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..... ___ ___ CC_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 …… _____ CC_ADDR1
   b. Line 2 ..... _____ CC_ADDR2
   c. Line 3 ..... _____ CC_ADDR3
   d. Line 4 ..... _____ CC_ADDR4
   e. City ..... _____ CC_CITY
   f. State ..... _____ CC_ST
   g. Zip/Postal Code ..... ___ ___ ___ ___ ___ CC_ZIP

3. Clinical Center Federal Express Shipping Address <u>for medications</u>: (required)
   a. Line 1 .. _____ CC_FDEX_ADDR1
   b. Line 2 . _____ CC_FDEX_ADDR2
   c. Line 3 . _____ CC_FDEX_ADDR3
   d. Line 4 . _____ CC_FDEX_ADDR4
   e. City ..... _____ CC_FDEX_CITY
   f. State ..... _____ CC_FDEX_ST
   g. Zip/Postal Code ..... ___ ___ ___ ___ ___ CC_FDEX_ZIP
   h. Mark to the attention of .. _____ CC_FDEX_ATTN

4. Clinical Center Shipping Address <u>for lab supplies:</u> (required)
   a. Line 1 . _____ CC_SUPPLIES_ADDR1
   b. Line 2 _____ CC_SUPPLIES_ADDR2
   c. Line 3 _____ CC_SUPPLIES_ADDR3
   d. Line 4 _____ CC_SUPPLIES_ADDR4
   e. City ..... _____ CC_SUPPLIES_CITY
   f. State ..... _____ CC_SUPPLIES_ST
   g. Zip/Postal Code ..... ___ ___ ___ ___ ___ CC_SUPPLIES_ZIP
   h. Mark to the attention of _____ CC_SUPPLIES_ATTN

Local Laboratory Details

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

COMBINE IRB Status and NIDDK Repository

(*for collection of repository biologic specimens*)

6. Date COMBINE protocol v1.0 approved by IRB (mm/dd/yyyy) _ _ /_ _ /_ _ _ _COMB_PROT_IRB_APP_DT
7. Was IRB approved repository consent approved by NIDDK? (0=no, 1=yes) ....___COMB_IRB_NIDDK_APP

COMBINE MRI Details

8. a. Does this clinical center use an MRI group that has a different IRB? ..... ___COMB_MRI_DIFF_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) ..... __ __ /__ __ /__ __ __ __COMB_MRI_IRB_APP_DT
9. MRI Manufacturer (1=GE; 2=Philips; 3=Siemens) .....___MANUFACTURER
10. Field Strength [Tesla] (1.5 or 3.0).....___ . ___FIELD_STRENGTH
11. MRI software version ..... ___ ___ ___ ___ ___ ___ ___ ___ ___ ___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) ..... ___COMB_IV_FUROSEMIDE

BASE IRB Status and NIDDK Repository

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

TarGut IRB Status - Leave blank for now

15. a. Will this site enroll participants into TarGut (0=no, 1=yes) .....___TARG_ENROLL_PTS
    If yes, complete item b
    b. Date TarGut protocol v1.0 approved by IRB (mm/dd/yyyy) ._ _/_ _ /_ _ _ _TARG_IRB_PROT_APP_DT

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

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

For DCC Use only:

202. MRI test case #1 quality approved by Core (0=no, 1=yes) .....___MRI_TEST1_APP
203. MRI test case #2 quality approved by Core (0=no, 1=yes) .....___ MRI_TEST2_APP

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 ..... ___ ___CC_N
   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 ..... _____SP_LNAME
   b. First name ..... _____SP_FNAME
   c. CKD Study Username ..... __ __ __ __ __ __ __SP_USERID
      (The Study Username will be populated automatically unless generated Username is not unique.)
   d. E-mail Address ..... _____SP_EMAIL
   e. Phone Number ..... (___ ___ ___) ___ ___ ___-___ ___ ___ ___SP_PHONE
   f. Extension ..... ___ ___ ___ ___ ___SP_EXT

3. Primary role in the CKD study? ..... ___ ___SP_ROLE
   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) ..... ___SP_STATUS
      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)..... _ _/_ _ /_ _ _ _SP_INACTIVE_DT

Certifications

MRI (Cardiac and BOLD Renal) - COMBINE

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

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

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

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

Anthropometry (Ankle Measurement) – BASE

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

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

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

201. Username of person compl/reviewing completeness of this form__ __ __ __ __ __ __COMP_USER

Clinical Center Use Only

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

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

Pilot Clinical Trials in CKD
Center Quarterly Urine Scale Calibration Form # 20 - COMBINE

Scales for weighing 24-hr urine collections will be used in COMBINE. These scales should be calibrated before study start and every three months thereafter during the course of the study.

1. Urine scale number being calibrated .....___ ___ ___ ___SCALE_NUMBER
2. Date of calibration (mm/dd/yyyy) .....___ ___ /___ ___ /___ ___ ___ ___CALIB_DT
3. Username of the person who performed the calibration . __ __ __ __ __ __ __CALIB_USERNAME1
4. a. Weight measured with 200g weight (g).....___ ___ ___ . ___WT_200_1
   b. Weight measured with 500g weight (g).....___ ___ ___ . ___WT_500_1
   c. Weight measured with both 500g and 200g weights together (g) ___ ___ ___ . __WT_200_500_1
5. Were all measured weights within 10% of the true weights? (0=no, 1=yes).....___WITHIN_10_1
   If Q5=1, skip to Q200. If Q5=0, read important information below and continue to Q6.

IMPORTANT: If Item 5 is no, that is, if any of the differences are off by more than 10%, notify your principal investigator and the DCC immediately, since this calls into question the last three months of urine volumes from your site. Then make sure the scale is on a flat surface, turn off the scale, wait at least 1 minute for the scale to reboot. Complete items 6 thru 9 repeating the calibration procedure. If this second measurement is also greater than 10%, the scale needs to be retired from use on COMBINE participants.

Repeat Calibration (if needed):

6. Username of the person performed the repeat calibration __ __ __ __ __ __ __CALIB_USERNAME2
7. a. Weight measured with 200g weight (g).....___ ___ ___ . ___WT_200_2
   b. Weight measured with 500g weight (g).....___ ___ ___ . ___WT_500_2
   c. Weight measured with both 500g and 200g weights together (g) ___ ___ ___ . __WT_200_500_2
8. Were all measured weights within 10% of the true weights? (0=no, 1=yes).....___WITHIN_10_2
9. If, Q8=0, date this scale was retired (mm/dd/yyyy).. ___ ___ /___ ___ /___ ___ ___ ___RETIRE_DT

   If a scale is retired, fill out another Form 20 for your backup scale and begin using it. Then, order a new backup scale.

200. Date this form completed (mm/dd/yyyy) ..... ___ ___ /___ ___ /___ ___ ___ ___COMP_DT
201. Username of person compl/revwing completeness of this form __ __ __ __ __ __ __COMP_USER

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

Pilot Clinical Trials in CKD
Screening Form #107 – COMBINE ELIGIBLE=0(no), 1=(yes)

Form 107 is completed and key entered for each participant who consents to the study.

																		C	

1. Identification Number PID
2. Alphacode AC
3. Date of Screening (mm/dd/yyyy) VISIT_DT
4. Study STUDY

Consent

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

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

   c. Date this participant signed the consent form for the Cardiac MRI? (mm/dd/yyyy) [Leave blank if participant did not consent for this]__ __/__ __/__ __ __ __CONS_CARD_DT

   d. Date this participant signed the consent form for the BOLD Renal MRI with IV furosemide? (mm/dd/yyyy) [Leave blank if pt did not consent for this] _ _/_ _/_ _ _ _CONS_BOLD_DT

Gender

6. Sex of participant? (1=male, 2=female)..... ___GENDER

Ethnic Category

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

Racial Category

8. Race? (*NIH format – Hispanics must choose a race)* ..... ___RACE

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

9. Times through Baseline for COMBINE? .....___TIMES_BASE
   (1=1st time through baseline for COMBINE; 2=2nd time through baseline for COMBINE; etc.)

Eligibility Items

10. Date of birth? (mm/dd/yyyy).....__ __/__ __/__ __ __ __DOB
    Note, for eligibility, age must be 18 years at the time of randomization.

11. History of allergic reaction to nicotinamide or niacin? ..... ___ALLERGY_N_N
    (0=no history of reaction; 1=flushing reaction only; 2=other allergic reaction)
    Note, for eligibility, must be 0 or 1.

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

12. Does the Site PI confirm that this participant is medically stable?..... ___STABLE

13. Is the participant able to read in English? ..... ___READ_ENG

14. Is the participant able to travel to study visits? .....___TRAVEL

15. 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? ..... ___COMPIANT

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

16. a. History of allergic reactions to multivitamin preparations? ..... ___ALLERGY_MV
    b. History of allergic reaction to lanthanum carbonate (Fosrenol)? .....___ALLERGY_LC
17. a. Liver disease: cirrhosis by imaging? .....___CIRRHOSIS_IMAGING
    b. Liver disease: cirrhosis by physician diagnosis? ..... ___CIRRHOSIS_MD_DIAG
18. Active abuse of alcohol or drugs as judged by the Site PI? .....___ALCH_DRUGS
19. Major hemorrhagic event within the past six months requiring in-patient admission?_HEMORRHAGIC
20. Blood or platelet transfusion within the past six months? .....___TRANSFUSION
21. Current, clinically significant malabsorption as judged by the Site PI?.....___MALABSORPTION
22. Anticipated initiation of dialysis or kidney transplantation within 12 months as assessed by and at the discretion of the Site PI? ..... ___TRANSPLANT
23. Current participation in another clinical trial or other interventional research? ..... ___OTH_TRIAL
24. Currently taking investigational drugs?.....___INVEST_DRUGS
25. Institutionalized, prisoner, or currently residing in a nursing home or rehab center?__INSTIT_PRISON
26. Malignancy requiring therapy within the last 2 years? ..... ___MALIGNANCY
    (basal or squamous cell skin carcinoma and localized prostate cancer are exempted)
27. Life expectancy < 12 months as determined by the Site PI? .....___LIFE_EXP
28. Hospitalization within the past 30 days? ..... ___HOSPITALIZATION
    (24 hour observation admissions are exempted but should be discussed with the Site PI.)
29. Plans to leave the immediate area within 12 months? ..... ___MOVING
30. Routinely leaves town for multiple weeks each year such that protocol visits would be missed? ..... ___LEAVES_ROUTINELY

Pregnancy-related questions (*skip to Q33 if male)*

31. Pregnant or planning to become pregnant or currently breast-feeding? (0=no, 1=yes) __PREGNANCY
32. a. Sex and childbearing potential status? ..... ___CHILD_BEAR_POT
    1=Surgically sterilized (includes endometrial ablation)
    2=Post-menopausal
    3=Not surgically sterilized and not post-menopausal: "woman of childbearing potential"
    b. If Item 32a=3 (woman of childbearing potential), does the participant agree to use birth control? (0=no, 1=yes) .....___BIRTH_CONTROL

Meal status

33. How many meals does the participant generally eat each day..... ___MEAL_STATUS
    (1=One or fewer meals, 2=Two meals with no snacks, 3=Two meals with one snack,
    4=Two meals with two or more snacks, 5=Three or more meals)
    Note, for eligibility must be 2, 3, 4 or 5.

Participant Source (not for eligibility)

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

Section for participants who consented to Cardiac MRI

35. Local MRI Safety Questions and PI judgment status ..... ___MRI_JUDGEMENT

0=Local MRI safety questions have NOT been reviewed with the participant
1=Local MRI safety questions have been reviewed with the participant; PI judges participant to be eligible for Cardiac MRI
2=Local MRI safety questions have been reviewed with the participant; PI judges participant NOT to be eligible for Cardiac MRI

Section for participants who consented to BOLD Renal MRI

36. BOLD Renal MRI PI judgment status ..... ___BOLD_JUDGEMENT

1=PI judges participant to be eligible for BOLD Renal MRI
2=PI judges participant NOT to be eligible for BOLD Renal MRI (includes participants with previous allergic reaction or contraindication for IV furosemide)

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

201. Username of person comp/revw completeness of this form .....__ __ __ __ __ __ __COMP_USER

Eligibility Status?

Participant is eligible (yes) OR

Participant is ineligible (no)

ELIGIBLE

Clinical Center Use Only

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

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

DCC Use Only

Dt DCC recvd a copy of consent signature page (mm/dd/yyyy) __ __/__ __/__ __ __ __
CONS_RECD_DT

DCC Use Only

Date of participant re-consent (mm/dd/yyyy) __ __/__ __/__ __ __ __ RECONSENT_DT
If participant never re-consented, field was set = '1/1/1960'

DSMB_RSN_NOMEDS – reasons why participants are on no study medications. Options are:

BASE/COMBINE Fine Grain Reasons why participants stopped taking study meds
(DSMB_RSN_NOMEDS)

Code	Reason	Details about this reason
11	GI symptoms	Study Coordinator or Patient reported GI symptoms leading up to the patient stopping meds.
12	Fluid retention	
21	Pill burden with New GI symptoms	Report of pill burden in a participant with moderate and/or severe GI symptoms appearing for the first time after randomization
31	Pill burden with GI symptoms: Not New	Report of pill burden in a participant with moderate and/or severe GI symptoms which were seen both in baseline and after randomization.
32	Pill burden without GI symptoms	Report of pill burden with no severe GI symptoms at all, and no moderate symptom appeared more than once.
41	Non-compliance	Participant quit taking study medications with no report of pill burden or GI symptoms or new comorbidity diagnosed. Participant continued to attend visits.
51	Comorbidity: Altered mental status at F4	
52	Comorbidity: Angina at F5	
53	Comorbidity: Anxiety/Chest pain at F7	
54	Comorbidity: Hemorrhage/Thrombocytopenia at F10	
55	Comorbidity: Hepatitis at F5	
56	Comorbidity: Multiple Major Diagnoses at F10	
57	Comorbidity: Non-Hodgkin's Lymphoma at F3	
58	Comorbidity: Parkinson's Disease at F10	
59	Comorbidity: Suicidal Ideation at W27	
60	Comorbidity: CHF due to volume overload at W11	
61	Comorbidity: Pneumonia/Chest Congestion at F11	
62	Comorbidity: ICD Lead infection at W23	
71	Hyperphosphatemia	
72	Concern over high bicarbonate	
81	Withdrew consent	
82	Quit attending visits	Quit attending visits with no reporting of pill burden or GI symptoms or new comorbidity, and the participant allows minimal passive data or phone visit. Known to be alive and not on dialysis as of target study W32/F12 end date.
83	Lost to follow-up	Disappeared off the face of the earth.
91	Uremia prior to dialysis or transplant	
92	Death	

DSMB_RSN_NOVIS – reasons why participants stopped coming to visits. Options are:
1=Participant is completely lost and cannot be found.
2=The person refused consent for any further follow-up data collection. The participant specifically says to you, I refuse to allow you to collect my data any more.
3=Passive data only. From randomization to day 224 (BASE) or day 365 (COMBINE), the site knew where the patient lived. The coordinator could follow the patient for death, transplant, and start of dialysis and may have also been able to collect some local data such as hospitalizations and labs at the local site. (Generally agreeable patients who won't come to in-person visits or participate in phone visits but have not refused consent so the study coordinator can still collect some data on them.)
4=Phone visits only. Participant willing to do questionnaires and otherwise provide data that can be captured without an in person visit (110025-COMBINE)
5=Participant moved or changed residence and will no longer come to visits at the BASE/COMBINE site
6=Participant is now institutionalized/in a nursing home or rehabilitation center

ALIVE_NO_DIAL_TX -

SAD_STORY – Gives information about the participant that we do not capture anywhere else.

CRITICAL_PHOS – Reports the number of "countable episodes" of serum phosphorous.
There were 71 values of serum phosphorus of 2.7 mg/dl or lower measured post-randomization in COMBINE patients; 54 of these were measured at Spectra and 16 were measured at the sites and reported on a local Form380 or 381. There were a total of 34 COMBINE patients with a serum phosphorus of 2.7 or lower measured post-randomization. There were 18 patients with "countable episodes."

Pilot Clinical Trials in CKD
Local Lab Serum and Plasma Screening Results Form #115 - COMBINE

This form is completed as part of the screening process when the clinical center team has results for all tests listed. *Note: Lab draw must be no more than 45 days before the screening date.* Serum collection should be drawn between noon and 6:00 pm.

The results recorded on this form must all be from the date documented in item 4. If some results are from a different date, complete an additional Form 115 labelled with that date. Each local lab test must be recorded on at least one form 115 in order for the participant to be eligible for randomization.

1. Identification Number PID	2. Alphacode AC	3a.Visit Type VIST	3b. Visit Number (Month) VISN_MO	(Week) VISN_WK	4. Date Serum drawn (mm/dd/yyyy) VISIT_DT	5. Study STUDY
		S				C

6. a. Intended Protocol Visit..... S 1
   b. Time blood drawn (use 24-hr clock) (hh:mm) ..... ___ ___:___ ___DRAW_TM
7. a. Serum Creatinine (mg/dL) ..... ___.___ ___CR
   b. Calculated eGFR (mL/min/1.73 m^2)..... ___ ___.___EGFR
   c. Is calculated eGFR w/n eligibility range 20-45 mL/min/1.73 m^2?(0=no, 1=yes)_____EGFR_IN_RANGE
   (*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.)*
8. Serum phosphate (mg/dL) ..... ___ ___.___PHOS
   If serum phosphate is < 2.8 mg/dL, then participant is not eligible.

Liver Function Test Results

9. Aspartate aminotransferase (AST) (IU/L) ..... ___ ___ ___.___AST
   If AST is > 80 IU/L, the participant is not eligible.
10. Alanine aminotransferase (ALT) (IU/L) ..... ___ ___ ___.___ALT
    If ALT is > 90 IU/L, the participant is not eligible.
11. Total bilirubin (mg/dL)..... ___ ___.___TBILI
    If T. bilirubin is > 2.4 mg/dL, the participant is not eligible.
12. Alkaline phosphatase (IU/L) ..... ___ ___ ___ALKP
    If alk phos is > 260 IU/L, the participant is not eligible.
13. Albumin (g/dL) ..... ___.___ALB
    If albumin is < 2.5 (mg/dL), the participant is not eligible

Other Test Results

14. Total Creatine Kinase (CK) (IU/L) ..... ___ ___ ___CK
    If total creatine kinase is > 400 IU/L, the participant is not eligible.
15. Intact PTH (pg/mL) ..... ___ ___ ___PTH
    If intact PTH is > 325pg/mL, the participant is not eligible.

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

Clinical Center Use Only

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

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

CKD_LAB_WB

Pilot Clinical Trials in CKD
Local Lab Whole Blood Screening Results Form #116 - COMBINE

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 116 documented with that date.

