

# Patient-Centered Outcomes Research Institute Program Development Committee(PDC) Report

PCORI Board of Governors  
Baltimore MD  
March 5, 2012



PPP

**Chair:** Gray Norquist

**Advisor:** Christine Goertz *non-voting*

**Members:**

Kerry Barnett

Carolyn Clancy

Arnie Epstein

Gail Hunt

Steve Lipstein

Sherine Gabriel

Clyde Yancy

Joe Selby

## Working Group

- Determines specific criteria to be considered by the PCORI Selection Committee in determining and recommending an appropriately balanced slate of awards.

Initial recommendations made. Under review by Methodology Committee

## PCORI Staff

- Analyzes the applications using priority score and the criteria.
- Provides a list of award options based on Working Group recommendations.
- Supports the PCORI Selection Committee and Board of Governors by providing revised options, as needed.

## PCORI Selection Committee

- Meets to review materials.
- Considers the balance of priority-scored applications across selected criteria, requesting additional analysis and options from staff, as needed.
- Prepares a recommended slate of selected projects for funding consideration.

## Board of Governors

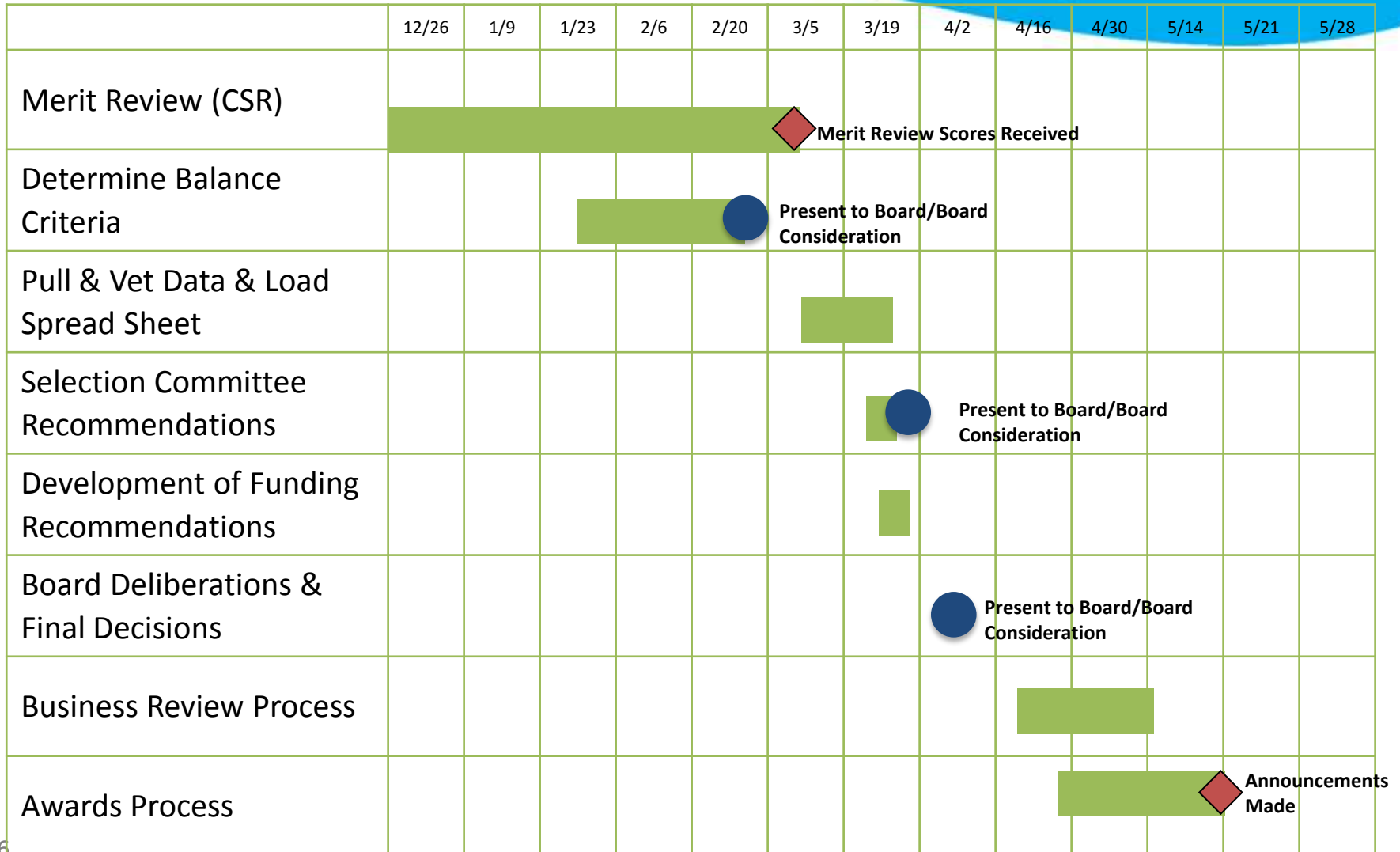
- Meets to consider the recommended slate.
- Reviews the slate based on priorities and balance to ensure appropriate distribution.
- Requests additional options, if needed.
- Approves a final slate of selected projects for funding.

