

Building the Network Foundation: Part 1

Engelberg Center for Health Care Reform
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Governance & Collaboration Task Force



Co-Leads

- Erin Holve – AcademyHealth
- Richard Platt – Harvard Pilgrim Health Care Institute



Deliverables

- Policies and procedures for PCORnet
- Collaboration guidelines and supporting materials for external partners.

Network Policies and Procedures Are Needed!

- Success requires
 - Clearly articulated goals and purpose
 - Transparent processes
 - A high level of organization
 - Forward thinking approach
 -to build a *culture of trust*



G&C Task Force Will Focus on PCORnet Policies

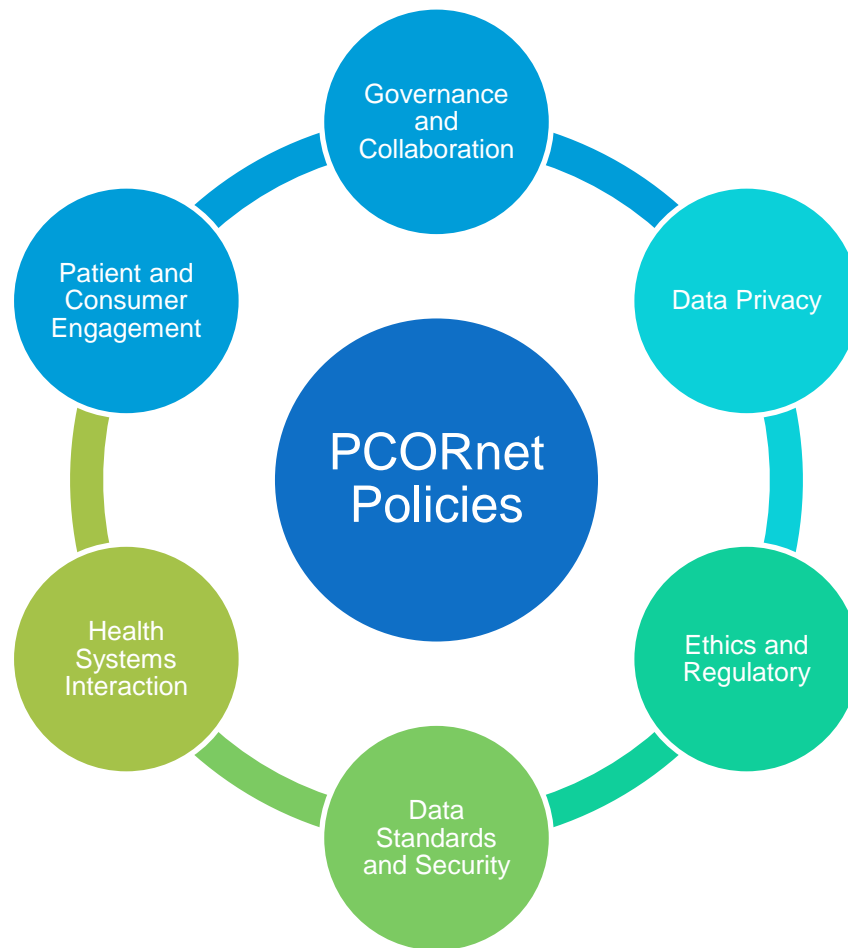
PCORnet Policies

- Policies guiding interactions among Networks in PCORnet
- Policies guiding Networks' interactions with PCORI

Resources And Assistance to

- Help partners develop local policies
- Guide PCORnet policies for external/future partners

Requires Collaboration and Input from Related Task Forces



Key PCORnet Governance Topics

Decision-Making and
Leadership

Data Access and Use

Rights and Expectations of
Network Partners

Privacy, Security, and
Confidentiality

Patient and Consumer
Engagement

Intellectual Property

Methodology Standards

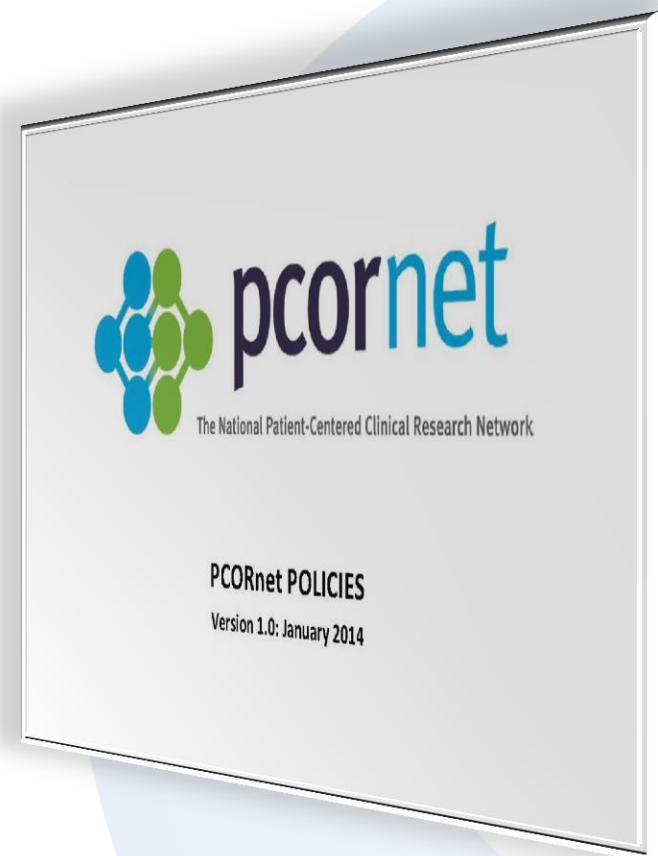
Conflicts of Interest

Human Subjects Policies

Translation and Dissemination

Coming Soon! PCORnet Policies - Version 1.0

- 🌐 Outlines shared goals, processes, and requirements for participating in PCORnet, including
 - Potential areas of policy guidance and planned policy development.
- 🌐 A living document that will:
 - Evolve over time to involve new partners, data, and uses.
 - Acknowledge natural variation within CDRNs and PPRNs



