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

- o For Community/Magee RAs:

    - ▪ Beginnings @ UPMC Cancer Center   _____

    - ▪ Beginnings @ Magee/UPMC hospital   _____

    - ▪ EPIC Training   _____

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

RA Skills Checklist Packet:

- The RA 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. Core Tasks
    8. Data Entry
    10. Monitoring and Implementation
    11. Laboratory and Research Samples
    14. Consents and Re-Consents
    15. Clinical

Completion of RA 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 19 – Current Workload
    — Mentor to complete page 20 – 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 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 list prioritized list of active studies within the center
			Mentee has database and other accesses for the studies they will be on and electronically introduced the mentee to the study monitor as applicable

Core Tasks			
Date Task Reviewed/Completed	**Mentee Initials**	**Mentor Initials**	**Task**
Charts/Folders for Patient Visits			
			Mentee shown how to prepare charts/folders for patient visits (i.e., printing visit checklists, re-consents, questionnaires, extra concomitant medication logs, etc.)
			Mentee prepared charts/folders for patient visits (i.e., printing visit checklists, re-consents, questionnaires, extra concomitant medication logs, etc.) with supervision
			Mentee prepared charts/folders for patient visits (i.e., printing visit checklists, re-consents, questionnaires, extra concomitant medication logs, etc.) with mentor checking packets Any issues noted:
			Mentee can prepare charts/folders for patient visits (i.e., printing visit checklists, re-consents, questionnaires, extra concomitant medication logs, etc.) independently
Research Charts			
			Mentee shown how to organize and file patient visit data in research charts referencing Chart Overview Quick Sheet and Green or Blue Research Chart Set-Up Schematic
			Mentee organized and filed patient visit data in research charts referencing Chart Overview Quick Sheet and Green or Blue Research Chart Set-Up Schematic with supervision
			Mentee organized and filed patient visit data in research charts referencing Chart Overview Quick Sheet and Green or Blue Research Chart Set-Up Schematic with mentor checking the work Any issues noted:
			Mentee can organize and file patient visit data in research charts referencing Chart Overview Quick Sheet and Green or Blue Research Chart Set-Up Schematic independently
Screening Packets			
			Mentee shown how to assemble charts and organize screening packets for newly enrolled patients
			Mentee assembled charts and organized screening packets for newly enrolled patients with supervision

			Mentee assembled charts and organized screening packets for newly enrolled patients with mentor checking the work Any issues noted:
			Mentee can assemble charts and organize screening packets for newly enrolled patients independently
AE Grading and Reporting			
			Mentee shown how to assist in verifying AE grading and reporting
			Mentee assisted in verifying AE grading and reporting with supervision
			Mentee assisted in verifying AE grading and reporting with mentor checking the work Any issues noted:
			Mentee can assist in verifying AE grading and reporting independently
Lab Kits and Lab Kit "Bin" Process			
			Mentee shown how to assemble lab kits and review the lab kit "bin" process (mentee can assist with any kit builds even if they are not assigned to the study)
			Mentee assembled lab kits and followed the lab kit "bin" process (mentee can assist with any kit builds, even if they are not assigned to the study) with supervision
			Mentee assembled lab kits and followed the lab kit "bin" process (mentee can assist with any kit builds, even if they are not assigned to the study) with mentor checking the work Any issues noted:
			Mentee can assist in assembling lab kits and follow the lab kit "bin" process (mentee can assist with any kit builds, even if they are not assigned to the study) independently
Weekly Lab/Clinic Lists			
			Mentee shown how to put together weekly lab/clinic lists
			Mentee put together weekly lab/clinic lists supervision
			Mentee put together weekly lab/clinic lists with mentor checking entries Any issues noted:
			Mentee puts together weekly lab/clinic lists independently
Outside Hospital Records Request for Screening Packets or SAE Reporting			

