**CHANGE CONTROL FOR REVISING OR UPDATING STANDARD OPERATING PROCEDURES (SOPs)**

1. **PURPOSE**

To define the procedures required for the revision and approval of SOPs.

1. **SCOPE**

Applies to all <name of Sponsor/Investigator> personnel.

1. **BACKGROUND**

This document serves to define the procedure for change control concerning SOP revision and approval for <name of Sponsor/Investigator>.

1. **PROCEDURE**
   1. Each SOP will be reviewed annually for updates. Each revision is consecutively numbered and dated as revised by changing the version number and date in the “header” section of the SOP.
   2. The revised SOP will be signed by <insert signatory person(s)>.
   3. Only those giving the authority to make changes to the SOPs may do so.
   4. Changes or updates to an SOP are documented on a Change Control Document. The author will state the former language followed by the revised language on the Change Control Form along with appropriate rationales and references. The author and all signatories for SOPs will sign this document. It will be kept in the SOP manual for the year the change or update occurred.
   5. <Name of Sponsor/Investigator> personnel will sign a training log documenting their training on the revised SOP.