# Research Dynamics Consulting Group

## August 2011 Newsletter

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Greetings from Lorraine Ellis!

Welcome to our end-of summer Newsletter! Hope you had a fantastic summer!

As some of you settle into a new school year, our training staff is also starting some new educational offerings. Our new webinars provide timely and easy training to new staff as well as staff who want to be up-to-date on their knowledge. Check our website for the latest trainings!

Also, check **our blog** for the latest updates and interesting news in the clinical research arena. For those of you working with devices, the rules for clinical trials are changing, so keep in touch with RDCG and FDA to learn the latest.

## Lorraine Ellis to moderate session on 510k device requirement changes

### MedTech Annual Conference
### Rochester NY

Lorraine D. Ellis will moderate panel session on the changing 510k environment:
"Understanding and Preparing for Impending Reform".

The session will be held during the MedTech Annual Conference 2011 on Tuesday September 13, at the Hyatt Hotel in Rochester NY. Several experts will discuss the changes in the 510k requirements for product clearance and how it may affect your product development.

For more info:
http://www.medtech.org/MEDTECH2011/Agenda.aspx.

And check out some of the latest FDA communications about the 510k requirements and device clinical trials:

Draft guidance published: FDA loosens requirements for some in-vitro diagnostic and radiology medical devices (.pdf)

Draft guidance on device clinical trials. FDA's current thinking in a draft document sent for comments (.pdf)

## FDAs Guidance on Investigator Supervisory Responsibilities

### How familiar are you?

FDA has recently issued a new guidance on Investigator Supervisory Responsibilities that includes some surprising new recommendations. Anyone who is responsible for study activities at a site, e.g., Investigators, Coordinators, Sponsors, Monitors, etc, should review their trial procedures with this guidance in mind.

Attention medical device sponsors! This guidance applies to all Clinical Investigators including drug, biologics and medical devices.

In the guidance FDA focuses its attention on the Investigator and describes what FDA interprets as "Supervisory" responsibility and "delegation". FDA notes that when the Investigator signs the FDA form 1572 or an Investigator Agreement, the Investigator agrees to conduct or supervise the trial. FDA describes how it plans to hold the Investigator responsible for this activity and will assign regulatory violations to the Investigator due to failure to supervise.

From my viewpoint, I would review procedures and SOPs on the following site activities as a result of this guidance. **You can read more on our blog**!

## Research Dynamics Products, Training, and Webinars

### Great ways to improve compliance and more!


Research Dynamics provides its expertise and experience to clinical research professionals through its training classes and clinical research products.

Our **training classes** are offered in several formats: Webinars, Regional, and custom classes depending on your training needs.

Our **products** provide training and reference materials for your staff and template SOPS for the Investigator Site.

Our next webinar is titled **"Improving Site Performance"** and is scheduled for Friday September 23rd. **Click here** for more information and to sign up!

Please review our training and product offerings and contact Alex Shortt with any questions at ashort@resdyncg.com or 585-381-1350 x246)

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Thanks for reading our update. Please don't hesitate to contact us with any questions!

**Sincerely,**

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