When used during screening: This form should be completed when the clinical center team has a result for all tests listed. *Note: Labs must be done at the screening visit or no more than 45 days prior to the screening visit.*

1. Identification Number ID	2. Alphacode AC	3a. Visit Type VIST	3b. Visit Number (Month) VISN_MO	(Week) VISN_WK	4. Date Blood Drawn (mm/dd/yyyy) VISIT_DT	5. Study STUDY
		S				C

6. Intended Protocol Visit .... _S_ _1_

7. Time blood drawn (24-hr clock) (hh:mm).. ___ ___:___ ___DRAW_TM

CBC Results

8. Hemoglobin (g/dL) .... ___ ___.___HGB
If hemoglobin is < 9.0 g/dL, the participant is not eligible.

9. Platelet count [1000/(mm^3)] .... ___ ___ ___PLT
If platelet count is < 125,000/mm^3, the participant is not eligible.

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

201. Username of person compl/revwing completeness of this form .... __ __ __ __ __ __ __COMP_USER

Clinical Center Use Only

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

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

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

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 PID	2. Alphacode AC	3. Date of Pregnancy Test (mm/dd/yyyy) VISIT_DT	4. Study STUDY

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

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

201. Username of person compl/revwing completeness of this form.__ __ __ __ __ __ __COMP_USER

Clinical Center Use Only

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

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

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	3b. Visit Number		4. Date of visit: (mm/dd/yyyy)	5. Study
PID	AC	Type	(Month)	(Week)	VISIT_DT	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 .....___MI
7. Congestive heart failure ..... ___CHF
8. Angina/chest pain .....___ANGINA
9. Revascularization: Coronary artery bypass or percutaneous intervention/angioplasty/stent___REVASCULARIZATION
10. Atrial fibrillation .....___ATRIAL_FIB
11. Positive cardiac stress test for ischemia.....___ISCHEMIA
12. Peripheral vascular disease ..... ___PVD
    (Exertional pain with walking (claudication), amputation not due to trauma or infection, or revascularization to leg arteries)
13. Cerebrovascular disease/Stroke .....___STROKE
    (Exclude Transient Ischemic Attack (TIA) or imaging abnormalities not associated with physical signs or symptoms of stroke.)
14. COPD (excludes asthma) .....___COPD
15. Uses CPAP at night?..... ___CPAP
16. Connective tissue disease (lupus or scleroderma or Sjogren's, for example) ..... ___CONN_TISSUE_DIS
17. Peptic ulcer disease (excludes GERD).....___PEPTIC_ULCER
18. Hemiplegia ..... ___HEMIPLEGIA
19. Leukemia ..... ___LEUKEMIA
20. Lymphoma ..... ___LYMPHOMA
21. Multiple myeloma.....___MM
22. Cancerous solid tumor (excludes non-melanoma skin cancer) ..... ___SOLID_TUMOR
    (0=None, 1=Yes, not metastatic, 2=Metastatic)
23. Diabetes mellitus .....___DIABETES
    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 .....___LIVER_DISEASE
    0=none, 1= mild disease (without portal hypertension, includes chronic hepatitis), 2=moderate, 3=severe
25. Hepatitis B positive?.....___HEP_B
    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, history of a Hep B infection (if Hep panel is available, HbSAg is negative, and both HbCAb and HbSAb are positive)
    2=Yes, current chronic active Hep B infection (if Hep panel is available, HbSAg is positive)

26. Hepatitis C positive? ..... ___HEP_C

27. Gout? ..... ___GOUT

28. Needs assistance with ambulation? (0=No, does not need assistance; 1=Generally uses a cane or walker; 2=Generally uses a wheelchair)..... ___AMBULATION

29. Deaf? ..... ___DEAF

30. Legally blind? ..... ___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 ..... ___HOSP_ADM
(0=Not admitted, 1=Admitted once, 2=Admitted more than once)

32. Primary cause of kidney disease:..... ___ ___PRIM_CAUSE
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 ..... ___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) ..... ___ACUTE_HEMO

FOR BASE Only

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

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

201. Username of person completing/reviewing completeness of this form__ __ __ __ __ __ __COMP_USER

Clinical Center Use Only

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

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

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

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				
ID	AC	VIST	VISN_MO	VISN_WK	VISIT_DT	STUDY

6. Marital status:.....___MARITAL
   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 .....___HOUSEHOLD
   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..... ___EDUCATION
   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) .....___PRIM_LANG

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

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

12. Current work status:..... ___ ___CURR_WORK
    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)..... ___HH_INCOME
    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?..... ___ ___HH_CT

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

Smoking History:

15. a. Do you or did you smoke cigarettes?..... ___SMOKE
(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?___ ___SMOKE_START_AGE

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

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

Drinking History:

16. a. Do you or did you drink alcohol? ..... ___ALC
(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? ___ ___ALC_DRINKS
(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).....___EXERCISE_FREQ

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

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

201. Username of person compl/revwing completeness of this form __ __ __ __ __ __ __COMP_USER

Clinical Center Use Only

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

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

CKD_INIT_PILLS

Pilot Clinical Trials in CKD
Baseline Initial Pill Dispensing Form #148 - COMBINE

This form is completed at the B0 baseline pill dispensing visit in the COMBINE Trial.
At B0, the participant is given:

- one bottle of 45 Lanthanum Carbonate/Placebo (Round White Pills). *Ideally*, prescriptions are the same as they will be at F0: participants who eat at least three meals a day should take 3 per day, one with each meal. Participants who eat 2 meals a day and no snacks should take 2 per day, one with each meal. Participants who eat 2 meals a day with at least one snack should take 3 per day, 2 with meals and 1 with a snack. *However, for the purpose of baseline compliance calculations, all participants are expected to take 2 per day.*
- one bottle of 80 Nicotinamide/Placebo (Football Shaped Pills). Participants should take 1 per day. It is recommended to take this pill with breakfast.

B0 pills should be dispensed within 1 calendar month of the Screening visit. At B0, the participant is instructed to start study medications with their next meal and to bring both bottles back at the B1 visit.

1. Identification Number PID	2. Alphacode AC	3. Visit Type VIST	4. Date pills dispensed (mm/dd/yyyy) VISIT_DT	5. Study STUDY
_ _ _ _ _ _	_ _	B	_ _ _ _ _ _ _ _	C

6. Visit Number Intended.. B 0 INTENDED_VISIT
   Baseline (B) visit 0.

7. Has the participant completed Form 285 Symptom Questionnaire? (0=no, 1=yes)........___SYMP_QUEST
   (Note, Form 285 is required to be completed prior to taking placebo medications. If the participant cannot complete Form 285 today, do not give out the study medication.)

8. a. How many Lanthanum Carbonate/Placebo (Round White Pills) were dispensed 45W_DISPENSED
   b. Bottle number .... __ __ __ __ __WHITE_BOTTLE_NO

9. a. How many Nicotinamide/Placebo (Football Shaped Pills) were dispensed...........80F_DISPENSED
   b. Bottle number ....__ __ __ __ __FOOTBALL_BOTTLE_NO

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

201. Username of person compl/revwing completeness of this form... __ __ __ __ __ __ __COMP_USER

Clinical Center Use Only

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

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

CKD_PILL_CT_C

Pilot Clinical Trials in CKD
Baseline Pill Counting Form # 149 - COMBINE

This form is completed at the B1 and B2 pill count for the COMBINE Trial.

The participant's own returned pills <u>should</u> be re-dispensed at the B1 pill count.

		B		**C**
1. Identification Number PID	2. Alphacode AC	3. Visit VISTType	4. Date pills reviewed (mm/dd/yyyy) VISIT_DT	5. Study STUDY

6. Visit Number Intended ..... _B_ ___INTENDED_VISIT
Baseline (B) visits are 1, 2, etc.

7.	Study Medication Type	Round White Pills *(Lanthanum Carbonate/ Placebo 500 mg)*	Football shaped pills *(Nicotinamide/ Placebo 750 mg pills)*
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)	__W_LOST	__F_LOST
b.	Were the pills counted (0=no, 1=yes)	__W_COUNTED	__F_COUNTED
c.	# days between visits (calculated and displayed)	__ __W_DAYS	__ __F_DAYS
d.	# pills at end of previous visit	__ __ __W_PREV_PILLS	__ __ __F_PREV_PILLS
e.	# pills should have taken (#days between visits times prescribed number of pills per day as pt leaves visit)	__ __ __W_EXPECTED	__ __ __F_EXPECTED
f.	Pill Count (# pills returned)	__ __ __W_RETURNED	__ __ __F_RETURNED
g.	# pills taken (# pills at end of previous visit minus # pills returned)	__ __ __W_TAKEN	__ __ __F_TAKEN
h.	Adherence (Percent taken (#taken divided by #should have taken times 100%)	__ __ __ . __W_ADHERENCE	__ __ __ . __F_ADHERENCE
i.	Were returned pills re-dispensed? (0=no, 1=yes)	__W_REDISPENSED	__F_REDISPENSED
j.	Prescribed # of pills per day as participant leaves this visit	Either 2 or 3 per day depending on meal pattern reported on Form 107 W_DAILY	1 per day F_DAILY

8. a. Was a <u>new</u> bottle of Lanthanum Carbonate/Placebo (Round White Pills) dispensed?(0=no, 1=yes) __W_NEW
   b. If yes, bottle number ..... ___ ___ ___ ___ ___W_BOTTLE_NO

9. a. Was a <u>new</u> bottle of Nicotinamide/Placebo (Football Shaped Pills) dispensed? (0=no, 1=yes) ___F_NEW
   b. If yes, bottle number ..... ___ ___ ___ ___ ___F_BOTTLE_NO

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

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

Clinical Center Use Only

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

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

Pilot Clinical Trials in CKD
Baseline Pill Counting Form # 149 – COMBINE
INSTRUCTIONS

July 1, 2015, revised details on pill counting and dispensing at the COMBINE B1 visit:

A. Baseline placebo should be dispensed at B0 (Form 148) and B1 (Form 149) and counted at B1 (Form 149) and B2 (Form 249). See forms completion schedule, pages 1 and 2.

B. The requirement for adherence is as shown in the protocol in Section 3.5. **Compliance assessment: "**Compliance with study procedures will be defined as attendance at Baseline visits 0 and 1 and pill count results showing > 80% adherence to baseline placebo medications during Baseline, as assessed at least once (either B1 or B2)."

C. Thus, if the mean B1 pill count is > 80%, the patient is already eligible by pill count, and the B2 pill count adherence will not need to be used to estimate adherence to determine eligiblity for randomization. Because of this, we have a potential for conserving lanthanum placebo.

1. If a participant had a mean B1 pill count >80% and does not need much more experience taking lanthanum placebo, just return his bottles to him (redispense the leftover pills available in the bottles) and tell him he should take the nicotinamide placebo and lanthanum placebo pills as prescribed. The nicotinamide placebo will last until B2 but the lanthanum placebo may run out. If the participant has been fully compliant and the number of days between B0 and B2 is greater than 15, you will know that the nicotinamide placebo will last until his B2 visit but the lanthanum placebo will run out before his B2 visit.

2. If a participant had a mean B1 pill count >80% but your PI and the COMBINE team at your site
   - judge that the participant would benefit from another full interval between visits to get more experience taking lanthanum placebo or
   - judge that your team would benefit from knowing more about the participant's experience taking lanthanum placebo

   It's okay to give the participant an additional bottle of lanthanum placebo at B1 if you want to be sure the participant has enough lanthanum placebo to last until a B2 visit that is more than 15 days from B0.

D. If the mean B1 pill count is <80%, the patient is not yet eligible by pill count, and the B2 pill count will be critical for eligiblity. Be sure that the participant has enough pills to last until B2 to allow for 100% adherence to both the baseline nicotinamide and lanthanum prescriptions. If there are not enough lanthanum left, use the bottle number assignment report to get an addition lanthanum placebo bottle number to dispense along with redispensed lanthanum. (The nicotinamide bottle originally dispensed will last as long as the allowable baseline time interval.)

Pilot Clinical Trials in CKD
Baseline Pre-Randomization Dropout Form # 163 - COMBINE

Instructions: This form is completed when it is determined that a participant who appeared to be eligible based on the Screening Form 107 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 the participant dies prior to randomization, complete the Death Notification Form 531.)

			C
1. Identification Number PID	2. Alphacode AC	3a. Pre-Randomized Dropout Date (mm/dd/yyyy) VISIT_DT	3b. Study STUDY

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

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

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

Timing-related code
1=More than thirty days (30 days) passed since Screening Visit data could be captured before Baseline 0 visit
2=More than six weeks (42 days) passed since Baseline Visit 0 before Baseline data could be captured

eGFR
80=GFR too low
81=GFR too high

Serum
3=No baseline protocol core serum phosphorus > 2.8 mg/dL
(Either only one was done and it was under 2.8 mg/dL or two were done and both were under 2.8 mg/dL)
4=Screening serum phosphate < 2.8 mg/dL
5=Screening AST > 80 U/L
6=Screening ALT > 100 U/L
7=Total bilirubin ≥ 3 mg/dL
8=Total alkaline phosphatase > 300 U/L
9=Screening albumin < 2.5 mg/dL
10=CK > 400 U/L
11=Intact PTH > 325 pg/mL
12=No baseline FGF23 sample collected

Whole Blood
13=Platelet count < 125,000 mm^3
14=Hemoglobin < 9 g/dL

Urine
16=Participant could not complete a 24-hour urine that could be analyzed

Pregnancy
17=Participant became pregnant during Baseline (Document also on Form 551)

Compliance-related codes
20=Did not attend baseline visits 1 and 2
21=Did not provide at least 1 of the 3 baseline Symptom Questionnaires Form 285
22=Did not meet the mean pill count adherence criterion

Medication-related codes
30=Detection of Allergic reaction to lanthanum carbonate, a multivitamin, nicotinamide, or niacin during baseline
31=Detection of/or initiation/change in dose of treatment with 1,25 (OH)2 vitamin D preparations
32=Detection of/or initiation/change in dose of treatment with active vitamin D
33=Detection of/or initiation/change in dose of treatment with sevelamer carbonate (Renvela)
34=Detection of/or initiation/change in dose of treatment with sevelamer hydrochloride (Renagel)
35=Detection of/or initiation/change in dose of treatment with calcium acetate (Phoslyra or PhosLo)
36=Detection of/or initiation/change in dose of treatment with aluminum hydroxide (for example, Alucaps, Basaljel)
37=Detection of/or initiation/change in dose of treatment with calcium acetate/magnesium carbonate (Renepho)
38=Detection of/or initiation/change in dose of treatment with phosphate binders greater than allowed by protocol
39=Detection of/or initiation/change in dose of treatment with Vitamin B (niacin or nicotinamide) greater than allowed by protocol
40=Detection of/or initiation/change in dose of new immunosuppressive medications during baseline (stable oral steroids ≤ 10 mg of prednisone/day or inhaled steroids are allowed)

Other Participant characteristics or events
45=Participant had 86th birthday before being randomized
46=Active liver disease identified during baseline
47=Significant malabsorption identified during baseline
48=Life expectancy determined to be < 12 months identified in baseline not known previously
49=Hemorrhage occurred during baseline
50=Blood or platelet transfusion done during baseline
51=Significant alcohol or substance abuse detected during baseline
52=Participant is now or will soon be incarcerated
53=Participant is now or will soon be otherwise institutionalized (chronic care hospital/skilled nursing facility)
54=Participant was lost during baseline; team can no longer locate this participant
55=Participant will not be at this center/site a sufficient amount of time during the next 12 months (Study team detected during baseline that he is moving or taking a long vacation such that he will miss protocol visits)
56=New malignancy identified during baseline
57=Bowel obstruction identified during baseline

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

Related to judgments or preference
70=Participant has changed his mind and does not want to be randomized, especially because he does not like collecting urine
71=Participant has changed his mind and does not want to be randomized; finds the protocol as a whole to be burdensome
72=Participant has changed his mind and does not want to be randomized; other reason
73=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
74=Participant's 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
75=Judgment of team is that this participant would not be adherent to the study protocol requirements
76=Study team preference; some other reason

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

200. Date this form completed (mm/dd/yyyy)..... ___ ___ /___ ___ /___ ___ ___ ___COMP_DT
201. Username of person compl/revwing completeness of this form . __ __ __ __ __ __ __COMP_USER

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

Pilot Clinical Trials in CKD
Visit Form # 203 – COMBINE

This form should be completed at:
- Protocol visits or missed protocol visits
- 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
- Extra visits for review of dietary information

COMBINE visits should be held at 12 noon or later so the COMBINE blood draws can be done in the afternoon.

1. Identification Number PID	2. Alphacode AC	3a.Visit Type VIST	3b. Visit Number (Month) VISN_MO	(Week) VISN_WK	4. Date of Visit (mm/dd/yyyy) VISIT_DT	5. Study STUDY
						C

6. a. Visit Number Intended..... ___ ___ ___INTENDED_VISIT
Screening (S) visit 0, Baseline (B) visits are 0, 1, 2. Follow-Up (F) Visits are 0, 1, 2, 3, 6, 9, 11, 12.
Code 99 for extra/non -protocol visits

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

c. Reason for visit .....___REASON
1=Protocol 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 for some other reason

7. How was this visit form completed? (1=In person, 2=By telephone interview)..... ___SETTING
(Note: Protocol visits should be conducted in person.)

8. Did the participant have a hospitalization or another SAE since the last visit?.....___HOSP_SAE
0=no [or this is the first visit form]; 1=yes, a hospitalization (complete F511-Hospitalization Notification Form)
2=yes, another SAE (complete F522-Details of SAEs, Not Hosp or Death Form), 3=both (complete F511-Hospitalization Notification Form and F522-Details of SAEs, Not Hosp or Death Form);
4=Patient was in the hospital and this is a phone visit (pt 310058)

9. Was the COMBINE Study Dietary Education Information discussed with the participant at this visit? (0=no, 1=yes)..... ___DIETARY_DISC

10. Did the participant bring in study pills? (0=no, 1=yes, 8=not applicable, this is Screening or B0).. ___PILLS
If not, counsel participant to bring study pills in for every visit, and remind him the day before the visit next time.

Response choices for Items 11, 12: **Participant response:** 0=not at all, 1=irregularly, 2=regularly (in every intended instance or almost every intended instance); **Other responses:** 8=Not Applicable – No study medication prescribed for the time period before this visit, 9=Unknown/coordinator forgot to ask/participant refused to answer.

11. a. "How often did you take your COMBINE Study "lanthanum/placebos" (round white pills)? ___WHITE_PILLS

b. "Did you take these with meals?"..... ___WHITE_MEALS

12. "How often did you take your COMBINE Study "nicotinamide/placebos" (football-shaped pills)? ___FOOTBALL_PILLS

If this was a <u>phone</u> visit (Item7=2), skip to item 200.

Note Baseline Visits 1 and 2 must be in person visits in order for the participant to be randomized.

