

# SPECIMEN COLLECTION FORM for ODD Follow-up Post-Dialysis Visit (DL31)

## 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 Post KRT VISIT #: \_\_\_\_\_

A3. FORM VERSION: 0 6 / 1 5 / 2 2

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

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**At the Post-Dialysis Visit, collect the following:**

<u>Samples:</u>	<u>Shipped to</u>	<u>Shipped:</u>
Serum	CBL	IMMEDIATELY

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

<u>Samples:</u>	<u>Shipped to:</u>	<u>Shipped:</u>
Serum (Biological)	NIDDK Biorepository	Batched (Ship in Jan, Apr, Jul or Oct)
Plasma (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.**

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**SECTION B: PREGNANCY TEST**

- B1. Is participant a female of child-bearing potential?  
Yes..... 1 (See PROMPT Below)  
No..... 2 (Skip to C1)

**PROMPT: QUESTION B2 IS FOR FEMALE PARTICIPANTS OF CHILD-BEARING POTENTIAL ONLY. BLOOD/URINE PREGNANCY TEST DATE MUST OCCUR ON DAY OF VISIT OR FALL WITHIN 72 HOURS BEFORE STUDY VISIT DATE.**

B2. a. Blood/Urine pregnancy test date: \_\_\_/\_\_\_/\_\_\_  
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- b. Pregnancy results:  
Positive..... 1 (END; COMPLETE TRANSITIONAL (TRS03) FORM)  
Negative..... 2

## SECTION C: POST-DIALYSIS VISIT BLOOD DRAW

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

**1** If participant consented to **BIOLOGICAL** samples:

Collect **12.5-13.5 mL** if participant is **< 30 kg** OR **18.5-19.5 mL** if participant is **≥ 30 kg**.

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

- 7 mL into (1) Tiger-Top SSTs for CBL & NIDDK BR
- 3 mL into (1) PST for NIDDK Biorepository
- 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:

- 11 mL into (2) Tiger-Top SSTs for CBL & NIDDK BR
- 5 mL into (2) PST for NIDDK Biorepository
- 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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**2** If participant did **NOT** consent to **BIOLOGICAL** samples:

Collect **3.5-4.5 mL** from all participants (regardless of weight) as specified below.

Immediately transfer (using 18 gauge needle) or draw:

- 1 mL into (1) Tiger-Top SSTs 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)**

SECTION C: POST-DIALYSIS 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. No FRIDAY shipments. Refrigerate specimen and ship on next business day.

**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)".

Complete the SM01 form, store sample in freezer at -70°C or lower, batch up to 40 samples and ship on dry ice quarterly (Jan, April, July and Oct) to the NIDDK BR. No Thursday/Friday shipments. When shipper is needed, complete "NIDDK BR Dry Ice Shipper Request Form" on CKiD website: <https://statepi.jhsph.edu/ckid/coordinator-resources/> Then, follow packaging instructions.

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.

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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**

<b>Reasons Code List*</b>	1 = Not required	4 = Red Blood Cell Contamination	7 = Exceeds 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:
C2. Renal/Uric Acid Chemistries (1.0 mL in Tiger Top SST)	1      2 (skip to c→)	_____ (skip to C3)	<b>Indicate the appearance of the serum after centrifuging.</b> Grossly (Dark Red).....1 Moderately (Red/Light Red).....2 Slightly (Pink).....3 Not Hemolyzed (Yellow).....4
C3. Local CBC (1.0 mL in Lavender Top tube)	1      2 (skip to C4)	_____ (skip to C4)	<b>N/A</b>
C4. Local Renal Panel (1.5 mL in Local SST)	1      2 (skip to D1)	_____ (skip to D1)	<b>N/A</b>

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.)

# SPECIMEN COLLECTION FORM for POST DIALYSIS VISIT (XX)

## SECTION D: NIDDK BIOREPOSITORY

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

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

<b>Reasons Code List*</b>	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:	(b) If No, specify reason *SEE CODE LIST ABOVE	(c) Additional Requirements:
	<u>Yes</u> <u>No</u>		
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

