CKD Pilot Study Forms – Microbiome Study

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Trial: M=MICROBIOME Trial only;, All = All three studies

CKD Pilot Study Forms – Microbiome Study

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CKD PILOT STUDIES
TarGut Microbiome Forms Completion Schedule

Non-Participant Forms

In order to make a clinical site ready to enroll

Form #	Form Name
F09	Clinical Center
F10	Study Personnel

Participant Information

Consent visit

Form #	Form Name
n/a	Informed Consent *(not entered into database) (Includes NIDDK Repository consent)*
n/a	Local Participant Information *(not entered into database- see MOP)*

Screening

Screening (S0)

Form #	Form Name
F105	Screening
F121	Local Lab Pregnancy Test Results
F122	Co-Morbidity and Medical History
F123	Baseline Demographics, Employment, and Income
F210	Concomitant Medications Part A (antibiotic review)
F211	Concomitant Medications Part B
F340	Local Lab CBC Results
	Review hemoglobin

As Needed during Screening

Form #	Form Name
F161	Baseline (Pre-Randomization) Drop-out
F282	Symptoms/Adverse Events Reported on Phone Calls or at Extra Non-Protocol Visits
F511	Hospitalization Notification
F512	Hospitalization Detail
F522	Details of SAEs that are Not Hospitalizations or Deaths
F531	Death Notification
F532	Death Details

TarGut Microbiome Weekly Visit Participant Forms Schedule

Follow-Up Visits:

No treatment: Weeks (W) 1, 2-3, 4, 5-6, 7, 8
Treatment: Weeks (W) 9, 10-11, 12, 13-15, 16, 17, 18, 19, 20
No treatment: Weeks (W) 21-23, 24, 25-26, 27, 28

W1 Visit (no treatment)

Form #	Form Name
F210	Concomitant Medications Part A (antibiotic review)
F211	Concomitant Medications Part B
F270	Food Frequency Questionnaire
F310	Visit/Blood Drawn and Stored
F281	Symptoms Questionnaire
F313	Spot Urine Specimen Collected and Stored
F316	Stool Specimen Collected and Stored

W2-3 Visit (no treatment)

Form #	Form Name
F210	Concomitant Medications Part A (antibiotic review)
F310	Visit/Blood Drawn and Stored
F313	Spot Urine Specimen Collected and Stored
F316	Stool Specimen Collected and Stored

W4 Visit (no treatment)

Form #	Form Name
F210	Concomitant Medications Part A (antibiotic review)
F211	Concomitant Medications Part B
F281	Symptoms Questionnaire
F310	Visit/Blood Drawn and Stored
F313	Spot Urine Specimen Collected and Stored
F316	Stool Specimen Collected and Stored

W5-6 Visit (no treatment)

Form #	Form Name
F210	Concomitant Medications Part A (antibiotic review)
F310	Visit/Blood Drawn and Stored
F313	Spot Urine Specimen Collected and Stored
F316	Stool Specimen Collected and Stored

W7 Visit (no treatment)

Form #	Form Name
F210	Concomitant Medications Part A (antibiotic review)
F310	Visit/Blood Drawn and Stored
F313	Spot Urine Specimen Collected and Stored
F316	Stool Specimen Collected and Stored

W8 Visit (treatment phase)

Form #	Form Name
F210	Concomitant Medications Part A (antibiotic review)
F211	Concomitant Medications Part B
F220	Initial Inulin Packet Dispensing
F270	Food Frequency Questionnaire
F281	Symptoms Questionnaire
F310	Visit/Blood Drawn and Stored
F313	Spot Urine Specimen Collected and Stored
F316	Stool Specimen Collected and Stored
F328	24-Hour Urine Collected and Stored
F340	Local Lab CBC Results

W9 Visit (treatment phase)

Form #	Form Name
F210	Concomitant Medications Part A (antibiotic review)
F310	Visit/Blood Drawn and Stored
F313	Spot Urine Specimen Collected and Stored
F316	Stool Specimen Collected and Stored
	Review Hemoglobin from W8

W10-11 Visit (treatment phase)

Form #	Form Name
F210	Concomitant Medications Part A (antibiotic review)
F310	Visit/Blood Drawn and Stored
F313	Spot Urine Specimen Collected and Stored
F316	Stool Specimen Collected and Stored

W12 Visit (treatment phase)

Form #	Form Name
F210	Concomitant Medications Part A (antibiotic review)
F211	Concomitant Medications Part B
F221	Packet Dispensing and Counting
F281	Symptoms Questionnaire
F310	Visit/Blood Drawn and Stored
F313	Spot Urine Specimen Collected and Stored
F316	Stool Specimen Collected and Stored

W13-15 Visit (treatment phase)

Form #	Form Name
F210	Concomitant Medications Part A (antibiotic review)
F310	Visit/Blood Drawn and Stored
F313	Spot Urine Specimen Collected and Stored
F316	Stool Specimen Collected and Stored

W16 Visit (treatment phase)

Form #	Form Name
F210	Concomitant Medications Part A (antibiotic review)
F211	Concomitant Medications Part B
F221	Packet Dispensing and Counting
F281	Symptoms Questionnaire
F310	Visit/Blood Drawn and Stored
F313	Spot Urine Specimen Collected and Stored
F316	Stool Specimen Collected and Stored
F340	Local Lab CBC Results

W17 Visit (treatment phase)

Form #	Form Name
F210	Concomitant Medications Part A (antibiotic review)
F310	Visit/Blood Drawn and Stored
F313	Spot Urine Specimen Collected and Stored
F316	Stool Specimen Collected and Stored

W18 Visit (treatment phase)

Form #	Form Name
F210	Concomitant Medications Part A (antibiotic review)
F310	Visit/Blood Drawn and Stored
F313	Spot Urine Specimen Collected and Stored
F316	Stool Specimen Collected and Stored

W19 Visit (treatment phase)

Form #	Form Name
F210	Concomitant Medications Part A (antibiotic review)
F310	Visit/Blood Drawn and Stored
F313	Spot Urine Specimen Collected and Stored
F316	Stool Specimen Collected and Stored

W20 Visit (treatment phase)

Form #	Form Name
F210	Concomitant Medications Part A (antibiotic review)
F211	Concomitant Medications Part B
F221	Packet Dispensing and Counting
F270	Food Frequency Questionnaire
F281	Symptoms Questionnaire
F310	Visit/Blood Drawn and Stored
F313	Spot Urine Specimen Collected and Stored
F316	Stool Specimen Collected and Stored
F328	24-Hour Urine Collected and Stored
F340	Local Lab CBC Results

W21-23 Visit (no treatment)

Form #	Form Name
F210	Concomitant Medications Part A (antibiotic review)
F310	Visit/Blood Drawn and Stored
F313	Spot Urine Specimen Collected and Stored
F316	Stool Specimen Collected and Stored
	Review hemoglobin from W20

W24 Visit (no treatment)

Form #	Form Name
F210	Concomitant Medications Part A (antibiotic review)
F211	Concomitant Medications Part B
F281	Symptoms Questionnaire
F310	Visit/Blood Drawn and Stored
F313	Spot Urine Specimen Collected and Stored
F316	Stool Specimen Collected and Stored

W25-26 Visit (no treatment)

Form #	Form Name
F210	Concomitant Medications Part A (antibiotic review)
F310	Visit/Blood Drawn and Stored
F313	Spot Urine Specimen Collected and Stored
F316	Stool Specimen Collected and Stored

W27 Visit (no treatment)

Form #	Form Name
F210	Concomitant Medications Part A (antibiotic review)
F310	Visit/Blood Drawn and Stored
F313	Spot Urine Specimen Collected and Stored
F316	Stool Specimen Collected and Stored

W28 Visit (no treatment)

Form #	Form Name
F210	Concomitant Medications Part A (antibiotic review)
F211	Concomitant Medications Part B
F270	Food Frequency Questionnaire
F281	Symptoms Questionnaire
F310	Visit/Blood Drawn and Stored
F313	Spot Urine Specimen Collected and Stored
F316	Stool Specimen Collected and Stored
F328	24-Hour Urine Collected and Stored
F340	Local Lab CBC Results
F477	Study Closeout

As Needed during Follow-Up

Form #	Form Name
F282	Symptoms/Adverse Events Reported on Phone Calls or at Extra Non-Protocol Visits
F320	U of Penn Lab Shipment
F511	Hospitalization Events Notification
F512	Hospitalization Events Details
F522	Details of SAEs that are Not Hospitalizations or Deaths
F531	Death Notification
F532	Detailed Death
F540	Event Information Sent to the DCC
F549	Vascular Access Created/Placed
F550	Initiation of Chronic Dialysis or Transplant

Shipping forms that need completed during follow-up

F311	Serum Samples Sent from Site to Penn
F312	Plasma Samples Sent from Site to Penn
F314	Urine Samples Sent from Site to Penn
F317	Stool Samples Sent from Site to Penn
F320	Serum Samples Received from Site at Penn
F321	Plasma Samples Received from Site at Penn
F322	Stool Samples Received from Site at Penn
F323	Spot Urine Samples Received from Site at Penn
F324	24-Hour Urine Samples Received from Site at Penn

MOP - Blood -. Specimens will be shipped at least once a month or sooner if a Clinical Center has enough specimens to fill a shipping box.

Completed by CKD Event Review Committee

Form #	**Form Name**
F612	Event Review Committee Hospitalizations Review
F622	Event Review Committee SAE's that are not Hospitalizations or Death Review
F632	Event Review Committee Death Review

Pilot Clinical Trials in CKD
Clinical Center Form #9 – ALL STUDIES

Instructions: Complete this form for each participating site. This form can be updated as many times as needed and should be kept current throughout the Pilot Clinical Trials. (Updates for individual staff members are done on Form 10.)

1. Clinical Center Number..... ___ ___
   11=George Washington University (Site PI- Dominic Raj)
   21=Northwestern University School of Medicine (Site PIs - Myles Wolf, Tamara Isakova)
   22=Northshore University Health System (Site PI - Stuart Sprague)
   31=University of California San Diego (Site PI - Joe Ix)
   32=Denver Nephrology (Site PI - Geoff Block)
   41=University of Utah (Site PIs - Alfred Cheung, Kalani Raphael)
   42=Baylor (Site PI – Donald Wesson)
   43=Utah VA (Site PIs - Alfred Cheung, Kalani Raphael)

2. Clinical Center Mailing Address:
   a. Line 1 …… _____
   b. Line 2 ..... _____
   c. Line 3 ..... _____
   d. Line 4 ..... _____
   e. City ..... _____
   f. State ..... _____
   g. Zip/Postal Code ..... ___ ___ ___ ___ ___
3. Clinical Center Federal Express Shipping Address <u>for medications</u>: (required)
   a. Line 1 ..... _____
   b. Line 2 ..... _____
   c. Line 3 ..... _____
   d. Line 4 ..... _____
   e. City ..... _____
   f. State ..... _____
   g. Zip/Postal Code ..... ___ ___ ___ ___ ___
   h. Mark to the attention of ..... _____
4. Clinical Center Shipping Address <u>for lab supplies:</u> (required)
   a. Line 1 ..... _____
   b. Line 2 ..... _____
   c. Line 3 ..... _____
   d. Line 4 ..... _____
   e. City ..... _____
   f. State ..... _____
   g. Zip/Postal Code ..... ___ ___ ___ ___ ___
   h. Mark to the attention of ..... _____

Local Laboratory Details

5. Does this site's laboratory use standardized IDMS creatinine? (0=no, 1=yes) ..... ___

COMBINE IRB Status and NIDDK Repository

(*for collection of repository biologic specimens*)

6. Date COMBINE protocol version 1.0 approved by IRB (mm/dd/yyyy) .... __ __ /__ __ /__ __ __ __
7. Was IRB approved repository consent approved by NIDDK? (0=no, 1=yes) ..... ___

COMBINE MRI Details

8. a. Does this clinical center use an MRI group that has a different IRB? ..... ___
   0=no, 1=yes: NIH (Site #11), 2=yes: U Colorado (Site #32)
   b. If yes, date COMBINE protocol version 1.0 approved by MRI group's IRB (mm/dd/yyyy) ..... __ __ /__ __ /__ __ __ __
9. MRI Manufacturer (1=GE; 2=Philips; 3=Siemens) ..... ___
10. Field Strength [Tesla] (1.5 or 3.0)..... ___ . ___
11. MRI software version ..... ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

COMBINE IV Furosemide

12. Will this site participate in the IV Furosemide component of the COMBINE Renal MRI? (0=no, 1=yes) ..... ___

BASE IRB Status and NIDDK Repository

13. Date BASE protocol version 1.1 approved by IRB (mm/dd/yyyy) ..... __ __ /__ __ /__ __ __ __
14. Was IRB approved repository consent approved by NIDDK (0=no, 1=yes)..... ___

TarGut IRB Status - Leave blank for now

15. a. Will this site enroll participants into TarGut (0=no, 1=yes) ..... ___
    If yes, complete item b
    b. Date TarGut protocol version 1.0 approved by IRB (mm/dd/yyyy) .. __ __ /__ __ /__ __ __ __

200. Date this form completed (mm/dd/yyyy) ..... __ __ /__ __ /__ __ __ __
201. Username of person completing / reviewing completeness of this form..... __ __ __ __ __ __ __

Clinical Center Use Only
Date Form Entered (mm/dd/yyyy) __ __/__ __/__ __ __ __
Username of person entering this form __ __ __ __ __ __ __

For DCC Use only:

202. MRI test case #1 quality approved by Core (0=no, 1=yes) ..... ___
203. MRI test case #2 quality approved by Core (0=no, 1=yes) ..... ___

Pilot Clinical Trials in CKD
Study Personnel Form #10 – ALL STUDIES

Instructions: Complete and enter this form for each person who will be collecting data that will be used in the CKD Pilot Clinical Trials. This form can be updated at any time.

Use this form to inactivate former CKD staff members as well. (To do this, go to Q4a-Staff Member Status. Place the cursor on the row of the individual you want to inactivate, type in "2=inactive". Update the date the staff member became inactive in Q4b.)

1. Clinical Center number .....___ ___
   11=George Washington University (Site PI- Dominic Raj)
   21=Northwestern University School of Medicine (Site PIs - Myles Wolf, Tamara Isakova)
   22=Northshore University Health System (Site PI - Stuart Sprague)
   31=University of California San Diego (Site PI - Joe Ix)
   32=Denver Nephrology (Site PI - Geoff Block)
   41=University of Utah (Site PIs - Alfred Cheung, Kalani Raphael)
   42=Baylor (Site PI – Donald Wesson)
   43=Utah VA (Site PIs - Alfred Cheung, Kalani Raphael)

2. a. Last name ..... _____
   b. First name ..... _____
   c. CKD Study Username .....__ __ __ __ __ __ __
      (The Study Username will be populated automatically unless generated Username is not unique.)
   d. E-mail Address ..... _____
   e. Phone Number .....(___ ___ ___) ___ ___ ___-___ ___ ___ ___
   f. Extension .....___ ___ ___ ___ ___

3. Primary role in the CKD study? .....___ ___
   01=Site PI
   02=Other Physician
   03=Physician's Assistant / Nurse Practitioner
   04=Senior Study Coordinator
   05=Study Coordinator
   06=Study Nurse, not serving as study coordinator
   07=Data Entry Person
   08=Lab Technician
   09=Other Participating Site team member

   20=MRI Technologist
   21=Other investigator (MD or PhD) working with MRI data

   30=Core MRI Lab Staff Member
   31=Core FGF23 Lab Staff Member

4. a. Staff member status (1=active, 2=inactive) .....___
      Everyone is active when the study starts.
      If someone leaves, their status needs to be changed to inactive.
   b. If 4a=2, date staff member became inactive (mm/dd/yyyy)..... __ __/__ __ /__ __ __ __

Certifications

MRI (Cardiac and BOLD Renal) - COMBINE

5. a. Date certified in Cardiac MRI (mm/dd/yyyy) ..... __ __/__ __ /__ __ __ __

   b. Username of the trainer .....__ __ __ __ __ __ __
   (First session trainer CarrM)

6. a. Date certified in BOLD Renal MRI (mm/dd/yyyy)..... __ __/__ __ /__ __ __ __

   b. Username of the trainer .....__ __ __ __ __ __ __
   (First session trainer PrasadP)

Anthropometry (Ankle Measurement) – BASE

7. a. Date certified (mm/dd/yyyy) ..... __ __/__ __ /__ __ __ __

   b. Username of the trainer .....__ __ __ __ __ __ __

200. Date this form completed (mm/dd/yyyy)..... ___ ___ /___ ___ /___ ___ ___ ___

201. Username of person completing/reviewing completeness of this form ..... __ __ __ __ __ __ __

Clinical Center Use Only

Date Form Entered (mm/dd/yyyy) __ __/__ __/__ __ __ __

Username of person entering this form__ __ __ __ __ __ __

Pilot Clinical Trials in CKD
Screening Form #105 – TarGut Microbiome

Form 105 is completed and key entered for each participant who consents to the study.

			T
1. Identification Number	2. Alphacode	3. Date of Screening (mm/dd/yyyy)	4. Study

Consent

5. a. Date this participant signed the consent form for this study? (mm/dd/yyyy) ...__ __/__ __/__ __ __ __

For items 5b-d, leave date blank if participant did not consent to storing samples:

b. Date this participant signed the consent form for storing <u>serum</u> at the Biosample Repository? (mm/dd/yyyy) ..... __ __/__ __/__ __ __ __

c. Date this participant signed the consent form for storing <u>urine</u> at the Biosample Repository? (mm/dd/yyyy) ..... __ __/__ __/__ __ __ __

d. Date this participant signed the consent form for storing <u>stool</u> at the Biosample Repository? (mm/dd/yyyy) ..... __ __/__ __/__ __ __ __

Age and Gender

6. Date of birth? (mm/dd/yyyy) .....___ ___/___ ___/___ ___ ___ ___
Note, for eligibility, age must be 18 years at the time of screening.

7. Sex of participant? (1=male, 2=female)..... ___

Ethnic Category

8. *For NIH:* Hispanic or Latino ethnicity? (0=no, 1=yes, 9=unknown or not reported)..... ___

Racial Category

9. Race? (*NIH format – Hispanics must choose a race)*..... ___

1=American Indian/Alaska Native
2=Asian
3=Native Hawaiian or Other Pacific Islander
4=Black or African American
5=White
6=More than one race
9=Unknown or not reported

Times through Baseline

10. Times through Baseline for TarGut Microbiome? ..... ___
(1=1st time through baseline for TarGut Microbiome; 2=2nd time through baseline for TarGut Microbiome; etc.)

Eligibility Items

11. Self-reported stool frequency..... ___

1=Average of less often than once every other day
2=Average between once every other day to once a day
3=Average of more than once a day

(*Note, for eligibility, response must be 2 or 3)*

Questions 12-16 must be answered "yes" in order for the participant to be eligible. (Respond 0=no, 1=yes.)

12. Does the Site PI confirm that this participant is medically stable? ..... ___
13. Is the participant able to read in English? ..... ___
14. Is the participant able to travel to study visits? ..... ___
15. In the judgment of the site investigator, is the participant willing and able to follow the study treatment regimen and comply with the site investigator's recommendations? ..... ___
16. In the judgment of the site investigator, this participant is capable of collecting frequent blood and stool samples? ..... ___

Questions 17-25 must be answered "no" in order for the participant to be eligible. (Respond 0=no, 1=yes)

17. In the judgment of the site investigator, will the patient start dialysis or receive a kidney transplantation within the next 9 months? ..... ___
18. Current participation in another clinical trial or other interventional research? ..... ___
19. Currently taking investigational drugs? ..... ___
20. Institutionalized, prisoner, or currently residing in a nursing home or rehabilitation center? ..... ___
21. Malignancy requiring therapy within the past 2 years? ..... ___
    (non- melanoma skin cancer and localized prostate cancer are exempted)
22. Life expectancy < 9 months as determined by the Site PI? ..... ___
23. Hospital admissions within the past 30 days? ..... ___
    (24-hour observation hospitalizations are exempted but should be discussed with the Site PI.)
24. Plans to leave the immediate area within 7 months, so could not complete protocol? ..... ___
25. Plans to be out of town for one week or more in the next 7 months, so protocol visits would be missed? ..... ___

Pregnancy-related questions (*skip to Q28 if male)*

26. Pregnant or planning to become pregnant or currently breast-feeding? (0=no, 1=yes) ..... ___
27. a. Sex and childbearing potential status? ..... ___
    1=Surgically sterilized (includes endometrial ablation)
    2=Post-menopausal (amenorrhea for ≥ 12 consecutive months without another cause, women with irregular menstrual periods and a documented serum follicle stimulating hormone (FSH) level > 35 mIU/mL or women on hormone replacement therapy (HRT))
    3=Not surgically sterilized and not post-menopausal: "woman of childbearing potential"
    Note: Women of childbearing potential require a pregnancy test within one week of the screening visit for eligibility.

    b. If Item 27a=3 (woman of childbearing potential), does the participant agree to use birth control (condom with spermicide, diaphragm and spermicide, cerivical cap and spermicide, hormonal contraception) up to 4 weeks after the last dose of the study drug? (0=no, 1=yes) ..... ___

For Questions 28-44 responses must be "no" for the participant to be eligible. (Respond 0=no, 1=yes)

28. Has this participant eaten probiotic yogurt (such as Activia with Lactobacillus bulgaricus, Streptococcus thermophiles, Bifidobacterium lactis; Yoplait Original with Lactobacillus acidophilus; or Stonyfield with Lactobacillus acidophilus, Streptococcus thermophiles) during the past 2 weeks? ..... ___

29. Has this participant consumed any probiotics other than yogurt (such as probiotic supplements, sourdough bread, sauerkraut, buttermilk, miso soup, kefir, tempeh, kimchi, or kombucha) during the past 2 months? ..... ___
30. Has this participant consumed prebiotics such as inulin or chicory root in the past 2 months? ..... ___
    Note detailed list of probiotics and prebiotics page 5 of this form and in the MOP.
31. Has this participant taken a proton pump inhibitor such as omeprazole (Prilosec, Prilosec OTC), lansoprazole (Prevacid, Prevacid 24-Hour), or esomeprazole (Nexium) at any time in the past month? ..... ___
32. Known to have HIV? ..... ___
33. Has a chronic wound infection? ..... ___
34. Has osteomyelitis? ..... ___
35. Has or is being treated for a periodontal infection? ..... ___
36. Has inflammatory bowel disease? ..... ___
37. In the judgment of the site PI, is this participant in the midst of an episode of acute kidney injury? ..... ___
38. Known to have chronic diarrhea? ..... ___
39. Has a current *C. difficile* infection? ..... ___
40. Has cirrhosis? ..... ___
41. Has chronic active hepatitis? ..... ___
42. Has been treated with prednisone >10 mg for more than one week in the past 3 months? ..... ___
43. Has there been a hemoglobin measure <9.0 g/dl at any time during the past 3 months? ..... ___
44. Has been treated with immunosuppressive medications in the past 6 months? ..... ___

Antibiotics Exclusion

45. Has this participant been treated with oral or IV antibiotics at any time during the past 3 months? ___
    0=no
    1=1 course of antibiotics in the last three months *(This makes a participant ineligible for now i.e., no antibiotics for 3 months.)*
    2=2 or more courses of antibiotics in the last three months *(This makes a participant ineligible for the next 6 months.)*

Serum Creatinine

46. a. Most recent serum creatinine draw date (mm/dd/yyyy) ..... __ __/__ __/__ __ __ __
    (Date of blood draw must be within the past 3 months)

    b. Serum Creatinine (mg/dL) ..... ___.___ ___

    c. Calculated eGFR (mL/min/1.73 m^2) ..... ___ ___.___
    (*Database will automatically calculate eGFR.. Write the value in the grayed out box above.)*

GFR Eligibility:

GFR <15.0 or >50.0 ml/min/1.73m^2 – not eligible
GFR between 15.0 and <45.0 ml/min/1.73m^2 – meet GFR criterion, can skip to Q52 (Q47-51 are not required)
GFR between ≥45.0 to ≤ 50.0: urine albumin to urine creatinine ratio must be
> 300 mg/g to be eligible – continue to Q47

Urine Albumin and creatinine results (both results must be from the same urine collection date)

47. Date spot urine collected (mm/dd/yyyy)..... __ __/__ __/__ __ __ __
(Date urine collected must be in the past 3 months)

48. What units is the urine albumin being reported (1=mg/dL, 2=ug/mL or mg/L)..... ___

If reported in mg/dL

49. Urine albumin (mg/dL) ..... ___ ___ ___ . ___
If the lab reports the albumin value is too low to detect, record 0.

If reported in ug/mL or mg/L

50. Urine albumin (ug/mL or mg/L) ..... ___ ___ ___ ___
If the lab reports the albumin value is too low to detect, record 0.

