New Set of SOPs

The Thomson Center for Clinical Research Practice, Wellesley, MA, has published "Standard Operating Procedures for Good Clinical Practice by Sponsors of Medical Device Research." These SOPs address the unique regulatory and business environment of medical device clinical trials. They include regulatory references (FDA regulations and ICH GCP guidelines) and detailed procedures. Checklists, report forms, templates, and regulatory documents are provided as management tools to implement SOPs into daily practice and to document that SOPs are being followed. Recent FDA warning letters to medical device manufacturers indicate that there are serious concerns about how device clinical trials are being monitored by sponsors. In order to assure the quality of data and the protection of human subjects, FDA insists that device clinical trials be held to the highest standards. Thus, SOPs are mandated. For more information about content and pricing, readers can contact CCRP at 781-431-6466. In addition, a detailed table of contents is available at www.ccrp.com.