can educate each other and add to what we don't know."



Objectives

Through active collaborative conversations in the Virtual Un-Meeting, participants will:

1. Summarize the historical evolutions of clinical research professional workforce development and professionalization.
2. Learn and apply the Un-Meeting process as a method of team science collaboration and communication.
3. Contribute to key discussions, solution finding and collaborations for key topics related to clinical research professional workforce development, especially focusing on the academic medical center workforce.
4. Impact future initiatives and research by becoming a member of new interactive teams, participating in key meeting outputs or generating local outputs.

Topics & Dates

All meetings will take place from 10AM to 12PM PDT (1PM to 3PM EST). The meetings will strive to stay on schedule and will be fast-paced.

September 16, 2020	**Kickoff Meeting and Keynote** ● **Arti Shah** - Welcome ● **Beth Harper -** Introduction of Dr. Kurilla ● **Mike Kurilla, MD**, NCATS - Keynote Speaker ● **Carolynn Jones** - Survey Results ● **Arti Shah** - Un-Meeting Intro and Instructions ● **Aric Lane and Karen Carter** - Technology Orientation
October 28, 2020	**Competency-Based Job Titles** ● **Denise Snyder** - 4x4 Speaker
November 18, 2020	**Issues in Onboarding Training** ● **Wendy Lloyd** - 4x4 Speaker
December 9, 2020	**Issues in Competency-Based CRP Continuing Education** ● **Mary-Tara Roth -** 4 x 4 Speaker
January 27, 2021	**Issues in Attrition, Retention and Progression** ● **Gerri O'Riordan** - 4 x 4 Speaker
February 17, 2021	**Enhancing the CRP Pipeline** ● **Clare Tyson** - 4 x 4 Speaker

How Are The Meetings Structured?

1. Welcome and Speaker Introduction
2. 4 X 4 Speaker- brief presentation of the focused topic
3. Full Group Brainstorming Session
4. Small Group Breakouts
5. Re-gathering and Presentations from Breakouts

Post-Meeting Summaries and Action Items

- Recorded meeting and transcripts
- Notes from Breakout Sessions
- Notes from Breakout Reports
- Post Meeting Qualtrics Evaluation
- Evolved action items and working teams
- Opportunities to continue discussions on a CLIC Discussion Forum

Registration

- Register online at: https://www.iths.org/education/professional-development/rc/collaborative-conversations/
- Complete the Online pre-meeting Survey in the confirmation email you receive upon registering
- Costs: None!
- Benefits of attending:
    - Collaborations and outcomes opportunities
    - Learning the Un-Meeting process
    - Contributing to solution-finding for enhancing the CRP workforce and clinical trial performance at Academic Medical Centers.
    - ACRP maintenance of certification contact hours: 6 ACRP contact hours

Location

Upon registration, individuals will be given a link for the Zoom meetings. A follow-up email will be sent to participants by email for inclusion in their calendars and for Zoom access.

Technology For The Best Experience

- Use a headset and camera.
- When not speaking, please mute your microphone.
- Consider joining Zoom by computer for the video and call into the meeting audio by phone to reduce internet bandwidth constraints.
- Download/Update Zoom desktop/laptop software (or join by web browser) https://zoom.us.

Key Meeting Facilitators

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Co-Director Workforce Development
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Speakers

Keynote Speaker

Michael G. Kurilla, MD, PhD
Director
Division of Clinical Innovation
National Center for Advancing Translational Sciences
National Institutes of Health

Michael Kurilla is the director of the Division of Clinical Innovation at NCATS. In this capacity, he oversees the **Clinical and Translational Science Awards (CTSA) Program**, which supports innovative solutions to advance the efficiency, quality and impact of translational science, with the ultimate goal of getting more treatments to more patients more quickly. Prior to joining NCATS, Kurilla served as the director of the Office of Biodefense Research Resources and Translational Research within the National Institute of Allergy and Infectious Diseases (NIAID), where he focused on translational efforts toward infectious disease product development, including vaccines, therapeutics and diagnostics, with emphasis on biodefense and emerging infectious disease threats. Prior to joining NIAID in 2003, Kurilla was an associate director for infectious diseases at Wyeth. He also worked in antimicrobials at DuPont and on clinical microbiology and molecular pathology at the University of Virginia Health Sciences Center.