51. Urine creatinine (mg/dL) ..... ___ ___ ___

Urine albumin to urine creatinine ratio:

___ ___ ___ . ___ (mg/g)

If *GFR between ≥45.0 to ≤50.0: urine albumin to urine creatinine ratio must be > 300 mg/g for eligibility.*

Participant Source (not for eligibility)

52. How did this participant first hear about the study? ..... ___ ___

1=Personal physician or personal physician's office
2=CKD Pilot Study physician
3=Other CKD Pilot Study staff member
4=Other physician or health professional
5=Relative/Friend
6=Saw a poster or brochure
7=Received information in mail
8=Health program or health fair
9=Saw a newspaper article
10=Saw a newspaper advertisement
11=This participant is from the Washington DC VA
98=Other, 99=Unknown

200. Date form completed (mm/dd/yyyy)..... __ __/__ __/__ __ __ __

201. Username of person completing/reviewing completeness of this form ..... __ __ __ __ __ __ __

Eligibility Status based on Screening Form 105 Data?

Participant is eligible (1=yes) OR Participant is ineligible (0=no)

Hemoglobin data from the local lab CBC form and (for women of child bearing potential) pregnancy test form are also needed in order to determine whether the participant is eligible to enroll in the TarGut Microbiome Study.

Clinical Center Use Only

Date Form Entered (mm/dd/yyyy) __ __/__ __/__ __ __ __

Username of person entering this form __ __ __ __ __ __ __

DCC Use Only

Confirm date of participant consent (mm/dd/yyyy) __ __/__ __/__ __ __ __

Prebiotics

- Inulin, prebiotic soluble fibers made from inulin and oligofructose
- Chicory root
- Xtend-Life Kiwi-Klenz
- GoLive Probiotic & Prebiotic Drinks and drink mixes
- pHion Balance pH Balance Prebiotic Fiber Dietary Supplement Powder
- Promend Prebiotic Fiber Gummies
- Sundown Naturals Inulin Fiber Prebiotic Capsules
- Bimuno prebiotic dietary supplements
- Prebiotin dietary supplements
- BioTrust Pro-X10
- MX Kiwi Biotic by Maxalife
- bifidobacteria

Probiotics

- Foods: sourdough bread, sauerkraut, buttermilk, miso soup, kefir, tempeh, kimchi
- Drinks: probiotic teas such as kombucha
- EZBiotics Daily probiotic supplement
- TruBiotics capsules
- Probiotic Defense
- Schiff® Digestive Advantage Probiotic gummies
- Nature Made Acidophilus Probiotic tablets
- Phillips'® Colon Health®
- Acidophilus Pearls™
- Lactobacillus acidophilus, found in yogurt with live cultures
- RepHresh Pro-B Probiotic Feminine Supplement Capsules
- Walgreens Probiotic Colon Support Dietary Supplement Capsules
- Meta Biotic Probiotic Supplement with Bio-Active 12, Capsules
- Enzymatic Therapy Pearls YB Yeast-Balancing Probiotics, Capsules
- ReNew Life Ultimate Flora Critical Care 50 Billion Dietary Supplement
- Culturelle Digestive Health Probiotic Chewables
- ReNew Life Ultimate Flora Vaginal Support Probiotic
- ReNew Life Ultimate Flora Senior Formula Probiotic
- Nature's Way Primadophilus Optima Digestive Balance
- Nature's Bounty Probiotic GX Gas & Bloating Formula, Capsules
- Jarrow Formulas Jarro-Dophilus EPS Vegetarian Capsules
- Walgreens Daily Probiotics Fiber Soft Chews
- Florax DS Ready-to-Drink Probiotic
- TruBiotics Probiotic, SmoothMint Chews
- pHion Balance pH Balance Prebiotic Fiber Dietary Supplement Powder
- check supplements labeled "digestive health"

Pilot Clinical Trials in CKD
Local Lab Pregnancy Test Results Form #121 – ALL STUDIES

Please refer to the study Protocol regarding when this form is completed.

Either blood or urine pregnancy test is acceptable. It is expected that most will be urine pregnancy test results.

1. Identification Number	2. Alphacode	3. Date of Pregnancy Test (mm/dd/yyyy)	4. Study

5. Results of pregnancy test (0=not pregnant, 1=pregnant) ..... ___

200. Date this form completed (mm/dd/yyyy) ..... ___ ___ /___ ___ /___ ___ ___ ___

201. Username of person completing/reviewing completeness of this form..... __ __ __ __ __ __ __

Clinical Center Use Only

Date Form Entered (mm/dd/yyyy) __ __/__ __/__ __ __ __

Username of person entering this form__ __ __ __ __ __ __

Pilot Clinical Trials in CKD
Co-Morbidity and Medical History Form # 122 – ALL STUDIES

The study coordinator and a site physician will work together to complete this form during Baseline.

1. Identification Number	2. Alphacode	3a. Visit Type	3b. Visit Number (Month)	(Week)	4. Date of visit: (mm/dd/yyyy)	5. Study
☐☐☐☐☐☐	☐☐	B	☐☐	☐☐	☐☐☐☐☐☐☐☐	☐

For items 6 to 30, code 0, 1 or as specified in the question. Code 0=no if the participant has no known history of the condition. Code 1=yes if the participant currently has the condition or is known to have had the condition in the past.

6. Myocardial infarction .... ___
7. Congestive heart failure .... ___
8. Angina/chest pain .... ___
9. Revascularization: Coronary artery bypass or percutaneous intervention/angioplasty/stent .... ___
10. Atrial fibrillation .... ___
11. Positive cardiac stress test for ischemia........ ___
12. Peripheral vascular disease .... ___
    (Exertional pain with walking (claudication), amputation not due to trauma or infection, or revascularization to leg arteries)
13. Cerebrovascular disease/Stroke .... ___
    (Exclude Transient Ischemic Attack (TIA) or imaging abnormalities not associated with physical signs or symptoms of stroke.)
14. COPD (excludes asthma) .... ___
15. Uses CPAP at night?........ ___
16. Connective tissue disease (lupus or scleroderma or Sjogren's, for example) .... ___
17. Peptic ulcer disease (excludes GERD) .... ___
18. Hemiplegia .... ___
19. Leukemia .... ___
20. Lymphoma .... ___
21. Multiple myeloma........ ___
22. Cancerous solid tumor (excludes non-melanoma skin cancer) .... ___
    (0=None, 1=Yes, not metastatic, 2=Metastatic)
23. Diabetes mellitus .... ___
    0=None; 1=diabetic nephropathy (with or without other end organ damage);
    2=Diabetes mellitus with some other or unknown renal diagnosis with other end organ damage;
    3=Diabetes mellitus with some other or unknown renal diagnosis with no other end organ damage
24. Liver disease .... ___
    0=none, 1= mild disease (without portal hypertension, includes chronic hepatitis), 2=moderate, 3=severe
25. Hepatitis B positive?........ ___
    0=No history of a Hep B infection (if Hep panel is available, Hep B surface antigen [HbSAg] and Hep B core antibody [HbCAb] are both negative. Hep B Surface Antibody [HbSAb] can be either positive or negative.)
    1=Yes, <u>history</u> of a Hep B infection (if Hep panel is available, HbSAg is negative, and both HbCAb and HbSAb are positive)
    2=Yes, <u>current</u> chronic active Hep B infection (if Hep panel is available, HbSAg is positive)

26. Hepatitis C positive? ..... ___
27. Gout? ..... ___
28. Needs assistance with ambulation? (0=No, does not need assistance; 1=Generally uses a cane or walker; 2=Generally uses a wheelchair)..... ___
29. Deaf?..... ___
30. Legally blind?..... ___
    Note: A participant is legally blind if he or she has central visual acuity of 20/200 or less in his or her better eye when his vision is measured using the best possible correction.

31. In the past year, how many times was the participant admitted to the hospital ..... ___
    (0=Not admitted, 1=Admitted once, 2=Admitted more than once)

32. Primary cause of kidney disease:..... ___ ___
    01=Diabetic nephropathy
    02=Hypertensive nephrosclerosis
    03=Glomerulonephritis (includes, but not limited to: membranous nephropathy, focal sclerosis, Membranoproliferative glomerulonephritis, mesangial proliferative glomerulonephritis, nephritic syndrome without biopsy, IGA nephropathy, other glomerulonephritis)
    04=Polycystic kidney disease
    05=Physical trauma
    06=Analgesic nephropathy
    07=Hereditary nephritis
    08=Pyelonephritis
    09=Other interstitial nephritis
    10=Vesico-ureteral reflux
    11=Renal artery stenosis
    12=Obstructive uropathy (includes, but not limited to: obstructive uropathy-acquired, obstructive uropathy-congenital, urinary tract stones)
    98=Other
    99=Unknown

33. Vascular access status ..... ___
    (0=no vascular access for chronic hemodialysis has been created/placed, 1=fistula creation surgery has been done, 2=AV graft placed, 3=PD catheter placed)
    Notify DCC if another code is needed.

34. Has the participant ever required acute hemodialysis? (0=no, 1=yes) ..... ___

FOR BASE Only

35. Has participant been diagnosed with GERD or acid reflux? (0=no, 1=yes) ..... ___
36. Right leg amputation (0=none, 1=below ankle, 2=above ankle)..... ___
37. Left leg amputation (0=none, 1=below ankle, 2=above ankle)..... ___

200. Date this form completed (mm/dd/yyyy) ..... __ __/__ __ /__ __ __ __

201. Username of person completing/reviewing completeness of this form ..... __ __ __ __ __ __ __

Clinical Center Use Only

Date Form Entered (mm/dd/yyyy) __ __/__ __/__ __ __ __

Username of person entering this form__ __ __ __ __ __ __

Pilot Clinical Trials in CKD
Demographics, Employment, and Income Form # 123 – ALL STUDIES

Instructions: This form is completed one time, during baseline, prior to randomization.

1. Identification Number	2. Alphacode	3a.Visit Type	3b. Visit Number (Month)	3b. Visit Number (Week)	4. Date of visit: (mm/dd/yyyy)	5. Study
		B				

6. Marital status: ___
   1=Never been married
   2=Married
   3=Common law marriage/partnered/ living together unmarried
   4=Separated
   5=Divorced
   6=Widowed
   9=Unknown or refused

7. Household status ___
   1=Lives alone
   2=Lives with family (spouse/partner, children, parents)
   3=Lives with others (roommates)
   9=Unknown or refused

8. Highest level of formal education achieved ___
   1=Less than or equal to 8th grade
   2=9th-12th grade, no diploma
   3=High school graduate
   4=Vocational/technical/business
   5=Some college, no degree
   6=Associate degree
   7=Bachelor's degree
   8=Advanced degree
   9=Unknown or refused

9. Participant's primary language? (1=English, 2=Spanish, 8=Other) ___

10. Ever been employed for pay? (0=no, 1=yes) ___

11. Last year the participant was employed ___ ___ ___ ___
    (Enter current year if currently employed)

12. Current work status: ___ ___
    1=Student, not employed
    2=Student, employed
    3=Homemaker
    4=Not working, not seeking work, disabled
    5=Not working, not seeking work, not disabled
    6=Not working, seeking work, disabled
    7=Not working, seeking work, not disabled
    8=Employed full-time
    9=Employed part-time
    10=Retired
    99=Unknown or refused

13. a. Current household gross annual income (U.S. dollars) ___
    1=<$10,000
    2=$10,000-$14,999
    3=$15,000-$19,999
    4=$20,000-$29,999
    5=$30,000-$39,999
    6=$40,000-$49,999
    7=$50,000-$99,999
    8=>$100,000
    9=Unknown or refused

    b. Number of people considered to be part of this household? ___ ___

14. Household zip code..... ___ ___ ___ ___ ___

Smoking History:

15. a. Do you or did you smoke cigarettes?..... ___
(0=No, never smoked-skip to Item 16, 1=Yes, former smoker, 2=Yes, current smoker, 9=Unknown or refused)

b. How old were you when you began to smoke cigarettes regularly?..... ___ ___

c. At approximately what age did you quit smoking? (leave this blank if you are still smoking) ..... ___ ___

d. In an average day, how many cigarettes do/did you usually smoke? ..... ___ ___
(20 if one pack, 40 if two packs, etc.)

Drinking History:

16. a. Do you or did you drink alcohol? ..... ___
(0=No, never drank alcohol, skip to Item 17, 1=Yes, in the past, 2=Yes, current drinker, 9=Unknown or refused)

b. Usual number of drinks of wine, beer or liquor during an average week?..... ___ ___
(a drink is 4 oz. of wine, a can of beer, or 1-1/2 oz. of hard liquor, including non-bonded liquor/moonshine)

Exercise History:

17. Current exercise frequency (times per week)..... ___

18. Current usual exercise duration (minutes)..... ___ ___ ___

200. Date this form completed (mm/dd/yyyy)..... __ __/__ __ /__ __ __ __

201. Username of person completing/reviewing completeness of this form..... __ __ __ __ __ __ __

Clinical Center Use Only

Date Form Entered (mm/dd/yyyy) __ __/__ __/__ __ __ __

Username of person entering this form__ __ __ __ __ __ __

Pilot Clinical Trials in CKD
Concomitant Medications Part A Form # 210 – TarGut Microbiome

This form is completed at Screening and at all weekly visits. It is used as a log to record use of antibiotics**,** pro-biotic supplements, and pre-biotic supplements (other than the TarGut study-provided inulin). *Participants are encouraged not to consume pro-biotic or pre-biotic food or supplements.* Note, if the Week 1 visit is held on a different day than the screening visit, this form should also be done at Week 1.

1. Identification Number	2. Alphacode	3a. Visit Type	3b. Visit Number (Month)	3b. Visit Number (Week)	4. Date of Visit (mm/dd/yyyy)	5. Study
						T

6. Is participant taking antibiotics or pro-biotic or pre-biotic supplements? (0=no, 1=yes) .... ___
If no, skip to item 200.

7. Medication Name (Database will store the WHODrug Code)	**Date clinical center first learned of the use of this drug, if different from visit date. (mm/dd/yyyy)**	**Medication START date for new antibiotics or supplements only – not used for ongoing drugs (mm/dd/yyyy)**	**Medication STOP date if drug was stopped since last visit (mm/dd/yyyy)**

200. Date this form completed (mm/dd/yyyy) .... ___ ___ /___ ___ /___ ___ ___ ___

201. Username of person completing/reviewing completeness of this form .... __ __ __ __ __ __ __

Clinical Center Use Only

Date Form Entered (mm/dd/yyyy) __ __/__ __/__ __ __ __

Username of person entering this form__ __ __ __ __ __ __

Examples of Pre-biotic Supplements	**Examples of Pro-biotic Supplements**	
Bimuno prebiotic dietary supplements	Acidophilus Pearls™	Phillips'® Colon Health®
Bifidobacteria	Culturelle Digestive Health Probiotic Chewables	pHion Balance pH Balance Prebiotic Fiber Dietary Supplement
BioTrust Pro-X10	Enzymatic Therapy Pearls YB Yeast-Balancing Probiotics Capsules	Probiotic Defense
Chicory root	EZBiotics Daily probiotic supplement	ReNew Life Ultimate Flora of any kind
GoLive Prebiotic drinks or mixes	Florax DS Ready-to-Drink Probiotic	RepHresh Pro-B Probiotic Feminine Supplement Capsules
MX Kiwi Biotic by Maxalife	Jarrow Formulas Jarro-Dophilus EPS Vegetarian Capsules	Schiff® Digestive Advantage Probiotic gummies
pHion Balance pH Balance Prebiotic Fiber Dietary Supplement	Meta Biotic Probiotic Supplement with Bio-Active 12, Capsules	TruBiotics Probiotic capsules
Promend Prebiotic Fiber Gummies	Nature Made Acidophilus Probiotic tablets	TruBiotics Probiotic SmoothMint Chews
Sundown Naturals Inulin Prebiotic Capsules	Nature's Way Primadophilus Optima Digestive Balance	Walgreens Daily Probiotics Fiber Soft Chews
Xtend-Life Kiwi-Klenz	Nature's Bounty Probiotic GX Gas & Bloating Formula Capsules	Walgreens Probiotic Colon Support Supplement Capsules

Pilot Clinical Trials in CKD
Concomitant Medications Part B Form # 211 – TarGut Microbiome

This form is completed for oral medications at Screening and at Weeks 1, 4, 8, 12, 16, 20, 24, and 28. (If the participant takes intravenous iron, notify the DCC.) Record all prescribed and over the counter meds, vitamins, supplements, and herbs taking special care to record Proton Pump Inhibitors [omeprazole (Prilosec, Prilosec OTC), lansoprazole (Prevacid, Prevacid 24-Hour), and esomeprazole (Nexium)].

- Recall that antibiotics and pre and post biotics are documented on Form 210, not on this Form 211.
- If the Week 1 visit is held on a different day than the screening visit, this form should also be done at Week 1.

																						T

1. Identification Number 2. Alphacode 3a. Visit Type 3b. Visit Number (Month) (Week) 4. Date of Visit (mm/dd/yyyy) 5. Study

6. Is this participant taking any concomitant medications? (0=no, 1=yes) .... ___
If no, skip to item 200.

7.

Brand or Generic Name of the Medication

Use an additional sheet of paper to document additional medications, if necessary. You will be able to key enter as many medications as needed. The medication name will be validated by WHODrug during data entry.

200. Date this form completed (mm/dd/yyyy).................................. ___ ___ /___ ___ /___ ___ ___ ___

201. Username of person completing/reviewing completeness of this form......... __ __ __ __ __ __ __

Clinical Center Use Only

Date Form Entered (mm/dd/yyyy) __ __/__ __/__ __ __ __

Username of person entering this form__ __ __ __ __ __ __

Pilot Clinical Trials in CKD
Initial Inulin Packet Dispensing Form # 220 – TarGut Microbiome

This form is completed when a TarGut participant is given follow up packets of inulin for the first time. The visit a patient is given inulin for the first time is considered the W8 visit.

1. Identification Number	2. Alphacode	3a. Visit Type	3b. Visit Number (Month)	(Week)	4. Date pills dispensed: (mm/dd/yyyy)	5. Study
☐☐☐☐☐☐	☐☐	W	☐☐	☐☐	☐☐☐☐☐☐☐☐	T

6. Visit number intended.. W 8
   Visit W8 target date is day 56. Recommended range is 53 to 59 days.

7. What size packets are being dispensed (2=2 grams, 4=4 grams).. ___

8. Number of inulin packets prescribed per day (all patients should be prescribed 16 g per day at W8) ...... ___
   4=Four 4 gram packets per day
   8=Eight 2 gram packets per day

9. Total number of full boxes dispensed (30 packets per box).. ___
   Participants are generally expected to receive:
   4=Four boxes of 4 gram packets
   8=Eight boxes of 2 gram packets

200. Date this form completed (mm/dd/yyyy).. __ __/__ __/__ __ __ __

201. Username of person completing/reviewing completeness of this form .... __ __ __ __ __ __ __

Clinical Center Use Only

Date Form Entered (mm/dd/yyyy) __ __/__ __/__ __ __ __

Username of person entering this form__ __ __ __ __ __ __

Pilot Clinical Trials in CKD
Packet Dispensing and Counting Form # 221 – TarGut Microbiome

This form is completed at W12, W16, and W20. Do not complete this form unless either packets were counted or the visit window has ended. ***The participant's own returned packets should not be re-dispensed.***

1. Identification Number	2. Alphacode	3a. Visit Type	3b. Visit Number (Month)	3b. Visit Number (Week)	4. Date packets counted/dispensed (mm/dd/yyyy)	5. Study
		W				T

6. Visit Number Intended..... W ___ ___
This form is expected at Week 12, 16, and 20. Code 99 for an extra or non -protocol visits.

7. Study Medication	
a. Were any packets lost or ruined? (0=no, all is well; 1=yes) (If any lost or ruined, don't count. Skip to Item 7j.)	__
b. Were the packets counted (0=no, 1=yes)	__
c. # days between visits (calculated and displayed)	__ __
d. # packets at end of previous visit	__ __ __
e. Prescribed # of packets per day at end of last visit	__
f. # packets should have taken (c times e)	__ __ __
g. Packet Count (# packets returned)	__ __ __
h. # packets taken (d minus g)	__ __ __
i. Adherence [Percent taken (h/f times 100%)]	__ __ __.__
j. What size packets are you dispensing (0=none, 2=2 grams, 4=4 grams)	__
k. Number of new packets dispensed (This is expected to be 0, 120 or 240)	__ __ __
l. Prescription type? 1=Per protocol (16g per day at W12 and W16 and 0 g per day at W20) 2=Reduced/halved for intolerance/symptom, 3=Discontinued for intolerance/symptom, 4=Reduced/halved for participant preference, 5=Discontinued for participant preference, 6=Reduced/halved for other reason,7=Discontinued for other reason	__
m. Prescribed dose **per day** as participant leaves this visit 0=none, 8=8g/day, 16=16g/day	__ __

8. If 7l is not "per protocol," explain why the dose was reduced or discontinued. If symptoms are noted, be sure these are documented on Form 281 or 282. If lab AEs are noted, be sure these are documented on Form 341.

200. Date this form completed (mm/dd/yyyy) __ __/__ __/__ __ __ __

201. Username of person completing/reviewing completeness of this form.....__ __ __ __ __ __ __

Clinical Center Use Only
Date Form Entered (mm/dd/yyyy) __ __/__ __/__ __ __ __
Username of person entering this form__ __ __ __ __ __ __

Pilot Clinical Trials in CKD
Food Frequency Questionnaire Form #270 – TarGut Microbiome

This questionnaire is completed online at W1, W8, W20, and W28 for TarGut Microbiome through the NutritionQuest website.

						T
1. Identification Number	2. Alphacode	3a. Visit Type	3b. Visit Number (Month)	(Week)	4. Date of Visit (mm/dd/yyyy)	5. Study

RESPONDENT ID NUMBER

TODAY'S DATE

Jan Feb Mar Apr May Jun Jul Aug Sep Oct Nov Dec

DAY

YEAR 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022 2023 2024

BRIEF FOOD QUESTIONNAIRE

This form is about the foods you usually eat.
It will take about 15 - 25 minutes to complete.

- **Please answer each question as best you can. Estimate if you aren't sure.**
- **Use only a No. 2 pencil.**
- **Fill in the circles completely, and erase completely if you make any changes.**

Please print your name in this box.

SEX
- Male
- Female

If female, are you pregnant or breast feeding?
- No
- Yes
- Not female

AGE

WEIGHT pounds

HEIGHT ft. in.

This form is about your usual eating habits in the past three months. This includes all meals or snacks, at home or in a restaurant or carry-out. There are two kinds of questions for each food.

HOW OFTEN, on average, did you eat the food?
*Please DO NOT SKIP any foods. Mark "Never" if you didn't eat it.

HOW MUCH did you usually eat of the food?
*Sometimes we ask how many you eat, such as 1 egg, 2 eggs, etc., ON THE DAYS YOU EAT IT.
*Sometimes we ask "how much" as A, B, C or D. LOOK AT THE ENCLOSED PICTURES. For each food, pick the picture (bowls or plates) that looks the most like the serving size you usually eat. (If you don't have pictures: A=1/4 cup, B=1/2 cup, C=1 cup, D= 2 cups.)

EXAMPLE: This person drank apple juice twice a week, and had one glass each time. Once a week he ate a "C"-sized serving of rice (about 1 cup).

