PCORnet: Building Evidence through Innovation and Collaboration

Engelberg Center for Health Care Reform
The Brookings Institution • Washington, DC
January 21-22, 2014
Proposal Word Map: What are PCORnet Partners Saying?
Multiple Networks Sharing Infrastructure

Mini-Sentinel, pcor.net, NIH Distributed Research Network

Health Plan 1, Health Plan 4, Health Plan 7, Hospital 1, Hospital 4

Health Plan 2, Health Plan 5, Health Plan 8, Hospital 2, Hospital 5

Health Plan 3, Health Plan 6, Health Plan 9, Hospital 3, Hospital 6

Outpatient clinic 1, Outpatient clinic 2, Outpatient clinic 3, Patient network 1, Patient network 2, Patient network 3
PCORnet Kickoff Meeting Agenda

Tuesday, January 21st

10:15 a.m. Welcome and Opening Remarks
Mark McClellan, Brookings Institution
Greg Daniel, Brookings Institution
Rachael Fleurence, Patient-Centered Outcomes Research Institute

10:30 a.m. Introduction to PCORnet
Mark McClellan – Moderator
Joe Selby, Patient-Centered Outcomes Research Institute
External Partners
Bray Patrick-Lake, Duke Translational Medicine Institute

12:30 p.m. Lunch and Informal Networking
PCORnet Kickoff Meeting Agenda

Tuesday, January 21st

1:30 p.m. Envisioning the Network’s Research
Mark McClellan – Moderator
Rob Califf, Duke Translational Medicine
Rich Platt, Harvard Pilgrim Health Care Institute

3:00 p.m. Break

3:15 p.m. Building the Network Foundation: Part 1
Mark McClellan – Moderator
Erin Holve, Governance Task Force
Eric Larson, Health Systems and Sustainability Task Force
Katherine Newton, Health Systems and Sustainability Task Force
Sean Tunis, Patient and Consumer Engagement Task Force
PCORnet Kickoff Meeting Agenda

Tuesday, January 21st

4:30 p.m.  Day Recap
  Mark McClellan – *Moderator*
  Joe Selby
  Rachael Fleurence

4:45 p.m.  Adjournment

5:00 p.m.  Cocktail Reception

6:00 p.m.  Dinner
PCORnet Kickoff Meeting Agenda

Wednesday, January 22\textsuperscript{nd}

9:00 a.m. Welcome and Recap of Day 1
Mark McClellan
Rachael Fleurence

9:15 a.m. Patient Engagement within PCORnet
Bray Patrick-Lake
Sue Sheridan, Patient-Centered Outcomes Research Institute
Sean Tunis

10:00 a.m. Building the Network Foundation: Part 2
Mark McClellan – \textit{Moderator}
Jeremy Sugarman, Regulatory and Ethics Task Force
Deven McGraw, Privacy Task Force
Jeffrey Brown, Data Security, Standards, and Data Infrastructure
PCORnet Kickoff Meeting Agenda

Wednesday, January 22nd

11:15 a.m. Break

11:30 a.m. Evaluation
Sarah Greene, Patient-Centered Outcomes Research Institute
– Moderator
Sarah Daugherty, Patient-Centered Outcomes Research Institute
Erin Holve
Eric Schneider, RAND Corporation

12:10 p.m. Lunch and Informal Networking
PCORnet Kickoff Meeting Agenda

Wednesday, January 22\textsuperscript{nd}

1:15 p.m. **Next Steps for Developing Core Research Capacities**
   - Mark McClellan – *Moderator*
   - Joe Selby
   - Rachael Fleurence
   - Richard Platt
   - Robert Califf

2:45 p.m. **Closing Remarks**
   - Mark McClellan – *Moderator*
   - Joe Selby
   - Rachael Fleurence
   - Richard Platt
   - Robert Califf

3:15 p.m. **Adjournment**
Introduction to PCORnet

Engelberg Center for Health Care Reform
The Brookings Institution • Washington, DC
January 21-22, 2014
Launching PCORnet, the National Patient-Centered Clinical Research Network

PCORnet Kickoff Meeting

January 21st, 2014
The goal of PCORI’s National Patient-Centered Clinical Research Network Program is to improve the nation’s capacity to conduct CER efficiently, by creating a large, highly representative, national patient-centered clinical research network for conducting clinical outcomes research.

