CLINICAL RESEARCH COORDINATOR ORIENTATION AND RESOURCE MANUAL

VERSION MARCH 2024

NIH NATIONAL CANCER INSTITUTE
Center for Cancer Research

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1 WELCOME AND INTRODUCTION

Welcome to the Office of Research Nursing (ORN) in the Center for Cancer Research (CCR)! Whether you are a federal employee or a contractor, nurse, or non-nurse, we are excited to have you join our team. The orientation and educational needs of our clinical research coordinators are complex due the level of knowledge necessary to fulfill the role at a professional level. Responsibilities include the interacting with patients and their families as well as the planning, coordination, and administrative aspects of the clinical research protocol itself.

This manual was developed as a supplement to the General Clinical Research Orientation and Resource Manual to delve further into topics that pertain to the role of the clinical research coordinator (CRC). It will help guide you through the complexities of the role, identify required activities for clinical research coordinators new to the CCR, and serve as a resource for current clinical research coordinators.

Each section of the manual includes content and required activities for new CRC hires. Please refer to the General Clinical Research Orientation and Resource Manual for comprehensive information about each section and required activities.

1.1 NURSES IN THE CRC ROLE

Nurses have been involved in the CRC role for decades. Two professional nursing associations have recognized this role and defined scope and standards of practice and competencies.

In 2007, the Oncology Nursing Society (ONS) working in collaboration with the Clinical Trials Nurse Special Interest Group began the process of developing competencies for the oncology nurse who is in the CRN Study Coordinator role. The first set of competencies was published in 2010 with a revision in 2016. Your performance is evaluated based on the 2016 competencies. Your ORN team lead will review these with you.

In 2009, the International Association of Clinical Research Nurses was established. In 2016, the American Nurses Association recognized the specialty practice of clinical research nursing. As defined in the Scope and Standards of Practice (2016), clinical research nursing is defined as the:

> "specialized practice of professional nursing focused on maintaining the equilibrium between care of the research participant and fidelity to the research protocol."

One of the roles of the CRN is that of the CRN Study Coordinator. This is your role!

1.2 REQUIRED ACTIVITIES FOR NEW CRC HIRES

1. For Nurse CRCs, read the following:
   - Oncology Nursing Society. (2016). *2016 Oncology clinical trials nurse competencies*. Pittsburgh, PA.
   - Ness E. (2020). The Oncology Clinical Research Nurse Study Co-Ordinator: Past, Present, and Future. *Asia Pacific Journal of Oncology Nursing, 7*(3), 237-42. doi: 10.4103/apjon.apjon_10_20

2 OVERVIEW OF THE NIH AND THE INTRAMURAL PROGRAM

Please refer to the General Clinical Research Orientation and Resource Manual.

3 OVERVIEW OF THE NATIONAL CANCER INSTITUTE (NCI)

Please refer to the General Clinical Research Orientation and Resource Manual.

4 OVERVIEW OF THE CENTER FOR CANCER RESEARCH (CCR)

Please refer to the General Clinical Research Orientation and Resource Manual.

4.1 REQUIRED ACTVITIES FOR NEW CRC HIRES

1. Bookmark the websites found here
2. View *Welcome to ROB: An Introduction to Radiation Oncology*, an Oncology Lunch & Learn from February 2024 for an overview of radiation oncology and the Radiation Oncology Branch (60 minutes)

5 OVERVIEW OF ROLES & RESPONSIBILITIES

5.1 CLINICAL RESEARCH COORDINATOR (CRC)

CRCs have many roles on a research team, as well as many names (Clinical Research Nurse, Research Nurse Specialist, Clinical Trial Nurse, Research Nurse Coordinator, Study Coordinator to name a few).

As defined by NCATS, a CRC manages and conducts the day-to-day activities of a clinical trial. The PI determines the CRC's specific responsibilities and works closely with the CRC. In general,

the CRC ensures the study implementation maintains accordance with the protocol, applicable regulations, and Good Clinical Practice (GCP) and Institutional Review Board (IRB) requirements.

Beyond administrative duties, responsibilities of a CRC may include acting as a liaison for the clinical site, ensuring staff are properly trained per the protocol, recruiting and/or registering participants, maintaining study guidelines, and collecting and/or reviewing the data or review before it is entered into a study database.

The CRC spends most of their time managing the study by coordinating within the multidisciplinary team, communicating with referring physicians and providing for protection of human subjects. The CRC is accountable for both the research participant and the protocol. If the CRC is also a registered nurse, all general nursing responsibilities apply (e.g., documentation, drug administration, participant triage).

New CRCs should complete the Collaborate Institutional Training Initiative (CITI) *CRC Foundations* course. This course can be completed at any time but is recommended after CCR and CRC orientation and within the first of year of employment. CRCs who are not new are welcome to take the course as well. Please click here to see the specific points in the training that are not consistent with NIH processes and policies.

Below is a list of typical CRC job duties and responsibilities focused on management of clinical trial patients and protocol compliance. Additional CRC responsibilities regarding referrals, informed consent, regulatory reporting, documentation and document management, data management, monitoring and auditing, are referenced by section in this manual and the general orientation manual.