TYPE OF FOOD	HOW OFTEN IN THE PAST 3 MONTHS									HOW MUCH EACH TIME SEE PORTION SIZE PICTURES FOR A-B-C-D				
	NEVER		ONCE per MONTH	2-3 TIMES per MONTH	ONCE per WEEK	TWICE per WEEK	3-4 TIMES per WEEK	5-6 TIMES per WEEK	EVERY DAY					
Apple juice	○		○	○	○	●	○	○	○	How many glasses each time	1 ●	2 ○	3 ○	4 ○
Rice	○		○	○	●	○	○	○	○	How much each time	A ○	B ○	C ●	D ○

PLEASE DO NOT WRITE IN THIS AREA

SERIAL #

  Phone (510)-704-8514 www.nutritionquest.com

TYPE OF FOOD	HOW OFTEN IN THE PAST 3 MONTHS									HOW MUCH EACH TIME SEE PORTION SIZE PICTURES FOR A-B-C-D				
	NEVER		ONCE per MONTH	2-3 TIMES per MONTH	ONCE per WEEK	TWICE per WEEK	3-4 TIMES per WEEK	5-6 TIMES per WEEK	EVERY DAY					
How often do you eat each of the following foods?														
Eggs, including egg biscuits or Egg McMuffins (Not egg substitutes)	○		○	○	○	○	○	○	○	How many eggs each time	○ 1	○ 2	○ 3	○ 4
Bacon or breakfast sausage, including sausage biscuit	○		○	○	○	○	○	○	○	How many pieces	○ 1	○ 2	○ 3	○ 4
Cooked cereals like oatmeal, cream of wheat or grits	○		○	○	○	○	○	○	○	Which bowl		○ B	○ C	○ D
Cold cereals like Corn Flakes, Cheerios, Special K, fiber cereals	○		○	○	○	○	○	○	○	Which bowl		○ B	○ C	○ D
Which cereal do you eat most often? **MARK ONLY ONE:** ○ Product 19, Just Right, Total ○ Bran Buds, Raisin Bran, Fruit-n-Fiber, other fiber cereals ○ Other cold cereal, like Corn Flakes, Cheerios, Special K														
Cheese, sliced cheese or cheese spread, including on sandwiches.	○		○	○	○	○	○	○	○	How many slices	○ 1	○ 2	○ 3	○ 4
Yogurt (not frozen yogurt)	○		○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
How often do you eat each of the following fruits?														
Bananas	○		○	○	○	○	○	○	○	How many each time	○ 1/2	○ 1	○ 2	○ 3
Apples or pears	○		○	○	○	○	○	○	○	How many	○ 1/2	○ 1	○ 2	○ 3
Oranges, tangerines, not including juice	○		○	○	○	○	○	○	○	How many	○ 1/2	○ 1	○ 2	○ 3
Applesauce, fruit cocktail, or any canned fruit	○		○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Any other fruit, like grapes, melon, strawberries, peaches	○		○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D

TYPE OF FOOD	HOW OFTEN IN THE PAST 3 MONTHS									HOW MUCH EACH TIME SEE PORTION SIZE PICTURES FOR A-B-C-D				
	NEVER		ONCE per MONTH	2-3 TIMES per MONTH	ONCE per WEEK	TWICE per WEEK	3-4 TIMES per WEEK	5-6 TIMES per WEEK	EVERY DAY					
How often do you eat each of the following vegetables, including fresh, frozen, canned or in stir fry, at home or in a restaurant?														
French fries, fried potatoes or hash browns	○		○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
White potatoes not fried, incl. boiled, baked, mashed & potato salad	○		○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Sweet potatoes, yams, or sweet potato pie	○		○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Rice, or dishes made with rice	○		○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Baked beans, chili with beans, pintos, any other dried beans	○		○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Refried beans	○		○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Green beans or green peas	○		○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Broccoli	○		○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Carrots, or stews or mixed vegetables containing carrots	○		○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Spinach, or greens like collards	○		○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Cole slaw, cabbage	○		○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Green salad	○		○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Raw tomatoes, including in salad	○		○	○	○	○	○	○	○	How much	○ 1/4	○ 1/2	○ 1	○ 2
Catsup, salsa or chile peppers	○		○	○	○	○	○	○	○	How many TBSP.	○ 1	○ 2	○ 3	○ 4
Salad dressing or mayonnaise (Not lowfat)	○		○	○	○	○	○	○	○	How many TBSP.	○ 1	○ 2	○ 3	○ 4
Any other vegetable, like corn, squash, okra, cooked green peppers, cooked onions	○		○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Vegetable soup, vegetable beef, chicken vegetable, or tomato soup	○		○	○	○	○	○	○	○	Which bowl		○ B	○ C	○ D

SERIAL # PLEASE DO NOT WRITE IN THIS AREA

TYPE OF FOOD	HOW OFTEN IN THE PAST 3 MONTHS: NEVER		ONCE per MONTH	2-3 TIMES per MONTH	ONCE per WEEK	TWICE per WEEK	3-4 TIMES per WEEK	5-6 TIMES per WEEK	EVERY DAY	HOW MUCH EACH TIME (SEE PORTION SIZE PICTURES FOR A-B-C-D)				
MEATS														
Do you ever eat chicken, meat or fish? ○ Yes ○ No IF NO, SKIP TO NEXT PAGE														
Hamburgers, cheeseburgers, meat loaf, at home or in a restaurant	○		○	○	○	○	○	○	○	How much meat	○ 1/8 lb.	○ 1/4 lb.	○ 1/2 lb.	○ 3/4 lb.
Tacos, burritos, enchiladas, tamales	○		○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Beef steaks, roasts, pot roast, or in frozen dinners or sandwiches	○		○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Pork, including chops, roasts, or dinner ham	○		○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
When you eat beef or pork, do you ○ Avoid eating the fat ○ Sometimes eat the fat ○ Often eat the fat ○ I don't eat meat														
Mixed dishes with meat or chicken, like stew, corned beef hash, chicken & dumplings, or in frozen meals	○		○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Fried chicken, at home or in a restaurant	○		○	○	○	○	○	○	○	# medium pieces	○ 1	○ 2	○ 3	○ 4
Chicken or turkey not fried, such as baked, grilled, or on sandwiches	○		○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
When you eat chicken, do you ○ Avoid eating the skin ○ Sometimes eat the skin ○ Often eat the skin ○ N/A														
Fried fish or fish sandwich, at home or in a restaurant	○		○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Any other fish or shellfish <u>not</u> fried, including tuna	○		○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Hot dogs, or sausage like Polish, Italian or Chorizo	○		○	○	○	○	○	○	○	How many	○ 1	○ 2	○ 3	○ 4
Boloney, sliced ham, turkey lunch meat, other lunch meat	○		○	○	○	○	○	○	○	How many slices	○ 1	○ 2	○ 3	○ 4
When you eat lunch meats, are they ○ Usually low-fat ○ Sometimes ○ Rarely low-fat ○ N/A														

SERIAL # PLEASE DO NOT WRITE IN THIS AREA

TYPE OF FOOD	HOW OFTEN IN THE PAST 3 MONTHS: NEVER		ONCE per MONTH	2-3 TIMES per MONTH	ONCE per WEEK	TWICE per WEEK	3-4 TIMES per WEEK	5-6 TIMES per WEEK	EVERY DAY	HOW MUCH EACH TIME (SEE PORTION SIZE PICTURES FOR A-B-C-D)				
Pasta, breads, spreads, snacks														
Spaghetti, lasagna, or other pasta with tomato sauce	○		○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Cheese dishes without tomato sauce, like macaroni and cheese	○		○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Pizza, including carry-out	○		○	○	○	○	○	○	○	How many slices	○ 1	○ 2	○ 3	○ 4
Biscuits, muffins	○		○	○	○	○	○	○	○	How many each time	○ 1	○ 2	○ 3	○ 4
Rolls, hamburger buns, English muffins, bagels	○		○	○	○	○	○	○	○	How many each time	○ 1/2	○ 1	○ 2	○ 3
White bread or toast, including French, Italian, or in sandwiches	○		○	○	○	○	○	○	○	How many slices	○ 1	○ 2	○ 3	○ 4
Dark bread like rye or whole wheat, including in sandwiches	○		○	○	○	○	○	○	○	How many slices	○ 1	○ 2	○ 3	○ 4
Tortillas	○		○	○	○	○	○	○	○	How many each time	○ 1	○ 2	○ 3	○ 4
Margarine on bread, potatoes or vegetables	○		○	○	○	○	○	○	○	How many pats (Tsp.)	○ 1	○ 2	○ 3	○ 4
Butter on bread, potatoes or vegetables	○		○	○	○	○	○	○	○	How many pats (Tsp.)	○ 1	○ 2	○ 3	○ 4
Peanuts or peanut butter	○		○	○	○	○	○	○	○	How many TBSP.	○ 1	○ 2	○ 3	○ 4
Snacks like potato chips, corn chips, popcorn (Not pretzels)	○		○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Doughnuts, cake, pastry, pie	○		○	○	○	○	○	○	○	How many pieces	○ 1	○ 2	○ 3	○ 4
Cookies (Not lowfat)	○		○	○	○	○	○	○	○	How many	○ 1-2	○ 3-5	○ 6-7	○ 8+
Ice cream, frozen yogurt, ice cream bars	○		○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
When you eat ice cream or frozen yogurt, is it	○ Usually low-fat	○ Sometimes	○ Rarely low-fat	○ N/A										
Chocolate candy, candy bars	○		○	○	○	○	○	○	○	How many bars	○ 1 small	○ 1 medium	○ 1 large	○ 2 large

TYPE OF BEVERAGE	HOW OFTEN IN THE PAST 3 MONTHS									HOW MUCH EACH TIME SEE PORTION SIZE PICTURES FOR A-B-C-D				
	NEVER		ONCE per MONTH	2-3 TIMES per MONTH	ONCE per WEEK	TWICE per WEEK	3-4 TIMES per WEEK	5-6 TIMES per WEEK	EVERY DAY					
How often do you drink the following beverages?														
Real orange or grapefruit juice, Welch's grape juice, Minutemaid juices, Juicy Juice	○		○	○	○	○	○	○	○	How many glasses each time	○ 1	○ 2	○ 3	○ 4
Hawaiian Punch, Sunny Delight, Hi-C, Tang, or Ocean Spray juices	○		○	○	○	○	○	○	○	How many glasses each time	○ 1	○ 2	○ 3	○ 4
Kool Aid, Capri Sun or Knudsen juices	○		○	○	○	○	○	○	○	How many glasses each time	○ 1	○ 2	○ 3	○ 4
Instant breakfast milkshakes like Carnation, diet shakes like Slimfast, or liquid supplements like Ensure	○		○	○	○	○	○	○	○	How many glasses or cans	○ 1	○ 2	○ 3	○ 4
Glasses of milk (any kind)	○		○	○	○	○	○	○	○	How many glasses	○ 1	○ 2	○ 3	○ 4
When you drink glasses of milk what kind do you <u>usually</u> drink? **MARK ONLY ONE:**	○ Whole milk ○ Reduced fat 2% milk ○ Low-fat 1% milk				○ Non-fat milk ○ Rice milk ○ Soy milk				○ I don't drink milk or soy milk					
Cream, Half-and-Half or non-dairy creamer in coffee or tea	○		○	○	○	○	○	○	○	Total TBSP. on those days	○ 1	○ 2	○ 3-4	○ 5+
Regular soft drinks, or bottled drinks like Snapple (<u>Not</u> diet drinks)	○		○	○	○	○	○	○	○	How many bottles or cans	○ 1	○ 2	○ 3-4	○ 5+
Beer	○		○	○	○	○	○	○	○	How many bottles or cans	○ 1	○ 2	○ 3-4	○ 5+
Wine or wine coolers	○		○	○	○	○	○	○	○	How many glasses	○ 1	○ 2	○ 3-4	○ 5+
Liquor or mixed drinks	○		○	○	○	○	○	○	○	How many drinks	○ 1	○ 2	○ 3-4	○ 5+

Do you take any vitamins or minerals regularly, at least once a month?

○ No, not regularly ○ Yes, fairly regularly →

(IF YES) WHAT DID YOU TAKE FAIRLY REGULARLY?

VITAMIN TYPE	HOW OFTEN					FOR HOW MANY YEARS?					
	DIDN'T TAKE	A FEW DAYS per MONTH	1-3 DAYS per WEEK	4-6 DAYS per WEEK	EVERY DAY	LESS THAN 1 YR.	1 YEAR	2 YEARS	3-4 YEARS	5-9 YEARS	10+ YEARS
Multiple Vitamins. Did you take…											
Regular Once-A-Day, Centrum, or Thera type	○	○	○	○	○	○	○	○	○	○	○
Stress-tabs or B-Complex type	○	○	○	○	○	○	○	○	○	○	○
Antioxidant combination type	○	○	○	○	○	○	○	○	○	○	○
Single Vitamins (not part of multiple vitamins)											
Vitamin A (not beta-carotene)	○	○	○	○	○	○	○	○	○	○	○
Beta-carotene	○	○	○	○	○	○	○	○	○	○	○
Vitamin C	○	○	○	○	○	○	○	○	○	○	○
Vitamin E	○	○	○	○	○	○	○	○	○	○	○
Folic acid, folate	○	○	○	○	○	○	○	○	○	○	○
Calcium or Tums, alone or combined with vit. D or magnesium	○	○	○	○	○	○	○	○	○	○	○
Zinc	○	○	○	○	○	○	○	○	○	○	○
Iron	○	○	○	○	○	○	○	○	○	○	○
Selenium	○	○	○	○	○	○	○	○	○	○	○
Vitamin D, alone or combined with calcium	○	○	○	○	○	○	○	○	○	○	○

If you took vitamin C or vitamin E:

How many milligrams of **vitamin C** did you usually take, on the days you took it?

○ 100 ○ 250 ○ 500 ○ 750 ○ 1000 ○ 1500 ○ 2000 ○ 3000+ ○ don't know

How many IUs of **vitamin E** did you usually take, on the days you took it?

○ 100 ○ 200 ○ 300 ○ 400 ○ 600 ○ 800 ○ 1000 ○ 2000+ ○ don't know

How often do you use fat or oil in cooking?

○ Less than once per week ○ A few times per week ○ Once a day ○ Twice a day ○ 3+ per day

What kinds of fat or oil do you usually use in cooking? MARK ONLY ONE OR TWO

○ Don't know, or Pam
○ Stick margarine
○ Soft tub margarine
○ Butter
○ Butter/margarine blend
○ Low-fat margarine
○ Corn oil, vegetable oil
○ Olive oil or canola oil
○ Lard, fatback, bacon fat
○ Crisco

Did you ever drink more beer, wine or liquor than you do now? ○ Yes ○ No

Do you smoke cigarettes now? ○ Yes ○ No

IF YES, On the average about how many cigarettes a day do you smoke now?

○ 1-5 ○ 6-14 ○ 15-24 ○ 25-34 ○ 35 or more

What is your ethnic group? (MARK ONE OR MORE)

○ Hispanic or Latino
○ White, not Hispanic
○ Black or African American
○ Asian
○ American Indian or Alaska Native
○ Native Hawaiian or Other Pacific Islander

Thank you very much for filling out this questionnaire. Please take a minute to go back and fill in anything you may have skipped.

PLEASE DO NOT WRITE IN THIS AREA

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PLEASE DO NOT WRITE IN THIS AREA

SERIAL #

Pilot Clinical Trials in CKD
Symptoms Questionnaire Form #281 – TarGut Microbiome

This form is completed at protocol visits S0, W1, 4, 8, 12, 16, 20, 24 and 28 for TarGut Microbiome.

1. Identification Number	2. Alphacode	3a. Visit Type	3b. Visit Number (Month)	(Week)	4. Date of Visit (mm/dd/yyyy)	5. Study
						T

6. Visit Number Intended .... ___ ___ ___
   TarGut Microbiome study visits: Screening (S0) and Weekly (W) Visits 1, 4, 8, 12, 16, 20, 24, and 28
   Code 99 for extra or intended non -protocol visits

7. How were the questions on this form answered?... ___
   1=Self-administered, 2=Interviewer-administered in person, 3=Interviewer-administered by telephone

Note: If the participant leaves an item blank in the GI Symptoms section, ask the participant if they could complete it. It is important for the participant's safety that we know if he/she is having GI symptoms.
(Baseline responses to the questions on nausea and diarrhea are required for randomization.)
If there is a question the participant will not answer even with prompting, code the question as a '9' on the database screen.

GI Symptoms experienced in the **LAST WEEK**?

		No discomfort at all	Mild discomfort	Moderate discomfort	Severe discomfort
8.	Have you been bothered by PAIN OR DISCOMFORT IN YOUR UPPER ABDOMEN OR THE PIT OF YOUR STOMACH during the past week? *[discomfort=10042101; abdominal pain upper=10000087]*	0	1	2	3
9.	Have you been bothered by HEARTBURN during the past week? (By heartburn, we mean an unpleasant stinging or burning sensation in the chest.) *[10019326]*	0	1	2	3
10.	Have you been bothered by ACID REFLUX during the past week? (By acid reflux, we mean the sensation of regurgitating small quantities of acid or flow of sour or bitter fluid from the stomach up to the throat.) *[10066872]*	0	1	2	3
11.	Have you been bothered by HUNGER PAINS in the stomach during the past week? (By hunger pain, we mean that hollow feeling in the stomach associated with the need to eat between meals.) *[10033407]*	0	1	2	3
12.	Have you been bothered by NAUSEA during the past week? (By nausea, we mean a feeling of wanting to throw up or vomit.) *[10028822]*	0	1	2	3
13.	Have you been bothered by RUMBLING in your stomach during the past week? (By rumbling, we mean vibrations or noise in the stomach.) *[10048720]*	0	1	2	3
14.	Has your stomach felt BLOATED during the past week? (By bloated, we mean a feeling of swelling often associated with a sensation of gas or air in the stomach.) *[10048746]*	0	1	2	3
15.	Have you been bothered by BURPING during the past week? (By burping we mean bringing up air or gas form the stomach via the mouth, often associated with easing a bloated feeling.)*[10006804]*	0	1	2	3
16.	Have you been bothered by PASSING GAS OR FLATUS during the past week? (By passing gas or flatus we mean the need to release air or gas from the bowel, often associated with easing a bloated feeling.) *[10016769]*	0	1	2	3

		No discomfort at all	Mild discomfort	Moderate discomfort	Severe discomfort
17.	Have you been bothered by CONSTIPATION during the past week? (By constipation we mean a reduced ability to empty the bowels.) *[10010774]*	0	1	2	3
18.	Have you been bothered by DIARRHEA during the past week? (By diarrhea we mean too frequent emptying of the bowels.) *[10012732]*	0	1	2	3
19.	Have you been bothered by LOOSE STOOLS during the past week? (If your bowel movements have been alternately hard and loose, this question only refers to the extent you have been bothered by the stools being loose.) *[10024840]*	0	1	2	3
20.	Have you been bothered by HARD STOOLS during the past week? (If your bowel movements have been alternately hard and loose, this question only refers to the extent you have been bothered by the stools being hard.) *[10042155]*	0	1	2	3
21.	Have you been bothered by an URGENT NEED TO HAVE A BOWEL MOVEMENT during the past week? (This urgent need to go to the toilet is often associated with a feeling that you are not in full control.) *[10012114]*	0	1	2	3
22.	When going to the toilet during the past week, have you had the SENSATION OF NOT COMPLETELY EMPTYING THE BOWELS? (By incomplete emptying, we mean that you still feel a need to pass more stools despite having exerted yourself to do so.) *[10040002]*	0	1	2	3

23.	When going to the toilet during the past week, please describe the typical form of your stools. Have your stools typically been:	Well Formed [1]	Semi-Formed (very soft but retain some form) [2]	Loose (no form, breaks apart) [3]	Liquid (mushy like applesauce or watery) [4]	
24.	Over the past week, what is the average number of stools you have made each day?	Less than 1 [1]	1 or 2 [2]	3 or 4 [3]	5 or 6 [4]	7 or more [5]

Inulin Specific Questions (Enter 0=no, 1=yes, 8=Not applicable, participant not taking Inulin)

25. a. Did the participant report that the inulin caused a bad taste in his/her mouth? ..... ___
    b. Did the participant report difficulty swallowing the inulin? ..... ___

Other (non-GI) Symptoms: For Q26-30, explicitly ask the participant, if he or she has/had any of the following non-GI symptoms since the last visit. (Enter a 0=no, 1=yes, and 9=unknown/not asked.) For Q26-30 code 2=if staff observes symptom but participant reports "no".

26. Flushing (10016825) ..... ___
27. Hives (10020197) ..... ___
28. Bruising (010006504) ..... ___
29. Bleeding (10005103) ..... ___
30. Headache (10019211) ..... ___

Staff member will question whether the participant has **any other symptoms to report.**
(Enter 1=Yes to all that the participant reports, enter a 2=Not reported as a symptom)

31. Backache (10003993) ..... ___
32. Common cold (10010106)..... ___
33. Loss of energy, feeling run down, fatigued (10024862)..... ___
34. Drowsy, sleepy, can't stay awake (10041018) ..... ___
35. Dizziness (10013580)..... ___
36. Insomnia, can't sleep (10022437) ..... ___
37. If the participant reported more symptoms, record these below. Do not repeat symptoms already captured. Use the back of this page if necessary.You will be able to enter as many symptoms as needed.
    [If the participant has been diagnosed with a new comorbidity, record this here as well]

Symptom	**MedDRA Code** *(will populate at data entry)*
a.	
b.	
c.	
d.	

200. Date this form completed (mm/dd/yyyy)..... __ __ /__ __ /__ __ __ __
201. Username of person completing/reviewing completeness of this form ..... __ __ __ __ __ __ __

Clinical Center Use Only
Date Form Entered (mm/dd/yyyy) __ __/__ __/__ __ __ __
Username of person entering this form__ __ __ __ __ __ __

Pilot Clinical Trials in CKD
Symptoms/Adverse Events Reported on Phone Calls or at Extra Non-Protocol Visits #282 – TarGut Microbiome

If a participant brings up a symptom or an adverse event during a phone call with a TarGut Microbiome Study Staff member or during a drop-off or pick-up or some other non-protocol visit, you can skip the fields that do not apply and enter only the symptoms or adverse events the participant reports.

1. Identification Number	2. Alphacode	3a.Visit Type	3b. Visit Number (Month)	3b. Visit Number (Week)	4. Date of Visit (mm/dd/yyyy)	5. Study
						T

6. Visit Number Intended ..... ___ 8 2

7. How were the questions on this form answered?..... ___
   2=In person during a drop-off or pick-up or some other non-protocol visit
   3=Telephone

GI Symptoms experienced in the **LAST WEEK**?

		No discomfort at all	Mild discomfort	Moderate discomfort	Severe discomfort
8.	Have you been bothered by PAIN OR DISCOMFORT IN YOUR UPPER ABDOMEN OR THE PIT OF YOUR STOMACH during the past week? *[discomfort=10042101; abdominal pain upper=10000087]*	0	1	2	3
9.	Have you been bothered by HEARTBURN during the past week? (By heartburn, we mean an unpleasant stinging or burning sensation in the chest.) *[10019326]*	0	1	2	3
10.	Have you been bothered by ACID REFLUX during the past week? (By acid reflux, we mean the sensation of regurgitating small quantities of acid or flow of sour or bitter fluid from the stomach up to the throat.) *[10066872]*	0	1	2	3
11.	Have you been bothered by HUNGER PAINS in the stomach during the past week? (By hunger pain, we mean that hollow feeling in the stomach associated with the need to eat between meals.) *[10033407]*	0	1	2	3
12.	Have you been bothered by NAUSEA during the past week? (By nausea, we mean a feeling of wanting to throw up or vomit.) *[10028822]*	0	1	2	3
13.	Have you been bothered by RUMBLING in your stomach during the past week? (By rumbling, we mean vibrations or noise in the stomach.) *[10048720]*	0	1	2	3
14.	Has your stomach felt BLOATED during the past week? (By bloated, we mean a feeling of swelling often associated with a sensation of gas or air in the stomach.) *[10048746]*	0	1	2	3
15.	Have you been bothered by BURPING during the past week? (By burping we mean bringing up air or gas form the stomach via the mouth, often associated with easing a bloated feeling.)*[10006804]*	0	1	2	3
16.	Have you been bothered by PASSING GAS OR FLATUS during the past week? (By passing gas or flatus we mean the need to release air or gas from the bowel, often associated with easing a bloated feeling.) *[10016769]*	0	1	2	3

		No discomfort at all	Mild discomfort	Moderate discomfort	Severe discomfort
17.	Have you been bothered by CONSTIPATION during the past week? (By constipation we mean a reduced ability to empty the bowels.) *[10010774]*	0	1	2	3
18.	Have you been bothered by DIARRHEA during the past week? (By diarrhea we mean too frequent emptying of the bowels.) *[10012732]*	0	1	2	3
19.	Have you been bothered by LOOSE STOOLS during the past week? (If your bowel movements have been alternately hard and loose, this question only refers to the extent you have been bothered by the stools being loose.) *[10024840]*	0	1	2	3
20.	Have you been bothered by HARD STOOLS during the past week? (If your bowel movements have been alternately hard and loose, this question only refers to the extent you have been bothered by the stools being hard.) *[10042155]*	0	1	2	3
21.	Have you been bothered by an URGENT NEED TO HAVE A BOWEL MOVEMENT during the past week? (This urgent need to go to the toilet is often associated with a feeling that you are not in full control.) *[10012114]*	0	1	2	3
22.	When going to the toilet during the past week, have you had the SENSATION OF NOT COMPLETELY EMPTYING THE BOWELS? (By incomplete emptying, we mean that you still feel a need to pass more stools despite having exerted yourself to do so.) *[10040002]*	0	1	2	3

23.	When going to the toilet during the past week, please describe the typical form of your stools. Have your stools typically been:	Well Formed [1]	Semi-Formed (very soft but retain some form) [2]	Loose (no form, breaks apart) [3]	Liquid (mushy like applesauce or watery) [4]	
24.	Over the past week, what is the average number of stools you have made each day?	Less than 1 [1]	1 or 2 [2]	3 or 4 [3]	5 or 6 [4]	7 or more [5]

Inulin Specific Questions (Enter 0=no, 1=yes, 8=Not applicable, participant not taking Inulin)

25. a. Did the participant report that the inulin caused a bad taste in his/her mouth? ..... ___
    b. Did the participant report difficulty swallowing the inulin? ..... ___

Other (non-GI) Symptoms: For Q26-30, explicitly ask the participant, if he or she has/had any of the following non-GI symptoms since the last visit. (Enter a 0=no, 1=yes, and 9=unknown/not asked.) For Q26-30 code 2=if staff observes symptom but participant reports "no".

