Research Education Across Atlantic Canada Hospitals (REACH)

Education Sessions 2014 — 2015

ICH-GCP Training for Investigators and Research Team Members

Note Date Change

Thursday, October 30, 2014 noon-1:30 pm (1.5 hours), Royal Bank Theatre, Halifax Infirmary

— Janet Gallant, BScN, CCRP, Program Manager, Research Education, Capital Health

ICH-GCP training is required by Health Canada for investigators and research team members who are working on clinical trials involving drugs or natural health products. As a result, pharmaceutical companies have required investigators and research teams to complete company specific ICH-GCP training before working on their drug trials, leading to extensive redundant training. This ICH-GCP training session will be accepted by 18 companies who are members TransCelerate, a non-profit organization. For a complete list of companies please see visit the TransCelerate website.

Common Audit Findings: Investigator Initiated Research

Thursday, November 13, 2014 noon-1 pm, Royal Bank Theatre, Halifax Infirmary

— Mary Kate Needler, MSc, Program Manager, Research Quality, Capital Health

Investigator-initiated research refers to research projects where the investigator has initiated the research, such as by designing and writing the research protocol. In such situations the investigator has many responsibilities and if the trial involves a drug or natural health product, these responsibilities increase even more. The research quality program has focused on investigator-initiated research over the past year and has noted this research presents special challenges to investigators and teams. This is an opportunity for you to hear about the common audit findings and better prepare yourself if you are planning on or currently doing investigator-initiated research.

Investigator Initiated Research: Project Management

Thursday, January 15, 2015 noon-1 pm, Royal Bank Theatre, Halifax Infirmary

— Sue Pleasance, BScN, Associate Research Director, Hematology Research, Capital Health

Running a multi-site investigator-initiated clinical trial is a complicated undertaking and if the investigator is acting as the sponsor there are certain responsibilities that must be fulfilled. This session will provide an overview of key steps to facilitate a successful project. Learn about the importance of study manuals, site operational manuals, data management, securing investigational product and other tips to manage setting up a trial at multiple sites.

Applicability of U.S. Regulations to Canadian Research

Thursday, March 12, 2015 noon-1 pm, Royal Bank Theatre, Halifax Infirmary

— Mary Kate Needler, MSc, Program Manager, Research Quality, Capital Health

An overview of U.S. regulations pertaining to drug trials, medical device trials and research funded with U.S. public money. Find out which requirements are mandatory, which are optional and how to talk to your sponsors about the difference. (This session was offered in 2012.)

Informed Consent

Thursday, May 14, 2015 noon-1pm

Royal Bank Theatre, Halifax Infirmary

— Blaine Gallant, RN, Research Coordinator, Hematology Research

This session will provide an entertaining overview of making the most of your informed consent discussion. In today's busy environment time efficiency is essential. Learn tips to streamline your process.