Kurilla received his M.D. and his Ph.D. in microbiology and immunology from Duke University. He was a postdoctoral research fellow at Harvard Medical School and completed a residency in pathology at Brigham and Women's Hospital. He received a B.S. in chemistry from the California Institute of Technology.

4 x 4 Speakers (listed alphabetically)

Wendy Lloyd, BA, LPN, CCRP
Senior Clinical Research Quality Analyst
Vanderbilt University
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Wendy received her Bachelor of Arts degree in Management in Human Relations from Trevecca Nazarene University in 2007. She has been a Licensed Practical Nurse since 1985. She has 19 years' research experience at Vanderbilt. In her role as a Senior Clinical Research Quality Analyst she is developing a competency program, New Employee Orientation as well as coordinates education/training for the Vanderbilt Coordinating Center. She has 13 years' experience in human subject protection, regulatory affairs and compliance adherence conducting random compliance reviews /directed audits and providing educational sessions across the Institution. Wendy serves on numerous Vanderbilt Committees including the Evidence Based Nurse Committee, Editorial Board member for The Empowered Nurses peer reviewed journal and is the Chairperson for the Nurses Week research poster session.

Gerri O'Riordan, RN, BSN, CNS, CCRN
Director of Clinical Research for Cardiovascular Medicine Division
Director of Stanford Clinical Research Preceptor Program
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Gerri O'Riordan, RN, BSN, CNS, CCRN, is Director of Clinical Research for the Cardiovascular Medicine Division at Stanford University. She also is Director of the Stanford Clinical Research Preceptor program. During her 25+ years at Stanford, Gerri has worked as clinical research coordinator in anesthesia, study facilitator at Spectrum Child Health, Chief Operating Officer and Senior Director of Regulatory Compliance at the Sean N. Parker Allergy Center.

Mary-Tara Roth, RN, MSN, MPH
Director, Clinical Research Resources Office
Assistant Director, Human Research Protection Program
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As Director of the Clinical Research Resources Office, Mary-Tara is responsible for defining the office's services and overseeing the implementation of those services to support clinical researchers at BMC/BU Medical Campus. In addition, she works at providing services to investigators and study teams, especially in the areas of regulatory consultation and training for all levels of the research team. Mary-Tara also oversees the Quality Assurance program within the Human Research Protection Program.

Mary-Tara has been involved in clinical research for more than 20 years. She has a BS in Psychology from Tufts, a BS in Nursing from Johns Hopkins, and a Master's in Nursing and a Master's in Public Health from Johns Hopkins.

Denise Snyder, MS, RD
Associate Dean for Clinical Research
Duke University
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Denise Snyder leads the Duke Office of Clinical Research (DOCR) a support office of expertise in coverage analysis, study logistics, data management, regulatory oversight, workforce innovation and guidance for clinical research operations for Duke as a site. Her team has transformed the workforce by developing and implementing competency-based job descriptions and progression pathways for clinical research professionals. Earlier in her career, after spending time in public health and clinical nutrition, Denise started work as a research coordinator and project manager in 2000 for NIH funded trials in oncology.

Clare Tyson, MA, CCRA
Research Coordination and Management Program Manager
Medical University of South Carolina
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Clare Tyson, MA, CCRA is the Research Coordination and Management (RCM) Program Manager for the South Carolina Clinical & Translational Research (SCTR) Institute at MUSC, the academic home of the National Institutes of Health (NIH) Clinical and Translational Science Award (CTSA) grant. In this role she works with investigators and departments to identify research support needs and provides fee-based nurse and research coordination services within MUSC. Through RCM she has developed a research coordinator and nurse coordinator mentorship and career development program that offers internal and external training opportunities to student interns and entry-level employees interested in research in the academic setting.

She currently serves as a co-lead of MUSC's Clinical Research Job Classification initiative. This initiative has evolved through a collaboration between MUSC's central Human Resources (HR) office and the MUSC research community and is focused on establishing a job classification track that enhances career and professional development opportunities for the clinical research workforce.

Clare has over 20 years of research experience and is a Certified Clinical Research Associate (CCRA) through the Association of Clinical Research Professionals (ACRP). Previously she served as the Project Manager of the South Carolina Node of the National Institutes on Drug Abuse (NIDA) Clinical Trials Network (CTN). She was responsible for implementing protocols in research-naïve community sites, providing quality assurance monitoring, regulatory support, training, and study management.

