UPMC | HILLMAN CANCER CENTER

Initial Meeting to be completed prior to the end of the On-Boarding Orientation. Mentee, Mentor, QA Team member, and Mentee's Manager are to be in attendance.

Date of Meeting: _____   QA Team Member: _____

Mentee: _____   Mentor(s): _____

Preferred Day and Time of Weekly/Bi-weekly meetings with QA Team Member: _____

QA/QC & Training Staff to confirm that CITI modules are completed: □ **Completed**   □ **Not completed** *If not completed, Mentee is to complete the CITI modules and provide copies to the QA/QC & Training Staff prior to the Mentee beginning the mentorship*
Date of CITI module completion: _____

Mentee's Preferred Learning Style:

Mentee's Preferred Style of Communication:

Mentee's Expectations of the Team:	Mentor's Expectations of the Mentee:
Mentee's Expectations of the Mentorship:	Mentor's Expectations of the Mentorship:

General Expectations for the Mentee:
- Take an active role in your learning!
- Review your Skills Checklist packet and discuss any experiences that are needed with your mentor
- Ensure that your Skills Checklist packet is completed by the Mentor as tasks are reviewed/completed
- In real time, ask questions or seek clarification as needed

General Expectations for the Mentor:
- Review the Skills Checklist packet with your Mentee and identify areas to either review or to provide exposure to/experience with
- Provide start/stop time expectations for Mentee
- Provide Mentee with 'debriefing' opportunities at the end of each day. This will allow the Mentee a chance to ask questions or seek clarification about the day's events.

Date reviewed: _____ Mentee initials: _____Mentor Initials: _____ QA Staff Initials: _____

Attendance to meetings and trainings:

Mentee should attend all center-specific meetings, SIVs, DSMB meetings, etc.

Mentee will attend job-specific training sessions and classes, including, but not limited to (QA to fill in dates of scheduled training):

- o Lab Training   _____

- o OnCore/eREG Training   _____

- o Biological Substances Shipping   _____

- o Antineoplastic Therapy and Immunotherapy Course   _____ _____ _____ _____

- o Antineoplastic Therapy and Immunotherapy Course Test   _____

- o Foundations (series of 5 courses):   _____ _____ _____ _____ _____

- o EPIC Training for Magee   _____

Protocols for Review

- o Mentee should be provided with a prioritized list of all protocols that the mentee will train on in eREG. Mentee will review protocols during downtime, or as requested by the mentor and/or Supervisor/Program Manager.
- o Mentee will email the study Regulatory Specialist and request that protocol training be assigned in eREG.
- o Mentee will ensure that his or her name is listed in eREG prior to performing any study-specific procedures for a patient.
- o Mentor to facilitate the mentee obtaining access to any protocol specific/required system (i.e., IVRS, IVWS)

Resources

- o Mentor and manager to ensure that mentee has access to any/all resources needed to complete tasks
- o Mentee to ask mentor, Supervisor, Program Manager, and/or QA/QC Training Coordinator if he/she is having difficulty locating a resource

Touch Base Meetings

Mentee, Mentor(s), Supervisor and/or Program Manager will meet with QA Team Member biweekly.

- o Discuss any issues identified
- o Discuss what was learned/reviewed from the time of the last meeting
- o Ensure that the Skills Checklist Packet is being completed
- o Review learning opportunities still needed
- o Identify any resources required/requested
- o Develop plan for upcoming week(s)
- o Ensure that protocol training is being completed and documented appropriately

RC Skills Checklist Packet

- The RC Skills Checklist Packet is broken down into tasks
- Tasks are listed alphabetically (except for the Introduction to Center) on the following pages:
    4. Introduction to Center
    5. Adverse Events
    6. Aria Order Entry
    7. Calculations
    7. Concomitant Medications – Documenting on Con Med Log
    8. Consent Withdrawal
    8. Disease Assessment and Imaging Core
    9. Deviations
    10. DSMB
    10. Informed Consent
    11. In-patient Admissions
    12. Monitoring
    12. New Study Implementation
    12. Note to File
    13. Off Treatment vs Off Study
    13. Overview of Patient Protocol Visit
    13. Post Visit
    14. Post Visit OnCore Documentation
    15. Protocol Amendments
    15. Questionnaires
    16. RC Note
    16. Re-consent
    16. Registration/Randomization
    17. Report to Treatment Room Nurse
    17. SAE/Expedited Reporting
    18. Scheduling
    20. Screening/Eligibility
    21. Vincent

Completion of RC Skills Checklist Packet:

- As the item is completed, the mentee is to write in the date the task was reviewed/completed. The mentee will then place their initials in the *Mentee Initials* column and the Mentor will place their initials in the *Mentor Initials* column.

