ARCH Stakeholder Engagement Policy

A. Purpose of the ARCH Stakeholder Engagement Policy
- To state and reinforce core engagement principles for promoting transparency of, and trust in, the ARCH 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. ARCH Core Engagement Definition and Principles
ARCH 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 ARCH 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 ARCH 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 ARCH 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 ARCH network sites.

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

Healthcare System Leaders: ARCH 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 ARCH 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 (ARCH Governance)
The Governance Committee ("GC") is the main governing body of ARCH. The Governance Committee is comprised of the ARCH Network Site PI of every Participating Institution, an ARCH Patient Co-Investigator, and the chairs of other standing committees.

D. Engagement in Practice
The practice of engagement is embedded into ARCH'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. ARCH 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 ARCH 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 polices 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 ARCH studies.

D.2. Conceptualization and Planning of Studies/Protocols
- Stakeholders shall be consulted in the earliest stage possible of investigator-initiated studies. ARCH will provide resources and support to investigators seeking to get guidance and feedback from stakeholders on research concepts.
- ARCH studies will require an approved engagement plan (Appendix 3 – ARCH engagement plan rubric)

- Stakeholders who seek to drive/lead research projects shall be encouraged and supported in framing research questions and submitting ARCH studies – ARCH will seek to identify site-collaborators to enable full utilization of resources
- ARCH 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

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

D.4. Resources and Platforms Supporting Engagement

- The ARCH website shall be leveraged to: distribute information to all ARCH stakeholders and the public, and as a platform/portal for potential researchers and stakeholders to engage the ARCH Network
- Publications that use the ARCH network as a part of their research will acknowledge the use of the ARCH network and the contributions of stakeholders
- ARCH will hold an all-hands annual meeting in Boston, MA to gather Site PIs, Committee members and other ARCH 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 ARCH 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.

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.
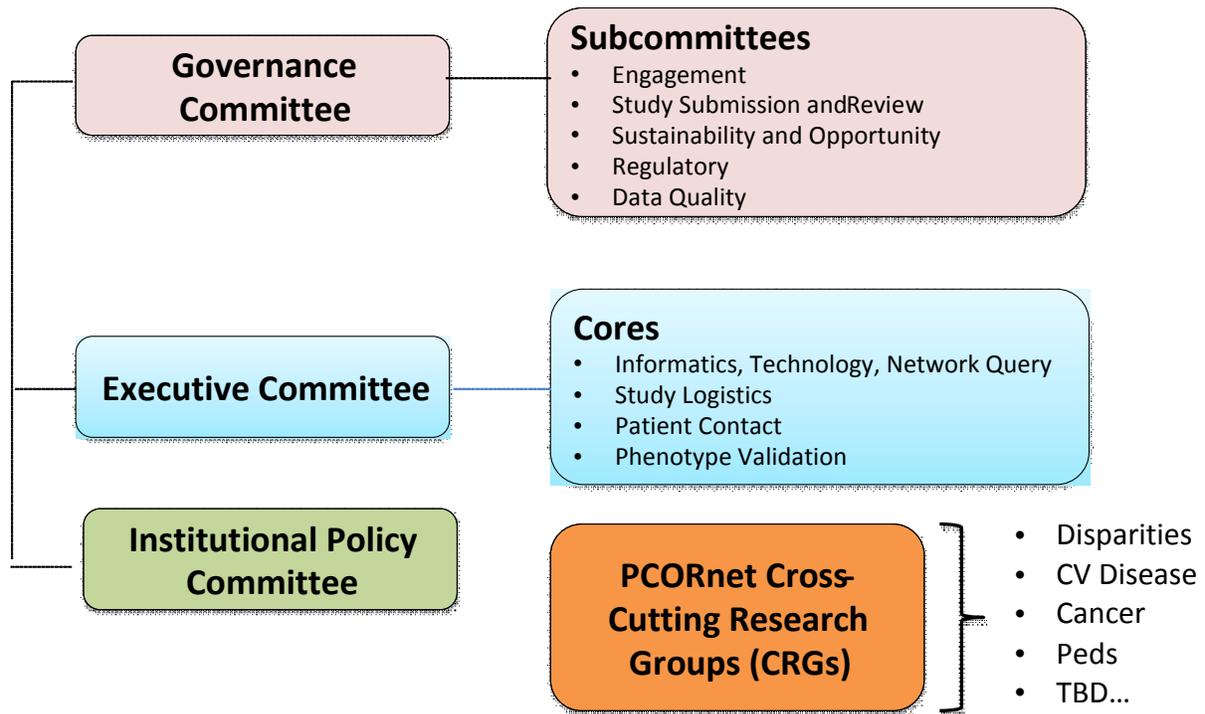
F. Conflicts of Interest

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 ARCH Network and any research that utilizes the ARCH 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 ARCH 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)

Appendix 2:

ARCH Organization

Appendix 3: **ARCH Stakeholder Engagement Rubric**

In accordance with ARCH Governance we encourage stakeholder engagement be present in all ARCH studies. ARCH considers high quality Engagement to be the involvement of Key Stakeholders* throughout the research process in a way that is meaningful and transparent. ARCH 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 ARCH Stakeholder Engagement Policy at arch-commons.org.

Key/Relevant Stakeholders*	Study Planning (i.e. identifying knowledge gap, developing the research questions, defining study population, choosing relevant outcomes, etc.)	Study Conduct (i.e. communicating study goals, developing study materials, recruiting study participants, collecting data, overseeing safety, etc.)	Dissemination of Results (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, ARCH Network Leadership