

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 #: 0 3

A3. FORM VERSION: 0 1 / 0 1 / 0 7

A4. SPECIMEN COLLECTION DATE: _____ / _____ / _____
M M D D Y Y Y Y

A5. FORM COMPLETED BY: _____
(INITIALS)

A6. Is this study visit an accelerated visit? Yes..... 1
No..... 2

The following sample should be collected.

<u>Samples:</u>	<u>Shipped to:</u>	<u>Shipped:</u>
Serum	CBL	IMMEDIATELY
Serum	CBL	BATCHED (Ship in Jan, Apr, Jul or Oct)
Urine	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:

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

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

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SECTION B: PREGNANCY TEST AND FIRST URINE COLLECTION

- B1. Is participant a female of child-bearing potential?
- 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: / /
- M M D D Y Y Y Y
- b. Urine pregnancy results:
- Positive..... 1 (END; COMPLETE DISENROLLMENT FORM)
- Negative..... 2

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 Obtained: <u>Yes</u> <u>No</u>	(b) If No, specify reason *SEE CODE LIST ABOVE	(c) Additional Requirements:
B3. 1 st Morning Urine (Urine Creatinine, Urine Protein) (5.0 mL–14.5 mL in Blue Top tube)	1 2 (skip to c→)	___ ___ (skip to C1)	i. Is this a first morning urine sample? Yes.....1 No.....2 ii. Time of Collection: ___ : ___ 1 = am, 2 = pm

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SECTION C: Visit 3 BLOOD DRAW

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

1 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**)

2 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 ≥ 30 kg.

If < 30 kg, immediately transfer (using 18 gauge needle) or draw:

- 9.5 mL into (2) Tiger-Top SSTs for CBL & NIDDK BR
- 3 mL into PST for NIDDK Biosample Repository
- 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 ≥ 30 kg, immediately transfer (using 18 gauge needle) or draw:

- 11.5 mL into (2) Tiger-Top SSTs for CBL & NIDDK BR
- 5 mL into PST for NIDDK Biosample Repository
- 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**)

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:

- 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**)

4 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 ≥ 30 kg.

If < 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)
- 9.5 mL into (2) Tiger-Top SST for CBL and NIDDK Biosample Repository
- 3 mL into (1) PST for NIDDK Biosample Repository
- 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 ≥ 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)
- 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)
- 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**)

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SECTION C: Visit 3 BLOOD DRAW PROCESSING

CBL & NIDDK BR (Serum)

Invert the Tiger Top SST 5-10 times gently to mix.

Stand SST upright to allow clotting at room temperature for 30 mins.

Centrifuge SST at 1100-1300g for 10 mins in swinghead OR 15 mins in fixed angle. *If incomplete separation, centrifuge again 10-15 mins.

If the sample is **GROSSLY HEMOLYZED (Dark Red)**, then collect 2.5 mL of additional blood in a SST. Centrifuge and then transfer serum into the extra Clear-Top Tube provided.

If sample is moderately, slightly or NOT HEMOLYZED, proceed with CBL and NIDDK BR preparation.

Using the disposable pipette, pipette 2.5 of serum into Clear-Top Transport Tube labeled for CBL chemistries (renal panel). Follow packaging instructions and ship to CBL with accompanying forms and urine. **No FRIDAY shipments.** Refrigerate specimen and ship on next business day.

Pipette 0.5 mL of serum into a red-top transport tube for CBL chemistries (iPTH & wrCRP).

Store sample in freezer at -70°C or lower and batch up to 20 samples and ship quarterly during the months of **January, April, July and October**. When shipper is needed, complete "iPTH/wrCRP Dry Ice Shipper Request Form" on the CKiD website: <http://www.statepi.jhsph.edu/ckid/admin/>. Then, follow packaging instructions.

When pickup has been scheduled, complete "On-line Shipping Form" on CKiD website to notify Paula Maier and Alicia Wentz that sample(s) have been shipped to CBL.

Pipette 1.5mL (<30kg) or 2.5mL (≥30kg) serum into clear top cryovial for NIDDK BR. *If there is any extra serum, then pipette the extra serum into the clear top cryovial marked "SERUM (Extra)".

Store sample in freezer at -70°C or lower, batch up to 40 samples and ship during **January, April, July and October**. When shipper is needed, complete "NIDDK BR Shipper Request Form" on the CKiD website: <http://www.statepi.jhsph.edu/ckid/admin/>. Then, follow packaging instructions.

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

NIDDK BR (Plasma)

Invert each PST 5-10 times gently to mix.

Centrifuge each PST at 1100-1300g for 10 mins (swinghead) OR 15 mins (fixed angle).

Pipette 1.5mL (<30kg) or 2.5mL (≥30kg) plasma into cryovial with green cap insert. *If there is any extra plasma, then pipette the extra plasma into the green cap insert cryovial marked "PLASMA (Extra)".