			Mentee shown how to assist CRCs to request outside hospital records for screening packets or SAE reporting
			Mentee assisted CRCs to request outside hospital records for screening packets or SAE reporting with supervision Any issues noted:
			Mentee can assist CRCs to request outside hospital records for screening packets or SAE reporting independently
**OnCore and eREG**		
			Mentee shown how to navigate OnCore and eREG and how to check the staff list in eREG. Note: If mentee is not listed in the staff list for their studies, email primary Regulatory Specialist to request protocol training to be assigned in eREG.
			Mentee navigated OnCore and eREG and checked the staff list in eREG with supervision Any issues noted:
			Mentee can navigate OnCore and eREG and can check the staff list in eREG independently Note: If mentee is not listed in the staff list for their studies, email primary Regulatory Specialist to request protocol training to be assigned in eREG.
**Electronic Medical Records (EMRs) - ARIA, PowerChart, and Epic**		
			Mentee shown how to use ARIA, PowerChart, and Epic to retrieve patient medical records
			Mentee used ARIA, PowerChart, and Epic to retrieve patient medical records with supervision.
			Mentee used ARIA, PowerChart, and Epic to retrieve patient medical records with mentor checking the work Any issues noted:
			Mentee can use ARIA, PowerChart, and Epic to retrieve patient medical records independently
**Biopsy Procedure Scheduling**		
			Mentee shown the biopsy scheduling procedure Note: May occur at any time during mentorship period, depending on available opportunities
			Mentee followed steps for biopsy scheduling procedure with supervision

			Mentee scheduled a biopsy procedure with mentor checking the work Any issues noted:
			Mentee can schedule a biopsy procedure independently
Pager Use
			Mentee shown how to learn proper use of pager: both individual and team pagers (if applicable)
			Mentee used both individual and team pagers (if applicable) with supervision
			Mentee can use both individual and team pagers (if applicable) independently

Data Entry
Date Task Reviewed/Completed	**Mentee Initials**	**Mentor Initials**	**Task**
Complexity/Workflow Analysis
			Mentee shown how to enter number of queries answered bi-weekly in OnCore
			Mentee entered number of queries answered biweekly in OnCore with supervision
			Mentee can enter number of queries answered biweekly in OnCore independently
Data Entry in REDCap (for IIT studies) □ N/A
			Mentee shown how to enter data in REDCap
			Mentee practiced entering data in REDCap with supervision
			Mentee practiced entering data in REDCap with mentor checking entries Any issues noted:
			Mentee can correctly enter data in REDCap independently
Data Entry in iMedidata RAVE (and other EDC systems e.g., InForm, TAO/Oracle, etc.)
			Mentee shown how to enter data in iMedidata RAVE
			Mentee practiced entering data in iMedidata RAVE with supervision
			Mentee practiced entering data in iMedidata RAVE with mentor checking entries Any issues noted:
			Mentee can correctly enter data in iMedidata RAVE independently

			Matrix Ray ☐ N/A
			Mentee shown how to use Matrix Ray to de-identify and retrieve scans for upload
			Mentee used Matrix Ray to de-identify and retrieve scans for upload with supervision
			Mentee can use Matrix Ray to de-identify and retrieve scans for upload independently
			EIMS
			Mentee shown how to upload scan images from a disk using EIMS (External Image Management System)
			Mentee uploaded scan images from a disk using EIMS (External Image Management System) with supervision
			Mentee can upload scan images from a disk using EIMS (External Image Management System) independently
			Scan Images Upload
			Mentee shown how to upload scan images to sponsor-specific imaging portal (e.g., AG Mednet, Bioclinica/Clario, Perceptive, etc.)
			Mentee uploaded scan images to sponsor-specific imaging portal (e.g., AG Mednet, Bioclinica/Clario, Perceptive, etc.) with supervision
			Mentee uploaded scan images to sponsor-specific imaging portal (e.g., AG Mednet, Bioclinica/Clario, Perceptive, etc.) with mentor checking the work (if applicable) Any issues noted:
			Mentee can upload scan images to sponsor-specific imaging portal (e.g., AG Mednet, Bioclinica/Clario, Perceptive, etc.) independently
			Query Resolution
			Mentee shown how to answer queries and work with study monitor on query resolution as applicable
			Mentee answered queries and worked with study monitor on query resolution with supervision
			Mentee answered queries and worked with study monitor on query resolution with mentor checking entries Any issues noted:
			Mentee can answer queries and work with study monitor on query resolution independently
			De-Identifying Data/Records
			Mentee shown how to de-identify data/records for submission to sponsor or central lab review

			Mentee de-identified data/records for submission to sponsor or central lab review with supervision
			Mentee de-identified data/records for submission to sponsor or central lab review with mentor checking the work Any issues noted:
			Mentee can de-identify data/records for submission to sponsor or central lab review independently

Data Entry SOPS:
- HCC-CRS-CLIN-004: Data Submission Timeline
- HCC-CRS-CLIN-013: Data Queries and Discrepancies Identified by Monitor
- HCC-CRS-CLIN-010: Case Report Form (CRF) Completion
- HCC-CRS-CLIN-015: Protocol Specific Investigator Initiated Trial CRFs
- HCC-CRS-CLIN-027: Data Verification for Analysis
- HCC-CRS-CLIN-018: Oral Study Drug Documentation
- HCC-CRS-CLIN-032: Tumor Measurement Process

