CKD Pilot Study Forms – BASE Study

FORMS TABLE OF CONTENTS

Trial: M=MICROBIOME Trial only; B=BASE Trial only, C=COMBINE Trial only, All = All three studies

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CKD PILOT STUDIES
BASE 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

Baseline Participant Forms

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 Visit (S0 visit)

Form #	Form Name
F106	Screening
F121	Local Lab Serum Pregnancy Test Results
F202	Visit/Phone Visit
F213	Concomitant Medications
F351	Local Lab Serum Results
F356	Local Lab Spot Urine Results

At some time between Screening and B0 Visit

Form #	Form Name
F122	Co-Morbidity and Medical History
F123	Baseline Demographics, Employment, and Income

At some time between Screening and prior to the B0 Visit

Report #	Report Name
Rpt	Ready for Baseline (B0) Placebo

B0 Visit

Form #	Form Name
F202	Visit/Phone Visit
F283	GI Symptoms and Other AEs
F213	Concomitant Medications
F146	Baseline Pill Dispensing
F351	Local Lab Serum Results
F354	Local Blood Gas Sub Study (for those who consented)
F356	Local Lab Spot Urine Results

B1 Visit

Form #	Form Name
F202	Visit/Phone Visit
F147	Baseline Pill Count
F213	Concomitant Medications
F283	GI Symptoms and Other AEs
F302	NIDDK Biorepository Serum, Plasma Mailing
F303	NIDDK Biorepository Urine Mailing
F326	Litholink 24-Hour Urine Mailing
F351	Local Lab Serum Results

Form Completed by Litholink Lab at B1

F355	*Litholink Lab 24-hour Urine Results*

B2, B3, etc. Visit (Held if needed to achieve target BP, serum potassium & optimize ACE-I/ARB)

Form #	Form Name
F202	Visit/Phone Visit
F147	Baseline Pill Count
F213	Concomitant Medications
F283	GI Symptoms and Other AEs

Report can be run at any time after B1

Form #	Report Name
Report	Ready to Randomize Report

Report that will be run when the participant is ready to be randomized

Form #	Report Name
Report	On-Line Randomization Report

As Needed during Baseline

Form #	Form Name
F15	Backup Litholink Sample Discard
F162	Baseline (Pre-Randomization) Drop-out
F284	Symptoms/Adverse Events Reported on Phone Calls or at Extra Non-Protocol Visits
F351	Local Lab Serum Results (as needed for recheck of serum bicarbonate and potassium)
F352	Local Lab Plasma Ionized Calcium
F402	Re-Enrollment of a Previously Enrolled Participant
F511	Hospitalization Notification
F512	Hospitalization Detail
F522	Details of SAEs that are Not Hospitalizations or Deaths
F531	Death Notification
F532	Death Details

BASE Follow-up Participant Forms Schedule

Follow-Up Visit Weeks (W) 0, 4, 8, 12, 16 (phone), 20, 24 (phone) 28, 32 (Off treatment)

Follow-up Visit: W0 (first post randomization visit): Randomization will sometimes be done at a Baseline visit. If this occurs, a separate W0 visit is not required.

Form #	Form Name
F230	Follow-Up Initial Pill Dispensing

Follow-up Visit: W4

Form #	Form Name
RPT	Ready for Up Titration (for high dose participants)
F202	Visit/Phone Visit
F213	Concomitant Medications
F231	Follow-Up Pill Dispensing and Counting
F283	GI Symptoms and Other AEs
F351	Local Lab Serum Results

Follow-up Visit: W8

Form #	Form Name
F202	Visit
F213	Concomitant Medications
F231	Follow-Up Pill Dispensing and Counting
F283	GI Symptoms and Other AEs
F351	Local Lab Serum Results

Follow-up Visit: W12

Form #	Form Name
F202	Visit/Phone Visit
F213	Concomitant Medications
F231	Follow-Up Pill Dispensing and Counting
F283	GI Symptoms and Other AEs
F302	NIDDK Biorepository Serum and Plasma Mailing
F303	NIDDK Biorepository Random (Spot) Urine Mailing
F326	Litholink 24-hour Urine Mailing
F351	Local Lab Serum Results
F356	Local Lab Spot Urine Results
F354	Local Blood Gas Sub Study (for those who consented)

Form Completed by Litholink Lab at W12

F355	*Litholink Lab 24-hour Urine Results*

Follow-up Visit: W16 (Phone Visit)

Form #	Form Name
F202	Visit/Phone Visit
F213	Concomitant Medications

Follow-up Visit: W20

Form #	Form Name
F202	Visit/Phone Visit
F213	Concomitant Medications
F231	Follow-Up Pill Dispensing and Counting
F283	GI Symptoms and Other AEs
F351	Local Lab Serum Results

Follow-up Visit: W24 (Phone Visit)

Form #	Form Name
F202	Visit/Phone Visit
F213	Concomitant Medications

Follow-up Visit: W28

Form #	Form Name
F202	Visit/Phone Visit
F213	Concomitant Medications
F231	Follow-Up Pill Dispensing and Counting
F283	GI Symptoms and Other AEs
F288	Participant End of Study Questionnaire
F302	NIDDK Biorepository Serum and Plasma Mailing
F303	NIDDK Biorepository Random (Spot) Urine Mailing
F326	Litholink 24-hour Urine Mailing
F351	Local Lab Serum Results
F356	Local Lab Spot Urine Results
F354	Local Blood Gas Sub Study (for those who consented)

Form Completed by Litholink Lab at W28

F355	*Litholink Lab 24-hour Urine Results*

Follow-up Visit: W32 (Off Treatment)

Form #	Form Name
F202	Visit/Phone Visit
F213	Concomitant Medications
F283	GI Symptoms and Other AEs
F351	Local Lab Serum Results
F476	Study Closeout

As Needed during Follow-Up

Form #	Form Name
F15	Back Up Litholink Sample Discard
F251	Between Visit Phone Medication Change
F284	Symptoms/Adverse Events Reported on Phone Calls or at Extra Non-Protocol Visits
F351	Local Lab Serum Results (as needed for recheck of serum bicarbonate and potassium)
F383	Extra Lab Measurements
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

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
Backup Litholink Sample Discard Form #15 – BASE

The following form is completed as needed, on days when backup Litholink samples are discarded because results have been received so the site knows the backup samples will not be needed. When you enter the ID and start date of the 24-hour urine collection, you are confirming that you are discarding all backup samples for that ID and date. It is expected that this form will be completed at least quarterly.

1. Clinical Center Number ..... ___ ___
   11=George Washington University (Site PI- Dominic Raj)
   21=Northwestern University School of Medicine (Site PIs - Myles Wolf, Tamara Isakova)
   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. Date samples discarded (mm/dd/yyyy) ..... __ __ /__ __ /__ __ __ __

3. Samples Discarded

ID	**Alpha Code**	**Start Date of Urine Collection (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__ __ __ __ __ __ __

Pilot Clinical Trials in CKD
Screening Form #106 - BASE

Form 106 is completed and key entered for each person who consents to the study.

☐☐☐☐☐☐	☐☐	☐☐☐☐☐☐☐☐	B
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)............ __ __/__ __/__ __ __ __

   b. Date this participant signed the consent form for the biosample repository? (mm/dd/yyyy) [Leave blank if patient did not consent for this]............ __ __/__ __/__ __ __ __

Age and Gender

6. Date of birth? (mm/dd/yyyy)............ __ __/__ __/__ __ __ __
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	5=White
2=Asian	6=More than one race
3=Native Hawaiian or Other Pacific Islander	9=Unknown or not reported
4=Black or African American	

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

Eligibility Items

The following must be answered "yes" in order for the participant to be eligible. (Respond 0=no, 1=yes.)

11. Does the Site PI confirm that this patient is medically stable?............ ___
12. Is the participant able to read in English?............ ___
13. Is the participant able to travel to study visits?............ ___
14. a. In the opinion of the site investigator, is the participant willing and able to follow the study treatment regimen and comply with the Site PI's recommendations?............ ___

    b. In the judgment of the site investigator, the participant's blood pressure medication regimen can be escalated (by adding a drug or increasing a dose) if the participant's blood pressure were uncontrolled?............ ___

    c. Participant has at least one ankle available to measure for edema?............ ___

The following must be answered "no" in order for the participant to be eligible. (Respond 0=no, 1=yes)

15. Self-reported vegetarian............ ___
16. Known left ventricular ejection fraction ≤ 30%?............ ___
17. Hospital admission for heart failure within the past 3 months............ ___

18. Does the participant have shortness of breath when walking on flat surfaces? (NYHA Class 3) ... ___
19. Does the participant have shortness of breath at rest? (NYHA Class 4) ... ___
20. Presence of indwelling urinary catheter or urinary conduit (such as neobladder or urostomy) ... ___
21. Factors judged to limit adherence to interventions (e.g., alcoholism, history of missing clinic visits, chronic gastrointestinal disorder that makes compliance with the interventions unreliable) ... ___
22. Organ transplant recipient *(cornea transplants are exempted)* ... ___
23. Anticipated initiation of dialysis or kidney transplantation within 12 months as assessed by and at the discretion of the Site PI? ... ___
24. Current participation in another clinical trial or other interventional research study? ... ___
25. Currently taking investigational drugs? ... ___
26. Institutionalized, prisoner, or currently residing in a nursing home or rehabilitation center? ... ___
27. Malignancy requiring therapy within the last 2 years? ... ___
    (non-melanoma skin cancer and localized prostate cancer are exempted)
28. Life expectancy < 12 months as determined by the Site PI? ... ___
29. Plans to leave the immediate area within 12 months? ... ___
30. Routinely leaves town for multiple weeks each year such that protocol visits would be missed? ... ___
31. Chronic use of supplemental oxygen? ... ___

