SPECIMEN COLLECTION FORM for Visit 3 (L31)

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 #:		<u>0</u> <u>3</u>			
A3.	FORM VERSIC	DN:	<u>0</u> <u>1</u> / <u>0</u> <u>1</u> / <u>0</u> <u>7</u>			
A4.	SPECIMEN CO DATE:	DLLECTION	$\frac{1}{M} \frac{1}{M} \frac{1}{D} \frac{1}{D} \frac{1}{Y} \frac{1}{Y} \frac{1}{Y} \frac{1}{Y} \frac{1}{Y}$			
A5.	FORM COMPL (INITIALS)	ETED BY:				
A6.	Is this study vis	it an accelerated	visit? Yes 1 No 2			
The	e following sam	ple should be co	ollected.			
	<u>nples:</u> um	<u>Shipped to:</u> CBL	<u>Shipped:</u> IMMEDIATELY			
Ser	um	CBL	BATCHED (Ship in Jan, Apr, Jul or Oct)			
Uri	ne	CBL	IMMEDIATELY			
	Please refer to questions 22 on the Eligibility Form to determine if biological consent was obtained.					
	Depending on the type of consent, the following samples may or may not be collected:					

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<u>Samples:</u> Serum (Biological)	<u>Shipped to:</u> NIDDK Biosample Repository	<u>Shipped:</u> BATCHED (Ship in Jan, Apr, Jul or Oct)
Plasma (Biological)	NIDDK Biosample Repository	BATCHED (Ship in Jan, Apr, Jul or Oct)
Urine (Biological)	NIDDK Biosample Repository	BATCHED (Ship in Jan, Apr, Jul or Oct)
*Whole Blood (Genetic	IMMEDIATELY	

*ONLY collect whole blood for Genetic Repository, if sample was not collected at V1b OR if sample collected at V1b was inadequate.



SECTION B: PREGNANCY TEST AND FIRST URINE COLLECTION

B1.	Is participan	t a female of	child-bearing	potential?
D 1.	io paraoipari		orma boaring	potorition

Yes	1 (See PROMPT Below)
No	2 (Skip to B3)

PROMPT: QUESTION B2 IS FOR FEMALE PARTICIPANTS OF CHILD-BEARING POTENTIAL ONLY. URINE PREGNANCY TEST DATE MUST FALL WITHIN 72 HOURS.

- B2. a. Urine pregnancy test date:

Positive...... 1 (END; COMPLETE DISENROLLMENT FORM)

FIRST MORNING URINE COLLECTION

Obtain urine collected at home in the specimen container that was shipped to the family before the visit. IF URINE WAS NOT collected at home, collect FRESH urine into a specimen container provided by central biochemistry laboratory (containers were shipped in batches to each site).

Pour 5 to 14.5 mL of urine into blue top urine collection tube and 5 mL into cryovial (provided by CBL).

Check that all information is correct on the urine collection tube and follow packaging instructions and ship to CBL.

Reasons Code List [*] :	1= Not required	3 = Participant Refused	5 = Inadvertently Destroyed
	2 = Difficult Urine Collection	4 = Collection Contamination	6 = Oversight

Sample Type (Required Volume in Top Color Tube Type):		(a) Sample Obt	ained:	(b) If No, specify reason *SEE CODE LIST ABOVE	(c) Additional Requirements:
		Yes	<u>No</u>		
В3.	1 st Morning Urine (Urine Creatinine, Urine Protein) (5.0 mL–14.5 mL in Blue Top tube)	1 (skip to c→)	2	(skip to C1)	i. Is this a first morning urine sample? Yes1 No2 ii. Time of Collection: : 1 = am, 2 = pm

SECTION C: Visit 3 BLOOD DRAW

For Initial Blood Draw with <u>Syringe</u>, <u>Vacutainer</u> OR <u>Butterfly</u> Method: Select the Type of Consent Obtained (options 1 through 4):

If participant did NOT consent to BIOLOGICAL samples and Genetic samples:

Collect 10.5-13.5 mL from all participants (regardless of weight) as specified below.

