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# Patient Engagement Advisory Panel

*October 2, 2014*

*Arlington, VA*

Patient-Centered Outcomes Research Institute

# Recap of Day 1, Overview of Day 2

**Sue Sheridan, MIM, MBA**

*Director of Patient Engagement*

Patient-Centered Outcomes Research Institute

# Agenda for Oct 2

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|---|---|
| **9:00 – 9:15 a.m.** | Recap of Day 1, Overview of Day 2 |
| **9:15 – 9:45 a.m.** | Q&A with Joe Selby |
| **9:45 – 10:15 a.m.** | Compensation Framework |
| **10:15 – 10:30 a.m.** | BREAK |
| **10:30 – 11:15 a.m.** | Update on PCORnet |
| **11:15 – 11:45 a.m.** | Privacy / Data and Safety Monitoring Board / Institutional Review Board |
| **11:45 a.m. – 12:30 p.m.** | Call for topics |
| **12:30 p.m.** | Meeting Adjourned |
| | Boxed Lunch |

# Q&A with Joe Selby

***Joe Selby, MD, MPH***

*Executive Director*

Patient-Centered Outcomes Research Institute

# Compensation Framework

***Charlotte W. Collins, JD***

*Chair*

***Compensation Subcommittee***

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# 15-Minute Break

*Refreshments outside.*

# Update on PCORnet

**Jaye Bea Smalley, MPA**

*Engagement Officer*

**Lorraine Johnson, JD, MBA**

*Chief Executive Officer, LymeDisease.org*

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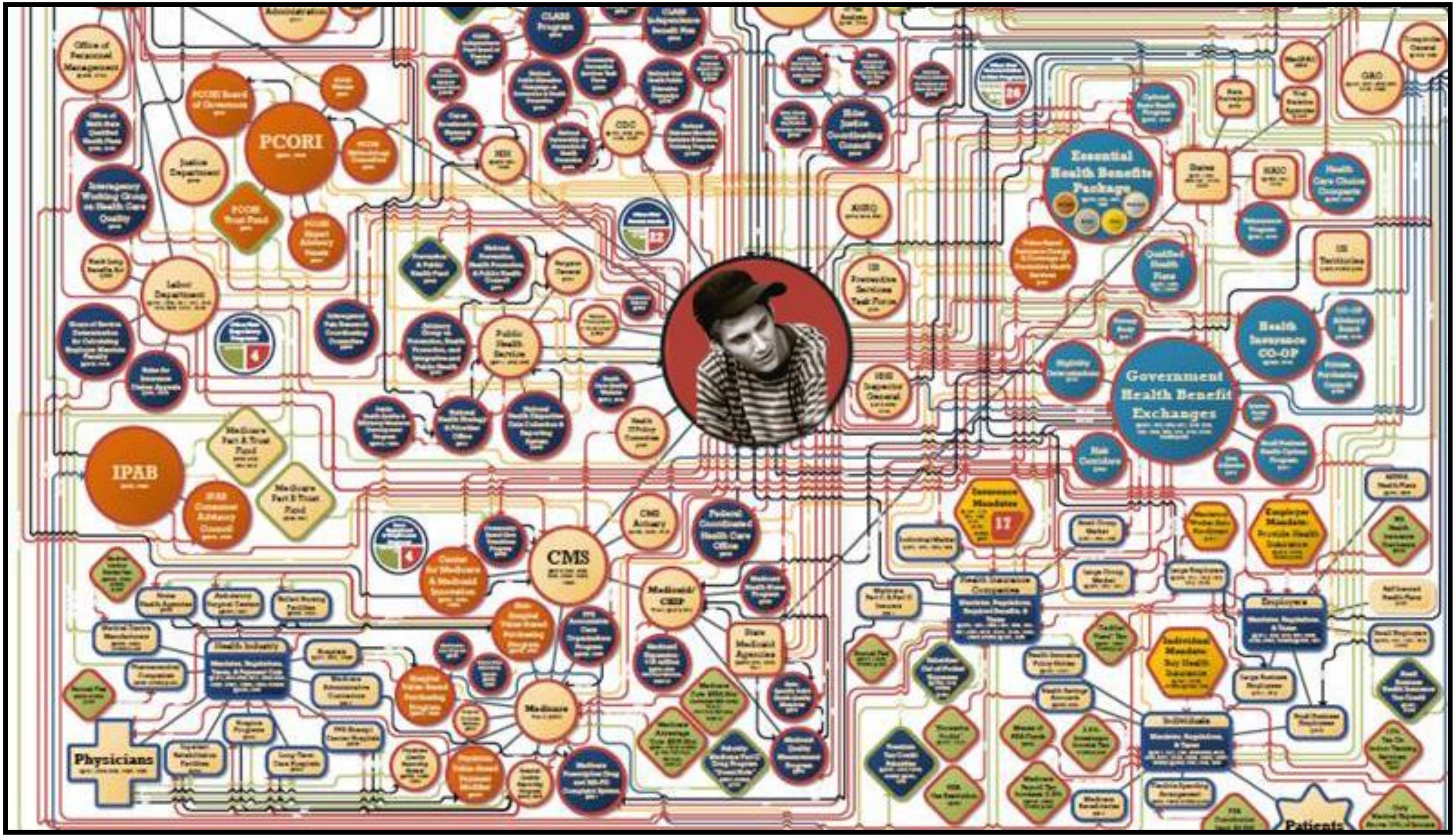
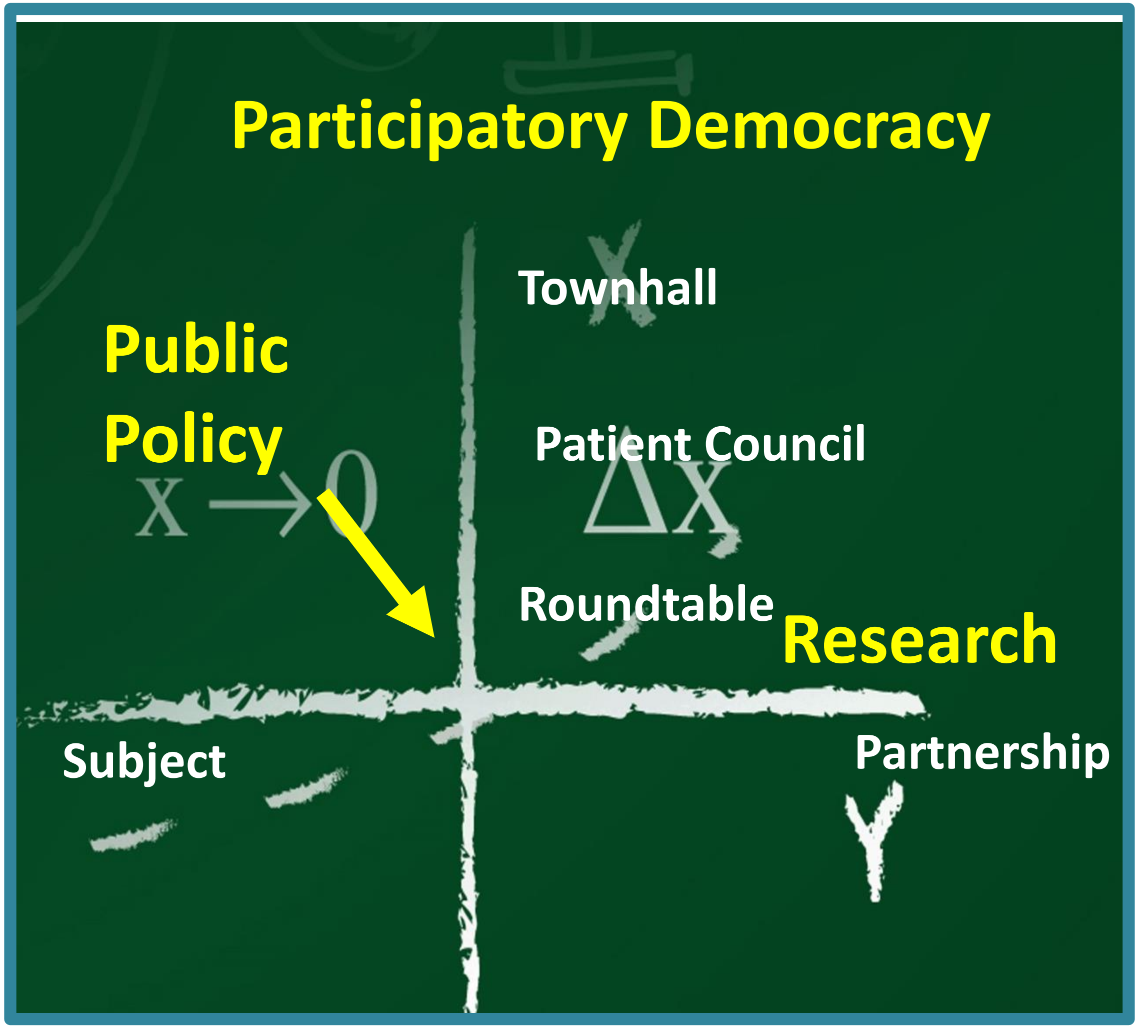
# Patient Council Status