- The mentor is to provide the mentee with time to learn the tasks through repetition. Mentor should demonstrate the task, then provide multiple opportunities (assisted and unassisted) for the mentee to practice the tasks. Mentee may also be paired with other staff to expand practice opportunities.

- The skills checklist is to be reviewed and completed prior to each touch base meeting.
    — Mentee to also complete page 22 – Current Workload
    — Mentor to complete page 23 – Assessment of Mentee

- The skills checklist will be brought to each touch base meeting and reviewed during the meeting.

Introduction to Center			
Date Task Reviewed/Completed	Mentee Initials	Mentor Initials	Task
			Mentee introduced to staff in the center, CRS lab staff, clinic staff, and all others as applicable
			Mentee provided with Center's Contact List
			Mentee provided with contact list for Physicians, Clinic Staff, and any other staff as applicable
			Mentee provided with any disease-specific resources (staging guidelines, tumor types, genetic markers, etc.)
			Mentor reviewed clinic schedules with mentee
			Program Manager/Supervisor ensured that mentee has disease center calendars and patient care calendars as applicable to the center • If center is utilizing SharePoint for the calendar, Program Manager/Supervisor ensured mentee has access to the Disease Center SharePoint Document Library
			Mentor reviewed with mentee how to utilize the disease center calendars and patient care calendars as applicable to the center
			Program Manager/Supervisor reviewed with mentee the call-off procedure, CRC/RC coverage, out of office, sign-outs
			Program Manager/Supervisor reviewed with mentee the team member roles: Program Manager, Supervisor, Regulatory, Safety, CRC, RC, RA, MDs, Administrative Support, Mid-levels, Collaborative Practice Nurses
			Mentor reviewed with mentee the location and use of the disease center shared folders on the Working Drive
			Program Manager/Supervisor ensured the mentee has been sent calendar invites for all disease center meetings
			Mentor reviewed with mentee the use of departmental and/or individual pagers as applicable
			Mentor ensured mentee has exposure to and demonstrates how to use the following applications: Outlook, Word, Excel, and PowerPoint. *Note: If mentee needs training in these applications, please discuss with Program Manager and QA/QC team*
			Mentee was provided a prioritized list of active studies within the center

Adverse Events			
Date Task Reviewed/Completed	**Mentee Initials**	**Mentor Initials**	**Task**
Identifying and Documenting AE			
			Mentee shown how to identify AEs and document AEs on electronic AE (eAE) log Note: This includes discussion of symptoms with patient and reviewing all of the following for potential AEs as applicable to the visit: vital signs, weight, lab results, ECG, echocardiograms, results of any other testing, MD note
			Mentee identified and documented AEs on eAE log with supervision Note: This includes discussion of symptoms with patient and reviewing all of the following for potential AEs as applicable to the visit: vital signs, weight, lab results, ECG, echocardiograms, results of any other testing, MD note
			Mentee identified and documented AEs on eAE log on own with mentor checking entry Note: This includes discussion of symptoms with patient and reviewing all of the following for potential AEs as applicable to the visit: vital signs, weight, lab results, ECG, echocardiograms, results of any other testing, MD note Any issues noted:
			Mentee can identify and document AEs on eAE log independently Note: This includes discussion of symptoms with patient and reviewing all of the following for potential AEs as applicable to the visit: vital signs, weight, lab results, ECG, echocardiograms, results of any other testing, MD note
Ensuring Study Investigator Completes AEs			
			Mentor discussed with the mentee the process for ensuring that the study investigator electronically signs the AE log and assigns study attribution and clinical significance – MD to also complete irAE and DLT as applicable to the study
			Mentee able to demonstrate follow up with study investigator if the study investigator does not electronically sign the AE log and assign study attribution and clinical significance – MD also completed irAE and DLT as applicable to the study
Requesting an eAE log			
			Mentee shown how to request an eAE log for a new patient (request form on the CRS Oncology Research SharePoint page)
			Mentee independently requests an eAE log for a new patient

