

SPECIMEN COLLECTION FORM for ODD Follow-up Visits (3, 5, 7...) (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 #:

A3. FORM VERSION:

0 8 / 0 1 / 1 6

A4. SPECIMEN COLLECTION DATE:

___ / ___ / ___
M M D D Y Y Y Y

A5. FORM COMPLETED BY (INITIALS):

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)
Plasma	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)</i>	<i>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.

**BATCHED SAMPLES SHOULD BE SHIPPED QUARTERLY (Jan, Apr, July or Oct)
OR MORE OFTEN IF DESIRED BY THE SITE COORDINATOR!**

**Samples should NOT be stored for more than one year.
For specific questions, contact your CCC prior to shipment.**

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SECTION B: PREGNANCY TEST AND FIRST MORNING 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 BEFORE STUDY VISIT DATE.

B2. a. Urine pregnancy test date: _____/_____/_____
 M M D D Y Y Y Y

- b. Urine pregnancy results:
- Positive..... 1 (END; COMPLETE TRANSITIONAL 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 at least 1 mL of urine into the CBL transport tube.



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):	(a) Sample Obtained:	(b) If No, specify reason *SEE CODE LIST ABOVE	(c) Additional Requirements:
	<u>Yes</u> <u>No</u>		
B3. Urine Creatinine, Urine Protein, Urine Albumin (CBL) (1 mL–10 mL)	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):
ONLY collect whole blood for Genetic Repository, if sample was not collected at V1b or sample collected at V1b was inadequate.

1 If participant consented to both BIOLOGICAL AND GENETIC samples:

Collect 22.5-23.5 mL if participant is < 30 kg OR 28.5-29.5 mL if participant is ≥ 30 kg.

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

- If not collected at V1b - 6 mL into (1) 6mL ACD tube for Rutgers Genetic Repository (ACD Tube must be COMPLETELY FILLED)
- 10 mL into (2) Tiger-Top SST for CBL and NIDDK Biosample Repository
- 4 mL into two (2) PSTs for CBL and NIDDK Biosample Repository
- 1 mL in lavender-top tube for local CBC (tube not provided in CBL kit)
- 1.5 mL in appropriate tube (*not provided*) for local Renal Panel
- 1 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:

- If not collected at V1b - 6 mL into (1) 6mL ACD tube for Rutgers Genetic Repository (ACD Tube must be COMPLETELY FILLED)
- 14 mL into (2) Tiger-Top SST for CBL and NIDDK Biosample Repository
- 6 mL into two (2) PSTs for NIDDK Biosample Repository
- 1 mL in lavender-top tube for local CBC (tube not provided in CBL kit)
- 1.5 mL in appropriate tube (*not provided*) for local Renal Panel
- 1 mL of additional blood in SST for CBL (if initial sample is grossly hemolyzed)

2 If participant consented to BIOLOGICAL samples ONLY:

Collect 16.5-17.5 mL if participant is < 30 kg OR 22.5-23.5 mL if participant is ≥ 30 kg.

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

- 10 mL into (2) Tiger-Top SSTs for CBL & NIDDK BR
- 4 mL into one (1) PSTs for CBL and NIDDK Biosample Repository
- 1 mL in lavender-top tube for local CBC (tube not provided in CBL kit)
- 1.5 mL in appropriate tube (*not provided*) for local Renal Panel
- 1 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:

- 14 mL into (2) Tiger-Top SSTs for CBL & NIDDK BR
- 6 mL into (2) PST for NIDDK Biosample Repository
- 1 mL in lavender-top tube for local CBC (tube not provided in CBL kit)
- 1.5 mL in appropriate tube (*not provided*) for local Renal Panel
- 1 mL of additional blood in SST for CBL (if initial sample is GROSSLY HEMOLYZED)

3 If participant consented to GENETIC samples ONLY, collect 13.5-14.5 mL from all participants (regardless of weight):

Immediately transfer or draw:

- If not collected at V1b - 6 mL into (1) 6mL ACD tube for Rutgers Genetic Repository (ACD Tube must be COMPLETELY FILLED)
- 4mL into (1) Tiger-Top SST for CBL
- 1 mL into PST for CBL
- 1 mL in lavender-top tube for local CBC (tube not provided in CBL kit)
- 1.5 mL in appropriate tube (*not provided*) for local Renal Panel
- 1 mL of additional blood in SST for CBL (if initial sample is GROSSLY HEMOLYZED)

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

Collect 7.5-8.5 mL from all participants (regardless of weight) as specified below.

Immediately transfer (using 18 gauge needle) or draw:

- 4 mL into (1) Tiger-Top SSTs for CBL
- 1 mL into PST for CBL
- 1 mL in lavender-top tube for local CBC (tube not provided in CBL kit)
- 1.5 mL in appropriate tube (*not provided*) for local Renal Panel
- 1 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 times gently to mix.

Stand SST upright to allow clotting at room temperature for 30 mins and not more than 1 hour (60 mins).

Centrifuge SST at MAX SPEED between 1100-1300g (3000rpm with 10cm radius rotor) for 10 mins in swinghead OR 15 mins in fixed angle. *If incomplete separation, centrifuge again 10-15 mins.

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

NIDDK (Serum)
Pipette 3mL (<30kg) or 5mL (≥30kg) serum into clear top cryovial for NIDDK BR (use different pipettes for serum and plasma).
**If there is any extra serum, then pipette the extra serum into the clear top cryovial marked "NIDDK BR SERUM"*

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

iPTH/hsCRP
Pipette 0.5 mL of serum into a red top cryovial tube for CBL iPTH & hsCRP

Vitamin D
Pipette 0.5 mL of serum into a red top cryovial for CBL Vitamin D

Cystatin C
Using the disposable pipette, pipette 0.5 mL of serum into Blue Screw-Top Cryovial for Cystatin C.

