



The Mechanics of Performing a Clinical Trial

Part II

Properly trained CRA's are happy CRA's

- Types of certification to look for
 - CCRP (Certified Clinical Research Professional): certification is through SOCRA or through ACRP.
- Train CRA's in what you want them to do or document previous experience showing they have the experience necessary.
- Complete any and all training provided by the pharmaceutical company and keep documentation
- Shipping biologic specimens
 - Call Environmental Safety for a training CD, keep it on file and up-to-date.



Task Delegation

- Document the tasks and duties you assign to your CRA and other members of your team.
 - Great for auditors to see that you are really following what your team is doing. This can be its own brief SOP.





Love your SOP's

- Make them useful.
- If you put it in an SOP, make sure you're doing what is in the SOP. They can protect data integrity, they can help train new staff in a pinch.

Adverse event reporting

- Pharmaceutical companies are very very (overly) cautious – they will report everything to you from other sites.
- It's the PI's responsibility to determine what information needs to be passed on to the IRB and to patients.
- Our local IRB is concerned with subject safety, if it doesn't affect the safety of the subject – it's not an AE.
- Many pharmaceutical companies will insist you report it to the IRB – in this case, do it as an acknowledgment of receipt.
- Adverse event reporting can start with the CRA but it's the PI's responsibility to make sure the info is accurate and is followed up. When in doubt about submitting to IRB, call them.



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