			Aria Order Entry
Date Task Reviewed/Completed	**Mentee Initials**	**Mentor Initials**	**Task**
			Lab Order Entry
			Mentee shown how to enter labs via "Tests" for whenever patient will have labs obtained at HCC
			Mentee entered labs via "Tests" with supervision
			Mentee entered labs via "Tests" on own with mentor checking entry Any issues noted:
			Mentee can enter labs via "Tests" independently
			Mentee shown how to enter labs via "Physician Orders" for whenever patient will have labs obtained somewhere other than HCC
			Mentee entered labs via "Physician Orders" with supervision
			Mentee entered labs via "Physician Orders" on own with mentor checking entry Any issues noted:
			Mentee can enter in labs via "Physician Orders" independently
			CT Scan, MRI, EKG, ECHO Order Entry
			Mentee shown how to enter CT scan, MRI, EKG, ECHO orders via "Physician Orders"
			Mentee entered CT scan, MRI, EKG, ECHO orders via "Physician Orders" with supervision
			Mentee entered CT scan, MRI, EKG, ECHO orders via "Physician Orders" on own with mentor checking entry Any issues noted:
			Mentee can enter CT scan, MRI, EKG, ECHO orders via "Physician Orders" independently

			Calculations
Date Task Reviewed/Completed	**Mentee Initials**	**Mentor Initials**	**Task**
			BSA Calculation
			Mentee shown how to calculate BSA
			Mentee calculated BSA with supervision
			Mentee calculated BSA on own with mentor checking calculation Any issues noted:
			Mentee can calculate BSA independently
			ANC Calculation
			Mentee shown how to calculate ANC
			Mentee calculated ANC with supervision
			Mentee calculated ANC on own with mentor checking calculation Any issues noted:
			Mentee can calculate ANC independently
			Creatinine Clearance Calculation
			Mentee shown how to calculate creatinine clearance
			Mentee calculated creatinine clearance with supervision
			Mentee calculated creatinine clearance on own with mentor checking calculation Any issues noted:
			Mentee can calculate creatinine clearance independently

			Concomitant Medications – Documenting on Con Med Log
Date Task Reviewed/Completed	**Mentee Initials**	**Mentor Initials**	**Task**
			Mentee shown how to document concomitant medications on the con med log
			Mentee documented concomitant medications on the con med log with supervision
			Mentee documented concomitant medications on the con med log on own with mentor checking entry Any issues noted:
			Mentee can document concomitant medications on the con med log independently

Consent Withdrawal			
Date Task Reviewed/Completed	Mentee Initials	Mentor Initials	Task
			Mentor discussed with mentee consent withdrawal • How to document • Status change in OnCore • Notification of study team • Notification of sponsor • Follow up
			Mentee witnessed a consent withdrawal
			Mentee completed a consent withdrawal with supervision
			Mentee can perform a consent withdrawal independently

Disease Assessment and Imaging Core			
Date Task Reviewed/Completed	Mentee Initials	Mentor Initials	Task
Disease Assessment			
			Mentee shown how to assess disease response as applicable to their center and the type of cancer Note: This includes how the disease response is captured on the form and the CRC responsibilities regarding the form
			Mentee assessed disease response as applicable to their center and the type of cancer with supervision Note: This includes how the disease response is captured on the form and the CRC responsibilities regarding the form
			Mentee assessed disease response as applicable to their center and the type of cancer on own with mentor doublechecking the form Note: This includes how the disease response is captured on the form and the CRC responsibilities regarding the form Any issues noted:
			Mentee can assess disease response as applicable to their center and the type of cancer independently Note: This includes how the disease response is captured on the form and the CRC responsibilities regarding the form
Imaging Core			
			Mentee completed the Imaging Core training provided by QA during week 5 of mentorship
Imaging Core Calendar			
			Mentee shown how to place a patient on the Imaging Core Calendar
			Mentee placed a patient on the Imaging Core Calendar with supervision

			Mentee placed a patient on the Imaging Core Calendar on own with mentor checking entry Any issues noted:
			Mentee can place a patient on the Imaging Core Calendar independently
			Mentor explained to the mentee how to identify if there are issues with the imaging core calendar entry
			Mentee able to explain how to identify if there are issues with the imaging core calendar entry
PowerShare			
			Mentee shown how to request images from an outside facility via PowerShare. Show mentee PowerShare resources in CRS Training Portal
			Mentee requested scan images via Powershare with supervision
			Mentee can request scan images from PowerShare independently
Imaging Core Assessments			
			Mentee shown how to obtain, print, and review the Imaging Core assessments
			Mentee can demonstrate how to obtain, print, and review the Imaging Core assessments with supervision
			Mentee can obtain, print, and review the Imaging Core assessments independently
			Mentor explained to the mentee how to address if there are issues noted with the Imaging Core assessments
			Mentee able to explain how to address issues noted with the Imaging Core assessments

