VISIT CHECKLIST FORM (VCL)

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 8 / 1 5 / 2 1

A4. DATE OF STUDY VISIT: ___ ___/ ___ ___/ ___ ___ ___ ___
M M D D Y Y Y Y

A5. FORM COMPLETED BY (INITIALS): ___ ___ ___

A6. Were adverse events experienced?
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.

Yes..... 1 **(Also Complete ADVERSE EVENT FORM)**

No..... 2

SECTION B: Ambulatory Blood Pressure Monitoring (ABPM)

B1. Is the study visit a V2, V4, V6, or subsequent even-numbered visit?

Yes..... 1

No..... 2 **(Skip to D1)**

B2. Was the ABPM sent home with the participant to INITIATE monitoring at home?

Yes..... 1 **(Skip to B4)**

No..... 2

B3. Was the ABPM testing initiated at the clinical site?

Yes..... 1

No..... 2

B4. Were there any problems experienced with the ABPM?

Yes..... 1

No..... 2 **(Skip to C1)**

a. Indicate which of the following problems were experienced with the ABPM. Circle "yes" to all that apply and "no" if not applicable.

		Yes	No
1.	Participant/Family refused.....	1	2
2.	No monitor available for date requested	1	2
3.	Monitor/Cuff Malfunction.....	1	2
4.	Inappropriate Cuff Size.....	1	2
5.	Other.....	1	2 **(Skip to C1)**

i. Specify:_____

SECTION C: ECHO and C-IMT Sub Study

C1. Is the study visit a V2, V6, V10, V14 or V18?

Yes..... 1

No..... 2 **(Skip to D1)**

a. Was the ECHO completed at the study visit?

Yes..... 1 **(Skip to C1c)**

No..... 2

b. Was the ECHO rescheduled?

Yes..... 1

No..... 2

c. Were there any problems experienced when performing the ECHO at the clinical site?

Yes..... 1

No..... 2 **(Skip to C2)**

d. Indicate which of the following problems were experienced when performing the ECHO at the clinical site. Circle "yes" to all that apply and "no" if not applicable.

		Yes	No	
1.	Participant/Family refused……	1	2	
2.	No CKiD sonographer available……	1	2	
3.	Scheduling difficulties……	1	2	
4.	Participant uncooperative/unable to tolerate procedure……	1	2	
5.	Other……	1	2	**(Skip to C2)**

i. Specify:_____

Participants who are five (5) years old or older at a site participating in the C-IMT sub-study are eligible to enroll in the C-IMT sub-study.

C2. Is the participant enrolled in the C-IMT sub-study?

Yes..... 1

No..... 2 **(Skip to D1)**

C3. a. Was the C-IMT testing completed at the study visit?

Yes..... 1 **(Skip to D1)**

No..... 2

b. Was the C-IMT testing rescheduled?

Yes..... 1

No..... 2

c. Please specify the reason(s) the C-IMT testing was not completed. Circle "yes" to all that apply and "no" if not applicable.

		Yes	No	
1.	Participant/Family refused……	1	2	
2.	No CKiD sonographer available……	1	2	
3.	Scheduling difficulties……	1	2	
4.	Participant uncooperative/unable to tolerate procedure……	1	2	
5.	Other……	1	2	**(Skip to D1)**

i. Specify:_____

SECTION D: Iohexol Study

Iohexol is only done at V1a, V2, V4, V6, and subsequent even visits for Cohort 3 participants who consent to iohexol protocol or Cohorts 1 & 2 participants with previous iGFR>90.

D1. Is this a cohort 3 participant or a cohort 1 & 2 participant with previous iGFR>90?

Yes..... 1
No..... 2 **(Skip to E1)**

D2. a. Was iohexol study completed at the study visit?

Yes..... 1 **(Skip to D3)**
No..... 2

b. Please specify the reason why iohexol study was not completed. Circle "yes" to all that apply and "no" if not applicable.

		Yes	No	
1.	Participant/Family refused……	1	2	
2.	Iohexol Infiltrated……	1	2	
3.	Scheduling difficulties……	1	2	
4.	Could not place IV (unsuccessful IV)……	1	2	
5.	Child was too upset to continue……	1	2	
6.	Iohexol Unavailable……	1	2	
7.	Iohexol not required (last iGFR less than 3 months ago)……	1	2	
8.	Participant/family concerned with multiple blood draw sticks	1	2	
9.	Other……	1	2	**(Skip to E1)**

i. Specify:_____

D3. a. Were there any problems/difficulties during the iohexol study?

Yes..... 1
No..... 2 **(Skip to E1)**

b. Please specify any problems/difficulties that occurred during the iohexol study visit. Circle "yes" to all that apply and "no" if not applicable.

