

**ADVERSE EVENTS**

**AE**

**subjid**  
**inits**  
**vnum**  
**vdate**  
**cc\_id**

Patient ID: 1 \_\_\_\_\_  
 Patient Initials: \_\_\_\_\_  
 Visit Number: \_\_\_\_\_  
 Current Date: \_\_\_\_/\_\_\_\_/\_\_\_\_  
month day year  
 Interviewer ID: \_\_\_\_\_

*(Clinic Coordinator completed)*

**01A** 1. Description of Adverse Event: \_\_\_\_\_

**02** 2. Date Adverse Event started \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_  
month day year

**03** 3. Adverse Event status <sub>1</sub> Stopped <sub>2</sub> Ongoing

**04** 4. Adverse Event status date \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_  
month day year

**04A** If event was resolved in less than 24 hours, provide duration: \_\_\_\_\_ hours

**05** 5. Adverse Event severity  
 No interruption of normal activities, protocol medications, or procedures <sub>1</sub> Mild  
 Brief interruption of normal activities, protocol medications, or procedures <sub>2</sub> Moderate  
 Significant interruption in activities and/or unlikely to continue with study <sub>3</sub> Severe

**06** 6. Did the patient seek medical care? <sub>1</sub> Yes <sub>0</sub> No  
 If **Yes**,

**06A** 6a. Was emergency care needed? <sub>1</sub> Yes <sub>0</sub> No

**06B** 6b. Was hospitalization needed? <sub>1</sub> Yes <sub>0</sub> No

**07** 7. Were any study medications altered? <sub>1</sub> Yes <sub>0</sub> No  
 If **Yes**, describe \_\_\_\_\_

**08** 8. Were any study procedures altered? <sub>1</sub> Yes <sub>0</sub> No  
 If **Yes**, describe \_\_\_\_\_

**09** 9. Did the patient take any medications for the Adverse Event other than those listed on the Allowed Medications reference card? <sub>1</sub> Yes <sub>0</sub> No  
 If **Yes**, describe \_\_\_\_\_

**10** 10. Did the patient experience a significant asthma exacerbation as defined in the Manual of Operations? <sub>1</sub> Yes <sub>0</sub> No  
 If **Yes**, please complete the Significant Asthma Exacerbation form (SIGEX).