The vision is to support a learning US healthcare system, which would allow for large-scale research to be conducted with enhanced accuracy and efficiency.
Overall objectives of PCORnet: achieving a single functional “network of networks”

- Engagement of patients, providers and health system leaders
- Support and conduct of multi-network observational and interventional CER studies
- External data and research partners participate with PCORI-funded networks
- Researchers not directly affiliated with PCORnet participate through collaborative arrangements.
- PCORnet partners will use the resources created with PCORI’s support for a range of activities supported by other organizations.
CDRN Highlights

- Networks of academic medical centers, hospitals and physician practices
- Networks of non-profit integrated health systems
- Networks of low income clinics
- Networks leveraging AHRQ investments and NIH investments (CTSAs)
- Inclusion of Health Information Exchanges
- Wide geographical spread
- Inclusion of underserved populations
- Range from 1M covered lives to 28M
PPRN Highlights

• Variety of **stakeholders** in participating organizations and in leadership team: patients, advocacy groups, physician organizations, academic centers, PBRNs etc.
• Strong understanding of **patient engagement**
• Significant range of **conditions and diseases**
• Variety in **populations** represented (including pediatrics, underserved populations etc.)
• 50% **rare diseases**
• Significant range in the **maturity** of the group in terms of data available
• Several have capacity to work with **biospecimens**
PCORnet Steering Committee

- Each Clinical Data Research Network
- Each Patient Powered Research Network
- Patient representative
- HHS agencies
  - NIH
  - FDA
  - AHRQ
  - CDC
  - CMS
  - ONC
  - ASPE
- Medical product / device manufacturers
- PCORI and Coordinating Center
Multiple Networks Sharing Infrastructure

- Each organization can participate in multiple networks
- Each network controls its governance and coordination
- Networks share infrastructure, data curation, analytics, lessons, security, software development
Bray Patrick-Lake
Patient Representative,
Executive Leadership Committee,
PCORnet Coordinating Center
Patients need relevant, high quality information for informed decision making

- Complex navigation of risk/benefit tradeoffs
- Dependent on where patients are in trajectory of the disease
- Delicate balance of co-morbidities
- Long term consequences vs. short term benefit
- Quality vs. quantity of life
- Respectful of cultural preferences
Based on my personal characteristics, what can I expect my outcome to be? **WE DON’T KNOW**

- Therapies reach market after study in cleanest population possible
- Smallest number of patients, shortest amount of time possible
- Results often an average; some receive benefit, others harm
- Subgroup analysis on single variables
- Things patients care about most are absent - QOL and PROs
The current system is broken; patients are over it.

- Incredible waste of resources on repetitive activities
- Unnecessary delays due to bureaucracy
- Recruitment and retention failures rampant
- Data that could help patients remains inaccessible
- Research results don’t get disseminated to patients or translated into decision support tools
Patients dream of …

A high quality clinical research system that is patient-centered and efficient, enabling reliable and timely access to evidence-based prevention & treatment options that are responsive to patients’ individual needs.

Maybe we should ask patients how to achieve this …
Evolution of patient engagement in research: PCORnet’s history in the making

- Patient
- Participant in Research
- Activated Patient
- Reviewer of Research
- Designer of Research
- Creator of Disease Specific Infrastructure
- Driver of National Research Infrastructure
PCORnet and its partners make the dream a reality

- Dream team of research and patient experts working on PCORnet
- Historic amount of patient engagement in research
- Unprecedented opportunities for collaboration, knowledge sharing, and community building
- **Together we will make a difference in the lives of millions of patients**
  
  *(and change our nation’s clinical research system forever!)*
Envisioning the Network's Research

Engelberg Center for Health Care Reform
The Brookings Institution • Washington, DC
January 21-22, 2014
Envisioning PCORnet’s research

Richard Platt, MD, MS
Robert Califf, MD
January 21, 2014
Our Clinical Research System is Not Generating the Evidence we Need to Support Practice!

- High % of decisions not supported by evidence
- Poor health status of US population
- Great disparities
- Questions about reliability of the system growing
- Current clinical research system is great except:
  - Too slow
  - Too expensive
  - Unreliable
  - Doesn’t answer the questions important to patients
  - Unattractive to providers and administrators in the system
Which Treatment is Best for Whom? High-Quality Evidence is Scarce < 15% of guideline recommendations supported by high quality evidence

Scientific Evidence Underlying the ACC/AHA Clinical Practice Guidelines

Pierluigi Tricoci, MD, MHS, PhD
Joseph M. Allen, MA
Judith M. Kramer, MD, MS
Robert M. Califf, MD
Sidney C. Smith Jr, MD

Context  The joint cardiovascular practice guidelines of the American College of Cardiology (ACC) and the American Heart Association (AHA) have become important documents for guiding cardiology practice and establishing benchmarks for quality of care.

Objective  To describe the evolution of recommendations in ACC/AHA cardiovascular guidelines and the distribution of recommendations across classes of recommendations and levels of evidence.

