The Harvard Catalyst QA/QI Subcommittee is a collaborative task force contributing to this poster and represented on this page. It is composed of members from Harvard affiliated institutions and Reliance Agreement signatory institutions. The Subcommittee's objective is to pool resources and expertise to problem-solve situations that raise potential non-compliance. Given the varied member backgrounds and institutions involved, the goal of the QA/ QI Subcommittee has been to provide adaptable tools that can be used in many contexts. Most resources are publicly available and can be adapted for use at any institution.

**Problem Statement**

Quality Assurance and Quality Improvement (QA/QI) are integral components of a Human Research Protection Program (HRPP). QA/QI activities ensure investigator and institutional compliance with human research regulations by providing ongoing support, education, study management tools, and best practice recommendations, with an emphasis on improving efficiency. Institutions seeking external accreditation must demonstrate robust QA/QI initiatives and activities. As a result, many institutions have responded by initiating a new program or revising and revitalizing an existing program. Often it is not clear how to start, what resources are available, and whom to consult for guidance.

**Harvard Catalyst Model**

The Harvard Catalyst QA/QI Subcommittee is a collaborative group of 19 local experts who meet regularly to share expertise, problem-solve situations that raise potential compliance concerns, discuss emerging challenges and issues, and develop compliance and educational tools for member institutions and the broader research community. The Subcommittee's strength stems, in part, from the members' diverse professional experiences and the varied organizations that they represent. The institutions contributing to this poster and represented on this page are as follows:

- Beth Israel Deaconess Medical Center
- Brigham and Women's Hospital
- Cambridge Health Alliance
- Dana-Farber/Harvard Cancer Center
- Harvard Faculty of Medicine
- Harvard T.H. Chan School of Public Health
- Harvard University
- Joslin Diabetes Center
- Massachusetts Eye and Ear Infirmary
- Massachusetts General Hospital
- McLean Hospital
- Mount Auburn Hospital
- New England Baptist Hospital
- Spaulding Rehabilitation Hospital
- Partners Healthcare
- Spaulding Rehabilitation Hospital
- Beth Israel Deaconess Medical Center
- Boston Children’s Hospital
- Dana-Farber Cancer Institute
- Massachusetts General Hospital
- McLean Hospital
- Mount Auburn Hospital
- New England Baptist Hospital
- Spaulding Rehabilitation Hospital
- Partners Healthcare
- Beth Israel Deaconess Medical Center
- Boston Children’s Hospital
- Dana-Farber Cancer Institute
- Massachusetts General Hospital

**Collaboration Strategy: Process for Institutions to Collaboratively Create Tools and Share Education and Learning**

- Form Subcommittee
- Identify Needs & Challenges
- Develop Materials & Improve Transparency
- Implement, Adopt & Deploy Best Practices, Tools & Materials

**Questions/Comments?**

Contact the QA/QI Subcommittee
Sabune Winkler, JD
Director, Regulatory Affairs Operations
Email: Sabune_Winkler@hms.harvard.edu

To learn more about the QA/QI Subcommittee and to download available materials: