

BREAKOUT SESSION DESCRIPTIONS:

Monday 8:00AM-8:45AM

- **Introduction**
 - **Presenting:** Russ Waitman
 - **Who:** Everyone
 - **What:** During this session we will go over PCORnet 1.0, and 2.0 with the new People Centered Research Foundation (PCRF). We will discuss designing the GPC going forward, and what we want to accomplish at this event.

Monday 8:55AM-10:30AM

- **Poster Walk**
 - **Presenting:** Pilot Program projects, along with various current GPC studies, capabilities, and groups
 - **Who:** Everyone
 - **8:55 – 9:10: Patient Advisors and Patient Engagement Officers gather with Kim and Cheryl in Town Center**
 - **What:** Sites will present status of their pilot winners, and we will also have updates on ADAPTABLE, Cancer Rapid Cycle Research, the Bariatric study, GROUSE, ROA/DROC intake processes, and EDC reports/data.

Monday 10:30AM-12:00PM

- **IRB**
 - **Presenting:** Karen Blackwell
 - **Who:** IRB members and anyone interested
 - **What:** During this session we will discuss best practices related to single IRB review. We will share tools and ideas about evaluating PI oversight plans, communicating with study teams, obtaining local context information and determining criteria for reliance.
- **Site PIs & Hackathon Teams**
 - **Presenting:** Russ Waitman & Dan Connolly
 - **Who:** Site PIs, Dev team members, and anyone interested
 - **What:** During this session we will review infrastructure and oversight processes (DROC, ROA, Governing Council, SHRINE, Babel, etc.). We will also discuss the following questions:

- What are the key infrastructure components to maintain/enhance given the change to our continuation funding?
- What is a PCORnet obligation, what are GPC means to meet PCORnet obligations, and what does the GPC need to continue to optimize CTSA/CTSI functionality?

- **Engagement**

- **Presenting:** Kim Kimminau and Cheryl Jernigan
- **Who:** Patient Advisors, Patient Engagement Officers, and anyone interested
- **What:** This session will serve as a welcome and onboarding, and will start with a "get to know you" activity followed by a brief history of engagement activities undertaken during GPC 1.0. This session is an opportunity for everyone to get (re)oriented, ask questions, and make suggestions for improving how we will work together and what we hope to accomplish in the next year.

Monday, 12:00PM-1:00PM

- **Working Lunch**

- **Presenting:** Table Topics
- **Who:** Everyone
- **What:** During lunch each table will have a designated conversation topic. Please choose to sit at any table with a topic that interests you. Topics will include, but not be limited to: newcomers welcoming/onboarding, CRG cancer research, ADAPTABLE follow-up, CDM follow-up, IRB, i2b2/SHRINE, and PCRf business development.

Monday 1:00PM-2:00PM

- **ADAPTABLE**

- **Presenting:** Danielle Riley
- **Who:** ADAPTABLE study team and anyone interested
- **What:** The purpose of this session is to discuss the challenges and lessons learned during recruitment and retention of participants for the ADAPTABLE Study. We will identify opportunities for site improvement and recommendations for achieving recruitment goals.

- **PCRf Orientation**

- **Presenting:** Russ Waitman and Steve Fennel
- **Who:** Anyone interested
- **What:** This session will highlight the differences anticipated as a network in PCRnet (PCORnet 2.0) in comparison to PCORnet Phase 1 and Phase 2. We will highlight the differences in working with PCRf vs. PCORI, differences in required deliverables and differences in the approaches that will be taken with business development.

- **Hackathon and GROUSE**

- **Presenting:** Dan Connolly
- **Who:** Dev team members and anyone interested
- **What:** Current status of GROUSE environment, planning going forward to extend its capabilities, and for onboarding additional projects and investigators to reuse the environment.

- **Pilots & Developing Larger Studies**

- **Presenting:** Molly Conroy, Elizabeth Chrischilles, Brad Taylor & Jim McClay
- **Who:** Site PIs and anyone interested in developing larger studies
- **What:** The purpose of this session is to discuss the current GPC "front door" process for developing new studies, both smaller pilots and larger multicenter proposals, and envision the best way to move forward in the future. We will use the process diagram developed at a previous LEC conference as a "straw man" or starting point for discussion, and discuss both how the current front door process has been working well and how it could be improved. An alternate model from another CDRN will be discussed, as will principles of collaboration to ensure trust and teamwork in multicenter proposals. The deliverable of this one-hour session will be a draft of a revised front door process to be presented to/commented upon by GPC leadership and team.

