HIV Program **Duke AIDS Clinical Trials Unit** **Standard Operating Procedure**	
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SOP Title: **Handling of safety documents for distribution to clinic medical staff and Duke University Medical Center Institutional Review Board and filing**	Effective Date: 05/19/06

PURPOSE: To establish the process for handling safety documents within Duke University Health System (DUHS) Division of Infectious Diseases (ID) Protocol Office for distributing to clinic medical staff and submitting to the Duke University Health System Institutional Review Board (IRB).

POLICY: The clinical research coordinator assigned to the Protocol Office will coordinate and oversee the handling of safety documents by the Protocol Office and ensure compliance with applicable guidelines and regulations of Good Clinical Practice, Code of Federal Regulations, sponsors and DUMC.

RESPONSIBILITY:
1. Clinical Research Coordinator (CRC) is educated and trained to ensure that safety documents are maintained and distributed as stated in this SOP.

PROCEDURE:
General Information

I.   The PI is required to review Serious Adverse Events (SAEs)/Investigation New Drug (IND) safety letters / Investigational Drug Brochures (IDB)/Package Inserts (PI) in terms of its relationship to the study and to address possible changes in the risk-benefit ratio that necessitate changes in the protocol and/or consent form.

II. The TRIALS 2000: Database on the J Drive: ID/Stewart on Midway is used for tracking and preparing reports for submission to the IRB.

A. Investigator's Drug Brochures (IDBs) and Package Inserts (PIs)
   1. ACTG and industry sponsors forward the latest IDBs and PIs for each study medication to the site for each protocol that uses the study medication. These documents must be forwarded to the DUHS IRB with the Report (Submission form) generated by the database.
   2. In the database select **Forms** from the *Object list* then select **IB and PI Form.**
   3. **ALWAYS SELECT RECORD** ▸ ☀ (bottom left corner of form). This will produce a clean form to enter the new data into.

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> **WARNING : If   ▶ ☀   is not selected new data will overwrite existing data! Contact CRC data manager immediately if this happens.**

4. Enter required fields. See Appendix 1.
5. Record Auto # on the IDB and make 1 copy of IDB for the Regulatory file.
6. Print report: Select from *Object list* **Reports→IB and PI Report→enter Parameter number→select file→print.**
7. Obtain PI signature on report make a copy of the report and file in "IB/PI Pending IRB Approval" folder then send original signed report with IDB/Package Insert to IRB.
8. Once IRB acknowledgement has been received, collate with the filed copy in the pending folder and file document in the specific protocol file folder "Investigational Brochure/Package Insert".

B. Serious Adverse Events (SAEs) Duke Subjects

1   The study coordinator should provide as much information as possible regarding the SAE. There is a generic form that provides basic information about the SAE that serves as the cover page for the study coordinator's submission to the Protocol Office. The types of information that can be provided are clinic notes, hospital computer records, CRF pages and sponsor SAE forms.

2   In the database select **Forms** from the *Object list* then select **IND safety Duke SAE.**

3   **ALWAYS SELECT RECORD** ▶ ☀   (bottom left corner of form). This will produce a clean form to enter the new data into.

> **WARNING : If   ▶ ☀   is not selected new data will overwrite existing data! CRC data manager immediately if this happens.**

4. Enter required fields. See Appendix 2.
5. Record Auto # on the SAE.
6. Print report: Select from *Object list* **Reports→SAE cover page new sort 2004→enter Parameter number→select file→print.**

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7. Obtain PI signature on report make copy of report and all documentation that was received from the study coordinator and file copy in "SAE Pending IRB Approval" then send original signed report with all documentation received from study coordinator to IRB.
8. Once IRB acknowledgement has been received, collate with the filed copy in the pending folder and file document in the specific protocol file folder "SAEs".

C. IND Safety Reports

Because ID works on multiple protocols that use the same investigational medications, ID receives multiple copies of the same IND Safety Reports (called Safety Alerts by ACTG). ID is required to submit the Safety letter along with information from the Safety Reports to the IRB and retain one copy of the Safety Report filed in the safety report filing cabinet. Multiple copies may be discarded once the Protocol Office is certain that one copy has been retained.

1. The database is a relational database and uses under lying tables to populate the report along with the raw data that is entered. Each IND safety letter is only entered once into the database. The database will generate a report for each study that uses that drug. The Safety letters must be forwarded to the DUHS IRB with the report (submission form) generated by the database. See Appendix 2
2. In the database select **Forms** from the *Object list* then select **IND safety Duke SAE.**
3. **ALWAYS SELECT RECORD** ▸ ☀ (bottom left corner of form). This will produce a clean form to enter the new data into.

   > **WARNING : If   ▸ ☀   is not selected new data will overwrite existing data! CRC data manager immediately if this happens.**

4. Enter required fields. See Appendix 2.
5. Record Auto # on the IND safety letter.

6. Print report: Select from *Object list* **Reports→SAE cover page new sort 2004→enter Parameter number→select file→print.**
7. For any IND safety letter in which "IRB Reportable " is Yes print page 2 report: Select from *Object list* **Reports →IND safety report and Duke SAE page 2→enter Parameter number→select file→print→Select pages→tab through reports and enter page number for individual report needed (page number can be found at bottom of screen)→print. Repeat procedure for each page 2 needed.**
8. Obtain each PIs signature on the front page and Page 2 that appears in the reports. Make a copy of report and each safety letter for the file. Attach all IND safety letters (in numeric order) to the report with original signatures and send to the IRB. File copy of report in the "IND pending Approval" folder and file letters by drug in the safety file cabinet.
9. Once IRB acknowledgement has been received, collate with the filed copy in the pending folder and file document in the Safety Binder.

History

Version	Effective Date	Supersedes	Review Date	Change
S006.1		NA		*Initial Release version S006.1*

Approval

Janet Mueller
_____
                          Signature   Date

Regulatory Coordinator

Charles B. Hicks, MD
_____
                          Signature   Date

Principal Investigator