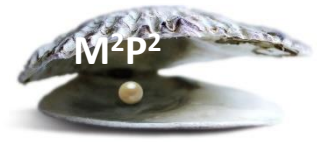

Monday Morning Practice Pearls #45

There are several email boxes used in the CCR. How do I know what to send to which email?

Below is a table that will help to guide you on what to send to the Office of the Clinical Director:

Email Box	What to Send and Other Tips
NCI CCR QA (NCICCRQA@mail.nih.gov)	• Reporting to Clinical Director - All deaths on study except due to progressive disease, regardless of relatedness to study, per protocol. • Monthly SAE/AESI log for IND/IDE protocols only • Scheduled monitoring visits, audits or inspections. Include the protocol number, PI, type of visit (e.g., routine monitoring, audit, FDA inspection), name of the sponsor and monitor, and which team member is the contact person for the visit. • Monitoring and audit visit reports/outcome email • Team response to monitoring and auditing visit reports
NCI CCR PSO (NCICCRPSO@mail.nih.gov)	A distribution list that emails everyone in PSO. This email should be reserved for instances of communication that pertain to all of PSO – not study-specific communication. • New CCR SOPs and requests for feedback • ASRC and OSRO/SROS monitoring schedules, regulatory file (i.e., NIH Box) requests
NCI CCR PSO Central (NCICCRPSOCentral@nih.gov)	A central mailbox that is managed by the PSO Regulatory Submissions Coordinator. The following should be sent to this mailbox for central processing by PSO: • IND Safety Reports for CCR-held IND protocols. Include the protocol # and PI determination of UP or non-UP • Investigator Brochures (IBs) for CCR-held IND protocols. Include the protocol # and PI determination of if a change to risk/benefit ratio • SAE reports sent to OSRO Safety for CCR-held IND protocols (initial and follow-up) • CTEP uses this mailbox for general correspondence and updates for CCR/CTEP studies • Copies of executed tech transfer agreements (or to Stacie Jeter) The following should be sent directly to the assigned PSO Manager *or to this mailbox if the assigned PSO Manager is not known or out of the office* for the study regulatory file*:* • IND Safety Reports for non-CCR held IND protocols. Include the protocol # and PI determination of UP or non-UP • Email correspondence between team members for protocol related issues • Email correspondence between PI/AI and sponsor • Email correspondence between PI/AI and manufacturer • Conflict of Interest email responses

	• Monitoring and auditing visit reports/outcome email (also to NCI CCR QA) • Team response to monitoring and auditing visit reports (also to NCI CCR QA) • Logs: screening, enrollment, monitoring, delegation of authority • Outside lab updates for FDA Form 1572 • Outside lab CLIAs and references ranges • SAE reports sent to outside sponsor (e.g., pharmaceutical company sponsored IND protocol)
CCR OEC NCICCROEC@mail.nih.gov	• General consultation or assistance • Access NIH Box account for monitoring visits • Site Qualification Questionnaires and on-site visit requests
Medical Oncology Referral Office NCIMO_Referrals@mail.nih.gov	• When your protocols open, close or anything significant in between

Below is a table that will help to guide you on what to send and where for CCR-sponsored IND and IDE protocols:

Email Box	**What to Send and Other Tips**
OSRO Safety NCIOSROSafety@mail.nih.gov or OSROSafety@mail.nih.gov	• SAEs for all CCR-sponsored IND and IDE protocols; use form and follow instructions on the OSRO website • CCR Pregnancy Report and Follow-up Form and CCR Pregnancy Outcome Form per the OSRO website • Dose Escalation Determination Form for required phase I studies • IBs, INDSRs, and other new safety information for OSRO review/ determination (usually sent by PSO)
OSRO Safety Coordinators ncisafetycoordinators@mail.nih.gov	Questions about SAE reporting, SAE reconciliation, DSMB/SMC, dose escalation reports
Sponsor and Regulatory Oversight Support (SROS) SROSMonitoring@tech-res.com	• Note: Site Initiation Visits (SIV) requests are done through an online portal at https://ncirfs.powerappsportals.com/add-rfs-information/ • Questions or clarifications for SIV • Site interim visit scheduling or follow-up (or contact monitor directly)
Sponsor and Regulatory Oversight Support (SROS) SROSERDG@tech-res.com	• Note: Site Essential Regulatory Documents are uploaded by PSO staff to OSRO's VeevaVault system. • Questions or issues related to essential documents
OSRO Monitoring NCIOSROMonitoring@mail.nih.gov	• For information regarding the OSRO Sponsor and Regulatory Oversight Support (SROS) Services Contract related to monitoring
OSRO Study Agents OSROStudyAgent@nih.gov	• Questions about study products, pharmacy and stability plans
OSRO Consultation NCIOSROConsultation@mail.nih.gov	• General consultations or questions