



### **Study Files:**

The IRB will maintain documentation on each study including all protocol submissions, correspondence, revisions, modifications, investigator information, and test article information. Records will be maintained for a minimum of 3 years after the last study expiration date.

IRC and the IRB fully understand the need for confidentiality of records and will strenuously strive to provide it. Some of what is contained in an IND or IDE application may be considered to be trade secret. Generally trade secrets are in the Investigators Brochure or the Report of Prior Investigations and are not included in the protocol itself. Trade secrets should be distinctively marked.

### **Policies and Procedures:**

IRC will maintain IRB policies and procedures which will be made available to the FDA.

### **IRB Roster:**

Current and previous membership rosters are posted in section 3.1.

**NAMES:** The names and addresses of the IRB chair and members will not be released except to firms that can indicate a regulatory requirement that they be released. Contractually, IRC will assure that the membership will comply with FDA requirements. A list of occupations will be provided.

### **IRB Audits:**

FDA inspectors must be allowed to review and copy all pertinent records as required by law and regulation. IRC will keep a log of or copies of all duplicates taken by the inspector.

### **Accreditation:**

Site visitors from a recognized human subjects accreditation organization will be allowed to view confidential files solely for the purpose of assessing IRB operations and human subject protection.

