

### SCILHS Stakeholder Engagement Policy

#### A. Purpose of the SCILHS Stakeholder Engagement Policy

- To state and reinforce core engagement principles for promoting transparency of, and trust in, the SCILHS network and its research activities
- To identify relevant stakeholder categories/groups for comprehensive representation and inclusion
- To outline organization and operational processes to support our practice of engagement, including how we set goals, identify opportunities, and evaluate progress

#### B. SCILHS Core Engagement Definition and Principles

SCILHS considers high quality engagement to be the involvement of Key Stakeholders throughout the research process in a way that is meaningful and transparent. High quality engagement will lead to research processes that are more patient centered and increase the likelihood of research relevance and implementation to the greater community.

The SCILHS Governance Agreement, signed by all sites and patient leaders, attests to the principles and goals of the network including engagement. Transparency and inclusion are core principles of the SCILHS engagement model. We employ them to promote and foster reciprocal relationships in order to create opportunities for continuous co-learning, competency building, accountability, and trust. We use engagement to assist us in our efforts to make good faith efforts to promote research that is relevant to patients and to disseminate results.

#### C. Stakeholders Groups

We have identified six key stakeholder groups that will be critical to the success of our network.

Patients, Families and Caregivers: These include patients, families and caregivers at our network sites, as well as our SCILHS patient leaders (Appendix 1). They may assume a variety of roles including research subjects, researchers, consultants, and/or as network leaders.

Clinicians and Providers: These include clinicians and providers at the SCILHS network sites.

Investigators / Researchers: SCILHS investigators / researchers are faculty members or employees of our network sites. These individuals become a part of the SCILHS community when they use the SCILHS network for their research.

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Healthcare System Leaders: SCILHS healthcare systems leaders are the responsible stewards of their local health systems data and infrastructure. They have knowledge and interest about how to leverage the data for research that is important to them and their local community of patients, researchers, and clinicians.

Health Advocacy Groups and Patient Powered Research Networks: Health Advocacy Groups and Patient Powered Research Networks are invested in promoting care and supporting research to benefit patients suffering from particular diseases/conditions. Their engagement with SCILHS will facilitate the inclusion of relevant perspectives and experiences of the patient populations they serve and represent, and accelerate the dissemination of research findings to their respective communities through established communication channels.

### Network leadership (SCILHS Governance)

The Governance Committee (“GC”) is the main governing body of SCILHS. The Governance Committee is comprised of the SCILHS Network Site PI of every Participating Institution, a SCILHS Patient Co-Investigator, and the chairs of other standing committees.

## **D. Engagement in Practice**

The practice of engagement is embedded into SCILHS’s organizational structure and governance model, and through meaningful activities and standard operating procedures (SOPs) that occur over the life-course of research projects.

D.1. Organization and Governance. SCILHS organization and governance includes representatives and leaders from the various stakeholder groups/partners (Appendix 2 – org chart). Decision making is a shared responsibility of the SCILHS committees, which seek to build consensus. Included in the organizational structure is the Engagement Committee, which is co-lead by a patient and clinician. The Engagement Committee is tasked with developing policies and activities around engagement. Ad Hoc Stakeholder Advisory Panels (e.g. Patient and Clinician, Health Systems etc.), are assembled for the purpose of providing guidance and advice on general strategies/approaches, policy development, and/or for specific SCILHS studies.

### D.2. Conceptualization and Planning of Studies/Protocols

- Stakeholders shall be consulted in the earliest stage possible of investigator-initiated studies. SCILHS will provide resources and support to investigators seeking to get guidance and feedback from stakeholders on research concepts.
- SCILHS studies will require an approved engagement plan (Appendix 3 – SCILHS engagement plan rubric)

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- Stakeholders who seek to drive/lead research projects shall be encouraged and supported in framing research questions and submitting SCILHS studies – SCILHS will seek to identify site-collaborators to enable full utilization of resources
- SCILHS will encourage stakeholders to engage with PCORnet where possible and appropriate

### D.3. Study Conduct

- Study goals and objectives shall be communicated in clear and meaningful way to stakeholders and study participants
- Opportunities and resources will be identified to share information with stakeholders on progress, challenges and opportunities
- Study Materials (e.g. consent forms, informational materials) shall be reviewed by patient and clinician partners.  
Engagement may include participation/input on how the research team conducts DSMBs, evaluation, analysis, and recruitment.

### D.3. Dissemination of Results

- SCILHS shall ensure that data and/or results are returned in a timely manner in clear and understandable language to study participants and stakeholders
- SCILHS will leverage its resources and platforms to support dissemination.

### D.4. Resources and Platforms Supporting Engagement

- The SCILHS website shall be leveraged to: distribute information to all SCILHS stakeholders and the public, and as a platform/portal for potential researchers and stakeholders to engage the SCILHS Network
- Publications that use the SCILHS network as a part of their research will acknowledge the use of the SCILHS network and the contributions of stakeholders.
- SCILHS will hold an all-hands annual meeting in Boston, MA to gather Site PIs, Committee members and other SCILHS stakeholders to communicate and collaborate on current network challenges, identify issues that need to be addressed and assign any resulting action items.

## E. Evaluation of Engagement

The Engagement Committee shall be responsible for evaluating stakeholder engagement in the SCILHS network. It will make recommendations to the Governance Committee regarding approval or amendments to Engagement policy and SOPs based on evaluation of activities. In particular, they will focus on value-added by the stakeholder groups.

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The Study Submission and Review Committee (SSRC) will evaluate study-specific engagement plans for studies applying to utilize the network. The evaluation will assess: 1) the identification of relevant stakeholder groups/individuals, and 2) the description of how stakeholders will contribute to conceptualization, planning, conduct and dissemination.

