**Welcome to the Johns Hopkins School of Public Health IRB’s**

**Quality Improvement through Self-Assessment**

**Web-Based Module Series**

Despite best intentions, it is sometimes difficult to know what is expected from the complicated world of the IRB and human subjects regulations.  This series of web-based modules is designed to help investigators who conduct human subjects research meet their commitment to comply with legal, regulatory, and institutional requirements associated with their research enterprise.  It is designed to help investigators and their study teams monitor their own research compliance requirements.  Each module addresses one aspect of the record-keeping required of investigators; we have tried to minimize redundancies across the modules.  Some questions are standard audit-type questions, and others are designed to make you think about issues that you otherwise might not consider.

The modules are open to public use.  We will not know who has completed the exercise.  You are encouraged to be honest so that the report of your responses available for download at the end of each module provides an accurate snapshot of the state of your human subjects research compliance.  You may start a module, and if you are interrupted, you may return to the same question for up to a week’s time – so long as you use the same computer.  You may also start over at any time.  Our intent is to empower you to take control of your compliance assessment, and for the IRB to assist when you need help.

Here is the list of the Modules in the series; more may be added over time.  Review them and select the ones that are relevant to your study.  The length of the modules varies; we will provide an indicator on each module to estimate the time required to complete it.

[Module 1: Research Participant Selection Process](http://jhsph.co1.qualtrics.com/jfe/form/SV_cD5QwYMDNWrh01v)

[Module 2: Focus Groups](http://jhsph.co1.qualtrics.com/jfe/form/SV_50U1Kr8d15Ybv0h)

[Module 3: Case Report Forms and Source Documentation](http://jhsph.co1.qualtrics.com/jfe/form/SV_29J1xgcPVxRD713)

[Module 4: Regulatory Documentation](http://jhsph.co1.qualtrics.com/jfe/form/SV_02PXsfBXFZFS2gJ)

[Module 5: Reporting to the IRB](http://jhsph.co1.qualtrics.com/jfe/form/SV_exiZEmc7U2q1b4p)

 Outcomes:  After completing your modules, you may have some actions to take.  Items that are administrative or minor departures from your approved protocol are **protocol deviations.** More significant departures from the approved research may amount to study **non-compliance.** The modules provide some guidance as to what to do, but this guidance is only advisory.  Investigators should consult with their reviewing IRB to report such issues.  The IRB will help you sort out these problems, and will assist with any mandatory reporting to government agencies or the sponsor.  In our experience, it is always better to be pro-active about self-assessment and reporting because it shows that you understand what is required and are committed to meeting those standards.

Thank you for using this series.  We welcome your comments about the modules; please feel free to respond to the request for comments or contact us directly via phone at 410-955-3193 or email at JHSPH.irboffice@jhu.edu.  If you link to or copy these modules, please provide attribution to the Johns Hopkins Bloomberg School of Public Health Institutional Review Board.