Monitoring and Implementation			
Date Task Reviewed/Completed	Mentee Initials	Mentor Initials	Task
Monitor and Pharmacy Visits			
			Mentee shown how to schedule Monitor visits and Pharmacy visits and add visit to OnCore
			Mentee scheduled Monitor visits and Pharmacy visits and add visit to OnCore with supervision
			Mentee scheduled Monitor visits and Pharmacy visits and add visit to OnCore with mentor checking entries Any issues noted:
			Mentee can schedule Monitor visits and Pharmacy visits and add visit to OnCore independently
Monitoring Expectations			
			Mentor will review monitoring expectations with mentee Note: Mentor or QA staff verify research chart organization
Attestation Form			
			Mentee shown how to complete an attestation form
			Mentee completed an attestation form with supervision
			Mentee can complete an attestation form independently
Site Initiation Visit (SIV) Scheduling			

			Mentee shown the procedures for scheduling a pharmaceutical trial SIV and add visit to OnCore
			Mentee scheduled a pharmaceutical trial SIV and add visit to OnCore with supervision and/or with mentor checking the work Any issues noted:
			Mentee scheduled a pharmaceutical trial SIV and add visit to OnCore independently
Protocol Deviations
			Mentee shown how to enter Protocol deviations into OnCore
			Mentee entered Protocol deviations into OnCore with supervision
			Mentee entered Protocol deviations into OnCore with mentor checking entries Any issues noted:
			Mentee can enter Protocol deviations into OnCore independently

Monitoring and Implementation SOPs:

- o HCC-CRS-CLIN-002: Protocol Compliance
- o HCC-CRS-CLIN-003: Adverse Event (AE), Serious Adverse Event (SAE), and Unanticipated Problem (UAP) Reporting
- o HCC-CRS-CLIN-006: Site Monitoring
- o HCC-CRS-CLIN-009: Implementation Meeting/Site Initiation Visit (SIV)
- o HCC-CRS-CLIN-013: Data Queries and Discrepancies Identified by the Monitor
- o HCC-CRS-CLIN-019: Protocol Deviations
- o HCC-CRS-CLIN-020: Internal Monitoring
- o HCC-CRS-CLIN-021: Sponsor and Monitor Access to Electronic Medical Record
- o HCC-CRS-CLIN-027: Data Verification for Analysis
- o HCC-CRS-REG-101: Delegation of Authority Log
     HCC-CRS-REG-110: Electronic Regulatory File

**Laboratory and Research Samples**
Date Task Reviewed/Completed	**Mentee Initials**	**Mentor Initials**	**Task**
Fresh Tissue Biopsy Preparation
			Mentee shown how to prepare for fresh tissue biopsy (may include: sending feasibility email, Short Stay Unit reservation, sending biopsy blast email, etc.)
			Mentee prepared for fresh tissue biopsy (may include: sending feasibility email, Short Stay Unit reservation, sending biopsy blast email, etc.) with supervision

			Mentee prepared for fresh tissue biopsy (may include: sending feasibility email, Short Stay Unit reservation, sending biopsy blast email, etc.) with mentor checking the work Any issues noted:
			Mentee can prepare for fresh tissue biopsy (may include: sending feasibility email, Short Stay Unit reservation, sending biopsy blast email, etc.) independently
**Attend Fresh Tissue Collection**		
			Mentee shown how to prepare for (label collection containers, prepare timesheet, etc.) and attend a fresh tissue collection with mentor **AND** CRS Lab staff
			Mentee prepared for (label collection containers, prepare timesheet, etc.) and attended a fresh tissue collection with supervision and/or with mentor **AND** CRS Lab staff checking the work Any issues noted:
			Mentee can prepare for (label collection containers, prepare timesheet, etc.) and attend a fresh tissue collection independently
**Archival Tissue Request (Internal - UPMC Facility)**		
			Mentee shown how to request archival tissue from Developmental Laboratory
			Mentee requested archival tissue from Developmental Laboratory and through outside institutions with supervision
			Mentee requested archival tissue from Developmental Laboratory and through outside institutions with mentor checking the work Any issues noted:
			Mentee can request archival tissue from Developmental Laboratory and through outside institutions independently
**Archival Tissue Request (External Facility)**		
			Mentee shown how to request archival tissue from outside institutions by utilizing the Clinical Research Trial Requisition for Obtaining Pathology Materials
			Mentee requested archival tissue from outside institutions by completing the Clinical Research Trial Requisition for Obtaining Pathology Materials with supervision