Pregnancy-related questions *(skip to Q34 if male)*

32. Pregnant or planning to become pregnant or currently breastfeeding? (0=no, 1=yes) ... ___
33. a. Sex and childbearing potential status? ... ___
    1=Surgically sterilized (includes endometrial ablation)
    2=Post-menopausal
    3=Not surgically sterilized and not post-menopausal: "woman of childbearing potential"

    b. If Item 33a=3 (woman of childbearing potential), does the participant agree to use birth control? (0=no, 1=yes) ... ___

Numeric exclusions questions

34. How many urinary tract infections does the participant estimate he or she has had in the last year? (0=None, 1=One, 2=Two, 3=Three, 4=Four or more) ... ___
    (Note, for eligibility, must be 0 or 1)
35. Does the participant have active glomerular disease? ... ___
    0=No
    1=Yes and it requires treatment with immunosuppressives
    2=Yes but in the judgment of the PI it could potentially require immunosuppressives in the next 1 year
    3=Yes but in the judgment of the PI there is no potential for a future requirement of immunosuppressive therapy
    (Note, for eligibility, must be 0 or 3)
36. Currently taking immunosuppressive medications? ... ___
    0=None
    1=Yes, but currently stable on oral steroids ≤ 10 mg of prednisone/day or inhaled steroids
    2=Yes, taking an immunosuppressive other than prednisone (at any dose) or taking a dose of prednisone that is not stable or taking a dose of prednisone that is > 10 mg/day. (*Everyone who has received a solid organ transplant is expected to fall into this category. This is an exclusion.)*

    (Note, for eligibility, must be 0 or 1)

37. On the average, about how often does the participant take a medication or supplement containing sodium bicarbonate, such as alka seltzer or baking soda?..... ___
    0=Never
    1=Less than once a week
    2=About once a week
    3=About twice a week
    4=More than twice a week *[This is considered to be chronic use and is an exclusion.]*

38. Does the participant currently take any form of sodium citrate (Ex. Bicitra, Oracit or Citra)? ..... ___
    0=Never
    1=Less than once a week
    2=About once a week
    3=About twice a week
    4=More than twice a week *[This is considered to be chronic use and is an exclusion.]*

39. How often does the participant take a medication or supplement containing potassium citrate, such as Urocit-K? ..... ___
    0=Never
    1=Less than once a week
    2=About once a week
    3=About twice a week
    4=More than twice a week *[This is considered to be chronic use and is an exclusion.]*

40. How often does the participant take a medication or supplement primarily consisting of calcium carbonate, such as Tums? ..... ___
    0=Never
    1=Fewer than half of the days in a month
    2=About half of the days in a month
    3=More than half of the days in a month, but $\leq$ 1500 mg/day
    4=More than half of the days in a month and >1500 mg/day
    (Note, for eligibility, must be 0, 1, 2, or 3.)
    (If participant is currently taking but is willing to stop, rescreen after 30 days of no calcium carbonate.)

41. Number of medications with antihypertensive properties the participant is on? Be sure to include any diuretics. (Note, combination drugs such as ACEI+diuretic or ARB+diuretic, counts as 2 medications with antihypertensive properties.) (0=None, 1=One, 2=Two, 3=Three, 4=Four, etc.)..... ___

Participant Source (not for eligibility)

42. 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?
Participant is eligible (yes) OR
Participant is ineligible (no)

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

DCC Use Only: Date of participant consent (mm/dd/yyyy) __ __/__ __/__ __ __ __

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
Baseline Pill Dispensing Form #146 - BASE

- This form is completed at the B0 pill dispensing visit in the BASE study only.
- Participant is given a bottle of 100 capsules of BASE Study placebo medication and instructed to take 4 per day, 2 in the morning and 2 later in the day.
- Participant is instructed to bring in the pill bottle and remaining pills at B1 (target for B1 is two weeks after the B0 visit.).

								B																				**B**			

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

6. Intended visit number ..... B 0

7. Has the participant completed Form 283 Symptom Questionnaire? (0=no, 1=yes) ..... ___
(Note, Form 283 is required to be completed prior to taking placebo medications. If the participant cannot complete Form 283 today, do not give out the study medication.)

8. How many capsules were dispensed? 1 0 0

9. Bottle number ..... __ __ __ __ __

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
Baseline Pill Counting Form #147 - BASE

BASE Study placebo medication pills are dispensed at B0. This form is completed when the pills are counted at B1. If the participant does not bring back pills to count at B1, do not complete this form. Instead, have the participant come back in a day or so and count their pills. This will be their B1 pill count. If the participant does not meet compliance at B1, give the bottle back to the participant with the remaining pills, dispense an additional bottle of pills if needed, and have the participant return for a pill count at B2.

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

6. Visit Number Intended .... B ___
(B1 is expected)

7.	Study Medication	Placebo
a.	Were any pills lost or ruined (0=no, all is well; 1=yes. This type of pill will not be counted. Skip to Item 8.)	—
b.	Were the pills counted? (0=no, 1=yes)	—
c.	# days between visits (calculated and displayed)	__ __
d.	# pills at end of previous visit	— — —
e.	# pills should have taken (days between visits times prescribed # of pills per day as participant leaves this visit)	— — —
f.	Pill Count (# pills returned)	— — —
g.	# pills taken (#of pills at end of previous visit minus # of pills returned)	— — —
h.	Adherence (Percent taken (#taken divided by #should have taken times 100%))	— — — . —
i.	Were returned pills re-dispensed? (0=no, 1=yes)	—
j.	Prescribed # of pills per day as participant leaves this visit	4 per day

8. a. Was a new bottle of capsules dispensed? (0=no, 1=yes) .... ___
   b. If yes, bottle number .... ___ ___ ___ ___ ___
   c. Number of pills in bottle 100

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
Baseline Pre-Randomization Dropout Form # 162 - BASE

Instructions: This form is completed when it is determined that a participant who appeared to be eligible based on the Screening Form 106 becomes ineligible prior to being randomized. (If the participant starts dialysis or is transplanted prior to randomization, complete Form 550-Initiation of Dialysis or Transplant. If pregnancy reported after screening, complete Form 551-Post-Screening Pregnancy Reported instead of this form. If the participant expires prior to randomization, complete the Death Notification Form 531 instead of this form.)

☐☐☐☐☐☐	☐☐	☐☐☐☐☐☐☐☐	**B**
1. Identification Number	2. Alphacode	3a. Pre-Randomized Dropout Date (mm/dd/yyyy)	3b. Study

Reason(s) Participant Not Randomized *(see list of possible reasons below)*

4. Primary reason this participant was not randomized.. ___ ___

5. Secondary reason this participant was not randomized (if applicable) .... ___ ___

<u>BP</u>
1=BP target of 160/100 could not achieved prior to the end of baseline

<u>Timing-related codes</u>
5=More than 4 weeks from Screening Visit to Baseline 0 visit
6=More than twelve weeks (84 days) from Baseline Visit 0 to randomization

<u>Lab-related codes</u>
10=Serum bicarbonate between 20-28 mEq/L could not be achieved prior to end of baseline (based on average of two most recent serum bicarb measures)
11=Serum potassium between 3.5 and 5.4 mEq/L could not be achieved prior to end of baseline

15=GFR too low
16=GFR too high (greater than 59.9)
17=GFR too high without albuminuria (GFR 45.0 to 59.9 with no albuminuria)

<u>Compliance-related codes</u>
20=Did not attend a minimum of two baseline visits
21=Decided to start or continue being vegetarian
22=Did not attend baseline visits 1 and 2
23=Did not provide at least 1 of the 3 baseline GI symptom questionnaires
24=Did not provide at least 1 of the 3 baseline non-GI symptoms forms
25=Did not meet the "mean pill count across both meds greater than 79.5%" criterion based on at least 7 days of taking prescribed pills
26=Did not do a baseline 24-hour urine collection

<u>Medication-related codes</u>
30=Detection of/or initiation of treatment with five or more antihypertensive medications
31=Detection of/or initiation of treatment with daily oral akali use (other than calcium carbonate <1500 mg for bone health)
32=Treated for >2 UTIs in the past year
33=Detection of/or initiation of new immunosuppressive medications during baseline (stable oral steroids < 10 mg of prednisone/day or inhaled steroids are allowed)
34=Extention of immunosuppressive medications during baseline (stable oral steroids < 10 mg of prednisone/day or inhaled steroids are allowed)
35=Detection of/or initiation of new ACEI or ARB medication such that both antihypertensive drugs are being used simulateously during baseline
36=Detection of/or initiation of supplemental oxygen prior to randomization

Other Participant characteristics or events
40=Age less than 18 prior to randomization
41=Unable to read English
42=Detection of gastrointestinal disorder prior to randomization that makes compliance with the intervention unreliable
43=Detection of/or surgery for indwelling urinary catheter or urinary conduit
44=Demonstration of missing visits

