



## 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
<a href="#">NCI CCR QA</a>	<ul style="list-style-type: none"> <li>Reporting to Clinical Director - All deaths on study except due to progressive disease, regardless of relatedness to study</li> <li>Monthly deviation tracking tool for each protocol, or nonadherence log for protocols monitored by OSRO</li> <li>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 which team member is the contact person for the visit.</li> <li>Monitoring and audit visit reports/outcome email</li> <li>Team response to monitoring and auditing visit reports</li> </ul>
<a href="#">Elizabeth Ness</a>	<ul style="list-style-type: none"> <li>Monthly SAE/AESI log for only IND/IDE protocols</li> </ul>
<a href="#">NCI Protocol Support Office</a>	<ul style="list-style-type: none"> <li>IND Safety Reports from non-CCR held IND protocols. Include the protocol # and PI determination of UP or non-UP.</li> <li>Email correspondence between team members for protocol related issues*</li> <li>Email correspondence between PI/AI and sponsor*</li> <li>Email correspondence between PI/AI and manufacturer*</li> <li>Conflict of Interest email responses</li> <li>Monitoring and auditing visit reports/outcome email (also to NCI CCR QA)</li> <li>Team response to monitoring and auditing visit reports (also to NCI CCR QA)</li> <li>Logs: screening, enrollment, monitoring, delegation of authority*</li> <li>Outside lab updates for FDA Form 1572*</li> <li>Outside lab CLIAs and references ranges*</li> <li>Copies of executed tech transfer agreements (or to Stacie Jeter)</li> <li>SAE reports to sponsor</li> </ul> <p><i>*Or send directly to assigned PSO Manager.</i></p>
<a href="#">Medical Oncology Referral Office</a>	<ul style="list-style-type: none"> <li>when your protocols open, close or anything significant in between</li> </ul>

Below is a table that will help to guide you on what to send to the Office of Sponsor and Regulatory Oversight (OSRO), for CCR-sponsored IND and IDE protocols:

<b>Email Box</b>	<b>What to Send and Other Tips</b>
<a href="#">OSRO Safety</a>	<ul style="list-style-type: none"><li>• SAEs for all CCR-sponsored IND and IDE protocols; use form and follow instructions on the <a href="#">OSRO website</a></li><li>• CCR Pregnancy Report and Follow-up Form and CCR Pregnancy Outcome Form per the <a href="#">OSRO website</a></li></ul>
<a href="#">OSRO Monitoring</a>	<ul style="list-style-type: none"><li>• Monthly nonadherence log (provided by OSRO) for CCR-sponsored IND/IDE protocols being monitored by OSRO</li></ul>