Monday 2:10PM-3:10PM

- **Engagement & IRB Group**

- **Presenting:** Kim Kimminau and Karen Blackwell
- **Who:** Patient Advisors, Patient Engagement Officers, IRB members, and anyone interested
- **What:** The Institutional Review Board Group (IRB) and the Engagement Group will discuss the informed consent process and novel methods of meeting federal requirements. We will develop a list of what we feel is 'key information' for potential research participants to consider. The group will review and discuss several formats of key information and plan for future discussion about improving the consent process

- **Cancer Collaborative Research Group & Rapid Cycle Research Meeting**

- **Presenting:** Elizabeth Chrischilles
- **Who:** Breast Cancer Cohort members and anyone interested
- **What:** Review of RCR project results and available datasets; updates from the cancer claims pilot (<https://informatics.gpcnetwork.org/trac/Project/wiki/CancerClaimsPilot>) including a discussion of the developed data resources; and discussion of how investigators can engage with these data sources.

- **Hackathon & SNOW SHRINE Replacement**

- **Presenting:** Dan Connolly and Jim Campbell

- **Who:** Dev team members and anyone interested
- **What:** With Wisconsin departing they are not supporting SHRINE for the GPC. What is our strategy: establishing a new SHRINE for the network, or piggybacking on NCATS ACT, or repurpose the i2b2 CDM on GROUSE for Honest Broker driven feasibility queries?

Monday 3:30PM-4:30PM

- **IRB Group & Engagement**

- **Presenting:** Kim Kimminau and Karen Blackwell
- **Who:** Patient Advisors, Patient Engagement Officers, IRB members and anyone interested
- **What:** This is a continuation of the previous session. The Institutional Review Board Group (IRB) and the Engagement Group will discuss the informed consent process and novel methods of meeting federal requirements. We will develop a list of what we feel is 'key information' for potential research participants to consider. The group will review and discuss several formats of key information and plan for future discussion about improving the consent process.

- **Business Development & Hackathon**

- **Presenting:** Dan Connolly, Russ Waitman, Sravani Chandaka & Jim McClay
- **Who:** Site PIs, Dev teams and anyone interested
- **What:** During this session we will look at our intake process and the technical aspects of running trials and observational studies.

Monday 4:40PM-5:15PM

- **Engagement in the GPC**

- **Presenting:** Jeff Ordway and Kim Kimminau
- **Who:** Everyone
- **What:** The People Centered Research Foundation held a meeting in October 2018 to set the direction for engagement that we will use for GPC 2.0. In this session, we will share the results of an evaluation of accomplishments during PCORNet, the draft framework, and some key take-aways we will use to inform our engagement efforts.

Tuesday 8:00AM-9:30AM

- **Structure Moving Forward & Identity**

- **Presenting:** Russ Waitman and Cheryl Jernigan
- **Who:** Site PIs, Project Managers and anyone interested

- **What:** Building upon what GPC and PCORnet have accomplished to date, how do we continue to structure our capabilities to be most effective to advance research for our campuses, investigators and patient partners?
- **Hackathon**
 - **Presenting:** Dan Connolly
 - **Who:** Dev teams and anyone interested
 - **What:** Technical discussion of opportunities for network efficiency related to infrastructure over the next two years. May include discussions about CDM development, text de-identification, etc.
- **Engagement**
 - **Presenting:** Kim Kimminau and Jeff Ordway
 - **Who:** Patient Advisors, Patient Engagement Officers and anyone interested
 - **What:** This session will explore engagement and the PCRf framework. The People Centered Research Foundation's framework for engagement includes some key elements. We will share the framework and discuss how to expand, refine, define or modify the framework for the GPC's work and objectives.
- **IRB Group**
 - **Presenting:** Karen Blackwell
 - **Who:** IRB members and anyone interested
 - **What:** The IRB group will discuss various strategies for budgeting for single IRB review, including recommendations from a federally-funded work group.

Tuesday 10:00AM-11:15AM

- **IRB Group**
 - **Presenting:** Karen Blackwell
 - **Who:** IRB members and anyone interested
 - **What:** The IRB group will discuss management of studies under single IRB review. We will explore metrics about study start-up times. We will also share recommendations about quality assurance oversight for studies under reliant review.
- **Hackathon & Site PIs**
 - **Presenting:** Russ Waitman & Dan Connolly
 - **Who:** Site PIs, Dev team members and anyone interested
 - **What:** This session will serve as a wrap up for the Hackathon sessions, and we will look at next steps going forward.

- **Engagement**

- **Presenting:** Kim Kimminau and Cheryl Jernigan
- **Who:** Patient Advisors, Patient Engagement Officers and anyone interested
- **What:** This session will explore engagement and impact. How will we know that we have made a difference? Engagement needs to move from concept to action, so we will discuss ways to assess the impact of patient and stakeholder engagement in work done during GPC 2.0. The goal of this session is to brainstorm a list of features and possible measures we associate with "doing engagement 'right'!"

Tuesday 11:30AM-12:00PM

- **Closing Session**

- **Presenting:** Russ Waitman and Kim Kimminau
- **Who:** Everyone
- **What:** Using small group discussion we will identify key learnings and direction for GPC 2.0.