- Priority Score

## **Among Highest Scoring Applications**

- Area of Interest
- Population
- Methods
- Geography
- Discipline of PI
- Seniority of PI
- Condition
- Stakeholder/Patient Involvement

# Pilot Projects Timeline



- **Post Survey Instrument**

- NIH administered PCORI-developed stakeholder and scientist surveys at the end of the merit review to gain insights into the review experience

- **Observational Instrument**

- Instrument was completed by PCORI observers in attendance at 10 randomly selected review meetings

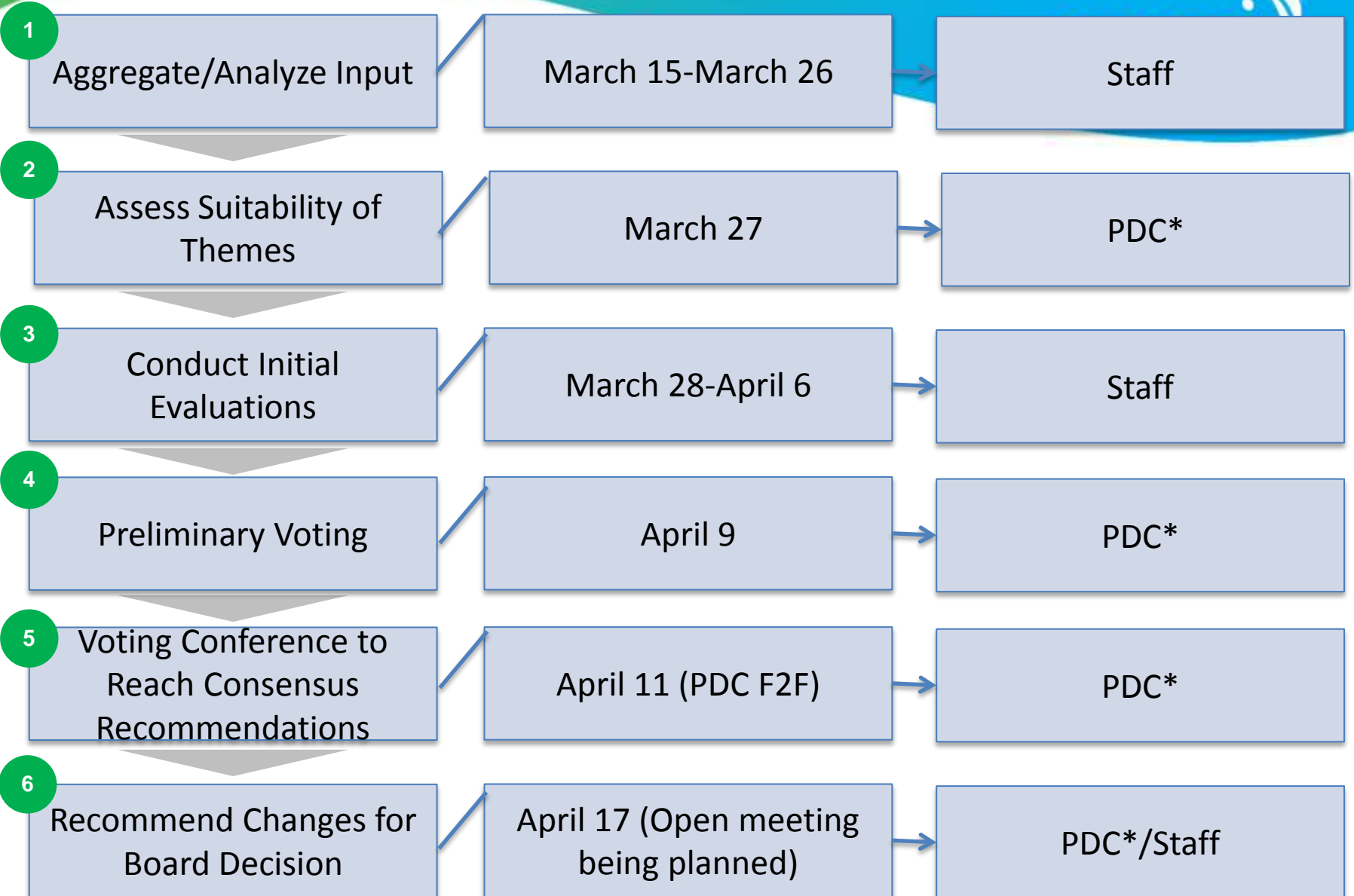
- **Merit Score Data**

- We have data on preliminary and final scores for each application, including information on the six PCORI Review Criteria