26. Flushing (10016825) ..... ___
27. Hives (10020197) ..... ___
28. Bruising (010006504) ..... ___
29. Bleeding (10005103) ..... ___
30. Headache (10019211) ..... ___

Staff member will question whether the participant has **any other symptoms to report.**
(Enter 1=Yes to all that the participant reports, enter a 2=Not reported as a symptom)

31. Backache (10003993) ..... ___
32. Common cold (10010106)..... ___
33. Loss of energy, feeling run down, fatigued (10024862)..... ___
34. Drowsy, sleepy, can't stay awake (10041018) ..... ___
35. Dizziness (10013580)..... ___
36. Insomnia, can't sleep (10022437) ..... ___
37. If the participant reported more symptoms, record these below. Do not repeat symptoms already captured. Use the back of this page if necessary.You will be able to enter as many symptoms as needed.
    [If the participant has been diagnosed with a new comorbidity, record this here as well]

Symptom	**MedDRA Code** *(will populate at data entry)*
a.	
b.	
c.	
d.	

200. Date this form completed (mm/dd/yyyy)..... __ __ /__ __ /__ __ __ __
201. Username of person completing/reviewing completeness of this form ..... __ __ __ __ __ __ __

Clinical Center Use Only
Date Form Entered (mm/dd/yyyy) __ __/__ __/__ __ __ __
Username of person entering this form__ __ __ __ __ __ __

Pilot Clinical Trials in CKD
Visit/Blood Drawn & Stored Locally Form # 310A – TarGut Microbiome

Form 310A is completed at each weekly TarGut visit when barcodes are scanned. Before each blood draw, study staff will review the most recent hemoglobin lab results from TarGut and from the participant's medical record. If this result is less than 9.0 g/dl, blood will not be collected until hemoglobin value is ≥ 9.0 g/dl.

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1. Identification Number 2. Alphacode 4. Date barcodes scanned (mm/dd/yyyy) 5. Study

12. Aliquot Bar Codes and Volumes *("Line #" is "01 to 13" to synchronize with ESRD study.)*
Scan the bar code for each cryovial label provided into the appropriate field. There will be no missing barcodes below. Once you have key entered this form, print a copy for the participant's study records so you have a record of the bar code associated with each cryovial.

Line #	Specimen Bar Code	Specimen Type	Aliquot #
12.01	Scan Cryovial Label Here	SER_RT	1
12.02	Scan Cryovial Label Here	SER_RT	2
12.03	Scan Cryovial Label Here	SER_RT	3
12.04	Scan Cryovial Label Here	SER_RT	4
12.05	Scan Cryovial Label Here	PL_EDTA	1
12.06	Scan Cryovial Label Here	PL_EDTA	2
12.07	Scan Cryovial Label Here	PL_EDTA	3
12.08	Scan Cryovial Label Here	PL_EDTA	4
12.09	Scan Cryovial Label Here	PL_EDTA	5
12.10	Scan Cryovial Label Here	PL_EDTA	6
12.11	Scan Cryovial Label Here	PL_EDTA	7
12.12	Scan Cryovial Label Here	PL_EDTA	8
12.13	Scan Cryovial Label Here	PL_EDTA	9

200. Date this form completed (mm/dd/yyyy).....__ __/__ __/__ __ __ __

201. Username of person completing/reviewing completeness of this form..... __ __ __ __ __ __ __

Clinical Center Use Only
Date Form Entered (mm/dd/yyyy) __ __/__ __/__ __ __ __
Username of person entering this form __ __ __ __ __ __ __

Pilot Clinical Trials in CKD
Visit/Blood Drawn & Stored Locally Form # 310B – TarGut Microbiome

Form 310 is completed at each weekly TarGut visit to document the visit and note when blood is drawn and stored. All blood samples are drawn by an experienced phlebotomist keeping in mind to preserve veins for future vascular access. Before each blood draw, study staff will review the most recent hemoglobin lab results from TarGut and from the participant's medical record. If this result is less than 9.0 g/dl, blood will not be collected until hemoglobin value is ≥ 9.0 g/dl.

At the W1 visit, this Form 310B must be the first form entered so that the visit number can be correctly calculated for all other weekly visits. Also, at visits (S, W8, W16, W20, and W28) where Local Lab CBC is drawn, the Form 340 Local Lab CBC Results Form needs to be entered prior to Form 310B.

☐☐☐☐☐☐	☐☐	W	☐☐ ☐☐	☐☐☐☐☐☐☐☐	T
1. Identification Number	2. Alphacode	3a.Visit Type	3b. Visit Number (Month) (Week)	4. Date of visit/blood drawn (mm/dd/yyyy)	5a. Study

5. b. Date barcodes scanned (mm/dd/yyyy) ....__ __/__ __/__ __ __ __
(Date must match the date barcodes scanned on Form 310A)

6. a. Visit Number intended ....**W** ___ ___

b. Status of this TarGut Visit .... ___ ___
0=Visit data not collected before the start of the next visit's window. (This is a missed visit.)
1=Visit held / visit data collected before start of next window.

c. Was a food frequency questionnaire completed at this visit? (0=no, 1=yes) ....___
(The Food Frequency Questionnaire is completed at W1, 8, 20 and 28.)

7. Date of the most recent hemoglobin (mm/dd/yyyy)...................................__ __/__ __/__ __ __ __
(From last Local Lab CBC Results Form 340.)

8. Blood draw status for this TarGut Visit...___
1=Blood was drawn
2=Blood was not drawn because most recent hemoglobin was < 9.0 g/dl
3=Blood was not drawn for some other reason

If blood not drawn, skip to item 200.

9. Time blood was drawn (24-hour clock) (hh:mm) ....___ ___ : ___ ___

10. Was whole blood sent to the local lab for analysis? (0=no, 1=yes) ....___

11. Cryovial Kit # for stored blood

Affix Label

12. Aliquot Bar Codes and Volumes *("Line #" is "01 to 13" to synchronize with ESRD study.)*
During data entry, scan the bar code for each cryovial label provided into the appropriate field whether that cryovial was collected and stored or the cryovial is empty. There will be no missing barcodes below. Indicate whether the aliquot was stored and if so, its volume. Once you have key entered this form, print a copy for the participant's study records so you have a record of the bar code associated with each cryovial.

Line #	Specimen Bar Code	Specimen Type	Aliquot #	Aliquot stored? (0=no, 1=yes)	Volume of this aliquot (ml)
12.01	Scan Cryovial Label Here	SER_RT	1		
12.02	Scan Cryovial Label Here	SER_RT	2		
12.03	Scan Cryovial Label Here	SER_RT	3		
12.04	Scan Cryovial Label Here	SER_RT	4		
12.05	Scan Cryovial Label Here	PL_EDTA	1		
12.06	Scan Cryovial Label Here	PL_EDTA	2		
12.07	Scan Cryovial Label Here	PL_EDTA	3		
12.08	Scan Cryovial Label Here	PL_EDTA	4		
12.09	Scan Cryovial Label Here	PL_EDTA	5		
12.10	Scan Cryovial Label Here	PL_EDTA	6		
12.11	Scan Cryovial Label Here	PL_EDTA	7		
12.12	Scan Cryovial Label Here	PL_EDTA	8		
12.13	Scan Cryovial Label Here	PL_EDTA	9		

13. Date samples frozen locally at -80ºC (mm/dd/yyyy) .....__ __/__ __/__ __ __ __

14. Time samples frozen (24-hour clock) (hh:mm).....___ ___ : ___ ___

15. Freezer and shelf where samples are stored locally (up to 50 char text)

200. Date this form completed (mm/dd/yyyy).....__ __/__ __/__ __ __ __

201. Username of person completing/reviewing completeness of this form..... __ __ __ __ __ __ __

Clinical Center Use Only
Date Form Entered (mm/dd/yyyy) __ __/__ __/__ __ __ __
Username of person entering this form __ __ __ __ __ __ __

Pilot Clinical Trials in CKD
Spot Urine Specimen Collected and
Stored Locally Form # 313A – TarGut Microbiome

Spot Urine samples (10 ml) will be collected for metabolomics studies at all weekly visits. This form is completed only when the barcodes are scanned.

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1. Identification Number 2. Alphacode 4. Date barcodes scanned (mm/dd/yyyy) 5. Study

9. Aliquot Bar Codes and Volumes
Scan the bar code for each cryovial label provided into the appropriate field. There will be no missing barcodes below. Once you have key entered this form, print a copy for the participant's study records so you have a record of the bar code associated with each cryovial.

Line #	Specimen Bar Code	Spec. Type (Vial Size)	Alliquot #
9.1	Scan Aliquot Label Here	Spot	1
9.2	Scan Aliquot Label Here	Spot	2
9.3	Scan Aliquot Label Here	Spot	3
9.4	Scan Aliquot Label Here	Spot	4

200. Date form completed (mm/dd/yyyy) .....__ __/__ __/__ __ __ __

201. Username of person completing/reviewing completeness of this form.....__ __ __ __ __ __ __

Clinical Center Use Only

Date Form Entered (mm/dd/yyyy) __ __/__ __/__ __ __ __

Username of person entering this form __ __ __ __ __ __ __

Pilot Clinical Trials in CKD
Spot Urine Specimen Collected and Stored Locally Form # 313B – TarGut Microbiome

Spot Urine samples (10 ml) will be collected for metabolomics studies at all weekly visits. The spot urine should be collected on the same day as the visit.

									W													T

1. Identification Number 2. Alphacode 3a.Visit Type 3b. Visit Number (Month) (Week) 4. Date of visit (mm/dd/yyyy) 5a. Study

5. b. Date barcodes scanned (mm/dd/yyyy) ....__ __/__ __/__ __ __ __
(Date must match the date barcodes scanned on Form 313A)

6. Visit Number intended.. **W** ___ ___
(Spot urine is collected every week.)

7. a. Date spot urine collected (mm/dd/yyyy) ....__ __/__ __/__ __ __ __

b. Time spot urine collected (24-hour clock) (hh:mm) ....___ ___ : ___ ___

c. Time spot urine received (24-hour clock) (hh:mm) ....___ ___ : ___ ___
(The sample must have been collected within 24 hours of being given to the site staff.)

8. Spot urine Kit # for stored spot urine

Affix Label

9. Aliquot Bar Codes and Volumes
Four tubes of urine should be aliquoted and stored.
During data entry, scan the bar code for each cryovial label provided into the appropriate field whether that cryovial was collected and stored or the cryovial is empty. There will be no missing barcodes below. Indicate whether the aliquot was stored and if so, its volume. Once you have key entered this form, print a copy for the participant's study records so you have a record of the bar code associated with each cryovial.

Line #	Specimen Bar Code	Spec. Type (Vial Size)	Alliquot #	Aliquot stored? (0=no, 1=yes)	Volume of this aliquot (ml)
9.1	Scan Aliquot Label Here	Spot	1		
9.2	Scan Aliquot Label Here	Spot	2		
9.3	Scan Aliquot Label Here	Spot	3		
9.4	Scan Aliquot Label Here	Spot	4		

10. Date samples frozen locally at -80°C (mm/dd/yyyy) .....__ __/__ __/__ __ __ __

11. Time samples frozen (24-hour clock) (hh:mm).....___ ___ : ___ ___

12. Freezer and shelf where samples are stored locally (up to 50 char text)

200. Date form completed (mm/dd/yyyy) .....__ __/__ __/__ __ __ __

201. Username of person completing/reviewing completeness of this form.....__ __ __ __ __ __ __

Clinical Center Use Only

Date Form Entered (mm/dd/yyyy) __ __/__ __/__ __ __ __

Username of person entering this form __ __ __ __ __ __ __

Pilot Clinical Trials in CKD

Stool Specimen Collected and Stored Locally Form # 316A – TarGut Microbiome

Form 316A is completed when only the barcodes are scanned into the CKD database.

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1. Identification Number 2. Alphacode 4. Date barcodes scanned mm/dd/yyyy 5. Study

9. Specimen information:
Scan the bar code for each cryovial label provided into the appropriate. There will be no missing barcodes below. Once you have key entered this form, print a copy for the participant's study records so you have a record of the bar code associated with each cryovial.

Line #	Specimen Bar Code	Spec. Type S=Short L=Long	Aliquot #
9.01	Scan Aliquot Label Here	S	1
9.02	Scan Aliquot Label Here	S	2
9.03	Scan Aliquot Label Here	S	3
9.04	Scan Aliquot Label Here	S	4
9.05	Scan Aliquot Label Here	S	5
9.06	Scan Aliquot Label Here	L	1
9.07	Scan Aliquot Label Here	L	2
9.08	Scan Aliquot Label Here	L	3
9.09	Scan Aliquot Label Here	L	4
9.10	Scan Aliquot Label Here	L	5

200. Date form completed (mm/dd/yyyy)..... __ __/__ __/__ __ __ __

201. Username of person completing/reviewing completeness of this form .....__ __ __ __ __ __ __

Clinical Center Use Only

Date Form Entered (mm/dd/yyyy) __ __/__ __/__ __ __ __

Username of person entering this form __ __ __ __ __ __ __

Pilot Clinical Trials in CKD

Stool Specimen Collected and Stored Locally Form # 316B – TarGut Microbiome

Form 316B is completed when a participant brings in aliquots of stool at each weekly visit.

[ ][ ][ ][ ][ ][ ]	[ ][ ]	[W]	[ ][ ]	[ ][ ]	[ ][ ][ ][ ][ ][ ][ ][ ]	[T]
1. Identification Number	2. Alphacode	3a.Visit Type	3b. Visit Number (Month)	(Week)	4. Date of Visit: mm/dd/yyyy	5s. Study

5. b. Date barcodes scanned (mm/dd/yyyy) ....__ __/__ __/__ __ __ __
(Date must match the date barcodes scanned on Form 316A)

6. Visit Number intended .... W ___ ___

7. a. Date stool collected (mm/dd/yyyy) ....__ __/__ __/__ __ __ __

b. Time stool collected (24-hour clock) (hh:mm) ....___ ___ : ___ ___

c. Time stool received (24-hour clock) (hh:mm) .... ___ ___ : ___ ___

d. Blood status ....___
(0=Participant reported no blood in the stool; 1=Participant reported blood in the stool;
9=Unknown; no blood status report data captured)

e. Diarrhea status ....___
(0=Participant reported no diarrhea; 1=Participant reported diarrhea;
9=Unknown; no diarrhea status report data captured)

f. Was sample handled/processed per protocol (0=no, 1=yes)...___

g. If item 7f is 0=no, please comment below:

8. Stool Kit # for stored stool

Affix Label

9. Specimen information:
Ten tubes of stool should be aliquoted and stored.
During data entry, scan the bar code for each cryovial label provided into the appropriate field whether that cryovial was collected and stored or the cryovial is empty. There will be no missing barcodes below. Indicate the status of the aliquot, if the vial was packed on ice and if the lid was tight. Once you have key entered this form, print a copy for the participant's study records so you have a record of the bar code associated with each cryovial.

Line #	Specimen Bar Code	Spec. Type S=Short L=Long	Aliquot #	Condition of Specimen when received by site		
				Status of aliquot: 0=Vial is missing 1=Vial is empty 2=Specimen in vial	Was the vial packed in ice? (0=no, 1=yes)	Was the lid on tight? (0=no, 1=yes)
9.01	Scan Aliquot Label Here	S	1			
9.02	Scan Aliquot Label Here	S	2			
9.03	Scan Aliquot Label Here	S	3			
9.04	Scan Aliquot Label Here	S	4			
9.05	Scan Aliquot Label Here	S	5			
9.06	Scan Aliquot Label Here	L	1			
9.07	Scan Aliquot Label Here	L	2			
9.08	Scan Aliquot Label Here	L	3			
9.09	Scan Aliquot Label Here	L	4			
9.10	Scan Aliquot Label Here	L	5			

10. Date samples frozen locally at -80ºC (mm/dd/yyyy) ..... __ __/__ __/__ __ __ __

11. Time samples frozen (24-hour clock) (hh:mm) ..... ___ ___ : ___ ___

12. Freezer and shelf where samples are stored locally (up to 50 char text)

200. Date form completed (mm/dd/yyyy)..... __ __/__ __/__ __ __ __

201. Username of person completing/reviewing completeness of this form .....__ __ __ __ __ __ __

Clinical Center Use Only
Date Form Entered (mm/dd/yyyy) __ __/__ __/__ __ __ __
Username of person entering this form __ __ __ __ __ __ __

Pilot Clinical Trials in CKD
Shipment of Specimens to U of Penn
Mailing Form #320 – TarGut Microbiome

Once each month, the staff at each TarGut Clinical Center will retrieve all samples (serum, plasma, spot urine, 24-hr urine and/or stool) from the local -80ºC freezer to ship samples to the University of Pennsylvania TCL. Specimens should be shipped on dry ice on Monday, Tuesday or Wednesday only. Make sure every specimen listed on the form is included. Include a copy of this form in the box. Do not send originals.

1. Clinical Center Number (11=GWU, 41=Univ of Utah)..... ___ ___

2. Date samples shipped to U of Penn (mm/dd/yyyy).....__ __/__ __/__ __ __ __
Note: If you plan to ship the box tomorrow, wait until tomorrow to key enter this form (i.e., enter the date you shipped the box, not the date you intend to ship the box.)

For shipment of serum, plasma spot urine, 24-hr urine and stool:

	PID	AC	Kit #
3.1			Key Enter Kit #
3.2			Key Enter Kit #
3.3			Key Enter Kit #
3.4			Key Enter Kit #
3.5			Key Enter Kit #
3.6			Key Enter Kit #
3.7			Key Enter Kit #
3.8			Key Enter Kit #
3.9			Key Enter Kit #
3.10			Key Enter Kit #
3.11			Key Enter Kit #
3.12			Key Enter Kit #
3.13			Key Enter Kit #
3.14			Key Enter Kit #
3.15			Key Enter Kit #
3.16			Key Enter Kit #
3.17			Key Enter Kit #
3.18			Key Enter Kit #
3.19			Key Enter Kit #
3.20			Key Enter Kit #
3.21			Key Enter Kit #
3.22			Key Enter Kit #
3.23			Key Enter Kit #

	PID	AC	Kit #
3.24			Key Enter Kit #
3.25			Key Enter Kit #
3.26			Key Enter Kit #
3.27			Key Enter Kit #
3.28			Key Enter Kit #
3.29			Key Enter Kit #
3.30			Key Enter Kit #
3.31			Key Enter Kit #
3.32			Key Enter Kit #
3.33			Key Enter Kit #
3.34			Key Enter Kit #
3.35			Key Enter Kit #
3.36			Key Enter Kit #
3.37			Key Enter Kit #
3.38			Key Enter Kit #
3.39			Key Enter Kit #
3.40			Key Enter Kit #
3.41			Key Enter Kit #
3.42			Key Enter Kit #
3.43			Key Enter Kit #
3.44			Key Enter Kit #
3.45			Key Enter Kit #

Items below are for individual center use only and will <u>not</u> be entered into the CKD database:

Shipment tracking # _____

Shipper's name _____

200. Date this form completed (mm/dd/yyyy) ..... __ __ /__ __ /__ __ __ __

201. Username of person completing/reviewing completeness of this form ..... __ __ __ __ __ __ __

Clinical Center Use Only

Date Form Entered (mm/dd/yyyy) __ __/__ __/__ __ __ __

Username of person entering this form__ __ __ __ __ __ __

Pilot Clinical Trials in CKD
U of Penn Lab Receipt of Specimens Form #321 – TarGut Microbiome

This form is completed when the U of Penn receives specimens of frozen serum, plasma, spot urine, stool, and/or 24-hr urine from a TarGut Microbiome site.

1. Clinical Center `Number` (11=GWU, 41=Univ of Utah) ..... ___ ___
2. Date specimens shipped from mailing Form 320 (mm/dd/yyyy) .....__ __/__ __/__ __ __ __
3. Date shipment received at U of Penn (mm/dd/yyyy).....__ __/__ __/__ __ __ __
4. Were the samples received at U of Penn frozen (0=no, 1=yes)..... ___

<u>For shipment of serum, plasma and spot urine:</u> status 0=not usable, 1=usable

	PID	AC	Kit #	Type of Specimen			
				Serum (0=no, 1=yes)	**Plasma** (0=no, 1=yes)	**Spot Urine** (0=no, 1=yes)	**24-Hr Urine** (0=no, 1=yes)
5.1			Scan Kit # label here				
5.2			Scan Kit # label here				
5.3			Scan Kit # label here				
5.4			Scan Kit # label here				
5.5			Scan Kit # label here				
5.6			Scan Kit # label here				
5.7			Scan Kit # label here				
5.8			Scan Kit # label here				
5.9			Scan Kit # label here				
5.11			Scan Kit # label here				
5.12			Scan Kit # label here				
5.13			Scan Kit # label here				
5.14			Scan Kit # label here				
5.15			Scan Kit # label here				
5.16			Scan Kit # label here				
5.17			Scan Kit # label here				
5.18			Scan Kit # label here				
5.19			Scan Kit # label here				
5.20			Scan Kit # label here				

200. Date this form completed (mm/dd/yyyy) ..... __ __ /__ __ /__ __ __ __

201. Username of person completing/reviewing completeness of this form ..... __ __ __ __ __ __ __

Clinical Center Use Only

Date Form Entered (mm/dd/yyyy) __ __/__ __/__ __ __ __

Username of person entering this form__ __ __ __ __ __ __

Pilot Clinical Trials in CKD

24-Hr Urine Collected and Stored Locally Form #328A – TarGut Microbiome

24-hour urine specimens will be collected at weeks 8, 20, and 28. This form is completed only when the barcodes are scanned.

															T	

1. Identification Number 2. Alphacode 4. Date barcodes scanned (mm/dd/yyyy) 5. Study

14. Aliquot Bar Codes and Volumes

Scan the bar code for each cryovial label provided into the appropriate field. Once you have key entered this form, print a copy for the participant's study records so you have a record of the bar code associated with each cryovial.

Line #	Specimen Bar Code	Spec. Type (Vial Size)	Aliquot #
14.1	Scan Aliquot Label Here	24	1
14.2	Scan Aliquot Label Here	24	2
14.3	Scan Aliquot Label Here	24	3
14.4	Scan Aliquot Label Here	24	4

200. Date this form reviewed for completeness (mm/dd/yyyy)..... ___ ___/___ ___/___ ___ ___ ___

201. Username of person completing/reviewing completeness of this form..... __ __ __ __ __ __ __

Clinical Center Use Only
Date Form Entered (mm/dd/yyyy) __ __/__ __/__ __ __ __
Username of person entering this form__ __ __ __ __ __ __

Pilot Clinical Trials in CKD

24-Hr Urine Collected and Stored Locally Form #328B – TarGut Microbiome

24 hour urine specimens will be collected at weeks 8, 20, and 28. All attempted 24-hour urine collections should be stored. If the participant does not bring in their urine and the visit window has not yet ended, do not complete this form. Complete the form when either the participant brings in urine or the visit window has ended and urine was not collected.

