



Title of Program: Recent Monitoring Guidance from the FDA

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Date of Program Nov. 3, 2011

**Location of Program : Allina Commons
2925 Chicago Ave. Mpls, MN 55407**

Parking is available at Allina Commons

DESCRIPTION This work session will review THREE recent releases from the FDA about Monitoring. The documents we will review include the information provided in the “Compliance Program Guidance Manual” for BIMO inspectors “**CHAPTER 48 – Bioresearch Monitoring**” (CPGM 7348.810 for sponsors, CROs and monitors and CPGM 7348.811 for clinical investigators and sponsor-investigators) for foods, biologics, drugs and devices which was implemented on March 11, 2011 and the LONG awaited “Guidance for Industry: Oversight of Clinical Investigations – A Risk-Based Approach to Monitoring” which was released August, 2011 to “enhance human subject protection and the quality of clinical trial data. Since 1988, we have been waiting for an update on the FDA guidance about monitoring and the update is finally here! Join us in an interactive dialog about what these documents should mean to all of us in the trenches when conducting trials, monitoring trials or being inspected by the FDA.

PROGRAM OBJECTIVES:

- 1) Describe the three guidance documents (guidance for sponsors as they train their monitors and the two guidance documents for BIMO inspectors as they oversee the conduct of clinical studies).
- 2) List key “risk-based” approaches to monitoring.
- 3) Develop components of a simple “monitoring plan” from the perspective of the monitor, coordinator, or inspector.

PROGRAM AGENDA:

Registration and Dinner:

6:15 - 6:30 PM

Presentation:

6:30 - 8:30 PM

TARGET AUDIENCE: Registered nurses, clinical research coordinators, clinical research associates, clinical research monitors, and project managers within the medical device industry

REGISTRATION BY (ENTER TWO DAYS PRIOR TO EVENT): Cancellations prior to (enter TWO days prior to event) receive full refund. Walk-ins are welcome, but CEU's are not available.

DINNER is INCLUDED with the Program

Chapter Member:	No CEU's = \$0	CEU's = \$10
National Member:	No CEU's = \$10	CEU's = \$20
Non-Member:	No CEU's = \$20	CEU's = \$30

Contact hour (s): 2.0 Contact Hours have been applied for through ACRP.