Deviations			
Date Task Reviewed/Completed	**Mentee Initials**	**Mentor Initials**	**Task**
			Mentor reviewed *CC-CRS-CLIN-019 Protocol Deviations* with mentee
			Mentee shown how to submit a protocol deviation
			Mentee submitted a protocol deviation with supervision
			Mentee submitted a protocol deviation on own with mentor checking entry Any issues noted:
			Mentee can submit a protocol deviation independently
Exceptions			
			Mentor discussed with mentee what an exception is
			Mentee shown how to submit an exception
			Mentee submitted an exception with supervision
			Mentee can submit an exception independently

			Risk Master
			Mentor discussed with mentee when a Risk Master needs to be submitted
			Mentee shown how to submit a Risk Master
			Mentee submitted a Risk Master with supervision
			Mentee can submit a Risk Master independently

DSMB (Data Safety Monitoring Board)			
Date Task Reviewed/Completed	**Mentee Initials**	**Mentor Initials**	**Task**
			Program Manager/Supervisor provided mentee with an overview of what the DSMB is and discussed meeting attendance • Reviewed HCC-CRS-REG-113 Data Safety Monitoring Board Meeting Attendance with mentee
			Mentee has received calendar invites to DSMB meeting and has attended DSMB meeting
Informed Consent			
Date Task Reviewed/Completed	**Mentee Initials**	**Mentor Initials**	**Task**
			Mentor reviewed *CC-CRS-CLIN-001 Informed Consent* with mentee
			Mentor reviewed *CC-CRS-CLIN-005 Timeframe for Entering Subjects into the Clinical Trials Management System (CTMS)* with mentee
			Mentor has explained informed consent process including all steps related to informed consent as noted below • Review of OnCore and eReg in determining if the MD, yourself, and your site is listed as being able to consent the patient • Determination of slot availability • How to locate and print the protocol specific informed consent • Reviewing informed consent document page by page with patient and verifying that that the patient understands • How to verify that the consent is completed appropriately by the patient (i.e. that the patient completed all required fields, that appropriate date and time is completed) • How to verify that the physician completes the consent appropriately (i.e. signs, dates, and times consent in all required fields) • Copy of signed informed consent provided to the patient • Patient entered into OnCore the same day the patient consents • CRC note to document the informed consent process – discuss key points to include in the CRC note • IVFC form completion and submission • Complete the study specific *Consent Process Form* • Upload copy of the consent into either Aria or EPIC as applicable to your site

			Mentee observed informed consent following above outline Treatment protocol? Yes / No HCC #:
			Mentee observed informed consent following above outline Treatment protocol? Yes / No HCC #:
			Mentee observed informed consent following above outline Treatment protocol? Yes / No HCC #:
			Mentee performed informed consent with supervision following above outline Treatment protocol? Yes / No HCC #:
			Mentee performed informed consent with supervision following above outline Treatment protocol? Yes / No HCC #:
			Mentee performed informed consent with supervision following above outline Treatment protocol? Yes / No HCC #:

In-Patient Admissions ☐ N/A			
Date Task Reviewed/Completed	**Mentee Initials**	**Mentor Initials**	**Task**
			Mentee completed In-Patient Admission training with QA trainer
			Mentee received access to the In-Patient Admissions SharePoint site
			Mentee shown all steps related to in-patient admissions utilizing the *In-Patient Admission Guidelines* from scheduling visit, to day of admission, to during admission, to upon discharge
			Mentee performed all steps related to in-patient admissions utilizing the *In-Patient Admission Guidelines* from scheduling visit, to day of admission, to during admission, to upon discharge with supervision
			Mentee performed all steps related to in-patient admissions utilizing the *In-Patient Admission Guidelines* from scheduling visit, to day of admission, to during admission, to upon discharge on own with mentor checking entry Any issues noted:
			Mentee can perform all steps related to in-patient admissions utilizing the *In-Patient Admission Guidelines* from scheduling visit, to day of admission, to during admission, to upon discharge independently

![UPMC Hillman Cancer Center logo]

Monitoring			
Date Task Reviewed/Completed	**Mentee Initials**	**Mentor Initials**	**Task**
			Mentor discussed with mentee monitoring expectations and CRC role
			Mentor reviewed the following SOPs with mentee • CC-CRS-CLIN-006 Site Monitoring • CC-CRS-CLIN-013 Data Queries and Discrepancies Identified by the Monitor • CC-CRS-CLIN-020 Internal Monitoring
			Mentee completed ECS-HSR training provided by QA during week 7 of mentorship
			Mentee participated in monitoring visit

