

INSTRUCTIONS: Complete this form each time an adverse event is finalized.

The Study PI or Clinical Center PI must review and sign this form.

Section A: KEY IDENTIFYING INFORMATION

- A1. Study Identification Number _____ - _____ - _____ - _____ - _____
- A2. Acrostic Identifier _____
- A3. Event number (Must match event# on R200) _____
- a. Onset Date (Must match event# on R200) _____ / _____ / _____
M M D D Y Y Y Y
- A4. Date form initiated _____ / _____ / _____
M M D D Y Y Y Y
- A5. Name of person completing form _____
PRINT FULL NAME INITIALS

Section B: RESOLUTION OF ADVERSE EVENT

- B1. Date event resolved _____ / _____ / _____
M M D D Y Y Y Y
- B2. Event resolved with long term sequelae? YES..... 1 NO 2 **(B3)**
- a. Specify _____
- B3. Patient listed for transplant? YES..... 1 **(Complete R108)** NO..... 2
- B4. Did patient die? YES..... 1 **(Complete R108)** NO..... 2 **(B5)**
- a. Date of death _____ / _____ / _____
M M D D Y Y Y Y
- b. Was death related to this SAE? YES..... 1 NO..... 2
- B5. **Final** MEDRA event code: _____
(if same as code in B6 on R200, record same code here)
- a. **Final** CTCAE short name/ specify field: _____
- B6. Brief description of resolution: _____

B7. Date faxed to PHN DCC

__	__	/	__	__	/	__	__	__	__
M	M		D	D		Y	Y	Y	Y

Final Report:

Signature of Clinical Center PI_____
Date

SUBMISSION INSTRUCTIONS:

- ***Please review this form with the Clinical Center Principal Investigator (PI) prior to data entry and submission to the Data Coordinating Center (DCC).***
- ***The Clinical Center PI must sign this form.***

Fax all forms to:

DCC AE Lead
PHN Data Coordinating Center
FAX NUMBER: **617-926-7090**

DATA ENTRY INSTRUCTIONS:

- This form must be entered into ADEPT within 3 days of being faxed to the DCC.