8:00-8:45 – INTERESTED IN CONDUCTING CLINICAL RESEARCH IN IH? WE ARE HERE TO HELP

Presenter: Coleen Adderley and/or Devin Harris

Interior Health now has a new Clinical Research Department. Join us and learn how our team can support Clinical Trials you may be interested in conducting within IH.

Learning Objectives

- Find out who we are and what we do
- Identify what you need to conduct research successfully as a Principal Investigator

9:00-9:45 – RESEARCH ETHICS 101

Presenter: Dorothy Herbert – IH Research Ethics Board Coordinator

Research Ethics Review is about protecting the rights of research participants, but applying the principles of ethical conduct in human research to your research project also has advantages for the researcher and for his/her institution. Learn about the key Canadian policy document that guides ethical reviews in Canada and take away strategies for successful recruitment, consent-form writing and more.

Learning Objectives

- When and why REB review is required
- The different levels of review
- What is included in “research involving humans”?
- Tips for writing consent forms for research

10:00-10:45 – WHAT IS OPERATIONAL APPROVAL AND DO I NEED IT?

Presenter: Wendy Petillion – IH Regional Practice Lead, Research

All research conducted in IH must have operative approval from the IH Administrator(s) responsible for the staff, services and/or sites involved in the research before the research begins.

Learning Objectives

- Learn how to apply for IH Operational Approval
- Identify when Clinical Trial Agreements, Sub-site Agreements, Privacy Impact Assessments or Information Sharing Agreements apply to a research project
- Discover how to register a biobank for biospecimens
- Know when the Certificate of Institutional Approval to Conduct a Research Project is issued
11:00-12:00 - ICH- E6 (R2) GCP - Status, Impact and Resources

Presenter: Jean Smart BC Academic Health Sciences Network – Clinical Trials BC

ICH E6 (R1) has been the standard for International Good Clinical Practice since 1996. ICH E6R2 has been approved in Canada and is moving towards full implementation for April 2018. This is the largest revision to the international GCP in twenty years and the impact will be widespread at all levels (national, provincial, sponsor, institution and sites). This presentation covers the top 10 ICH revisions in relation to the impact on systems and process. The resources that are available or in development provincially and nationally to assist with the implementation are identified and described.

Learning Objectives

- List the main proposed changes to E6 GCP
- Identify the site training requirements that will be associated with the change
- Understand what the impact of the changes will be on practice
- Discover access points for resources

12:15-12:45 – Responsibilities of a Principal Investigator

Presenter: Coleen Adderley

Every clinical trial is led by a Principal Investigator who is responsible for ensuring the study is conducted according to the protocol and applicable regulations. Learn about the specific training requirements a PI needs in order to comply with Health Canada and the sponsor.

Learning Objectives

- Understand what education is required by Health Canada
- Learn how to access the education and the time required

13:00-14:00 – QUALITY, CALIBRATION & MAINTENANCE OF EQUIPMENT IN CLINICAL TRIALS

Presenter: Jean Smart BC Academic Health Sciences Network – Clinical Trials BC

Quality management systems and process requirements are necessary to satisfy regulatory and industry expectations related to calibration and equipment maintenance. The key components of effective equipment management will be discussed. Groups will have the opportunity to develop tools to support equipment management for their site. Handouts are included.

Learning Objectives:

- List the key sections and content of an Equipment Calibration and Maintenance procedure
- Familiarize yourself with quality tools to record effective equipment management
- Identify examples of specialized equipment that may require on-site validation, frequent maintenance or a study specific procedure
- Name the equipment related components necessary to ensure compliance
- Identify the main components of a Vendor Qualification System
14:15-15:15 – QUALITY MANAGEMENT SYSTEMS OVERVIEW

Presenter: Jean Smart BC Academic Health Sciences Network – Clinical Trials BC

Quality Management Systems (QMS) is a required component of Good Clinical Practices. This presentation provides an overview of the quality management system and how the QMS subsystems fit and work together. It covers the history, new regulatory requirements, branches and usages in research at the site, program and health authority levels.

Learning Objectives

- Recognize the nine QMS subsystems
- Identify the regulatory related site requirements that are associated with QMS
- Name three applications of QMS in research

For physician attendees only - Hours can be submitted to College of Physicians for Continuing Education!

You will receive a certificate recognizing your participation for each lecture you attend. Please be sure to email Coleen Adderley at Coleen.Adderley@interiorhealth.ca and sign up for the lectures of your choice.