Summary of CCR Quality Management Activities for FY2022

(1/17/2023)

CCR QM Goals and Activities for FY2022

The table below lists CCR QM goals and activities for FY2022.

Fy2022 QM Goal	**Activities and Accomplishments**
Provide clinical research staff training and education based on consultation requests, monitoring/audit trends and changes in regulations and/or IRP polices and guidances.	Conducted numerous team-specific training sessions/meetings as well as answering numerous questions/consults on a daily basis related to research conduct and existing regulatory/ policy implementation.

Provide education for clinical research staff targeting regulatory and other clinical research conduct topics based on QA activities and new/revised IRP and CCR policies.	• Provided 12 education and training sessions to all CCR clinical research staff pertaining to regulatory and clinical research topics.
	• Provided 10 educational sessions related to oncology and other clinical topics.
	• Provided 3 clinical trial orientation sessions for CCR clinical research staff (RN, DM, PSO, NP, PA). Each session consisted of 3 virtual meetings that built upon the online learning modules to focus on how clinical research is operationalized in the NIH IRP and the CCR. Each session totaled 6.5 hours.
	• Conducted 3 sessions dedicated to the research nurse study coordinator. Each session consisted of 4 virtual meetings each specifically focused on their role. Each session totaled 10 hours.
	• Reviewed and revised 90% of all M2P2s. Three new M2P2s created:
	  • #68: *I know what a Curriculum Vitae (CV) is, but are there any particulars that I need to know related to CCR requirements?*
	  • #69 *What is iMedConsent™?*
	  • #70: *What is an Expanded Access Use IND/IDE (also called "Single Patient" or "Compassionate Use")?*

Continue to develop, review and revise CCR SOPs and guidelines	New CCR SOPS • PM-5: *Research Protocol Training Requirements.* • PM-16: *Protocol Deviation Tracking* • RPS-25: *Registering Research Studies on ClinicalTrials.gov*

	• RPS-26: *Results Reporting for Research Studies on ClinicalTrials.gov* Revised CCR SOPS • ADGC-1: *SOP Review and Approval Process* • ADGC-5: *Tumor/Normal Whole Exome Sequencing: Consenting, Ordering, and Obtaining Results* • ADCR-5: *Travel and Lodging Reimbursement for CCR Clinical Research Participants, Pediatric Guardians, and Authorized Attendants* • PM-1: *Principal Investigator (PI)Delegation of Tasks for Research* • PM-6: *Guidelines for the Development and Maintenance of Regulatory Files/Binders* • PM-7: *Clinical Research Study Initiation* • PM-9: *Research Team Amendment Training* • PM-13: *Center for Cancer Research and Industry Sponsored Monitoring and Audit Visits* – split into 3 separate SOPs ○ 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 (Arctic Slope Regional Corporation).* • RPS-21 *Establishing a Genomic Data Sharing Project and Required Documents* • RPS-22: *Requesting a Genomic Data Sharing Exception* • PRS-23: *Registering a Clinical Trial in dbGaP*
Conduct informed consent audits on protocols actively enrolling participants and follow-up as needed.	• Informed consent audits on 3 protocols were conducted. • Instituted 100% monitoring of informed consent and eligibility for all subjects enrolled on non-IND treatment and observational studies.
Conduct routine audits for observational studies, starting with natural history studies.	Instituted risk-based routine audits for all non-IND treatment and observational studies. These are conducted by ASRC.

	• 92% (44/48) of non-IND/IDE protocols monitored • 12% (12/104) of observational protocol monitored and 15% (16/104) audited.
Evaluate effectiveness of CAPA responses, including external sponsor protocols.	There were 2 formal CAPAs requested by sponsor and/or IRB. These were reviewed periodically to ensure that all activities are completed, and no further trends noted.
Ensure compliance with IRB outcome letter requirements when protocols are put on hold due to safety issue	Implemented process for Protocol Support Office to notify the Office of Education and Compliance (OEC) for all IRB outcome letters that require action by the research team. This allows OEC to follow-up with teams for further actions as needed. These are not limited to only protocols that have been placed on hold for safety issues.
Monitor timeliness of SAE/AESI reporting to sponsor	There were 202 self-reported SAEs with 4% being reported late to the sponsor with a median of 2 days late reporting. Since FY18 we have ranged from 3.5% (FY19) - 9% (FY18) late reporting.
Develop and implement a protocol deviation tracking database.	Protocol Deviation Tracking System (PDTS) database implemented along with User Manual, effective November 2021.
Conduct risk-based audits as a result of other QA activities.	None required.

Summary of Trends in QM Activities

There are 5 main trends noted from the QM activities.

1. Overall improvement in informed consent process, including documentation in CRIS. However, there is still a lack of understanding with some teams of the short form consent process and implementation of process in iMED.
2. Lack of timely reconsenting when required by the IRB, especially when new risk information is added to the revised consent.
3. Lack of documentation of initial protocol and amendment training as required by GCP and CCR SOPs.
4. Majority of audit and monitoring findings involve issues with documentation and data management (database inconsistent with source documents, lack of source documents, inadequate source documentation, missing data in database, late data entry). Education and training of the research teams continue to help decrease data management issues.
5. Some data being entered into PDTS database lacks sufficient detail to assess team's preventive actions to decrease protocol deviations.

CCR QM Goals and Activities for FY2023

The following are the CCR QM goals and activities for FY2023:

1. Provide clinical research staff training and education based on consultation requests, monitoring/audit trends and changes in regulations and/or IRP polices and guidances.
2. Review and revise CCR SOPs and guidelines.
3. Develop new CCR SOPs and guidelines based on regulatory updates, NIH policy revisions, and audit/monitoring report findings
4. Audit CCR SOP compliance for selected SOPs, including protocol training, amendment training and informed consent as needed.
5. Monitor timeliness of SAE/EASI reporting to sponsor.
6. Track and trend monitoring and audit report findings.
7. Track and trend protocol deviations and revise PDTS as needed.
8. Ensure compliance with IRB outcome letters requirements.

These will be accomplished by the following metrics.

Quality Management Activity	Oct-22	Nov-22	Dec-22	Jan-23	Feb-23	Mar-23	Apr-23	May-23	Jun-23	Jul-23	Aug-23	Sep-23
Track timeliness of SAE reporting	X	X	X	X	X	X	X	X	X	X	X	X
Track & trend deviations	X	X	X	X	X	X	X	X	X	X	X	X
Track & trend all audits, monitoring visits, inspections	X	X	X	X	X	X	X	X	X	X	X	X
Conduct study start up meeting for CTEP sponsored protocols	X	X	X	X	X	X	X	X	X	X	X	X
Develop, review and revise SOPs	X	X	X	X	X	X	X	X	X	X	X	X
IC/EC review for non-IND intervention and observational protocols (done by ASRC)	X	X	X	X	X	X	X	X	X	X	X	X
Monitoring of non-IND interventional and observational protocols (done by ASRC)	X	X	X	X	X	X	X	X	X	X	X	X
IC audit for Industry sponsored protocols (include embedded questions in PRES)	X					X						
Informed consent audit for CTEP/Network protocols (include embedded questions in PRES)						X						
Audit Embedded Questions in PRES for CCR INDs							X					
iMed protocol consent audit										X		
Audit appropriate use of 01C0129					X							
Audit appropriate use of 04C0165 - include who consented in the audit											X	
Amendment training SOP audit				X								
Protocol training SOP audit								X				