Store sample in freezer at -70°C or lower, batch up to 40 samples and ship during the months of **January, April, July and October**. When shipper is needed, complete "NIDDK BR Shipper Request Form" on the CKiD website: <http://www.statepi.jhsph.edu/ckid/admin/>. Then, follow packaging instructions.

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

RUTGERS

Invert each of the 3 pediatric yellow-top ACD Tubes 6 times gently to mix blood with additives.

Keep tubes at room temperature. **DO NOT FREEZE.**

Follow packaging instructions and ship immediately to Rutgers Repository with accompanying forms. **Specimen can be shipped on Friday.**

Complete "On-line Shipping Form" on CKiD website to notify Alicia Wentz that sample(s) have been shipped to Rutgers. Also, notify Rutgers Repository by completing Shipping Blood log on Rutgers' website by clicking on the link: <http://rucdr.rutgers.edu>

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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: <u>Yes</u> <u>No</u>	(b) If No, specify reason *SEE CODE LIST ABOVE	(c) Additional Requirements:
C2. Renal Chemistries (5.0 mL in Tiger Top SST)	1 (skip to c→)	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 Not Hemolyzed (Clear).....4
C3. Serum for iPTH & wrCRP (1.5 mL of blood in Tiger Top SST)	1 (skip to c→)	2	Date Frozen: ____ ____ / ____ ____ / ____ ____ M M D D Y Y Y Y
C4a. Local CBC (1.0 mL in Lavender Top tube)	1 (skip to C4b)	2	N/A
C4b. Local Renal Panel (3.0 mL in Local SST)	1 (skip to C5)	2	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.)

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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):	(a) Sample Obtained:	(b) If No, specify reason *SEE CODE LIST ABOVE	(c) Additional Requirements:
	Yes No		
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: ____ / ____ / ____ M M D D Y Y Y Y
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: ____ / ____ / ____ M M D D Y Y Y Y

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

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SECTION D: Visit 3 URINE COLLECTION AND PROCESSING FOR REPOSITORY

Collect FRESH urine into an initial urine collection cup or hat (provided by the site).

Pour 15-60 mL (preferably 60 mL) of FRESH urine into blue top urine collection cup with 4 protease inhibitor tablets. Do not fill the urine past the 60 mL mark on the collection cup. One protease inhibitor tablet should be used for 10-15 mL of urine (see Table A). For example if 30 mL of urine is collected, ONLY 2 PI tablets are needed. (Like all unused supplies), **unused protease inhibitor tablets should be returned to the CBL.**

Urine Volume	# of Protease Inhibitor Tablets
10 – 15 mL	1
16 – 30 mL	2
31 – 45 mL	3
46 – 60 mL	4

Invert the urine cup gently 5 – 10 times.

The PROTEASE INHIBITOR TABLET(S) MUST BE **COMPLETELY** DISSOLVED in the urine.

Once the protease inhibitor tablets are completely dissolved, pour urine into six (6) 10 mL urine centrifuge tubes. (**For each tube:** remove clear top cap, pour urine into tube and SNAP cap back onto tube.) Place no more than 10 mL in each tube.
 – OR –
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: <http://www.statepi.ihsp.edu/ckid/admin/>. 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 Collection 3 = Participant Refused 4 = Collection Contamination 5 = Inadvertently Destroyed 6 = Oversight

Sample Type (Required Volume in Top Color Tube Type):	(a) Sample Obtained: <small>Yes No</small>	(b) If No, specify reason <small>*SEE CODE LIST ABOVE</small>	(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)	<table style="margin: auto;"> <tr> <td style="text-align: center;">1</td> <td style="text-align: center;">2</td> </tr> <tr> <td colspan="2" style="text-align: center;">(skip to c→)</td> </tr> </table>	1	2	(skip to c→)		<p>— — — (skip to E1→)</p>	i. Was supernate decanted into urine transport cryovials? Yes.....1 No.....2 ii. Date Frozen: ___ ___ / ___ / ___ ___ ___ <div style="text-align: center; font-size: small;"> M M D D Y Y Y Y </div>
1	2						
(skip to c→)							

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SECTION E: WHOLE BLOOD FOR GENETIC REPOSITORY

BLOOD FOR THE GENETIC REPOSITORY SHOULD BE SHIPPED ONLY IF THE SAMPLE WAS NOT 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 *SEE CODE LIST ABOVE	(c) Additional Requirements:
	Yes	No		
E2. Whole Blood for Rutgers Cell & DNA Repository (7.8 mL of blood in 3 pediatric (2.6 mL) Yellow Top ACD tubes)	1	2 (skip to c→)	_____ (skip to END)	i. Date of Blood Draw: ____ / ____ / ____ M M D D Y Y Y Y ii. Blood Drawn By : _____ (initials) iii. Gender of participant : Male.....1 Female.....2 iv. Age of participant : _____ years

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