1. Identification Number	2. Alphacode	3a. Visit Type	3b. Visit Number (Month)	(Week)	4. Start Date of Urine Collection (mm/dd/yyyy)	5a. Study
						T

5. b. Date barcodes scanned (mm/dd/yyyy) ..... __ __/__ __/__ __ __ __
(Date must match the date barcodes scanned on Form 328A)

6. Visit Number Intended ..... _W_ ___ ___

7. Status of reminder call ..... ___
0=No call done; 1=Done by coordinator; 2=Done automatically

8. Did the participant return with urine in the study urine container? (0=no, 1=yes)..... ___
If no (visit window has ended and urine was not completed), skip to item 200.

9. Participant report on completeness of the collection..... ___
1=Complete, 2=Missed or spilled some, 3=Collected too much (e.g., didn't discard first urine), 9=Unknown
Submit urine regardless of completeness.

10. Start time of urine collection (24-hour clock) (hh:mm)..... __ __: __ __

11. a. End date of urine collection (mm/dd/yyyy) ..... __ __/__ __ /__ __ __ __

b. End time of urine collection (24-hour clock) (hh:mm)..... __ __: __ __

Database calculates number of hours…….....__ __.__ __

c. Date urine collection received (mm/dd/yyyy) ..... __ __/__ __ /__ __ __ __

d. Time urine collection received (24-hour clock) (hh:mm)..... __ __: __ __

12. a. Measured volume of the first 24-hour urine collection jug (ml) per volumetric flask ..... __ __ __ __
Item 12.b. is used for a second jug in the rare instance where a participant collects more than 4L and needs a second jug.
b. Measured volume of the second 24-hour urine collection jug (ml) per volumetric flask. __ __ __ __

13. 24-hour urine Kit # for stored 24-hour urine

Affix Label

14. Aliquot Bar Codes and Volumes
Four tubes of urine should be aliquoted and stored locally.

During data entry, scan the bar code for each cryovial label provided into the appropriate field whether that cryovial was stored or not. Indicate whether the aliquot was stored and if so, its volume. Once you have key entered this form, print a copy for the participant's study records so you have a record of the bar code associated with each cryovial.

Line #	Specimen Bar Code	Spec. Type (Vial Size)	Aliquot #	Aliquot stored? (0=no, 1=yes)	Volume of this aliquot *(ml)*
14.1	Scan Aliquot Label Here	24	1		
14.2	Scan Aliquot Label Here	24	2		
14.3	Scan Aliquot Label Here	24	3		
14.4	Scan Aliquot Label Here	24	4		

15. Date samples frozen locally at -80ºC (mm/dd/yyyy) .....__ __/__ __/__ __ __ __

16. Time samples frozen (24-hour clock) (hh:mm).....__ __:__ __

17. Freezer and shelf where samples are stored locally (up to 50 char text)

200. Date this form reviewed for completeness (mm/dd/yyyy)..... ___ ___/___ ___/___ ___ ___ ___

201. Username of person completing/reviewing completeness of this form.....__ __ __ __ __ __ __

Clinical Center Use Only
Date Form Entered (mm/dd/yyyy) __ __/__ __/__ __ __ __
Username of person entering this form__ __ __ __ __ __ __

Revision of 09/19/2016

Pilot Clinical Trials in CKD
Local Lab CBC Results Form #340 – TarGut Microbiome

This form is completed routinely at Screening (S) Visit 0, and Follow-Up Visit at Weeks (W) 8, 16, 20, 28 and whenever a value needs to be rechecked. At the Screening visit, hemoglobin must have been measured within the last three months in order to determine eligibility. All blood samples will be obtained by an experienced phlebotomist keeping in mind to preserve veins for future vascular access. Before each blood draw, study staff will review the most recent hemoglobin lab results in the medical record. If this result is less than 9.0 g/dl, blood will not be collected until the hemoglobin value is 9.0 g/dl or greater. The results recorded on this form must all match the date in item 4. If some results are from a different date, complete an additional Form 340 for results from that date.

1. Identification Number	2. Alphacode	3a. Visit Type	3b. Visit Number (Month)	(Week)	4. Date blood drawn (mm/dd/yyyy)	5. Study
						T

6. Visit Number Intended.. ___ ___ ___
   Any visit in the three months prior to the Screening visit may be used as the Screening (S) visit 0 value.
   Follow-up measures are done at Week (W) visits 8, 16, 20 and 28.
   Code a visit number of 99 for any extra blood draws.

7. a. Location of measures (1=same city as site; 2=another city) .... ___
   b. If 7a=2 (another city), date blood shipped (mm/dd/yyyy) .... __ __/__ __/__ __ __ __

8. Date blood analyzed (mm/dd/yyyy) .... __ __/__ __/__ __ __ __

Protocol CBC Results

9. WBC (1000/mcL) .... ___ ___ . ___ ___
10. RBC (1000/mcL).. ___ ___ . ___ ___
11. Hemoglobin (g/dL) .... ___ ___ . ___
    (Note, for eligibility, value must be ≥ 9 g/dl)
12. Hematocrit (%) .... ___ ___ . ___
13. Platelet count (1000/mcL)... ___ ___ ___

WBC Differential

14. Neutrophils (%)... ___ ___ ___
15. Lymphocytes (%)... ___ ___ ___
16. Monocytes (%).. ___ ___ ___
17. Basophils (%).. ___ ___ ___
18. Eosinophils (%)... ___ ___ ___

200. Date form completed (mm/dd/yyyy).. __ __/__ __/__ __ __ __
201. Username of person completing/reviewing completeness of this form .... __ __ __ __ __ __ __

Clinical Center Use Only
Date Form Entered (mm/dd/yyyy) __ __/__ __/__ __ __ __
Username of person entering this form__ __ __ __ __ __ __

Pilot Clinical Trials in CKD
Local Lab Serum (Adverse Events) Results
Form #341 – TarGut Microbiome

Local serum measures are not part of TarGut.
This form is done when the clinical center wants to report serum values measured from outside the TarGut Microbiome protocol that are considered an Adverse Event or result in an inulin dose reduction.

1. Identification Number	2. Alphacode	3a.Visit Type	3b. Visit Number (Month)	3b. Visit Number (Week)	4. Date Serum drawn (mm/dd/yyyy)	5. Study
						T

6. Phosphorus (mg/dL) ..... ___ ___.___
   Considered an AE when phosphorous > 7.0 mg/dL

7. Calcium (mg/dL) ..... ___ ___.___
   Considered an AE if Hypocalcemia (serum calcium < 7.0 mg/dL) or
   Hypercalcemia (serum calcium > 11.0 mg/dL)

8. PTH (pg/mL) ..... ___ ___ ___.___
   Considered an AE when PTH > 700 pg/mL

200. Date form completed (mm/dd/yyyy)..... __ __/__ __/__ __ __ __

201. Username of person completing/reviewing completeness of this form ..... __ __ __ __ __ __ __

Clinical Center Use Only
Date Form Entered (mm/dd/yyyy) __ __/__ __/__ __ __ __
Username of person entering this form__ __ __ __ __ __ __

Pilot Clinical Trials in CKD
Study Closeout Form # 477 – TarGut Microbiome

This form is completed when the Site PI determines that all data have been collected and entered at the end of the TarGut Microbiome trial for this participant. A participant may consent for another Pilot Clinical Trial in CKD one month after the date listed in item 4.

1. Identification Number	2. Alphacode	3a. Visit Type	3b. Visit Number (Month)	(Week)	4. Date PI determined no more data will be coming for this pt (mm/dd/yyyy)	5. Study
						T

6. Does the participant have any remaining TarGut study medication? ..... ___
   0=No (All packets have been taken or turned in)
   1=Yes

7. Did the participant indicate that he or she would like to keep taking inulin? (0=no, 1=yes)..... ___

8. In the opinion of the Site PI, have all possible TarGut study data been collected and entered in the database for this participant? (0=no, 1=yes) ..... ___

200. Date this form completed (mm/dd/yyyy)..... __ __ / __ __ / __ __ __ __

201. Username of person completing/reviewing completeness of this form..... __ __ __ __ __ __ __

Clinical Center Use Only

Date Form Entered (mm/dd/yyyy) __ __/__ __/__ __ __ __

Username of person entering this form __ __ __ __ __ __ __

Pilot Clinical Trials in CKD
Hospitalization Notification Form #511 – ALL STUDIES

Form 511 must be completed for all hospitalizations. This form should be completed as soon as the Clinical Center becomes aware that a participant has been hospitalized. Form 512 (Hospitalization Details Form) should be completed and entered as soon as details are available.

1. Identification Number	2. Alphacode	3a. Visit Type	3b. Visit Number (Month)	3b. Visit Number (Week)	4. Date of Hospitalization (mm/dd/yyyy)	5. Study

6. Did this patient's hospitalization begin by way of the ER? (0=no, 1=yes, 9=unknown)..... ___

7. Is the patient still in the hospital? ..... ___
   0=No-alive, no longer in hospital (enter discharge date on Form 512)
   1=No-died (enter Forms 531 and 532)
   2=Yes-still in hospital
   9=Unknown

Remember to complete a Form 512, Hospitalization Details Form, within two weeks after the patient is discharged.

In the space below, write what you currently know about this SAE. *Do not data enter.*

200. Date this form completed (mm/dd/yyyy) ..... ___ ___ /___ ___ /___ ___ ___ ___

201. Username of person completing/reviewing completeness of this form..... __ __ __ __ __ __ __

Clinical Center Use Only

Date Form Entered (mm/dd/yyyy) __ __/__ __/__ __ __ __

Username of person entering this form__ __ __ __ __ __ __

Pilot Clinical Trials in CKD
Hospitalization Details Form #512 – ALL STUDIES

Enter a Hospitalization Notification Form 511 as soon as you learn that a participant has been hospitalized. *(If there is a death, enter a Death Notification Form (Form 531) to notify the DCC that the participant died and complete the Detailed Death Form (Form 532) as soon as possible.)* This Hospitalization Details Form 512 should be entered as soon as possible after a hospitalization discharge. Try to complete this form within 30 days of the SAE.

After each hospitalization, the study coordinator should assemble photocopies of the discharge summary and other pertinent documents (or an event narrative if the Site Physician and Executive Committee confirm that the discharge summary cannot be obtained.) If SAE will be reviewed by the Event Committee, these documents will be de-identified and scanned for Event Committee Review.

1. Identification Number	2. Alphacode	3a.Visit Type	3b. Visit Number (Month)	3b. Visit Number (Week)	4. Date of Hospital Admission (mm/dd/yyyy)	5. Study

SAE Categorization:

6. a. What type of SAE was this? ..... ___ ___
   1=Hospitalization ending with discharge to home
   2=Hospitalization ending with discharge to rehab, nursing home or other facility
   3=Hospitalization, participant still hospitalized (use if participant hospitalized > 30 days)
   4=Hospitalization ending in death (Complete Forms 531 and 532)

   b. If item a=1 or 2, date of discharge (mm/dd/yyyy)..... __ __ /__ __ /__ __ __ __

7. What information does the study team have? (Code 0=no, 1=yes)

   a. Discharge summary (preferred)..... ___
   If the hospitalization occurred at a hospital where the site PI has privileges, a discharge summary is required.

   b. No discharge summary / spoke to caregivers in the hospital..... ___

   c. No discharge summary / spoke to participant's primary care doctor or nephrologist..... ___

   d. No discharge summary / spoke to participant, family member, or friend ..... ___
   If the hospitalization occurred at a hospital where the site PI has privileges, a discharge summary is required.

8. a. Primary diagnosis for this SAE event (use code list attached)..... ___ ___ ___ ___ ___

   Document the primary diagnosis that, in the site physician's judgment, is felt to be the cause of the event. If there was a kidney transplant, be sure to include procedure code15AQ0. The primary diagnosis *code here does not have to agree with the diagnoses noted on the discharge summary. A terminal code of 0 indicates a procedure, not a primary reason code.*

   b. Secondary diagnosis/procedure for this SAE event..... ___ ___ ___ ___ ___

   Additional diagnoses/procedures (if available/needed):

   c. Additional diagnosis/procedure #1 (use code list attached) ..... ___ ___ ___ ___ ___

   d. Additional diagnosis/procedure #2 (use code list attached)..... ___ ___ ___ ___ ___

   e. Additional diagnosis/procedure #3 (use code list attached)..... ___ ___ ___ ___ ___

   f. Additional diagnosis/procedure #4 (use code list attached)..... ___ ___ ___ ___ ___

   Note: If more than 4 additional diagnoses/procedures, have site physician review and identify the most important ones.

9. Does the Site PI consider this to be a cardiovascular hospitalization? (0=no, 1=yes) ..... ___

Other Signs and Symptoms:

10. If there are any signs or symptoms surrounding this SAE that you would like to report, please enter the information below. (Do not repeat information from the Primary and Secondary diagnoses section.) Do not repeat any information already noted in Q8.

Sign or Symptom	MedDRA Code

Both studies: **BASE and COMBINE**

11. In the judgment of the Site PI, was the event caused by any procedure (such as blood draw or MRI or baseline placebo) that was specifically done as part of the clinical trial protocol?..... ___
(0=no, 1=unlikely, 2=possibly, 3=probably, 4=definitely)

Causation judgment: **COMBINE** Only

12. a. In the judgment of the Site PI, was the event caused by the participant's randomly assigned Nicotinamide treatment regimen?..... ___
(0=no, 1=unlikely, 2=possibly, 3=probably, 4=definitely, 8=N/A, participant in Baseline)

b. In the judgment of the Site PI, was the event caused by the participant's randomly assigned Lanthanum Carbonate treatment regimen?..... ___
(0=no, 1=unlikely, 2=possibly, 3=probably, 4=definitely, 8=N/A, participant in Baseline)

Study medication questions: **COMBINE** only

13. a. Does the site physician feel that this SAE necessitates that this participant discontinue the COMBINE Nicotinamide arm? (0=no, 1=yes, 8=N/A, participant in Baseline)..... ___

b. Does the site physician feel that this SAE necessitates that this participant discontinue the COMBINE Lanthanum Carbonate arm? (0=no, 1=yes, 8=N/A, participant in Baseline). ..... ___

Causation judgment: **BASE** Only

14. In the judgment of the Site PI, was the event caused by the participant's randomly assigned Sodium Bicarbonate treatment regimen?..... ___
(0=no, 1=unlikely, 2=possibly, 3=probably, 4=definitely, 8=N/A, participant in Baseline)

Study medication question: **BASE** only

15. Does the site physician feel that this SAE necessitates this participant discontinue randomized BASE study medication? (0=no, 1=yes, 8=N/A, participant in Baseline)..... ___

Potential Classification as an "Unanticipated Problem" *as defined by HHS"*

16. a. In the judgment of the Site PI, was this event expected in this research? ..... ___
0=no, not expected
1=yes, expected because of the characteristics of the study's subject population
2=yes, expected and described in protocol-related documents, such as the IRB-approved research protocol and informed consent document
3=yes, both 1 and 2

b. In the judgment of the Site PI, does this event suggest that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized? (0=no, 1=yes) ..... ___

If this event was
- judged by the site physician to be possibly, probably or definitely related in either Q11, 12, 13, 14 or 15
- not expected in Q16a, and
- places study subjects or others at greater risk of harm than previously known or recognized as noted in Q16b,

the event will be considered an "Unanticipated Problem" *as defined by HHS"*
and reported to NIH and all site physicians when this form is entered into the database.

17. Summary **(required)**: Describe what happened, what actions were taken, and what outcome occurred. Use as much space as necessary. **At least three sentences are expected**.

18. Comments on relatedness (**required** if event is considered possibly, probably, or definitely related to any study procedure or treatment.

200. Date this form completed (mm/dd/yyyy) ..... ___ ___ /___ ___ /___ ___ ___ ___

201. Username of person completing/reviewing completeness of this form ..... __ __ __ __ __ __ __

Clinical Center Use Only

Date Form Entered (mm/dd/yyyy) __ __/__ __/__ __ __ __

Username of person entering this form__ __ __ __ __ __ __

Code List of Diagnoses and Procedures (For Form 512, Q8 a-f)

Coding Instructions: When parentheses (_) are next to the code, you need to add one of the following: 1 = New, 2 = Worsening, 3 = Not a new condition
Note: A terminal code of 0 indicates a procedure and cannot be used as a primary reason code in Q8a.

1. ISCHEMIC HEART DISEASE (IHD)

Also see category: coronary heart disease (CHD) or coronary artery disease (CAD)

01AA(_) Chest pain of non-cardiac or unclear etiology (R/O MI admission)
01AB(_) CAD
01AC(_) Angina
01AD0 Bypass surgery (CABG)
01AE0 Coronary angiographies
01AF0 Percutaneous coronary intervention (PCI) (e.g., angioplasty + stent)
01AG Myocardial infarction (acute) (MI)
01AH Cardiac arrest

2. CONGESTIVE HEART FAILURE (CHF)

02AA(_) CHF (NOS)
02AB(_) CHF due to volume overload
02AC(_) Pulmonary edema (cardiogenic)
02AD(_) Pleural effusion(s)
02AE0 Thoracentesis (diagnostic or therapeutic)
02AF Cardiogenic shock

3. ARRHYTHMIAS AND CONDUCTION PROBLEMS

03AA(_) Syncope (also presyncope and syncopal episode)
03AB(_) Atrial fibrillation
03AC(_) Ventricular tachycardia
03AD(_) Supraventricular tachycardia
03AE(_) Sick sinus (tachy-brady) syndrome
03AF(_) Atrioventricular conduction block
03AG(_) Arrhythmias and conduction problems with hyperkalemia
03AH(_) Other new or other arrhythmia and conduction problem
03AI0 Cardioversion
03AJ0 Electrophysiologic studies (EPS)
03AK0 Pacemaker placement
03AL0 Pacemaker malfunction/repair
03AM0 Implantable cardioverter-defibrillator (ICD)

4. OTHER HEART DISEASES AND CONDITIONS (OHD)

04AA(_) Pericarditis
04AB(_) Endocarditis
04AC(_) Myocarditis
04AD(_) Cardiomyopathy (without IHD or CHF)
04AE(_) Pericardial effusion
04AF(_) Aortic valve stenosis or insufficiency
04AG(_) Mitral valve stenosis, regurgitation, or prolapse

04AH(_) Other valve defect
04AI(_) Other heart condition
04AJ(_) Cardiac tamponade
04AK0 Pericardiocentesis
04AL0 Aortic valve replacement
04AM0 Mitral valve replacement
04AN0 Balloon valvuloplasty
04AP0 Pericardial Window

5. HYPERTENSION (HTN) / HYPOTENSION

05AA(_) Hypertensive crisis or accelerated HTN
05AB(_) Hypotensive crisis or accelerated hypotension

6. CEREBRAL VASCULAR DISEASE (CVD)

06AA(_) Transient ischemic attack (TIA)
06AB(_) Cerebral vascular accident (CVA)
06AC(_) Carotid artery stenosis
06AD(_) Cerebral artery aneurysm
06AE(_) Subarachnoid or cerebral hemorrhage
06AF(_) Other CVD condition
06AG0 Carotid endarterectomy (CEA)
06AH0 Carotid angiogram

7. VASCULAR DISEASES

07AA(_) Deep vein thrombosis (DVT)
07AB(_) Pulmonary embolism
07AC(_) Peripheral vascular disease
07AD(_) Ischemic foot ulcers
07AE(_) Gangrene of toes or foot
07AF(_) Abdominal aortic aneurysm (AAA)
07AG(_) Thoracic aortic aneurysm (TAA)
07AH(_) Hemorrhage from ruptured vascular aneurysm
07AI(_) Aortic aneurysm (not specified)
07AJ(_) Other aneurysm (non-cerebral)
07AK(_) Mesenteric ischemia or infarction (ischemic bowel)
07AL(_) Cellulitis (non-access related) includes diabetic foot infection
07AM(_) Gangrene with septicemia-shock due to PVD
07AN(_) Other condition due to PVD or other disorder of arteries
07AO(_) Polyarteritis nodosa and other arteritides
07AP Arterial embolism
07AQ0 Abdominal aortic aneurysm (AAA) repair
07AR0 Thoracic aortic aneurysm (TAA) repair
07AS0 Angioplasty for PVD
07AT0 Bypass graft for PVD
07AW0 Amputation site: toe(s)$^{+}$
07AX0 Amputation site: transmetatarsal^{+}
07BA0 Left below the knee amputation^{+}
07BB0 Right below the knee amputation^{+}
07BC0 Left above the knee amputation^{+}
07BD0 Right above the knee amputation^{+}

8. DIABETES MELLITUS (DM) AND ENDOCRINE DISORDERS

08AA(_) Diabetic foot infection
08AB(_) Gangrene of foot or toes (absence of PVD)
08AC(_) Hypothyroidism
08AD(_) Other disorders of thyroid gland
08AE Diabetes with ketoacidosis
08AF Diabetes with hyperosmolar state or coma
08AG Hypoglycemia with coma
08AH0 Pancreatic transplant
08AI(_) Other endocrine disorder
08AJ Onset of diabetes
08AK0 Parathyroidectomy
08AL(_) Hyperparathyroidism
08AM(_) Hypoparathyroidism
08AN(_) Other calcium-phosphorus disorder
08AO(_) Hyperglycemia
08AP(_) Diabetic foot ulcer
08AQ(_) Hypoglycemia without coma

9. RESPIRATORY DISEASES

09AA(_) Asthma
09AB(_) COPD
09AC(_) Bronchitis
09AD(_) Pneumothorax
09AE(_) Empyema
09AF(_) Lung abscess
09AG(_) Pulmonary TB *(note: Extrapulmonary TB is code 18AC)*
09AH(_) Respiratory failure not requiring intubation and mechanical ventilation
09AI(_) Respiratory failure requiring intubation and mechanical ventilation
09AJ(_) Adult Respiratory Distress Syndrome (ARDS)
09AK Respiratory failure of unknown cause
09AL(_) Other respiratory disease
09AM(_) Pulmonary hemorrhage
09AN(_) Pneumonia (nosocomial)
09AO(_) Pneumonia (community acquired)
09AP(_) Pneumonia-sepsis
09AQ(_) Pneumonia (bacterial)
09AR(_) Pneumonia (fungal)
09AS(_) Pneumonia (viral)
09AT(_) Pneumocystis pneumonia
09AU(_) Aspiration pneumonia
09AV(_) Pneumonia (unspecified pathogen)
09AW0 Open lung biopsy
09AX0 Lung lobectomy
09AY(_) Upper respiratory tract disorders (including dyspnea, shortness of breath)
09AZ0 ENT procedures
09BA Angioedema
09BB Acute epiglottitis

10. MALIGNANCY

10AA(_) Hematologic malignancy (AML, ALL, CLL)
10AB(_) Lymphoma (unspecified)
10AC(_) Hodgkin's lymphoma
10AD(_) Non-Hodgkin's lymphoma
10AE(_) Multiple myeloma
10AF(_) Colon cancer
10AG(_) Breast cancer
10AH(_) Prostatic cancer
10AI(_) Ovarian cancer
10AJ(_) Lung cancer
10AK(_) Gastric cancer
10AL(_) Pancreatic cancer
10AM(_) Thyroid cancer
10AN(_) Cervical cancer
10AO(_) Endometrial cancer
10AP(_) Primary cancer of liver
10AQ(_) Head and neck squamous cell carcinoma
10AR(_) Testicular cancer
10AS(_) Renal cancer
10AT(_) Bladder cancer
10AU(_) Melanoma
10AV(_) Other skin cancer
10AW(_) Other malignancy or neoplasia
10AX(_) Metastatic carcinoma unknown primary
10AY(_) Complication(s) of pre-admission diagnosed cancer
10BA0 Diagnosis: surgical biopsy
10BB0 Other biopsy procedure
10BC0 Other diagnostic procedure
10BD0 Treatment: radiation therapy
10BE0 chemotherapy
10BF0 surgical excision
10BG0 other treatment
10BH0 Mastectomy (subtotal or total)
10BI0 Hysterectomy

11. HEPATOBILIARY DISEASE

11AA(_) Hepatitis B
11AB(_) Hepatitis C
11AC(_) Toxic/drug-induced hepatitis
11AD(_) Hepatitis (other; unknown cause)
11AE(_) Cirrhosis
11AF(_) Ascites
11AG(_) Portal hypertension or esophageal varices
11AH(_) Variceal bleed
11AI(_) Hepatic failure/severe dysfunction
11AJ(_) Cholecystitis/cholangitis
11AK(_) Other hepatobiliary disease
11AL(_) Biliary sepsis
11AM0 Cholecystectomy