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 "CBL Dry Ice Shipper Request Form" on the CKiD website: <http://www.statepi.jhsph.edu/ckid/admin/> Then, follow packaging instructions and ship to CBL with accompanying forms. **No FRIDAY shipments**. Ship on next business day.

FGF-23
Pipette 0.5 mL of plasma into a cryovial with green cap insert for CBL FGF-23

Pipette 1.5mL (<30kg) or 2.5mL (≥30kg) plasma into cryovial with green cap insert (use different pipettes for serum and plasma).
**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 **Jan, April, July and Oct**. 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.

CBL & NIDDK BR (Plasma)

Invert each PST 8-10 times gently to mix.

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

RUTGERS

Invert the ACD Tube 6 times gently to mix blood with additives.

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

Follow packaging instructions, complete RUCDR Collection Form 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 KIDMAC that sample(s) have been shipped to Rutgers.

You must send hemolyzed sample to CBL. Also if the sample is **GROSSLY HEMOLYZED (Dark Red)**, then collect 1 mL of additional blood in a SST. Centrifuge and then transfer serum into the extra Orange Top Transport Tube provided.

CBL Studies
Using the disposable pipette, pipette 0.5 of serum into Orange Top Transport Tube labeled "Serum CBL" for CBL renal/uric acid). Follow packaging instructions and ship to CBL with accompanying forms and urine. **No FRIDAY shipments**. Refrigerate specimen and ship on next business day.

When pickup has been scheduled, complete "On-line Shipping Form" on CKiD website: <http://www.statepi.jhsph.edu/ckid/admin/> to notify the appropriate personnel from the CBL and the NIDDK BR.

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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:		(b) If No, specify reason *SEE CODE LIST ABOVE	(c) Additional Requirements:
	Yes	No		
C2a. Renal/Uric Acid Chemistries (1.0* mL in Tiger Top SST)	1 (skip to c→)	2	_____ (skip to C2b)	i. Indicate the appearance of the serum after centrifuging. Grossly (Dark Red).....1 Moderately (Red/Light Red).....2 Slightly (Pink).....3 Not Hemolyzed (Yellow).....4
C2b. Cystatin C (1.0 mL in Tiger Top SST)	1 (skip to c→)	2	_____ (skip to C3)	Date Frozen: ____ / ____ / ____ M M D D Y Y Y Y
C3a. Serum for iPTH, hsCRP & Vitamin D (2.0 mL of blood in Tiger Top SST)	1 (skip to c→)	2	_____ (skip to C3b)	Date Frozen: ____ / ____ / ____ M M D D Y Y Y Y
C3b. Plasma for FGF-23 (1.0 mL of blood in PST)	1 (skip to c→)	2	_____ (skip to C4a)	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	_____ (skip to C4b)	N/A
C4b. Local Renal Panel (1.5 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://statepiaps6.jhsph.edu/nephron/groups/aspprocl/>, 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 **(Skip to 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 (**6.0 mL or **10.0 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 6.0 mL of whole blood for participants < 30 kg and 10.0 mL for participants ≥ 30 kg

*** Collect 3.0 mL of whole blood for participants < 30 kg and 5.0 mL for participants ≥ 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 90 mL 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 up to six (6) 10 mL urine centrifuge tubes. (**For each tube:** remove yellow top cap, pour urine into tube and SCREW 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 (3000rpm with 10cm radius rotor) for 10 mins (swinghead units) – **OR** – 15 mins (fixed angle units).

Decant (pour off) the supernates (liquid reaction) into up to 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 cryovials, promptly freeze and store sample(s) at -70°C or lower. Batch samples and ship at least quarterly (include maximum of 36 cryovials per shipper). When shipper(s) is needed, complete “NIDDK Shipper Request Form” on CKiD website: <http://www.statepi.jhsph.edu/ckid/admin/>. Then, follow packaging instructions.

When pickup has been scheduled, complete “Online Shipping Form” on CKiD website to notify Heather Higgins and KIDMAC 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: <u>Yes</u> <u>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 2 (skip to c→)	_____ (skip to D2→)	i. Was supernate decanted into urine transport cryovials? Yes.....1 No.....2 ii. Date Frozen: ____ / ____ / ____ M M D D Y Y Y Y

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OPTIONAL LOCAL LAB TEST (IF CLINICALLY INDICATED)

Check with the PI at your clinical site to determine whether or not it is **CLINICALLY INDICATED** to obtain urine for local lab. These are instances when the PI needs results immediately and/or the participant needs additional local labs performed (i.e., local Urine Creatinine and Urine Protein).

D2. Was a urine protein to creatinine ratio assay performed at the clinical site's local laboratory?

Yes..... 1 → **Complete Local Urine Assay Results Form L06, ONLY if local labs are CLINICALLY INDICATED**
 No..... 2

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 FORM)

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:
E2. Whole Blood for Rutgers Cell & DNA Repository (6 mL of blood in 1 (6 mL) ACD tube)	1	2	i. Date of Blood Draw: ____ / ____ / ____ M M D D Y Y Y Y
	(skip to c→)		ii. Blood Drawn By : ____ (initials)
	(END FORM)		iii. Gender of participant : Male.....1 Female.....2
	(END FORM)		iv. Age of participant : ____ years