Protocol measurement for visits Screening, B1, B2, F3, F6, F9, and F12; optional for other visits

13. Weight (kg) (measured)..... __ __ __ . __WT_KG

For Screening:

14. Height (cm) (measured).....__ __ __ . __HT_CM

For Screening, B1, B2, F3, F6, F9 and F12

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

15. Blood Pressure 1 (systolic/diastolic) (mmHg).....__ __ __/__ __ __SYS1/DIA1
16 Blood Pressure 2 (systolic/diastolic) (mmHg).....__ __ __/__ __ __SYS2/DIA2
17. Blood Pressure 3 (systolic/diastolic) (mmHg).....__ __ __/__ __ __SYS3/DIA3

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

18. Pulse (beats per minute).....__ __ __PULSE
(If the BP device measures pulse with each BP, report the pulse that is measured with the 3rd BP reading.)
19. Username person measuring BP and pulse..... __ __ __ __ __ __ __ __BP_PULSE_USERNAME

Checking the status of the staff blind at quarterly visits (F3, F6, F9, F12)

Study Coordinator completing/reviewing completeness of this form:

20. Do you know what this participant's round white pill is? (0=no, 1=yes) .....____SC_WHITE_GUESS
21. Do you know what this participant's football-shaped pill is? (0=no,1=yes)____SC_FOOTBALL_GUESS

Site PI:

22. CKD username ..... __ __ __ __ __ __ __PI_USERNAME
23. Do you know what this participant's round white pill is? (0=no, 1=yes) .....____PI_WHITE_GUESS
24. Do you know what this participant's football-shaped pill is? (0=no, 1=yes)
____PT_FOOTBALL_GUESS

200. Date this form completed (mm/dd/yyyy)..... __ __ /__ __ /__ __ __ __COMP_DT
201. Username of person compl/reving completeness of this form__ __ __ __ __ __ __ __COMP_USER

Clinical Center Use Only

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

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

Pilot Clinical Trials in CKD
Concomitant Medications Part A Form # 214 - COMBINE

This form is completed at Screening, F3, F6, F9 and F12. This Part A form includes medications that may exclude a participant prior to randomization and medications that must be monitored carefully during follow-up. This Part A form should be completed in conjunction with COMBINE Concomitant Medications Part B Form 215.

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
						C
PID	AC	VIST	VISN_MO	VISN_WK	VISIT_DT	STUDY

Phosphate Binders not containing calcium:

6. In the last 14 days, has the pt taken sevelamer carbonate (Renvela)? (0=no, 1=yes) .... ___SEV_CARBON
7. In the last 14 days, has the pt taken sevelamer hydrochloride (Renagel)? (0=no, 1=yes) ___SEV_HYDRO
8. In the last 14 days, has the pt taken aluminium hydroxide (for example, Alucaps, Basaljel)? (0=no, 1=yes).....___ALUMINIUM
9. In the last 14 days, has the pt taken lanthanum carbonate (Fosrenol)? (0=no, 1=yes)___LANTH_CARBON

Note, if participant is on the following phosphate binders: Sucrofferic Oxyhydroxide (Velphoro) or Ferric Citrate, discuss this with the PI.

Phosphate Binders containing calcium:

10. Is the participant currently taking a calcium acetate-based phosphate binder (Calphron, Eliphos, PhosLo, Phoslyra)? (0=no, 1=yes).....___CA_BASED_PHOS
11. Is the participant currently taking a calcium acetate/magnesium carbonate based phosphate binder (Renepho)? (0=no, 1=yes)..... ___CA_MAG_BASED_PHOS

If any of Items 6-11 were taken in the 14 days prior to screening or at any time during baseline, this is an exclusion. This form can be updated to reflect any changes during baseline. If the participant starts any of these meds, the participant will be excluded.

Other drugs containing calcium:

Other drugs containing calcium may include calcium carbonate supplements such as Caltrate 600, Calci-Chew, Os-Cal, calcium citrate supplements such as Cal-Citrate and calcitrate, and calcium carbonate antacids such as Chooz, Rolaids, and Tums. (Do not count multivitamins because they contain low amounts of calcium. Also, do not include "atorvastatin calcium" aka Lipitor since it will not materially bind phosphate.)

12. How many times per day does this participant take a drug containing calcium?.....___CALCIUM
    (0=None, 1=One, 2=Two, 3=Three, 4=Four or more)
    If three or more during baseline, this is an exclusion.

Record drugs that do not contain calcium below

13. Currently taking immunosuppressive medications?.....___IMMUNO_MEDS
    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.)*
14. Currently taking cinacalcet (Sensipar)? (0=no, 1=yes) .....___CINACALCET
    If yes, this is an exclusion

Vitamin D *(Note, for eligibility Q15-17, must be 1 or 3)*

15. In the last 14 days, has the participant taken 1,25(OH)$_2$ Vitamin D (calcitriol)? ..... ___VIT_D
    1=Has not taken calcitriol in the last 14 days
    2=Has taken calcitriol in the last 14 days and is or was on a dose that may be stopped or may increase or decrease during the 12 months of the COMBINE study
    3=Has taken calcitriol in the last 14 days and is on a dose not expected to be stopped, increased, or decreased during the 12 months of the COMBINE study

16. Participant's doxercalciferol (Hectorol) status..... ___DOXERCALC
    1=Has not taken doxercalciferol in the last 14 days
    2=Has taken doxercalciferol in the last 14 days and is or was on a dose that may be stopped or may increase or decrease during the 12 months of the COMBINE study
    3=Has taken doxercalciferol in the last 14 days and is on a dose not expected to be stopped, increased, or decreased during the 12 months of the COMBINE study

17. Participant's paricalcitol (Zemplar) status ..... ___PARICALC
    1=Has not taken paricalcitol in the last 14 days
    2=Has taken paricalcitol in the last 14 days and is or was on a dose that may be stopped or may increase or decrease during the 12 months of the COMBINE study.
    3=Has taken paricalcitol in the last 14 days and is on a dose not expected to be stopped, increased, or decreased during the 12 months of the COMBINE study.

Niacin and Nicotinamide

18. a. In the last 14 days, has the participant taken a Vitamin B3 supplement (not as part of a multivitamin)? (0=no, 1=yes) ..... ___VITAMIN_B3
    b. If yes, mg of niacin per day taken as part of a Vitamin B3 supplement? ..... ___ ___ ___NIACIN
    c. If yes, mg of niacinamide/nicotinamide taken as part of a Vitamin B3 supplement? ..... ___ ___ ___NIAC_NICO

19. a. Does the participant currently take a daily multivitamin? (0=no, 1=yes) ..... ___MULTIVIT
    b. If yes,

Name of multivitamin	Niacin (mg)	Niacinamide/Nicotinamide (mg)
MULTIVIT1	NIACIN1	N_N1
MULTIVIT2	NIACIN2	N_N2

20. What is the sum of the niacin or nicotinamide in the Vitamin B3 supplement and the niacin or nicotinamide in the multivitamin? (mg/day)..... ___ ___ ___ ___N_N_TOTAL
    If Q18=0 and Q19a=0, then enter '0' in Q20.
    Note, for eligibility, the sum must be less than or equal to 100 mg.

Screening Only Question

21. During the next 12 months, what will the participant do with respect to Vitamin B3 supplementation? ..... ___VIT_B3_PLAN
    0=Take no supplement containing niacin or nicotinamide
    1=Take a B3 supplement of 100 mg or less AND no multivitamin
    2=Take a multivitamin containing 100 mg/day B3 or less AND no Vitamin B3 supplement
    3=Take both a B3 supplement and a multivitamin, but together the pills contain less than 100 mg Vitamin B3
    4=Take more than 100 mg/day of niacin and or nicotinamide *(This is an exclusion)*

200. Date this form completed (mm/dd/yyyy) ..... ___ ___ /___ ___ /___ ___ ___ ___COMP_DT
201. Username of person compl/revwing completeness of this form.__ __ __ __ __ __ __COMP_USER

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

Pilot Clinical Trials in CKD
Concomitant Medications Part B Form # 215 - COMBINE

This form is completed at Screening, F3, F6, F9 and F12. Part A of this form includes medications that may exclude a participant during baseline and medications that must be monitored carefully during follow-up. This Part B form should be completed in conjunction with COMBINE Concomitant Medications Part A - Form 214.
Drugs containing calcium should be reported below.
Except for calcium, do not repeat any medication listed from Form 214 on this Form 215.

Record all oral medications and prescription transdermal patches if either
1) the participant is currently prescribed (regardless of whether it is a pill to be taken daily or to be taken PRN) or
2) reports to have taken in the previous 24 hours.
Also, list all over the counter PPIs, such as omeprazole /Prilosec or lansoprazole /Prevacid, whether the participant took it that day or not.

This is a snapshot of that day. (If the participant missed a medication that they normally take on this day, that medication should still be recorded.) Include prescribed and over the counter meds, vitamins, supplements, and herbs (topical creams and suppositories are not captured on this form.) Each medication is validated against the WHO Drug database as it is key entered.

1. Identification Number	2. Alphacode	3a. Visit Type	3b. Visit Number (Month)	(Week)	4. Date of visit: mm/dd/yyyy	5. Study
PID	AC	VIST	VISN_MO	VISN_WK	VISIT_DT	STUDY
						C

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

7.

Medication Brand or Generic Name
TABLE: CKD_CONCOM_MEDS_B_DTL
DRUG/CODE

Use an additional sheet of paper to document additional medications, if necessary. You will be able to key enter as many medications as needed.

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

201. Username of person comp/revwing completeness of this form..__ __ __ __ __ __ __COMP_USER

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

Pilot Clinical Trials in CKD
Medication Dosages Form # 216 - COMBINE

This form is completed at Screening, F3, F6, F9 and F12 to record dosages for participants who are taking one of these medications orally at the time of the visit: 1) 1, 25(OH)$_2$ Vitamin D (calcitriol), 2) doxercalciferol (Hectorol), or 3) paricalcitol (Zemplar). *If a participant reports taking one of these medications in an injection or IV, or on an as needed basis, this form cannot be used for dosage data; get input from your site's Principal Investigator.*

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

6. Visit Number Intended..... ___ ___ INTENDED_VISIT
The Screening (S) visit is numbered 0, Baseline (B) visits are 0, 1, 2, and
Follow-Up (F) Visits are 0, 1, 2, 3, 6, 9, 11, 12. Code 99 for extra/non-protocol visits

7. a. Is this participant currently taking 1, 25(OH)$_2$ Vitamin D (calcitriol)? (0=no, 1=yes) ..... ___ VITD
   b. If yes, how many days does the pt take this pill in a 14-day time period?... ___ ___ VITD_DAYS
   (Enter the number of days, for example, 2 for once a week, 4 for twice a week, 6 for three times a week, 7 for every other day, 8=for four times a week, 10=for five times a week, 14 for every day.)
   c. On days when the participant takes this pill, how many pills are taken?..... ___ . ___ VITD_AMT
   d. What is the dosage of these pills in mcg? *(expected values 0.25 or 0.50)*..... __ . __ __ VITD_DOSE

8. a. Is this participant currently taking doxercalciferol (Hectorol)? (0=no, 1=yes)..... ___ DOXERCAL
   b. If yes, how many days does the pt take this pill in a 14-day time period?__ __ DOXERCAL_DAYS
   (Enter the number of days, for example, 2 for once a week, 4 for twice a week, 6 for three times a weeks, 7 for every other day, or 14 for every day.)
   c. On days when the participant takes this pill, how many pills are taken?.._ . __ DOXERCAL_AMT
   d. What is the dosage of these pills in mcg? *(expected values 0.5, 1.0, or 2.5)*__ . ___ DOXERCAL_DOSE

9. a. Is this participant currently taking paricalcitol (Zemplar)? (0=no, 1=yes) ..... ___ PARICAL
   b. If yes, how many days does the pt take this pill in a 14-day time period?..__ __ PARICAL_DAYS
   (Enter the number of days, for example, 2 for once a week, 4 for twice a week, 6 for three times a weeks, 7 for every other day, or 14 for every day.)
   c. On days when the participant takes this pill, how many pills are taken?___ . ___ PARICAL_AMT
   d. What is the dosage of these pills in mcg? *(expected values 1.0, 2.0, or 4.0)*___ . ___ PARICAL_DOSE

200. Date this form completed (mm/dd/yyyy) ..... ___ ___ /___ ___ /___ ___ ___ ___ COMP_DT
201. Username of person compl/reviewing completeness of this form__ __ __ __ __ __ __ COMP_USER

Clinical Center Use Only

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

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

CKD_FU_INIT_PILLS

Pilot Clinical Trials in CKD
Follow-Up Initial Pill Dispensing Form # 248 - COMBINE

This form is completed once when the participant is given his or her first follow up medication. This should be done as soon as possible after Randomization. The participant should be reminded to bring pills or empty pill bottles back at each follow up visit.

1. Identification Number PID	2. Alphacode AC	3a. Visit Type VIST	3b. Visit Number. (Month) VISN_MO	(Week) VISN_WK	4. Date pills dispensed: (mm/dd/yyyy) VISIT_DT	5. Study STUDY
		F				C

6. Visit Number Intended ..... F 0 INTENDED_VISIT
This form is completed at F0.

7. Current COMBINE Meal Pattern ..... __MEAL_PATTERN
1=3 or more meals/day (prescribe 3 for F0 to F1)
2=2 meals, no snacks (prescribe 2 for F0 to F1)
3=2 meals, 1 snack (prescribe 3 for F0 to F1)
4=2 meals, 2 or more snacks (prescribe 3 for F0 to F1)

8. a. How many Lanthanum Carbonate/Placebo (Round White Pills) dispensed __ __ __ W_DISPENSED
Those are the Lanthanum Carbonate/Placebo 500 mg chewable tablets / answer will be 45 or a multiple of 45)

b. Bottle number 1 ..... ___ ___ ___ ___ ___WHITE_BOTTLE_NO1
c. Bottle number 2 ..... ___ ___ ___ ___ ___ WHITE_BOTTLE_NO2
d. Bottle number 3 ..... ___ ___ ___ ___ ___ WHITE_BOTTLE_NO2
During month 1, participants take no more than 3 pills per day.3 bottles will last 45 days.
Only dispense a fourth bottle if you think F1 will be outside the window, delayed by more than 2 weeks.
e. Bottle number 4 ..... ___ ___ ___ ___ ___ WHITE_BOTTLE_NO4

9. a. How many Nicotinamide/Placebo (Football Shaped Pills) were dispensed .....8 0F_DISPENSED
Those are the Nicotinamide/Placebo 750 mg pills/ answer will be 80)

b. Bottle number ..... ___ ___ ___ ___ ___FOOTBALL_BOTTLE_NO

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

201. Username of person compl/revwing completeness of this form... __ __ __ __ __ __ __COMP_USER

Clinical Center Use Only

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

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

Pilot Clinical Trials in CKD
Follow-Up Pill Dispensing and Counting Form # 249 - COMBINE

This form is completed for all Protocol visits and for any extra follow-up visit at which pills are dispensed or counted. Participants should bring their pill bottles to all visits, whether pills will be counted or not.

If the participant comes in before the end of the visit window and forgets the pills, ask the participant to come in again before the visit window ends and bring the pills. Don't complete this form until either the pills were counted or the visit window ends. **The participant's own returned pills <u>should not</u> be re-dispensed at any follow-up visit.** Follow local procedures for destruction of study meds that are not re-dispensed.

Pill counts are expected at F1, F2, F3, and F12.

1. Identification Number PID	2. Alphacode AC	3a.Visit Type	3b. Visit Number (Month) (Week)	4. Date pills counted or dispensed (mm/dd/yyyy) VISIT_DT	5. Study STUDY
☐☐☐☐☐☐	☐☐	F	☐ ☐☐☐	☐☐/☐☐/☐☐☐☐	C

6. Visit Number Intended.. F ___ ___INTENDED_VISIT
Follow-Up (F) Visits are 1, 2, 3, 6, 9, 11, 12. Code 99 for extra/non -protocol visits

7.	Study Medication Type	Lanthanum Carbonate/ Placebo 500 mg *(Round white pills)*	Nicotinamide/ Placebo 750 mg *(Football- shaped pills)*
a.	Were any pills lost or ruined?*	__ W_LOST	__F_LOST
b.	Were the pills counted (0=no, 1=yes) (if no, skip to j)	__W_COUNTED	__F_COUNTED
c.	# days between visits (calculated and displayed)	__ __W_DAYS	__ __F_DAYS
d.	# pills at end of previous visit	__ __ __W_PREV_PILLS	__ __ __ F_PREV_PILLS
e.	Prescribed # of pills per day at end of last visit	depends on meal pattern/AEs W_PRESC_LAST	Depends on AEs F_PRESC_LAST
f.	# pills should have taken (# days between visits times prescribed # pills per day at end of last visit)	__ __ __W_EXPECTED	__ __ __F_EXPECTED
g.	Pill Count (# pills returned)	__ __ __W_RETURNED	__ __ __F_RETURNED
h.	# pills taken (# pills at end of previous visit minus # pills returned)	__ __ __W_TAKEN	__ __ __F_TAKEN
i.	Adherence *Percent taken* (#taken divided by #should have taken times 100%)	__ __ __.__ W_ADHERENCE	__ __ __.__ F_ADHERENCE
j.	# "returned" unopened bottles that are redispensed *(This should be 0 unless unopened bottles are redispensed)*	__ W_NO_REDISPENSED	__ F_NO_REDISPENSED
k.	COMBINE Meal Pattern planned for after this visit**	__ W_MEAL_PATTERN	__F_MEAL_PATTERN
l.	# new bottles dispensed	__ __ W_BOTTLES_DISP	__ __ F_BOTTLES_DISP
m.	# pills dispensed	__ __ __ W_PILLS_DISP Must be a multiple of 45	__ __ __ F_PILLS_DISP Must be a multiple of 80
n.	Prescription type? ***	__W_PRES_TYPE	__F_PRES_TYPE
o.	Prescribed # of pills **per day** as participant leaves visit	__ W_DAILY	__ F_DAILY

*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 j.)
** Codes for COMBINE Meal Pattern planned: 1=3 meals/day *(prescribe 6);* 2=2 meals, no snacks *(prescribe 4),* 3=2 meals, 1 snack *(prescribe 5),* 4=2 meals, 2 or more snacks *(prescribe 6)*
*** Codes for "Prescription type?"
1=Standard per protocol for participant's COMBINE Meal Pattern and month of follow-up
2=Cut in half per protocol due to hyper or hypophosphatemia. Document in item 8 below.
3=Cut in half per protocol due to platelets. Document in item 8 below.
4=Cut in half per protocol/MOP for symptoms or other reasons. Document in item 8 below

5=Cut in half or reduced due to local physician judgment. Document in item 8 below.
6=Discontinued due to local physician judgment. Document in item 8 below.
7=Cut in half or reduced due to participant preference/non-adherence. Document in item 8 below.
9=Discontinued due to participant preference/non-adherence. Document in item 8 below.
0=Prescription discontinuation required per protocol (or for end of study).

