Quality Assurance/Quality Improvement (QA/QI)  
In Human Subjects Research  
Hynes Convention Center- Boston, MA  
November 12, 2015

Offered in conjunction with the Harvard T.H. Chan School of Public Health Office of Human Research Administration (and serving as the 4th 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. Two different afternoon break-out sessions are offered to reach both beginner and advanced audiences. 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.

<table>
<thead>
<tr>
<th>Time</th>
<th>Session Title</th>
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<tbody>
<tr>
<td>7:00-8:30 AM</td>
<td>Registration (breakfast on your own)</td>
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<tr>
<td>8:30-8:40 AM</td>
<td>Welcome and Introduction</td>
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| 8:40-9:45 AM | Panel: Key Ingredients for a Strong QA/QI Program  
*Moderator:* Delia Y. Wolf, MD, JD, MSCI, CIP  
*Panelists:* Jennifer A. Graf, BA; Nareg Grigorian; Kathleen Lawry, MSSA,CIP  
The panel will open with an overview of the key features necessary in developing an effective QA/QI Program or function. Panelists from different institutions—academic and hospital-based, both small and large—will spotlight their respective programs and highlight key lessons learned. |
| 9:45-10:00 AM | Break                                                                                             |
| 10:00-11:00 AM | Auditing Tips and Tricks  
*Faculty:* Leslie Howes, MPH, CIP  
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. Options for overcoming financial and human resource constraints will be addressed. |
| 11:00 AM-12:00 PM | Communicating for Compliance: How to Effectively Share Findings  
*Faculty:* Terry VandenBosch, PhD, RN, CIP, CCRP  
QA/QI teams 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 both the target audience and their specific needs. Attendees will breakout into small groups to role-play ways to provide constructive, supportive and effective feedback to a PI and study team. Bring a sense of humor. |
| 12:00-1:00 PM | Lunch (provided)                                                                                 |
November 12, 2015 (cont.)

**Afternoon Breakout Sessions – Track 1: Beginner**

1:00-2:00 PM  **Uncovering the Hidden Potential: Opportunities to Educate**  
*Faculty:* Alyssa Ashley Knotts Speier, MS, CIP  
Attendees will learn how to incorporate training and educational opportunities into everyday QA/QI activities even in the absence of a formal education program. This session will share effective strategies, both established and novel, for engaging various learners. A review of some of the technology for making learning efficient, meaningful, engaging, and possible will be provided.

2:00-2:45 PM  **QA/QI Services and Tools Show and Tell**  
*Faculty:* Eunice Yim Newbert, MPH  
Attendees will hear some of the common and not so common “human research support” services and corresponding study management tools that QA/QI programs may offer. Attendees will be encouraged to share their own offerings along with what’s been successful and what’s not.

2:45-3:00 PM  *Break*

3:00-5:00 PM  **Investigator Mock Audit**  
*Faculty:* Lisa Gabel, BA, CIP; Leslie Howes, MPH, CIP; Alyssa Ashley Knotts Speier, MS, CIP  
A hallmark of the Harvard 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*

**Afternoon Breakout Sessions – Track 2: Advanced**

1:00-2:00 PM  **Beyond Investigator Compliance: QA/QI of the IRB**  
*Faculty:* Jessica A. Randall, MA, CIP  
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.

2:00-3:00 PM  **What to Measure and How to Measure it – Let’s Talk Metrics!**  
*Faculty:* Sarah A. White, MPH, CIP  
A review of common metrics will be highlighted. Considerations for establishing benchmarks as well as strategies for tracking and reporting them will be discussed. Attendees will be encouraged to share what metrics they have collected and how they are being used. This session reviews considerations for developing and maximizing the potential of a QA/QI database in order to facilitate the collection of metrics.

3:00-3:15 PM  *Break*

3:15-4:30 PM  **Auditing from Afar: How to Effectively Audit Remotely**  
*Faculty:* Stanley Estime, MSCI, CIP  
Elevate your current audit function by learning how to effectively reach you research community remotely. Hear about various platforms to facilitate data sharing, training, and connecting virtually.

4:30 PM  *Adjournment*

*Please note the agenda is subject to change.*