		Yes	No	
1.	Difficulty placing IV……	1	2	
2.	Access failure (i.e, access is non-functional)..	1	2	
3.	Multiple venipunctures (i.e., multiple sticks).....	1	2	
4.	Unable to obtain last blood draw.....	1	2	
5.	Problem obtaining/documenting the times (timer malfunction)……	1	2	
6.	Syringe was not weighed and/or documented	1	2	
7.	Other……	1	2	**(Skip to E1)**

i. Specify:_____

SECTION E: Fitness Measurements

Participants who are five (5) years old or older are recommended for the Actigraph study.

E1. Is the participant eligible to wear the Actigraph? If your site is currently not performing the Actigraph, please select "No IRB approval at site".

Yes..... 1
No..... 2 **(Skip to E3)**
No IRB approval at site…….…… 3 **(Skip to E3)**

E2. a. Was the Actigraph device given to the participant (i.e. the Actigraph was placed on the participant or given to be placed on the participant at home)?

Yes……..... 1 **(Skip to E3)**
No..... 2

b. Please specify why the Actigraph device was not given to the participant. Circle "yes" to all that apply and "no" if not applicable.

		Yes	No	
1.	Participant/Family refused…….……	1	2	
2.	Scheduling difficulties……..……..	1	2	
3.	Site decision (participant not good candidate)	1	2	
4.	Other ……	1	2	**(Skip to E3)**

i. Specify: _____

Participants who are six (6) years old or older are eligible to perform the grip strength test.

E3. a. Is the study visit a V3, V5, or subsequent odd numbered visit?

Yes..... 1
No..... 2 **(Skip to F1)**

b. Is the participant eligible to perform the grip strength test (i.e., 6 years old or older)?

Yes……..... 1
No..... 2 **(Skip to F1)**
V1b, Not applicable..... -1 **(Skip to F1)**

E4. a. Did the participant complete the grip strength test?

Yes……..... 1 **(Skip to F1)**
No..... 2

b. Please specify the reason the grip strength test was not completed. Circle "yes" to all that apply and "no" if not applicable.

		Yes	No	
1.	Participant/Family refused…….	1	2	
2.	Physical limitation ……..…	1	2	**(Skip to E4b3)**
	i. Specify: _____			
3.	Other ……	1	2	**(Skip to F1)**
	i. Specify: _____			

SECTION F: Core Neurocognitive Testing

Participants who are three (3) years old or older should complete the NIH toolbox.

F1. Is the participant ≥ 3 years old?
Yes..... 1
No..... 2 **(Skip to F4)**

F2. Is the study visit a V1b, V3, V5, or subsequent odd numbered visit?
Yes..... 1
No..... 2 **(Skip to G1)**

F3. a. Was NIH toolbox testing completed at the study visit?

Yes..... 1 **(Skip to F4)**
No..... 2

b. Was NIH toolbox testing rescheduled?

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

c. Were there any problems experienced with the NIH toolbox testing at the clinical site?
Yes..... 1
No..... 2 **(Skip to F4)**

d. Please specify the reason why NIH toolbox testing was not completed. Circle "yes" to all that apply and "no" if not applicable.

		Yes	No	
1.	Participant/Family refused……	1	2	
2.	No one available to administer test…….	1	2	
3.	Technical difficulties with iPad……	1	2	
4.	Scheduling difficulties……	1	2	
5.	Irregular visit……	1	2	
6.	Other……	1	2	**(Skip to F4)**

i. Specify:_____

F4. a. Were cognitive paper and pencil tests (i.e., Mullen, WPPSI or WASI) completed at the study visit?

Yes..... 1 **(Skip to G1)**
No..... 2

b. Was the cognitive testing rescheduled?

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

c. Were there any problems experienced with the cognitive testing at the clinical site?
Yes..... 1
No..... 2 **(Skip to G1)**

d. Please specify the reason why paper and pencil cognitive testing was not completed. Circle "yes" to all that apply and "no" if not applicable.

		Yes	No	
1.	Participant/Family refused……	1	2	
2.	No one available to administer test……	1	2	
3.	Scheduling difficulties……	1	2	
4.	Irregular visit……	1	2	
5.	Other……	1	2	**(Skip to G1)**

i. Specify:_____

SECTION G: Cardiac MRI

Participants who are eight (8) years old or older with an eGFR ≤ 30 are eligible for cardiac MRI testing at sites qualified to perform cardiac MRI. This cardiac MRI is only measured one time.

G1. Is the participant eligible for cardiac MRI testing (8 years old or older, eGFR ≤ 30, and at a site qualified to perform cardiac MRI)?

Yes..... 1
No..... 2 **(END)**

a. Was the cardiac MRI test completed at the study visit?

Yes..... 1 **(END)**
No..... 2

b. Was the cardiac MRI test performed at a previous study visit?

Yes..... 1 **(END)**
No..... 2

c. Was the cardiac MRI test rescheduled?

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

d. Please specify the reason the cardiac MRI testing was not completed

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