Definitions

Academic Medical Centers and Affiliates for the purposes of this meeting, academic medical centers (AMC) are defined as tertiary care hospitals, medical centers, affiliated with a medical school. This definition also includes partners and affiliates who collaborate in clinical research and care of participants and communities of clinical research, conducting government-sponsored, industry-sponsored and investigator-initiated clinical research.

Clinical research includes all research involving human participants. It does not include secondary studies using existing biological specimens or data collected without identifiers or data that are publicly available. (https://humansubjects.nih.gov/glossary)

Clinical trials are clinical research studies involving human participants assigned to an intervention in which the study is designed to evaluate the effect(s) of the intervention on the participant and the effect being evaluated is a health-related biomedical or behavioral outcomes.

Clinical Research Professionals are individuals whose role is the support and conduct of clinical research following GCP guidelines. CRPs have variety of job titles and levels work in a variety of settings. As professionals, CRPs possess a variety of competency-based education and training and certifications related to the field of clinical research. Some CRPs are licensed healthcare professionals (e.g., RN) who perform their roles as Clinical Research Nurses.

Competency focuses on the knowledge, skills and abilities (KSAs) needed to successfully accomplish the responsibilities of the job role.

JTF Competency Framework consists of 8 competency domains for clinical research professionals to conduct safe, ethical and effective clinical research. The eight domains are: (1) Scientific Concepts and Research Design; (2) Ethical and Participant Safety Considerations; (3) Investigational Products Development and Regulation; (4) Clinical Study Operations (GCPs); (5) Study and Site Management; (6) Data Management and Informatics; (7) Leadership and Professionalism; (8) Communication and Teamwork. The JTF Competency Wheel and detailed leveled core competencies can be found at: https://mrctcenter.org/clinical-trial-competency/ (Sonstein, et al, 2014).

(Credit: Sonstein et al, 2014)

Un-Meeting Elements

4x4 Speakers- *presentations* from *subject matter experts presenting a brief presentation on the topic- 4 slides in 4 minutes (5th slide is title slide only to provide transition). Talks should be succinct, thought provoking, motivating to stimulate the subsequent idea generation, brainstorming session.*

Idea Generation- *after 4x4 speakers, attendees brainstorm openly to identify the subjects and topics they are most interested in discussing. They will receive a link to a live survey to provide input for discussion which are later organized by event coordinators into logical categories – these categories create topics for conversation in the break-out sessions. Breakouts are zoom breakout rooms.*

Break-out Sessions- *Now that we are virtual, we will have one breakout session but there may be multiple (e.g., 6 or more) discussion pods occurring simultaneously, depending on the number of registrants. Each discussion pod will include a facilitator (conversation catalyst) and scribe (co-host). Collectively these individuals will prepare a rapid fire report of activities at the end of the meeting.*

Un-Meeting Roles

Core Planning Team and Steering Committee: *Organizing, managing, directing event processes. Leads/Co-Leads will maintain detailed records of planning steps, outcomes, timelines, lists of responsibilities. Smaller workgroups may evolve to handle varied meeting outputs.*

Masters of Ceremony (MC): *Key to helping presenters stay on track, on schedule. Provides opening remarks, lead, guide and engage attendees, drive the Un-Meeting throughout the day. (Can be 2 individuals). Have abilities to motivate, inspire, direct.*

Break-out Room Facilitators "Conversation Catalysts": *Facilitates the breakout session, helps to keep conversations going when there is a lull, uses open ended questions that are pre-prepared.*

Time Keepers and Chat Box Moderators: *Keeps the breakout time clock, gives a 5 min warning when it is time to wrap up. Assists scribes. Monitors the chat box to ensure all voices are heard. May also help troubleshoot or make connections for technology issues.*

Scribes: *During open and breakout sessions, scribes will be assigned to take notes, documenting, assisting with report generation post breakout. They will work with the breakout facilitators to generate reports back to the group.*

4x4 Presenters: *Subject matter experts presenting brief presentation on the topic- 4 slides in 4 minutes.*

Potential Targeted Outputs

Several outputs are expected from each meeting session. Workgroups will naturally evolve. The Steering Committee will assist with some of the outputs, including the post-meeting report. Examples of outputs include:

- *Publications about this meeting process and content*
- *White papers on key topics from the meeting*
- *Projects/initiatives*
- *Research on the profession, roles, professionalism*
- *Team Science and CRPs*
- *Evolving trends in clinical research*
- *NIH-Industry-Community-Non-IND – working across types of studies, funders*
- *Collaborative opportunities*
- *Future meetings, regional meetings*