New Study Implementation			
Date Task Reviewed/Completed	**Mentee Initials**	**Mentor Initials**	**Task**
			Program Manager/Supervisor performed the following with mentee • Reviewed the process for a new study start up (i.e. pre-study visit, pre-sub) with mentee • Discussed how lead CRC, RC, RA is assigned for each study • Reviewed role of lead RC • Discussed site initiation visits • Reviewed *CC-CRS-CLIN 009 Implementation Meeting* • Reviewed *CC-CRS-CLIN-015 Protocol Specific Investigator Initiated Trial Case Report Forms*
			Mentee attended SIV
			Mentee assigned as lead RC to a study
			Mentee trained on creating of study specific source documents *Note: Please reach out to QA as needed*
			Mentee has created study specific source documents

Note to File			
Date Task Reviewed/Completed	**Mentee Initials**	**Mentor Initials**	**Task**
			Mentor discussed with mentee what a Note to File is • Location of form • Reason for utilizing form
			Mentee shown how to complete a Note to File
			Mentee completed a Note to File with supervision
			Mentee can complete a Note to File independently

			Off Treatment vs Off Study
Date Task Reviewed/Completed	**Mentee Initials**	**Mentor Initials**	**Task**
			Mentor reviewed with mentee the difference between off treatment and off study • How to review protocol for any follow up required • How to capture status in OnCore
			Mentee able to recognize difference between off treatment and off study including how to capture in OnCore

			Overview of Patient Protocol Visit
Date Task Reviewed/Completed	**Mentee Initials**	**Mentor Initials**	**Task**
			Mentee introduced to MDs, Collaborative Practice Nurses, and/or mid-levels associated with clinic
			Mentor reviewed with mentee Oncore and eReg to determine who in the practice/clinic has the ability to sign consent, perform a physical exam, sign off on protocol medications, and other study related tasks
			Mentor discussed with mentee role of RC during a patient's visit
			Mentor reviewed *CC-CRS-CLIN-023 Clinical Procedures Performed by Research Staff* with mentee

			Post Visit
Date Task Reviewed/Completed	**Mentee Initials**	**Mentor Initials**	**Task**
			Printing of Source Documents Post Test/Procedure/Treatment
			Mentee shown how to print off all source documentation related to patient's visit Note: This includes but is not limited to CRC note, MD note, script for oral medications, vital signs, labs, drug administration record
			Mentee printed off all source documentation related to patient's visit with supervision Note: This includes but is not limited to CRC note, MD note, script for oral medications, vital signs, labs, drug administration record
			Mentee printed off all source documentation related to patient's visit on own with mentor checking documents printed Note: This includes but is not limited to CRC note, MD note, script for oral medications, vital signs, labs, drug administration record Any issues noted:

			Mentee can print off all source documentation related to patient's visit independently Note: This includes but is not limited to CRC note, MD note, script for oral medications, vital signs, labs, drug administration record
**Overview Post Visit**
			Mentor demonstrated to mentee how to review all information from the visit to determine if there are any protocol deviations. Protocol to be reviewed along with all tests/treatments for the visit including but not limited to vital signs, research draws, EKGs, drug administration, etc.
			Mentee demonstrated how to review all information from the visit to determine if there are any protocol deviations. Protocol to be reviewed along with all tests/treatments for the visit including but not limited to vital signs, research draws, EKGs, drug administration, etc.
			Mentor reviewed/discussed/demonstrated how to complete all source documents post visit • Mentor reviewed *CC-CRC-CLIN-002 Protocol Compliance* with mentee
			Mentee demonstrated how to complete all source documents post visit
			Mentor reviewed with mentee how to ensure treating investigator signs all required forms (i.e. physical exam form) and how to address if treating investigator does not sign
			Mentee ensured that treating investigator signs all required forms (i.e. physical exam form) and explains or follows up with what to do if the investigator does not sign
			Mentor discussed timing of providing post treatment packet to RA • Mentor reviewed *CC-CRS-CLIN-004 Data Submission Timeline* with mentee
			Mentee submitting post treatment packet to RA within 48 hours of the visit on a consistent basis

