Collaboratively Delivering QA/QI Support, Tools, and Resources by Leveraging Internal and External Expertise: A Harvard Catalyst Model

**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 Subcommittee 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 General Hospital
- New England Baptist Hospital
- New England Baptist Hospital, Dana-Farber Cancer Institute, and Massachusetts General Hospital.

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**QA/QI Subcommittee Deliverables**
- A customizable and downloadable Regulatory Binder including 22 tabs appropriate for a wide range of research from Social, Behavioral, and Education research to FDA-regulated studies. In 2014, this aid was downloaded over 6,200 times. The binder is reviewed annually and updated as needed.
- IRB Reliance Agreement Standard Operating Procedures and checklists to support multi-institution study audits where single IRB review has been implemented.
- Model Audit Tools including 8 sample checklists and instruments for developing or enhancing an institution's audit capabilities. The tools are available by request.
- IRB Consult Service, which offers an opportunity for institutions seeking resources to access the expertise of the Subcommittee through individualized interactions. Originally limited to Harvard-affiliated institutions, the Consult Service provided 11 consultations to 6 institutions, and expanded in 2015 to include institutions considering joining a Master IRB Reliance Agreement. For more information, please visit http://catalyst.harvard.edu/programs/regulatory/reliance.html

**Collaboration Strategy:**
**Process for Institutions to Collaboratively Create Tools and Share Education and Learning**
- **Form Subcommittee**
  - **Identify Needs & Challenges**
    - Identify need
    - Project management plan
    - Identify and convene leadership, content experts
    - Determine best way to share content
  - **Develop Materials & Improve Transparency**
    - Lack of Knowledge & Expertise
    - Need Tools & Roadmap
    - Opportunity to design programs and initiatives
  - **Implement, Adopt & Deploy Best Practices, Tools & Materials**
    - Standing Meeting
    - Share resources
    - Benchmark
    - Collaboratively develop new materials

**Scalability**
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.

**Coming Soon**
- QA/QI Handbook designed as an instructional how-to manual that provides HRPP professionals the knowledge and tools to create, implement, and evaluate a QA/QI program or function. The Handbook serves as a reference, which provides a step-by-step approach. It includes common models, flow charts, examples, sample forms and templates, and slide decks.
- QA/QI Basic serves as a toolkit of QA/QI resources for HRPPs seeking to implement a QA/QI program or function with limited resources and human support.
- Self-Assessment Checklists for Investigators offer a user-friendly alternative to the customary audit by allowing investigators to identify weaknesses and potential non-compliance.

**Questions/Comments?**
Contact the QA/QI Subcommittee
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To learn more about the QA/QI Subcommittee and to download available materials:
https://catalyst.harvard.edu/programs/regulatory/qaqi.html

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