- Works with PCC(s) to set up screening, baseline, active treatment and follow up visits per protocol
    - Reviews patient calendars/schedules to ensure protocol compliance ("independent double check")
- Uses CRIS protocol order sets (Nurse CRCs only). However, CRCs may not enter orders that require medical decision making even if they are a part of protocol order sets, including:
    - CT scans requiring use of contrast
    - Pulmonary Function tests requiring inhalants
    - Bone marrow biopsies
- Confirms protocol eligibility with PI, ensures all baseline studies are completed prior to initiating protocol therapy
- Ensures all protocol related studies are ordered, scheduled and completed at each timepoint
- Coordinates research specimen collection with research laboratory and relevant Clinical Center (CC) units, ensures CC staff has all supplies including blood tubes or pharmacokinetic (PK) sheets, if applicable

- Coordinates inpatient admission with relevant unit and admitting team, including admission ATV
- Understands and implements team process for scheduling with OR, IR and 3SW-N Procedure Unit including SISWeb access/training, being added to any relevant email listservs, Teams channels, etc
- Understands and implements team process for scheduling phlebotomy, outpatient clinic and day hospital appointments, including being added to any relevant email listservs, Teams channels, etc
- Follows protocol and Clinical Center blood draw limits for adult and pediatric research participants
    - Refer to M95-9 *Guidelines for Limits of Blood Drawn for Research Purposes in the Clinical Center*
- Refers patients/families to Clinical Center Social Work Services as needed
- Learns how course and response assessment are conducted per protocol(s)
- Takes patients off treatment and off study per protocol (via PRES) and documents in CRIS
- Coordinates with outside providers as indicated to ensure patient safety and continuity of care
- Identifies facilitators and barriers to protocol compliance and seeks solutions in collaboration with the PI and rest of the research team

This section outlines the roles and responsibilities of various members of the research team.

5.2 CLINICAL CENTER NURSING

The nurses in the CC are referred to as Clinical Research Nurses (CRNs). They provide wide ranging support for intramural protocols through activities such as:

- Clinical care in support of patients participating in research
- Patient education about the research protocols
- Data collection, entry and analysis
- Investigational drug administration
- New idea generation and clinical study design
- Dissemination of research findings.

5.2.1 WORKING WITH THE 3RD FLOOR DAY HOSPITAL (3SEDH)

The 3rd floor hematology-oncology day hospital (3SEDH) is located on 3SE-S and provides care for adult research participants/patients with hematologic disorders and malignancies, solid tumor cancers and immunodeficiencies enrolled in a variety of National Institutes of Health (NIH) research studies.

The 3SEDH provides services for patients that have to spend many hours at the Clinical Center receiving treatments or procedures.

Examples of 3SEDH appointments:

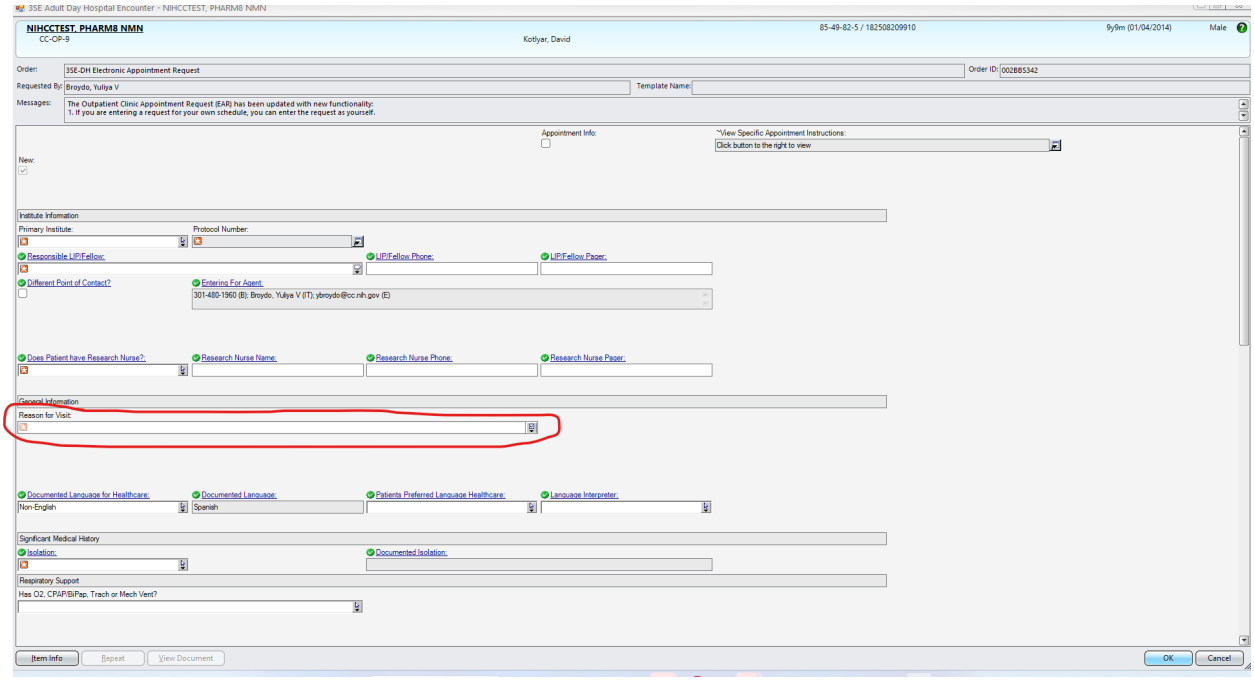
- Treatment of side effects or complications resulting from disease process or protocol (e.g. nausea, vomiting, shortness of breath, rash, pain, anemia, thrombocytopenia, fever with neutropenia.)
- Chemotherapy/Biotherapy Treatment
    - Day 1 patients after completing their visit/assessment in clinic.
    - Non-Day 1 patients (if no assessment needed, orders in CRIS)
- Post procedure recovery
- Transplant patients – during first 100 days
- Timed PK's.

For new CRCs, Legna Hernandez provides a 2-hour orientation to the 3SEDH which includes a tour and how to effectively work with the DH. Contact her via email to set up an appointment.

5.2.1.1 DAY HOSPITAL SCHEDULING

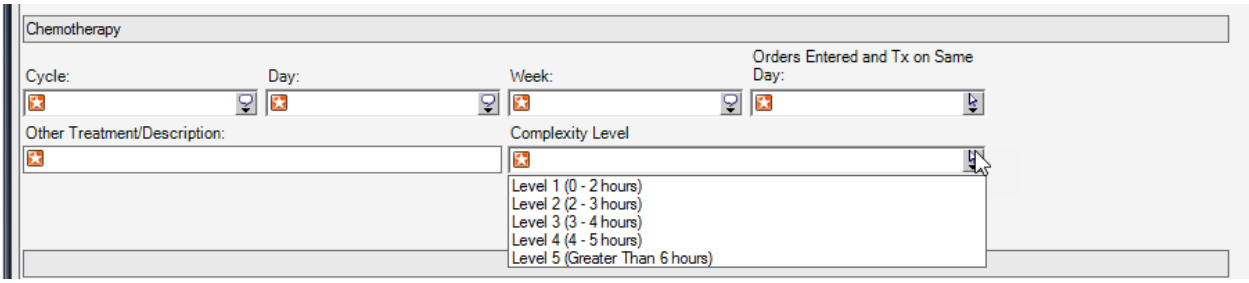
As of December 2023, 3SEDH now schedules all appointments via CRIS order "3SE-DH Electronic Appointment Request."

