SPECIMEN COLLECTION FORM for ODD Follow-up Post-Transplant Visit (TL31)

CKiD Chronic Kidney Disease in Children Cohort Study (CKiD)

SECTION A: GENERAL INFORMATION

A1. PARTICIPANT ID: AFFIX ID LABEL OR ENTER NUMBER IF ID LABEL IS NOT AVAILABLE

|__| - |__|__| - |__|__|__|

A2. CKiD Post KRT VISIT #: ___ ___ ___

A3. FORM VERSION: **0 7 / 0 1 / 1 9a**

A4. SPECIMEN COLLECTION DATE: ___ ___/ ___ ___/ ___ ___ ___ ___
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A5. FORM COMPLETED BY (INITIALS): ___ ___ ___

At the Post-Transplant Visit, collect the following:

Samples:	**Shipped to:**	**Shipped:**
Serum	**CBL**	**IMMEDIATELY**
Serum	**CBL**	**Batched (Ship in Jan, Apr, Jul or Oct)**
Urine	**CBL**	**IMMEDIATELY**

If consent is obtained for biological samples, collect the following:

Samples:	**Shipped to:**	**Shipped:**
Serum (Biological)	**NIDDK Biorepository**	**Batched (Ship in Jan, Apr, Jul or Oct)**
Plasma (Biological)	**NIDDK Biorepository**	**Batched (Ship in Jan, Apr, Jul or Oct)**
Urine (Biological)	**NIDDK Biorepository**	**Batched (Ship in Jan, Apr, Jul or Oct)**

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 six (6) months.
For specific questions, contact your CCC prior to shipment.

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 OCCUR ON DAY OF VISIT OR FALL WITHIN 72 HOURS BEFORE STUDY VISIT DATE.

B2. a. Urine pregnancy test date: ___ ___/ ___ ___/ ___ ___ ___ ___
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b. Urine pregnancy results:

Positive..... 1 **(END; COMPLETE TRANSITIONAL (TRS03) FORM)**

Negative..... 2

Post-Transplant Visit
FIRST MORNING URINE COLLECTION for CBL

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 the central biochemistry laboratory.

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	7=Insufficient Volume
	2 = Difficult Urine Collection	4 = Collection Contamination	6 = Oversight	

Sample Type (Required Volume):	**(a) Sample Obtained:** Yes / No	**(b) If No, specify reason** *SEE CODE LIST ABOVE	**(c) Additional Requirements:**
B3. Urine Creatinine, Urine Protein (1 mL–10 mL)	1 / 2 **(skip to c→)**	__ __ **(skip to B4)**	i. Is this a first morning urine sample? Yes.....1 No.....2
			ii. Time of Collection: __ __ : __ __ 1 = am, 2 = pm

OPTIONAL TESTS
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).

B4. 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 C: ODD NUMBERED POST-TRANSPLANT VISIT BLOOD DRAW

For Initial Blood Draw with Syringe, Vacutainer OR Butterfly Method: Select the type of consent obtained (options 1 through 2):

1 **If participant consented to BIOLOGICAL samples:**
Collect **13.5-14.5** mL if participant is < **30 kg** **OR** **19.5-20.5** mL if participant is ≥ **30 kg**.

If < **30 kg**, immediately transfer **(using 18 gauge needle)** or draw:
- 8 mL into (1) Tiger-Top SST for CBL & NIDDK BR
- 3 mL into (1) 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)***

If ≥ **30 kg**, immediately transfer **(using 18 gauge needle)** or draw:
- 12 mL into (2) Tiger-Top SSTs for CBL & NIDDK BR
- 5 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)***

2 **If participant did NOT consent to BIOLOGICAL samples:**
Collect **4.5-5.5** mL from all participants (regardless of weight) as specified below.

Immediately transfer (using 18 gauge needle) or draw:
- 2 mL into (1) Tiger-Top SSTs for CBL (renal panel, uric acid & cystatin C)
- 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)***

SECTION C: POST-TRANSPLANT VISIT BLOOD DRAW PROCESSING

Invert the SST 5 times & PST 8-10 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 & PST at MAX SPEED between 1100-1300g (3000rpm with 10cm radius rotor) for 10 minutes in swinghead units **OR** 15 minutes in fixed angle units (balance tube in centrifuge).*If incomplete separation, centrifuge again for 10-15 minutes.