8. a. Regarding "Prescription type" in Item 7n for "Lanthanum/Lanthanum placebo" column, what is the primary reason the L prescription is reduced or stopped?.....__ __ __ , __ __ ___ , __ __ __
(Codes are listed beginning on Page 3. Secondary and tertiary reasons may also be specified.) L_RSN_1, L_RSN_2, L_RSN_3

b. Regarding "Prescription type" in Item 7n for "Nicotinamide/Nicotinamide placebo" column, what is the primary reason the N prescription is reduced or stopped? .....__ __ __ , __ __ ___ , __ __ __
(Codes are listed beginning on Page 3. Secondary and tertiary reasons may also be specified.) N_RSN_1, N_RSN_2, N_RSN_3

9. If item 7l column 1 indicates new Lanthanum Carbonate/Placebo (round white pills) were dispensed

L Bottle Number 1	L Bottle number 2	L Bottle number 3	L Bottle number 4
__ __ __ __ __ W_BOTTLE_NO1	__ __ __ __ __ W_BOTTLE_NO2	__ __ __ __ __ W_BOTTLE_NO3	__ __ __ __ __ W_BOTTLE_NO4
L Bottle Number 5	L Bottle number 6	L Bottle number 7	L Bottle number 8
__ __ __ __ __ W_BOTTLE_NO5	__ __ __ __ __ W_BOTTLE_NO6	__ __ __ __ __ W_BOTTLE_NO7	__ __ __ __ __ W_BOTTLE_NO8
L Bottle Number 9	L Bottle number 10	L Bottle number 11	L Bottle number 12
__ __ __ __ __ W_BOTTLE_NO9	__ __ __ __ __ W_BOTTLE_NO10	__ __ __ __ __ W_BOTTLE_NO11	__ __ __ __ __ W_BOTTLE_NO12
L Bottle Number 13	L Bottle number 14	L Bottle number 15	*L Bottle number 16**
__ __ __ __ __ W_BOTTLE_NO13	__ __ __ __ __ W_BOTTLE_NO14	__ __ __ __ __ W_BOTTLE_NO15	__ __ __ __ __ W_BOTTLE_NO16

**Unless F3 (or F4) is early in the window AND F6 (or F9) is planned for late in its window, 15 bottles will be sufficient for dispensing at F3 and F6.*

10. If item 7l column 2 indicates new Nicotinamide/Placebo (football-shaped pills) were dispensed

N Bottle Number 1	N Bottle number 2	N Bottle number 3	N Bottle number 4
__ __ __ __ __ F_BOTTLE_NO1	__ __ __ __ __ F_BOTTLE_NO2	__ __ __ __ __ F_BOTTLE_NO3	__ __ __ __ __ F_BOTTLE_NO4

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

201. Username of person compl/reviewing completeness of this form . __ __ __ __ __ __ __COMP_USER

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

MED_CHANGE_STORY – description of why the participant was off one or both study meds.

CODES FOR PARTICIPANTS NO LONGER ATTENDING VISITS (Used for (*the first)* Form 249/250 when participant quits coming) *Use the code below as the first reason but additional reasons should also be documented.)*

100=Not attending visits; participant is not taking or has reduced study medications
101=Not attending visits; participant is not taking or has reduced study medications; has refused consent for any further follow-up.
102=Not attending visits; participant is not taking or has reduced study medications; site knows where participant lives but cannot communicate with participant, participant unresponsive
103=Not attending visits; participant is not taking or has reduced study medications; site no longer knows where the participant lives, participant completely lost.
104=Not attending visits; participant is not taking or has reduced study medications; has changed residence such that the COMBINE site is inaccessible
105=Not attending visits; participant is not taking or has reduced study medications; institutionalized, nursing home or rehabilitation center
106=Not attending visits; participant is not taking or has reduced study medications; incarcerated and is no longer attending visits; is allowing passive follow-up.

Return from lost to follow up
115=Patient was previously lost to follow up but has now returned, restarting meds at a reduced dose

CODES FOR PARTICIPANTS ATTENDING VISITS

Codes related to participant burden
120=Participant is attending visits but not taking or has reduced study medications due to pill burden
121=Participant is attending visits but not taking or has reduced study medications due to complexity of the study (such as the number of visits and procedures)

Codes related to participant concerns about detrimental effects of the medication
130=Participant is attending visits, not taking or has reduced study medications, concerned about the impact of medication on liver function, concerned for LFTs in others
131=Participant is attending visits, not taking or has reduced study medications, concerned about the impact of medication on renal function

Codes related to non-GI symptoms on Forms 285/286
140=Bone fracture
141=Flushing (previously coded as 5 prior to 1/5/2016)
142=Hives (previously coded as 6 prior to 1/5/2016)
143=Bruising (previously coded as 1 prior to 1/5/2016)
144=Bleeding (previously coded as 2 prior to 1/5/2016)
145=Headache
146=Wheezing
147=Backache
148=Common cold
149=Loss of energy, feeling run down, fatigued
150=Drowsy, sleepy, can't stay awake
151=Dizziness
152=Insomnia

Codes related to GI symptoms reported by the participant on Forms 285/286

165=UPPER ABDOMEN OR PIT OF STOMACH PAIN mild,
166=UPPER ABDOMEN OR PIT OF STOMACH PAIN moderate,
167=UPPER ABDOMEN OR PIT OF STOMACH PAIN severe,
168=HEARTBURN mild
169=HEARTBURN moderate
170=HEARTBURN severe
171=ACID REFLUX mild
172=ACID REFLUX moderate
173=ACID REFLUX severe
174=HUNGER PAINS mild
175=HUNGER PAINS moderate
176=HUNGER PAINS severe
177=NAUSEA mild
178=NAUSEA moderate
179=NAUSEA severe (previously coded as 4 prior to 1/5/2016)
180=RUMBLING in the stomach mild
181=RUMBLING in the stomach moderate
182=RUMBLING in the stomach severe
183=Stomach felt BLOATED mild
184=Stomach felt BLOATED moderate
185=Stomach felt BLOATED severe
186=BURPING mild
187=BURPING moderate
188=BURPING severe
189=PASSING GAS mild
190=PASSING GAS moderate
191=PASSING GAS severe
192=CONSTIPATION mild
193=CONSTIPATION moderate
194=CONSTIPATION severe (previously coded as 8 prior to 1/5/2016)
195=DIARRHEA mild
196=DIARRHEA moderate
197=DIARRHEA severe (previously coded as 3 prior to 1/5/2016)
198=LOOSE STOOLS mild
199=LOOSE STOOLS moderate
200=LOOSE STOOLS severe
201=HARD STOOLS mild
202=HARD STOOLS moderate
203=HARD STOOLS severe
204=URGENT NEED TO HAVE BOWEL MOVEMENT mild
205=URGENT NEED TO HAVE BOWEL MOVEMENT moderate
206=URGENT NEED TO HAVE BOWEL MOVEMENT severe
207=SENSATION OF NOT EMPTYING BOWELS mild
208=SENSATION OF NOT EMPTYING BOWELS moderate
209=SENSATION OF NOT EMPTYING BOWELS severe

Codes related to other GI Symptoms
220=Vomiting

Codes related to SAE, Illness, or Comorbidity

Codes related to SAEs, Hospitalizations and Illness
230=Aftermath of a hospitalization SAE (details of the hospitalization will be on SAE Form 512)
231=Aftermath of a non-hospitalization SAE (details of the non-hospitalization SAE will be on SAE Form 522)

Previous comorbid condition noted on the baseline Comorbidity Form 122
240=Myocardial infarction
241=Congestive heart failure
242=Angina/chest pain
243=Atrial fibrillation
244=Ischemia
245=Peripheral vascular disease
246=Cerebrovascular disease/Stroke
247=COPD (excludes asthma)
248=Connective tissue disease
249=Peptic ulcer disease (excludes GERD)
250=Hemiplegia
251=Leukemia
252=Lymphoma
253=Multiple myeloma
254=Cancerous solid tumor
255=Diabetes mellitus
256=Liver disease
257=Hepatitis B
258=Hepatitis C
259=Gout
260=Needs a wheelchair to get around
261=Deaf
262=Legally blind

Codes related to **NEW** comorbid condition/**NEW** diagnosis that was **not** noted on the baseline Comorbidity Form 122

270=Myocardial infarction – New
271=Congestive heart failure – New
272=Angina/chest pain – New
273=Atrial fibrillation – New
274=Ischemia – New
275=Peripheral vascular disease – New
276=Cerebrovascular disease/Stroke – New
277=COPD (excludes asthma) – New
278=Connective tissue disease – New
279=Peptic ulcer disease (excludes GERD) – New
280=Hemiplegia – New
281=Leukemia – New
282=Lymphoma – New

283=Multiple myeloma – New
284=Cancerous solid tumor – New
285=Diabetes mellitus – New
286=Liver disease – New
287=Hepatitis B – New
288=Hepatitis C – New
289=Gout – New
290=Loss of ability to ambulate/needs for a wheelchair to get around – New
291=Loss of hearing – New
292=Loss of vision – New
293=Uremia - New

Codes for items not on Form 122 (Comorbidity Form)
300=Started dialysis
301=Had a renal transplant
302=Became pregnant
303=Death

Code related to illness
310=Pneumonia
311=Shingles
312=Viral Syndrome

Codes related to other symptoms
325=Muscle cramps
326=Sinus congestion
327=Change in perception of taste
328=Muscle weakness
329=Difficulty standing
330=Rectal bleeding

Code related to trauma
350=Aftermath of trauma (trauma that was not a hospitalization or SAE): broken arm

Codes related to lab values. (These are broken down in a way that allows the DCC to make sure the actual values are documented on study lab forms.)

400=Single measure of hypophosphatemia, central
401=Single measure of hypophosphatemia, local
402=More than one measure of hypophosphatemia, central
403=More than one measure of hypophosphatemia, local
404=More than one measure of hypophosphatemia, local and central

410=Single measure of hyperphosphatemia, central
411=Single measure of hyperphosphatemia, local
412=More than one measure of hyperphosphatemia, central
413=More than one measure of hyperphosphatemia, local
414=More than one measure of hyperphosphatemia, local and central

420=Single measure of low platelets, central
421=Single measure of low platelets, local
422=More than one measure of low platelets, central
423=More than one measure of low platelets, local
424=More than one measure of low platelets, local and central

430=Single measure of low WBC, central
431=Single measure of low WBC, local
432=More than one measure of low WBC, central
433=More than one measure of low WBC, local
434=More than one measure of low WBC, local and central

440=Single measure of high AST, central
441=Single measure of high AST, local
442=More than one measure of high AST, central
443=More than one measure of high AST, local
444=More than one measure of high AST, local and central

450=Single measure of high ALT, central
451=Single measure of high ALT, local
452=More than one measure of high ALT, central
453=More than one measure of high ALT, local
454=More than one measure of high ALT, local and central

460=Single measure of high total bilirubin, central
461=Single measure of high total bilirubin, local
462=More than one measure of high total bilirubin, central
463=More than one measure of high total bilirubin, local
464=More than one measure of high total bilirubin, local and central

470=Single measure of high alkaline phosphatase, central
471=Single measure of high alkaline phosphatase, local
472=More than one measure of high alkaline phosphatase, central
473=More than one measure of high alkaline phosphatase, local
474=More than one measure of high alkaline phosphatase, local and central

480=Single measure of low neutrophils, central
481=Single measure of low neutrophils, local
482=More than one measure of low neutrophils, central
483=More than one measure of low neutrophils, local
484=More than one measure of low neutrophils, local and central

490=Single measure of high creatine kinase, central
491=Single measure of high creatine kinase, local
492=More than one measure of high creatine kinase, central
493=More than one measure of high creatine kinase, local
494=More than one measure of high creatine kinase, local and central

(DCC will add code numbers on request for reasons that lead to a participant going off or reducing study medications)

Pilot Clinical Trials in CKD
Between Visit Phone Medication Change Form # 250 – COMBINE

This form is completed during Follow-up when a prescription changes during a telephone call between visits and no visit form is completed. If new pills are dispensed, use Form 249 instead of this form.

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 PID	2. Alphacode AC	3a.Visit Type VIST	3b. Visit Number (Month) VISN_MO	(Week) VISN_WK	4. Date pill prescription changed (mm/dd/yyyy) VISIT_DT	5. Study STUDY
		F				C

	Study Medication Type	Lanthanum Carbonate/ Placebo 500 mg *(Round white pills)*	Nicotinamide/ Placebo 750 mg *(Football-shaped pills)*
6.	Prescription type? ***	W_PRES_TYPE	F_PRES_TYPE
7.	Prescribed # of pills **per day**	W_DAILY	F_DAILY

*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 j.)
** Codes for COMBINE Meal Pattern planned: 1=3 meals/day *(prescribe 6);* 2=2 meals, no snacks *(prescribe 4),* 3=2 meals, 1 snack *(prescribe 5),* 4=2 meals, 2 or more snacks *(prescribe 6)*
*** Codes for "Prescription type?"
1=Standard per protocol for participant's COMBINE Meal Pattern and month of follow-up
2=Cut in half per protocol due to hyper or hypophosphatemia. Document in item 8 below.
3=Cut in half per protocol due to platelets. Document in item 8 below.
4=Cut in half per protocol/MOP for symptoms or other reasons. Document in item 8 below
5=Cut in half or reduced due to local physician judgment. Document in item 8 below.
6=Discontinued due to local physician judgment. Document in item 8 below.
7=Cut in half or reduced due to participant preference/non-adherence. Document in item 8 below.
9=Discontinued due to participant preference/non-adherence. Document in item 8 below.
0=Prescription discontinuation required per protocol (or for end of study)

8. a. Regarding "Prescription type" in Item 7n for "Lanthanum/Lanthanum placebo" column, what is the primary reason the L prescription is reduced or stopped?.....__ __ __ , __ __ ___ , __ __ __
(Codes are listed beginning on Page 3. Secondary and tertiary reasons may also be specified.) L_RSN_1, L_RSN_2, L_RSN_3

b. Regarding "Prescription type" in Item 7n for "Nicotinamide/Nicotinamide placebo" column, what is the primary reason the N prescription is reduced or stopped? .....__ __ __ , __ __ ___ , __ __ __
(Codes are listed beginning on Page 3. Secondary and tertiary reasons may also be specified.) N_RSN_1, N_RSN_2, N_RSN_3

9. Was this symptom documented on a Symptoms/Adverse Events Reported on Phone Calls or at Extra Non-Protocol Visits Form 286? (0=no, 1=yes) ..... ___SYMPTOMS_DOC

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

201. Username of person compl/revwing completeness of this form.....__ __ __ __ __ __ __COMP_USER

Clinical Center Use Only

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

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

CODES FOR PARTICIPANTS NO LONGER ATTENDING VISITS (Used for (*the first)* Form 249/250 when participant quits coming) *Use the code below as the first reason but additional reasons should also be documented.)*

100=Not attending visits; participant is not taking or has reduced study medications
101=Not attending visits; participant is not taking or has reduced study medications; has refused consent for any further follow-up.
102=Not attending visits; participant is not taking or has reduced study medications; site knows where participant lives but cannot communicate with participant, participant unresponsive
103=Not attending visits; participant is not taking or has reduced study medications; site no longer knows where the participant lives, participant completely lost.
104=Not attending visits; participant is not taking or has reduced study medications; has changed residence such that the COMBINE site is inaccessible
105=Not attending visits; participant is not taking or has reduced study medications; institutionalized, nursing home or rehabilitation center
106=Not attending visits; participant is not taking or has reduced study medications; incarcerated and is no longer attending visits; is allowing passive follow-up.

Return from lost to follow up
115=Patient was previously lost to follow up but has now returned, restarting meds at a reduced dose

CODES FOR PARTICIPANTS ATTENDING VISITS

Codes related to participant burden
120=Participant is attending visits but not taking or has reduced study medications due to pill burden
121=Participant is attending visits but not taking or has reduced study medications due to complexity of the study (such as the number of visits and procedures)

Codes related to participant concerns about detrimental effects of the medication
130=Participant is attending visits, not taking or has reduced study medications, concerned about the impact of medication on liver function, concerned for LFTs in others
131=Participant is attending visits, not taking or has reduced study medications, concerned about the impact of medication on renal function

Codes related to non-GI symptoms on Forms 285/286
140=Bone fracture
141=Flushing (previously coded as 5 prior to 1/5/2016)
142=Hives (previously coded as 6 prior to 1/5/2016)
143=Bruising (previously coded as 1 prior to 1/5/2016)
144=Bleeding (previously coded as 2 prior to 1/5/2016)
145=Headache
146=Wheezing
147=Backache
148=Common cold
149=Loss of energy, feeling run down, fatigued
150=Drowsy, sleepy, can't stay awake
151=Dizziness
152=Insomnia

Codes related to GI symptoms reported by the participant on Forms 285/286

165=UPPER ABDOMEN OR PIT OF STOMACH PAIN mild,
166=UPPER ABDOMEN OR PIT OF STOMACH PAIN moderate,
167=UPPER ABDOMEN OR PIT OF STOMACH PAIN severe,
168=HEARTBURN mild
169=HEARTBURN moderate
170=HEARTBURN severe
171=ACID REFLUX mild
172=ACID REFLUX moderate
173=ACID REFLUX severe
174=HUNGER PAINS mild
175=HUNGER PAINS moderate
176=HUNGER PAINS severe
177=NAUSEA mild
178=NAUSEA moderate
179=NAUSEA severe (previously coded as 4 prior to 1/5/2016)
180=RUMBLING in the stomach mild
181=RUMBLING in the stomach moderate
182=RUMBLING in the stomach severe
183=Stomach felt BLOATED mild
184=Stomach felt BLOATED moderate
185=Stomach felt BLOATED severe
186=BURPING mild
187=BURPING moderate
188=BURPING severe
189=PASSING GAS mild
190=PASSING GAS moderate
191=PASSING GAS severe
192=CONSTIPATION mild
193=CONSTIPATION moderate
194=CONSTIPATION severe (previously coded as 8 prior to 1/5/2016)
195=DIARRHEA mild
196=DIARRHEA moderate
197=DIARRHEA severe (previously coded as 3 prior to 1/5/2016)
198=LOOSE STOOLS mild
199=LOOSE STOOLS moderate
200=LOOSE STOOLS severe
201=HARD STOOLS mild
202=HARD STOOLS moderate
203=HARD STOOLS severe
204=URGENT NEED TO HAVE BOWEL MOVEMENT mild
205=URGENT NEED TO HAVE BOWEL MOVEMENT moderate
206=URGENT NEED TO HAVE BOWEL MOVEMENT severe
207=SENSATION OF NOT EMPTYING BOWELS mild
208=SENSATION OF NOT EMPTYING BOWELS moderate
209=SENSATION OF NOT EMPTYING BOWELS severe

Codes related to other GI Symptoms
220=Vomiting

Codes related to SAE, Illness, or Comorbidity

Codes related to SAEs, Hospitalizations and Illness
230=Aftermath of a hospitalization SAE (details of the hospitalization will be on SAE Form 512)
231=Aftermath of a non-hospitalization SAE (details of the non-hospitalization SAE will be on SAE Form 522)

Previous comorbid condition noted on the baseline Comorbidity Form 122
240=Myocardial infarction
241=Congestive heart failure
242=Angina/chest pain
243=Atrial fibrillation
244=Ischemia
245=Peripheral vascular disease
246=Cerebrovascular disease/Stroke
247=COPD (excludes asthma)
248=Connective tissue disease
249=Peptic ulcer disease (excludes GERD)
250=Hemiplegia
251=Leukemia
252=Lymphoma
253=Multiple myeloma
254=Cancerous solid tumor
255=Diabetes mellitus
256=Liver disease
257=Hepatitis B
258=Hepatitis C
259=Gout
260=Needs a wheelchair to get around
261=Deaf
262=Legally blind

Codes related to **NEW** comorbid condition/**NEW** diagnosis that was **not** noted on the baseline Comorbidity Form 122

270=Myocardial infarction – New
271=Congestive heart failure – New
272=Angina/chest pain – New
273=Atrial fibrillation – New
274=Ischemia – New
275=Peripheral vascular disease – New
276=Cerebrovascular disease/Stroke – New
277=COPD (excludes asthma) – New
278=Connective tissue disease – New
279=Peptic ulcer disease (excludes GERD) – New
280=Hemiplegia – New
281=Leukemia – New
282=Lymphoma – New

283=Multiple myeloma – New
284=Cancerous solid tumor – New
285=Diabetes mellitus – New
286=Liver disease – New
287=Hepatitis B – New
288=Hepatitis C – New
289=Gout – New
290=Loss of ability to ambulate/needs for a wheelchair to get around – New
291=Loss of hearing – New
292=Loss of vision – New
293=Uremia - New

Codes for items not on Form 122 (Comorbidity Form)
300=Started dialysis
301=Had a renal transplant
302=Became pregnant
303=Death

Code related to illness
310=Pneumonia
311=Shingles
312=Viral Syndrome

Codes related to other symptoms
325=Muscle cramps
326=Sinus congestion
327=Change in perception of taste
328=Muscle weakness
329=Difficulty standing
330=Rectal bleeding

Code related to trauma
350=Aftermath of trauma (trauma that was not a hospitalization or SAE): broken arm

Codes related to lab values. (These are broken down in a way that allows the DCC to make sure the actual values are documented on study lab forms.)