50=Active liver disease identified during baseline
51=Significant malabsorption identified during baseline
52=Life expectancy determined to be < 12 months during baseline
53=Lean Body Weight determined to be too low
54=Other exclusion criterion identified during baseline

60=Significant alcohol or substance abuse detected during baseline
61=Participant is now or will soon be incarcerated
62=Participant is now or will soon be otherwise institutionalized (chronic care hospital/skilled nursing facility)
63=Participant was lost during baseline; team can no longer locate this participant
64=Participant will not be at this center/site a sufficient amount of time during the next 12 months (Study team detected baseline that he is moving or taking a long vacation such that he will miss protocol visits)

Other conflicting research
70=Participant is now or will soon be participating in another intervention study
71=Participant is now or will soon be taking investigational drugs

Related to judgments or preference
80=Participant has changed his mind and does not want to be randomized, especially because he does not like collecting urine
81=Participant has changed his mind and does not want to be randomized; finds the protocol as a whole to be burdensome
82=Participant has changed his mind and does not want to be randomized; other reason
83=Family/significant other(s) have expressed disapproval of participant joining the study/following study protocol requirements to the extent that team expects protocol requirements will not be met
84=Participants physician has expressed disapproval of participant joining the study/following study protocol requirements to the extent that team expects protocol requirements will not be met
85=Judgment of team is that this participant would not be adherent to the study protocol requirements
86=Study team preference – some other reason

Codes to save for later: 90=Center/site no longer randomizing participants

If a new reason is identified, notify the DCC via e-mail at ckd_dcc@bio.ri.ccf.org and a new code will be added.

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/Phone Visit Form # 202 - BASE

This form should be completed at:

Protocol visits (Screening, all Baseline visits, W4, W8, W12, W16 (phone), W20, W24 (phone), W28 and W32) or missed protocol visits. (Note, Protocol v1.1 table 1.8 needs updated)
Extra visits done for safety or side effects
Extra visits where the team heard about a hospitalization or other SAE
Extra visits where the team measures blood pressure

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

6. a. Visit Number Intended..... ___ ___ ___
Screening (S) visit 0, Baseline (B) Visits 0, 1, 2, 3, 4,
Week (W) visits 0, 4, 8, 12, 16 (phone), 20, 24 (phone) 28, 32
Code 99 for extra or intended non -protocol visits.

b. Status of visit ..... ___ ___
0=Visit data not collected before the start of the next visit's window/missed
1=Visit held /visit data collected before start of next window
99=This is an extra/non-protocol visit

c. Type of visit (1=Done in person, 2=Done by telephone interview) ..... ___

d. Reason for visit ..... ___
1=Protocol visit/phone visit; 2=Initiated by participant due to side effects, 3=Initiated by participant for some other reason; 4=Initiated by study team in order to draw safety labs; 5=Initiated by study team to encourage compliance (for example, extra adherence phone visits); 6=Initiated by study team for some other reason

7. Has the participant had an SAE (hospitalization, death, other) since the last visit?..... ___
0=No [or this is the first visit form]; 1=Yes, a hospitalization (complete F511/512-Hospitalization Forms)
2=Yes, another SAE (complete F522-Details of SAEs, Not Hosp or Death Form), 3=Both (complete F511/112-Hospitalization Forms and F522-Details of SAEs, Not Hosp or Death Form)

8. Is the study team or another physician attempting to change serum potassium level?..... ___
0=No action taken; 1=Participant counseled to restrict potassium; 2=Participant advised to increase potassium; 3=Potassium supplements are being prescribed; 4=Potassium supplement dose increased 5=Both 2 and (3 or 4); 6=Potassium supplement reduced; 7=Potassium supplement discontinued; 8=Not applicable, this is Screening or B0; 9=Diuretic dose decreased

Ask the participant:

9. "How often did you take your study medication?"..... ___
0=Not at all, 1=Irregularly, 2=Regularly (in every intended instance or almost every intended instance);
Other responses: 8=Not Applicable – No study med prescribed for the time period before this visit, 9=Unknown/coordinator forgot to ask/participant refused to answer.

10. Did you measure and note the value of your blood pressure since your last study visit?..... ___
0=No [or this visit is the first visit form]; 1=Yes, home; 2=Yes, some other location; 3=Yes, both home and some other location

For those who have measured blood pressure at home and noted value since last visit

11. Approximate blood pressure observed most recently (systolic/diastolic) (mmHg) ... __ __ __/__ __ __

For those who have measured blood pressure at some other location since last visit

12. Approximate blood pressure observed most recently (systolic/diastolic) (mmHg) ... __ __ __/__ __ __

(If this was a phone visit, skip to item 111.)

For all Screening and Baseline visits

13. If a participant's ACEI/ARB regimen has been optimized to a tolerable dose up to the maximum recommended dose, the regimen follows good medical practice and the participant's ACEI/ARB dose will be unlikely to change during follow-up. In the judgment of the site PI, has the participant's ACEI/ARB dose been optimized to a tolerable dose up to the maximum recommended dose? ..... ___

0=No, not yet
1=On ACEI and dose is optimized
2=On ARB and dose is optimized
3=On ACEI and ARB both (Per protocol, this is not considered to be optimal therapy.)
4=On neither ACEI nor ARB because these drugs are not indicated (e.g., bp, albuminuria and cardiac status are good without ACE or ARB)
5=On neither ACEI nor ARB because of intolerance, allergies or contraindications
(Note, must be 1, 2, 4 or 5 at the last baseline visit in order for the participant to be randomized.)

Measured once at Screening or before B0

100. Height (cm) (measured)..... __ __ __ . __

For all Protocol In-Person visits

101. Weight (kg) (measured) ..... __ __ __ . __

Lean body weight (LBW) (kg) will display on screen: __ __ __ . __
(Note for eligibility, LBW must be 37.5 to 96.0 kg at screening.)

Before measuring blood pressure, let the participant sit quietly for 5 minutes. Wait one minute between measures.

102. Blood Pressure 1 (systolic/diastolic) (mmHg) ..... __ __ __/__ __ __

103. Blood Pressure 2 (systolic/diastolic) (mmHg) ..... __ __ __/__ __ __

104. Blood Pressure 3 (systolic/diastolic) (mmHg) ..... __ __ __/__ __ __

Visit blood pressure (mean of measures 2 and 3) will display on screen: __ __ __/__ __ __

Note for Screening eligibility, blood pressure must be <160/100 mm Hg.
Note for Randomization eligibility, blood pressure must be <150/100 mm Hg.

105. Pulse (beats per minute)..... __ __ __
(If the BP device measures pulse with each BP, report the pulse that is measured with the 3rd BP reading.)

106. Username of person measuring blood pressure and pulse ..... __ __ __ __ __ __ __

107. BASE team medication response to BP measurement (per Protocol section 3.2) ..... ___
1=No changes being made/No response required. BP is under 150/100
2=No changes planned for right now but BP is >150/100
3=The participant is being counseled regarding antihypertensive medication compliance
4=Antihypertensive medication changes are being prescribed at this visit. (Please document medication changes on Form 213.)
5=Antihypertensive medication changes are planned for the future.

108. BASE team lifestyle change response to BP measurement (per Protocol section 3.2)..... ___
1=No changes being made/No response required. BP is under 150/100
2=No changes planned for right now but BP is >150/100
3=The participant is being counseled regarding compliance to lifestyle changes previously recommended
4=New lifestyle changes (for example, dietary salt) are being recommended at this visit. (Please document these in the participant chart.)
5=Lifestyle change recommendations are planned for the future

Edema (Note, if there is a ≥ 10% increase in total ankle circumference from baseline, the participant cannot be uptitrated.)

109. a. Ankle circumference - right (cm) ..... __ __ __ . __

c. Was this measurement taken with the compression stocking on (0=no, 1=yes)..... ___

110. a. Ankle circumference - left (cm)..... __ __ __ . __

c. Was this measurement taken with the compression stocking on (0=no, 1=yes)..... ___

For Phone Visits Only:

111. Ask participant about swelling:..... ___
1=Participant reports no swelling
2=Participant reports swelling but less than last visit
3=Participant reports swelling similar to last visit
4=Participant reports more swelling than last visit

Complete this section of the form for participants who had to reduce or half study medications but the BASE physician feels the participant may now be able to go back up to full dose

112. a. Was the possibility of going back up to full dose on BASE study medication discussed with the participant? (0=No, 1=Yes, by a BASE physician, 2=Yes, by a coordinator)..... ___

b. If Item 112a=yes, what was the participant's response? ..... ___
0=Participant will not go back up to full dose of study meds, 1=Participant will go back up to full dose

Complete this section of the form for participants who had to discontinue study medications but the BASE physician feels the participant may now be able to restart

113. a. Was the possibility of going back on BASE study medication discussed with the participant? (0=No, 1=Yes, by a BASE physician, 2=Yes, by a coordinator)..... ___

b. If Item 113a=yes, what was the participant's response? ..... ___
0=Participant will not restart study meds, 1=Participant will restart at half randomized dose, 2=Participant will restart at full dose

Checking the status of the staff blind (W28 only)

Study Coordinator completing/reviewing completeness of this form:

120. Do you know what this participant's capsule contained*?.....___
1=I am sure it is bicarbonate, 2=I think it is most likely bicarbonate, 3=I do not know,
4=I think it is mosly likely not bicarbonate, 5=I am sure it is not bicarbonate

*Base your judgement on the last time capsules were given to the participant.
If the participant never received a single capsule, notify the DCC.