			Post Visit OnCore Documentation
Date Task Reviewed/Completed	**Mentee Initials**	**Mentor Initials**	**Task**
			Mentor reviewed *CC-CRS-CLIN-005 Timeframe for Entering Subjects into the Clinical Trials Management System (CTMS)* with the mentee
			Mentee shown how to document any test, procedure, treatment patient has received via OnCore and explained the timeframe for completion
			Mentee documented any test, procedure, treatment patient has received via OnCore with supervision and has completed the documentation within 48 hours of the test/procedure/treatment
			Mentee documented any test, procedure, treatment patient has received via OnCore within 48 hours of the test/procedure/treatment on own with mentor checking entry Any issues noted:
			Mentee can document any test, procedure, treatment patient has received via OnCore within 48 hours of the test/procedure/treatment independently

			Protocol Amendments
Date Task Reviewed/Completed	**Mentee Initials**	**Mentor Initials**	**Task**
			Mentor reviewed with mentee how we are notified of protocol amendments • Reviewed *CC-CRS-CLIN-014 Protocol Amendments, Modifications, Revisions, and Updates*
			Mentor reviewed with mentee how to identify changes to the protocol (i.e. summary of changes, red-lined version of protocol)
			Mentor reviewed with mentee that the source documents will require updates and whose responsibility it is to make the updates

			Questionnaires
Date Task Reviewed/Completed	**Mentee Initials**	**Mentor Initials**	**Task**
			Mentee shown how to address protocol specific questionnaires Note: This includes paper and electronic questionnaires
			Mentee addressed protocol specific questionnaires with supervision
			Mentee addressed protocol specific questionnaires on own with mentor reviewing after questionnaires are completed Any issues noted:
			Mentee can address protocol specific questionnaires independently

RC Note			
Date Task Reviewed/Completed	**Mentee Initials**	**Mentor Initials**	**Task**
			Mentee shown how to document RC note
			Mentee documented RC note with supervision
			Mentee documented RC note on own with mentor checking entry Any issues noted:
			Mentee can document RC note independently

Re-Consent			
Date Task Reviewed/Completed	**Mentee Initials**	**Mentor Initials**	**Task**
			Mentor discussed with mentee re-consent procedures - How the team is notified that a re-consent is required - Re-consent process - Re-consent process form - When the patient is to be re-consented - Documenting re-consent in OnCore
			Mentee witnessed a re-consent as per above
			Mentee performed a re-consent with supervision as per above
			Mentee can perform re-consent independently as per above

Registration/Randomization			
Date Task Reviewed/Completed	**Mentee Initials**	**Mentor Initials**	**Task**
			Mentor discussed the following with mentee - How to determine registration/randomization process for the study - IDS pharmacy notification process - Updating OnCore status
			Mentee shown how to register/randomize a patient as per above
			Mentee registered/randomized a patient with supervision as per above
			Mentee can register/randomize a patient independently as per above

			Report to Treatment Room Nurse
Date Task Reviewed/Completed	**Mentee Initials**	**Mentor Initials**	**Task**
			Mentor reviewed *CC-CRS-CLIN 26 Clinical Research Orders Sign Off Between CRC and Treatment Room RN* with the mentee
			Mentee shown how to provide and document face-to-face report to the treatment room nurse Note: This includes performing the CRC sign-off in Aria
			Mentee provided and documented face-to-face report to the treatment room nurse with supervision Note: This includes performing the CRC sign-off in Aria
			Mentee can provide and document face-to-face report to the treatment room nurse independently Note: This includes performing the CRC sign-off in Aria

			SAE/Expedited Reporting
Date Task Reviewed/Completed	**Mentee Initials**	**Mentor Initials**	**Task**
			Mentor assisted mentee in reaching out to center's Safety Specialist whenever the mentee has their first SAE/expedited reporting submission
			SAE
			Mentor reviewed *CC-CRS-CLIN-003 AE, SAE, and UAP reporting* with mentee
			Mentor reviewed process of SAE reporting with mentee • Reviewing protocol to determine if AE meets SAE reporting requirements • Sending SAE notification email to study team • Receiving treating MD response regarding relatedness to study drug or alternative causality as applicable • Reviewing protocol to determine how SAE is to be reported • Reporting SAE per protocol • Entering SAE into OnCore • Adding SAE to AE log • Writing note about becoming aware of SAE • Obtaining hospital records • Recording all AEs and con meds on appropriate forms as per the protocol • Submitting follow up SAE reports as applicable • Any other steps as applicable
			Mentee observed an SAE submission as per above
			Mentee performed an SAE submission with supervision as per above

