PRIM&R
PUBLIC RESPONSIBILITY IN MEDICINE AND RESEARCH

Quality Assurance/Quality Improvement (QA/QI) In Human Subjects Research

Henry B. Gonzalez Convention Center - San Antonio, TX
November 5, 2017

Offered in conjunction with the Harvard T.H. Chan School of Public Health Office of Regulatory Affairs and Research Compliance (and serving as the 6th Annual QA/QI Boot Camp), this educational program will provide attendees with the core concepts and fundamental knowledge needed to establish a sound and successful QA/QI function, taking into consideration institution type, size, and budgetary restraints. The program content will be shared in a variety of formats, including lecture, interactive discussion, role play, and mock audit. This program is ideal for those new to the field, or those interested in evaluating and improving upon their existing QA/QI program/function.

November 5, 2017

7:00-8:30 AM — *On-Site Check-In (breakfast on your own)*

8:30-8:45 AM — **Welcome and Introduction**

8:45-10:00 AM — **Panel: Developing a Sustainable QA/QI Program**
Moderator: Delia Y. Wolf, MD, JD, MSCI, Harvard T.H. Chan School of Public Health
Panelists: Amy Ben-Arieh, JD, MPH The Fenway Institute
Stephanie deRijke, RN, MSN, Emory University
Daniel G. Jones, MSN RN, Partners HealthCare

This session will examine approaches in developing a thriving QA/QI program. Panelists will each have 15 minutes to introduce their QA/QI Program, including its structure; how they defined its scope and goals, and/or how each program effectively engages their respective research communities. The moderator will facilitate an open question and answer period.

10:00-10:15 AM — *Break*

10:15-11:15 AM — **Auditing Fundamentals**
Speakers: Leslie M. Howes, MPH, CIP, Harvard T.H. Chan School of Public Health

This session will examine the anatomy of the audit, both for-cause and not-for-cause, and provide an overview of the audit life cycle. In addition, this session will highlight options and considerations when designing a new audit function or improving upon an existing one.

11:15 AM-12:15 PM — **Communicating for Compliance: How to Effectively Share Findings**
Speakers: Alyssa A.K. Speier, MS, CIP, Harvard T.H. Chan School of Public Health

QA/QI programs need to communicate their findings across a wide range of audiences including investigators, IRB staff/members, and senior leadership at an organization. This session will provide strategies for presenting findings/data, being mindful of the target audience(s) and their specific needs. Attendees will breakout into small groups to role-play ways to provide constructive, supportive, and effective feedback to IRB staff/members/senior

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leadership as well as PI and study team. The large group will wrap up by reviewing and commenting on their experience.

12:15-1:15 PM *Lunch (provided)*

1:15-2:15 PM **How to Get the Biggest Bang for Your Buck: QA/QI Services and Tools**
Speakers: Eunice Yim Newbert, MPH, Boston Children's Hospital

Attendees will receive an overview of possible QA/QI services and corresponding study management tools that QA/QI programs may offer. They will learn how to pick and choose those that will provide the greatest impact for their research communities and will be encouraged to share their own offerings along with what has been successful and what has not.

2:15-3:15 PM **Moving Beyond Investigator Compliance to Evaluate the IRB/HRPP**
Speakers: Jessica A. Randall, MA, CIP, Yale University

Attendees will learn some ways in which the Human Research Protection Program/IRB compliance can be evaluated and improved. The discussion will cover audits of the IRB files, meeting minutes, and membership composition. Considerations for establishing benchmarks as well as strategies for tracking and reporting them will be discussed.

3:15-3:30 PM *Break*

3:30-5:00 PM **Investigator Mock Audit**
Speakers: Leslie M. Howes, MPH, CIP, Harvard T.H. Chan School of Public Health
Alyssa A.K. Speier, MS, CIP, Harvard T.H. Chan School of Public Health

A hallmark of the Harvard Chan School QA/QI Boot Camps, the mock audit provides a simulated audit of an investigator's files. Attendees will receive study files kept on-site by a fictitious PI and will be asked to identify deficiencies in the record keeping practices. The group will come together to discuss findings and possible corrective actions/best practice recommendations.

5:00 PM *Adjournment*

Please note the agenda is subject to change.