

## **Cancer Research And Biostatistics**

### **Site monitoring in accordance with GCP and Federal Regulations**

CRAB provides site monitoring services that are performed in compliance with FDA regulatory requirements (21 CFR part 312.50 and 21 CFR part 312.56) and Good Clinical Practices guidelines. The site monitoring staff confirms the investigator is conducting the clinical trial according to the requirements specified by the FDA and ICH GCP guidelines. These services include a review of the investigator's IRB approved informed consent form and protocol documents as well as the review of the case report forms and corresponding source documentation. The site monitor will ensure adverse events are being reported accurately and as required by the protocol and FDA regulations (21 CFR part 312.32) and ICH GCP guidelines.

For clinical trials that require the monitoring of study drug accountability, CRAB site monitors will review the study drug accountability records according to the FDA regulatory requirements (21 CFR part 312.57, 21 CFR part 312.61 and 21 CFR part 312.69) as well as the ICH GCP guidelines.

At the conclusion of each site monitoring visit, the sponsor will be provided with a report summarizing the results of the visit and if needed, any follow-up actions required by the investigator to correct deficiencies.