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, invoitandard Operating Procedures