Development of a Collaborative Quality Improvement Program for Institutions with Small Research Programs: A Harvard Catalyst Approach

Amy Hudspeth Cabell, JD, MBA, Meghan Cashman, Rita Cosgrove, CIP, Betsy Draper, Leigh Read, CIP, Pamela Richmond, MSW, CIP, Andrea Saltzman, CIP, Hila Bernstein, MS, MPH, Jacqueyn-Mo Do, MPH, Aaron Kirby, MSc, Barbara Bierer, MD

BACKGROUND

Quality Assurance and Quality Improvement (QA/QI) are essential elements of an institution’s human research protection program (HRPP). However, organizations with smaller research programs or HRPPs often have only 1-2 personnel to handle all research oversight activities, including QA/QI, and struggle to address this need. Small research programs are identified as having fewer than 200 open protocols and three or fewer (usually one or two) IRB staff.

ABOUT US

Since its inception in 2015, the Collaborative Quality Improvement Program (CQIP) brings together local HRPP leaders from smaller institutions or institutions with small HRPPs through monthly meetings to discuss challenges, share expertise, and collaboratively develop solutions to strengthen their institutions’ QA/QI activities.

Recognizing the power and value of combining resources, members of this group rely on each other to perform routine reviews of IRB records, policies and procedures, and HRPP effectiveness, quality, and efficiency. The group also provides a mechanism for members to rely on each other to conduct for-cause and not-for-cause audits of investigator research records. Annually, members identify and prioritize resources and tools for development, with the overall aim of standardizing tools across member institutions and decreasing member burden when conducting QA/QI activities.

Since the initiation of CQIP, participating members have benefited from a shared space and opportunity to pool resources, develop materials, and provide support and feedback regarding their HRPPs. The group has developed and implemented standardized checklists for regulatory review of IRB meeting minutes and audit of an IRB’s Not Human Subjects Research Determinations.

In addition to the resource development, members have had the opportunity to learn from other HRPP staff at local partner institutions with established QA/QI programs through a consultation service hosted by Harvard Catalyst (catalyst.harvard.edu/services/qacconsult).

HOW WE WORK

The group’s iterative resource development process took time to implement to ensure that resulting tools and checklists were comprehensive enough to meet member needs and that all members were ready to utilize the developed resources. Early on in the collaboration, the group developed, and each member signed, a non-disclosure agreement to protect the confidentiality of materials shared and reviewed, as well as of the group’s discussions. REDCap allows members to securely share materials (including completed document reviews) and provides easy access to these materials from any computing device.

Iterative Resource Development Process

To date, each institution’s IRB meeting minutes and Not Human Subjects Research (NHSR) determinations have undergone group review. These materials are freely available online for adoption and adaptation.

LIMITATIONS

Launching and maintaining this type of program requires an investment of time and resources by member institutions. The seven CQIP members are part of a committee of HRPP leadership from local-participating institutions and other regional institutions, which has convened on a monthly basis for over a decade. CQIP benefits from the relationships and trust developed within this established network. Institutions located further apart may leverage web or telephone conference toward similar aims.

DISCUSSION

CQIP has successfully served as an inter-institutional QA/QI resource for HRPP staff at smaller institutions/small HRPPs. A collaborative group structure similar to the CQIP is a potentially valuable option for other institutions interested in establishing a broader support system and avoiding “reinventing” the wheel through use of standardized resources. Monthly meetings enable members to quickly implement new tools and changes to workflow.

Examples of recommended changes identified during review of IRB Meeting Minutes Quality Improvement Assessment:

- Include “scientific” and “non-scientific” member status.
- Include “voting” and “non-voting” member status.
- Indicate # of members required for a quorum.
- Include the presence of a quorum.
- Include the start and end times of meeting.
- Include justification for waiver of informed consent.
- Indicate at least one non-scientist was involved in the review and vote.
- Indicate at least one non-institutional member was involved in the review and vote.
- Include a brief summary of each business item (e.g. educational items, announcements).

This material is the work of the Harvard Catalyst Regulatory Foundations, Ethics, and Law Program, affiliated with Harvard Catalyst | The Harvard Clinical and Translational Science Center. Funded by the NIH National Center for Advancing Translational Sciences through its Clinical and Translational Science Awards Program, grant number UL1TR002542.01. For more information, please visit catalyst.harvard.edu/programs/regulatory.