400=Single measure of hypophosphatemia, central
401=Single measure of hypophosphatemia, local
402=More than one measure of hypophosphatemia, central
403=More than one measure of hypophosphatemia, local
404=More than one measure of hypophosphatemia, local and central

410=Single measure of hyperphosphatemia, central
411=Single measure of hyperphosphatemia, local
412=More than one measure of hyperphosphatemia, central
413=More than one measure of hyperphosphatemia, local
414=More than one measure of hyperphosphatemia, local and central

420=Single measure of low platelets, central
421=Single measure of low platelets, local
422=More than one measure of low platelets, central
423=More than one measure of low platelets, local
424=More than one measure of low platelets, local and central

430=Single measure of low WBC, central
431=Single measure of low WBC, local
432=More than one measure of low WBC, central
433=More than one measure of low WBC, local
434=More than one measure of low WBC, local and central

440=Single measure of high AST, central
441=Single measure of high AST, local
442=More than one measure of high AST, central
443=More than one measure of high AST, local
444=More than one measure of high AST, local and central

450=Single measure of high ALT, central
451=Single measure of high ALT, local
452=More than one measure of high ALT, central
453=More than one measure of high ALT, local
454=More than one measure of high ALT, local and central

460=Single measure of high total bilirubin, central
461=Single measure of high total bilirubin, local
462=More than one measure of high total bilirubin, central
463=More than one measure of high total bilirubin, local
464=More than one measure of high total bilirubin, local and central

470=Single measure of high alkaline phosphatase, central
471=Single measure of high alkaline phosphatase, local
472=More than one measure of high alkaline phosphatase, central
473=More than one measure of high alkaline phosphatase, local
474=More than one measure of high alkaline phosphatase, local and central

480=Single measure of low neutrophils, central
481=Single measure of low neutrophils, local
482=More than one measure of low neutrophils, central
483=More than one measure of low neutrophils, local
484=More than one measure of low neutrophils, local and central

490=Single measure of high creatine kinase, central
491=Single measure of high creatine kinase, local
492=More than one measure of high creatine kinase, central
493=More than one measure of high creatine kinase, local
494=More than one measure of high creatine kinase, local and central

(DCC will add code numbers on request for reasons that lead to a participant going off or reducing study medications)

Pilot Clinical Trials in CKD
Symptoms Questionnaire # 285 – COMBINE

This form is completed at all protocol visits for COMBINE.

1. Identification Number	2. Alphacode	3a. Visit Type	3b. Visit Number (Month)	(Week)	4. Date of Visit (mm/dd/yyyy)	5. Study
PID	AC	VIST	VISN_MO	VISN_WK	VISIT_DT	STUDY
						C

6. Visit Number Intended .... ___ ___ ___ INTENDED_VISIT
Baseline (B) visits are 0, 1, 2. Follow-Up (F) Visits are 1, 2, 3, 6, 9, 11, 12. Code 99 for extra/non -protocol visits

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

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

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

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

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

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

Other (non-GI) Symptoms: For Q25-30, Explicitly ask the participant, if he or she has/had any of the following non-GI symptoms since the last visit. (Enter a 0=no, 1=yes, and 9=unknown/not asked.) For Q26-29 code 2=if staff observes symptom but participant reports "no".

25. Bone fracture (10017076) ..... ___BONE_FRACTURE
26. Flushing (10016825) ..... ___FLUSHING
27. Hives (10020197) ..... ___HIVES
28. Bruising (010006504) ..... ___BRUISING
29. Bleeding (10005103) ..... ___BLEEDING
30. Headache (10019211) ..... ___HEADACHE

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

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

Symptom **TABLE: CKD_SYMPTOMS_DTL**	**MedDRA Code** *(will populate at data entry)*
a. SYMPTOM	MEDDRA
b. SYMPTOM	MEDDRA
c. SYMPTOM	MEDDRA
d. SYMPTOM	MEDDRA

200. Date this form completed (mm/dd/yyyy)..... __ __ /__ __ /__ __ __ __COMPT_DT
201. Username of person compl/revwing completeness of this form ...__ __ __ __ __ __ __COMP_USER

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

Pilot Clinical Trials in CKD
Symptoms/Adverse Events Reported on Phone Calls\Email or at Extra Non-Protocol Visits Form # 286 – COMBINE

If a participant brings up a symptom or an adverse event during a phone call/email exchange with a COMBINE 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. (In the unusual case where a protocol visit must be conducted by telephone, use Form 285.)

						C	
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 6

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/Email

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

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

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

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

Other (non-GI) Symptoms: For Q25-30, Explicitly ask the participant, if he or she has/had any of the following non-GI symptoms since the last visit. (Enter a 0=no, 1=yes, and 9=unknown/not asked.) For Q26-29 code 2=if staff observes symptom but participant reports "no".

25. Bone fracture (10017076) ..... ___
26. Flushing (10016825) ..... ___
27. Hives (10020197) ..... ___
28. Bruising (010006504) ..... ___
29. Bleeding (10005103) ..... ___
30. Headache (10019211) ..... ___

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

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

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

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

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

Pilot Clinical Trials in CKD
Participant End of Study Questionnaire # 289 - COMBINE

This form is completed once at the end of the study (F12).

1. Identification Number PID	2. Alphacode AC	3a.Visit Type VIST	3b. Visit Number (Month) VISN_MO	(Week) VISN_WK	4. Date of visit (mm/dd/yyyy) VISIT_DT	5. Study STUDY
						C

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

This form will capture participant's opinions on COMBINE 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 lanthanum carbonate or lanthanum carbonate placebo (chewable round white) study medications? .... ___LANTH

8. What was your opinion regarding taking the nicotinamide or nicotinamide placebo (football-shaped) study medications? .... ___NICO

9. What was your opinion regarding the Cardiac MRI? *(leave blank if participant did not consent to MRI)* .... ___MRI

10. What was your opinion regarding having all visits in the afternoon? .... ___AFTERNOON

11. What was your opinion regarding the frequency of visits? ....___VIST_FREQ

12. What was your opinion regarding the frequency of blood draws? .... ___SERUM_FREQ

13. What was your opinion regarding the process of collecting 24-hour urine samples? ..___URINE

14. What was your opinion regarding the process of collecting spot urine samples?___SPOT_URINE

Checking the status of the participant blind

15. Do you know what the lanthanum carbonate or lanthanum carbonate placebo (chewable round white) pill is? .... ___LANTH_BLIND
(1=I am sure it is lanthanum, 2=I think it is most likely lanthanum, 3=I do not know, 4=I think it is most likely not lanthanum, 5=I am sure it is not lanthanum)

16. Do you know what nicotinamide or nicotinamide placebo (football-shaped) pill is?___NICO_BLIND
(1=I am sure it is nicotinamide, 2=I think it is most likely nicotinamide, 3=I do not know, 4=I think it is most likely not nicotinamide, 5=I am sure it is not nicotinamide)

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

201. Username of person completing/reviewing completeness of this form _ _ _ _ _ _ _COMP_USER

Clinical Center Use Only

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

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

Pilot Clinical Trials in CKD
Cardiac and BOLD Renal MRI Submission Form #291 - COMBINE

This form is completed at Baseline and F12 for each participant who consented to MRI. (If a participant is beyond F6 about to begin dialysis or have a transplant, do a pre-emptive MRI beforehand.) MRIs should not be done on participants who have begun dialysis or have been transplanted. The window for F12 MRI includes all of month 11 and all of month 12.	Screening Form 203 height (in cm) *(not key entered)* __ __ __ Screening/F11 Form 203 weight (in kg) *(not key entered)* __ __ __ . __

Questions #1 to #9 are completed by the Study Coordinator. Note, if the participant has been randomized, Q3a Visit Type must be "F". Also, please write the naming convention of the MRI for this participant at the end of this form (the study name, underscore followed by the ID number, alpha code, and visit type (visit type will either be "B" for Baseline or "F" for Follow-Up. For example: COMBINE_210014XMB).

							C
1. Identification Number PID	2. Alphacode AC	3a. Visit Type	3b. Visit Number (Month)	Visit Number (Week)	4. Date of MRI being submitted (mm/dd/yyyy) VISIT_DT		5. Study STUDY

6. Type of study..... ___STUDY_TYPE
   1=Baseline; 2=Repeat Baseline; 3=prior to transplant; 4=prior to initiation of dialysis; 5=F12; 6=Repeat F12

7. Was the cardiac MRI done? .....___CARDIAC_MRI_DONE
   If there is still time to reschedule the MRI, reschedule it. Don't answer no.
   0=Participant did not consent to this portion of MRI
   1=Yes
   2=No, logistics problem related to the participant
   3=No, participant was too claustrophobic
   4=No, participant was too large to fit into machine
   5=No, pacemaker or metallic implant or other medical contraindication/safety issue detected
   6=No, logistic problem related to the COMBINE clinical center site (e.g., staffing, scheduling, IRB)
   7=No, logistic problem related to local MRI facility
   8=No, participant refused

8. Was the BOLD renal MRI done? .....___BOLD_MRI_DONE
   If there is still time to reschedule the MRI, reschedule it. Don't answer no.
   0=Participant did not consent to this portion of MRI
   1=Yes
   2=No, logistics problem related to the participant
   3=No, participant was too claustrophobic
   4=No, participant was too large to fit into machine
   5=No, pacemaker or metallic implant or other medical contraindication/safety issue detected
   6=No, logistic problem related to the COMBINE clinical center site (e.g., staffing, scheduling, IRB)
   7=No, logistic problem related to local MRI facility
   8=No, participant refused
   9=No, participant has polycystic kidney disease

If BOLD Renal MRI was done, continue to Q9. **NOTE:** Participants with polycystic kidney disease need not have the renal MRI; PKD images are unusable (see COMBINE MRI MOP Chapter). If the BOLD Renal MRI was not done, skip to Q10. If neither the BOLD Renal MRI nor the Cardiac MRI was done, skip to Q200.

BOLD Renal imaging details:

9. a. Number of hours fasting..... ___ ___ . ___ ___FASTING_HRS
   b. NSAID Status *(Aspirin is not an NSAID)*..... ___NSAID_STATUS
      0=No NSAIDS have been taken in the prior three days; 1=NSAIDs have been taken in the prior three days
   c. ACE ARB Status ..... ___ACE_ARB_STATUS
      0=none taken today prior to this exam; 1=ACE and/or ARB taken earlier today
   d. Furosemide/other loop diuretic status ..... ___FUROSEMIDE_STATUS
      0=Neither taken today prior to this exam; 1=Taken earlier today

Naming convention of MRI *(not key entered)*: COMBINE_ __ __ __ __ __ __ __ __ __

If Cardiac MRI was not done, skip to Q14.

The following questions are completed by local site MRI lab personnel.

Cardiac imaging details:

10. Sequence(s) used: (respond with 0=no, 1=yes for items a-g)
    a. Short Axis LA stack ..... ___SHORT_AXIS_LA_STACK
    b. Short Axis LV stack ..... ___ SHORT_AXIS_LV_STACK
    c. 2 Chamber TrueFISP..... ___CHAM_TRUEFISP_2
    d. 4 Chamber Multi-slice TrueFISP ..... ___ CHAM_TRUEFISP_4
    e. 3 Chamber TrueFISP..... ___ CHAM_TRUEFISP_3
    f. Mitral Valve 2D Flow ..... ___MITRAL_2D
    g. 4 Chamber 2D Flow ..... ___CHAM_2D_4
11. Average heart rate during MRI (bpm) ..... ___ ___ ___AVG_HR_MRI
12. Was there a cardiac rhythm disturbance during MRI? (0=no, 1=yes)..... ___CARD_DISTURB
13. Username of certified MRI technician performing Cardiac MRI .....__ __ __ __ __ __ __
    CARDIAC_TECH_USERNAME

If the BOLD Renal MRI was not done, skip to Q18.

BOLD Renal Imaging Details:

14. Kidney scanned (1=right kidney, 2=left kidney, 3=both) ..... ___KIDNEY_SCANNED
15. BOLD MRI Sequence used? (0=no, 1=yes).....___BOLD_MRI_SEQ
16. a. Was furosemide administered? ..... ___FUROSEMIDE_ADMIN
    1=yes
    2=no; site does not participate in furosemide protocol
    3=no; patient is allergic to or does not tolerate furosemide
    4=no; patient refused
    5=no; logistic problem related to patient
    6=no; logistic problem related to local MRI facility

    b. If yes, Furosemide dosage (mg)..... ___ ___FUROSEMIDE_DOSAGE
    c. Time of injection of Furosemide (24-hour clock) (hh:mm)...__ __ : __ __FUROSEMIDE_INJ_TIME
17. Username of certified MRI technician performing BOLD Renal MRI .....__ __ __ __ __ __ __
    BOLD_TECH_USERNAME

Transmission details for Cardiac and/or BOLD Renal MRI

18. Method of transmission (1=secure ftp, 2=performed at Core Lab, 3=CD mailed) .....___TRANS_METHOD
    (Notify DCC if another code is needed.)
19. Date file transmitted/mailed toCentral MRI Facility (mm/dd/yyyy)__ __ /__ __ /__ __ __ __FILE_TRANS_DT
    (Date file transmitted/mailed must be greater or equal to the date the form is completed.)

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

Clinical Center Use Only

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

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

Pilot Clinical Trials in CKD
Biorepository Serum and Plasma Mailing Form # 300 - COMBINE

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) 686-4703 (Heather Higgins)
Phone (240) 686-4702 (Sandra Ke)
Fax: (301) 515-4049

Serum and plasma biorepository samples should be collected at B1, B2, F3, F6 and F12. You will need to complete a separate Form 300 for each participant in the shipment. Ship samples to the address above in the mailer provided. Ship tubes on the cold pack provided in the kit. Ship only on Mondays through Thursdays and notify the repository of shipments via e-mail or by facsimile on the day the package is picked up by FedEx. Refer to MOP Chapter 46 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.

1a.Site Number SITE	1b. Patient Identification # PID	2. Alphacode AC	3a.Visit Type VIST	3b. Visit Number (Month) VISN_MO	3b. Visit Number (Week) VISN_WK	4. Date blood collected (mm/dd/yyyy) VISIT_DT	5. Study STUDY
___	______	__	_	__	__	________	C

5. b. Visit number intended.....__ ___ ___INTENDED_VISIT
Baseline (B) visits are 1, 2. Follow-Up (F) Visits are 1, 2, 3, 6, 9 and 12. Code 99 for extra/non-protocol visits.

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

Serum

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

Plasma

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

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

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)

Note:
The DCC will email a report with the data on this form to the repository as soon as the form is key entered.

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

201. Username of person compl/revwing completeness of this form __ __ __ __ __ __ __COMP_USER

Clinical Center Use Only

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

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

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 24-Hour Urine Mailing Form #301 - COMBINE

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) 686-4703 (Heather Higgins)
Phone (240) 686-4702 (Sandra Ke)
Fax: (301) 515-4049

A 24-hour urine biorepository sample should be collected at B1, B2, F3, F6 and F12. Complete a separate Form 301 for each participant in the shipment. Ship COMBINE samples only to the address above in the mailer provided. Ship urine cup on cold pack provided in 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 46 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 10 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 trial site:

☐☐☐ - ☐☐☐☐☐☐	☐☐	☐	☐☐	☐☐	☐☐☐☐☐☐☐☐	C
1a.Site Number SITE	1b. Patient Identification # PID	2. Alphacode AC	3a.Visit Type VIST	3b. Visit Number (Month) VISN_MO	(Week) VISN_WK	4. Date 24-hour urine collection began (mm/dd/yyyy) VISIT_DT	5. Study STUDY

5. b. Visit number intended..... ___ ___ ___INTENDED_VISIT
Baseline (B) visits are 1, 2. Follow-Up (F) Visits are 1, 2, 3, 6, 9 and 12. Code 99 for extra/non-protocol visits.

24-hour Urine Sample:

6. Date urine collection ended (mm/dd/yyyy).....__ __/__ __/__ __ __ __END_DT

7. a. Time urine collection started (24-hour clock) (hh:mm) ..... __ __ : __ __START_TM

b. Time urine collection ended (24-hour clock) (hh:mm) ..... __ __ : __ __END_TM

DCC Use
unusable?