11AN0 Liver transplant
11AO0 Shunt procedure
11AP0 Paracentesis (diagnostic or therapeutic)
11AQ(_) Choledocholithiasis
11AR(_) Ischemic Hepatitis

12. MUSCULOSKELETAL AND CONNECTIVE TISSUE DISEASES

12AA(_) Gout
12AB(_) Wegener's granulomatosis
12AC(_) Systemic vasculitis
12AD(_) Systemic Lupus Erythematosus (SLE)
12AE(_) Avascular necrosis
12AF(_) Osteomyelitis
12AG(_) Septic arthritis
12AH(_) Back problems
12AI(_) Other musculoskeletal or connective tissue disease
12AJ(_) Bone fracture
12AK0 Carpal tunnel surgery
12AL0 Arthroscopy
12AM0 Hip replacement
12AN0 Knee replacement
12AO0 Knee procedures (other than replacement)
12AP0 Internal fixation or surgical reduction of bone fracture
12AQ0 Other orthopedic surgery
12AR0 Back and/or neck procedure
12AS(_) Musculoskeletal pain
12AT0 Orthopedic related rehabilitation
12AU(_) Cervical stenosis

13. GASTROINTESTINAL CONDITIONS (GI)

13AA(_) Upper GI bleed
13AB(_) Lower GI bleed
13AC(_) GI bleeding, site unknown
13AD(_) Peptic/duodenal ulcer disease
13AE(_) Gastritis
13AF(_) Reflux esophagitis (with or without hiatal hernia)
13AG(_) Diverticulitis
13AH(_) Colonic polyps
13AI(_) Ulcerative colitis (UC)
13AJ(_) Enteritis (Crohn's disease)
13AK(_) Septicemia due to peritonitis
13AL(_) Pancreatitis
13AM(_) Necrotizing enterocolitis
13AN(_) *C. difficile* associated enterocolitis
13AO(_) Peritonitis
13AP(_) Fungal peritonitis
13AQ(_) Appendicitis
13AR(_) Ischemic bowel
13AS(_) Intra-abdominal abscess
13AT(_) Abdominal pain, cause unknown

13AU(_) Malabsorption
13AV(_) Perforated viscus (peptic ulcer or bowel)
13AX(_) Gastroparesis
13BA0 Colectomy (partial or total)
13BB0 Gastrectomy
13BC0 Colostomy or ileostomy
13BD0 Gastrostomy/enterostomy
13BE0 Appendectomy
13BF0 Laparotomy
13BG0 Other GI procedure
13BH(_) Other GI Condition

14. NONVASCULAR NERVOUS SYSTEM DISEASES

14AA(_) Mental status change (acute)
14AB(_) Seizure disorder
14AC(_) Disequilibrium - syndrome
14AD(_) Coma-stupor (traumatic cause)
14AE(_) Coma-stupor (toxic-drug induced)
14AF(_) Coma-stupor (metabolic cause, non-diabetic)
14AG(_) Coma-stupor (anoxic encephalopathy)
14AH(_) Coma-stupor (other unknown cause)
14AI(_) Alcohol non-accidental
14AJ(_) Drug overdose
14AK(_) Head trauma
14AL(_) Parkinson's disease
14AM(_) Multiple sclerosis
14AN(_) Subdural or epidural hematoma
14AO(_) Depression
14AP(_) Nervous system neoplasm
14AQ(_) Alcohol/drug abuse related (detoxification included)
14AR(_) Other psychiatric or mental disorder
14AS(_) Viral meningitis
14AT(_) Meningitis (non-viral)
14AU(_) Other CNS infection
14AV(_) Ataxia
14AW(_) Cranial or peripheral nerve disorder
14AX(_) Other nonvascular nervous system condition
14AY(_) Suicide attempt
14AZ(_) Neuropic pain in extremity
14BA(_) Anxiety attack
14BB(_) Headache: migraine
14BC(_) Suicidal ideation

15. URINARY TRACT CONDITIONS/RENAL CONDITIONS

15AA(_) Urinary tract infection requiring antibiotics
15AB(_) Nephrolithiasis
15AC(_) Benign prostatic hypertrophy (BPH)
15AD(_) Prostatitis
15AE(_) Orchitis
15AF(_) Cystic kidney disease (PKD or acquired)

15AG(_) Cyst-related hemorrhage
15AH(_) Cyst-related infection
15AI(_) Urinary tract hemorrhage
15AJ0 Nephrectomy unilateral
15AK0 Nephrectomy bilateral
15AL0 Prostatectomy (radical)
15AM0 Transurethral prostatectomy (TURP)
15AN0 Other transurethral procedures (cystoscopy included)
15AO0 Other urologic procedure
15AP(_) Hematuria
15AQ0 Kidney transplant
15AR(_) Acute transplant rejection
15AS(_) Uremia/Renal failure
15AT(_) Acute Kidney Injury (AKI) (Uremia/acute renal insufficiency)
15AU Evaluation for transplant
15AV(_) Urinary retention
15AW(_) Chronic transplant rejection
15AX(_) Chronic Kidney Disease (CKD)

16. HIV/AIDS

16AA(_) AIDS-related infection
16AB(_) Other AIDS-related condition (non-infection)
16AC(_) HIV positive

17. OPHTHALMOLOGIC CONDITIONS

17AA(_) Retinal or vitreous hemorrhage
17AB(_) Endophthalmitis
17AC(_) Other disorder of the eye
17AD0 Iris or lens procedure (cataract surgery included)
17AG0 Orbital procedure (vitrectomy included)
17AH0 Retina procedure (laser surgery included)
17AI0 Other ophthalmologic procedure

18. INFECTIONS

18AA(_) Abscess (lung, empyema, intra-abdominal, brain, soft tissue--not access-related)
18AB(_) Miliary TB
18AC(_) Extrapulmonary TB *(note: Pulmonary TB is code 09AG)*
18AD(_) Disseminated candidiasis
18AE(_) Other fungal infection
18AF(_) Viral infection (including CMV)
18AG(_) Other viral infection (not hepatitis)
18AH(_) Protozoan or parasitic infection (not PCP)
18AI(_) Other infection (not recorded in previous category)
18AJ(_) Septic shock
18AK(_) Bacteremia (known source, not access-related)
18AL(_) Bacteremia (unknown source, not access-related)
18AM(_) Bacteremia (known source, access-related)
18AN(_) Bacteremia (unknown source, access-related)
18AO(_) Fever of unknown origin

19. NON-MALIGNANT HEMATOLOGIC CONDITIONS

19AA(_) Coagulation disorders
19AB(_) Thrombocytopenia (secondary)
19AC(_) Thrombocytopenia (idiopathic)
19AD(_) Disseminated Intravascular Coagulation (DIC)
19AE(_) Other consumption coagulopathy
19AF(_) Thrombotic thrombocytopenic purpura (TTP) and hemolytic uremic syndrome (HUS)
19AG(_) Other, including peripheral hematoma
19AH(_) Anemia
19AI Monitor anticoagulation status for elective surgery (i.e., dental)
19AJ(_) Neutropenia, leukopenia
19AK(_) Other WBC-related condition, not otherwise specified

20. HEMODIALYSIS VASCULAR ACCESS COMPLICATIONS

20AA0 Elective surgical access repair
20AB(_) Soft tissue infection, cellulitis, abscess (access related)
20AC(_) Bacteremia or sepsis, access related
20AD(_) Clotted access
20AE(_) Venous thrombosis, access related
20AF(_) Arterial thrombosis or embolism, access related
20AG(_) Steal syndrome, limb ischemia, access related
20AH(_) Hemorrhage from vascular access
20AI(_) Nerve entrapment, access related
20AJ0 Fistulogram, arteriogram, or other invasive imaging procedure
20AK0 Access declotting procedure
20AL0 Angioplasty or stent placement for vascular access
20AM0 Non-elective surgical access repair
20AN0 Temporary access placement
20AO(_) Pneumothorax, hemothorax as result of temporary access placement
20AP(_) Subclavian vein stenosis as result of temporary access
20AQ0 New access creation (AV-fistula)
20AR0 New access placement (AV-graft)
20AS(_) Other access-related condition
20AT0 Other access-related procedure
20AU(_) New vascular access needed
20AV0 New perm-cath placement

21. OTHER HEMODIALYSIS COMPLICATIONS

21AA(_) Symptoms of uremia due to complications of hemodialysis
21AB(_) Hemorrhage from dialysis circuit
21AC(_) Air embolism
21AD(_) Anaphylaxis, treatment related
21AE(_) Hemolysis, treatment related
21AF(_) Electrolyte and acid-base disorder (other than hyperkalemia), treatment related
21AG(_) Dialysis-induced hypotension
21AH(_) Other accident related to treatment
21AI(_) Febrile reaction, not infection
21AJ0 Start of hemodialysis
21AK Withdrawal from dialysis

21AL Dialysis treatment completed at a location different than usual dialysis unit

22. OTHER SURGICAL PROCEDURES

22AA(_) Trauma
22AB(_) Major hemorrhage (not GI or pulmonary)
22AC(_) Hemorrhagic shock
22AD0 Skin graft/skin ulcer debridement
22AE0 Hernia procedure
22AF0 Other elective surgery procedure
22AG0 Removal of benign tumor
22AH0 Elective dental surgical procedure

23. OTHER

23AA(_) Other hemorrhage
23AB(_) Other trauma
23AC(_) Drug overdose (accidental)
23AD Accident unrelated to treatment
23AE Drug reaction (anaphylaxis)
23AF Drug reaction (not anaphylaxis, not overdose)
23AG Other electrolyte/acid-base disorder, not treatment related
23AH Cachexia
23AI Morbid Obesity
23AJ Gynecologic or obstetric condition
23AK Autoimmune condition affecting skin
23AL Fatigue

24. ELECTROLYTE DISORDERS (for Pilot Clinical Trials in CKD)

24AA(_) Hyponatremia
24AB(_) Hypernatremia
24AC(_) Hypokalemia
24AD(_) Hyperkalemia
24AE(_) Acidosis
24AF(_) Alkalosis
24AG(_) Hypophosphatemia
24AH(_) Hyperphosphatemia
24AI(_) Other electrolyte disorder

88. UNKNOWN

88AA Unknown reason for hospitalization

++++*If you have a condition not found on this listing, please contact the DCC (CKD_dcc@bio.ri.ccf.org) for a new code*+++++

Pilot Clinical Trials in CKD
Details of SAEs that are
Not Hospitalizations or Deaths Form #522 – ALL STUDIES

This form is only for the rare SAE that leads to neither a hospitalization nor a death. If the participant was hospitalized for this SAE, complete Forms 511 and 512 instead. If this SAE was a death, complete Forms 531 and 532 instead.

								Visit Type and Number are not entered									

1. Identification Number 2. Alphacode 3a.Visit Type 3b. Visit Number (Month) (Week) 4. Date of SAE (mm/dd/yyyy) 5. Study

6. Date Clinical Center learned of the SAE (mm/dd/yyyy)..... __ __ /__ __ /__ __ __ __

SAE Categorization:

7. What type of SAE was this? ..... ___ ___

6=Life threatening event (without hospitalization) *[Use this code if an event has occurred which did not include an ER visit but is so potentially dangerous that the event necessitates the patient's randomized treatment regimen must be stopped – for example, for two measures of serum phosphate under 1.4]*
7=Event resulting in a persistent or significant disability/ incapacity (without hospitalization)
8=Event resulting in a congenital anomaly/birth defect (without hospitalization)
9=Event exceeding severity risk greater than described in protocol (without hospitalization)
10=Abuse of, or dependency on study medications (without hospitalization)
18=Spontaneous abortion (without hospitalization)

Emergency Room Visits which are defined as SAEs for **BASE**
21=ER Visit for edema, heart failure, or pulmonary (without hospitalization)
22=ER Visit for hypertension (without hospitalization)
23=ER Visit for low serum potassium level (without hospitalization)
24=ER visit for high serum potassium level (without hospitalization)
25=ER Visit for high serum bicarbonate level (without hospitalization)
26=ER Visit for low serum bicarbonate level (without hospitalization)

Emergency Room Visits considered to be important for **COMBINE**
31=ER Visit for hypophosphatemia (without hospitalization)
32=ER visit for hyperphosphatemia (without hospitalization)
33=ER Visit for thrombocytopenia (without hospitalization)
34=ER Visit for blood transfusion (without hospitalization)
35=ER Visit for bruising or bleeding (without hospitalization)
36=ER Visit for diarrhea (without hospitalization)
37=ER Visit for other GI symptoms (without hospitalization)

51=Any other important medical event, including new cancer diagnosis, which may jeopardize the participant, or may require intervention to prevent permanent impairment or damage or other outcome listed above (without hospitalization)

8. What information does the study team have? (Code 0=no, 1=yes)

a. Medical records..... ___
b. Spoke to medical personnel familiar with this SAE, such as ER personnel..... ___
c. Spoke to participant's primary care doctor or nephrologist ..... ___
d. Spoke to participant or family member or friend ..... ___

9. a. Primary diagnosis for this SAE event (use code list attached) ..... ___ ___ ___ ___ ___
Document the primary diagnosis that, in the site physician's judgment, is felt to be the cause of the event. This does not have to agree with the diagnoses noted on the discharge summary. A terminal code of 0 indicates a procedure, not a primary reason code.

b. Secondary diagnosis/procedure for this SAE event..... ___ ___ ___ ___ ___

Additional diagnoses/procedures (if available/needed):

c. Additional diagnosis/procedure #1 (use code list attached) ..... ___ ___ ___ ___ ___

d. Additional diagnosis/procedure #2 (use code list attached)..... ___ ___ ___ ___ ___

e. Additional diagnosis/procedure #3 (use code list attached)..... ___ ___ ___ ___ ___

f. Additional diagnosis/procedure #4 (use code list attached)..... ___ ___ ___ ___ ___

Note: If more than 4 additional diagnoses/procedures, have site physician review and identify the most important ones.

Other Signs and Symptoms:

10. If there are any signs or symptoms surrounding this SAE that you would like to report, please enter the information below. (Type %<TERM>% substituting for <TERM> a word, phrase, or word fragment to limit the search in Column I below. Click on the ellipses (…) or press F9 to display the codes containing your specified term. You may scroll through the displayed codes to select the one you want. Highlight the appropriate diagnoses, sign or symptom and press **Enter**. This will populate Column II with the corresponding MedDRA Code. You may enter as many conditions and MedDRA Codes as needed.) Do not repeat any information already noted in Q9.

Sign or Symptom	MedDRA Code
a.	
b.	
c.	

Both studies: **BASE and COMBINE**

11. In the judgment of the Site PI, was the event caused by any procedure (such as blood draw or MRI or baseline placebo) that was specifically done as part of the clinical trial protocol?..... ___
(0=no, 1=unlikely, 2=possibly, 3=probably, 4=definitely)

Causation judgment: **COMBINE** Only

12. a. In the judgment of the Site PI, was the event caused by the participant's randomly assigned Nicotinamide treatment regimen?..... ___
(0=no, 1=unlikely, 2=possibly, 3=probably, 4=definitely, 8=N/A, participant in Baseline)

b. In the judgment of the Site PI, was the event caused by the participant's randomly assigned Lanthanum Carbonate treatment regimen?..... ___
(0=no, 1=unlikely, 2=possibly, 3=probably, 4=definitely, 8=N/A, participant in Baseline)

Study medication questions: **COMBINE** only

13. a. Does the site physician feel that this SAE necessitates that this participant discontinue the COMBINE Nicotinamide arm? (0=no, 1=yes, 8=N/A, participant in Baseline)..... ___

b. Does the site physician feel that this SAE necessitates that this participant discontinue the COMBINE Lanthanum Carbonate arm? (0=no, 1=yes, 8=N/A, participant in Baseline). ..... ___

Causation judgment: **BASE** Only

14. In the judgment of the Site PI, was the event caused by the participant's randomly assigned Sodium Bicarbonate treatment regimen?..... ___
(0=no, 1=unlikely, 2=possibly, 3=probably, 4=definitely, 8=N/A, participant in Baseline)

Study medication question: **BASE** only

15. Does the site physician feel that this SAE necessitates this participant discontinue randomized BASE study medication? (0=no, 1=yes, 8=N/A, participant in Baseline)..... ___

Potential Classification as an "Unanticipated Problem" *as defined by HHS"*

16. a. In the judgment of the Site PI, was this event expected in this research? ..... ___
0=no, not expected
1=yes, expected because of the characteristics of the study's subject population
2=yes, expected and described in protocol-related documents, such as the IRB-approved research protocol and informed consent document
3=yes, both 1 and 2

b. In the judgment of the Site PI, does this event suggest that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized? (0=no, 1=yes) ..... ___

If this event was 1) judged by the site physician to be possibly, probably or definitely related in either Q11, 12, 13, 14 or 15, 2) not expected in Q16a, and 3) places study subjects or others at greater risk of harm than previously known or recognized as noted in Q16b, the event will be considered an "Unanticipated Problem" *as defined by HHS"*and reported to NIH and all site physicians when this form is entered into the database.

17. Summary **(required)**: Describe what happened, what actions were taken, and what outcome occurred. Use as much space as necessary. **At least three sentences are expected**.

18. Comments on relatedness (**required** if event is considered possibly, probably, or definitely related to any study procedure or treatment.

200. Date this form completed (mm/dd/yyyy)..... ___ ___ /___ ___ /___ ___ ___ ___

201. Username of person completing/reviewing completeness of this form..... __ __ __ __ __ __ __ __

Clinical Center Use Only

Date Form Entered (mm/dd/yyyy) __ __/__ __/__ __ __ __

Username of person entering this form__ __ __ __ __ __ __ __

Code List of Diagnoses and Procedures (For Form 522, Q9 a-f)

Coding Instructions: When parentheses (_) are next to the code, you need to add one of the following: 1 = New, 2 = Worsening, 3 = Not a new condition
Note: A terminal code of 0 indicates a procedure and cannot be used as a primary reason code in Q9a.

1. ISCHEMIC HEART DISEASE (IHD)

Also see category: coronary heart disease (CHD) or coronary artery disease (CAD)

01AA(_) Chest pain of non-cardiac or unclear etiology (R/O MI admission)
01AB(_) CAD
01AC(_) Angina
01AD0 Bypass surgery (CABG)
01AE0 Coronary angiographies
01AF0 Percutaneous coronary intervention (PCI) (e.g., angioplasty + stent)
01AG Myocardial infarction (acute) (MI)
01AH Cardiac arrest

2. CONGESTIVE HEART FAILURE (CHF)

02AA(_) CHF (NOS)
02AB(_) CHF due to volume overload
02AC(_) Pulmonary edema (cardiogenic)
02AD(_) Pleural effusion(s)
02AE0 Thoracentesis (diagnostic or therapeutic)
02AF Cardiogenic shock

3. ARRHYTHMIAS AND CONDUCTION PROBLEMS

03AA(_) Syncope (also presyncope and syncopal episode)
03AB(_) Atrial fibrillation
03AC(_) Ventricular tachycardia
03AD(_) Supraventricular tachycardia
03AE(_) Sick sinus (tachy-brady) syndrome
03AF(_) Atrioventricular conduction block
03AG(_) Arrhythmias and conduction problems with hyperkalemia
03AH(_) Other new or other arrhythmia and conduction problem
03AI0 Cardioversion
03AJ0 Electrophysiologic studies (EPS)
03AK0 Pacemaker placement
03AL0 Pacemaker malfunction/repair
03AM0 Implantable cardioverter-defibrillator (ICD)

4. OTHER HEART DISEASES AND CONDITIONS (OHD)

04AA(_) Pericarditis
04AB(_) Endocarditis
04AC(_) Myocarditis
04AD(_) Cardiomyopathy (without IHD or CHF)
04AE(_) Pericardial effusion
04AF(_) Aortic valve stenosis or insufficiency
04AG(_) Mitral valve stenosis, regurgitation, or prolapse

04AH(_) Other valve defect
04AI(_) Other heart condition
04AJ(_) Cardiac tamponade
04AK0 Pericardiocentesis
04AL0 Aortic valve replacement
04AM0 Mitral valve replacement
04AN0 Balloon valvuloplasty
04AP0 Pericardial Window

5. HYPERTENSION (HTN) / HYPOTENSION

05AA(_) Hypertensive crisis or accelerated HTN
05AB(_) Hypotensive crisis or accelerated hypotension

6. CEREBRAL VASCULAR DISEASE (CVD)

06AA(_) Transient ischemic attack (TIA)
06AB(_) Cerebral vascular accident (CVA)
06AC(_) Carotid artery stenosis
06AD(_) Cerebral artery aneurysm
06AE(_) Subarachnoid or cerebral hemorrhage
06AF(_) Other CVD condition
06AG0 Carotid endarterectomy (CEA)
06AH0 Carotid angiogram

7. VASCULAR DISEASES

07AA(_) Deep vein thrombosis (DVT)
07AB(_) Pulmonary embolism
07AC(_) Peripheral vascular disease
07AD(_) Ischemic foot ulcers
07AE(_) Gangrene of toes or foot
07AF(_) Abdominal aortic aneurysm (AAA)
07AG(_) Thoracic aortic aneurysm (TAA)
07AH(_) Hemorrhage from ruptured vascular aneurysm
07AI(_) Aortic aneurysm (not specified)
07AJ(_) Other aneurysm (non-cerebral)
07AK(_) Mesenteric ischemia or infarction (ischemic bowel)
07AL(_) Cellulitis (non-access related) includes diabetic foot infection
07AM(_) Gangrene with septicemia-shock due to PVD
07AN(_) Other condition due to PVD or other disorder of arteries
07AO(_) Polyarteritis nodosa and other arteritides
07AP Arterial embolism
07AQ0 Abdominal aortic aneurysm (AAA) repair
07AR0 Thoracic aortic aneurysm (TAA) repair
07AS0 Angioplasty for PVD
07AT0 Bypass graft for PVD
07AW0 Amputation site: toe(s)$^{+}$
07AX0 Amputation site: transmetatarsal^{+}
07BA0 Left below the knee amputation^{+}
07BB0 Right below the knee amputation^{+}
07BC0 Left above the knee amputation^{+}
07BD0 Right above the knee amputation^{+}

8. DIABETES MELLITUS (DM) AND ENDOCRINE DISORDERS

08AA(_) Diabetic foot infection
08AB(_) Gangrene of foot or toes (absence of PVD)
08AC(_) Hypothyroidism
08AD(_) Other disorders of thyroid gland
08AE Diabetes with ketoacidosis
08AF Diabetes with hyperosmolar state or coma
08AG Hypoglycemia with coma
08AH0 Pancreatic transplant
08AI(_) Other endocrine disorder
08AJ Onset of diabetes
08AK0 Parathyroidectomy
08AL(_) Hyperparathyroidism
08AM(_) Hypoparathyroidism
08AN(_) Other calcium-phosphorus disorder
08AO(_) Hyperglycemia
08AP(_) Diabetic foot ulcer
08AQ(_) Hypoglycemia without coma

9. RESPIRATORY DISEASES

09AA(_) Asthma
09AB(_) COPD
09AC(_) Bronchitis
09AD(_) Pneumothorax
09AE(_) Empyema
09AF(_) Lung abscess
09AG(_) Pulmonary TB *(note: Extrapulmonary TB is code 18AC)*
09AH(_) Respiratory failure not requiring intubation and mechanical ventilation
09AI(_) Respiratory failure requiring intubation and mechanical ventilation
09AJ(_) Adult Respiratory Distress Syndrome (ARDS)
09AK Respiratory failure of unknown cause
09AL(_) Other respiratory disease
09AM(_) Pulmonary hemorrhage
09AN(_) Pneumonia (nosocomial)
09AO(_) Pneumonia (community acquired)
09AP(_) Pneumonia-sepsis
09AQ(_) Pneumonia (bacterial)
09AR(_) Pneumonia (fungal)
09AS(_) Pneumonia (viral)
09AT(_) Pneumocystis pneumonia
09AU(_) Aspiration pneumonia
09AV(_) Pneumonia (unspecified pathogen)
09AW0 Open lung biopsy
09AX0 Lung lobectomy
09AY(_) Upper respiratory tract disorders (including dyspnea, shortness of breath)
09AZ0 ENT procedures
09BA Angioedema
09BB Acute epiglottitis

