1 PURPOSE

This policy and associated procedures sets up the guidelines that are required to support the use of electronic documents (e-documents), providing a consistent management of records within the Office of Human Research for IND safety letters received from the sponsor.

2 GENERAL INSTRUCTIONS AND RESPONSIBILITIES

Given the substantial volume of documents related to each study, especially Investigational New Drug (IND) Safety Letters, and the need to ensure fast and accurate retrieval of safety information, an effective document filing system is essential.

This policy will:

a) Ensure research personnel will maintain safety information (IND Safety Letters) as a research asset within a single repository.

b) Ensure that safety information is readily accessible to staff who require it to fulfill their duties.

c) Ensure IND Safety Letters are maintained in a consistent manner.

d) Facilitate effective retention of records.

e) Define roles and responsibilities with regards to e-documents creation and maintenance.

f) Enable the Office of Human Research to use e-documents to meet regulatory obligations.
3 SPECIFIC PROCEDURES

3.1 Creation/ maintenance of IND Safety Letter - electronic format

a) IND Safety Letters will be maintained in a folder within the S: Drive. Each study will have an electronic folder. A sub e-folder named “IND SAFETY LETTERS” will be created under the “RX” folder of each study. This e-folder will keep only the safety information associated with that particular study.

b) IND Safety Letters received electronically (via e-mail) or uploaded from the sponsor’s website will be transferred to the e-folder pertaining to the related study. Hard (paper) IND Safety Letters received from the sponsor will be scanned by the regulatory coordinator and saved under the e-folder pertaining to the related study. Paper copies will be destroyed using a shredding system to ensure confidentiality.

c) In order to guarantee that the Principal Investigator (PI) is aware of the safety information, the regulatory coordinator will create a log listing the IND Safety Reports. This log and a CD including the IND Safety Letters listed will be sent to the PI for acknowledgement. After it has been signed, this log will be scanned and combined with the related IND Safety Letters. Only the log will be maintained in paper format and filed in the Regulatory Trial Master File. In case the sponsor’s website has a PI read-tracking system, the creation of this log is not required.

d) IND Safety Letters that are reportable to the Institutional Review Board will be listed in the IRB / WIRB form and reported according to the policy.

4 REFERENCES TO OTHER APPLICABLE SOPS

- SOP 605 Adverse Event Recognition and Reporting

5 ATTACHMENTS

A. IND Safety Reports Log

6 APPLICABLE REGULATIONS AND GUIDELINES

- General Principles of the IND Submission (21 CFR 312.22)
- IND Safety Reports (21 CFR 312.32)
- Annual Reports (21 CFR 312.33)
- Safety Reporting (ICH E6, Section 4.11)
- Trial Management, Data Handling, and Record Keeping (ICH E6, Section 5.5)
Investigator Standard Operating Procedures

- Safety Information (ICH E6, Section 5.16)
- Adverse Drug Reaction Reporting (ICH E6, Section 5.17)