8. Number of urine cups sent to Biorepository (1 is expected)..... ___ | ___
CUPS_NO U_UNUSABLE

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

Contact Information*: (note: Items 11a-d are required by Biorepository 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).....__ __/__ __/__ __ __ __COMP_DT

201. Username of person compl/revwing completeness of this form __ __ __ __ __ __ __COMP_USER

Clinical Center Use Only

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

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

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
FGF23 and R01 Sample Drawn and Stored Form # 329 - COMBINE

This form is completed at B1, B2, F1, F2, F3, F6, F9 and F12 when the samples for FGF23 and the R01 are drawn and stored locally. Complete Form 330 at the time the samples are shipped (use the shipping schedule on Form 330).

1. Identification Number PID	2. Alphacode AC	3a.Visit Type VIST	3b. Visit Number (Month) VISN_MO	(Week) VISN_WK	4. Date Blood Collected (mm/dd/yyyy) VISIT_DT	5. Study STUDY
						C

6. Visit number intended..... ___ ___ ___INTENDED_VISIT
Baseline (B) visits are 1, 2. Follow-Up (F) visits are 1, 2, 3, 6, 9 and 12.

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

8. Time blood spun (24-hour clock) (hh:mm) .....__ __:__ __SPUN_TM

9. a. Number of cryovials of plasma available to freeze .....___PLASMA_CYROVIAL_CT
(Two vials of plasma are expected. Cryovials should be frozen immediately.)

b. Plasma barcode 1 PLASMA_BARCODE1 .....

Place Requisition bar code label here
CM __ __ __ __ __
PLASMA

c. Did plasma sample 1 need to be respun? (0=no, 1=yes) ..... ___PLASMA_RESPUN1

d. Plasma barcode 2 PLASMA_BARCODE2 .....

Place Requisition bar code label here
CM __ __ __ __ __
PLASMA

e. Did plasma sample 2 need to be respun? (0=no, 1=yes) .....___ PLASMA_RESPUN2

10. a. Number of cryovials of serum available to freeze.....___SERUM_CRYOVIAL_CT
(Two vials of serum are expected. Cyrovials should be frozen immediately)

b. Serum barcode 1 SERUM_BARCODE1 .....

Place Requisition bar code label here
CM __ __ __ __ __
SERUM

c. Serum barcode 2 SERUM_BARCODE2 .....

Place Requisition bar code label here
CM __ __ __ __ __
SERUM

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

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

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

STORAGE_LOC

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

201. Username of person compl/revwing completeness of this form__ __ __ __ __ __ __COMP_USER

Clinical Center Use Only

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

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

Pilot Clinical Trials in CKD
FGF23 and R01 Sample Mailing Form # 330 - COMBINE

Once each month*, the staff at each COMBINE Clinical Center will retrieve all FGF23 and R01 samples from the local -80ºC freezer to ship samples to the University of Washington FGF23 Core Lab.

- Review shipping schedule (see below) and check that the correct amount of dry ice is available.
- Ship on dry ice on Monday, Tuesday or Wednesday only.
- Send email message with tracking number to: kvleuven@u.washington.edu and ahoof@u.washington.edu.
- For every participant visit included, the box should include copies of both this form F330 and Form 329. (Do not send originals.)

1. Identification Number PID	2. Alphacode AC	3a. Visit Type VIST	3b. Visit Number (Month) VISN_MO	(Week) VISN_WK	4. Date Blood Collected (mm/dd/yyyy) VISIT_DT	5. Study STUDY
						C

6. Number of cryovials of plasma shipped for this COMBINE ID ......___PLASMA_CRYOVIAL_CT
(2 vials are expected for each participant)

7. Number of cryovials of serum shipped for this COMBINE ID..........___SERUM_CRYOVIAL_CT
(2 vials are expected for each participant)

8. Date shipped to UW Core Lab (mm/dd/yyyy)............................ __ __/__ __/__ __ __ __SHIP_DT
Note: If you plan to ship the box tomorrow, wait until tomorrow to key enter this form (i.e., enter the date you shipped the box, not the date you intend to ship the box.)

***The following shipping schedule should be followed each month**

Clinical Center 11:	George Washington University	Days 1 to 5
Clinical Center 21:	Northwestern University School of Medicine	Days 6 to 10
Clinical Center 22:	NorthShore University Health System (COMBINE Only)	Days 11 to 15
Clinical Center 31:	University of California San Diego	Days 16 to 20
Clinical Center 32:	Denver Nephrology	Days 21 to 25
Clinical Center 41:	Univ. of Utah and Clinical Center 43: Utah VA	Days 26 to 30

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

201. Username of person compl/revwing completeness of this form__ __ __ __ __ __ __COMP_USER

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

Pilot Clinical Trials in CKD
Spectra Lab Serum/Blood/Spot Urine Mailing #331 – COMBINE

COMBINE blood should be drawn between 12 noon and 6:00 pm.
Serum is collected at B1, B2, F1, F2, F3, F6, F9 and F12.
Whole blood is collected at B1, B2, F1, F2, F3, F6, F9 and F12. *If you missed whole blood collection at B1, please collect at B2.*
Spot urine is collected at B1, B2, F3, F6 and F12.
If samples are collected on different days, use a separate form for each day samples are collected.

Place Spectra 'REQUISITION' bar coded label here

Use the barcodes from the same sheet as this "Requisition" barcode when labeling your tubes.

Shipping instructions: It is recommended that samples be shipped on the same day they were collected. Use the shipping materials provided by Spectra to ship the samples overnight. Instructions on packaging and completing the FedEx air bill are provided in the MOP Spectra Chapter. Contact the Spectra team (see contact information in the address directory) if there are technical questions concerning sample collection and processing or if additional supplies are needed.

1. Identification Number PID	2. Alphacode AC	3a. Visit Type	3b. Visit Number (Month)	Visit Number (Week)	4. Date sample(s) collected (mm/dd/yyyy) VISIT_DT	5a. Study STUDY
						C

5. b. Visit number intended ..... ___ ___ ___INTENDED_VISIT
Baseline (B) visits are 1, 2. Follow-Up (F) Visits are 1, 2, 3, 6, 9 and 12. Code 99 for extra/non -protocol visits.

Serum (use "SST Gel" barcode label)

6. a. Number of 8.5 ml SST (tiger top) tubes (serum) sent to Spectra Lab..... ___ | DCC use only ___
(When collected, 1 tube is expected. If no tubes are sent, enter 0.) SST_CT SST_UNUSABLE

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

Whole Blood (for 1st tube, use "Lavender" barcode label; for 2nd tube, use "Miscellaneous" barcode label)

7. a. Number of 2 ml EDTA (lavender top) tubes sent to Spectra Lab..... ___ | DCC use only ___
(When collected, 2 tubes are expected at B1, F3, F6, F9 & F12. One tube is expected at B2, F1 & F2.
If no tubes are sent, enter 0) EDTA_CT EDTA_UNUSABLE

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

Spot Urine (use "Urine Chemistries" barcode label)

8. a. Number of yellow conical tubes sent to Spectra Lab..... ___ | DCC use only ___
(When collected, 1 tube is expected. If no tubes are sent, enter 0.) CONICAL_TUBE_CT/URINE_UNUSABLE

b. Time of spot urine collection (24-hour clock) (hh:mm) .....__ __ : __ __URINE_COLL_TM

c. Where was the urine collected (1=In clinic (preferred), 2=Elsewhere) ..... ___URINE_COLL_LOC

9. Date shipped to Spectra Lab (mm/dd/yyyy)..... __ __/__ __ /__ __ __ __SHIP_DT

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

201. Username of person compl/revwing completeness of form __ __ __ __ __ __ __ __COMP_USER

Clinical Center Use Only

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

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

SST_UNUSABLE, EDTA_UNUSABLE and URINE_UNUSABLE – 1=results could not be reported, 2=Usable for PTH only.

Pilot Clinical Trials in CKD
Spectra Lab 24-Hr Urine Mailing Form #335 - COMBINE

Place Requisition bar code label here

Use the barcodes from the same sheet as this "Requisition" barcode when labeling your conical tubes.

24-hour collections should be done at B1, B2, F3, F6 and F12. Attempted collections should be sent to Spectra regardless of length or participant report on completeness. A copy of this form should be sent with the box to Spectra. The original form should be kept in the participant binder.
Also, remember that a biorepository urine sample needs to be sent using Form 301 each time a 24-hour urine collection is obtained.

1. Identification Number PID	2. Alphacode AC	3a. Visit Type	3b. Visit Number (Month) (Week)	4. Visit Date: (mm/dd/yyyy) VISIT_DT	5. Study STUDY
					C

6. Visit Number Intended .... ___ ___ ___INTENDED_VISIT
   Baseline (B) visits are 1, 2. Follow-Up (F) Visits are 3, 6, and 12. Code 99 for extra/non -protocol visits.
7. Status of reminder call .... ___REMINDER_CALL
   0=not done, 1=done by coordinator, 2=done automatically
8. Did the pt return with urine in the study urine container? (0=no, 1=yes)___CONTAINER_RETURNED
   If no, skip to item 200.
9. Participant report on completeness .... ___COMPLETENESS
   1=Complete (collected all urine during the time period) and accurate, 2=Missed some, 3=Collected too much (e.g., didn't discard first urine), 9=unknown
   Submit all urines, regardless of completeness.

*** SPECTRA *** The results should be labeled with the start date of the urine collection (Q10a)

10. a. Start date of urine collection (mm/dd/yyyy) .... __ __/__ __ /__ __ __ __START_DT
    b. Start time of urine collection (24-hour clock) (hh:mm) ....__ __ : __ __START_TM
11. a. End date of urine collection (mm/dd/yyyy) ....__ __/__ __ /__ __ __ __END_DT
    b. End time of urine collection (24-hour clock) (hh:mm)............................... __ __ : __ __END_TM
12. Approximate volume of the urine based on jug lines ....__ __ __ __URN_JUG_VOL
13. Weight of the 24-hour urine collection (g).. __ __ __ __URN_WT_G
    (For collections <= 4,000 g, this weight includes the urine, jug with lid, and the preservative and for collectins > 4,000 g, the exact weight will be used without subtracting the container.)

    Volume of urine based on weight and assuming 1 g = 1 ml _____ ml URN_VOL

    For collcections <= 4,000g, this is the recorded weight above minus the weight of the (jug + lid + preservative)
14. Number of yellow conical tubes sent to Spectra (1 is expected) ....___CONICAL_TUBE_CT
    (Use "Urine Chemistries" barcode label. Must be pulled from the same sheet as the "Requisition" barcode label above.)
15. Date shipped to Spectra Lab (mm/dd/yyyy) .... __ __/__ __ /__ __ __ __SHIP_DT

200. Date this form reviewed for completeness (mm/dd/yyyy).. ___ ___/___ ___/___ ___ ___ ___COMP_DT
201. Username of person compl/revwing completeness of this form__ __ __ __ __ __ __COMP_USER

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

Pilot Clinical Trials in CKD
Spectra Lab iPTH Results Form #359 - COMBINE

Spectra Laboratory PTH data will be securely transferred and loaded into a table in the central CKD Trials Oracle database at the Data Coordinating Center. A Spectra Lab PTH Results Report that includes the data on this form will be emailed to the clinical center when these data are received.

☐☐☐☐☐☐	☐☐	☐	☐☐	☐☐	☐☐☐☐☐☐☐☐	C
1. Identification Number PID	2. Alphacode AC	3a.Visit Type VIST	3b. Visit Number (Month) VISN_MO	(Week) VISN_WK	4. Date Blood for Panel Drawn (mm/dd/yyyy) VISIT_DT	5. Study

6. Bar code number on the tube .... __ __ __ __ __ __ __ __ __ __
7. Date sample received at Spectra (mm/dd/yyyy) .... __ __/__ __/__ __ __ __RECVD_DT
8. Date sample analyzed (mm/dd/yyyy) .... __ __/__ __/__ __ __ __ANALYSIS_DT

9. Intact PTH (pg/mL) .... ___ ___ ___PTH

Pilot Clinical Trials in CKD
Spectra Lab Serum Results Form #360 - COMBINE

Spectra Laboratory data will be securely transferred and loaded into a table in the central CKD Trials Oracle database at the Data Coordinating Center. A Spectra Lab Results Report that includes the data on this form will be emailed to the clinical center when these data are received.

☐☐☐☐☐☐	☐☐	☐	☐	☐	☐☐☐☐☐☐☐☐	C
1. Identification Number PID	2. Alphacode AC	3a. Visit Type VIST	3b. Visit Number (Month) VISN_MO	(Week) VISN_WK	4. Date Serum for Panel Drawn (mm/dd/yyyy) VISIT_DT	5. Study

6. Bar code number on the tube .... __ __ __ __ __ __ __ __ __ __
7. Date sample received at Spectra (mm/dd/yyyy) ....__ __/__ __/__ __ __ __ RECEIVED_DT
8. Date sample analyzed (mm/dd/yyyy) ....__ __/__ __/__ __ __ __ANALYSIS_DT

9. Sodium (mEq/L) .... ___ ___ ___NA
10. Potassium (mEql/L) .... ___.___ K
11. Chloride (mEql/L) .... ___ ___ ___CHLOR
12. Bicarbonate (mEq/L).. ___ ___BICARB
13. Serum Urea Nitrogen (BUN) (mg/dL) .... ___ ___BUN
14. a. Serum Creatinine (mg/dL) .... ___.___ ___SCR
b. Calculated eGFR (mL/min/1.73 m²)... ___ ___

The CKD-EPI equation, expressed as a single equation, is:
$GFR = 141 \times \min(Scr/\kappa,1)^{\alpha} \times \max(Scr/\kappa,1)^{-1.209} \times 0.993^{Age} \times 1.018$ [if female] $\times 1.159$ [if black]
Where Scr is serum creatinine (mg/dL), κ is 0.7 for females and 0.9 for males, α is –0.329 for females and –0.411 for males, min indicates the minimum of Scr/κ or 1, and max indicates the maximum of Scr/κ or 1.

15. Calcium (mg/dL) .... ___ ___.___CAL
16. Serum phosphate (mg/dL).. ___ ___.___ PHOS

Liver Function Tests Results

17. Aspartate aminotransferase (AST) (U/L) ....___ ___ ___.___AST
18. Alanine aminotransferase (ALT) (U/L) ....___ ___ ___.___ALT
19. Total bilirubin (mg/dL)...___ ___.___TBILI
20. Alkaline phosphatase (U/L)...___ ___ ___ALKP
21. Albumin (g/dL)... ___.___ALB

Other Results

22. Creatine Kinase (CK) (U/L) .... ___ ___ ___CK
23. Serum uric acid (mg/dL) .... ___ ___.___ UACID

Pilot Clinical Trials in CKD
Spectra Lab Whole Blood / HgbA1c Results Form #361 - COMBINE

The data captured below will be securely transferred in a file, not entered on a data form.

1. Identification Number PID	2. Alphacode AC	3a.Visit Type VIST	3b. Visit Number (Month) VISN_MO	(Week) VISN_WK	4. Date Blood Drawn (mm/dd/yyyy) VISIT_DT	5. Study
						C

6. Bar code number on the tube..... __ __ __ __ __ __ __ __ __ __

7. Date sample received at Spectra (mm/dd/yyyy) .....__ __/__ __/__ __ __ __RECEIVED_DT

8. Date sample analyzed (mm/dd/yyyy).....__ __/__ __/__ __ __ __ANALYSIS_DT

Hemoglobin A1C

9. Hemoglobin A1c (%) ..... ___ ___.___A1C

Protocol CBC Results

10. WBC (1000/mcL).....___ ___ ___WBC

11. Hemoglobin (g/dL) ..... ___ ___ . ___HGB

12. Hematocrit (%).....___ ___ . ___HCT

13. Platelet count (1000/mcL) .....___ ___ ___PLATELET

- On two consecutive measures, participant is found to have a platelet count <100,000 with clinical signs of platelet dysfunction (bruising or bleeding noted at a study visit and documented on the symptom form) or <75,000 without clinical signs

  If this is less than 100,000 1X the trigger email should say "platelets are less than 100,000. Please REPEAT THIS LOCALLY ASAP.
  If this is less than 75,000 trigger 1X an email that says platelets are less than 75,000 so you need to repeat this locally ASAP because platelets less than 75,000 lead to a half nicotinamide prescription.
  If this is less than 75,000 on 2 consecutive occasions say "check local repeat Form 380 to see if this participant has had 2 consecutive platelet values under 75,000. If so cut nicotinamide dose in half."

Extra Results

14. a. Red Blood Cell Count (RBC) (mill/mcL).....___ ___ ___RBC

    b. Red blood Cell Distribution Width (RDW) (%).....__ __ __ . __ RDW

15. Mean Corpuscular Volume (MCV) (fl) .....___ ___ ___MCV

16. Mean Corpuscular Hemoglobin (MCH) (pg).....___ ___ ___MCH

17. Mean Corpuscular Hemoglobin Concentration (MCHC) (g/dL).....___ ___ ___MCHC

WBC Differential

18. Neutrophils (%) ..... ___ ___ ___NEUTRO

19. Lymphocytes (%) ..... ___ ___ ___LYMPH

20. Monocytes (%) ..... ___ ___ ___MONO

21. Basophils (%) .....___ ___ ___BASO

22. Eosinophils (%) .....___ ___ ___EOS

23. LUCs (%) .....___ ___ ___LUC

Pilot Clinical Trials in CKD
UW Core Lab Receipt of FGF23/R01 Samples Form # 362 – COMBINE

The University of Washington (UW) FGF23 Core Lab will enter this data as each sample is received. Because samples are shipped Fedex within 30 days after they are drawn, once 40 days has passed from the date a sample was drawn, this form will be in the database showing that the specimen arrived at the UW Core Lab in acceptable condition.

1. Identification Number	2. Alphacode	3a. Visit Type	3b. Visit Number (Month)	(Week)	4. Date Blood Collected (mm/dd/yyyy)	5. Study
PID	AC	VIST	VISN_MO	VISN_WK	VISIT_DT	STUDY
						C

6. Date this participant's samples were received at UW Core Lab (mm/dd/yyyy) ..... __ __/__ __/__ __ __ __RECD_DT

7. a. Plasma Sample Status? .....___PLASMA_STATUS
   0=No samples received
   1=Only one sample received
   2=Two samples received

   b. Plasma bar code 1 ..... **CM** ___ ___ ___ ___ ___PLASMA_BARCODE1

   c. Condition of plasma sample 1 .....___PLASMA_CONDITION1
   1=It was in acceptable condition and had sufficient volume for intended analyses.
   2=It was unusable due to condition or volume.

   d. Plasma bar code 2 ..... **CM** ___ ___ ___ ___ ___PLASMA_BARCODE2

   e. Condition of plasma sample 2.....___PLASMA_CONDITION2
   1=It was in acceptable condition and had sufficient volume for intended analyses.
   2=It was unusable due to condition or volume.