The requestor (CRC, PCC or a provider) will have to specify a reason for the visit. Based on the selection, the requestor will be prompted for additional information which will determine scheduling event and complexity level for the appointment.



For patients receiving chemotherapy, the requestor will be able to specify the following:

- Cycle/Day/Week of chemo treatment
- If the patient be seen in Clinic and also treated in 3SEDH on the same day, or on different days
- Free text field to indicate treatments/descriptions
- Complexity level field which will be used to capture the complexity level of the chemotherapy treatment, and factor into the calculation of the overall appointment duration



The system will default to the highest Level of Care of all the selected reasons for visit.

For non-chemo visit, the Level of Care is already built in there is no calculation of complexity level. Just select the various reason for visit and system will compute for you.

The level of care for chemo will be determined by the following formula

> 3SEDH Treatment Time per Protocol (Level Of Care) =
> Pre-Medication Administration time + Treatment Medication Administration Time + total Observation time and/or the total time for the collection of any post infusion labs

Hence: Level of Care = 3SEDH Treatment Time per Protocol

For a combination visit of chemo and non-chemo care, the chemo part of the visit will be calculated using the 3SEDH Treatment time per protocol. The non-chemo Level of Care is already built into the program.

	Level I	**Level II**	**Level III**	**Level IV**	**Level V**
3SEDH Treatment Time Per Protocol	<2 hours	2.01 to 3 hours	3.01 to 4 hours	4.01 to 5 hours	5.01 to >6 hours
Total DH Length of Stay	2 hours	3 hours	4 hours	5 hours	>6 hours
Non-Chemo /bio	-Coordinating Care -24hr PK	-Pain Management	-Therapeutic Phlebotomy	-Recovery organ (liver,	-Blood Administr

	-Simple Dressing change -Recovery Line Removal (PICC) -Routine blood work -Growth Factor	-IV Hydration -IV Electrolytes -IV Antibiotic/ antivirals/ antifungals -Cortisol Stem Test, -Recovery Line Removal (Femoral) -Recovery (Lumbar Puncture) -Ommaya sampling -Blood Administration (1-unit PRBC)	-Recovery Bone Marrow Biopsy -IV SQ or IgG Recovery (4hr), -Cortisol with blood work, - -Blood Administration (Platelets) -Pre-transplant Teaching	lung) with Treatment	ation (2 units RBC) -Routine Bloodwork with Blood Product administration -Blood product and Medication administration -Blood product and IV Electrolytes - Extended Specimen collection
Definitions: Treatment Plan Verification = ~ 1 hour 3SEDH Treatment Time per Protocol = Pre- Medication Administration + Treatment Medication Administration + Observations/ Post treatment blood collection Total Point of Care Time = Treatment Plan Verification + 3SDEDH Treatment Time per Protocol					

CRCs and PCCs need to work together per patient and protocol to determine how best to schedule patients given the fields in the EAR.

The day hospital recommends scheduling 3SEDH appointments about 2 hours after the clinic appointment. Patients should check in at the 3SEDH after clinic and leave their phone number in the event they can be treated sooner than the scheduled time if staffing and acuity permits.

If a patient leaves the 3SEDH to go to another department (e.g. radiology for a CT scan), and will return to the 3SEDH, they will need an additional EAR to return to the DH. This is because 3SEDH considers the patients appointment completed when they leave for another appointment or procedure; this is for patient safety to ensure CRIS accurately reflects where the patient is in the system.

Appointments should be scheduled no more than 6 months in advance. For patients who need to be seen same day or in less than 24 hours, requestors should schedule the appointment in CRIS and call the 3SE-DH (301-451-1152).

5.2.1.2 PROTOCOL IMPACT QUERY FORM FOR NEW DH PROTOCOLS

The oncology and critical care service protocol impact query (PIQ) system facilitates the scheduling of patients who need treatment, blood draws and/or supportive care. You will need to complete the PIQ form to provide a concise synopsis of the new protocol. This form is also used by respective units/clinics to evaluate the intensity of the protocol's impact. This is an essential step in protocol implementation. At least four (4) weeks prior to protocol implementation in the DH, you will need to do the following:

- Complete the PIQ Form (see Appendix A) and send it via email to CC-NURS OCC Protocol Impact Query Team with the subject line "PIQ Form." You will receive an acknowledgement notice within 72 hours.
- Once this information is obtained, the DH protocol coordinator or designee in collaboration with Unit/Clinic leadership will review the protocol and collaborate with you to make the necessary adjustments to support protocol implementation. These adjustments may include:
    - Making special arrangements with different departments (EKG-imaging or molecular diagnostic test)
    - Obtaining special tubes for PK's or PD (laboratory tests)
    - Developing patient education materials
    - Altering staffing patterns to support day and timing of treatments (anticipate adequate staffing)
    - Anticipating unit-based staff education (including disease, new equipment, medication, side effects, new high risk nursing skill and competencies)
- The DH protocol coordinator or designee will contact the research team to coordinate an in-service. It is recommended that in-services be scheduled within two weeks preceding the first patient arrival. If applicable. PK/PD worksheets need to be available for the in-service.

5.2.2 WORKING WITH THE INPATIENT UNITS

Inpatient admissions may be planned for indicated protocol treatments and/or procedures, or unplanned for further management and monitoring of clinical issues. As a CRC, keep in mind that if your patient has an unplanned admission, either at the Clinical Center or an outside hospital, it may be due to a serious adverse event that requires expedited reporting to the Sponsor. Check your protocol for more information to see if this applies.