			Mentee requested archival tissue from outside institutions by completing the Clinical Research Trial Requisition for Obtaining Pathology Materials with mentor checking the work Any issues noted:
			Mentee can request archival tissue from outside institutions by completing the Clinical Research Trial Requisition for Obtaining Pathology Materials independently
**Research Lab Supplies Ordering/Re-Ordering**
			Mentee shown how to order research lab supplies from study vendor/central lab
			Mentee ordered research lab supplies from study vendor/central lab with supervision
			Mentee ordered research lab supplies from study vendor/central lab with mentor checking entries Any issues noted:
			Mentee can order research lab supplies from study vendor/central lab independently
**Research Lab Supplies Inventory**
			Mentee shown how to complete inventory of research kits, shippers, and other lab-related supplies on-site for each study using Slope, spreadsheet, etc.
			Mentee completed inventory of research kits, shippers, and other lab-related supplies on-site for each study using Slope, spreadsheet, etc. with supervision
			Mentee can complete inventory of research kits, shippers, and other lab-related supplies on-site for each study using Slope, spreadsheet, etc. independently
**BioMS/ECOG-ACRIN/SWOG Specimen Tracking System □ N/A**
			Mentee shown how to log samples and prepare shipments
			Mentee logged samples and prepared shipments with supervision
			Mentee logged samples and prepared shipments with mentor checking entries and/or the work Any issues noted:
			Mentee can log samples and prepare shipment independently
**Lab SOPs:**
o HCC-CRS-CLIN-029: Lab Specimen Collection, Processing, and Shipping o HCC-CRS-LAB-001: Specimen Receipts o HCC-CRS-LAB-002: Laboratory Safety

			HCC-CRS-LAB-003: Tissue Requests
		o	HCC-CRS-LAB-004: Lab Kit Retention and Destruction

Consents and Re-Consents			
Date Task Reviewed/Completed	**Mentee Initials**	**Mentor Initials**	**Task**
Registry/Tissue Consent Process □ N/A			
			Mentor discussed with mentee registry/tissue consent procedures; allow mentee to practice 'mock' consenting on other staff • How the team is notified when consent is needed • Consent process • Consent process form • Registering the patient in OnCore • When the patient is to be re-consented
			Mentee demonstrated the process when obtaining registry/tissue consent with supervision
			Mentee demonstrated the process when obtaining registry/tissue consent with mentor checking the work Any issues noted:
			Mentee can demonstrate the process when obtaining registry/tissue consent independently
Re-Consent			
			Mentee shown how to prepare patient chart for re-consent
			Mentee prepared patient chart for re-consent with supervision
			Mentee prepared patient chart for re-consent with mentor checking the work Any issues noted:
			Mentee can prepare patient chart for re-consent independently
Consent SOPs:			
		o	HCC-CRS-CLIN-001: Informed Consent
		o	HCC-CRS-CLIN-008: Re-Consent Policy
		o	HCC-CRS-CLIN-014: Protocol Amendments, Modifications, Revisions, and Update

Clinical			
Date Task Reviewed/Completed	**Mentee Initials**	**Mentor Initials**	**Task**
Questionnaires (QOLs/ePRO)			
			Mentee shown how to complete in-clinic questionnaires with patients: should include both paper questionnaires and tablet questionnaires, as applicable
			Mentee completed in-clinic questionnaires with patients: should include both paper questionnaires and tablet questionnaires, as applicable, with supervision
			Mentee completed in-clinic questionnaires with patients: should include both paper questionnaires and tablet questionnaires, as applicable, with mentor checking the work Any issues noted:
			Mentee can complete in-clinic questionnaires with patients: should include both paper questionnaires and tablet questionnaires, as applicable, independently
OnCore Entry of Screening Patients □ N/A			
			Mentee shown how to enter or register Screening patients in OnCore
			Mentee entered or registered Screening patients in OnCore with supervision
			Mentee entered or registered Screening patients in OnCore with mentor checking the work Any issues noted:
			Mentee can enter or register Screening patients in OnCore independently
IWRS/IVRS/Other Randomization or Drug Dispense Systems □ N/A			
			Mentee shown how to complete study drug assignment using IWRS/IVRS/other systems, as applicable
			Mentee completed study drug assignment using IWRS/IVRS/other systems, as applicable, with supervision