8. a. Serum Sample Status?..... ___SERUM_STATUS
   0=No samples received
   1=Only one sample received
   2=Two samples received

   b. Serum bar code 1 ..... **CM** ___ ___ ___ ___ ___SERUM_BARCODE1

   c. Condition of serum sample 1 .....___SERUM_CONDITION1
   1=It was in acceptable condition and had sufficient volume for intended analyses.
   2=It was unusable due to condition or volume.

   d. Serum bar code 2 ..... **CM** ___ ___ ___ ___ ___SERUM_BARCODE2

   e. Condition of serum sample 2 .....___SERUM_CONDITION2
   1=It was in acceptable condition and had sufficient volume for intended analyses.
   2=It was unusable due to condition or volume

9. Date samples were stored in a UW Core Lab freezer (mm/dd/yyyy) ....._ _/_ _/_ _ _ _FREEZER_DT

10. Where in the UW Core Lab were the samples stored (up to 50 char text)

STORAGE_LOC

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

201. Username of person confirming storage of the number of samples listed _ _ _ _ _ _ _COMP_USER

UW Core Lab Use Only

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

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

Pilot Clinical Trials in CKD
Spectra Lab 24-Hr Urine Results Form #368 - COMBINE

Spectra Laboratory data will be securely transferred and loaded into a table in the central CKD Trials Oracle database at the Data Coordinating Center. A Spectra Lab Results Report that includes the data on this form plus calculated values will be emailed to the clinical center when these data are received.

1. Identification Number PID	2. Alphacode AC	3a. Visit Type VIST	3b. Visit Number (Month) VISN_MO	(Week) VISN_WK	4. Date urine collection started (mm/dd/yyyy) VISIT_DT	5. Study STUDY
						C

6. Bar code on the tube ..... __ __ __ __ __ __ __ __ __

7. Date sample received at Spectra (mm/dd/yyyy) ..... __ __/__ __ /__ __ __ __RECEIVED_DT

8. Date sample analyzed (mm/dd/yyyy) ..... __ __/__ __ /__ __ __ __ ANALYSIS_DT

Results transmitted to the DCC from Spectra

9. Urine calcium (mg/dL) ..... __ __ __UCAL

10. Urine creatinine (mg/dL) ..... __.__UCR

11. Urine phosphorus (mg/dL) ..... __ __ __ __.__UPHOS

12. Urine urea nitrogen (mg/dL) ..... __ __UUN

The DCC Generated report to the clinical centers will include the following:

13. Date urine collection started (mm/dd/yyyy) .....__ __ / __ __ / __ __ __ __VISIT_DT
14. Volume of 24/hr urine collection (ml) ..... __ __ __URN_VOL
15. Urine calcium (mg/dL)..... __ __ __ UCAL
16. Urine creatinine (mg/dL)..... __.__UCR
17. Urine phosphorus (mg/dL) ..... __ __ __ __.__ UPHOS
18. Urine urea nitrogen (mg/dL) .....__ __UUN
19. Urine calcium (mg/24 hrs) ..... __ __ __NEWUCAL
20. Urine creatinine (g/24 hrs)..... __.__NEWUCR
21. Urine phosphorus (mg/24 hrs) ..... __ __ __ __.__NEWUPHOS
22. Urine urea nitrogen (g/24 hr) .....__ __ NEWUUN

Equation D will be used to estimate completeness of the urine collection. The ratio showing completeness of urine collection will be reported to the clinical center with the data from this report.
**Equation D: eCER = 579.59 + 12.51 x weight (kg) – 6.19 x age + (34.51 if black) – (379.42 if female).*
**mCER – eCER (positive values indicate that mCER > eCER).*

Pilot Clinical Trials in CKD
Spectra Lab Spot Urine Results Form #369 - COMBINE

Spot urines are sent to Spectra at B1, B2, F3, F6, and F12. Spectra Laboratory data will be securely transferred and loaded into a table in the central CKD Trials Oracle database at the Data Coordinating Center. A Spectra Lab Results Report will be emailed to the clinical center (This form is provided for informational purposes only.)

1. Identification Number PID	2. Alphacode AC	3a. Visit Type VIST	3b. Visit Number (Month) VISN_MO	(Week) VISN_WK	4. Date urine collection started (mm/dd/yyyy) VISIT_DT	5. Study
						C

6. Bar code on the tube ..... __ __ __ __ __ __ __ __ __ __

7. Date sample received at Spectra (mm/dd/yyyy) ..... __ __/__ __ /__ __ __ __ RECEIVED_DT

8. Date sample analyzed (mm/dd/yyyy) ..... __ __/__ __ /__ __ __ __ ANALYSIS_DT

Results:

9. Urine calcium (mg/dL)..... __ __ __.__ UCAL

10. Urine creatinine (mg/dL)..... __ __ __ UCR

11. Urine phosphorus (mg/dL) ..... __ __ __ UPHOS

12. Urine albumin (mg/dL) .....__ __.__ UALB

Pilot Clinical Trials in CKD
Local Lab Adverse Event Recheck Form #380 - COMBINE

This form is completed during follow-up when a lab safety value occurs in Spectra data and a local recheck is needed. Please share all results that are provided when labs are rechecked for safety reasons. All results recorded on this form must all be from the date documented in item 4. If some results are from a different date, complete an additional Form 380 labeled with that date.

1. Identification Number PID	2. Alphacode AC	3a. Visit Type	3b. Visit Number (Month)	(Week)	4. Date Blood Drawn (mm/dd/yyyy) for the Recheck VISIT_DT	5. Study STUDY
		F				C

6. Time blood drawn (use 24-hr clock) (hh:mm)..___ ___:___ ___DRAW_TM
7. a. Date of the blood draw that led to the serum phosphate AE (mm/dd/yyyy) . _ _/_ _/_ _ _ _PHOS_DT
   b. Serum phosphate at time of recheck (mg/dL) .... ___ ___.___PHOS

Liver Function Tests Results

8. a. Date of the blood draw that led to the aspartate aminotransferase (AST) AE (mm/dd/yyyy) .... __ __/__ __/__ __ __ __AST_DT
   b. Aspartate aminotransferase (AST) at time of recheck (IU/L) ....___ ___ ___.___AST
9. a. Date of the blood draw that led to the alanine aminotransferase (ALT) AE (mm/dd/yyyy) .... __ __/__ __/__ __ __ __ALT_DT
   b. Alanine aminotransferase (ALT) at time of recheck (IU/L)........................... ___ ___ ___.___ALT
10. a. Date of the blood draw that led to the total bilirubin AE (mm/dd/yyyy)__ __/__ __/__ __ __ __TBILI_DT
    b. Total bilirubin at time of recheck (mg/dL)... ___ ___.___TBILI
11. a. Date of the blood draw that led to the alkaline phosphatase AE (mm/dd/yyyy) .... __ __/__ __/__ __ __ __ALKP_DT
    b. Alkaline phosphatase at time of recheck (IU/L) .... ___ ___ ___ALKP

Other Test Results

12. a. Date of the blood draw that led to the Total Creatine Kinase (CK) AE (mm/dd/yyyy) .... __ __/__ __/__ __ __ __CK_DT
    b. Total Creatine Kinase (CK) at time of recheck (IU/L) .... ___ ___ ___CK
13. a. Date of the blood draw that led to the intact PTH AE (mm/dd/yyyy)__ __/__ __/__ __ __ __PTH_DT
    b. Intact PTH at time of recheck (pg/mL) .... ___ ___ ___PTH

Whole Blood Test Results

14. a. Date of the blood draw that led to the platelet AE (mm/dd/yyyy)__ __/__ __/__ __ __ __PLATELET_DT
    b. Platelet count at time of recheck [1000/(mm^3)] .... ___ ___ ___PLATELET_CT

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

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

Pilot Clinical Trials in CKD
Extra Lab Measurements Form #381 - COMBINE

This form is completed during follow-up when, although the protocol does not require it, the local lab 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 381 labeled with that date.

1. Identification Number PID	2. Alphacode AC	3a. Visit Type VIST	3b. Visit Number (Month) VISN_MO	(Week) VISN_WK	4. Date Blood Drawn (mm/dd/yyyy) for the Recheck VISIT_DT	5. Study STUDY
		F				C

6. Time blood drawn (use 24-hr clock) (hh:mm)..___ ___:___ ___ DRAW_TM
7. Sodium (mEq/L) .... ___ ___ ___SODIUM
8. Potassium (mEql/L) .... ___.___POTASSIUM
9. Bicarbonate (mEq/L)... ___ ___BICARBONATE
10. Serum Urea Nitrogen (BUN) (mg/dL) .... ___ ___ ___BUN
11. Serum Creatinine (mg/dL) ....___ ___.___ ___CREATININE
12. Glucose (mg/dL) .... ___ ___ ___GLUCOSE
13. Serum phosphate (mg/dL).. ___ ___.___PHOS
14. Aspartate aminotransferase (AST) (IU/L) .... ___ ___ ___AST
15. Alanine aminotransferase (ALT) (IU/L).. ___ ___ ___ALT
16. Total bilirubin (mg/dL)...___ ___.___TBILI
17. Alkaline phosphatase (IU/L) ....___ ___ ___ALKP
18. Creatine Kinase (CK) (IU/L) .... ___ ___ ___ ___CK
19. Serum uric acid (mg/dL) .... ___ ___.___URIC_ACID
20. WBC (1000/mcL) .... ___ ___.___ ___WBC
21. Hemoglobin (g/dL) ....___ ___.___HGB
22. Hematocrit (%) .... ___ ___.___HCT
23. Platelet count [1000/(mm^3)] ....___ ___ ___PLATELET_CT

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

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

Pilot Clinical Trials in CKD
Hospitalization Liver Function Tests for Participant 210001 UR Form #384 - COMBINE

This form is completed to document representative liver function tests for the beginning, middle and end of participant 210001 UR hospitalizations. All results recorded on this form must all be from the date in item 4.

(Reference: Wagener E, Souma N, Hodakowski A, Martinez C, Fox P, Mehta R, O'Brien MJ, Bolon M, Kulik L, Yang GY, Isakova T, for the CKD Optimal Management with Binders and NicotinamidE (COMBINE) Investigators. A patient with CKD develops cholestatic liver injury during a clinical trial. KI Reports 2017.)

									F												C

1. Identification Number PID
2. Alphacode AC
3a. Visit Type VIST
3b. Visit Number (Month) VISN_MO (Week) VISN_WK
4. Date Blood Drawn (mm/dd/yyyy) for the Recheck VISIT_DT
5. Study STUDY

6. Time blood drawn (use 24-hr clock) (hh:mm)..___ ___:___ ___DRAW_TM

7. Aspartate aminotransferase (AST) (IU/L) .... ___ ___ ___AST
8. Alanine aminotransferase (ALT) (IU/L) .... ___ ___ ___ALT
9. Total bilirubin (mg/dL) ....___ ___.___TBILI
10. Alkaline phosphatase (IU/L) ....___ ___ ___ALKP

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

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

Pilot Clinical Trials in CKD
Re-Enrollment of a Previously Enrolled Participant Form # 403 - COMBINE

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

Re-Enrollment Procedure:
Participants who enter the screening period and are subsequently excluded can be re-screened after at least **7 days** have passed from the date the Baseline Dropout Form is entered into the database. Refer to the MOP for additional instructions.

Completed this Form 403 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 (except for the MRI) are collected. MRI results can be used up to six months for the date of the MRI. 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 <u>not</u> change. Do <u>not</u> give the participant a new ID/Alphacode.

3. Pre-randomization dropout date listed on Form 163-
(Baseline Dropout Form) (mm/dd/yyyy)..... ___ ___/___ ___ /___ ___ ___ ___

Before faxing or scanning this Form 403 to the DCC, you must have the following new forms fully completed (<u>but not data entered</u>) and ready to re-enroll: Forms 107 (COMBINE Screening), Form 115 (Local Lab Screening).

Identify the date of visit for the following forms below:

4. a. New Form 107 (COMBINE Trial Screening) date of screening (mm/dd/yyyy) ..... ___ ___/___ ___ /___ ___ ___ ___

b. New Form 115 (Local Lab Screening) date of visit (mm/dd/yyyy) ..... ___ ___/___ ___ /___ ___ ___ ___

Note: Form 115 must be within 45 days of the new screening date.

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

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

DCC Use Only

Date Form Entered <u>at the DCC</u> (mm/dd/yyyy) __ __/__ __/__ __ __ __

Username of person entering this form <u>at the DCC</u> __ __ __ __ __ __ __

Pilot Clinical Trials in CKD
Study Closeout Form # 475 – COMBINE

This form is completed when the Site PI determines that all data have been collected and entered at the end of the COMBINE 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 PID	2. Alphacode AC	3a. Visit Type VIST	3b. Visit Number (Month) VISN_MO	(Week) VISN_WK	4. Date PI determined no more data will be coming for this pt (mm/dd/yyyy) VISIT_DT	5. Study STUDY
						C

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

7. Has a final (F12) Cardiac MRI Form 291 been submitted? .....___MRI
   (0=no, 1=yes) (L*eave blank if participant did not consent to MRI.)*
   (Recall that Form 291 captures whether the MRI was done or not)

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

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

201. Username of person completing/reviewing completeness of this form...._ _ _ _ _ _ _COMP_USER

Clinical Center Use Only

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

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

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 PID	2. Alphacode AC	3a. Visit Type VIST	3b. Visit Number (Month) VISN_MO	(Week) VISN_WK	4. Date of Hospitalization (mm/dd/yyyy) VISIT_DT	5. Study STUDY

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

7. Is the patient still in the hospital? ..... ___IN_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.*

NOT DATA ENTERED

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

201. Username of person compl/revwing completeness of this form.__ __ __ __ __ __ __COMP_USER

Clinical Center Use Only

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

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

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 PID	2. Alphacode AC	3a.Visit Type VIST	3b. Visit Number (Month) VISN_MO	(Week) VISN_WK	4. Date of Hospital Admission (mm/dd/yyyy) VISIT_DT	5. Study STUDY

SAE Categorization:

6. a. What type of SAE was this? ..... ___ ___SAE_TYPE
   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)..... __ __ /__ __ /__ __ __ __DISCHARGE_DT

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

   a. Discharge summary (preferred)..... ___DISCHARGE_SUM
   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..... ___PERSONNEL_TALK

   c. No discharge summary/spoke to pt's primary care doctor or nephrologist.___NEPHR_TALK

   d. No discharge summary / spoke to participant, family member, or friend .___FAMILY_TALK
   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)___ ___ ___ ___ ___PRIM_DIAG

   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..... ___ ___ ___ ___ ___SEC_DIAG

   Additional diagnoses/procedures (if available/needed):

   c. Additional diagnosis/procedure #1 (use code list attached) ..... ___ ___ ___ ___ ___DIAG3

   d. Additional diagnosis/procedure #2 (use code list attached)..... ___ ___ ___ ___ ___DIAG4

   e. Additional diagnosis/procedure #3 (use code list attached)..... ___ ___ ___ ___ ___DIAG5

   f. Additional diagnosis/procedure #4 (use code list attached)..... ___ ___ ___ ___ ___DIAG6

   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) ___CARD_EVENT

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
CKD_HOSP_DTL	

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) PROCEDURE_CAUSE

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?..... ___N_TRT_REG
(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?.....___L_TRT_REG
(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)___N_DISCONTINUE

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). ___
L_DISCONTINUE

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?.....___SB_TRT_REG
(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)..... ___SB_DISCONTINUE

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? ..... ___EXPECTED
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) ___
GREATER_HARM

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**.

BRIEF_SUMMARY

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

REL_COMMENTS

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

201. Username of person compl/reviewing completeness of this form __ __ __ __ __ __ __COMP_USER

Clinical Center Use Only

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

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

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 PID | 2. Alphacode AC | 3a.Visit Type | 3b. Visit Number (Month) (Week) | 4. Date of SAE (mm/dd/yyyy) VISIT_DT | 5. Study STUDY

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

SAE Categorization:

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

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.....___MED_RECORDS
   b. Spoke to medical personnel familiar with SAE, such as ER personnel___ PERSONNEL_TALK
   c. Spoke to participant's primary care doctor or nephrologist .....___NEPHR_TALK
   d. Spoke to participant or family member or friend .....___FAMILY_TALK

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

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..... ___ ___ ___ ___ ___SEC_DIAG

Additional diagnoses/procedures (if available/needed):

c. Additional diagnosis/procedure #1 (use code list attached) ..... ___ ___ ___ ___ ___DIAG3

d. Additional diagnosis/procedure #2 (use code list attached)..... ___ ___ ___ ___ ___DIAG4

e. Additional diagnosis/procedure #3 (use code list attached)..... ___ ___ ___ ___ ___DIAG5

f. Additional diagnosis/procedure #4 (use code list attached)..... ___ ___ ___ ___ ___DIAG6

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. CKD_SAE_DTL	MEDDRA_CD
b. SYMPTOM	MEDDRA_CD
c. SYMPTOM	MEDDRA_CD

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 clinical trial protocol?..... ___
(0=no, 1=unlikely, 2=possibly, 3=probably, 4=definitely) PROCEDURE_CAUSE

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?..... ___N_TRT_REG
(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?.....___L_TRT_REG
(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)___N_DISCONTINUE

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). ___ .
L_DISCONTINUE

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?.....___SB_TRT_REG
(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)..... ___SB_DISCONTINUE

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? ..... ___EXPECTED
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) ___
GREATER_HARM

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**.

BRIEF_SUMMARY

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

REL_COMMENTS

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

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

Clinical Center Use Only

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

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

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
PID	AC	VIST	VISN_MO	VISN_WK	VISIT_DT	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 ..... ___ ___ ___ ___CAUSE_PRIM

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

c. Other cause of death ..... ___ ___ ___ ___CAUSE_OTH1

d. Other cause of death ..... ___ ___ ___ ___CAUSE_OTH2

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

201. Username of person compl/revwing completeness of this form.__ __ __ __ __ __ __COMP_USER

Clinical Center Use Only

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

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

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
PID	AC	VIST	VISN_MO	VISN_WK	VIST	STUDY

Part 1: To be completed by the Study Coordinator:

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

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) ..... __ __/__ __/__ __ __ __ADM_DT

7. Was an autopsy performed? (0=no, 1=yes, 9=unknown) ..... ___AUTOPSY
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) ..... ___ ___ ___ ___CAUSE_PRIM

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

c. Other cause of death ..... ___ ___ ___ ___CAUSE_OTH1

d. Other cause of death ..... ___ ___ ___ ___CAUSE_OTH2

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? ___ANGINA_ISCHEMA

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

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

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

e. Was there new onset of or worsening other heart disease (exclude pericarditis) .... ___OTH_HEART
(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? ___PROTOCOL_CAUSED
(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? ..... ___N_REGIMEN_CAUSED
(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?..... ___L_REGIMEN_CAUSED
(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?..... ___SB_REGIMEN_CAUSED
(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?___UNANTICIPATED
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)___HARM

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? .....___ ___SAE_OCCURANCE
(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).....___
F522_ENTERED

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

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.)