Admissions are coordinated directly with each inpatient unit. Pediatric CCR patients are admitted to 1NW. Adult CCR patients are mainly admitted to one of the third floor oncology units (3NW, 3NE or 3SE-N), but some research teams admit to fifth floor units as well.

Individual inpatient units have specific forms that must be completed with research patient and research team information with deadlines for submission. They may also have email

distribution lists and/or calendars outlining admissions and discharges. Please work with your research teams to ensure access to all of these. All inpatient admissions also require an ATV.

Please coordinate with your clinical team regarding placing inpatient orders so that all orders are placed and efforts are not duplicated. Protocol specific orders that are a part of a research protocol order set (e.g. labs, vital signs) may be placed by a nurse CRC. These may need to be placed "on hold" in CRIS ahead of the admission, or once a patient has been admitted and assessed by the research team, depending on the situation.

5.2.3 WORKING WITH THE OUTPATIENT CLINICS

The outpatient clinics serve as the home base for research participants/patients and thus the location where most of their outpatient visits should occur.

Examples of clinic visits include:

- Day 1 patients – (and any patient that needs an assessment and discussion/decisions regarding treatment.)
- Protocol screening appointments
- Injection administration (SQ/IM/ID).
    - Ex. immunizations, vaccines, skin testing/reading, GCSF, androgen deprivation therapy **(**ADT), and denosumab.
- Quick clinical support (i.e. blood draws peripheral/ports/lines, Vital Signs, VAD flush, line pulls, or dressing changes)
- Provider assessments
- Un-timed PK's.
- Transplant patients after 100 days.

Clinic appointments may be scheduled in CRIS via Electronic Appointment requests. Certain clinics may have additional email distribution lists that send out clinic schedules in advance, please work with your research team to get added to these lists.

5.3 REQUIRED ACTIVITIES FOR NEW CRC HIRES

1. Complete the *Responsibilities of the Research Team* online learning module
2. View *Responsibilities of the Principal Investigator Part 1: What You Need to Know & Do Before Your Protocol Starts.*
3. View *Responsibilities of the Principal Investigator Part 2: Implementation of a Clinical Research Protocol*
4. Read CCR SOP PM-1 *PI Delegation of Tasks for Research*
5. Complete Signature Sheet, if needed, and submit to your PSO manager per the guidelines under CCR SOP PM-1

6. Identify the Sponsor for your protocol(s) (CCR, CTEP, Industry, No Sponsor)
7. Complete the *Drug Development: Role of the FDA and Sponsor* online learning module
8. Learn team process for scheduling with OR, IR and 3SW-N Procedure Unit
9. Review M95-9 *Guidelines for Limits of Blood Drawn for Research Purposes in the Clinical Center*
10. Learn team process for scheduling phlebotomy, outpatient clinic and day hospital appointments
11. Read Guidelines for Completing the Delegation of Tasks Log
12. Complete *CRC Foundations* CITI training course
13. Review the CCR Delegation of Activities Log
14. Work with PCC to set up initial visit; including ATVs, sending consent(s), maps and directions to participants
15. Confirm protocol eligibility with PI, ensure baseline studies are completed prior to initiating protocol therapy
16. Ensure all protocol related studies are ordered, scheduled and completed at each timepoint
17. Review research participant calendars/schedules to ensure they are protocol compliant
18. Use CRIS protocol order sets, compare them to the protocol for accuracy
19. Coordinate research specimen collection with research laboratory and relevant CC units, provide PK sheets and/or supplies as needed
20. Coordinate inpatient admission with relevant unit, admitting team and place admit ATV
21. Learn how course and response assessment are conducted per your protocol(s)
22. Take participants off treatment and off study per protocol in PRES and document in CRIS
23. Refer participants to Social Work as needed
24. Meet your team's Nurse Practitioner(s) (NP) and/or Physician Assistant(s) (PA), learn their role
25. Meet your team's Patient Care Coordinator(s) (PCC), learn their role
26. Contact Legna Hernandez to schedule orientation to 3SE-S day hospital
27. Meet your team's Protocol Support Office (PSO) Manager(s), learn their role
28. Meet your team's Data Manager(s) (DM), learn their role
29. Meet your team's pharmacist(s), learn their role

6 ADMINISTRATIVE – CLINICAL RESEARCH

Please refer to the General Clinical Research Orientation and Resource Manual.

6.1 REQUIRED ACTIVITY FOR NEW CRC HIRE

1. Read CCR SOP ADCR-5 *Travel and Lodging Reimbursement for CCR Clinical Research Participants, Pediatric Guardians, and Authorized Attendants*
2. Review your protocol(s) in PROTRAK/PQS, including the most recent patient travel form
3. Review ThinkAndor® resources

4. Read CCR SOP ADCR-14 *Authorization of Outside Medical Services (AOMS) for Research Participants*
5. Review CC Safety Tracking and Reporting System (STARS)
6. Read CCR SOP ADCR-2 *CCR Participant Registration & Status Updates*
7. View the PRES training video
8. Read CCR SOP ADCR-4 *Admission, Travel and Voucher (ATV) Process*
9. Request a financial assessment for a research participant in ATV
10. Register a participant in PRES
11. Review M2P2 #71 *What is Embedded Agreement Information in PRES?*

7 OVERVIEW OF CLINICAL RESEARCH

Please refer to the General Clinical Research Orientation and Resource Manual.

7.1 REQUIRED ACTIVITES FOR NEW CRC HIRES

1. Read *The Belmont Report*
2. Complete the *Good Clinical Practice (GCP) and Human Subjects Protection (HSP)* online learning module
3. Complete the *Clinical Trial Design* online learning module

8 PROTOCOL DEVELOPMENT & ANCILLARY REVIEWS

Please refer to the General Clinical Research Orientation and Resource Manual.