If sample is GROSSLY HEMOLYZED.

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

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

CBL Studies

Using the disposable pipette, pipette 0.5 mL 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.

Cystatin C

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

NIDDK BR (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"*

NIDDK BR (Plasma)

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 -70ºC 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 "Dry Ice Shipper Request Form" on the CKiD website: https://statepi.jhsph.edu/ckid/coordinator-resources/ Then, follow packaging instructions and ship to CBL with accompanying forms. **No FRIDAY shipments.** Ship on next business day.

Store sample in freezer at -70ºC or lower and batch up to 40 samples and ship quarterly during the months of **January, April, July and October**. When shipper is needed, complete "Dry Ice Shipper Request Form" on the CKiD website: https://statepi.jhsph.edu/ckid/coordinator-resources/ Then, follow packaging instructions and ship to CBL with accompanying forms. **No FRIDAY shipments.** Ship on next business day.

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

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

PROMPT: IF SUSPECTED BLOOD DRAW ADVERSE EVENT (i.e., infection), complete Adverse Event (ADVR) Form

Reasons Code List*:			
	1= Not required	4 = Red Blood Cell Contamination	7 = Exceed maximum allowable volume
	2 = Difficult Blood Draw	5 = Inadvertently Destroyed	
	3 = Participant Refused	6 = Oversight	

Sample Type (Required Volume in Top Color Tube Type):	**(a) Sample Obtained:** Yes / No	**(b) If No, specify reason *SEE CODE LIST ABOVE**	**(c) Additional Requirements:**
C2a. Renal/Uric Acid Chemistries (1.0 mL in Tiger Top SST)	1 **(skip to c→)** / 2	___ ___ **(skip to C2b)**	**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 C3a)**	Date Frozen: ___ ___ / ___ ___ / ___ ___ ___ ___ M M D D Y Y Y Y
C3a. Local CBC (1.0 mL in Lavender Top tube)	1 **(skip to C3b)** / 2	___ ___ **(skip to C3b)**	**N/A**
C3b. Local Renal Panel (1.5 mL in Local SST)	1 **(skip to D1)** / 2	___ ___ **(skip to D1)**	**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://statepiaps8.jhsph.edu/nephron/groups/aspproc/**, click on “Report Menu” and choose the appropriate lab report (i.e., Selected Renal Panel Lab Variables Report.)

SECTION D: NIDDK BIOREPOSITORY

D1. Did the participant consent to have biological samples (i.e., serum, plasma and urine samples) stored at the NIDDK Biorepository?

Yes..... 1

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

Reasons Code List*:	1= Not required	4 = Red Blood Cell Contamination	7 = Exceed maximum allowable volume
	2 = Difficult Blood Draw	5 = Inadvertently Destroyed	
	3 = Participant Refused	6 = Oversight	

Sample Type (Required Volume in Top Color Tube Type):	**(a) Sample Obtained:** Yes / No	**(b) If No, specify reason *SEE CODE LIST ABOVE**	**(c) Additional Requirements:**
D2. Serum for NIDDK Biorepository (**6.0 mL or **10.0 mL of blood in Tiger Top SST)	1 / 2 **(skip to c→)**	___ ___ **(skip to D3)**	Date Frozen: ___ ___/ ___ ___/ ___ ___ ___ ___ M M D D Y Y Y Y
D3. Plasma for NIDDK Biorepository (***3.0 mL of blood in one Green Top or ***5.0 mL in two Green Top PSTs)	1 / 2 **(skip to c→)**	___ ___ **(skip to E1)**	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 E: 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 protease inibitor tablets are needed. (Like all unused supplies, **unused protease inhibitor tablets should be returned to the CBL**.)

TABLE A:

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 tablet(s) 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, complete the SM01 form and promptly freeze and store sample(s) at -70ºC 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: https://statepi.jhsph.edu/ckid/coordinator-resources/. Then, follow packaging instructions. **No Thursday/Friday shipments.**

When pickup has been scheduled, complete *"Online Shipping Form"* on CKiD website to notify the NIDDK BR 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 | 7 = Insufficient volume

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