			Mentee can submit an SAE independently as per above
			Expedited Reporting
			Mentee provided with CTEP-AERS resources • SharePoint site *CRS Training Portal > CRS Process Training > CTEP-AERS Training* • CTEP-AERS website with multiple resources available: Welcome to CTEP-AERS (nih.gov)
			Mentor reviewed expedited reporting with mentee • Expedited reporting requirements for cooperative group studies (NCI, Theradex, Alliance, ECOG-ACRIN, NRG, SWOG) • How to review the protocol to determine if an adverse event meets expedited reporting requirements • Following steps under SAE submission, however all expedited reporting occurs via CTEP-AERS • AE reported via CTEP-AERS
			Mentee observed CTEP-AERS submission as per above and per SAE submission
			Mentee performed a CTEP-AERS submission as per above and per SAE submission with observation
			Mentee can submit CTEP-AERS submission as per above and per SAE submission independently

Scheduling			
Date Task Reviewed/Completed	**Mentee Initials**	**Mentor Initials**	**Task**
Scheduling a Screening EKG or ECHO at a UPMC Facility			
			Mentee shown how to schedule a screening EKG or ECHO at a UPMC facility Includes: Actual scheduling of test, order entry, printing order, emailing order to case management, faxing order to UPMC facility, scheduling test visit in Aria, providing patient with copy of the order
			Mentee scheduled a screening EKG or ECHO at a UPMC facility with supervision Includes: Actual scheduling of test, order entry, printing order, emailing order to case management, faxing order to UPMC facility, scheduling test visit in Aria, providing patient with copy of the order
			Mentee scheduled a screening EKG or ECHO at a UPMC facility on own with mentor checking entry Includes: Actual scheduling of test, order entry, printing order, emailing order to case management, faxing order to UPMC facility, scheduling test visit in Aria, providing patient with copy of the order Any issues noted:
			Mentee can schedule a screening EKG or ECHO at a UPMC facility independently

			Includes: Actual scheduling of test, order entry, printing order, emailing order to case management, faxing order to UPMC facility, scheduling test visit in Aria, providing patient with copy of the order
Scheduling a Screening EKG or ECHO at a non-UPMC Facility			
			Mentee shown how to schedule a screening EKG or ECHO at a non-UPMC facility Includes: Obtaining pre-auth for tests being billed to insurance, obtaining manager approval for tests being billed to research, actual scheduling of test, completion of External Requestion form, order entry, printing order, emailing order to case management, faxing order to UPMC facility, scheduling test visit in Aria, providing patient with copy of the order
			Mentee scheduled a screening EKG or ECHO at a non-UPMC facility with supervision Includes: Obtaining pre-auth for tests being billed to insurance, obtaining manager approval for tests being billed to research, actual scheduling of test, completion of External Requestion form, order entry, printing order, emailing order to case management, faxing order to UPMC facility, scheduling test visit in Aria, providing patient with copy of the order
			Mentee scheduled a screening EKG or ECHO at a non-UPMC facility on own with mentor checking entry Includes: Obtaining pre-auth for tests being billed to insurance, obtaining manager approval for tests being billed to research, actual scheduling of test, completion of External Requestion form, order entry, printing order, emailing order to case management, faxing order to UPMC facility, scheduling test visit in Aria, providing patient with copy of the order Any issues noted:
			Mentee can schedule a screening EKG or ECHO at a non-UPMC facility independently Includes: Obtaining pre-auth for tests being billed to insurance, obtaining manager approval for tests being billed to research, actual scheduling of test, completion of External Requestion form, order entry, printing order, emailing order to case management, faxing order to UPMC facility, scheduling test visit in Aria, providing patient with copy of the order
Scheduling On-STUDY CT scan, MRI, EKG, ECHO			
			Mentee completed the Scheduling Portal training provided by QA during week 3 of mentorship
			Mentee shown how to schedule an on-study CT scan, MRI, EKG, ECHO via Scheduling portal
			Mentee scheduled an on-study CT scan, MRI, EKG, ECHO via Scheduling portal with supervision
			Mentee scheduled on-study CT scan, MRI, EKG, ECHO via Scheduling portal on own with mentor checking entry Any issues noted:
			Mentee can schedule on-study CT scan, MRI, EKG, ECHO via Scheduling portal independently