Site PI:

130. CKD username ..... __ __ __ __ __ __ __

131. Do you know what this participant's capsule contained*?.....___
1=I am sure it is bicarbonate, 2=I think it is most likely bicarbonate, 3=I do not know,
4=I think it is mosly likely not bicarbonate, 5=I am sure it is not bicarbonate

*Base your judgement on the last time capsules were given to the participant.
If the participant never received a single capsule, notify the DCC.

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 Form # 213 - BASE

This form is completed at Screening, and all Baseline and Follow-Up visits, including the W16 and W24 telephone visits. (Note, Protocol version 1.1 Table 1.8 needs to be updated.)

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. Was the participant prescribed a change in the overall strength of ACEI/ARB medications at this visit or any time since the last BASE visit? ..... ___
   0=Takes neither ACEI nor ARB (use this code at each visit where the participant is not on ACEI/ARB)
   [Code 4 the first time dose of ACEI/ARB regimen is reduced to zero/stopped]
   1=Overall strength of ACEI/ARB regimen was reduced
   2=Strength of ACEI/ARB regimen remained the same
   3=Overall strength of ACEI/ARB regimen was increased

   Note, if Q6 shows any change during Baseline, measure serum potassium after 7 days of the change.

7. Was the participant prescribed a change in the overall strength of diuretic medications at this visit or any time since the last BASE visit? ..... ___
   0=Takes no diuretics (use this code at each visit where the participant is not on a diuretic)
   [Code 4 the first time dose of diuretic regimen is reduced to zero/stopped]
   1=Overall strength of diuretic regimen was reduced
   2=Strength of diuretic regimen remained the same
   3=Overall strength of diuretic regimen was increased

   Note, if Q7 shows any change during Baseline, measure serum potassium after 7 days of the change.

8. Was the participant prescribed a change in the overall strength of their antihypertensive medication regimen in general at this visit or any time since the last BASE visit (this includes ACEI/ARB, diuretics and other medications with antihypertensive properties)?..... ___
   0=Takes no antihypertensives (use this code at each visit where the participant is not on an antihypertensive)
   [Code 4 the first time dose of antihypertensive regimen is reduced to zero/stopped]
   1=Overall strength of antihypertensive regimen was reduced
   2=Strength of antihypertensive regimen remained the same
   3=Overall strength of antihypertensive strength was increased

If this is the first Form 213 entered for the participant, the cursor will skip to Q12.

9. How often since the last BASE visit did the participant take a medication (antacids like Tums) or supplement containing calcium carbonate? ..... ___
   0=Never
   1=Fewer than half of the days since the last visit
   2=About half of the days since the last visit
   3=More than half of the days since the last visit, but ≤ 1500 mg/day
   4=More than half of the days since the last visit and > 1500 mg/day
   Note, if Q9=4 during Baseline, this is an exclusion.

10. How often since the last BASE visit did the participant take a medication (such as Alka Seltzer) or supplement containing sodium bicarbonate? ..... ___
    0=Never
    1=Fewer than half of the days since the last visit
    2=About half of the days since the last visit
    3=More than half of the days since the last visit

11. How often since the last BASE visit did the participant take a potassium supplement? ..... ___
    0=Never
    1=Fewer than half of the days since the last visit
    2=About half of the days since the last visit
    3=More than half of the days since the last visit

12. Was the participant prescribed or recommended (or did the participant report) a change in the overall strength of his or her proton-pump inhibitor (PPI) and/or H_2 blocker regimen? ..... ___
    0=No, does not take PPI or H_2 blocker
    1=Taking PPI or H_2 blocker but dose has not changed
    2=Newly prescribed or recommended
    3=Overall strength has increased
    4=Overall strength has decreased

For item 13, Record all prescribed or over the counter medications or supplements that the participant has been prescribed or reports taking now. Include those listed above. This is a snapshot of today, but if the participant missed a medication that they normally take on this day, that medication should still be recorded. **BASE Med Categories** are: 1=ACEI, 2=ARB, 3=Diuretic, 4=Other medication with antihypertensive properties, 5=Medication or supplement primarily containing calcium carbonate; 6=Medication or supplement containing sodium bicarbonate, 7=Potassium Supplement, 8=PPI or H_2 Blocker, 9=All others

13.

BASE Med Category	**Medication Brand or Generic Name** (will be validated against WHODrug, and WHODrug code will be stored in the database)
___	
___	
___	
___	
___	
___	
___	
___	

Use an extra sheet if necessary. You will be able to key enter as many medications as needed.

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
Follow Up Initial Pill Dispensing Form # 230 - BASE

This form is completed when the participant is given follow up pills for the first time.

For Initial Pill Dispensing, each BASE participant is to receive the BASE Low Dose, regardless of his or her randomized group.

								W																**B**

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

6. Visit number Intended..... W 0

   Visit W4 target date is 28 days. Recommended range is 21 to 35 days.

7. Number of pills prescribed per day..... ___
   Should match the "Initial Follow-up Prescription (.5 mEq Dose for All)".
   This will be between 2 and 4.

8. Bottle numbers dispensed (100 capsules are in each bottle)
   a. First bottle ..... __ __ __ __ __
   b. Second bottle (if needed) ..... __ __ __ __ __
   c. Third bottle number (if needed)..... __ __ __ __ __

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
Follow-Up Pill Dispensing and Counting Form # 231 - BASE

This form is completed at W4, W8, W12, W20 and W28. If a participant comes in before the end of the visit window with no pills, ask the participant to bring the pills before the visit window ends. Do not complete this form unless either pills were counted or the visit window has ended. ***The participant's own returned pills should be re-dispensed at any follow-up visit.***

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

6. Visit Number Intended..... _W_ ___ ___
BASE Follow-Up (W) Visits 4, 8, 12, 20, 28. Code 99 for extra/non -protocol visits.

R1 LBW = ### kg, Participant's Randomized Dose Level = *(.5 or .8)* mEq/day, Protocol Prescription = # capsules/day

7. Study Medication	
a. Were any pills lost or ruined or otherwise unavailable?*	__
b. Were the pills counted (0=no, 1=yes)	__
c. # days between visits (calculated and displayed)	__ __
d. # pills at end of previous visit	__ __ __
e. Prescribed # of pills per day at end of last visit	__
f. # pills should have taken (c times e)	__ __ __
g. Pill Count (# pills returned)	__ __ __
h. # pills taken (d minus g)	__ __ __
i. Adherence [Percent taken (h/f times 100%)]	__ __ __.__
j. # "returned" pills redispensed	__ __ __
k. Number of new pills dispensed (will be either 0, 100, 200, 300, or 400)	__ __ __
l. Prescription type? **	__
m. Prescribed # of pills **per day** as participant leaves this visit	__

*Codes for "any pills lost or ruined?" 0=no, all is well; 1=yes. (If any lost or ruined, don't count. Skip to Item 9.)

** Codes for "Prescription type? 1=0.5/day per protocol, 2=0.8/day per protocol, 3=Reduced/halved for symptom or lab AE, 4=Discontinued for symptom or lab AE (complete Form 572), 6=Discontinued due to local physician judgment, 8=Reduced/halved for anticipated participant non-compliance or protocol non-adherence, 9=Discontinued for anticipated participant non-compliance or protocol non-adherence, 0=Prescription discontinuation required per protocol (for end of study. Also includes Jan 2017 discontinuations after Week 26)

8. Regarding "Prescription type," which AE(s) lead to prescription adjustment? .....__ __, __ __ , __ __

0=Not adjusted or discontinued	5=Diastolic ≥ 110 once/Form 202	9=GI symptoms on Form 283
1=Bicarb ≥ 33 once	6=Diastolic ≥ 110 twice/Form 202	10=Up titration per protocol
2=Bicarb ≥ 33 twice	7=Potassium ≤ 2.9	11=Cardiac symptoms on Form 283
3=Systolic ≥ 170 once/Form 202	8=Weight gain due to fluid retention	12=Urinary symptoms on Form 283
4=Systolic ≥ 170 twice/Form 202		

(Notify DCC if another code is needed)

9. If item 7k shows new pills were dispensed:..... Bottle #1 __ __ __ __ __..... Bottle #2 __ __ __ __ __
Bottle #3 __ __ __ __ __..... Bottle #4 __ __ __ __ __

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
Between Visit Phone Medication Change Form # 251 – BASE

This form is completed during Follow-up when a prescription changes during a telephone call between visits and no visit form is completed.

Note that if this form is completed, the next pill count will not be used to estimate compliance since it cannot be accurately calculated.