Immediately transfer (using 18 gauge needle) or draw:

- 6.5 mL into (2) Tiger-Top SSTs for CBL
- 1 mL in lavender-top tube fore local CBC (tube not provided in CBL kit)
- 3 mL in another tube (not provided) for local Renal Panel
- 2.5 mL of additional blood in SST for CBL (if initial sample is GROSSLY HEMOLYZED)
- If participant consented to BIOLOGICAL samples ONLY:

Collect 16.5-19.0 mL if participant is < 30 kg OR 20.5-23.0 mL if participant is $\ge 30 \text{ kg}$.

If < 30 kg, immediately transfer (using 18 gauge needle) or draw:	If \geq 30 kg, immediately transfer (using 18 gauge needle) or draw:
• 9.5 mL into (2) Tiger-Top SSTs for CBL & NIDDK BR	• 11.5 mL into (2) Tiger-Top SSTs for CBL & NIDDK BR
3 mL into PST for NIDDK Biosample Repository	• 5 mL into PST for NIDDK Biosample Repository
• 1 mL in lavender-top tube fore local CBC (tube not provided in CBL kit)	• 1 mL in lavender-top tube fore local CBC (tube not provided in CBL kit)
• 3 mL in another tube (<i>not provided</i>) for local Renal Panel	• 3 mL in another tube (<i>not provided</i>) for local Renal Panel
• 2.5 mL of additional blood in SST for CBL (if initial sample is GROSSLY HEMOLYZED)	• 2.5 mL of additional blood in SST for CBL (if initial sample is GROSSLY HEMOLYZED)

ONLY collect whole blood for Genetic Repository, if sample was not collected at V1b or sample collected at V1b was inadequate.

3 If participant consented to GENETIC samples ONLY: Collect 18.3-20.8 mL from all participants (regardless of weight)

Immediately transfer or draw:

2

- 7.8 mL into (3) 2.6mL ACD tubes for Rutgers Genetic Repository (ACD Tubes must be COMPLETELY FILLED TO THE TOP)
- 6.5 mL into (1) Tiger-Top SST for CBL
- 1 mL in lavender-top tube fore local CBC (tube not provided in CBL kit)
- 3 mL in another tube (not provided) for local Renal Panel
- 2.5 mL of additional blood in SST for CBL (if initial sample is GROSSLY HEMOLYZED)

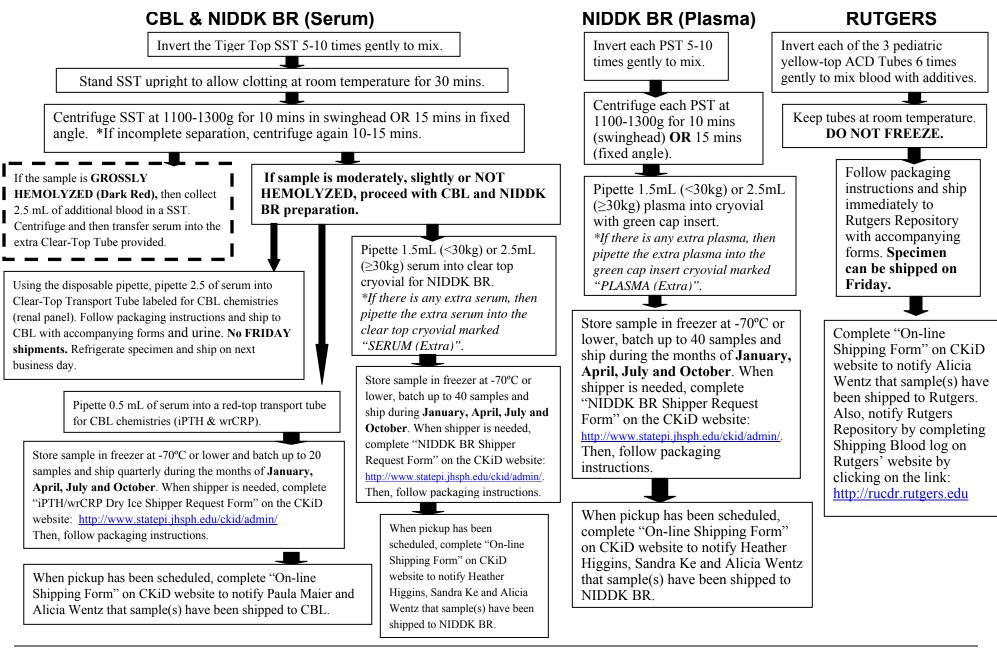
A If participant consented to both BIOLOGICAL AND GENETIC samples:

Collect 24.3-26.8 mL if participant is < 30 kg OR 28.3-30.8 mL if participant is $\geq 30 \text{ kg}$.