Data Sources and Study Selection  Data from all ACC/AHA practice guidelines issued from 1984 to September 2008 were abstracted by personnel in the ACC Science and Quality Division. Fifty-three guidelines on 22 topics, including a total of 7196 recommendations, were abstracted.
## Age-Standardized Years of Life Lost Relative to Comparator Countries and Ranking by Cause in 2010

<table>
<thead>
<tr>
<th>Cause</th>
<th>Sweden</th>
<th>Italy</th>
<th>Spain</th>
<th>Australia</th>
<th>Norway</th>
<th>Netherlands</th>
<th>Austria</th>
<th>Luxembourg</th>
<th>Germany</th>
<th>Canada</th>
<th>France</th>
<th>Ireland</th>
<th>Greece</th>
<th>UK</th>
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<td>Other cardiovascular and circulatory</td>
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<td>Congenital anomalies</td>
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<td>9</td>
<td>18</td>
<td>16</td>
<td>19</td>
</tr>
</tbody>
</table>

- **Green**: Lower than mean
- **Yellow**: Indistinguishable from mean
- **Red**: Higher than mean

GBD 2010 Study. *Lancet* 2012 December
Mortality Experiences of the 8 Americas

Males

- America 1
- America 2
- America 3
- America 4

- America 5
- America 6
- America 7
- America 8

Year:
- 1982
- 1984
- 1986
- 1988
- 1990
- 1992
- 1994
- 1996
- 1998
- 2000

Life expectancy at birth (years):
- 60
- 70
- 80
- 90

Females

- America 1
- America 2
- America 3
- America 4

- America 5
- America 6
- America 7
- America 8

Year:
- 1982
- 1984
- 1986
- 1988
- 1990
- 1992
- 1994
- 1996
- 1998
- 2000

Life expectancy at birth (years):
- 60
- 70
- 80
- 90

Learning health care systems

In a learning health care system, research influences practice and practice influences research.

**EVALUATE**
Collect data and analyze results to show what works and what doesn’t.

**IMPLEMENT**
Apply plan in pilot and control settings.

**DESIGN**
Design care and evaluation based on evidence generated here and elsewhere.

**ADJUST**
Use evidence to influence continual improvement.

**DISSEMINATE**
Share results to improve care for everyone.

**INTERNAL AND EXTERNAL SCAN**
Identify problems and potentially innovative solutions.
1

Prioritize Key Questions

Choose Topic

Refine Protocol Design

- Contact and Involve Patients
- Assess Population

Patients Providers

Simulate Trial Procedures

Assess EHR / Registries / Other

Contract / Study Procedures

Simulate with Providers and Patients

Design Data Collection Instruments

Select sites and Steering Committee and Data Monitoring Committee

Refine Protocol

Finalize Protocol
Start with Final Protocol, Contract and Budget

Contract and Budget

Send to Sites

IRB

Provider and Administration

Site Training

Patients and Facilities

Develop and Distribute Study Materials

Assess Regulatory Status

Site Initiated

Devise Quality by Design Plan
Site Initiated → Enroll Patients → Conduct Trial

- QBD Reassess Early for Issues
- Evaluate HRPP Plan as trial goes on
- Trial Communication, Protocol Amendments

→ Data Monitoring Committee
→ Data Monitoring Committee / HRPP

Trial Closeout
Obesity-related Questions Suited for PCORnet: Rare Exposures or Outcomes

🔗 To what extent is gestational diabetes associated with offspring obesity and type 2 DM?
  - Using sib-pair design to control for confounding
  - Among subpopulations at higher risk of GDM

🔗 Which antipsychotics are most associated with weight gain and incident type 2 DM?
  - Are there class effects? Single drug effects?

🔗 Which types of bariatric surgery result in best outcomes with least cost and risk?
  - Better biochemical outcomes
  - Lower utilization, cost, adverse events, morbidity/mortality
Obesity-related Questions Suited for PCORnet: Practice Variation

What explains variation in bariatric surgery type and frequency?
- Is regionalization or high volume associated with better benefit/risk?

How much variation exists in uptake of new weight-loss drugs?
- What are the determinants of this variation at the health plan, delivery system, provider, and patient levels?
Obesity-related Questions Suited for PCORnet: Natural Experiments

To what extent does introduction of state policies on school nutrition or child BMI screening, which vary widely across states, influence maternal and child obesity rates?