1. Identification Number	2. Alphacode	3a.Visit Type	3b. Visit Number (Month)	3b. Visit Number (Week)	4. Date pill prescription changed (mm/dd/yyyy)	5. Study
		W				B

	Study Medication Type	
6.	Prescription type? ***	___
7.	Prescribed # of pills **per day**	___

*** Codes for "Prescription type? 1=0.5/day, 2=0.8/day, 3=Reduced/halved for symptom or lab AE, 4=Discontinued for symptom or lab AE (complete Form 572), 6=Discontinued due to local physician judgment, 8=Reduced/halved for anticipated participant non-compliance or protocol non-adherence, 9=Discontinued for anticipated participant non-compliance or protocol non-adherence, 0=Prescription discontinuation required per protocol (for end of study. Also includes Jan 2017 discontinuations after Week 26)

8. Regarding "Prescription type," which AE(s) lead to prescription adjustment?.....__ __, __ __ , __ __

0=No AE
1=Bicarb ≥ 33 once
2=Bicarb ≥ 33 twice
3=Systolic ≥ 170 once/Form 202
4=Systolic ≥ 170 twice/Form 202
5=Diastolic ≥ 110 once/Form 202
6=Diastolic ≥ 110 twice/Form 202
7=Potassium ≤ 2.9
8=Weight gain due to fluid retention
9=GI symptoms on Form 284
10=Up titration per protocol
11=Cardiac symptoms on Form 284
12=Urinary symptoms on Form 284

(Notify DCC if another code is needed)

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
GI Symptoms and Other AE's Form #283 – BASE

This form is completed twice before randomization, once prior to taking the placebo and again after taking the placebo. In Follow-Up, this form is complete at every protocol visit.

																								B	

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

6. Visit Number Intended ..... ___ ___ ___
   BASE study visits: Baseline (B) Visits 0, 1
   Follow-Up (W) Visits 0, 4, 8, 12, 20, 28, 32
   Code 99 for extra or 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 him if he could complete it. It is important for the participant's safety that we know if he/she is having GI symptoms.

If there is a question the participant will not answer even with prompting, code the question as a '9' on the database screen.

Both baseline measures are required for randomization.

Short form 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=10013084; abdominal pain upper=10000087*]	0	1	2	3
9.	Have you been bothered by NAUSEA during the Past week? (By nausea, we mean a feeling of wanting to throw up or vomit.) [*Nauseated alone=10048364, nauseated=10028822*]	0	1	2	3
10.	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.) *[abdominal bloating=10048746]*	0	1	2	3
11.	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.) *[burping=10006804]*	0	1	2	3
12.	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.) *[flatus=10016769]*	0	1	2	3

Non-GI Symptoms

Explicitly ask the participant if he or she has/had any of these non-GI symptoms.

13. Do you feel swollen? ..... ___
    0=No, not at all
    1=Yes, but less than at the last BASE visit
    2=Yes, but the same as the last BASE visit
    3=Yes, but more than at the last BASE visit
    9=Unknown/not asked

14. Do you feel your weight has changed since your last Form 283 was completed? ..... ___
    1=No, weight has stayed the same; 2=Yes, lost weight; 3=Yes, gained weight; 8=not applicable, this is the first Form 283; 9=Unknown/not asked

For Items 15-22, BASE 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.)

15. Headache (10019211) ..... ___
16. Backache (10003993) ..... ___
17. Common cold (10010106)..... ___
18. Have you felt dizzy? (10013580) ..... ___
19. Loss of energy, feeling run down, fatigued (10024862)..... ___
20. Drowsy, sleepy, can't stay awake (10041018) ..... ___
21. Insomnia, can't sleep (10022437) ..... ___
22. 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 Form # 284 – BASE

If a participant brings up a symptom or an adverse event during a phone call with a BASE 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.

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

6. Visit Number Intended ..... F 8 4

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

Short form 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=10013084; abdominal pain upper=10000087*]	0	1	2	3
9.	Have you been bothered by NAUSEA during the Past week? (By nausea, we mean a feeling of wanting to throw up or vomit.) [*Nauseated alone=10048364, nauseated=10028822*]	0	1	2	3
10.	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.) *[abdominal bloating=10048746]*	0	1	2	3
11.	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.) *[burping=10006804]*	0	1	2	3
12.	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.) *[flatus=10016769]*	0	1	2	3

Non-GI Symptoms

Explicitly ask the participant if he or she has/had any of these non-GI symptoms.

13. Do you feel swollen? ..... ___
    0=No, not at all
    1=Yes, but less than at the last BASE visit
    2=Yes, but the same as the last BASE visit
    3=Yes, but more than at the last BASE visit
    9=Unknown/not asked

14. Do you feel your weight has changed since your last Symptoms Form was completed? ..... ___
    1=No, weight has stayed the same; 2=Yes, lost weight; 3=Yes, gained weight; 8=not applicable, this is the first time symptoms are recorded; 9=Unknown/not asked

For Items 15-22, BASE 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.)

15. Headache (10019211) ..... ___
16. Backache (10003993) ..... ___
17. Common cold (10010106)..... ___
18. Have you felt dizzy? (10013580) ..... ___
19. Loss of energy, feeling run down, fatigued (10024862)..... ___
20. Drowsy, sleepy, can't stay awake (10041018) ..... ___
21. Insomnia, can't sleep (10022437) ..... ___
22. 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
Participant End of Study Questionnaire # 288 - BASE

This form is completed once at the end of the study (W28).

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

6. How were the questions of this form answered? .... ___
(1=Self-administered, 2=Interview-administered in person, 3=Interview-administered by telephone)

This form will capture "Your opinion on BASE study activities." Participants will be asked to rate study procedures on a scale from 1=very difficult to 5=very easy, using a scale like this.

Very Difficult — Very Easy

1 ……………………...……2…………..……..……………3……..………..…………4…………………..…………5

7. What was your opinion regarding taking the capsules? .... ___
8. What was your opinion regarding the 24 hour urine collections? .... ___
9. What was your opinion regarding the frequency of visits? .... ___

Checking the status of the participant blind (W28 only)

10. Participant: Do you know what is in your study capsule? .... ___
1=I am sure it is bicarbonate, 2=I think it is most likely bicarbonate, 3=I do not know,
4=I think it is most likely not bicarbonate, 5=I am sure it is not bicarbonate

Very Unlikely — Very Likely

1 ……………………...……2…………..……..……………3……..………..…………4…………………..…………5

11. Using the scale above, how likely would you be to enroll in a 2- to 3-year study similar to the BASE Study? .... ___

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
Biorepository Serum and Plasma Mailing Form # 302 - BASE

Biorepository Contact Information

Address: Fisher BioServices
Attn: Lab Manager
NIDDK Repository
20301 Century Blvd.
Building 6, Suite 400
Germantown, MD 20874

Email: **Bio-NIDDKRepository@thermofisher.com**

Phone: (240) 686-4747 (Niveen Mulholland)
Phone (240) 686-4702 (Sandra Ke)
Fax: (301) 515-4049

Serum and plasma biorepository samples are collected prior to randomization, W12 and W28. You will need to complete a separate Form 302 for each participant in the shipment. Ship BASE samples only to the address above in the mailer provided. Ship tubes on a cold pack provided in the kit. Ship only on Mondays through Thursdays and notify the biorepository of shipments via e-mail* or by facsimile on the day the package is picked up by FedEx. Refer to the MOP Chapter 34 for details on how to process tubes for shipment. ***Do not ship on Fridays*. Enclose this original form in the mailer**. Keep a copy of this form. *Enter items 1 to 9 only into the CKD Trials database.*

*Send an email shipment notification to *Bio-NIDDKRepository@thermofisher.com* on the day the package is picked up by FedEx. Include the 12-digit FedEx tracking number, study name and your contact information in the notification.

B			-																					B
1a.Site Number				1b. Patient Identification #							2. Alphacode		3a.Visit Type	3b. Visit Number (Month)		3b. Visit Number (Week)		4. Date blood collected (mm/dd/yyyy)							5a. Study

5. b. Visit number intended ..... ___ ___ ___
Collection visits are once in Baseline (B) and visit weeks W12, W28. Code 99 for extra/non-protocol visits.

6. Time of blood draw (24-hour clock) (hh:mm) ..... __ __: __ __

Serum

	DCC Use *# unusable?*
7. Number of 4.0 mL SST tubes (serum) (gold top) sent to Biorepository ..... ___ *(1 tube is expected)*	___

Plasma

	DCC Use *# unusable?*
8. Number of 4.5 mL PST tubes (plasma) (light green top) sent to Biorepository .___ *(1 tube is expected)*	___

9. Date shipped to Biorepository (mm/dd/yyyy) ..... __ __/__ __/__ __ __ __

Continued on next page.

Contact Information*: (note: Items 10a-d are required by NIDDK Repository at Fisher but not entered into the database.)*

10. a. Name of Contact: _____

    b. Telephone number:..... __ __ __/__ __ __-__ __ __ __

    c. E-mail address: _____

    d. Name of CKD Clinical Center: ..... _____

Items contained in the boxes below are for individual center use only. They will not be entered into the database.

BioRepository notified via Email ____ Fax ____	Notified by:	Date of Notification:	Time: __ __ : __ __
Fed Ex Tracking #: _____		__ __ / __ __/ __ __ __ __ (mm/dd/yyyy)	(24-hour clock) (hh:mm)

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 __ __ __ __ __ __ __

Section B: To be completed by the Biorepository at Fisher

Completed by _____ Date of Receipt (mm/dd/yyyy) __ __/ __ __/ __ __ __ __

Do the PID's on this form correspond with the PID's on the shipping tube labels?.....Yes __ No __

Were the samples usable? (If completely unusable or just slightly unusable because it is hemolyzed, notify DCC at ckd_dcc@bio.ri.ccf.org)

Pilot Clinical Trials in CKD
Biorepository Random (Spot) Urine Mailing Form #303 - BASE

Biorepository Contact Information

Address: Fisher BioServices
Attn: Lab Manager
NIDDK Repository
20301 Century Blvd.
Building 6, Suite 400
Germantown, MD 20874

Email: **Bio-NIDDKRepository@thermofisher.com**

Phone: (240) 686-4747 (Niveen Mulholland)
Phone (240) 686-4702 (Sandra Ke)
Fax: (301) 515-4049

A random (spot) urine biorepository sample should be collected prior to randomization, W12 and W28. Complete a separate Form 303 for each participant in the shipment. Ship BASE sample only to the address above in the mailer provided. Ship urine cup on the cold pack provided in the kit. Ship only on Mondays through Thursdays and notify the repository of shipments by e-mail* or by facsimile on the day the package is picked up by FedEx. Refer to Chapter 34 for details on how to process urine cup for shipment. **Do not ship on Fridays**. Enclose this original form in the mailer. Keep a copy of this form. Enter items 1 to 8 into the Pilot Clinical Trials in CKD database.

