1. **PURPOSE**

   To define the procedure utilized to contact the Principal Investigator prior to conducting a compliance activity.

2. **SCOPE**

   This procedure applies to all compliance activities performed by the Education and Compliance Office.

3. **RESPONSIBILITIES**

   The Education and Compliance Coordinators are responsible for contacting the Principal Investigator to arrange for the compliance activity.

4. **PROCEDURES**

4.1. The principal investigator will be contacted to make arrangements for the compliance activity. With the investigator’s permission, arrangements can be made through the clinical research coordinator or other designated research staff. This initial contact should take place within one week of the delivery of the e-mail notification.

4.2. Departmental audits may be scheduled at a mutually agreeable time, preferably within one month of the audit notification.

4.3. “For Cause” audits should be scheduled within two weeks of receipt of the audit notification. If the investigator is unable to comply with the two-week time frame, the IRB Executive Committee will be notified of problems in scheduling the audit in a timely manner. Unless the Education and Compliance Office is directed otherwise by the IRB Executive Committee, the audit date will be set at the first agreeable date between the investigator and the Education and Compliance Office.

5. **REFERENCES/DOCUMENTATION**

   NA

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