



ADVERSE EXPERIENCE FORM

MCC Use Only
Date Rec'd.:

COBLT Recipient ID:

COBLT Name Code:

Center Code:

Date of Onset:

M D Y

*Complete the form and attach a narrative description of the event and patient status.
Submit the form to the MCC as described in the COBLT MOP, Chapter 3, Section 3.2.*

1. Document adverse experience: _____

2. Is this an unexpected serious adverse experience? 1 Yes 2 No
3. Severity of the adverse experience 1 Mild 2 Moderate 3 Severe 4 Life-threatening 5 Fatal
4. Suspected relationship to study therapy ... 1 Definite 2 Probable 3 Possible 4 Remote 5 None
5. Effect on study therapy 1 No Change 2 Reduced 3 Held 4 Discontinued
6. Was treatment required? 1 Required Med(s) 2 None 9 Other, specify: _____
7. Status of adverse experience 1 Resolved 2 Continuing
8. Date of resolution (if known)

M D Y

9. Has this adverse experience been reported to your Institutional Review Board? 1 Yes 2 No
If yes, attach report.

Comments: _____

Coordinator Signature	Date	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Study ID		
Principal Investigator Signature	Date	