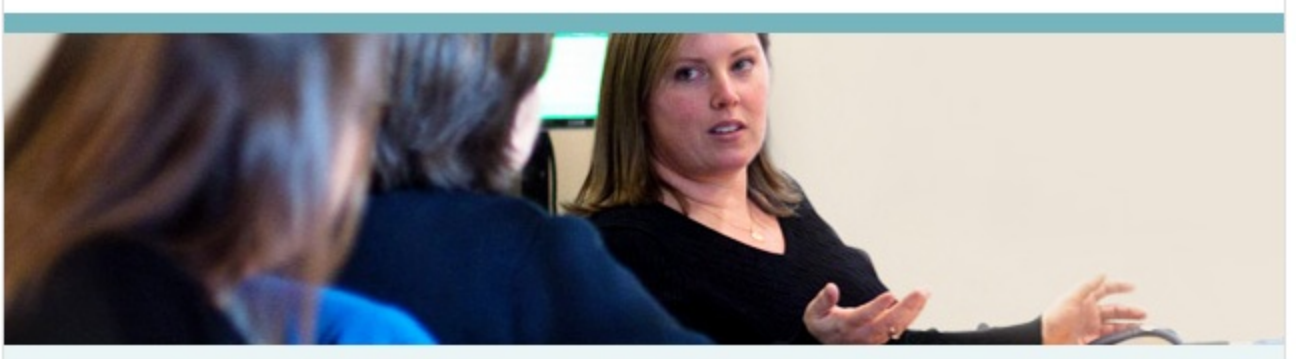
December, 2012 - Standard Operating Procedures:



GREETINGS FROM LORRAINE

Although Standard Operating Procedures are difficult to write well, after doing many audits, I know that they are worth the effort and make a difference in the quality of clinical research.

As we approach the end of the year, I encourage you to review your SOPs if you have them or write new SOPs if you need them. SOPs set the standard and metrics for quality and should be reviewed and updated at least annually so they are up to date with GCP and other requirements. They also should be reviewed for comparing the SOP procedures with your actual procedures. You may be surprised at how the procedures drift away from the standards over the years.

For more information about SOPs and how they can improve your research quality, read this month's blog on the topic.

Happy Holidays!

- Lorraine

Learn More - Research Dynamics Blog

BLOG POST: SOPs

Standard Operating Procedures, Metrics, and Clinical Research Quality

Quality in clinical research starts with a systems approach. The "systems" include training programs, role definition, organizational structure, responsibilities and accountability, Standard Operating Procedures (SOPs) and processes, documentation, and metrics.

So how do you start building quality systems? Click to read more.

FDA NEWS

FDA Has issued some new guidance documents:

Draft Guidance for IRBs, Clinical Investigators and Sponsors - IRB Responsibilities for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the Determination of Whether an IND/IDE is Needed

This new draft guidance describes to the IRBs their responsibilities in reviewing the qualifications of the Principal Investigator and the clinical research facility. The IRB also had a role in the determination of whether an IND or IDE is required for the study.

This draft guidance was a joint effort to harmonize human subject protection requirements with the OHRP, HHS, and FDA.

Guidance for Industry Electronic Source Data in Clinical Investigations

This draft guidance document provides recommendations to Sponsors, CROs, Investigators, data management centers, and others involved in capturing, reviewing, and archiving electronic source data in FDA-regulated clinical investigations.

One note of many in the guidance: It mentions that many data elements (e.g. blood pressure) can be entered directly into the eCRF by a "data originator" (defined in the guidance document). It comments that this direct entry may eliminate data transcriptions from a paper step before entry into the eCRF. In this case the eCRF is the source.

END OF THE YEAR SALE

SOP Templates and Reference Materials 10% Off

As 2012 come to an end, we are offering 10% off from now through December 31st on our SOP Template Kit and our books - GCP for the Clinical Investigator, CRA Activity Guide, and CRC Activity Guide.

As mentioned by Lorraine above and in her latest blog post, having up-to-date SOPs is extremely important and helps to ensure effortless compliance throughout your year. Our training books are a great way to help improve GCP compliance and help increase productivity and the overall quality of your work!

Learn More - Research Dynamics products site

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As always, thanks for reading, and please contact us with any questions or comments! Happy holidays!

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