If < 30 kg, immediately transfer or draw:	If \geq 30 kg, immediately transfer or draw:
 7.8 mL into (3) 2.6mL ACD tubes for Rutgers Genetic Repository (ACD Tubes must be COMPLETELY FILLED TO THE TOP) 	7.8 mL into (3) 2.6mL ACD tubes for Rutgers Genetic Repository (ACD Tubes must be COMPLETELY FILLED TO THE TOP)
 9.5 mL into (2) Tiger-Top SST for CBL and NIDDK Biosample Repository 3 mL into (1) PST for NIDDK Biosample Repository 	 11.5 mL into (2) Tiger-Top SST for CBL and NIDDK Biosample Repository 5 mL into two (2) PSTs for NIDDK Biosample Repository
• 1 mL in lavender-top tube fore local CBC (tube not provided in CBL kit)	• 1 mL in lavender-top tube fore local CBC (tube not provided in CBL kit)
 3 mL in another tube (not provided) for local Renal Panel 2.5 mL of additional blood in SST for CBL (if initial sample is grossly hemolyzed) 	 3 mL in another tube (not provided) for local Renal Panel 2.5 mL of additional blood in SST for CBL (if initial sample is grossly hemolyzed)

SPECIMEN COLLECTION FORM for Visit V3 (L31)

SECTION C: Visit 3 BLOOD DRAW PROCESSING



SECTION C: Visit 3 BLOOD DRAW AND PROCESSING

C1. ACTUAL TIME OF BLOOD DRAW _____ : ____ 1 = AM 2 = PM

 Reasons Code List:
 1= Not required
 3 = Participant Refused
 5 = Inadvertently Destroyed

 2 = Difficult Blood Draw
 4 = Red Blood Cell Contamination
 6 = Oversight

Sample Type (Required Volume in Top Color Tube Type):		(a) Sample Obtained:		(b) If No, specify reason *SEE CODE LIST ABOVE	(c) Additional Requirements:
C2.	Renal Chemistries (5.0 mL in Tiger Top SST)	<u>Yes</u> 1 (skip to c→)	<u>No</u> 2	(skip to C3)	i. Indicate the appearance of the serum after centrifuging. Grossly (Dark Red)1 Moderately (Red/Light Red)2 Slightly (Pink)3
C3.	Serum for iPTH & wrCRP (1.5 mL of blood in Tiger Top SST)	1 (skip to c→)	2	 (skip to C4a)	Not Hemolyzed (Clear)4 Date Frozen: ///
C4a.	Local CBC (1.0 mL in Lavender Top tube)	1 (skip to C4b)	2	(skip to C4b)	N/A
C4b.	Local Renal Panel (3.0 mL in Local SST)	1 (skip to C5)	2	(skip to C5)	N/A

Sites can obtain results for lab values that have been identified as "KEY VARIABLES". To obtain results, go the CKiD Nephron Website:

https://statepiaps.jhsph.edu/nephron/groups/aspproc/, click on "Report Menu" and choose the appropriate lab report (i.e., Selected Renal Panel Lab Variables Report.)

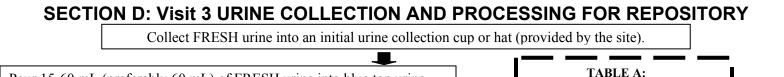
C5. Did the participant consent to have biological samples (i.e., serum, plasma and urine) stored at NIDDK Biosample Repository?

