Does my Quality Improvement (QI)/Quality Assurance (QA) Initiative Require IRB Review?

Distinguishing between QI/QA initiatives and human subjects’ research requiring IRB review is often challenging. This may be attributable to the fact that there are several common features between QI activities and research. In addition, there is no clear definition for a QI activity in the federal regulations for human subjects’ protections. Although this distinction can be challenging, it is an important one, because human subjects’ research requires IRB review and generally, activities that fall within the QI domain are not considered to be research and therefore are not subject to IRB review. In order to assist members of the Penn community in determining whether their proposed projects qualify as QI/QA or as research requiring further IRB review in circumstances where this determination is unknown.

Through this streamlined review process, the IRB provides a determination of whether the proposed initiative qualifies as QI/QA or as research requiring further IRB review in circumstances where this determination is unknown.

In this presentation, members of the IRB staff and PSOM faculty specializing in QI will review the difference between QI projects and research, discuss the QI review process and share lessons learned from the submissions reviewed through this process to date.

September 21st
9:30 – 11:00 AM
HUP Flyers/Sixers Surgery Theatre
Ground Floor, White Building

New IRB Requirements for Electronic Data Protection for Research Involving PHI

The Penn IRB has released a new document outlining requirements for electronic data protection for research involving the use of directly-identifiable protected health information. A companion guide has also been developed that outlines key features of IRB-approved mechanisms for data storage and transmission that comply with the new requirements. All new submissions received after August 1, 2016 that involve the use of directly-identifiable electronic protected health information will be required to include data confidentiality plans that align with these new requirements.

Join representatives from the IRB and Penn Medicine Academic Computing Services [PMACS] to review the IRB’s new requirements, including the background and rationale for their implementation. Guidance will be provided for working with local support providers/security liaisons to develop a data protection plan and describing your plan in study documents submitted for IRB review. Sufficient time will be allotted to answer questions about the new requirements and how they apply to specific research initiatives.

Please Note: There are two sessions offered. Each session will cover the same material. Please only register for one session.

Orientation to the IRB’s New Submission Forms & Processes

In Summer 2016, the IRB released new submissions forms. The purpose of this session is to review these forms and provide guidance as to how they should be used in relationship to the existing electronic submission system, HS-ERA. Forthcoming changes to HS-ERA will also be briefly reviewed. This session will provide specific tips for compilation of submissions for IRB review, focusing primarily on continuing review and modification submissions using the new submission forms.

This training session is appropriate for both new and experienced research support staff who have questions or need tips on IRB expectations related to the new forms. Sufficient time will be allotted for to address specific questions.

Please note: A discussion of initial submissions will not be included in this session.

Questions?
Please contact the Office of the Regulatory Affairs at (215) 573-2540.