CREATION AND MAINTENANCE OF TRAINING FILES

1. **PURPOSE**

To describe the content for Sponsor/investigator staff training files.

1. **SCOPE**

Applies to all <name of Sponsor/Investigator> personnel involved in the implementation and coordination of clinical investigations.

1. **BACKGROUND**

All Sponsor/investigator staff will have training files to document their orientation, training and continuing education concerning Good Clinical Practices.

**In accordance with:**

Site Policies and Procedures

GCP and ICH Guidelines

1. **PROCEDURE**
   1. The <insert correct title> will create and maintain Training Files for each clinical research employee.
   2. The content of the Training Files will include:
      1. Updated CV of the employee (current within 2 years). The CV will be signed and dated by the employee. New employees are required to update their CV within their orientation period.
      2. Copy of any professional license for the employee.
      3. Copy of any certification (CCRC, CCRA, RAC, etc.) that is current for the employee.
      4. Training Documentation Forms (to document SOP training)
      5. Evidence of a Basic Clinical Research Course and / or completion of orientation. *(attach an outline of the orientation course to document site specific training).*
      6. Hazardous Materials Shipping certification.
      7. NIH Tutorial documentation *(if your site requires it).*
      8. CPR, ACLS etc. (*if required by your site)*
      9. OSHA Training documentation
   3. Training Files for current and former employees will be kept in the <insert correct title> office (or specify secure site for storage).