

Checklist for Required Activities for New Clinical Research Coordinators (CRCs)
 (Note: mirrors the current version of the *Clinical Research Coordinators Orientation and Resource Manual*)

Required Activity	Date Completed
Section 1: Welcome and Introduction to Clinical Research Nursing	
Review Section 1 of the <i>CRC Orientation and Resource Manual</i>	
Nurse CRC: Review the ONS 2016 Oncology Clinical Trials Nurse Competencies	
Section 2: Introduction to the NIH, NCI, and CCR	
Review Section 2 of the <i>CRC Orientation and Resource Manual</i>	
View video of NIH: https://www.youtube.com/watch?v=ezpi8J1UQA0	
Nurse CRC: Read The Oncology Clinical Research Nurse Study Co-Ordinator: Past, Present, and Future	
Bookmark the websites found at: https://ccrod.cancer.gov/confluence/display/CCRCRO/Important+Web+sites	
Section 3: Administrative – Human Resources	
Review Section 3 of the <i>CRC Orientation and Resource Manual</i>	
Nurse CRC: Complete the CCND credential verification process	
Complete CRIS training	
Complete NIH New Employee Orientation (federal employees only)	
Complete NCI Orientation (federal employees only)	
Complete CC Orientation	
Complete the CCR Clinical Trials Orientation Web Modules (10 modules) and mail certificates to Tracy Kirby	
Attend CCR Clinical Trials Orientation	
Attend CCR Study Coordinator Orientation	
Complete set up computer including VPN connection, phone, and pager, if applicable	
Confirm information in NED is correct	
Federal CRC: Confirm access to ITAS	
Federal CRC: Sign on to your initial ePMAP	
Section 4: Administrative – Clinical Research	
Review Section 4 of the <i>CRC Orientation and Resource Manual</i>	
Read CCR SOP ADCR-2 CCR Participant Registration & Status Update	
View the PRES training video	
Read CCR SOP ADCR-14 Authorization of Outside Medical Services (AOMS) for Research Participants	
Review ThinkAndor® resources	
Review M2P2 #71	
Section 5: Overview of Clinical Research	
Review Section 5 of the <i>CRC Orientation and Resource Manual</i>	
Read The Belmont Report	
Complete the Good Clinical Practice (GCP) and Human Subjects Protection (HSP) online learning module	

Complete the Clinical Trial Design online learning module	
Section 6: Protocol Development & Ancillary Reviews	
Review Section 6 of the <i>CRC Orientation and Resource Manual</i>	
Federal CRC: Complete the HHS Form 717-1 form once contacted by the NCI Ethics Office for federal employees and for contractors. Contract CRC: Complete the <i>Conflict of Interest (COI) Certification for Non-Federal Employees</i> form sent by PSO for each protocol you are listed as an investigator on.	
Review the CCR Scientific Review SOP	
Complete Technology Transfer training. Log into the LMS home page . Search for the NIH Online Technology Transfer course which should have a "current" box next to the version.	
Section 7: Institutional Review Board	
Review Section 7 of the <i>CRC Orientation and Resource Manual</i>	
Section 8: Post Initial IRB Approval	
Read Section 8 of the <i>CRC Orientation and Resource Manual</i>	
Read SOP PM-5, Research Protocol Training Requirements	
Read SOP PM-9, Research Team Amendment Training	
Review M2P2 #17 What information needs to be reported to the IRB at the time of continuing review (CR)?	
Review M2P2 #41 What is the primary completion date (PCD) and the anticipated completion date (ACD)? Why are these dates important?	
Section 9: Overview of Roles & Responsibilities	
Read Section 9 of the <i>CRC Orientation and Resource Manual</i>	
Complete the Responsibilities of the Research Team online learning module	
View Responsibilities of the Principal Investigator Part 1: What You Need to Know & Do Before Your Protocol Starts.	
View Responsibilities of the Principal Investigator Part 2: Implementation of a Clinical Research Protocol	
Read CCR SOP PM-1 Delegation of Tasks for Research	
Read Guidelines for Completing the Delegation of Tasks Log	
Review the Delegation of Task Log	
Contact Legna Hernandez to schedule orientation to the day hospital.	
Section 10: Patient Referrals	
Read Section 10 of the <i>CRC Orientation and Resource Manual</i>	
Determine how referrals are processed in your team	
Determine your role within your team, as it pertains to referrals	
Review the studies currently open and recruiting in your team. What are the diagnoses required for eligibility? Is there a requirement for prior therapy?	
Listen to at least 2 phone calls between your team member/preceptor/referral nurse and referring individual; both those who are potentially eligible and those who are not	
Review at least 2 emails from your team to MORO regarding a referral	
Review the CCR Referrals Application Training Guide (See Appendix D in the Manual)	

