Page 2 – The Clinical Center personnel need to fill out this form and key-enter it immediately after page 1 of the report is received. The whole report will then need to be forwarded to the DCC, and if the event in both unexpected and related to the study medication (see introduction explanation on p. 1) – to the Project Officer at the NIH and the local IRB.

Patient ID .....__ __ __ __ __ __

Patient Name Code .....__ __ __ __

Date of Event ..... __ __/__ __/__ __ __ __

Type of Event, which triggered the report.....__ __

Nature of Event

15. Full clinical description (including symptoms and diagnosis) to the extent required by your local IRB

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16. Date faxed to the DCC..... __ __/__ __/__ __ __ __

Reporter Information

Physician in Charge:

Name: _____ Signature: _____

Date Signed: _____

Name of the person completing this page:_____

Signature of the person completing this page: _____

Date this page completed:..... __ __/__ __/__ __ __ __