Timeline of G&C Task Force Activities

Identify and prioritize
policies and
procedures required
for PCORnet start-up
phase

(January 2014)

Identify areas for
additional policy
development

(Next 18 months)

Establish Task Force
and co-chairs
Review and vetting of
policies
(February 2014)

HEALTH SYSTEMS INTERACTIONS and SUSTAINABILITY: Issues and Challenges

Eric Larson, MD, MPH
Katherine Newton, PhD
Group Health Research Institute



pcornet

The National Patient-Centered Clinical Research Network

Consider the following question

- Should researchers need additional participant consent (reconsent) to submit existing data to the federal database of Genotypes and Phenotypes (dbGaP)?



Participant Answers

- What proportion said yes at re-consent?
 - 1,340 / 1,159 (86%)
- How important was it that they were asked?
 - Very (69%) or somewhat (21%)
- Were notification only / opt-out acceptable?
 - NO** 67% / 40 % unacceptable



Consider the Following Study:

- ❁ **Cluster Randomized Trial**
- ❁ **Unit of Randomization: Clinic**
- ❁ **Intervention: New approach to counseling about physical activity**
- ❁ **Control: Usual care**
- ❁ **Data collected from the EHR**

The Belmont Report - 1979

Ethical Principles and Guidelines for the Protection of Human Subjects of Research

1. Respect for Persons

2. Beneficence

3. Justice

Informed Consent: Respect for persons requires that subjects . . . be given the opportunity to choose what shall or shall not happen to them.

Who should provide consent?

Physicians? Intervention patients? Control patients?



Take Away Messages

- Being patient centered sometimes give us answers we don't like, or that make our work harder
- Resolving differences in how our systems view these and other issues is critical to PCORnet's success, and our success depends on our willingness to do so

Lessons Learned from NIH Collaboratory

- 🌐 The ultimate goal is providing benefits for patients and clinicians through answering practical, relevant research questions
- 🌐 Trust is essential and is not automatic
- 🌐 Think sustainability from the beginning

The Peaceable Kingdome






Goal of HSI Task Force

- ❁ Clarify issues individual partners face in ensuring they can maintain and sustain the systems and policies needed to participate in the network
- ❁ Establish a common vision of health systems involvement and sustainability.
- ❁ Explore concerns about patient trust, provider burden and impacts on workflow
- ❁ Facilitate alignment and standardization of practices across CDRNs to optimize activities

Collaboration

Pragmatic trials and network observational studies offer healthcare researchers and HCS the chance to be a part of a new era. However, require:

-  Research and HCS teams that listen closely to each other**
-  A common commitment to a sustainable interventions tested in clinical settings (trials)**
-  An ability to compromise to achieve both research and clinical priorities (trials and data studies)**

NIH Collaboratory PCT Engagement White paper

- ❁ Close relationship between researchers and HCS leaders, administrators, clinical and IT staff.
- ❁ Time commitment from all parties because communication and negotiation occur before, during, and after the study period.
- ❁ Researchers must remember that traditional RCT-type data are not possible in the everyday environment of PCTs, but results will almost certainly be more easily translated than traditional RCT findings.
- ❁ HCS must remember that participation will pay off in actionable results and tools to improve clinical care and provide professional opportunities for HCS leadership, and clinicians.

NIH Collaboratory PCT Engagement White paper

- ❁ Researchers must get buy-in and input from all levels of the organization.
- ❁ Even if a HCS is willing, researchers must have an objective way to determine if the system has the structure and capacity to participate.
- ❁ A good collaboration usually starts with a pilot project—and ends with a sustainable, evidence-based healthcare intervention and a long-term scientific relationship.
- ❁ The ultimate goal is providing benefits for patients and clinicians through answering practical, relevant research questions.

Attitude check

The goal is improving healthcare - HCS leaders and clinical staff are the experts in that area.

- 🌐 Research questions should focus on what the HCS wants to learn
- 🌐 Generalizable knowledge is likely to be a worthwhile byproduct of the research
- 🌐 Research must demonstrate value for the HCS, such as improved patient outcomes, experience or satisfaction; increased efficiency; or reduced burden for clinical staff

Span boundaries

- Effective communication must address that **activities, culture, language and priorities differ** for researchers and healthcare systems
- Researchers with clinical experience can help to convey practice changes to doctors.
- In turn, HCS leaders with academic experience understand the culture, language, and priorities of researchers

“For PCTs to be designed and implemented well while addressing questions that matter to clinicians and care systems, it is very important to have boundary-spanners—people who straddle the gap between care and research,”
Leif Solberg, MD of HealthPartners

Monitor the environment for change

- 🌐 **Opportunities for natural experiments** arise when clinical practice is affected by changes to healthcare policy or insurance benefits, introduction of new **diagnostics** or therapies, or changes in clinical workflow.
- 🌐 These **changes give researchers a chance to observe** how a specific healthcare change that occurs in the ordinary clinical environment affects patient outcomes.
- 🌐 Researchers with an **active connection to HCS are in a position** to hear about natural experiment opportunities in time to plan for a PCT.

Think sustainability from the start

- 🌐 Carry out pilot tests will determine
 - technical issues, feasibility
 - commitment to the partnership.
- 🌐 Research activities should provide the HCS with useful tools, information, and an evidence-based, effective intervention.
 - If the intervention was not effective, offer a rigorous analysis of why and suggests what might be done to increase effectiveness.
- 🌐 Tailor reports and follow-up information to the interests of each group.