# Public Comment Results

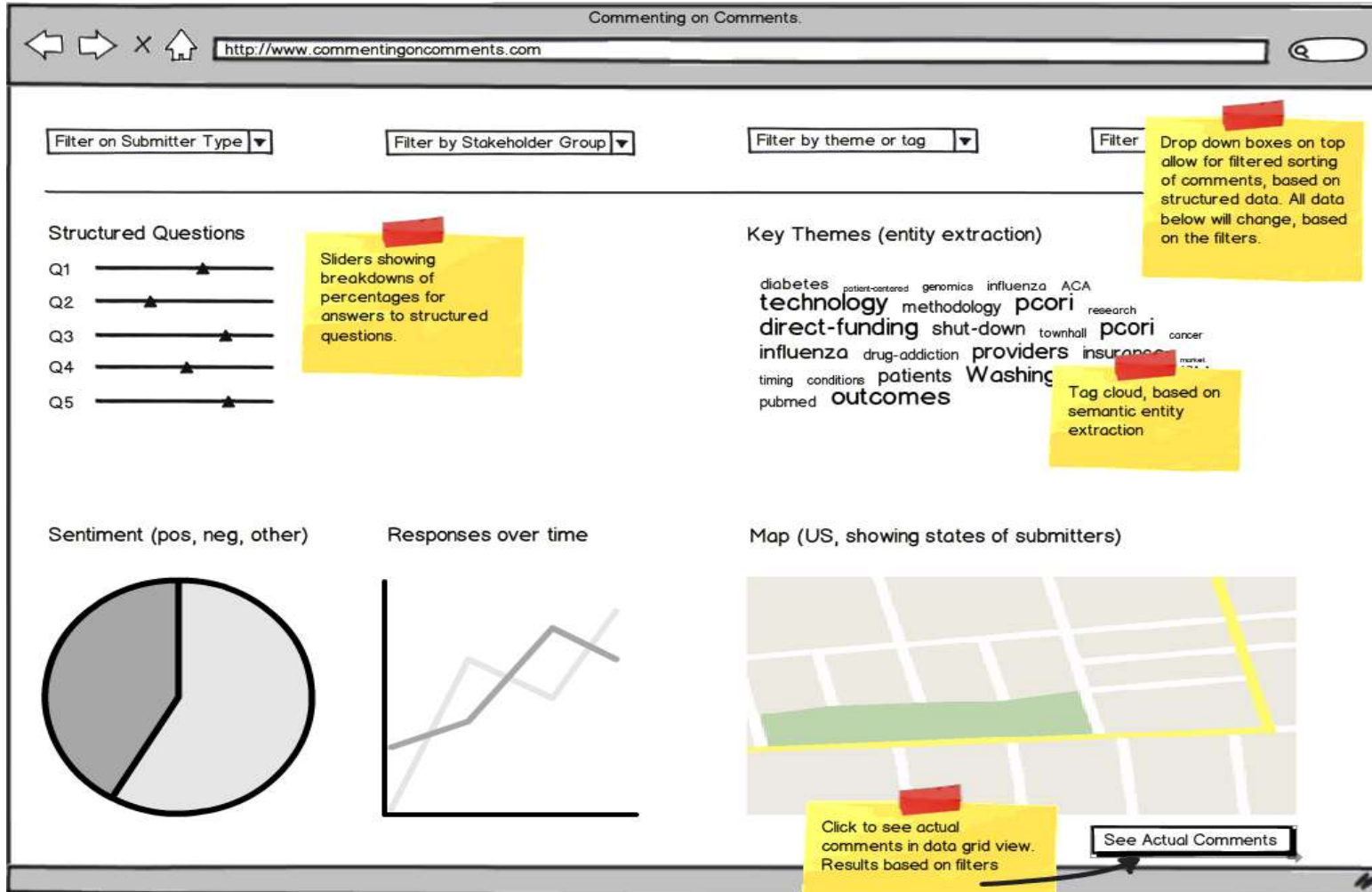


# Public Comment Process and Timeline



\*Any interested Board/MC Member is welcome to participate

# Public Comment Analytics


























































# May, 2012 PFA Process and Timeline

# Timeline for Development of First PFAs



|   | 1  | 2   | 3  | 4   | 5   | 6  | 7   | 8  | 9   |   |   |   |   |  |   |   |
|---|--|---|--|---|---|--|---|--|---|---|---|---|---|--|---|---|
| Month   | Jan  | Feb   | Mar  | Apr   | May   | Jun  | July  | Aug  | Sept  |   |   |   |   |  |   |   |
| Designate PFA WG Leads  |     |   |  |   |   |  |   |  |   |   |   |   |   |  |   |   |
| Hire (Contract) PFA Writers                                       |     |   |   |   |   |  |   |  |   |   |   |   |   |  |   |   |
| Draft Broad PFAs (May PFAs)                                       |  |   |  |   |   |  |   |  |   |   |   |   |   |  |   |   |
| Targeted Priority #5 PFAs (July)                                  |  |   |  |   |   |  |  |  |   |   |   |   |   |  |   |   |
