



## Monitoring

### **Policies, Overview, Regulatory Support:**

All industry sponsored clinical trials are monitored routinely by a Clinical Research Associate representing the sponsor. Their role is to insure that the principal Investigator is adhering to ICH guidelines of Good Clinical Practice and adhering to the protocol.

The CRA is required to have access to the medical records; source data and the Case report Forms (CRF). Authorization is obtained from subjects in the Informed Consent.