### **F. Conflicts of Interest**

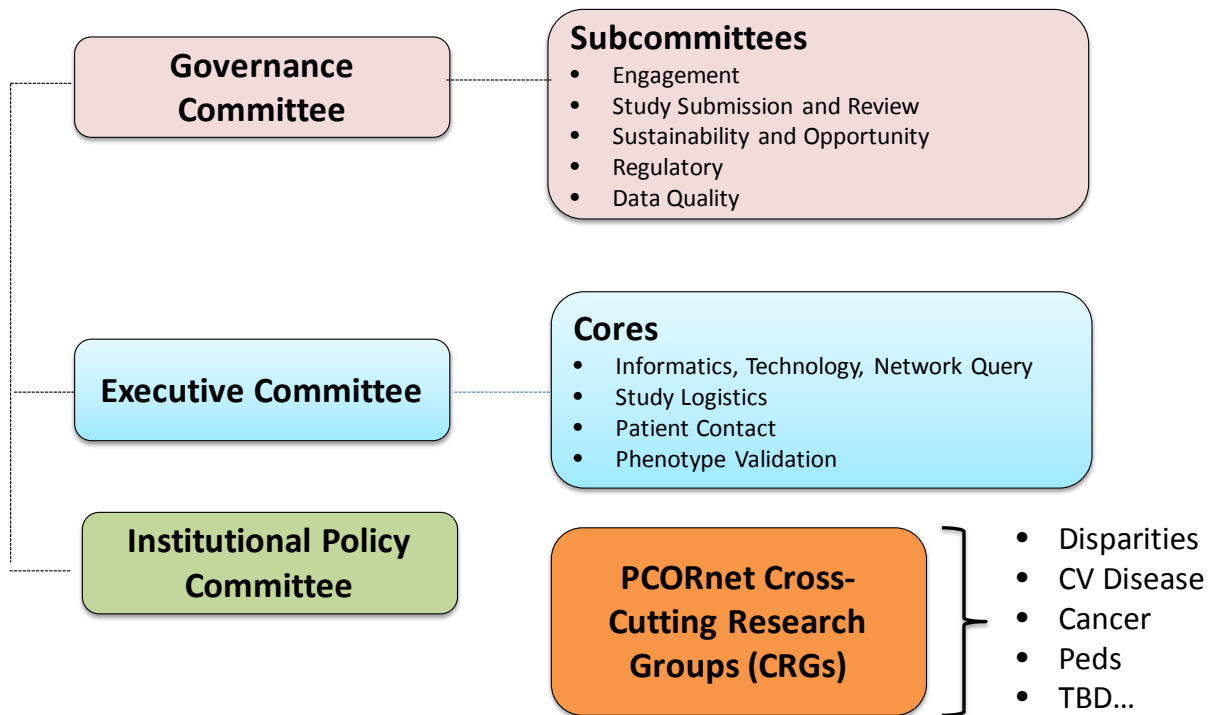
Stakeholders will fully disclose potential conflicts of interest, or the appearance of conflict of interest, as a consequence of involvement in commercial, private, or government entities that compete with or might appear to benefit from the SCILHS Network and any research that utilizes the SCILHS network. Conflicts of interest will be explained to the executive stakeholders and they will be provided a process for disclosing the conflicts they do have or develop throughout the length of the study. This process will follow any guidelines created by PCORnet and the institution engaged in research.

**G. Compensation.** Stakeholders who serve on SCILHS committees and panels will be compensated for their time, travel and costs associated with participation in accordance with our PCORI contract. Compensation for study participation will be specified by the study protocol and in accordance with the sponsor.

### Appendix 1:

1. Beth Israel Deaconess Medical Center
2. BJC HealthCare
3. Boston Children's Hospital
4. Boston Medical Center
5. Brigham and Women's Hospital
6. Grady Hospital
7. Harvard Medical School
8. Massachusetts General Hospital
9. Morehouse School of Medicine
10. University of California, Davis
11. University of Texas - Houston
12. Wake Forest University Health Sciences
13. Matthew Might, PhD (Patient Leader)
14. Aliaa Barakat, PhD (Patient Leader)

# SCILHS Organization



## Appendix 3: SCILHS Stakeholder Engagement Rubric

In accordance with SCILHS Governance we encourage stakeholder engagement be present in all SCILHS studies. SCILHS considers high quality Engagement to be the involvement of Key Stakeholders\* throughout the research process in a way that is meaningful and transparent. SCILHS expects high quality Engagement to lead to research processes that are more patient-centered and increase the likelihood of research relevance and implementation to the greater community. Using the table below, please list your stakeholders relevant to your project who would need to be included for the project to be as successful as possible, and provide details regarding how you plan to engage them/incorporate their input during stages of your study. For more information please review SCILHS Stakeholder Engagement Policy here: (link to policy).

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<b>Key/Relevant Stakeholders*</b>	<b>Study Planning</b> (i.e. identifying knowledge gap, developing the research questions, defining study population, choosing relevant outcomes, etc.)	<b>Study Conduct</b> (i.e. communicating study goals, developing study materials, recruiting study participants, collecting data, overseeing safety, etc.)	<b>Dissemination of Results</b> (i.e. authoring papers, sharing lay summaries with patient populations, identifying ways to speed implementation of findings into practice, etc.)

\*Stakeholders can be Patients or Patient Caregivers/Families, Clinicians/Clinical Care Providers, Investigators/Researchers, Healthcare System Leaders, Health Advocacy Groups, SCILHS Network Leadership