8.1 REQUIRED ACTIVITIES FOR NEW CRC HIRES

1. Federal employees: Complete the HHS Form 717-1 form.
2. Contract employees: Complete the *Conflict of Interest (COI) Certification for Non-Federal Employees* form sent by the PSO for each protocol you are listed as an investigator on.
3. Review the *CCR Scientific Review SOP*
4. 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.

9 INSTITUTIONAL REVIEW BOARD

Please refer to the General Clinical Research Orientation and Resource Manual.

9.1 REQUIRED ACTIVITIES FOR NEW CRC HIRES

1. Request PROTECT account, attend training class
2. Complete the *Protocol Development, Review and Approval* online learning module

10 POST INITIAL IRB APPROVAL

Please refer to the General Clinical Research Orientation and Resource Manual.

10.1 REQUIRED ACTIVITIES FOR NEW CRC HIRES

1. Read CCR SOP PM-5, *Research Protocol Training Requirements*
2. Read CCR SOP PM-7, *Clinical Research Study Initiation*
3. Read CCR SOP PM-9, *Research Team Training Requirements for IRB Modifications*
4. Review M2P2 #17 *What information needs to be reported to the IRB at the time of continuing review (CR)?*
5. Review CCR SOP PM-15, *Preparation of Safety Monitoring Committee (SMC) Report*
6. Review CCR SOP RPS-20, *Preparation of Study Closure*
7. Review M2P2 #41 *What is the primary completion date (PCD) and the anticipated completion date (ACD)? Why are these dates important?*
8. Review M2P2 #76 *Who should be notified when a primary completion date (PCD) is met for one of my clinical trials?*
9. Review M2P2 #77 *What is a Good Cause Extension (GCE) for reporting results in ClinicalTrials.gov?*
10. Review M2P2 #78 *Is it mandatory to redact certain information from a protocol and/or consent for results reporting to ClinicalTrials.gov?*
11. Review Civil Money Penalties Relating to the ClinicalTrials.gov Data Bank
12. Watch the FDA 3 part webinar series on ClinicalTrials.gov

11 PATIENT RECRUITMENT AND REFERRALS

Please refer to the General Clinical Research Orientation and Resource Manual.

11.1 REQUIRED ACTIVITES FOR THE NEW CRC HIRE

1. Determine how referrals are processed in your team (i.e., utilizes one of the referral offices or receives referrals directly)
    a. Determine if there is a specific individual(s) assigned to this task
2. Determine your role within your team, as it pertains to referrals
3. Read 04-C-0165 Protocol and Consent
4. Find existing records in CRIS
5. Review the process of using the Cyracom language line. See Appendix D in the General Clinical Reserach Orientation and Resource Manual.
6. Review the studies currently open and recruiting in your team. What are the diagnoses required for eligibility? Is there a requirement for prior therapy?

7. 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
8. Learn what outside records to request for your protocol(s) and request via e-fax
9. Review outside records for protocol eligibility including current medication list
10. Review at least 2 emails from your team to MORO regarding a referral if your team utilizes the services of MORO
11. Review the *CCR Referrals Application Training Guide* if your team utilizes the services of MORO
12. Retrieve outside records and upload to CRIS per CCR SOP PM-4, *Submitting Outside Record for Entry in CRIS*
13. Review the process of uploading images to the NIH Radiology drop box and bookmark this page: https://cc.nih.gov/dcri/imaginglibrary.html
14. Review the process of submitting pathology materials once a patient is appropriately consented and registered
15. Review M2P2 #54 *What should I do to get biologic material (e.g., pathology samples) from outside the U.S. to the NIH?*

12 INFORMED CONSENT

Please refer to the General Clinical Research Orientation and Resource Manual.

12.1 REQUIRED ACTIVITIES FOR NEW CRC HIRES

1. Complete the *Informed Consent* online learning module
2. Read HRPP Policy 301 *Informed Consent*
3. Read HRPP Informed Consent FAQs
4. Read CCR SOP PM-2 *Informed Consent Process – General Information*
5. Read CCR SOP PM-2a, *Obtaining and Documenting the Informed Consent Process – Adult English Speaking participants (Including Decisionally Impaired and Enrollment of NIH Staff)*
6. Read CCR SOP PM-2b, *Obtaining and Documenting the Informed Consent Process -- Adult Non- English Speaking (Including Decisionally Impaired)*
7. Read CCR SOP PM-2c, *Obtaining and Documenting the Informed Consent Process – English-Speaking Children and Parents/Guardians*
8. Read CCR SOP PM-2d, *Obtaining and Documenting the Informed Consent Process – Non-English-Speaking Children and Parents (including when only child speaks English)*
9. View the OHSRP webinar *Informed Consent Procedures in the Era of Covid-19: Beyond the Use of a Standard Written Consent Document*
10. View the OHSRP webinar *Informed Consent One Year after the 2018 Common Rule Revisions: Updated Information and Processes*
11. Read the *User Guide iMedConsent™*
12. View the iMedConsent™ training video
13. View the *Patient Mobile Signature Education Video*

14. Read M2P2 #24: *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*
15. Read M2P2 #25: *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*
16. Read M2P2 #26: *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?*
17. Read M2P2 #27 *If consenting is an ongoing process, what does re-consenting mean?*

12.2 ADDITIONAL RESOURCES

- OHRP Informed Consent FAQs
- OHRP Informed Consent videos
- Guidance for obtaining consent to participate in research from non-English speaking participants (OHSRP under Policy 301)
- CCR FAQs

13 SOURCE DOCUMENTATION

This section will expand on CRC documentation. Please refer to the General Clinical Research Orientation and Resource Manual for an overview of all source documentation.

13.1 CRC DOCUMENTATION

Research source documentation is never by exception. Documentation that is acceptable in clinical practice may need additional details when the patient enters a clinical trial. CRC documentation in the medical record is critical for providing details regarding a patient's research study involvement, including education throughout the course of their study participation. This is also a part of ongoing informed consent.

CRCs should document all patient encounters in CRIS (inpatient, outpatient, telephone calls, etc) within 3 days of the encounter.

