ENGELBERG CENTER for Health Care Reform at BROOKINGS

Building the Network Foundation: Part 2

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Ethics and Regulatory Task Force

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Coordinator: Joe Ali

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The National Patient-Centered Clinical Research Network

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

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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

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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

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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

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Privacy Task Force

Chair: Deven McGraw

Project Manager: Alice Leiter

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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

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Specific Aims

- Develop privacy policies for PCORnet.
- Surface particularly challenging privacy issues for PCORnet Partners and collect promising or best practices for addressing them.
  - Potential issues to be addressed:
    - Data identifiability and de-identification methodologies
    - Models for data sharing
    - Approaches to transparency and consent

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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

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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

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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

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The Common Rule

- 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).

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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 practicably conducted w/out the waiver; and
  - When appropriate, subjects are provided with additional info after participation.

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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

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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?

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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*

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The National Patient-Centered Clinical Research Network

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

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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

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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

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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

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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

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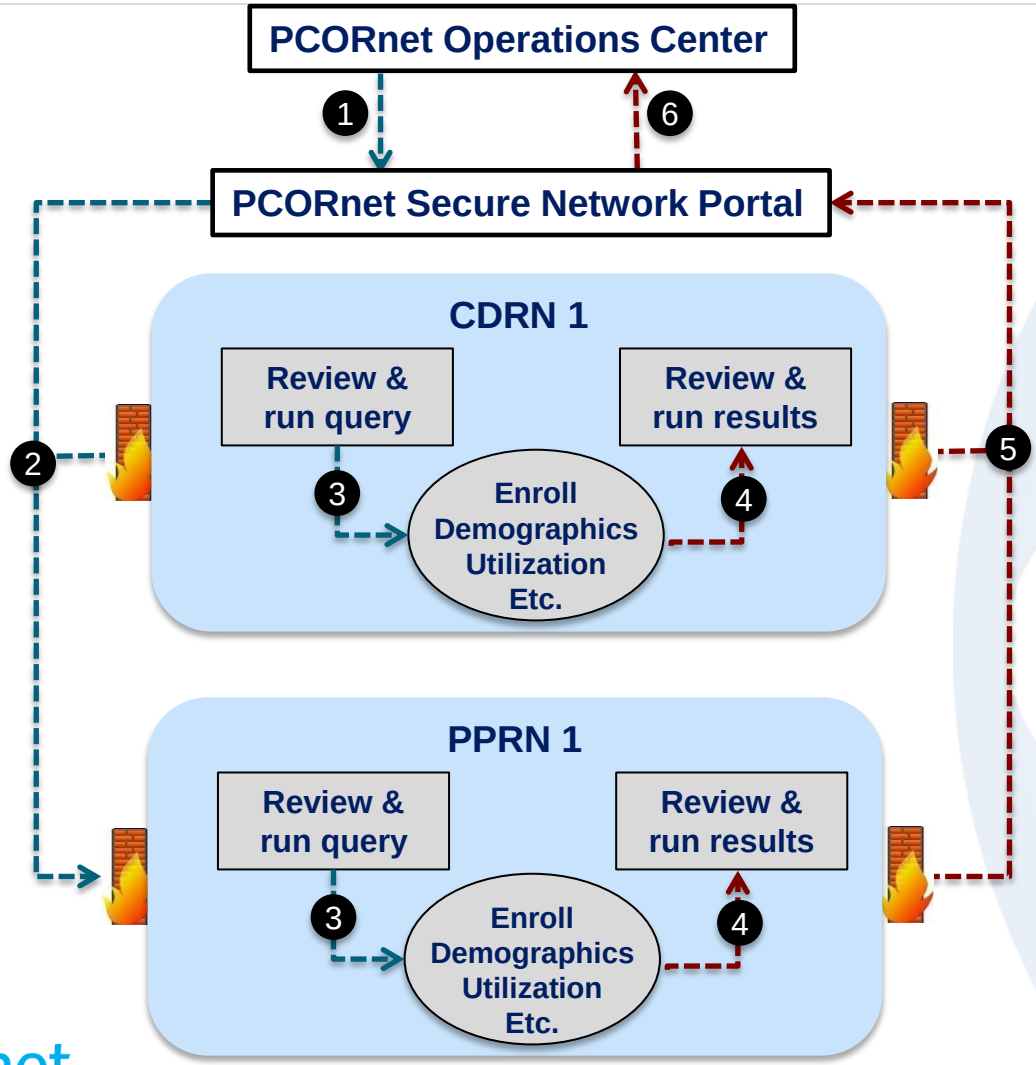
PCORnet Distributed Analysis



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

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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

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Thank you