4.0 REVIEW OF ADVERSE EVENT FORM

4.1 All AE Reports submitted to the ORA shall be reviewed by both the CRC Manager and the BNL IRB.

4.2 Upon completion of the review, the conclusions of each reviewing group shall be recorded on the AE Report.

4.3 All AE Reports, after review by the CRC Manager and the BNL IRB, shall be presented to the