Nurse CRCs may use several note templates, including the "Research Nurse Protocol Note", "Patient Education Note", "Telephone Contact Note," "Documentation of Research Consent," etc.

Non nurse CRCs may independently use the "Clinical Research Coordinator Note" and "Documentation of Research Consent" notes.

What are some examples of CRC documentation?

- Scheduled study visit details, including any protocol-specific activities completed such as biopsies, surveys, research bloods
- Study status changes, including enrollment, off treatment and off study events
- Participant education, including:
    - Review of study calendar/schedule
    - Instructions on how to complete medication diaries or other protocol related forms
    - Contact information given for research team during business hours and after hours
    - Any other questions answered or information given to patients and caregivers.
- Informed Consent
- Adverse Events
- Drug Accountability (Nurse CRCs only) CRCs also play a role in educating other research team members and clinical staff regarding appropriate and accurate source documentation. Every data point that is entered into the clinical research study database needs to be verified within the source documentation. For more information regarding documentation requirements refer to CCR SOP PM-3 *Clinical Research Documentation*.

13.2 REQUIRED ACTIVITIES FOR NEW CRC HIRES

1. Visit and review the CRIS Learning Resources website
2. Review the HIMD handbook
3. Complete Part 1 of the *Documentation and Document Management* online learning module
4. Read CCR SOP PM-3 *Clinical Research Documentation*
5. Read CCR SOP PM-8 *Conducting and Documenting Drug Accountability for Oral Investigational Products that are Self-Administered by Research Participants*
6. Read CCR SOP ADCR-8 *Certifying Scanned Paper Documents*
7. Document CRC visit with participant in CRIS per CCR SOP PM-3
8. Document participant education in CRIS (i.e., participant given a copy of consent, study calendar/schedule, research team contact information, after hours contact information, instructions on how to complete medication diaries or other protocol related forms)

14 ESSENTIAL DOCUMENTS

Please refer to the General Clinical Research Orientation and Resource Manual.

14.1 REQUIRED ACTIVITIES FOR NEW CRC HIRES

1. Complete Part 2 of the *Documentation and Document Management* online learning module
2. Read CCR SOP PM-6 *Guidelines for Development and Maintenance of Regulatory Files/Binders.*
3. Maintain screening and enrollment log(s) per Sponsor/institutional requirements
4. Maintain monitoring visit log(s) per Sponsor/institutional requirements
5. Pull an enrollment report from PRES

15 ADVERSE EVENTS

Please refer to the General Clinical Research Orientation and Resource Manual.

15.1 REQUIRED ACTIVITIES FOR NEW CRC HIRES

1. Complete Parts 1 and 2 of the *Adverse Event* online learning module
2. Review your protocol(s) definition of a dose limiting toxicity (DLT), if applicable. How are these defined, managed and reported?

16 EXPEDITED REPORTING OF ADVERSE EVENTS AND OTHER EVENTS

Please refer to the General Clinical Research Orientation and Resource Manual.

16.1 REQUIRED ACTIVITIES FOR NEW CRC HIRES

1. Complete Parts 3 and 4 of the *Adverse Event* online learning module
2. Work with PI to report SAE(s) per sponsor requirements
3. Review M2P2 #8 *When do I submit a Reportable New Information (RNI) form to the IRB and what happens after the submission?*
4. Submit a RNI form in PROTECT
5. Enter a deviation in the Protocol Deviation Tracking System (PDTS)

17 CLINICAL DATA MANAGEMENT

Please refer to the General Clinical Research Orientation and Resource Manual.

17.1 REQUIRED ACTIVITIES FOR NEW CRC HIRES

1. Complete the *Clinical Data Management* online learning module
2. Participate in database build for a new protocol
3. Collaborate with team to develop/maintain a data quality assurance (QA) plan (meetings, systems, schedules)

4. Quality check (QC) data in case report forms (CRFs), compare to source documentation

18 MONITORING AND AUDITING

This section will expand on how CRCs prepare for monitoring and auditing visits. Please refer to the General Clinical Research Orientation and Resource Manual for an overview of all monitoring and auditing.

18.1 PREPARING FOR A VISIT

Preparation is key to ensuring a quality visit as it will maximize everyone's time, and is more likely to increase the amount of data a monitor or auditor can review and reduce queries.

The CCR has 4 SOPs that cover monitoring and auditing depending on the type of visit:

- CCR SOP PM-12 *NCI CTEP and Network Audits*
- CCR SOP PM-13 *Industry-Sponsored Studies Monitoring and Audit Visits*
- CCR SOP PM-13a *Center for Cancer Research Sponsored Studies Monitoring and Audit Visits*
- CCR SOP PM-13b *Monitoring and Audit Visits by ASRC (Artic Slope Regional Corporation)*

Please follow the appropriate SOP for the type of visit.

The first step to prepare for a visit it to make sure OEC is aware of the visit, via the NCI CCR QA (nciccrqa@mail.nih.gov) mailbox. The following should be sent:

- Confirmation letters or other correspondence regarding scheduled monitoring visits, audits or inspections. Include the protocol number, PI, type of visit (e.g., routine monitoring, audit, FDA inspection), dates of the visit, name of the sponsor and which team member is the contact person for the visit.
- All visit reports
- Team response to monitoring and auditing visit reports

In the weeks leading up to the visit, the CRC coordinates access to the regulatory files, medical records and research records. Below is a table outlining these processes based on the sponsor.