			Mentee completed study drug assignment using IWRS/IVRS/other systems, as applicable, with mentor checking entries Any issues noted:
			Mentee can complete study drug assignment using IWRS/IVRS/other systems, as applicable, independently
Follow-up visits/Survival Follow-up			
			Mentee shown how to confirm patient survival and update the patient calendar in OnCore
			Mentee confirmed patient survival and update the patient calendar in OnCore, with supervision
			Mentee confirmed patient survival and update the patient calendar in OnCore, with mentor checking work Any issues noted:
			Mentee confirmed patient survival and update the patient calendar in OnCore independently

Clinical SOPs:
- o HCC-CRS-CLIN-005: Timeframe for entering subjects into the Clinical Trials Management System (CTMS)
- o HCC-CRS-CLIN-007: Subject Eligibility

Implementation Slides ☐ N/A			
			Mentee shown how to create implementation slides (for Cooperative Group and IIT trials)
			Mentee created implementation slides (for Cooperative Group and IIT trials) with supervision
			Mentee created implementation slides (for Cooperative Group and IIT trials) with mentor checking the work Any issues noted:
			Mentee can create implementation slides (for Cooperative Group and IIT trials) independently
Medical Records			
			Mentor shown how to assist CRC in screening patients, such as requesting and/or printing medical records and prior treatment records, etc.
			Mentee assisted CRC in screening patients, such as requesting and/or printing medical records and prior treatment records, etc. with supervision

			Mentee can assist CRC in screening patients, such as requesting and/or printing medical records and prior treatment records, etc. independently
			ECGs
			Mentor shown how to perform ECGs (for protocols requiring use of study machine): should also include instruction of how ECGs are transmitted to the sponsor/vendor
			Mentee performed ECGs (for protocols requiring use of study machine) and transmitted ECGs to the sponsor/vendor with supervision Any issues noted:
			Mentee can perform ECGs (for protocols requiring use of study machine) and transmit ECGs to the sponsor/vendor independently
			SAE Reporting
			Mentor shown how to assist CRC in reporting SAE – print medical records and assist with form completion, as necessary: discuss procedures for direct database entry
			Mentee assisted CRC in reporting SAE – print medical records and assist with form completion, as necessary: performed direct database entry with supervision
			Mentee assisted CRC in reporting SAE – print medical records and assist with form completion, as necessary: performed direct database entry with mentor checking the work or entries Any issues noted:
			Mentee can assist CRC in reporting SAE – print medical records and assist with form completion, as necessary: performs direct database entry independently
			Dose Modifications
			Mentor shown how to assist CRC in determining if dose modifications are appropriate
			Mentee assisted CRC in determining if dose modifications are appropriate with supervision
			Mentee can assist CRC in determining if dose modifications are appropriate independently
			Source Documents Creation
			Mentee shown how to create source documents, such as CRS source logs and forms, visit checklists, etc. for New Study Start-Up
			Mentee created source documents, such as CRS source logs and forms, visit checklists, etc. for New Study Start-Up with supervision

			Mentee created source documents, such as CRS source logs and forms, visit checklists, etc. for New Study Start-Up with mentor checking the work Any issues noted:
			Mentee can create source documents, such as CRS source logs and forms, visit checklists, etc. for New Study Start-Up independently
	Source Documents Update for Protocol Amendments		
			Mentee shown how to update source documents for protocol amendments
			Mentee updated source documents for protocol amendments with supervision
			Mentee updated source documents for protocol amendments with mentor checking the work Any issues noted:
			Mentee can update source documents for protocol amendments independently
	Source Documentation Review		
			Mentor shown how to review AEs, Con Meds, RECIST, pill diaries, vital signs, weight, etc. during visits
			Mentee reviewed AEs, Con Meds, RECIST, pill diaries, vital signs, weight, etc. during visits with supervision
			Mentee reviewed AEs, Con Meds, RECIST, pill diaries, vital signs, weight, etc. during visits with mentor checking the work Any issues noted:
			Mentee can review AEs, Con Meds, RECIST, pill diaries, vital signs, weight, etc. during visits independently
	Protocol-Specific Treatment Criteria		
			Mentor shown how to ensure patient meets all protocol-specific treatment criteria
			Mentee ensured patient meets all protocol-specific treatment criteria with supervision
			Mentee can ensure patient meets all protocol-specific treatment criteria independently
	Note to File		
			Mentee shown how to complete a Note to File (NTF)
			Mentee completed a Note to File (NTF) with supervision

			Mentee completed a Note to File (NTF) with mentor checking the work Any issues noted:
			Mentee can complete a Note to File (NTF) independently

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 RA'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
---	---	---	---	---	---
	N/A	N/A	N/A		

				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	

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	

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