# Healthcare Policy and the Messy Intersection of Participatory Democracy and Research



Participatory Democracy

Public Policy

Townhall

Patient Council

Roundtable

Research

Subject

Partnership

# Patient Councils are Deliberative Bodies

- Patient Councils and citizen juries are deliberative bodies that engage in “egalitarian, uncoerced, competent” deliberation “free from power and strategy”
- They are used for a variety of activities.
  - research ethics controversies
  - healthcare policy and reform
  - public good and personal privacy
- They  create tension  between instrumental needs and deliberative democracy principles.

Street (2014): The use of citizens' juries in health policy decision-making: A systematic review

# International Association of Public Participation: Core Values

- Those affected by a decision have a right to be involved
- Promise that the public's contribution will influence the decision.
- Recognizes needs and interests of all participants, including decision makers.
- Facilitates the involvement of those potentially affected by or interested in a decision.
- Participants involved n designing how they participate.
- **Participants given information needed for meaningful participation**
- Participants told how their input affected the decision.

# Status Update

- **Members:**
  - Lorraine Johnson: PCORnet Steering Committee Patient Rep.
  - Bill Clark: COPD PPRN
  - Cheryl Jernigan: GPC CDRN and PCE TF
  - Celeste Castillo-Lee: Vasculitis PPRN
  - Jessica Burris: CCFA PPRN, Ethics TF
  - Mellanie True-Hills: Health eHeart PPRN, PRO TF
  - Sue Sheridan: PCORI, Director of Patient Engagemen
- **Role:** to provide heightened scrutiny of big data research issues concerning patients: privacy, consent, and autonomy because these issues hold a special place in our society as rights retained by the individual that are not subject to majoritarian rule.
- **Process:** We will do this by providing input on policies and by reviewing revised policies before they are adopted by the Steering Committee and advising PCORI whether we believe they adequately address patient concerns. And, if not, make recommendations to PCORI to address this issue.

# PCORnet PPC Concepts:

## AUTONOMY, PRIVACY, DISCLOSURE AND CONSENT

### FRAMING CONTEXT:

- What does patient centered consent/autonomy look like?
- What does patient centered transparency/disclosure look like?
- What does patient centered privacy/confidentiality look like?

# PRACTICAL CONTEXT:

- Research activities limit clinical discretion or patient choice (autonomy) and privacy?
  - Individual randomized trials
  - Cluster randomized trials
  - Observational trials
  - Counts
- CDRNs versus PPRNs: The role trusted third party intermediaries.

# Consent Principle Concepts

Types of Consent:

- Blanket consent
- Hybrid: Blanket, AskMe, Opt out
- Granular consent
- Blanket with right to revoke
- Opt out

Concerns (high risks)

Autonomy : Aspirin vs Breast Cancer Trade-offs
Privacy: De-identified vs PHI vs Re-identified

- Blanket consents are inappropriate as a “sole option”
- Consent on a continuum
  - Observational trials using de-identified data, blanket consent ok with opt-out option
  - Therapeutic interventions that raise issues of autonomy or value dependent trade-offs

# Privacy/ Data and Safety Monitoring Board/ Institutional Review Board

***Suzanne Schrandt, JD***

*Deputy Director of Patient Engagement*

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# Call for Topics

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# Thank you!

*Safe travels home!*

*Boxed Lunch is served outside the room.*