Sponsor	Monitoring / Audit Group	Regulatory Files	Access to Medical Records	"Paper" Research Records
OSRO	SROS	Uploaded to Veeva Vault by PSO Manager; Monitor has access to	Study coordinator must request access to the Clinician Portal for the monitor via the	Study coordinator sends via Secure Email File

		Veeva Vault by OSRO directly; Box is not used	Regulatory Audit Scheduling Portal and a list of patients to be reviewed must be sent to "CC-HIMD Regulatory Audit" no later than the Wednesday prior to the scheduled visit	Transfer (SEFT) to monitor
Industry	Sponsor or CRO	OEC/PSO Manager work together to upload files into Box; OEC will give Box access to monitor so need to be aware of visit		Study coordinator sends to OEC for upload into Box
Sponsor	**Monitoring / Audit Group**	**Regulatory Files**	**Access to Medical Records**	**"Paper" Research Records**
CTEP / NCI Network	Theradex / Network auditors	OEC/PSO Manager work together to upload files into Box; OEC will give Box access to monitor so need to be aware of visit	OEC will schedule the visit with HIMD via the portal and provide the patient list	Study coordinator sends to OEC for upload into Box
N/A	ASRC	Have read-only access to regulatory files on Network	Have read-only access to CRIS, no HIMD scheduling is required	Study coordinator sends via encrypted email to monitor

The CRC should work with the PSO manager to make sure regulatory files are up to date, including SAE reports, protocol training, amendment/modification training, etc.

This is also the time to make sure that the clinical database is updated and accurate. The CRC and data manager work together ensure eCRF completion. The CRC should then prioritize quality checking eCRFs for all monitored subjects prior to the visit.

CRCs also schedule close out meetings with the monitor/auditor. These can be scheduled in advance, or during the visit, depending on Sponsor preference. PIs should be present, as the monitors/auditors need to document PI participation in the visit, and data managers and PSO managers are optional. These meetings do not have to be scheduled for the last day of the visit if schedules do not align. These can be scheduled for approximately 30 minutes virtually, or in person.

18.2 DURING THE VISIT

During the visit, CRCs should be prepared to provide support to the monitor/auditor(s) as needed, or direct them to the appropriate resource. If it is an onsite visit, please meet them in person and escort them to where they need to go.

The CRC should be accessible (either virtually or in person) as much as possible during the visit. For virtual visits, it is courteous to check in via email the first morning of the visit to see how

things are going, if they have access to everything they need (e, the EMR, regulatory binder, research records) and if they have any questions.

Anticipate managing your time differently on monitoring/auditing visit days as there may be more interruptions and questions. If the CRC can address these inquiries promptly this will likely lead to a smoother visit as items can be clarified and resolved, which may lead to fewer post visit action items or queries. Please note that the EMR access that Industry and OSRO gain access to (Clinician Portal) visually looks different than the CRIS screen CRCs can see, so if you are going to guide them toward source documentation use names instead of locations. These monitors/auditors will receive a handbook via email from HIMD to guide them on how to use Clinician Portal.

18.2.1 CLOSE OUT MEETING

The CRC, monitor/auditor, the PI and sometimes the data manager and/or PSO manager will attend. As the CRC, you can prepare for this meeting by having a list of questions or items to address, including any unresolved queries from previous visits. The monitor/auditor do the same. They will likely give an overview of visit progress, and sometimes ask for clarification on essential documents or source documentation (verbal queries). The CRC is not expected to answer all on the spot queries, it is acceptable to wait for the written report so the matter can be investigated more thoroughly. However if the monitor/auditor brings up any issues that could meet the criteria of expedited reporting to the IRB, those need to be further explored promptly as the “clock” for research team notification starts then.

The meeting should also include a discussion regarding when the final report will be issued, and a plan for the timing of the next visit.

Please remember to ask each monitor/auditor to sign the site visit log. If the visit is multiple days, a signature for each day is required.

18.3 AFTER THE VISIT

The written report will be issued within a few weeks of the visit including any queries/action items. The CRC should forward to relevant staff (NCI CCR QA, PSO manager, PI, and/or DM) if they were not already included. The report should be saved to the regulatory binder.

The report will contain information regarding:

- Date(s) of visit
- Names of monitors/auditors
- What patients were reviewed (source documentation – medical and/or research records)
- Case report forms reviewed (clinical database)

- If pharmacy and/or the research lab were involved in the visit
- Essential documents reviewed (ie: staff training, delegation logs, SAE reports, Notes to File)
- New queries regarding missing, incomplete or erroneous information found in source documentation, clinical database and/or essential documents
- Resolution to prior queries including any outstanding items

18.3.1 RESPONDING TO QUERIES

The CRC works with DM, PI and/or PSO manager to address queries. Queries may come in a report and/or directly into a database.

Reports should be reviewed promptly upon receipt as some findings (ie: major deviations, noncompliance) may require expedited reporting to the IRB (if they didn't already come up at the close out visit)

Otherwise, the research team must follow sponsor deadlines for addressing and responding to queries. Some sponsors and ASRC will want you to send a written response within a certain timeframe. Other sponsors, such as OSRO, do not require a written response but will expect you to address all findings prior to the next visit, you can however email them if you have any questions about queries.

Work together to double check findings in regulatory binder, source documentation, and/or clinical database prior to addressing. Discrepant data can be corrected or clarified. Missing or incomplete data may be able to be recovered depending on the type of data and how long ago it was, work within your team to determine if this is possible or consider filing a deviation if not. Occasionally a monitor/auditor will query in error, it is possible they were not able to find all or any of what they were looking for so you can point them in the right direction.

If you need assistance in responding to queries, please reach out to OEC.

18.4 REQUIRED ACTIVITIES FOR NEW CRC HIRES

1. Complete Part 1 of the *Monitoring and Auditing in Clinical Trials* online learning module
2. Read CCR SOP PM-13 *Industry-Sponsored Studies Monitoring and Audit Visits*
3. Read CCR SOP PM-13a *Center for Cancer Research Sponsored Studies Monitoring and Audit Visits*
4. Read CCR SOP PM-13b *Monitoring and Audit Visits by ASRC (Artic Slope Regional Corporation)*
5. Review the HIMD Regulatory Audit Guide (located under "Resources")
6. Work with research team to prepare for a monitoring or auditing visit per relevant SOP
7. Attend a close out meeting during a monitoring or auditing visit

8. Work with the DM(s), PI and/or other members of the research team to address queries from monitoring or auditing visits

19 PROFESSIONAL DEVELOPMENT

This section will outline certification options for CRCs. Please refer to the General Clinical Research Orientation and Resource Manual for an overview of curriculum vitaes, portfolios, professional development activity offerings, and organizations.