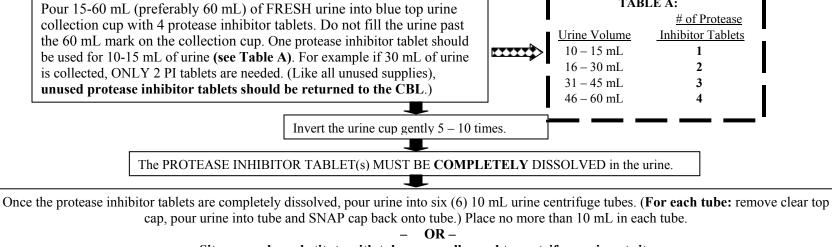
Yes	1
No	2 (E1)

Reasons Code List*	1= Not required	3 = Participant Refused	5 = Inadvertently Destroyed
_	2 = Difficult Blood Draw	4 = Red Blood Cell Contamination	6 = Oversight

	Sample Type (Required Volume in Top Color Tube Type):		ned:	(b) If No, specify reason *SEE CODE LIST ABOVE	(c) Additional Requirements:
		Yes	<u>No</u>		
C6.	Serum for NIDDK Biosample Repository (**3.0 mL or **5.0 mL of blood in Tiger Top SST)	1 (skip to c→)	2	(skip to C7)	Date Frozen: ///
C7.	Plasma for NIDDK Biosample Repository (**3.0 mL of blood (1) Green Top or **5.0 mL (2) Green Top PSTs)	1 (skip to c→)	2	(skip to D1)	Date Frozen: ///

** Collect 3.0 mL of whole blood for children < 30 kg and 5.0 mL for children \ge 30 kg





Sites may also substitute with tubes normally used to centrifuge urine at site.

Centrifuge urine tube(s) at MAX SPEED (between 1100-1300g) for 10 mins (swinghead units) – **OR** – 15 mins (fixed angle units).

Decant (pour off) the supernates (liquid reaction) into seven (7) 10 mL urine cryovials. Pour no more than 9 mL of urine into each 10 mL cryovial to allow for expansion.

Check that all information is correct on the urine transport tube, promptly freeze and store sample(s) at -70°C or lower. Batch up to 36 samples. When shipper is needed, complete "*NIDDK Shipper Request Form*" on CKiD website: <u>http://www.statepi.jhsph.edu/ckid/admin/</u>. Then, follow packaging instructions.

When pickup has been scheduled, complete "Online Shipping Form" on CKiD website to notify Heather Higgins and Alicia Wentz that sample(s) have been shipped to NIDDK BR.

Reasons Code List :	1= Not required	2 = Difficult Urine	3 = Participant	4 = Collection	5 = Inadvertently	6 = Oversight
		Collection	Refused	Contamination	Destroyed	

Sample Type (Required Volume in Top Color Tube Type):		(a) Sample Obtained: <u>Yes No</u>		(b) If No, specify reason *SEE CODE LIST ABOVE	(c) Additional Requirements:	
D1.	Urine for NIDDK Biosample Repository (15.0 - 60.0 mL of urine in specimen container and transferred into collection cup with protease inhibitors)	1 (skip to c→)	2	(skip to E1→)	i. Was supernate decanted into urine transport cryovials? Yes1 No2 ii. Date Frozen: //	

SECTION E: WHOLE BLOOD FOR GENETIC REPOSITORY

BLOOD FOR THE GENETIC REPOSITORY SHOULD BE SHIPPED ONLY IF THE SAMPLE <u>WAS NOT</u> COLLECTED AT V1B OR IF THE SAMPLE OBTAINED AT V1B WAS INADEQUATE (i.e, cell lines were not immortalized).

If participant has consented to have blood stored at Rutgers but it is not necessary to collect the blood for the Genetic Repository, Code question E2b as "01."

E1. Did the participant consent to have whole blood stored at Rutgers, the Genetic Repository?

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

Reasons Code List [*] : 1= Not required		3 = Participant Refused	5 = Inadvertently Destroyed	
	2 = Difficult Blood Draw	4 = Red Blood Cell Contamination	6 = Oversight	

Sample Type (Required Volume in Top Color Tube Type):		(a) Sample Obtained:		(b) If No, specify reason	(c) Additional Requirements:
		Yes	No	*SEE CODE LIST ABOVE	
E2.	Whole Blood for Rutgers Cell & DNA Repository (7.8 mL of blood in 3 pediatric (2.6 mL) Yellow Top ACD tubes)	1 (skip to c→)	2	 (skip to END)	i. Date of Blood Draw: / / /
					iv. Age of participant : years

COPY THIS PAGE AND SHIPMENT TRACKING FORM (ST04) AND SEND TO RUTGERS WITH RUTGERS SPECIMEN.