Confidentiality of clinical trial information

1. **PURPOSE**

To describe the policy concerning clinical research activities and related confidentiality of clinical research materials and information.

1. **SCOPE**

Applies to all clinical site research personnel involved in the implementation and coordination of clinical investigations.

Personnel responsible: Principal Investigator and, *when delegated by the investigator,* sub‑investigator(s) and clinical research coordinators.

1. **BACKGROUND**

**In accordance with:**

Clinical Trial Agreement(s)

Non-Disclosure Agreement(s)

1. **PROCEDURE**
   1. The principal investigator or his designee will sign a copy of the Sponsor’s non-disclosure agreement in order to obtain the clinical trial information for evaluation.
   2. This agreement applies to any clinical trial material(s) received or any discussions held with Sponsor personnel or their agents.
   3. Clinical research materials will not be left in other departments where non research personnel may have access.
   4. Any questions concerning the scope and application of this SOP will be directed to the Director or designee and/or Corporate Counsel.
   5. Any suspected breach in confidentiality will be reported to the Director or designee in person or in writing within 24hours.