			Screening/Eligibility
Date Task Reviewed/Completed	**Mentee Initials**	**Mentor Initials**	**Task**
			Mentor reviewed *CC-CRS-CLIN-007 Subject Eligibility* with the mentee
			Mentor discussed with mentee all steps for screening a patient including but not limited to the following • Review of the protocol to determine all required protocol specific screening and the allowable timeframes • Review of the protocol to determine registration/randomization timeframes and how to register/randomize the patient • Ensuring that all research related tests were performed after the informed consent was obtained • Scheduling all required screening tests/procedures and visits as applicable • Updating the patient's calendar in OnCore • IDS pharmacy notification • Completing all CRS study specific forms • Obtaining all source documents (i.e. treatment records, pathology reports) • Completing screening/eligibility packet and performing a 1st check • Completing CRS study specific eligibility checklist • Completing sponsor specific eligibility checklist as applicable • Ensuring MD signatures on all documents (i.e. EKG, eligibility checklists, Baseline Medical Problems form)
			Mentor discussed with mentee actions to take if patient is ineligible
			Mentee able to describe actions to take if patient is ineligible
			Mentee observed screening/eligibility as per above HCC#
			Mentee observed screening/eligibility as per above HCC#
			Mentee completed screening/eligibility as per above with supervision HCC#
			Mentee completed screening/eligibility as per above with supervision HCC#
			Mentee completed screening/eligibility on own as per above with mentor review HCC#
			Mentee completed screening/eligibility on own as per above with mentor review HCC#
			Mentee can complete screening/eligibility independently as per above

Vincent			
Date Task Reviewed/Completed	Mentee Initials	Mentor Initials	Task
UPMC Vincent ☐ N/A			
			Mentee completed the UPMC Vincent training provided by QA during week 3 of mentorship
			Mentee received access into the UPMC Vincent system
			Mentor reviewed how to determine if patient requires reimbursement for a visit
			Mentee utilized the UPMC Vincent system to reimburse a patient for their visit
Pitt Vincent ☐ N/A			
			Mentee completed the Pitt Vincent training provided by QA during week 3 of mentorship
			Mentee received access into the Pitt Vincent system
			Mentor reviewed how to determine if patient requires reimbursement for a visit
			Mentee utilized the Pitt Vincent system to reimburse a patient for their visit

Current Workload Mentee to complete this prior to each touch base meeting *Mentee to be assigned patients beginning week 4 or 5.* *Patient assignment is to be added to each week as appropriate to slowly build up CRC's workload.*					
Week #	**Number of Patients in Screening**	**Number of Patients on Study**	**Number of Patient in Follow Up**	**Other Assignments/Workload and/or Comments**	**Mentee Initials**

Week #	Protocol compliance	Timeliness of tasks	Attention to details	Organizational skills such as time management, prioritization of tasks, delegation, and communication skills	Comments
	Observational With Supervision Semi-independent Independent	Observational With Supervision Semi-independent Independent	Observational With Supervision Semi-independent Independent	Observational With Supervision Semi-independent Independent	
	Observational With Supervision Semi-independent Independent	Observational With Supervision Semi-independent Independent	Observational With Supervision Semi-independent Independent	Observational With Supervision Semi-independent Independent	
	Observational With Supervision Semi-independent Independent	Observational With Supervision Semi-independent Independent	Observational With Supervision Semi-independent Independent	Observational With Supervision Semi-independent Independent	
	Observational With Supervision Semi-independent Independent	Observational With Supervision Semi-independent Independent	Observational With Supervision Semi-independent Independent	Observational With Supervision Semi-independent Independent	
	Observational With Supervision Semi-independent Independent	Observational With Supervision Semi-independent Independent	Observational With Supervision Semi-independent Independent	Observational With Supervision Semi-independent Independent	
	Observational With Supervision Semi-independent Independent	Observational With Supervision Semi-independent Independent	Observational With Supervision Semi-independent Independent	Observational With Supervision Semi-independent Independent	
	Observational With Supervision Semi-independent Independent	Observational With Supervision Semi-independent Independent	Observational With Supervision Semi-independent Independent	Observational With Supervision Semi-independent Independent	

Assessment of Mentee
Mentor is to complete this prior to each touch base meeting
Circle item in each column for the week that most closely matches mentee's capability for each task

Anyone who has placed their initials on this form should provide their initials and signature below:

Initials	Signature	Initials	Signature

By signing this document, we acknowledge that the mentee has received training for the skills and processes listed within the pages of this packet and that the mentee has formally completed the mentorship.

_____   _____

Mentee Signature   Date

_____   _____

Mentor Signature   Date

_____   _____

Manager/Supervisor Signature   Date

_____   _____

QA/QC Manager Signature   Date