ADVERSE EVENT FORM

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: 1 0 / 0 1 / 1 2

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): ___ ___ ___

Report **any event related to a study procedure**. Also report events **not related to the study that occur within 24 hours** of study procedures. Your PI should determine if the event was related or not related.

A7. Was the Adverse Event determined to be completely UNRELATED to study procedure?

Yes..... 1 **(Skip to C1)**
No..... 2 **(You have indicated that the adverse event was related to the study procedure, Go to B1)**

SECTION B: TYPE OF STUDY RELATED ADVERSE EVENT

B1. Suspected Iohexol Reaction?

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

B2. Type of Suspected Iohexol Reaction

		Yes	No	
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	**(Skip to B3)**

i. Specify:_____
_____

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

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

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?

	Yes	No
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 **(END)**

No..... 2 **(END)**

SECTION C: TYPE OF NON-STUDY RELATED ADVERSE EVENT

C1. Indicate the type of non-study related adverse event experienced.
Circle "yes" to all that apply and "no" if not applicable.

		Yes	No	
1.	Headache.....	1	2	
2.	Dizziness.....	1	2	
3.	GI Problem (i.e. Vomiting)	1	2	
4.	Low Blood Pressure (During Vitals).....	1	2	
5.	Cold/Flu Symptoms.....	1	2	
6.	Dehydration.....	1	2	
7.	Musculoskeletal injuries (sprained or broken bones)....	1	2	
8.	Other.....	1	2	**(END)**
	i Specify: _____			

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

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.