- How much does extent of implementation drive the results?
Obesity-related Questions Suited for PCORnet: Dissemination

- How well do delivery system interventions that are proven to prevent childhood obesity (or change obesity-related behaviors) in local cluster RCTs perform in broader settings?
Obesity-related Questions Suited for PCORnet: Simulation of Best Practices

Simulation of best practices

- How well do systems science models of implementation of multiple-component obesity prevention interventions perform in widely varying settings?
Obesity-related Questions Suited for PCORnet: Clinical Trials

Cluster randomized controlled trial
- EMR-based identification, monitoring, evaluation, referral and knowledge transfer
  - E.g., to moderate excessive gestational weight gain
  - E.g., to treat obesity in school age children
  - [EpicCare has created tools for each of these examples]

Individual randomized controlled trial
- Comparative effectiveness trial of the 2 newly approved drugs for obesity treatment in adults: lorcaserin vs. phentermine/topiramate
  - Weight loss, improvements in metabolic parameters
  - Adverse events, toxicity
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
<table>
<thead>
<tr>
<th>Key PCORnet Governance Topics</th>
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<tbody>
<tr>
<td>Decision-Making and Leadership</td>
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<tr>
<td>Rights and Expectations of Network Partners</td>
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<td>Patient and Consumer Engagement</td>
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<td>Methodology Standards</td>
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<td>Human Subjects Policies</td>
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<td>Data Access and Use</td>
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<td>Privacy, Security, and Confidentiality</td>
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<td>Intellectual Property</td>
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<tr>
<td>Conflicts of Interest</td>
</tr>
<tr>
<td>Translation and Dissemination</td>
</tr>
</tbody>
</table>
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)
- Establish Task Force and co-chairs
  Review and vetting of policies
  (February 2014)
- Identify areas for additional policy development
  (Next 18 months)
HEALTH SYSTEMS INTERACTIONS and SUSTAINABILITY: Issues and Challenges

Eric Larson, MD, MPH
Katherine Newton, PhD
Group Health Research Institute
Consider the following question

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

Ludman E. Glad you asked: participants’ opinions of re-consent for dbGAP data submission. J Empir Res Hum Res Ethics 2019 5:9-16
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.

Ludman E. Glad you asked: participants’ opinions of re-consent for dbGAP data submission. J Empir Res Hum Res Ethics 2019 5:9-16
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 Kingdom
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)
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.

Relationship tips for researchers and HCS in PCTs
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
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.
Ethics and Regulatory Task Force

Co-Chairs: Rob Califf and Jeremy Sugarman
Coordinator: Joe Ali
Project Manager: Tammy Reece
The Ethics and Regulatory Minefield

- Consent and notification
- Determining “minimal risk”
- Use of FDA approved products
- Research design
  - Cluster randomization
  - Pre-randomization
- IRB oversight
- Data monitoring
- Privacy and transparency
- Ethics and engagement
- Ethics of broadly collaborative research
Lessons from the NIH HCS Research Collaboratory

- Early discussions with multiple stakeholders can clarify issues and identify a path forward.
- Investigators should articulate carefully why a proposed endeavor should be considered as “minimal risk” in appropriate settings.

https://www.nihcollaboratory.org/Pages/sachrp.aspx
Current Plans

Serve as consultants, upon request, to PCORnet for emerging ethical and regulatory issues and to catalogue these issues.

Conduct desk & document reviews to inform issue briefs describing ethical and regulatory challenges as well as strategies for managing IRB and oversight processes.
Towards Efficiency

- There are broad moral claims to garner knowledge to improve clinical care and to enhance research efficiency.
- Doing so will be associated with some predictable (and unpredictable) practical, regulatory and ethical challenges.
- With collaboration and communication, PCORnet is well-positioned to navigate these challenges and develop appropriate means of overcoming them.
Privacy Task Force

Chair: Deven McGraw
Project Manager: Alice Leiter
Task Force Goals

- Work collectively to develop a set of privacy policies to govern data sharing by the National Patient-Centered Clinical Research Network (PCORnet).

- Identify privacy issues raising particular challenges for PCORnet Partners; issue white papers highlighting promising or best practices for addressing them.
Specific Aims

$class.Underline
Develop privacy policies for PCORnet.

Surface particularly challenging privacy issues for PCORnet Partners and collect promising or best practices for addressing them.

