



## Research Dynamics Consulting Group September 2011 Newsletter

Greetings!

Autumn is a great time to do some housekeeping - to make sure everyone on your staff is up to date on the most current FDA guidance and GCP requirements.

That's why, for a limited time, we are offering a **10% off sale** on all our most popular products, including our [SOP Template Kit](#) and our [GCP Books](#) and [Activity Guides](#)!

### Thoughts From Lorraine Ellis

Back to school and football this month!

To keep your education up-to-date, check our new webinar described below and our 10% discount on our products and SOPs. To keep your organization's knowledge up-to-date, request a quote for an on-site training session that can be customized to your SOPs or other requirements. See our list of potential and upcoming courses in the [Training](#) section of our website or contact [Alex Shortt](#).



FDA issued a new draft monitoring guidance after 23 years! (1988 was the last one). Although it brings monitoring up to the 21st century options, it appears to be controversial as it redefines the "gold standard" of monitoring to a more "risk based approach" with well-defined monitoring plans.

For those working with medical devices, FDA continues to deliver on its 25 item action plan to revise the 510(k) process and requirements. Watch for several new guidance documents this month including the "510(k) Paradigm Guidance" that is planned to provide greater clarity for clinical trial data requirements for these products.

For those interested in improving site performance, register for our webinar next week that has some practical ideas on the subject. For more information, [visit our site](#).

Have a great month!

Regards, Lorraine

### Reminder: Webinar on Improving Site Performance is Friday, September 30th!

The latest installment in our [Webinar series](#) is taking place Friday, September 30th at 12:30pm EST.

"Improving Site Performance" is a must-attend for sites, investigators, coordinators, CRAs and more. We will be covering and reviewing key attributes of highly performing sites and discuss actions to improve poor site performance.

This is a very economical way to help improve data quality and overall site performance. [Visit our website](#) for more information and to sign up!

### Latest FDA News

**New Monitoring Draft Guidance from FDA:** FDA has withdrawn the 1988 guidance on Monitoring and has issued this new draft guidance. If you have been following GCP blogs, it has caused considerable controversy because it is decreasing the emphasis on on-site monitoring visits and allowing more "centralized" monitoring using systems such as EDC. FDA describes that each study needs to have a "risk-based" monitoring plan that should be based on the characteristics of the study and that can include centralized monitoring.

Lorraine has provided several comments on this guidance and there are some good discussions:

Here are the links:

[GxP Perspectives](#)

Lorraine's commentary on September 4, 2011.

[The GXP group discussion on linkedin.](#)

[The draft monitoring guidance](#)

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### Featured Product



### SOP Template Kit

Updated for 2011 with 2 brand-new SOPs! Developing custom SOPs can be time consuming and difficult when starting from scratch. Our 26 SOP templates provide a "quick start" on developing your own custom SOPs. The basic methods are clearly written and ready for your specific procedures to be added.

[Visit our website to learn more and to order.](#)

### Investigator Sign Up

Investigators! [Click Here](#) to fill out our sign up form to be added to our Investigator Database, for consideration in future Research Dynamics trials!

### White Paper: "Integrating Trial Data Process Across Functional Areas Using EDC Technology"

The white paper describes how to implement the use of EDC systems across clinical, data management, biostatistics and the Investigator sites to maximize the benefits of the latest EDC systems. Available in our [White Papers](#) section in about a week!

[Join Our Mailing List!](#)

Save  
10%!

On all Research Dynamics productivity and training products. Our SOP Template Kit, GCP for the Clinical Investigator, CRA Activity Guide, and CRC Activity Guide are 10% off for fall 2011. [Click here](#) to view our Product Catalog and to order.

Offer Expires: 10-31-2011

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