

**ADVERSE EVENT FORM**  
**(ONLY COMPLETED If Study-Related Adverse Event**  
**within 24 Hours of Procedure)**

---

**CKiD Chronic Kidney Disease in Children Cohort Study**

**SECTION A: GENERAL INFORMATION**

A1. PARTICIPANT ID: AFFIX ID LABEL OR ENTER NUMBER IF ID LABEL IS NOT AVAILABLE

|\_| - |\_|\_| - |\_|\_|\_|

A2. CKiD VISIT NUMBER:

\_\_\_ \_

A3. FORM VERSION:

0 6 / 0 1 / 0 8a

A4. DATE OF ADVERSE EVENT:

\_\_\_ \_\_\_ / \_\_\_ \_\_\_ / \_\_\_ \_\_\_ \_\_\_ \_\_\_  
M M D D Y Y Y Y

A5. DATE FORM COMPLETED:

\_\_\_ \_\_\_ / \_\_\_ \_\_\_ / \_\_\_ \_\_\_ \_\_\_ \_\_\_  
M M D D Y Y Y Y

A6. FORM COMPLETED BY (INITIALS):

\_\_\_ \_\_\_

A7. Is this study visit an irregular (accelerated) visit? Yes..... 1  
No..... 2

**SECTION B: TYPE OF ADVERSE EVENT**

B1. Suspected Iohexol Reaction?

Yes..... 1  
No..... 2 **(Skip to B4)**

B2. Type of Suspected Iohexol Reaction

	<u>Yes</u>	<u>No</u>	
a. Rash.....	1	2	
b. Decreased Systolic Blood Pressure (more than 25 mmHg).....	1	2	
c. Decreased Diastolic Blood Pressure (more than 20 mmHg).....	1	2	
d. Increased Pulse (Heart Rate > 20 beats/min).....	1	2	
e. Decreased Pulse (Heart Rate > 20 beats/min).....	1	2	
f. Other.....	1	2	<b>(Skip to B3)</b>
i. Specify: _____			

B3. Please indicate the likelihood that the reaction was due to Iohexol.

Most Probably..... 1  
Probably..... 2  
Possibly..... 3  
Probably Not..... 4

**ADVERSE EVENT FORM**  
**(ONLY COMPLETE If Study-Related Adverse Event**  
**within 24 Hours of Procedure)**

---

B4. Suspected Blood Draw Adverse Event?

- Yes..... 1  
 No..... 2 **(Skip to B7)**

B5. Type of Suspected Blood Draw Adverse Event Yes No

- a. Infection..... 1 2  
 b. Other..... 1 2 **(Skip to B6)**

i. Specify: \_\_\_\_\_

B6. Please indicate the likelihood that the adverse event was related to the blood draw.

- Most Probably..... 1  
 Probably..... 2  
 Possibly..... 3  
 Probably Not..... 4

B7. Suspected ABPM Adverse Event?

- Yes..... 1  
 No..... 2 **(Skip to B10)**

B8. Type of Suspected ABPM Adverse Event Yes No

- a. Bruising..... 1 2  
 b. Other..... 1 2 **(Skip to B9)**

i. Specify: \_\_\_\_\_

B9. Please indicate the likelihood that the adverse event was related to the ambulatory blood pressure monitor.

- Most Probably..... 1  
 Probably..... 2  
 Possibly..... 3  
 Probably Not..... 4

B10. Did the adverse event result in a prolonged observational period or another type of adverse event?

- |                                     | <u>Yes</u> | <u>No</u> |
|-------------------------------------|------------|-----------|
| Prolonged observational period..... | 1          | 2         |
| Emergency room visit.....           | 1          | 2         |
| Hospitalization .....               | 1          | 2         |
| Other.....                          | 1          | 2         |

i. Specify: \_\_\_\_\_

B11. Did the adverse event cause the participant to withdraw from the study?

- Yes..... 1  
 No..... 2

**PROMPT:**  
**If a participant has a serious adverse event (SAE) related to a study procedure (i.e., iohexol GFR) within 24 hours of the procedure, the event must be reported within specified local IRB time guidelines to the local IRB. Please notify the Data Coordinating Center via fax at (410)-955-7587.**