10. MALIGNANCY

10AA(_) Hematologic malignancy (AML, ALL, CLL)
10AB(_) Lymphoma (unspecified)
10AC(_) Hodgkin's lymphoma
10AD(_) Non-Hodgkin's lymphoma
10AE(_) Multiple myeloma
10AF(_) Colon cancer
10AG(_) Breast cancer
10AH(_) Prostatic cancer
10AI(_) Ovarian cancer
10AJ(_) Lung cancer
10AK(_) Gastric cancer
10AL(_) Pancreatic cancer
10AM(_) Thyroid cancer
10AN(_) Cervical cancer
10AO(_) Endometrial cancer
10AP(_) Primary cancer of liver
10AQ(_) Head and neck squamous cell carcinoma
10AR(_) Testicular cancer
10AS(_) Renal cancer
10AT(_) Bladder cancer
10AU(_) Melanoma
10AV(_) Other skin cancer
10AW(_) Other malignancy or neoplasia
10AX(_) Metastatic carcinoma unknown primary
10AY(_) Complication(s) of pre-admission diagnosed cancer
10BA0 Diagnosis: surgical biopsy
10BB0 Other biopsy procedure
10BC0 Other diagnostic procedure
10BD0 Treatment: radiation therapy
10BE0 chemotherapy
10BF0 surgical excision
10BG0 other treatment
10BH0 Mastectomy (subtotal or total)
10BI0 Hysterectomy

11. HEPATOBILIARY DISEASE

11AA(_) Hepatitis B
11AB(_) Hepatitis C
11AC(_) Toxic/drug-induced hepatitis
11AD(_) Hepatitis (other; unknown cause)
11AE(_) Cirrhosis
11AF(_) Ascites
11AG(_) Portal hypertension or esophageal varices
11AH(_) Variceal bleed
11AI(_) Hepatic failure/severe dysfunction
11AJ(_) Cholecystitis/cholangitis
11AK(_) Other hepatobiliary disease
11AL(_) Biliary sepsis
11AM0 Cholecystectomy

11AN0 Liver transplant
11AO0 Shunt procedure
11AP0 Paracentesis (diagnostic or therapeutic)
11AQ(_) Choledocholithiasis
11AR(_) Ischemic Hepatitis

12. MUSCULOSKELETAL AND CONNECTIVE TISSUE DISEASES

12AA(_) Gout
12AB(_) Wegener's granulomatosis
12AC(_) Systemic vasculitis
12AD(_) Systemic Lupus Erythematosus (SLE)
12AE(_) Avascular necrosis
12AF(_) Osteomyelitis
12AG(_) Septic arthritis
12AH(_) Back problems
12AI(_) Other musculoskeletal or connective tissue disease
12AJ(_) Bone fracture
12AK0 Carpal tunnel surgery
12AL0 Arthroscopy
12AM0 Hip replacement
12AN0 Knee replacement
12AO0 Knee procedures (other than replacement)
12AP0 Internal fixation or surgical reduction of bone fracture
12AQ0 Other orthopedic surgery
12AR0 Back and/or neck procedure
12AS(_) Musculoskeletal pain
12AT0 Orthopedic related rehabilitation
12AU(_) Cervical stenosis

13. GASTROINTESTINAL CONDITIONS (GI)

13AA(_) Upper GI bleed
13AB(_) Lower GI bleed
13AC(_) GI bleeding, site unknown
13AD(_) Peptic/duodenal ulcer disease
13AE(_) Gastritis
13AF(_) Reflux esophagitis (with or without hiatal hernia)
13AG(_) Diverticulitis
13AH(_) Colonic polyps
13AI(_) Ulcerative colitis (UC)
13AJ(_) Enteritis (Crohn's disease)
13AK(_) Septicemia due to peritonitis
13AL(_) Pancreatitis
13AM(_) Necrotizing enterocolitis
13AN(_) *C. difficile* associated enterocolitis
13AO(_) Peritonitis
13AP(_) Fungal peritonitis
13AQ(_) Appendicitis
13AR(_) Ischemic bowel
13AS(_) Intra-abdominal abscess
13AT(_) Abdominal pain, cause unknown

13AU(_) Malabsorption
13AV(_) Perforated viscus (peptic ulcer or bowel)
13AX(_) Gastroparesis
13BA0 Colectomy (partial or total)
13BB0 Gastrectomy
13BC0 Colostomy or ileostomy
13BD0 Gastrostomy/enterostomy
13BE0 Appendectomy
13BF0 Laparotomy
13BG0 Other GI procedure
13BH(_) Other GI Condition

14. NONVASCULAR NERVOUS SYSTEM DISEASES

14AA(_) Mental status change (acute)
14AB(_) Seizure disorder
14AC(_) Disequilibrium - syndrome
14AD(_) Coma-stupor (traumatic cause)
14AE(_) Coma-stupor (toxic-drug induced)
14AF(_) Coma-stupor (metabolic cause, non-diabetic)
14AG(_) Coma-stupor (anoxic encephalopathy)
14AH(_) Coma-stupor (other unknown cause)
14AI(_) Alcohol non-accidental
14AJ(_) Drug overdose
14AK(_) Head trauma
14AL(_) Parkinson's disease
14AM(_) Multiple sclerosis
14AN(_) Subdural or epidural hematoma
14AO(_) Depression
14AP(_) Nervous system neoplasm
14AQ(_) Alcohol/drug abuse related (detoxification included)
14AR(_) Other psychiatric or mental disorder
14AS(_) Viral meningitis
14AT(_) Meningitis (non-viral)
14AU(_) Other CNS infection
14AV(_) Ataxia
14AW(_) Cranial or peripheral nerve disorder
14AX(_) Other nonvascular nervous system condition
14AY(_) Suicide attempt
14AZ(_) Neuropic pain in extremity
14BA(_) Anxiety attack
14BB(_) Headache: migraine
14BC(_) Suicidal ideation

15. URINARY TRACT CONDITIONS/RENAL CONDITIONS

15AA(_) Urinary tract infection requiring antibiotics
15AB(_) Nephrolithiasis
15AC(_) Benign prostatic hypertrophy (BPH)
15AD(_) Prostatitis
15AE(_) Orchitis
15AF(_) Cystic kidney disease (PKD or acquired)

15AG(_) Cyst-related hemorrhage
15AH(_) Cyst-related infection
15AI(_) Urinary tract hemorrhage
15AJ0 Nephrectomy unilateral
15AK0 Nephrectomy bilateral
15AL0 Prostatectomy (radical)
15AM0 Transurethral prostatectomy (TURP)
15AN0 Other transurethral procedures (cystoscopy included)
15AO0 Other urologic procedure
15AP(_) Hematuria
15AQ0 Kidney transplant
15AR(_) Acute transplant rejection
15AS(_) Uremia/Renal failure
15AT(_) Acute Kidney Injury (AKI) (Uremia/acute renal insufficiency)
15AU Evaluation for transplant
15AV(_) Urinary retention
15AW(_) Chronic transplant rejection
15AX(_) Chronic Kidney Disease (CKD)

16. HIV/AIDS

16AA(_) AIDS-related infection
16AB(_) Other AIDS-related condition (non-infection)
16AC(_) HIV positive

17. OPHTHALMOLOGIC CONDITIONS

17AA(_) Retinal or vitreous hemorrhage
17AB(_) Endophthalmitis
17AC(_) Other disorder of the eye
17AD0 Iris or lens procedure (cataract surgery included)
17AG0 Orbital procedure (vitrectomy included)
17AH0 Retina procedure (laser surgery included)
17AI0 Other ophthalmologic procedure

18. INFECTIONS

18AA(_) Abscess (lung, empyema, intra-abdominal, brain, soft tissue--not access-related)
18AB(_) Miliary TB
18AC(_) Extrapulmonary TB *(note: Pulmonary TB is code 09AG)*
18AD(_) Disseminated candidiasis
18AE(_) Other fungal infection
18AF(_) Viral infection (including CMV)
18AG(_) Other viral infection (not hepatitis)
18AH(_) Protozoan or parasitic infection (not PCP)
18AI(_) Other infection (not recorded in previous category)
18AJ(_) Septic shock
18AK(_) Bacteremia (known source, not access-related)
18AL(_) Bacteremia (unknown source, not access-related)
18AM(_) Bacteremia (known source, access-related)
18AN(_) Bacteremia (unknown source, access-related)
18AO(_) Fever of unknown origin

19. NON-MALIGNANT HEMATOLOGIC CONDITIONS

19AA(_) Coagulation disorders
19AB(_) Thrombocytopenia (secondary)
19AC(_) Thrombocytopenia (idiopathic)
19AD(_) Disseminated Intravascular Coagulation (DIC)
19AE(_) Other consumption coagulopathy
19AF(_) Thrombotic thrombocytopenic purpura (TTP) and hemolytic uremic syndrome (HUS)
19AG(_) Other, including peripheral hematoma
19AH(_) Anemia
19AI Monitor anticoagulation status for elective surgery (i.e., dental)
19AJ(_) Neutropenia, leukopenia
19AK(_) Other WBC-related condition, not otherwise specified

20. HEMODIALYSIS VASCULAR ACCESS COMPLICATIONS

20AA0 Elective surgical access repair
20AB(_) Soft tissue infection, cellulitis, abscess (access related)
20AC(_) Bacteremia or sepsis, access related
20AD(_) Clotted access
20AE(_) Venous thrombosis, access related
20AF(_) Arterial thrombosis or embolism, access related
20AG(_) Steal syndrome, limb ischemia, access related
20AH(_) Hemorrhage from vascular access
20AI(_) Nerve entrapment, access related
20AJ0 Fistulogram, arteriogram, or other invasive imaging procedure
20AK0 Access declotting procedure
20AL0 Angioplasty or stent placement for vascular access
20AM0 Non-elective surgical access repair
20AN0 Temporary access placement
20AO(_) Pneumothorax, hemothorax as result of temporary access placement
20AP(_) Subclavian vein stenosis as result of temporary access
20AQ0 New access creation (AV-fistula)
20AR0 New access placement (AV-graft)
20AS(_) Other access-related condition
20AT0 Other access-related procedure
20AU(_) New vascular access needed
20AV0 New perm-cath placement

21. OTHER HEMODIALYSIS COMPLICATIONS

21AA(_) Symptoms of uremia due to complications of hemodialysis
21AB(_) Hemorrhage from dialysis circuit
21AC(_) Air embolism
21AD(_) Anaphylaxis, treatment related
21AE(_) Hemolysis, treatment related
21AF(_) Electrolyte and acid-base disorder (other than hyperkalemia), treatment related
21AG(_) Dialysis-induced hypotension
21AH(_) Other accident related to treatment
21AI(_) Febrile reaction, not infection
21AJ0 Start of hemodialysis

21AK Withdrawal from dialysis
21AL Dialysis treatment completed at a location different than usual dialysis unit

22. OTHER SURGICAL PROCEDURES
22AA(_) Trauma
22AB(_) Major hemorrhage (not GI or pulmonary)
22AC(_) Hemorrhagic shock
22AD0 Skin graft/skin ulcer debridement
22AE0 Hernia procedure
22AF0 Other elective surgery procedure
22AG0 Removal of benign tumor
22AH0 Elective dental surgical procedure

23. OTHER
23AA(_) Other hemorrhage
23AB(_) Other trauma
23AC(_) Drug overdose (accidental)
23AD Accident unrelated to treatment
23AE Drug reaction (anaphylaxis)
23AF Drug reaction (not anaphylaxis, not overdose)
23AG Other electrolyte/acid-base disorder, not treatment related
23AH Cachexia
23AI Morbid Obesity
23AJ Gynecologic or obstetric condition
23AK Autoimmune condition affecting skin
23AL Fatigue

24. ELECTROLYTE DISORDERS (for Pilot Clinical Trials in CKD)
24AA(_) Hyponatremia
24AB(_) Hypernatremia
24AC(_) Hypokalemia
24AD(_) Hyperkalemia
24AE(_) Acidosis
24AF(_) Alkalosis
24AG(_) Hypophosphatemia
24AH(_) Hyperphosphatemia
24AI(_) Other electrolyte disorder

88. UNKNOWN
88AA Unknown reason for hospitalization

++++If you have a condition not found on this listing, please contact the DCC (CKD_dcc@bio.ri.ccf.org) for a new code+++++

Pilot Clinical Trials in CKD
Death Notification Form #531 – ALL STUDIES

This Form 531 is completed as soon as the Clinical Center becomes aware that a participant has died. A Form 532 is then entered that will give details regarding the death.

Detailed documentation regarding the participant's death (if hospitalized at time of death: expiration summary, autopsy report, lab reports, etc., or, if not hospitalized at time of death: physician summary, autopsy, office notes, etc.) must be submitted within 6 weeks after the participant expired.

1. Identification Number	2. Alphacode	3a. Visit Type	3b. Visit Number (Month)	3b. Visit Number (Week)	4. Date of Death (mm/dd/yyyy)	5. Study

Based on the information you have available to you now, what do you think is the cause(s) of death? (for Causes of Death, use the Death Code List from Form 532.)

6. a. Primary cause of death ..... ___ ___ ___ ___

   b. Secondary cause of death ..... ___ ___ ___ ___

   c. Other cause of death ..... ___ ___ ___ ___

   d. Other cause of death ..... ___ ___ ___ ___

200. Date this form completed (mm/dd/yyyy) ..... ___ ___ /___ ___ /___ ___ ___ ___

201. Username of person completing/reviewing completeness of this form..... __ __ __ __ __ __ __

Clinical Center Use Only

Date Form Entered (mm/dd/yyyy) __ __/__ __/__ __ __ __

Username of person entering this form__ __ __ __ __ __ __

Pilot Clinical Trials in CKD
Detailed Death Form #532 – ALL STUDIES

If a death occurred during the baseline period or during follow-up, complete Forms 531 and 532. Detailed documentation* will be required particularly if it was identified that the trial may have caused the particpant's death.

*Detailed documentation regarding the patient's death (if hospitalized at time of death: expiration summary, autopsy report, lab reports, etc., or, if not hospitalized at time of death: physician summary, autopsy, office notes, etc.) must be submitted within 6 weeks after the participant expired.

1. Identification Number	2. Alphacode	3a.Visit Type	3b. Visit Number (Month)	3b. Visit Number (Week)	4. Date of Death: mm/dd/yyyy	5. Study

Part 1: To be completed by the Study Coordinator:

6. a. Where did the death occur? ..... ___

1=In a hospital, in the emergency room
2=In a hospital, not in the emergency room
3=In the dialysis unit
4=In a nursing home or other skilled care facility
5=In the patient's home
6=Other known location
9=Location unknown

b. If 6a=1 or 2, what was the date of hospital or ER admission? (mm/dd/yyyy) ..... __ __/__ __/__ __ __ __

7. Was an autopsy performed? (0=no, 1=yes, 9=unknown) ..... ___
If YES, be sure to include the autopsy report in the Death Review Packet.

Part 2: To be completed by the Principal Investigator:

8. For causes of death, use the attached Death Code List.

a. Primary cause of death (cannot be a procedure) ..... ___ ___ ___ ___

b. Secondary cause of death ..... ___ ___ ___ ___

c. Other cause of death ..... ___ ___ ___ ___

d. Other cause of death ..... ___ ___ ___ ___

9. Death due to **Cardiovascular** disease (Code 0=no, 1=yes**)**

a. Was there new onset of or worsening angina pectoris or ischemic heart disease? .....___

b. Was there new onset of or worsening congestive heart failure (left ventricular dysfunction)? ..___

c. Was there a myocardial infarction? .....___

d. Was there new onset of or worsening arrhythmias? .....___

e. Was there new onset of or worsening other heart disease (exclude pericarditis) .....___
(Note - if any of the above are "Yes", this was a cardiovascular death)

Both studies: **BASE and COMBINE**

10. In the judgment of the Site PI, was the death caused by any procedure (such as blood draw Or MRI) that was specifically done as part of the clinical trial protocol? ..... ___
(0=no, 1=unlikely, 2=possibly, 3=probably, 4=definitely)

Causation judgment: **COMBINE** Only

11. a. In the judgment of the Site PI, was the death caused by the participant's randomly assigned Nicotinamide treatment regimen? ..... ___
(0=no, 1=unlikely, 2=possibly, 3=probably, 4=definitely, 5=N/A, patient in Baseline)

b. In the judgment of the Site PI, was the death caused by the participant's randomly assigned Lanthanum Carbonate treatment regimen?..... ___
(0=no, 1=unlikely, 2=possibly, 3=probably, 4=definitely, 5=N/A, patient in Baseline)

Causation judgment: **BASE** Only

12. In the judgment of the Site PI, was the death caused by the participant's randomly assigned Sodium Bicarbonate treatment regimen?..... ___
(0=no, 1=unlikely, 2=possibly, 3=probably, 4=definitely, 5=N/A, patient in Baseline)

Potential Classification as an "Unanticipated Problem"

13. a. In the judgment of the Site PI, was this death expected in this research?..... ___
0=no, not expected
1=yes, expected because of the characteristics of the study's subject population
2=yes, expected and described in protocol-related documents, such as the IRB-approved research protocol and informed consent document
3=yes, both 1 and 2

b. In the judgment of the Site PI, does this death suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized?(0=no, 1=yes) .....___

If this event was

- judged by the site physician to be possibly, probably or definitely related in either Q10, 11, or 12
- not expected in Q13a, and
- places study subjects or others at greater risk of harm than previously known or recognized as noted in Q13b,

the event will be considered an "Unanticipated Problem" and reported to NIH and all site physicians when this form is entered into the database.

14. a. Did any of these SAEs occur before this death? ..... ___ ___
(Choose the primary one or the best one that applies)
6=Life threatening event (without hospitalization)
7=Event resulting in a persistent or significant disability/ incapacity (without hospitalization)
8=Event resulting in a congenital anomaly/birth defect (without hospitalization)
9=Event exceeding severity risk greater than described in protocol (without hospitalization)
10=Abuse of, or dependency on study medications (without hospitalization)
18 =Spontaneous abortion (without hospitalization)

Emergency Room Visit SAEs **(required to be reported as SAEs for BASE)**
21=ER Visit for edema, heart failure, or pulmonary (without hospitalization)
22=ER Visit for hypertension (without hospitalization)
23=ER Visit for low serum potassium level (without hospitalization)
24=ER visit for high serum potassium level (without hospitalization)
25=ER Visit for high serum bicarbonate level (without hospitalization)
26=ER Visit for low serum bicarbonate level (without hospitalization)
27=Any other important medical event, including new cancer diagnosis, which may jeopardize the participant, or may require intervention to prevent permanent impairment or damage or other outcome listed above (without hospitalization)

Emergency Room Visits considered to be important for **COMBINE**
31=ER Visit for hypophosphatemia (without hospitalization)
32=ER visit for hyperphosphatemia (without hospitalization)
33=ER Visit for thrombocytopenia (without hospitalization)
34=ER Visit for blood transfusion (without hospitalization)
35=ER Visit for bruising or bleeding (without hospitalization)
36=ER Visit for diarrhea (without hospitalization)
37=ER Visit for other GI symptoms (without hospitalization)

b. Was a Form 522 (Details of SAEs that are Not Hosp or Deaths) entered? (0=no, 1=yes) ..... ___

c. If yes, date of SAE documented on F522 (Details of SAEs that are Not Hosp or Deaths)?
(mm/dd/yyyy) .....__ __/__ __/__ __ __ __

15. **Required:** Death Narrative. (For participants who expired, provide a detailed summary of what happened. Note if an SAE preceeded this death. Use back of sheet if necessary. Key enter text.)

16. Comments on relatedness (**required** if event is considered possibly, probably, or definitely related to any study procedure or treatment).

200. Date this form completed (mm/dd/yyyy).....___ ___/___ ___/___ ___ ___ ___

201. Username of person completing/reviewing completeness of this form..... __ __ __ __ __ __ __

Clinical Center Use Only

Date Form Entered (mm/dd/yyyy) __ __/__ __/__ __ __ __

Username of person entering this form__ __ __ __ __ __ __

CODE LIST OF CAUSES OF DEATH

Note: A "2" indicates that the disease or condition could only be a secondary or other cause of death and not the primary cause.

1. ISCHEMIC HEART DISEASE (IHD)

01DA Sudden death (due to IHD)
01DB Myocardial infarction (acute) (MI)
01DC Angina:2
01DD Atherosclerotic heart disease (CAD):2
01DE Other acute and subacute forms of ischemic heart disease
01DF Old myocardial infarction:2
01DG Other forms of chronic ischemic heart disease:2

2. CONGESTIVE HEART FAILURE (CHF)

02DA CHF
02DB CHF or pulmonary edema due to exogenous fluid (volume overload)
02DC Pulmonary edema (cardiogenic)
02DD Cardiogenic shock

3. ARRHYTHMIAS AND CONDUCTION PROBLEMS

03DA Sudden death (due to arrhythmia, not due to IHD)
03DB Atrioventricular conduction block
03DC Sick sinus syndrome
03DD Atrial fibrillation
03DE Ventricular tachycardia
03DF Other cardiac arrhythmia and conduction disorder
03DG Hyperkalemia
03DH Ventricular fibrillation

4. OTHER HEART DISEASES AND CONDITIONS (OHD)

04DA Sudden death (due to heart conditions thought most likely due to other than IHD/arrhythmia)
04DB Pericarditis
04DC Endocarditis
04DD Myocarditis
04DE Pericardial effusion:2
04DF Cardiac tamponade
04DG Aortic valve stenosis or insufficiency:2
04DH Mitral valve stenosis, regurgitation, or prolapse:2
04DI Other valve defect:2
04DJ Prosthetic valve malfunction:2
04DK Cardiomyopathy (without IHD or CHF)

5. HYPERTENSION (HTN)/HYPOTENSION

05DA Hypertensive crisis or accelerated HTN
05DB Hypotensive crisis or accelerated hypotension

6. CEREBRAL VASCULAR DISEASE (CVD)

06DA Cerebral vascular accident (CVA)
06DB Carotid artery stenosis:2
06DC Cerebral artery aneurysm:2
06DD Subarachnoid or cerebral hemorrhage
06DE Other cerebrovascular disease

7. VASCULAR DISEASES

07DA Hemorrhage from ruptured vascular aneurysm
07DB Peripheral vascular disease (atherosclerotic):2
07DC Deep vein thrombosis (DVT):2
07DD Pulmonary embolism (PE)
07DE Abdominal aortic aneurysm (AAA):2
07DF Thoracic aortic aneurysm (TAA):2
07DG Aortic aneurysm (not specified as AAA or TAA):2
07DH Other aneurysm:2
07DI Arterial embolism and thrombosis
07DJ Mesenteric ischemia or infarction/ischemic bowel
07DK Gangrene with septicemia-shock due to PVD
07DL Polyarteritis nodosa and other arteritides:2
07DM Other disorders of arteries:2
07DN Arteriovenous malformation (AVM)

8. DIABETES MELLITUS (DM) AND ENDOCRINE DISORDERS

08DA Diabetes mellitus, Type I (insulin dependent):2
08DB Diabetes mellitus, Type II (non insulin dependent, could be insulin required):2
08DC Diabetes mellitus, type unclassified or unknown:2
08DD Diabetes with ketoacidosis
08DE Diabetes with hyperosmolar state or coma (hyperglycemia)
08DF Diabetes with other coma
08DG Hypoglycemia coma
08DH Diabetic foot infection
08DI Hypothyroidism:2
08DJ Disorders of the thyroid gland:2
08DK Other endocrine disorder:2
08DL Hyperparathyroidism:2
08DM Hypoparathyroidism:2
08DN Other disorder of calcium and phosphorus metabolism

Notation: A "2" indicates that the disease or condition could only be a secondary or other cause of death and not the primary cause.