Review the process of uploading images to the NIH Radiology drop box and bookmark this page: https://cc.nih.gov/dcrl/imaginglibrary.html	
Review the process of submitting pathology materials once a patient is appropriately consented and registered (See Appendix X.X)	
Review M2P2 #54 <i>What should I do to get biologic material (e.g., pathology samples) from outside the U.S. to the NIH?</i>	
Review the process of using the Cyacom language line. See Appendix D in the <i>CRC Orientation and Resource Manual</i>	
Section 11: Informed Consent	
Read Section 11 of the <i>CRC Orientation and Resource Manual</i>	
Complete the Informed Consent online learning module	
Read HRPP Policy 301 Informed Consent	
Read HRPP Informed Consent FAQs	
Read CCR SOP PM-2 Obtaining and Documenting the Informed Consent Process (Adult and Pediatric)	
View the OHSRP webinar Informed Consent Procedures in the Era of Covid-19: Beyond the Use of a Standard Written Consent Document	
View the OHSRP webinar Informed Consent One Year after the 2018 Common Rule Revisions: Updated Information and Processes	
Read the User Guide iMEDConsent™	
View the iMEDConsent™ training video	
View the Patient Mobile Signature Education Video	
Read M2P2 #24 : <i>You learn that your patient doesn't speak English and you don't have an IRB-approved protocol consent in the patient's native language. What do you do? Part 1: Seeking IRB Approval & Securing Translator</i>	
Read M2P2 #25 : <i>You learn that your patient doesn't speak English and you don't have an IRB-approved protocol consent in the patient's native language. What do you do? Part 2: Consent Discussion and Documentation</i>	
Read M2P2 #26 : <i>You learn that your patient doesn't speak English BUT you have an IRB-approved protocol consent in the patient's native language (i.e., the full English version translated). How does the consenting process differ when not using the short form consenting process?</i>	
Read M2P2 #27 <i>If consenting is an ongoing process, what does re-consenting mean?</i>	
Section 12: Source Documentation	
Read Section 12 of the <i>CRC Orientation and Resource Manual</i>	
Visit and review the CRIS Learning Resources website	
Review the HIMD handbook	
Complete Part 1 of the Documentation and Document Management online learning module	
Read CCR SOP PM-3 Clinical Research Documentation	
Read CCR SOP PM-8 Conducting and Documenting Drug Accountability for Oral Investigational Products that are Self-Administered by Research Participants	
Section 13: Essential Documents	

<i>Under development</i>	
Section 14: Adverse Events	
Read Section 14 of the <i>CRC Orientation and Resource Manual</i>	
Complete Parts 1 and 2 of the Adverse Event online learning module	
Section 15: Expedited Reporting of Adverse Events and Other Events	
Read Section 15 of the <i>CRC Orientation and Resource Manual</i>	
Complete Parts 3 and 4 of the Adverse Event online learning module	
Section 16: Clinical Data Management	
<i>Under development</i>	
Section 17: Monitoring and Auditing	
Read Section 17 of the <i>CRC Orientation and Resource Manual</i>	
Complete Part 1 of the Monitoring and Auditing in Clinical Trials online learning module	
Review the HIMD Regulatory Audit Guide	
Read CCR SOP PM-13 <i>Industry-Sponsored Studies Monitoring and Audit Visits</i>	
Read CCR SOP PM-13a <i>Center for Cancer Research Sponsored Studies Monitoring and Audit Visits</i>	
Read CCR SOP PM-13b <i>Monitoring and Audit Visits by ASRC (Artic Slope Regional Corporation)</i>	
Section 18: Professional Development	
Develop or revise existing CV to include current CRC role	