19.1 CERTIFICATION

Certification is formal recognition based on specific criteria with established parameters that reflect assessment of educational preparation and knowledge, skills, and abilities or competence developed through experience in a specialty area of practice. Certification promotes public safety by establishing minimal competency standards for CRCs who have met those standards.

19.1.1 CRC CERTIFICATIONS

Both ACRP and SoCRA offer research specific certification. ACRP offers 4 types of certifications based on your role. For you as a CRC, the clinical research coordinator (CCRC®) certification is the best fit. SoCRA offers one certification program, the certified clinical research professional (CCRP®).

19.1.2 NURSE CRC CERTIFICATIONS

19.1.2.1 ONCOLOGY NURSING CERTIFICATION CORPORATION (ONCC)

The Oncology Nursing Certification Corporation (ONCC) is the premier provider of nationally accredited certification for nurses in oncology and related specialties. It was founded in 1984 and administered the first Oncology Certified Nurse (OCN®) examination in 1986. Through ONCC, there are over 40,000 certified nurses. Currently, ONCC offers eight certification programs:

- Oncology Certified Nurse (OCN®)
- Certified Pediatric Hematology Oncology Nurse (CPHON®)
- Certified Breast Care Nurse (CBCN®)
- Blood & Marrow Transplant Certified Nurse (BMTCN®)
- Advanced Oncology Certified Nurse Practitioner (AOCNP®)
- Advanced Oncology Certified Clinical Nurse Specialist (AOCNS®) (renewal only)
- Certified Pediatric Oncology Nurse (CPON®) (renewal only)
- Advanced Oncology Certified Nurse (AOCN®) (renewal only)

19.1.2.2 CLINICAL RESEARCH NURSING CERTIFICATION COUNCIL

The Clinical Research Nursing Certification Council (CRNCC) is the only organization that formally recognizes the specialized body of knowledge unique to the clinical research nurse. Established in 2020, the purpose of CRNCC is to establish and maintain excellence in the

specialty practice of clinical research nursing through credentialing (CRN-BC™). The CRN-BC™ directly or indirectly impacts the care of clinical research participants across the care continuum in all clinical specialties and settings, ensuring protection of consumers engaged in clinical research and the public who benefit from research discovery. Certification is through portfolio. Visit their website to learn more.

19.2 REQUIRED ACTIVITIES FOR THE NEW CRC HIRES

1. Develop or revise existing CV to include current role
2. Start a professional development log

20 APPENDICES

20.1 APPENDIX A: DAY HOSPITAL PROTOCOL IMPACT QUERY

Oncology and Critical Care Service

Protocol Impact Query Form

Protocol Title	
Protocol Number	
Research Type	☐ Observational ☐ Interventional
Principal Investigator	
Associate Investigator(s)	
Research Nurse Coordinator & Phone number	
Patient Population (disease, newly diagnosed, relapsed, etc.)	
Anticipated Visit Location(s) *(Check all that apply)*	**INPATIENT UNIT:** Choose an item. Other: _____ **ICU** ☐ **OUTPATIENT CLINIC:** Choose an item. **3 SE DAY HOSPITAL:** ☐
Number of Patients to be enrolled	
Anticipated first treatment	
Treatment Schema	**Study Drugs**:
	Anticipated Length of infusion(s):
	Total length of treatment: (Including pre-meds, pre-hydration, etc.)
	Length of the cycle:
	Treatment Day(s) of the Week:

	INPATIENT UNIT Anticipated Length of Stay: ____ Cycle/Day/Frequency:	**3 SE DAY HOSPITAL** Anticipated Duration of Visit(hrs): ____ Cycle/Day/Frequency:	**OUTPATIENT CLINIC** Clinic/Visit Day of week Choose an item. Cycle/Day/Frequency:
Anticipated Side Effects			
Protocol Requirements Pre, During and Post Study Drug Administration	Observation Time: Vital Signs frequency: Telemetry Monitoring: ☐ Yes ☐ No Additional diagnostic test (EKG/X-Ray/Saliva/Biopsy etc.):		
Access device required by protocol	☐ Central VAD ☐ Peripheral VAD ☐ Other: _____		
Special Equipment required by protocol *(i.e. syringe pump, etc.)*			
INPATIENT UNIT **Pharmacokinetics (PK) / Pharmacodynamics (PD)/ Research blood** ***(Attach PK Sheet if applicable)***	☐ Not Applicable (N/A) ☐ See Section ___ of protocol for research lab details Can PK/PD be drawn from the same lumen as drug infusion? ☐ Yes ☐ No Can PK/PD be drawn from the same site/arm as drug infusion? ☐ Yes ☐ No Cycle/Day/Frequency: *Special Instruction(s):*		
3 SE DAY HOSPITAL **Pharmacokinetics (PK) / Pharmacodynamics (PD)/ Research blood** ***(Attach PK Sheet if applicable)***	☐ Not Applicable (N/A) ☐ See Section ___ of protocol for research lab details Can PK/PD be drawn from the same lumen as drug infusion? ☐ Yes ☐ No Can PK/PD be drawn from the same site/arm as drug infusion? ☐ Yes ☐ No Cycle/Day/Frequency: *Special Instruction(s):*		
OUTPATIENT CLINIC	☐ Not Applicable (N/A)		

Pharmacokinetics (PK) / Pharmacodynamics (PD)/ Research blood ***(Attach PK Sheet if applicable)***	☐ See Section ___ of protocol for research lab details Can PK/PD be drawn from the same lumen as drug infusion? ☐ Yes ☐ No Can PK/PD be drawn from the same site/arm as drug infusion? ☐ Yes ☐ No Cycle/Day/Frequency: *Special Instruction(s):*
Days of the week preferable for In-service	****Reminder: Please email completed form to "**CC-NURS OCC Protocol Impact Query Team**"*
Additional Comment(s)	