9. RESPIRATORY DISEASES

09DA Asthma
09DB COPD exacerbation
09DC Bronchitis (chronic):2
09DD COPD:2
09DE Pneumonia (community acquired)
09DF Pneumonia (nosocomial)
09DG Pneumonia-sepsis
09DH Pneumonia (bacterial)
09DI Pneumonia (fungal)
09DJ Pneumonia (viral)
09DK Pneumocystic pneumonia
09DL Pneumonia (unspecified pathogen)
09DM Empyema
09DN Lung abscess
09DO Pneumothorax
09DP Pulmonary hemorrhage
09DQ Cor pulmonale:2
09DR Pulmonary TB
09DS Aspiration pneumonia
09DT Adult Respiratory Distress Syndrome (ARDS)
09DU Respiratory failure of unknown cause
09DV Sleep apnea:2
09DW Other respiratory cause

10. MALIGNANCY

10DA Hematologic malignancy (AML, CML, ALL, CLL)
10DB Lymphoma (unspecified)
10DC Hodgkin's lymphoma
10DD Non-Hodgkin's lymphoma
10DE Multiple myeloma
10DF Colon cancer
10DG Breast cancer
10DH Prostate cancer
10DI Ovarian cancer
10DJ Lung cancer
10DK Gastric cancer
10DL Pancreatic cancer
10DM Thyroid cancer
10DN Cervical cancer
10DO Endometrial cancer
10DP Primary cancer of the liver
10DQ Head and neck squamous cell carcinoma
10DR Testicular cancer
10DS Renal cancer

Notation: A "2" indicates that the disease or condition could only be a secondary or other cause of death and not the primary cause.

10DT Bladder cancer
10DU Melanoma
10DV Other skin cancer
10DW Other malignancy or neoplasia
10DX Metastatic cancer with unknown primary

11. HEPATOBILIARY DISEASES
11DA Hepatitis B
11DB Hepatitis C
11DC Toxic/drug induced hepatitis
11DD Hepatitis (other unknown cause)
11DE Cirrhosis:2
11DF Ascites:2
11DG Portal hypertension or esophageal varices:2
11DH Hemorrhage from esophageal varices
11DI Hepatic (liver) failure/severe hepatic dysfunction
11DJ Polycystic liver disease:2
11DK Cholecystitis/cholangitis
11DL Biliary sepsis
11DM Other hepatobiliary disease

12. MUSCULOSKELETAL AND CONNECTIVE TISSUE DISEASES
12DA Wegener's granulomatosis
12DB Systemic vasculitis
12DC Rheumatoid arthritis:2
12DD Systemic lupus erythematosus (SLE)
12DE Osteomyelitis
12DF Septic arthritis
12DG Osteoporosis:2
12DH Bone fracture(s):2
12DI Renal osteodystrophy:2

13. GASTROINTESTINAL CONDITIONS (GI)
13DA Upper GI bleed
13DB Lower GI bleed
13DC GI bleeding, site unknown
13DD Peptic ulcer disease:2
13DE Gastritis:2
13DF Diverticulosis:2
13DG Ulcerative colitis (UC):2
13DH Enteritis (Crohn's disease):2
13DI Perforation of peptic ulcer
13DJ Perforation of bowel
13DK Diverticulitis
13DL Necrotizing enterocolitis

Notation: A "2" indicates that the disease or condition could only be a secondary or other cause of death and not the primary cause.

13DM *C. difficile* associated enterocolitis
13DN Peritonitis
13DO Appendicitis
13DP Septicemia due to peritonitis
13DQ Fungal peritonitis
13DR Pancreatitis
13DS Intra-abdominal abscess

13DU Other GI condition:2

14. NONVASCULAR NERVOUS SYSTEM DISEASES
14DA Dementia (Alzheimer's):2
14DB Dementia (other, unknown, including dialysis dementia):2
14DC Seizure disorder (chronic):2
14DD Seizure episode
14DE Depression:2
14DF Suicide (not due to withdrawal from dialysis, which is code 23DA)
14DG Drug overdose (alcohol/drug abuse--street drugs or other non-accidental chemical abuse)
14DH Subdural or epidural hematoma (spontaneous or traumatic)
14DI Meningitis (non viral, bacterial, or fungal or TB)
14DJ Brain abscess
14DK Other CNS infection
14DL Head trauma (brain injury)
14DM Ischemic brain damage, anoxic encephalopathy
14DN Other psychiatric or mental disorder:2
14DO Parkinson's disease:2
14DP Multiple sclerosis (MS):2
14DQ Other demyelinating diseases of CNS:2
14DR Cranial or peripheral nerve disorder:2
14DS Other nonvascular nervous system condition

15. URINARY TRACT CONDITIONS
15DA Urinary tract infection (chronic UTIs):2
15DB UTI-septicemia
15DC Nephrolithiasis:2
15DD Prostatitis
15DE Benign prostatic hypertrophy:2
15DF Orchitis
15DG Cystic kidney disease (PKD or acquired):2
15DH Cyst-related hemorrhage
15DI Cyst-related infection
15DJ Urinary tract hemorrhage
15DK Hemorrhage from renal transplant site
15DL Other renal and urologic condition (excluding ESRD)

Notation: A "2" indicates that the disease or condition could only be a secondary or other cause of death and not the primary cause.

16. HIV/AIDS

16DA HIV positive (not AIDS)
16DB AIDS
16DC AIDS-related infection
16DD Other AIDS-related condition (not infection)

17. OPHTHALMOLOGIC CONDITIONS

17DA Endophthalmitis
17DB Legally blind:2

18. INFECTIONS (NOT ACCESS RELATED)

18DA Abscess (not recorded in previous category)
18DB Other infection (not recorded in previous category)
18DC Septic shock
18DD Septicemia (bacteremia) (known source, not access related)
18DE Septicemia (bacteremia) (unknown source, not access related)
18DF Extrapulmonary TB
18DG Miliary TB
18DH Disseminated candida infection
18DI Other fungal infection
18DJ Viral infection (CMV)
18DK Other viral infection (not hepatitis)
18DL Protozoan or parasitic infection (not PCP)

19. NON-MALIGNANT HEMATOLOGIC CONDITIONS

19DA Anemia:2
19DB Bone marrow depression:2
19DC Leukocytopenia:2
19DD Coagulation disorder:2
19DE Thrombocytopenia:2
19DF Disseminated Intravascular Coagulation (DIC)
19DG Other consumption coagulopathy:2
19DH Thrombotic thrombocytopenic purpura (TTP) and hemolytic uremic syndrome (HUS)
19DI Other non-malignant hematologic condition

20. HEMODIALYSIS VASCULAR ACCESS COMPLICATIONS

20DA Septicemia (bacteremia) access related
20DB Hemorrhage from vascular access
20DC Venous thrombosis access related:2
20DD Arterial thrombosis or embolism access related
20DE Other access infection
20DF Other complication of temporary access placement

Notation: A "2" indicates that the disease or condition could only be a secondary or other cause of death and not the primary cause.

21. OTHER HEMODIALYSIS COMPLICATIONS

21DA Hemorrhage from dialysis circuit
21DB Air embolism
21DC Anaphylaxis, treatment related
21DD Hemolysis, treatment related
21DE Electrolyte and acid-base disorder, treatment related (other than hyperkalemia)
21DF Dialysis-induced hypotension
21DG Other accident related to treatment

22. OTHER SURGICAL COMPLICATIONS

22DA Hemorrhage from surgery
22DB Complications from surgery
22DC Complications from anesthesia

23. OTHER

23DA Withdrawal from dialysis:2
23DB Other hemorrhage
23DC Cachexia
23DD Other trauma
23DE Drug overdose (accidental)
23DF Accident unrelated to treatment
23DG Drug reaction, anaphylaxis
23DH Drug reaction, not anaphylaxis, not overdose
23DI Other electrolyte and acid-base disorder (not related to hemodialysis treatment)
23DJ Homicide
23DK Refusal of lifesaving therapy
23DL Multi-organ system failure (pt. in ICU):2
23DM Multi-organ system failure (pt. not in ICU):2
23DN Multi-organ system failure (therapy induced):2
23DO Multi-organ system failure (not therapy induced):2
23DP Natural cause
23DQ Patient ever on immunosuppressive therapy

24. UNKNOWN

24DA Sudden death, unknown cause
24DB Other death, unknown cause

25. HYPERTENSIVE CARDIOVASCULAR DISEASE (HCVD)

25DA Hypertensive cardiovascular disease

Notation: A "2" indicates that the disease or condition could only be a secondary or other cause of death and not the primary cause.

Pilot Clinical Trials in CKD
Event Information Sent to the DCC Form #540 – ALL STUDIES

Instructions: The Data Coordinating Center (DCC) will notify the clinical center staff to complete and enter this form when an event (hospitalization, ER visit, other SAE and/or death) shows that a packet needs to be scanned and emailed to Karen Brittain **(brittak@ccf.org) and** Susan Sherer **(sherers@ccf.org)** at the Data Coordinating Center (DCC). See the MOP for detailed instructions on processing the packet.

Forms 511 and 512 for hospitalizations, Form 522 for Details of SAEs that are Not Hospitalizations or Deaths, and Forms 531 and 532 for a death must be entered by the clinical center before this form is entered into the database.

NOTE: Do NOT send any packets to the DCC unless notified to do so by the DCC.

1. Identification Number	2. Alphacode	3a.Visit Type	3b. Visit Number (Month)	(Week)	4. Date of event: mm/dd/yyyy	5. Study

6. Type of event reported in item 4 above ..... ___
   1=Hospitalization reported on Form 512
   2=SAE that is not a hospitalization reported on Form 522
   3=Death reported on Form 532

7. Date event packet scanned and emailed to the DCC? (mm/dd/yyyy)..... __ __ /__ __ /__ __ __ __

8. Type of information scanned and emailed to the DCC:
   a. Discharge summary (0=no, 1=yes)..... ___
   b. ER summary note (0=no, 1=yes)..... ___
   c. Physician's narrative summary (0=no, 1=yes) ..... ___
   d. Autopsy report (0=no, 1=yes) ..... ___
   e. Death certificate (0=no, 1=yes) ..... ___
   f. Other information sent (0=no, 1=yes) ..... ___

   If other, describe other material provided

200. Date this form completed (mm/dd/yyyy)..... __ __ /__ __ /__ __ __ __

201. Username of person completing/reviewing completeness of this form..... __ __ __ __ __ __ __ __

Clinical Center Use Only

Date Form Entered (mm/dd/yyyy) __ __/__ __/__ __ __ __

Username of person entering this form__ __ __ __ __ __ __ __

Pilot Clinical Trials in CKD
Vascular Access Created/Placed Form #549 – ALL STUDIES

If you learn that a participant has had an access placed, complete outcome measures early in the visit window.

1. Identification Number	2. Alphacode	3a.Visit Type	3b. Visit Number (Month)	3b. Visit Number (Week)	4. Date vascular access created/placed (mm/dd/yyyy)	5. Study

6. What vascular access procedure was done? ..... ___
   1=fistula created
   2=first phase of a 2-stage fistula creation surgery
   3=graft placed
   4=other access placed

200. Date this form completed (mm/dd/yyyy) ..... ___ ___ /___ ___ /___ ___ ___ ___

201. Username of person completing/reviewing completeness of this form..... __ __ __ __ __ __ __

Clinical Center Use Only

Date Form Entered (mm/dd/yyyy) __ __/__ __/__ __ __ __

Username of person entering this form__ __ __ __ __ __ __

Pilot Clinical Trials in CKD
Initiation of Chronic Dialysis or
Transplant Form # 550 – ALL STUDIES

Once a study participant has had a kidney transplanted or has begun chronic dialysis, the participant will continue to be followed for mortality only. Study data will be censored at the time of kidney transplant admission or initiation of chronic dialysis. If clinical center staff members learn that a participant is going to receive a kidney transplant or start chronic dialysis, the next visit's measurements should be completed early in the visit window.

1. Identification Number	2. Alphacode	3a. Visit Type	3b. Visit Number (Month)	3b. Visit Number (Week)	4. Date of initiation of dialysis or kidney transplant (mm/dd/yyyy)	5. Study

6. Reason this form is being completed? ..... ___
(1=Had a kidney transplant, 2=Initiation of chronic dialysis)

If Item 6=1 (transplant), skip to item 200

7. Dialysis status at time of initiation (1=Hemodialysis, 2=Peritoneal dialysis)..... ___

8. If hemodialysis, access to be used at initiation of dialysis ..... ___
1=catheter
2=graft
3=mature fistula
9=unknown

200. Date this form completed (mm/dd/yyyy) ..... ___ ___ /___ ___ /___ ___ ___ ___

201. Username of person completing/reviewing completeness of this form..... __ __ __ __ __ __ __

Clinical Center Use Only

Date Form Entered (mm/dd/yyyy) __ __/__ __/__ __ __ __

Username of person entering this form__ __ __ __ __ __ __

Pilot Clinical Trials in CKD
Event Review Committee Hospitalization Form # 612 – ALL STUDIES

This form is completed by the Event Review Committee when either 1) there is a report that an SAE is possibly, probably or definitely related to a study treament or procedure or 2) an SAE was selected for QC.

For all Event Review Committee reviews, the committee will consider whether the CKD Study participant should discontinue a randomized treatment assignment for a safety reasons.

1. Identification Number	2. Alphacode	3a.Visit Type	3b. Visit Number (Month)	(Week)	4. Date of Hospital Admission: (mm/dd/yyyy)	5. Study

6. Date of Event Review Committee call (mm/dd/yyyy)..... ___ ___ /___ ___ /___ ___ ___ ___

7. Primary reviewer..... __ __ __ __ __ __ __
(Full Committee (FULLCTT), Dr. Fried and Dr. Abbott (LFANDKA), or first six letters of last name and first letter of first name)

8. What type of review is this? ..... ___
1=Event form said event was possibly, probably or definitely related to a study treatment or procedure
2=Unrelated SAE selected for QC review

Event Review Committee Classification of Relatedness

9. In the Event Reviewer Committee's judgment, was this event caused by the participant's randomly assigned medication regimen?..... ___
(0=no, 1=unlikely, 2=possibly, 3=probably, 4=definitely)

10. In the Event Review Committee's judgment, was this event caused by any device or procedure that was specifically done as part of the CKD Trial Protocol?..... ___
(0=no, 1=unlikely, 2=possibly, 3=probably, 4=definitely)

11. Comments on relatedness (Add an additional sheet of paper if desired.) Required if Q9 or 10 is possibly, probably or definitely.

Event Committee Reviewer classification of treatment stop point for safety reasons:

13. Does the **Event Committee Reviewer** believe that the randomized treatment assignment **must** be discontinued for the duration of the study **for safety reasons** (0=no, 1=yes)..... ___
If yes, complete Q14.

Reason(s) Event Committee Reviewer recommended stopping randomized treatment

14. Comments on the Treatment Stop (Add an additional sheet of paper if desired.) Required if Q13 is 1=yes.

200. Date this form completed (mm/dd/yyyy)..... __ __ /__ __ /__ __ __ __

201. Username of person completing/reviewing completeness of this form..... __ __ __ __ __ __ __ __

DCC Use Only

Date Form Entered (mm/dd/yyyy) __ __/__ __/__ __ __ __

Username of person entering this form __ __ __ __ __ __ __ __

Pilot Clinical Trials in CKD
Event Review Committee SAEs that are not Hospitalizations or Deaths Review Form # 622 – ALL STUDIES

1. Identification Number	2. Alphacode	3a. Visit Type	3b. Visit Number (Month)	3b. Visit Number (Week)	4. Date of Event (mm/dd/yyyy)	5. Study

6. Date of Event Review Committee call (mm/dd/yyyy)..... ___ ___ /___ ___ /___ ___ ___ ___

7. Primary reviewer..... __ __ __ __ __ __ __
(Full Committee (FULLCTT), Dr. Fried and Dr. Abbott (LFANDKA), or first six letters of last name and first letter of first name)

8. What type of review is this? ..... ___
1=Event form said event was possibly, probably or definitely related to a study treatment or procedure
2=Unrelated SAE selected for QC review

9. What was the event being reviewed? (According to the Form 522 Q7 being reviewed) ..... ___ ___

Event Review Committee Classification of Relatedness

10. In the Event Reviewer Committee's judgment, was this event caused by the participant's randomly assigned medication regimen?..... ___
(0=no, 1=unlikely, 2=possibly, 3=probably, 4=definitely)

11. In the Event Review Committee's judgment, was this event caused by any device or procedure that was specifically done as part of the CKD Protocol? ..... ___
(0=no, 1=unlikely, 2=possibly, 3=probably, 4=definitely)

12. Comments on relatedness (Add an additional sheet of paper if desired.) Required if Q10 or 11 is possibly, probably or definitely related.

Event Committee Reviewer classification of treatment stop point for safety reasons:

14. Does the **Event Committee Reviewer** believe that the randomized treatment assignment **must** be discontinued for the duration of the study **for safety reasons** (0=no, 1=yes)..... ___
If yes, complete Q15. If no, skip to Q201.

Reason(s) Event Committee Reviewer recommended stopping randomized treatment

15. Comments on the Treatment Stop (Add an additional sheet of paper if desired.). Required if Q14 are yes.

201. Date this form completed (mm/dd/yyyy)..... __ __ /__ __ /__ __ __ __

202. Username of person completing/reviewing completeness of this form..... __ __ __ __ __ __ __ __

DCC Use Only

Date Form Entered (mm/dd/yyyy) __ __/__ __/__ __ __ __

Username of person entering this form __ __ __ __ __ __ __ __

Pilot Clinical Trials in CKD
MSD Inflammation Panel Data Transmission Form # 900 – MICROBIOME

																		M	

1. Identification Number 2. Visit date (mm/dd/yyyy) 3. Study

4. Intended visit .....**W** __ __
5. Barcode .....__ __ __ __ __ __ __ __
6. Patient ID .....__ __ __ __
7. Visit..... __ __ - __ __
8. Plasma VTID .....__ __
9. IL-1β (pg/mL) ..... __ __ __•__ __ __
10. IL-1β Comment (extrapolated low or undetectable low) ....._____
11. IL-2 (pg/mL) ..... __•__ __ __
12. IL-2 Comment (extrapolated low or -777 CV > 10%) ....._____
13. IL-4 (pg/mL) ..... __ __ __•__ __ __
14. IL-4 Comment (extrapolated low or undetectable low) ....._____
15. IL-6 (pg/mL) ..... __•__ __ __
16. IL-6 Comment....._____
17. IL-10 (pg/mL) ..... __•__ __ __
18. IL-10 Comment....._____
19. TNF-α (pg/mL) ..... __ __•__ __ __
20. TNF-α Comment....._____

Pilot Clinical Trials in CKD
IL-22 Data Transmission Form # 901 – MICROBIOME

																		M	

1. Identification Number 2. Visit date (mm/dd/yyyy) 3. Study

4. Intended visit .....**W** __ __
5. Barcode .....__ __ __ __ __ __ __ __
6. Patient ID .....__ __ __ __
7. Visit..... __ __ - __ __
8. Plasma VTID .....__ __
9. IL-22 (pg/mL) ..... __ __ __•__ __ __
9. Comment (out of range low or undetectable low < 0.1)....._____

Pilot Clinical Trials in CKD
IL-17 Data Transmission Form # 902 – MICROBIOME

																		M	

1. Identification Number 2. Visit date (mm/dd/yyyy) 3. Study

4. Intended visit .....**W** __ __
5. Barcode .....__ __ __ __ __ __ __ __
6. Patient ID .....__ __ __ __
7. Visit..... __ __ - __ __
8. Plasma VTID .....__ __
9. IL-17A (pg/mL) ..... __•__ __ __
9. Comment (out of range low)....._____

Pilot Clinical Trials in CKD
CRP and CysC Data Transmission Form # 903 – MICROBIOME

																M	

1. Identification Number 2. Visit date (mm/dd/yyyy) 3. Study

4. Intended visit .....**W** __ __
5. Barcode .....__ __ __ __ __ __ __ __
6. Patient ID .....__ __ __ __
7. Visit..... __ __ - __ __
8. Plasma VTID .....__ __
9. CRP (μg/mL)..... __ __ __•__ __
10. CRP Comment (undetectable low < 0.1)....._____
11. CysC (mg/L) ..... __ __ __•__ __
12. Cys C Comment (undetectable low < .03) ....._____

Pilot Clinical Trials in CKD
MPO Data Transmission Form # 904 – MICROBIOME

																M	

1. Identification Number 2. Visit date (mm/dd/yyyy) 3. Study

4. Intended visit .....**W** __ __
5. Barcode .....__ __ __ __ __ __ __ __
6. Patient ID .....__ __ __ __
7. Visit..... __ __ - __ __
8. Plasma VTID .....__ __
9. MPO (ng/mL)..... __ __ __•__ __
10. Comment (undetectable high > 100) ....._____

Pilot Clinical Trials in CKD
CD14 Data Transmission Form # 905 – MICROBIOME

																		M	

1. Identification Number 2. Visit date (mm/dd/yyyy) 3. Study

4. Intended visit .....**W** __ __
5. Barcode .....__ __ __ __ __ __ __ __
6. Patient ID .....__ __ __ __
7. Visit..... __ __ - __ __
8. Plasma VTID .....__ __
9. CD14 (ng/mL)..... __ __ __ __•__ __
10. Comment (undetectable high > 3216)....._____

Pilot Clinical Trials in CKD
FGF-23 Data Transmission Form # 906 – MICROBIOME

															M	

1. Identification Number 2. Visit date (mm/dd/yyyy) 3. Study

4. Intended visit .....**W** __ __
5. Barcode .....__ __ __ __ __ __ __ __
6. Patient ID .....__ __ __ __
7. Visit..... **V1** - **28**
8. Plasma VTID .....__ __
9. FGF-23 (RU/mL) ..... __ __ __ •__ __ __
10. Comment....._____

Pilot Clinical Trials in CKD
LBP Data Transmission Form # 907 – MICROBIOME

		M
1. Identification Number	2. Visit date (mm/dd/yyyy)	3. Study

4. Intended visit .....**W** __ __
5. Barcode .....__ __ __ __ __ __ __ __
6. Patient ID .....__ __ __ __
7. Visit..... **V1** - **28**
8. Plasma VTID .....__ __
9. LBP (ng/mL) ..... __ __ __ __ •__ __
10. Comment....._____

Pilot Clinical Trials in CKD
TNF-RI and TNF-RII Data Transmission Form # 908 – MICROBIOME

																M	

1. Identification Number 2. Visit date (mm/dd/yyyy) 3. Study

4. Intended visit .....**W** __ __
5. Barcode .....__ __ __ __ __ __ __ __
6. Patient ID .....__ __ __ __
7. Visit..... **V1** - **28**
8. Plasma VTID .....__ __
9. TNF-RI (pg/mL) ..... __ __ __ __ •__ __
10. TNF-RI Comment....._____
11. TNF-RII (pg/mL) ..... __ __ __ __ __•__ __
12. TNF-RII Comment ....._____

Pilot Clinical Trials in CKD
UVMMC Serum Data Transmission Form # 909 – MICROBIOME

																M	

1. Identification Number 2. Visit date (mm/dd/yyyy) 3. Study

4. Barcode Vial 1 .....__ __ __ __ __ __ __ __
5. Barcode Vial 2 .....__ __ __ __ __ __ __ __
6. Encounter code .....__ __ __ __
7. Visit.....__ __
8. Serum ID No.....__ __
9. Potassium (mEq/L)..... __ • __
10. Sodium (mEq/L).....__ __ __
11. Chloride (mEq/L).....__ __ __
12. C02 (mEq/L) .....__ __
13. Alkaline Phosphatase (U/L) .....__ __
14. Total Bilirubin (mg/dl)..... __ __ • __
15. AST (U/L) .....__ __
16. ALT (U/L) ..... __ __ __
17. Albumin (g/dl)..... __ • __
18. Total Protein (g/dl) ..... __ • __
19. Creatinine (mg/dl)..... __ • __ __
20. eGFR (ml/min/1.73m2) .....__ __
21. BUN (mg/dl) .....__ __
22. Calcium (mg/dl)..... __ __ • __
23. Calculated Calcium (mg/dl) .....__ __ • __
24. Glucose (mg/dl) .....__ __ __ __
25. Magnesium (mg/dl)..... __ • __
26. Phosphorus (mg/dl)..... __ • __
27. Comments ....._____

Pilot Clinical Trials in CKD
UVMMC Urine Data Transmission Form # 910 – MICROBIOME

		M
1. Identification Number	2. Visit Date (mm/dd/yyyy)	3. Study

4. Intended Visit..... __ __ __
5. Barcode Vial 1 ..... __ __ __ __ __ __ __ __
6. Barcode Vial 2 ..... __ __ __ __ __ __ __ __
7. Patient ID ..... __ __ __ __
8. Visit..... __ __ - __ __
9. Urine VT ID..... __ __
10. Creatinine (mg/dl)..... __ __ __ • __
11. Urea Nitrogen (mg/dl) ..... __ __ __
12. Calcium (mg/dl)..... __ __ • __
13. Magnesium (mg/dl)..... __ __ • __
14. Phosphorus (mg/dl)..... __ __ • __
15. Uric Acid (mg/dl)..... __ __ • __