*Send an email shipment notification to *Bio-NIDDKRepository@thermofisher.com* on the day the package is picked up by FedEx. Include the 12-digit FedEx tracking number, study name and your contact information in the notification.

Section A: To be completed at the CKD BASE Study site:

B			-																					B
1a.Site Number				1b. Patient Identification #						2. Alphacode		3a.Visit Type	3b. Visit Number (Month)		3b. Visit Number (Week)		4. Date spot urine collected (mm/dd/yyyy)							5a. Study

5. b. Visit number intended ..... ___ ___ ___
Collection visits are once in Baseline (B) and visit weeks W12, W28. Code 99 for extra/non-protocol visits.

Random (Spot) Urine Collection

6. Time urine collected (24-hour clock) (hh:mm)..... __ __:__ __

DCC Use
unusable?

7. Number of urine cups sent to Biorepository (1 is expected)..... ___ | ___
(a minimum of 20 mls of urine is requested)

8. Date shipped to Biorepository (mm/dd/yyyy) .....__ __/__ __/__ __ __ __

Continued on next page.

Contact Information*: (note: Items 11a-d are required by Biorepository at Fisher but not entered into the database.)*

9. a. Name of Contact: _____

   b. Telephone number: ..... __ __ __/__ __ __-__ __ __ __

   c. E-mail address:_____

   d. Name of CKD Clinical Center:....._____

Items contained in the boxes below are for individual center use only. They will not be entered into the database.

Biorepository notified via Email ____ Fax ____	Notified by:	Date of Notification:	Time:
Fed Ex Tracking #: _____		__ __ / __ __/ __ __ __ __ (mm/dd/yyyy)	__ __ : __ __ (24 hour clock) (hh:mm)

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 __ __ __ __ __ __ __ __

Section B: To be completed by the Biorepository at Fisher

Completed by _____ Date of Receipt (mm/dd/yyyy)...__ __/ __ __ __/ __ __ __ __

Do the PID's on this form correspond with the PID's on the tubes' labels?..... Yes __ No __

Were the samples usable? (If completely unusable), notify DCC at ckd_dcc@bio.ri.ccf.org)

Pilot Clinical Trials in CKD
Litholink 24-Hr Urine Mailing Form #326 - BASE

24-hour urine is collected at B1, W12, W28. All attempted collections should be sent to Litholink. If a baseline collection is <20 or >28 hours, a repeat collection is required. Complete this form when either 1) the participant brings in urine or 2) the visit window has ended and urine was not collected. A copy of this form should be sent to Litholink along with the tube(s). This original form should be kept in the participant binder. Save two 20-ml back-up tubes from each jug, label them, and freeze locally at -20° C until you receive a report that the urine has been analyzed at Litholink.

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

6. Visit Number Intended .... ___ ___ ___
   Baseline (B) visits are B1. Follow-Up Visits are at W12 and W28. Code 99 for extra/non -protocol visits.
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. Was the preservative observed to be in the urine container by BASE staff? .... ___
   0=No, 1=Yes, per protocol, one open vial and its cap were seen in the jug; 2=Other (e.g., only an open vial, only a lid, a closed vial)
10. Participant report on vial .... ___
    0=Not added, 1=Yes, added to jug prior at start of collecton, 2=Vial added to jug later
11. 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. If not complete at Baseline, an additional collection is required.
12. Start time of urine collection (24-hour clock) (hh:mm) .... __ __ : __ __
13. a. End date of urine collection (mm/dd/yyyy) .... __ __/__ __ /__ __ __ __
    b. End time of urine collection (24-hour clock) (hh:mm) .... __ __ : __ __

    Total number of hours collected (Duration must be between 20-28 hours) __ __.__ __

    *** If Baseline collection duration is < 20 or > 28 hours, an additional collection is required.***
14. a. Estimated volume of the 24-hour urine collection to the nearest 100 mls (ml) .... __ __ __ __
    b. Estimated volume of additional urine (second jug) collected to the nearest 100 mls (ml) __ __ __ __
15. a. Weight of the 24-hr urine collection jug (g) .... __ __ __ __
    b. Weight of the second 24-hr urine collection jug (g) .... __ __ __ __

    Volume of the urine based on weight, assuming 1 g = 1 ml ________________ml

    This is the recorded weight above minus the weight of the (jug+lid+preservative)
16. Number of 50 ml (green top) tubes sent (submit one from each jug, filled to at least 40 ml) .... ___
17. Number of back-up tubes frozen locally (save two 20 ml tubes filled to at least 10 ml for each jug) .... ___
18. Date shipped to Litholink (mm/dd/yyyy) .... ___ ___/___ ___/___ ___ ___ ___

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
Local Lab Serum Results Form #351 - BASE

This form is completed routinely at Screening (S) Visit 0, Baseline (B) Visits 0, 1, and Follow-Up Visit at Weeks (W) 4, 8, 12, 20, 28, 32 and it is completed whenever serum bicarbonate or serum potassium needs to be rechecked.

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 351 documented with that date.

Note: Screening labs must be done at the screening visit or no more than 2 calendar months prior to the screening visit.

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
						B

6. a. Visit Number Intended..... ___ ___ ___
   Code 99 for extra/non-protocol visit

   b. Is this for a follow-up SAE recheck of lab results? ..... ___
   0=No, 1=Yes, for bicarbonate, 2=Yes, for potassium, 3=Yes, for bicarbonate and potassium

7. Bicarbonate (mEq/L) ..... ___ ___
   (Note for Screening eligibility, value must be 20 to 28 mEq/L)
   (Note for Randomization eligibility, the mean of the last two baseline values must be 20 to 28 mEq/L.)
   (Note for follow-up, any measure > 32 mEq/L call the participant and switch to half dose immediately and measure ionized calcium. If repeat bicarbonate is > 32 mEq/L, then stop meds and file Form 572.)

8. Potassium (mEq/L) ..... ___.___
   (Note for Screening eligibility, value must be 3.3 to 5.4 mEq/L.)
   (Note for Randomization eligibility, value must be 3.5 to 5.4 mEq/L.)
   (Note for follow-up, any measure < 3.0 mEq/L call the participant and switch to half dose immediately. If repeat measure < 3.0 mEq/L, stop meds and file Form 572.)

9. a. Serum Creatinine (mg/dL) ..... ___.___ ___

   b. Calculated eGFR (mL/min/1.73 m^2) ..... ___ ___.___
   (Note: Required at Screening for GFR eligibility).

   c. Is calculated eGFR within trial eligibility range of 20.0-44.9 mL/min/1.73 m^2? ..... ___
   (0=no, 1=yes, 2=GFR between 45.0 and 59.9 then urine albumin to urine creatinine ratio (Form 356) must be $\geq$ 50 mg/gm)
   (*Database will automatically calculate eGFR. Write the values in the grayed out boxes on the paper form. The eGFR value will also be sent via email.)*

10. Sodium (mmol/L) ..... ___ ___ ___
11. Chloride (mmol/L) ..... ___ ___ ___
12. Urea Nitrogen (BUN) (mg/dL) ..... ___ ___ ___
13. Glucose, non-fasting (mg/dL) ..... ___ ___ ___
14. Calcium (mg/dL) ..... ___ ___.___

Needed once in Baseline and at W12 and W28 only

15. Albumin (g/dL) ..... ___.___
16. Phosphate (mg/dL) ..... ___ ___.___

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 Blood Gas Sub Study Form #354 - BASE

This form is completed for those participants who consent to participant in the Blood Gas Sub Study at B0, W12 and W28.

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 354 documented with that date.