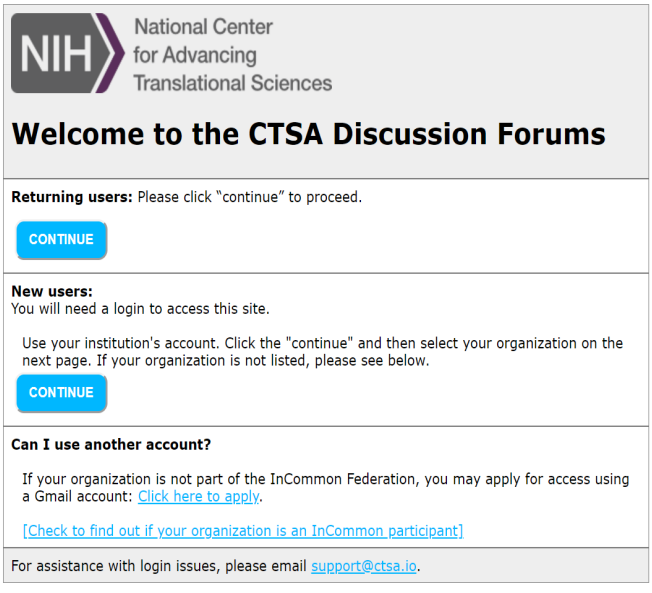
Continuing the Conversations – "New" CRP Discussion Forum

We have established a Clinical Research Professional Discussion Forum Discussion Group to continue these conversations and to begin new ones. Please take a few moments to sign up and share with your community of Clinical Research Professionals.

First **-**go to the Clinical Research Professional Discussion Forum Discussion Forum Start Page. This will take you to the "**Welcome to the CTSA Discussion Forums**" welcome page that looks like this:

If you are a member of a CTSA, clicking "Continue" will take you to a login page where you can select your organization and log in.

If you are not able to log in with institutional credentials please apply for special access using the *"Click here to apply"* form.



Once logged in you will see our home page - From the homepage you will have the option to apply to join by clicking the green button labelled "Apply to Join the DF" which looks like this:

If you need help accessing the site you can contact Bob Kolb at: kolbhr@ufl.edu or CTSA Support at: support@ctsa.io. See you in the forum.

Parting Shot: *The "Un-Rules" of Engagement in an Un-Meeting*

The Law of Mobility.
By design, Un-Meetings are very fluid and flexible in nature. Attendees are free to go where interests lie, and leave if interest wanes. Similarly, potential collaborators may want to start working on ideas right away, claiming a place to chat with coffee.

The Law of Curiosity.
No one knows everything … just ask! There are NO wrong questions … or answers. This goes for acronyms and jargon too. Feel free to "translate in real time" when more explanation about specific terms is needed.

The Law of Efficiency.
We want to make every second count. The day is in your hands, and we are open to opportunities for efficiency. Feel free to start jotting down ideas early. Or, when your breakout group meets, start talking right away. If no one has started the discussion yet, feel free to jump in.

The Law of Flow.
Be open to however the Un-Meeting might unfold. Whatever happens … happens. Whoever comes are the right people. Whatever happens is the only thing that could have. Whenever it starts is the right time. When it's over, it's over.

The Law of Momentum.
The Un-Meeting is as much about what happens after the event, as it is about the event itself. We hope you'll pledge at least one action item as you leave. We want to continue the conversation. Together, we can turn possibility into reality.

The Law of Making Space.
Strive to let all voices be heard. Each individual has valuable knowledge, experience and contributions to bring to the table. Be cognizant of your own style of communicating and flex if possible. Do you usually speak up first? Try waiting an extra moment. Do you usually spend most of the time listening? Try speaking up earlier. As a group we want to have the utmost respect, consideration, and time for all viewpoints.

ITHS Institute of Translational Health Sciences
ACCELERATING RESEARCH. IMPROVING HEALTH.

UF Clinical and Translational Science Institute
UNIVERSITY of FLORIDA

THE OHIO STATE UNIVERSITY
CENTER FOR CLINICAL AND TRANSLATIONAL SCIENCE

UNIVERSITY of ROCHESTER MEDICAL CENTER | CTSI
CLINICAL & TRANSLATIONAL SCIENCE INSTITUTE

Thank you for YOUR participation!

ACRP

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Notes

Collaborations

Action Items