Introduction to the U of R and CTSI – see Outline for Coordinator Training

Module 1: Introduction to Clinical Research, Regulatory Oversight, Informed Consent and Good Clinical Practice Guidelines

Introduction to Clinical Research –

a. Glossary Terms (highlighted in medium blue)
b. https://www.youtube.com/watch?v=vYBtlItAT3c
c. Review URMC Offices involved with Clinical Trials and their Roles
d. OHSP Orientation to Conducting Human Subject Research (MyPath)
e. OHSP Conflict of Interest training
f. OHSP Research Boot Camp Intro (in addition, introduce new CLICK and IORA Systems, what they are, what they are used for, how to get access and that CLICK has replaced ROSS)
g. A Clinical Trials Manual – Chapter 1 (History of Clinical Trials)

Regulatory Oversight -

a. Glossary Terms (highlighted in medium blue)
b. A Clinical Trials Manual – Chapter 5 (Institutional Review Boards)
c. OHSP Research Boot Camp IRB Review Process
d. IRB speaker none

Informed Consent –

a. Glossary Terms (highlighted in medium blue)
b. A Clinical Trials Manual – Chapter 4 (Informed Consent)
c. OHSP Research Boot Camp Informed Consent
d. Consent Speaker Kelly Unsworth (8/27, 1 to 3pm with Carrie 2 to 3pm)
e. https://www.youtube.com/watch?v=l26hdCD9g2I
f. https://www.youtube.com/watch?v=b71Hz4QLHpc watching a participant being consented
g. https://www.youtube.com/watch?v=G9qFAWNF4f0 watching a participant being consented

Good Clinical Practice Guidelines -

a. Glossary Terms (highlighted in medium blue)
b. The CRC's guide to Coordinating Clinical Research – Chapter 3 (Regulations and Good Clinical Practices)
c. A Clinical Trials Manual – Chapter 3 (Good Clinical Practice and Regulations)
d. CITI training

Module 2: Investigational Product Development, Medical Device Development

a. Glossary Terms (highlighted in green)
b. https://myscrs.org/modules/ClinicalResearchOverview/story_html5.html
c. A Clinical Trials Manual – Chapter 2 (The Process: Developing New Drugs, Biologics and Devices)
d. PPT slides IP development
e. PPT slides for Medical Device Development
f. SoCRA Kathi Durdon September 8th & September 29th

Module 3: The Clinical Research Team: Roles and Responsibilities

a. Glossary Terms (high-lighted in orange)
b. The CRC's guide to Coordinating Clinical Research – Chapter 1 (The Clinical Research Coordinator)
c. A Clinical Trials Manual – Chapter 8 (The Principal Investigator, The Clinical Research Coordinator, and the Study Site)
d. OHSP Core 2 PI Oversight – Sections 1 – 4
e. PPT Coordinator
f. The Research Clinic Video

Module 4: Clinical Study Protocol Breakdown, Feasibility Evaluation and Site Selection

a. Glossary Terms (highlighted in purple)
b. OHSP Research Boot Camp Study Protocol Basics
c. OHSP Core 1 Study Design – Sections 1, 2 & 3
d. Review CDAs, MSAs, CTAs, CSAs, SOWs
e. A Clinical Trials Manual – Chapter 10 (Study Feasibility: Reviewing a Specific Protocol)

Module 5: Source Documentation, Case-Report Forms, Study Tool Development, and Standard Operating Procedures, eRecord, OnCore Training

a. Glossary Terms (highlighted in pink)
b. OHSP Research Boot Camp Study's Approved, What's Next?
c. Practice amending a consent for IRB approval (REALM-1) then review
d. Work in teams to create source documents for clinical trial (REALM-1) then review
e. Practice consenting using consent process document
f. Create source documents & visit checklists for Concert Alopecia & Abbvie AD then review
g. SOPs https://slideplayer.com/slide/3949685/
h. Duke SOP review
i. The CRC's guide to Coordinating Clinical Research – Appendix D
j. The CRC's guide to Coordinating Clinical Research – Chapter 10 (CRFs and EDC)

Module 6: Study Initiation, Start-up, and Ongoing Management Activities

a. Glossary Terms (highlighted in lime green)
b. Map out life cycle of a clinical trial
c. Creating a Regulatory Binder – Essential Documents
d. The CRC's guide to Coordinating Clinical Research – Chapter 8 (Pre-study Preparing for a Study)
e. A Clinical Trials Manual – Chapter 12 (Study Documents/Essential Documents)
f. A Clinical Trials Manual – Chapter 11 (Anatomy of a Clinical Trial)
g. OHSP Core 4 - Study Operations
h. URMC data security form review - https://www.rochester.edu/ohsp/documents/ohsp/pdf/policiesAndGuidance/Guideline_on_HSR_Research_Data_Security_Requirements.pdf

Module 7: Recruitment and Retention

a. Glossary Terms (highlighted in yellow)
b. Recruitment and Retention (Carrie Dykes) 9/17/21 3pm
c. The CRC's guide to Coordinating Clinical Research – Chapter 12 (Working with Study Participants)

Module 8: Safety Reporting: Definitions and Reporting Requirements

a. Glossary Terms (highlighted in gray)
b. PPT – Safety Practices and Reporting in Clinical Research
c. A Clinical Trials Manual – Chapter 6 (Adverse Events and Unanticipated Problems)
d. The CRC's guide to Coordinating Clinical Research – Chapter 14 (Adverse Events and Safety Monitoring)

Module 9: Accountability for the Investigational Product

a. Glossary Terms
b. A Clinical Trials Manual – Chapter 13 (Management of Study Drugs, Biologics, and Devices)
c. The CRC's guide to Coordinating Clinical Research – Chapter 11 Investigational Product Accountability
d. https://www.youtube.com/watch?v=G8tmlTkrwsM
e. PPT slides
f. Pharmacy Speaker

Module 10: Regulatory Compliance and Quality Assurance

a. Glossary Terms
b. A Clinical Trials Manual – Chapter 7 (Monitoring, Audits, and Inspections)
c. The CRC's guide to Coordinating Clinical Research – Chapter 15 (Audits and Inspections)
d. OHSP Quality Assurance Speaker
e. Talk about the monitoring process

Module 11: Overview of Clinical Research Finances

a. Glossary Terms
b. MyPath CT-01 Overview of UR Clinical Research Billing Policy and Standard Operating Procedures
c. Overview of Pre-award and post-award workbooks, invoicing, etc.
d. OCR speaker

Module 12: Clinical Trials Software Systems and other training

a. eRecord training, 9/10/21
b. OnCore training
c. Clinical Trials.gov (Carrie Dykes)
d. Phlebotomy
e. CLICK
f. REDCap
g. TriNetX