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

6. a. Visit Number Intended..... ___ ___ ___
   Code 99 for extra/non-protocol visit

7. Date the participant consented to the Blood Gas Sub Study (mm/dd/yyyy) .....__ __/__ __/__ __ __ __

8. pH ..... ___ . ___ ___ ___

9. PCO_2 (mm Hg) ..... ___ ___ ___ . ___

10. PO_2 (mm Hg)..... ___ ___ ___

11. Base Excess (BE) (mmol/L) ..... ___ ___ ___

12. HCO_3 (mmol/L)..... ___ ___ . ___

13. TCO_2 (mmol/L) ..... ___ ___

14. sO_2 (%) ..... ___ ___ ___

15. Na (Sodium) (mmol/L) ..... ___ ___ ___

16. K (Potassium) (mmol/L)..... ___ . ___

17. iCa (ionized calcium) (mmol/L)..... ___ . ___ ___

18. Glucose (mg/dL) ..... ___ ___ ___

19. Hct (hematocrit) (%) ..... ___ ___

20. Hb (hemoglobin) (g/dL)..... ___ ___ . ___

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
Litholink Lab 24-hour Urine Results Form #355 - BASE

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

6. Date specimen received at Litholink (mm/dd/yyyy) ..... __ __/__ __ /__ __ __ __

7. Date results analyzed (mm/dd/yyyy) ..... __ __/__ __ /__ __ __ __

Results reported to the DCC only, not sent to the Clinical Center

8. U. Ammonium (NH_4) (mmol/L) ..... __ __ __.__

9. U. Sodium (mmol/L) ..... __ __ __.__

10. U. Potassium (mmol/L) ..... __ __ __.__ __

11. U. Chloride (mmol/L)..... __ __ __.__

12. U. Urea nitrogen (mg/dL) ..... __ __ __ __.__

13. U. pH ..... __ __.__ __ __

14. U. Phosphorus (mg/dL)..... __ __ __.__ __

15. Fluoride (mg/L)..... __ __.__ __ __

Results sent to the clinical center in real time

16. Litholink estimated volume based on fluoride (mL)..... __ __ __ __.__

17. U. Creatinine (mg/dL)..... __ __ __.__ __

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

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

Litholink Use Only

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

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

Pilot Clinical Trials in CKD
Local Lab Spot Urine Results Form # 356 - BASE

Local random (spot) urines are done at Screening, B0, W12 and W28.

At the Screening visit, the date urine was collected cannot be more than 2 calendar months before the screening date.

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

6. Date of results (mm/dd/yyyy) .... ___ ___/___ ___ /___ ___ ___ ___

Albumin and Creatinine results (both results must be from the same urine collection date):

Enter urine albumin/microalbumin as reported by your local laboratory.

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

<u>If reported in mg/dL</u>

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

<u>If reported in ug/mL or mg/L</u>

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

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

Urine albumin to urine creatinine ratio: __ __ __ . __ (mg/gm)

For eligibility, if GFR is between 45.0 and 59.9, ratio must be ≥ 50 mg/gm

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
Extra Lab Measurements Form #383 - BASE

This form is completed during follow-up when, although the protocol does not require it, the clinical center has a value they would like to have documented in the study database. All results recorded on this form must all be from the date in item 4. If some results are from a different date, complete an additional Form 383 labeled with that date.

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
						B

6. Time blood drawn (use 24-hr clock) (hh:mm) ..... ___ ___:___ ___
7. Bicarbonate (mEq/L) ..... ___ ___
8. Potassium (mEq/L) ..... ___.___
9. Serum Creatinine (mg/dL) ..... ___.___ ___
10. Sodium (mmol/L) ..... ___ ___ ___
11. Chloride (mmol/L) ..... ___ ___ ___
12. Urea Nitrogen (BUN) (mg/dL) ..... ___ ___ ___
13. Glucose, non-fasting (mg/dL) ..... ___ ___ ___
14. Calcium (mg/dL) ..... ___ ___.___
15. Albumin (g/dL) ..... ___.___
16. Phosphate (mg/dL) ..... ___ ___.___

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
Re-Enrollment of a Previously Enrolled Participant Form # 402 - BASE

This form is completed when a previously enrolled participant re-enrolls in the BASE Study.

Re-Enrollment Procedure:
Participants who enter the screening period and are subsequently excluded can be re-screened after at least **one month** has passed from the date the Baseline Dropout Form 162 is entered into the database. Refer to the MOP for additional instructions.

Completed this Form 402 and fax (216-445-2781) or scan and email (ckd_dcc@bio.ri.ccf.org) it to the DCC.

When a participant is rescreened and re-enters Baseline, all new baseline data are collected. Check with your local IRB to see if the participant needs to sign a new consent.

1. Identification Number

2. Alphacode

Note that the Identification Number and the Alphacode will not change. Do <u>not</u> give the participant a new ID/Alphacode.

3. Pre-randomization dropout date listed on Form 162 (Baseline Dropout Form)
(mm/dd/yyyy) ..... __ __/__ __ /__ __ __ __

Before faxing this Form 402 to the DCC, you must have the following forms fully completed (but not data entered) and ready to re-enroll: Forms 106 (BASE Screening), Form 115 (Local Lab Screening).

Identify the date of visit for the following forms below:

4. a. Form 106 (BASE Screening) date of screening (mm/dd/yyyy) ..... __ __/__ __ /__ __ __ __

b. Form 351 (Local Lab Serum Results) date serum drawn (mm/dd/yyyy) ..... __ __/__ __ /__ __ __ __

5. Date re-enrolled in BASE Trial (mm/dd/yyyy) ..... __ __/__ __ /__ __ __ __
(Use the Date of Screening from the new Form 106- BASE Screening Form)

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
Study Closeout Form # 476 – BASE

This form is completed when the Site PI determines that all data have been collected and entered at the end of the BASE 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)	3b. Visit Number (Week)	4. Date PI determined no more data will be coming for this pt (mm/dd/yyyy)	5. Study
						B

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

7. In the opinion of the Site PI, have all possible BASE 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
Event Review Committee Death Review Form # 632 – ALL STUDIES

This form is completed by the Event Review Committee when there is Form 531 and 532 documenting that a participant has 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

6. Date of Event Review 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. a. Was this death the outcome of a reported hospitalization? ..... ___
0=No, participant not hospitalized at time of death
1=Yes, participant was hospitalized at time of death (complete item 8b)

b. Hospital admission date (mm/dd/yyyy) (must match date on F512).....__ __/__ __/__ __ __ __

Event Committee Reviewer Classification of Relatedness

9. In the Event Committee Reviewer's judgment, was this death 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 death caused by any device or procedure that was specifically done as part of the CKD Study 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 Q10 is possibly, probably or definitely related.

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
Ready for Baseline (B0) Placebo Report - BASE

This report can be run as frequently as needed in preparation for dispensing placebo medication in baseline.

Participant information at top of report:

ID, alpha code 040010 QX
Date of screening visit (Form 106) February 20, 2015
Last possible date for B0 mm/dd/yyyy
(Maximum time between Screening (date of screening on Form 106) and B0 is ≤ 4 weeks.)

Screening Form #106
Form entered in database and endorses eligibility? ..... **YES**

Concomitant Medications Form # 213
Form entered in database and endorses eligibility? ..... **YES**
For eligibility, participant cannot be on both ACEi and ARB (Q13)

Local Lab Serum Results Form #351
Form entered in database and endorses eligibility? ..... **YES**
Screening serum creatinine results in database? ..... Yes
Most recent serum creatinine date? ..... mm/dd/yyyy
Serum creatinine yields an in-range eGFR? ..... Yes
GFR Eligibility: GFR under 20.0 ml/min/1.73m^2 – not eligible
GFR between 20.0 and 44.9 ml/min/1.73m^2 – eligible
If GFR between 45.0 to 59.9 then urine albumin to urine creatinine ratio (Form 356) must be ≥ 50 mg/gm to be eligible
GFR over 59.9 ml/min/1.73m^2 – not eligible
Screening serum bicarbonate results in database? ..... Yes
Most recent serum bicarbonate date? ..... mm/dd/yyyy
Screening serum bicarbonate between 20 to 28 mEq/L? ..... Yes
Screening serum potassium results in database? ..... Yes
Most recent serum potassium date? ..... mm/dd/yyyy
Screening serum potassium between 3.3 to 5.4 mEq/L? ..... Yes

Local Lab Spot Urine Form #356
Form entered in database? ..... **YES**
Screening urine albumin results in database? ..... Yes
Screening urine creatinine results in database? ..... Yes
If GFR between 45.0 to 59.9 on Form 351, then urine albumin to urine creatinine ratio must be ≥ 50 mg/gm to be eligible.

Visit/Phone Visit Form #202
Form entered and shows visit was held in database ..... **YES**
Height is measured ..... Yes
Weight is measured ..... Yes
Lean body weight is between 37.5-96.0 kg ..... Yes
Complete set of blood pressure readings and must be <160/100 mmHg at Screening ..... Yes
(Target blood pressure is < 140/90 mmHg.)

Pilot Clinical Trials in CKD
Ready for Baseline (B0) Placebo Report - BASE

Local Lab Pregnancy Test Results Form #121

Negative pregnancy test results available on Form 121? ..... **N/A, NO, YES**

Woman of childbearing potential? ..... Yes

If yes, pregnancy test results key entered? ..... Yes

Is this participant ready for B0 and baseline pills can be dispensed? ..... YES

Last allowed date for Baseline 0 ..... March 13, 2015

Participant must receive baseline placebo medications ≤ 4 weeks from the date of the Screening visit (Form 106).

- If the participant is eligible for B0, you can run the "Baseline Placebo Bottle Assignment Report."

Note: Participant must be randomized ≤ 12 weeks from the B0 (baseline placebo) visit (Form 146).

Pilot Clinical Trials in CKD
Ready to Randomize Report - BASE

This report can be run as frequently as needed in preparation for randomizing the participant.