$bullet Potential issues to be addressed:
  $•$ Data identifiability and de-identification methodologies
  $•$ Models for data sharing
  $•$ Approaches to transparency and consent
Compliance with Laws

- The Common Rule (governs federally funded research on human subjects)
- HIPAA (governs “covered entities” and their business associates)
- State laws may apply
- FDA in some cases
Fair Information Practices

- Openness and transparency
- Purpose specification and minimization
- Collection limitation
- Use limitation
- Individual participation and control
- Data integrity and quality
- Security safeguards and controls
- Accountability and Oversight
- Remedies
Data Minimization

- The Common Rule applies only to data that are identifiable to the researcher.
- Data that meets HIPAA’s de-identification standards are not subject to HIPAA’s research rules.
  - Data in a “limited data set” are subject to less stringent regulation (consent not required, but data use agreement required)
- Data disclosed/shared by PCORnet Partners will be de-identified; however, access to the information to run research questions will likely involve identifiable health information
Research requires review of Institutional Review Board

- Can be “expedited” if research falls into an approved category (for ex., research involving data already collected for clinical purposes & prospective collection of biospecimens through noninvasive means).
The Common Rule (cont.)

Consent required, although can be waived if:

- The research involves no more than minimal risk;
- The waiver will not adversely affect the rights & welfare of subjects;
- The research could not be practically conducted w/out the waiver; and
- When appropriate, subjects are provided with additional info after participation.
HIPAA

Before fully identifiable information can be used for research purposes, the patient’s authorization must be obtained (previous rule required authorizations to be specific – but Omnibus rule allows for authorizations for future research, as long as that future research is “sufficiently described”)

- Can be waived by a Privacy Board or IRB if risk to privacy is considered to be low
- Some exceptions (review of data onsite in preparation for research, research on decedent’s info, and use of limited data set)

Scope of new rule uncertain
Common Challenges for Multi-Site Research Networks

- Genuine confusion about both content and application of the rules
- Different tolerances for risk lead to different interpretations of the rules
- Concerns about sharing an institutional asset
- How to better leverage patients to build trust in research and research networks
Questions for Discussion

Do you have policies and procedures in place to assure that each participant in your network is in compliance with all applicable federal and state laws?

If your network involves more than one organizational or institutional participant, do you have network-wide policies and procedures that enable the network to be used for the efficient conduct of research?

Are you prepared as an organization/institution or network to work with the Coordinating Center and other participants in PCORINet to develop and implement the necessary PCORINet policies? If not, what would it take to help you get there?
Data Standards, Security, Networking, and Infrastructure (DSSNI) Task Force

**Co-Chairs:** Jeff Brown, Lesley Curtis, and Ed Hammond

**Project Managers:** Jenny Ibarra and Brie Purcell

**Technical Leads:** Shelley Rusincovitch and Jessica Sturtevant

**PopMedNet Coordinator:** Jessica Malenfant
PCORnet Distributed Research Network Aims

Create a research-ready PCORnet Distributed Research Network (DRN)
- 11 Clinical Data Research Networks
- 18 Patient-Powered Research Networks
- Other interested participants

Leverage evolving resources and capabilities of HHS existing multipurpose clinically embedded networks, electronic data, and clinical research initiatives
Data Standards, Security & Network Infrastructure Task Force

**Key responsibilities**

- Create a distributed research network capable of supporting rapid, efficient, and reproducible multi-network research
- Ensure that CDRNs/PPRNs maintain physical and operational control over their data
- Use distributed analysis methods that minimize the need to share patient level data
Create a distributed research network

- Operations center
  - Network development and implementation
  - Knowledge management
  - Analytic tools

- Secure network to send queries and receive responses

- Flexible query approaches and interfaces

- Distribution of executable code to conserve scarce programming resources and assure uniformity of analysis
  - Code should run without change
CDRN and PPRNs maintain physical and operational control over their data

- Distributed approach allows partners to maintain control of their data and all uses
- Partners have option to review requests before execution and review results before release
- No need to change local workflow related to release of information
- All activities secure and audited
Use distributed analysis methods that minimize the need to share patient level data

- Only the minimum information necessary should be requested and shared
- PCORnet DRN operations center oversees minimum necessary policy implementation
- Many analyses can be completed without sharing any protected information
  - Risk sets
  - Propensity scores
  - Highly aggregated and summarized person-level information
PCORnet Distributed Analysis

1- User creates and submits query (a computer program)

2- Data partners retrieve query

3- Data partners review and run query against their local data

4- Data partners review results

5- Data partners return results via secure network

6 Results are aggregated

PCORnet Operations Center

PCORnet Secure Network Portal

CDRN 1

Review & run query

Review & run results

Enroll Demographics Utilization Etc.

PPRN 1

Review & run query

Review & run results

Enroll Demographics Utilization Etc.
Building blocks of the PCORnet DRN

- CDRNs and PPRNs
- Guiding principles
  - Network
  - Data model
- Common Data Model
- Operations Center
  - Secure portal
  - Querying capability
  - Development of new networking and collaboration tools and functionality
Thank you