| 1st Draft of Literature Review; Knowledge Gaps; Example Questions |  |   |  |   |   |  |   |  |   |   |   |   |   |  |   |   |
| Incorporate PPP Input   |  |   |  |   |   |  |   |  |   |   |   |   |   |  |   |   |
| Revised Version Incorporating Comments                            |  |   |  |  |   |  |   |  |   |   |   |   |   |  |   |   |
| Finalized PFA   |  |   |  |   |    |  |   |  |   |   |   |   |   |  |   |   |
| PDC Calls   |     |  |   |    |     |   |  |   |  |  |  |  |  |   |  |  |
| PDC F2F   |  |  |   |  |   |   |   |   |   |   |   |   |   |  |   |   |
| Board of Governors' Call  |     |  |   |    |     |   |  |   |  |  |  |  |  |   |  |   |
| Board of Governors' F2F   |  |   |  |   |   |  |   |  |   |   |   |   |   |  |   |   |
| Grants Management Process   |  |   |  |   |   |  |   |  |   |   |   |   |   |  |   |   |
| MC Report   |  |   |  |   |  |  |   |  |   |   |   |   |   |  |   |   |
| Incorporate Public Comment Input                                  |  |   |  |   |   |  |   |  |   |   |   |   |   |  |   |   |

Red Board of Governors  
Green Program Development Committee  
Purple Staff  
Blue Methodology Committee