Participant information at top of report:

ID, alpha code, Date of screening visit.....**040010 QX**
Date of Screening Visit (Form 106).....**February 20, 2015**
Time between Screening and B0 is ≤ 4 weeks.....**YES**
Time between B0 and today is ≤ 12 weeks.....**YES**

Confirming items checked at B0

Local Lab Serum Results Form #351

Form entered in database and endorses eligibility?.....**YES**
Screening serum creatinine results in database?.....Yes
Most recent serum creatinine date?.....mm/dd/yyyy
Serum creatinine yields an in-range eGFR?.....Yes

GFR Eligibility: *GFR under 20.0 ml/min/1.73m^2 – not eligible*
GFR between 20.0 and 44.9 ml/min/1.73m^2 – eligible
If GFR between 45.0 to 59.9 then urine albumin to urine creatinine ratio (Form 356) must be ≥ 50 mg/gm to be eligible
GFR over 59.9 ml/min/1.73m^2 – not eligible

Screening serum bicarbonate results in database?.....Yes
Most recent serum bicarbonate date?.....mm/dd/yyyy
Screening serum bicarbonate between 20 to 28 mEq/L?.....Yes
Screening serum potassium results in database?.....Yes
Most recent serum potassium date?.....mm/dd/yyyy
Screening serum potassium between 3.3 to 5.4 mEq/L?.....Yes

Local Lab Spot Urine Form #356

Form entered in database?.....**YES**
Screening urine albumin results in database?.....Yes
Screening urine creatinine results in database?.....Yes
If GFR between 45.0 to 59.9 on Form 351, then urine albumin to urine creatinine ratio must be ≥ 50 mg/gm to be eligible.

Local Lab Pregnancy Test Results Form #121

Form entered in database and endorses eligibility?.....**N/A, NO, YES**

Additional Randomization Requirements

BASE Visit/Phone Visit Form #202

At least two baseline forms with complete blood pressure measurements entered in database?.....**YES**
ACEI/ARB regimen has been optimized to a tolerable dose up to the maximum recommended dose on the most recent baseline form? (Q13 must be 1, 2, 4 or 5).....Yes
Most recent baseline blood pressure is < 150/100 mm Hg.....Yes
(Target blood pressure is < 140/90 mmHg.)

Pilot Clinical Trials in CKD
Ready to Randomize Report - BASE

Concomitant Medications Form #213

Forms B0 and B1 entered in database and endorses eligibility? ..... **YES**
For eligibility, participant cannot be on both ACEi and ARB (Q13)

Most recent Form 213 Calcium Carbonate item 9 shows eligibility ..... Yes
(NOT eligible if item 9=4 taken more than half of the days AND more than 1500 mg/day)

If anytime during Baseline, Q6 (adjustment made to ACEI/ARB) or Q7 (adjustment made to diuretic) shows an adjustment was made, serum potassium must be rechecked.

Date of most recent Form 213 where (Q6) shows an adjustment was made to ACEI/ARB? ..... mm/dd/yyyy
Date of Form 351 (Local Lab Serum Results) where serum potassium was rechecked?
(Date on F351 must be at least 7 days after medication is changed on F213) ..... mm/dd/yyyy
Serum potassium result? ..... ___.___
Serum potassium is 3.5-5.4 mEq/L? ..... Yes
Form 202 with the same date as repeat local lab shows blood pressure is < 150/100 mm Hg ..... Yes
(Target blood pressure is < 140/90 mmHg.)

Date of most recent Form 213 where (Q7) shows an adjustment made to diuretic? ..... mm/dd/yyyy
Date of Form 351 (Local Lab Serum Results) where serum potassium was rechecked?
(date on F351 must be at least 7 days after medication is changed on F213) ..... mm/dd/yyyy
Serum potassium result? ..... ___.___
Serum potassium is 3.5-5.4 mEq/L? ..... Yes
Form 202 with the same date as repeat local lab shows blood pressure is < 150/100 mm Hg ..... Yes
(Target blood pressure is < 140/90 mmHg.)

Local Lab Serum Results Form #351

Form entered in database and endorses eligibility? ..... **YES**
Baseline local serum bicarbonate results in database ..... Yes
Most recent local serum bicarbonate date? ..... mm/dd/yyyy
Second most recent local serum bicarbonate date? ..... mm/dd/yyyy
The mean of the two most recent local serum bicarbonate values are 20-28 mEq/L? ..... Yes

Baseline local serum potassium results in database ..... Yes
Most recent local serum potassium is 3.5-5.4 mEq/L? ..... Yes

Baseline local serum sodium results in database? ..... Yes
Baseline local serum chloride results in database? ..... Yes
Baseline local serum urea nitrogen (BUN) results in database? ..... Yes
Baseline local serum glucose (non-fasting) results in database? ..... Yes
Baseline local serum calcium results in database? ..... Yes
Baseline local serum albumin results in database? ..... Yes
Baseline local serum phosphate results in database? ..... Yes

Pilot Clinical Trials in CKD
Ready to Randomize Report - BASE

Co-Morbidity and Medical History Form #122

Form entered in database and endorses eligibility? ..... **YES**

For those with a right ankle (Based on Form 122, Q36=0 or 1)

At least one right ankle circumference available on Form 202 ..... Yes

For those with a left ankle (Based on Form 122, Q37=0 or 1)

At least one left ankle circumference available on Form 202 ..... Yes

Demographics, Employment, and Income Form #123

Form entered in database? ..... **YES**

Baseline Pill Count Form #147

Form entered in database and endorses eligibility? ..... **YES**

- One placebo pill count available? ..... Yes
- Participant was taking pills for at least 7 days? ..... Yes
- Placebo pill count ≥ 80.0%? ..... Yes

Symptoms Questionnaire #283

At least one form entered in database? ..... **YES**

Valid responses to F283 (bloating and burping) on at least one baseline Form 283 ..... Yes

(Ideally one Form 283 at B0 and one Form 283 at B1.)

Central Lab Urine

Litholink 24-Hour Urine Mailing Form #326

At least one form entered in database and endorses eligibility? ..... **YES**

- Form shows preservative observed in urine container (Q9=1) ..... Yes
- Form shows preservative added (Q10=1 or 2) ..... Yes
- Form shows that collection was complete (Q11=1) ..... Yes
- Form shows tube sent to Litholink (Q16=1 or 2) ..... Yes
- Collection was between 20 and 28 hours? ..... Yes

Litholink Results Form #355

At least one Litholink urine results form with ammonium results ..... **YES**

DCC has copy of participant's de-identified Consent Form signature page on file ..... **YES**

Eligible for Randomization

All eligibility criteria met and can be randomized ..... **YES**

If this report states that the participant is eligible to be randomized, go to the "Randomization" screen.

Pilot Clinical Trials in CKD
Ready for Follow-Up Week 4 Up Titration
(for High Dose Participants) Report - BASE

How this works: Participant comes in for follow-up Week 4 visit. Labs are drawn. Symptoms and visit forms are collected. If participant reports severe abdominal discomfort on symptoms form, participant is told to stay on .5 mEq/day dose. If the visit form shows increased ankle circumference, weight gain (5 kg), or high blood pressure, the participant is told to stay on .5 mEq/day dose.

The lab results most likely will not be available prior to the participant leaving the clinic. The participant can be told to up-titrate before leaving the clinic as long as the criteria above have been met.

This report will be re-run when Week 4 serum data are available. If the lab value(s) for serum bicarbonate and serum potassium come back showing a Serious Adverse Event (Serum bicarbonate >32 mEq/L or Serum potassium <3.0 mEq/L), the dose will be reduced.

Participant information at top of report:

ID, alpha code 040010 QX
Date of randomization..... 07/07/2015
Have at least 21 days passed since randomization?..... Yes

Abdominal Discomfort
- Week 4 Form 283 in database ..... Yes
- Week 4 Form 283 date (must be at least 21 days post randomization) ..... mm/dd/yyyy
- Level of discomfort is none, mild, or moderate (if severe, this will say no) ..... Yes

Weight
- Baseline Weight (last weight measured before randomization) ..... 70.3 kg
- Week 4 weight results in database..... Yes
- Week 4 weight date (must be at least 21 days post randomization)..... mm/dd/yyyy
- Maximum weight allowed for up titration (Baseline weight + 4.9 kg) ..... 7 5 . 2
- Week 4 weight..... 73.9 kg
- Is week 4 weight less than maximum weight allowed for up titration? ..... Yes

Blood Pressure
- Week 4 systolic results in database ..... Yes
- Week 4 systolic results date (must be at least 21 days post randomization) ..... mm/dd/yyyy
- Systolic value?..... 160
- Systolic < 170 mmHg..... Yes

- Week 4 diastolic results in database..... Yes
- Week 4 diastolic results date (must be at least 21 days post randomization)..... mm/dd/yyyy
- Diastolic value? 90
- Diastolic < 110 mmHg ..... Yes

Edema
- Week 4 Visit Form 202 in database ..... Yes
- Week 4 Visit Form 202 date (must be at least 21 days post randomization) ..... mm/dd/yyyy
- Edema Status:
  - Yes if acceptable, No if severe edema (≥ 10%% increase in total ankle circumference from baseline) ... Yes

Pilot Clinical Trials in CKD
Ready for Follow-Up Week 4 Up Titration
(for High Dose Participants) Report - BASE

Lab Data

Week 4 serum bicarbonate results in database? ..... Yes
Week 4 serum bicarbonate date (must be at least 21 days post randomization) ..... mm/dd/yyyy
Serum bicarbonate value 31
Serum bicarbonate ≤ 32 mEq/L? ..... Yes

Week 4 serum potassium results in database? ..... Yes
Week 4 serum potassium date (must be at least 21 days post randomization) ..... mm/dd/yyyy
Serum potassium value 3.3
Serum potassium ≥ 3.0 mEq/L? ..... Yes