Meetings  
 Milestones

LEGEND

① PFA WG Membership  
② Specificity for May Announcements

DECISIONS

- PFA prepared by PCORI staff, contracted research organization (CRO) and Board participants
- CRO's sign confidentiality agreement and are barred from submitting application to any of the 5 PFAs until 3rd round – March 2013
- Open competition
- Applications reviewed by CSR a la PPP's
- Successful applications administered by PCORI

# PFA Development Teams



| National Priority  | Board/MC Member 1 | Board/MC Member 2 | Board/MC Member 3 | PCORI Staff | Scientist Identified   |
|--|-------------------|-------------------|-------------------|-------------|------------------------|
| Comparative Assessment of Options for Prevention, Diagnosis, and Treatment | Harlan Krumholz   |                   |                   |             | RFP Issued             |
| Improving Healthcare Systems   | Arnie Epstein     | Christine Goertz  | Leah Hole-Curry   |             | RFP Issued             |
| Communication and Dissemination Research                                   | Gray Norquist     |                   |                   |             | Dominick Frosch        |
| Addressing Disparities   | Carolyn Clancy    |                   |                   | Anne Beal   | RFP Issued             |
| Accelerating PCOR and Methodological Research                              | Michael Lauer     | Jean Slutsky      |                   |             | Contract with AHRQ/NIH |

## Clinical Research Data Infrastructure

- PFA written by PCORI staff, AHRQ staff, NIH staff, MC
- Separate Funding Announcement (i.e., separate from that written for analytic methods)
- Solicitation and Review managed by AHRQ and NIH through contracts from PCORI to AHRQ and NIH
- “Focused Competition” – with clear data and governance requirements, including engagement of relevant stakeholders
- Funding through Cooperative Agreement grant mechanism with shared as well as project-specific goals.



- AHRQ and NIH have years of experience in this area that will be invaluable in helping to write the PFA and overseeing the research
- We have a clearer idea of gaps and opportunities– the PFA must be fairly specific (i.e., targeted)
- AHRQ and NIH staff have knowledge of current state of the science
- The proposed funding arrangement is a cooperative agreement, where grantees work together with PCORI, AHRQ, and NIH
- AHRQ and NIH have expertise running cooperative agreements
- The statute explicitly encourages PCORI to contract with AHRQ, NIH and other federal funders of CER; experience of AHRQ and NIH → efficiency and value for taxpayers

- Close collaboration with the MC
- AHRQ and NIH have a long track record of working on CER/PCOR methods research – having them involved helps minimize risks of redundancy
- PFA is more likely to be targeted than priorities 1-4 but probably not as targeted as that for research data infrastructure.
- Not as clear this would be a cooperative agreement, though it could be.

# Patient-Centered Outcomes Research Institute PCORI Dissemination Workgroup

March 5, 2012



## Members of the Workgroup

Carolyn Clancy, *Co-Chair*

Sharon Levine, *Co-Chair*

Lawrence Becker

Allen Douma

Howard Holland

Gail Hunt

Freda Lewis-Hall

Steve Lipstein

Brian Mittman

Robin Newhouse

Grayson Norquist

Jean Slutsky

## Dissemination Accelerating Components: Proposed Checklist

### Stakeholders

Identify stakeholders (stakeholders include patients, caregivers, clinicians, communities, policy makers and institutions) relevant to your proposed study

### Engagement Points

Describe at which points in your proposed study stakeholders will be engaged

### Engagement Type

Describe how you will engage stakeholders at each identified point during the study and at its conclusion

### Governance Plan

Please describe how you will develop a governance plan for the project that articulates specific roles and responsibilities for the research team and stakeholder groups and defines rules for decision making, especially in the context of different opinions

## Dissemination Accelerating Components: Proposed Checklist (cont'd)

### Conflict Management

Describe how conflicts – true and perceived – will be managed

### Study Results

Describe how you will convey study results to stakeholders and study participants

### Barriers Assessment

Please describe how you will assess barriers and facilitators to incorporating the results into practice, beyond communicating the study results to stakeholders