DEATH_NARRATIVE

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

COMMENTS

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

201. Username of person compl/revwing completeness of this form.__ __ __ __ __ __ __COMP_USER

Clinical Center Use Only

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

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

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 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)	3b. Visit Number (Week)	4. Date of event: mm/dd/yyyy	5. Study
PID	AC	VIST	VISN_MO	VISN_WK	VISIT_DT	STUDY

6. Type of event reported in item 4 above ..... ___EVENT_TYPE
   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) __ __ /__ __ /__ __ __ __EMAIL_DT

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

   If other, describe other material provided

OTHER_TEXT

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

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

Clinical Center Use Only

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

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

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

6. What vascular access procedure was done? ..... ___ VAS_PROC
   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) ..... ___ ___ /___ ___ /___ ___ ___ ___ COMP_DT

201. Username of person completing/reviewing completeness of this form.. _ _ _ _ _ _ _ COMP_USER

Clinical Center Use Only

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

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

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)	(Week)	4. Date of initiation of dialysis or kidney transplant (mm/dd/yyyy)	5. Study
PID	AC	VIST	VISN_MO	VISN_WK	VISIT_DT	STUDY

6. Reason this form is being completed? ..... ___REASON
(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)..... ___DIAL_STAT

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

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

201. Username of person compl/reviewing completeness of this form__ __ __ __ __ __ __COMP_USER

Clinical Center Use Only

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

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

Pilot Clinical Trials in CKD
Request for/Report Unblinding Form # 593 - COMBINE

This form is completed by the Clinical Center staff member to request or report unblinding. This form should be faxed or scanned and emailed to the DCC for data entry. If the site requests unblinding, a report will be generated for the Event Review Committee. The report will include details of the SAE and the details on this form. **Note:** *Remember that a site PI may stop any drug at any time for safety reasons without being unblinded.*

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

6. Which type of SAE is this request for unblinding associated with? ..... ___SAE_TYPE
   1=Hospitalization (details reported on Form 512)
   2=Other SAE (details reported on Form 522)
   3=Death (details reported on Form 532)

7. Date of SAE (mm/dd/yyyy) ..... ___ ___ /___ ___ /___ ___ ___ ___SAE_DT

8. a. Unblinding of Lanthanum Carbonate treatment regimen..... ___UNBLIND_LANTH
   1=Site is currently blinded and unblinding is not necessary
   2=PI requests unblinding
   3=Site is reporting unblinding to the lanthanum carbonate arm
   4=Unblinding has been documented previously

   b. Unblinding of Nicotinamide treatment regimen..... ___UNBLIND_NICOT
   1=Site is currently blinded and unblinding is not necessary
   2=PI requests unblinding
   3=Site is reporting unblinding to the nicotinamide arm
   4=Unblinding has been documented previously

9. If item 8a or b=2, provide reason(s) for unblinding request:

UNBLIND_REASON

10. a. If item 8a =3, date of unblinding of Lanthanum Carbonate (mm/dd/yyyy).....__ __/__ __/__ __ __ __UNBLIND_LANTH_DT

    b. It item 8b=3, date of unblinding of Nicotinamide (mm/dd/yyyy)_ _/_ _/_ _ _ _UNBLIND_NICOT_DT

    c. Who is unblinded? (1=participant, 2=staff, 3=both) ..... ___WHO_UNBLIND

    d. Describe the circumstances surrounding the unblinding:

UNBLIND_CIRCUM

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

DCC Use Only
Date Form Entered (mm/dd/yyyy) __ __/__ __/__ __ __ __ ENTER_DT
Username of person entering this form__ __ __ __ __ __ __ ENTER_USER

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)	3b. Visit Number (Week)	4. Date of Hospital Admission: (mm/dd/yyyy)	5. Study
PID	AC	VIST	VISN_MO	VISN_WK	VISIT_DT	STUDY

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

7. Primary reviewer..... __ __ __ __ __ __ __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? ..... ___REVIEW_TYPE
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? ..... ___RELATED_MEDS
(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? ..... ___RELATED_DEV_PROC
(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.

RELATED_COMMENTS

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)___REVIEWER_DISC
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.

REVIEWER_COMMENTS

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

201. Username of person completing/reviewing completeness of this form__ __ __ __ __ __ __COMP_USER

DCC Use Only

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

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

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
PID	AC	VIST	VISN_MO	VISN_WK	VISIT_DT	STUDY

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

7. Primary reviewer..... __ __ __ __ __ __ __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? ..... ___REVIEW_TYPE
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) ____ ____SAE_EVENT

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?..... ___RELATED_MEDS
(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? ..... ___RELATED_DEV_PROC
(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.

RELATED_COMMENTS

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)___REVIEWER_DISC
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.

REVIEWER_COMMENTS

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

202. Username of person completing/reviewing completeness of this form__ __ __ __ __ __ __ __COMP_USER

DCC Use Only

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

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

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 PID	2. Alphacode AC	3a. Visit Type VIST	3b. Visit Number (Month) VISN_MO	(Week) VISN_WK	4. Date of Death (mm/dd/yyyy) VISIT_DT	5. Study STUDY

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

7. Primary reviewer..... __ __ __ __ __ __ __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? ..... ___OUTCOME_HOSP
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)__ __/__ __/__ __ __ __ ADMIT_DT

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? ..... ___RELATED_MEDS
(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? ..... ___RELATED_DEV_PROC
(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.

RELATED_COMMENTS

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

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

DCC Use Only

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

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

Pilot Clinical Trials in CKD
Core Receipt of BOLD Renal MRI Form # 702 - COMBINE

The BOLD Renal MRI Core receives files passed on from the Cardiac MRI Core. If the BOLD Renal MRI Core receives an unusable file, the Core staff will contact the site and ask that the MRI be re-transmitted. If this takes several tries, this form need not be completed each time the MRI is transmitted. This form is completed when a readable file is received (that is, image(s) can be seen on the file) or when it is determined that the file cannot be salvaged despite best efforts and repeat attempts of sending.

1. Identification Number PID	2. Alphacode AC	3a.Visit Type VIST	3b. Visit Number (Month) VISN_MO	(Week) VISN_WK	4. BOLD Renal MRI Date: (mm/dd/yyyy) VISIT_DT	5. Study STUDY
						C

6. Date transmitted file or mailed CD received at BOLD Renal MRI Core Lab (mm/dd/yyyy) ..... __ __/ __ __/__ __ __ __RECVD_DT

7. Were the dicom images received uncorrupted? .....___UNCORRUPTED
0=No, this file could not be salvaged despite best efforts and repeat attempts; 1=Yes

<u>COMBINE Study BOLD Renal MRI Quality Assessment</u>

8. Is this study complete? .....___STUDY_COMPLETE
0=No, the file does not include all images; 1=Yes, the file includes all images

9. a. Artifact (0=None, 1=Little, 2=More than a little).....___QUALITY
   b. Blurring due to motion due to improper breath holding on BOLD Renal MRI (0=no, 1=yes) ___ BLURRING_ARTIFACT
   c. Susceptibility artifacts on BOLD Renal MRI (0=no, 1=yes)..... ___SUSCEPTIBILITY_ARTIFACT
   d. EPI artifacts on diffusion MRI (0=None, 1=Minimal, 2=Moderate, 3=Severe) ..... ___EPI_ARTIFIACT

10. Is the study acceptable? (0=Rejected, 1=Acceptable) .....___ACCEPTABLE

If the study is complete (Q8=1) and the overall image quality is acceptable (Q10=1), it will be analyzed by NorthShore. If not, the core will contact the site to see if a revised image set will meet these criteria. If even after a recontact, the study is un-interpretable due to poor image quality, complete Q11-201.

11. Comments from the core lab on what went wrong and/or recommendations on how to prevent this in the future:

CORE_COMMENT

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

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

MRI Core Lab Use Only

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

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

Pilot Clinical Trials in CKD
Core Receipt of Cardiac MRI Form # 703 - COMBINE

This form is completed when the Cardiac MRI Core receives a file from a COMBINE Clinical Center.

1. Identification Number PID	2. Alphacode AC	3a.Visit Type	3b. Visit Number (Month)	(Week)	4. Date of Cardiac MRI (mm/dd/yyyy) VISIT_DT	5. Study STUDY
						C

6. Date transmitted file or mailed CD received at Cardiac MRI Core Lab (mm/dd/yyyy) ..... __ __/__ __/__ __ __ __RECVD_DT

7. Were the dicom images received uncorrupted? ..... ___UNCORRUPTED
0=no, this file could not be salvaged despite best efforts and repeat attempts; 1=yes

COMBINE Study Cardiac MRI Quality Assessment - Left Atrium

8. Are the MR images of the left atrium complete? .....___ATRIUM_COMPLETE
0=no, the image does not include all of these: Short Axis Stack LA, 4 Chamber Multi-slice TrueFISP
1=yes, the image includes all of these: Short Axis Stack LA, 4 Chamber Multi-slice TrueFISP

9. Image Quality ..... ___ATRIUM_QUALITY
1=Excellent (borders are clearly delineated)
2=Acceptable (sufficient for diagnosis)
3=Poor (insufficient for diagnosis)

10. Artifact .....___ATRIUM_ARTIFACT
1=Little to none (atrial wall and blood pool not significant affected)
2=Mild to moderate (some obscuring of atrial wall and blood pool)
3=Moderate to severe (much of the atrial wall and blood pool is obscured)

11. Are the MR images of the left atrium acceptable? (0=Rejected, 1=Acceptable) ___ATRIUM_ACCEPTABLE

COMBINE Study Cardiac MRI Quality Assessment - Left Ventricle

12. Are the MR images of the left ventricle complete? ..... ___VENTRICLE_COMPLETE
0=no, the image does not include all of these: Short Axis Stack LV, 2 Chamber TrueFISP, 3 Chamber TrueFISP
1=yes, the image includes all of these: Short Axis Stack LV, 2 Chamber TrueFISP, 3 Chamber TrueFISP

13. Image Quality .....___VENTRICLE_QUALITY
1=Excellent (borders are clearly delineated),
2=Acceptable (sufficient for diagnosis),
3=Poor (insufficient for diagnosis)

14. Artifact ..... ___VENTRICLE_ARTIFACT
1=Little to none (myocardium and blood pool not significant affected),
2=Mild to moderate (some obscuring of myocardium and blood pool)
3=Moderate to severe (much of the myocardium and blood pool is obscured)

15. Are the MR images of the left ventricle acceptable? (0=Rejected, 1=Acceptable) .....___
VENTRICLE_ACCEPTABLE

+Quality Assessments done prior to 06/25/2015 were done using Form 701

COMBINE Study Cardiac MRI Quality Assessment - Mitral Valve

16. Are the MR images of the mitral valve complete? .....___MITRAL_COMPLETE
    0=no, the image does not include all of these: Mitral Valve 2D Flow, 4 Chamber 2D Flow
    1=yes, the image includes all of these: Mitral Valve 2D Flow, 4 Chamber 2D Flow

17. Image Quality.....___MITRAL_QUALITY
    1=Excellent (Appropriate positioning, VENC)
    2=Acceptable (Adequate positioning, VENC)
    3=Poor (Limited positioning, VENC)

18. Artifact ..... ___MITRAL_ARTIFACT
    1=Little to none (valve apparatus, annular ring, blood pool not significant affected)
    2=Mild to moderate (some obscuring of valve apparatus, annular ring, and blood pool)
    3=Moderate to severe (much of the valve apparatus, annular ring, and blood pool is obscured)

19. Are the MR images of the mitral valve acceptable? (0=Rejected, 1=Acceptable)___MITRAL_ACCEPTABLE

COMBINE Study Cardiac MRI - Accept/Reject Classification

20. Overall Study Disposition ..... ___DISPOSITION
    0=Reject; No cardiac MRI study components are considered acceptable (Q11, Q15, Q19)
    1=Partial Accept; At least one cardiac MRI study component is considered acceptable (Q11, Q15, Q19)
    2=Complete Accept; all cardiac MRI study components are considered acceptable (Q11, Q15, Q19)

If any component of the study is considered acceptable (Q11, Q15, Q19) those components will be analyzed by NURAD4D. For individual components or entire studies that are considered unacceptable for analysis, the core will contact the site to see if a revised image set will meet these criteria. If even after a recontact, the study is uninterpretable due to poor image quality, complete Q21-201.

21. Comments from the Core Lab on what went wrong and/or recommendations on how to prevent this in the future:

CORE_COMMENT

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

201. Username of person compl/reviewing completeness of this form .. __ __ __ __ __ __ __COMP_USER

MRI Core Lab Use Only

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

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

+Quality Assessments done prior to 06/25/2015 were done using Form 701

Pilot Clinical Trials in CKD
Central MRI Facility
Cardiac MRI Incidental Finding(s) Form #711 – COMBINE

This form is to be completed and entered by the Central MRI Facility when a clinical alert or an incidental finding(s) has been identified on the Cardiac MRI. Once this form is entered, a report will automatically be sent to the clinical center.

1. Identification Number PID	2. Alphacode AC	3a.Visit Type VIST	3b. Visit Number (Month) VISN_MO	(Week) VISN_WK	4. Date of Cardiac MRI (mm/dd/yyyy) VISIT_DT	5. Study STUDY
						C

6. Date image received at central facility (mm/dd/yyyy) __ __ /__ __ /__ __ __ __IMAGE_RECD_DT

7. Date data read at central facility (mm/dd/yyyy) ..... __ __ /__ __ /__ __ __ __READ_DT

8. Username of person reading the cardiac MRI .....__ __ __ __ __ __ __READ_USERNAME

Clinical Alerts: Please comment on what was found on this Cardiac MRI.

9. Comments (do not use commas when typing in your comments below):

MRI_COMMENTS

10. Has someone at the Central MRI Facility spoken to someone at the center? (0=no, 1=yes) ...___ SPOKEN_CENTER

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

201. Username of person completing/reviewing completeness of this form_ _ _ _ _ _ _COMP_USER

MRI Core Lab Use Only

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

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

Pilot Clinical Trials in CKD
Central MRI Facility
BOLD Renal MRI Incidental Finding(s) Form #712 – COMBINE

This form is to be completed and entered by the Central BOLD Renal MRI Facility when an incidental finding(s) has been identified on the Renal MRI. Once this form is entered, a report will automatically be sent to the clinical center.

1. Identification Number PID	2. Alphacode AC	3a. Visit Type VIST	3b. Visit Number (Month) VISN_MO	(Week) VISN_WK	4. Date of BOLD Renal MRI (mm/dd/yyyy) VISIT_DT	5. Study STUDY: C

6. Date image received at central facility (mm/dd/yyyy) __ __ /__ __ /__ __ __ __IMAGE_RECD_DT

7. Date data read at central facility (mm/dd/yyyy) .... __ __ /__ __ /__ __ __ __READ_DT

8. Username of person reading the BOLD Renal MRI... __ __ __ __ __ __ __READ_USERNAME

Clinical Alerts: Please comment on what was found on this BOLD Renal MRI.

9. Comments (do not use commas when entering your comments below):

MRI_COMMENTS

10. Has someone at the MRI Facility spoken to someone at the center? (0=no, 1=yes)___SPOKEN_CENTER

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

201. Username of person completing/reviewing completeness of this form_ _ _ _ _ _ _COMP_USER

MRI Core Lab Use Only

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

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

Pilot Clinical Trials in CKD
BOLD Renal MRI Core Results Form # 722 – COMBINE

This form is completed at the BOLD Renal MRI Core. A staff member from the MRI Core will enter these results into the study database.

1. Identification Number PID	2. Alphacode AC	3a.Visit Type VIST	3b. Visit Number (Month) VISN_MO	(Week) VISN_WK	4. BOLD Renal MRI Date: (mm/dd/yyyy) VISIT_DT	5. Study STUDY
						C

6. Date this BOLD renal MRI read (mm/dd/yyyy)..... __ __/__ __ /__ __ __ __READ_DT

Measurements of Right Kidney:

7. ADC (cortex) ($10^{-3}mm^2/s$)..... ___ ___ ___ ___ . ___ ___ ___ ___ADC_CORTEX_R
8. ADC (kidney) ($10^{-3}mm^2/s$) .....___ ___ ___ ___ . ___ ___ ___ ___ADC_KIDNEY_R
9. Baseline (pre-furosemide) R2* (cortex) (s^{-1})..___ ___ ___ ___ . ___ ___ ___ ___BASE_CORTEX_R
10. Baseline (pre-furosemide) R2* (medulla) (s^{-1})___ ___ ___ ___ . ___ ___ ___ ___ BASE_MEDULLA_R
11. Baseline (pre-furosemide) R2* (kidney) (s^{-1}) ___ ___ ___ ___ . ___ ___ ___ ___ BASE_KIDNEY_R
12. Post-furosemide R2* (cortex) (s^{-1}). ..... ___ ___ ___ ___ . ___ ___ ___ ___POST_CORTEX_R
13. Post-furosemide R2* (medulla) (s^{-1}) ..... ___ ___ ___ ___ . ___ ___ ___ ___ POST_MEDULLA_R
14. Post-furosemide R2* (kidney) (s^{-1}) .....___ ___ ___ ___ . ___ ___ ___ ___POST_KIDNEY_R

Measurements of Left Kidney:

15. ADC (cortex) ($10^{-3}mm^2/s$).....___ ___ ___ ___ . ___ ___ ___ ___ADC_CORTEX_L
16. ADC (kidney) ($10^{-3}mm^2/s$) .....___ ___ ___ ___ . ___ ___ ___ ___ADC_KIDNEY_L
17. Baseline (pre-furosemide) R2* (cortex) (s^{-1})..___ ___ ___ ___ . ___ ___ ___ ___BASE_CORTEX_L
18. Baseline (pre-furosemide) R2* (medulla) (s^{-1})___ ___ ___ ___ . ___ ___ ___ ___BASE_MEDULLA_L
19. Baseline (pre-furosemide) R2* (kidney) (s^{-1})..___ ___ ___ ___ . ___ ___ ___ ___BASE_KIDNEY_L
20. Post-furosemide R2* (cortex) (s^{-1})..... ___ ___ ___ ___ . ___ ___ ___ ___POST_CORTEX_L
21. Post-furosemide R2* (medulla) (s^{-1}) ..... ___ ___ ___ ___ . ___ ___ ___ ___POST_MEDULLA_L
22. Post-furosemide R2* (kidney) (s^{-1}) .....___ ___ ___ ___ . ___ ___ ___ ___POST_KIDNEY_L

199. Username of MRI Core staff member completing MRI tracings . _ _ _ _ _ _ _ _TRACER_USER

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

MRI Core Lab Use Only
Date Form Entered (mm/dd/yyyy) __ __/__ __/__ __ __ __ENTER_DT
Username of person entering this form__ __ __ __ __ __ __ENTER_USER

Pilot Clinical Trials in CKD
Cardiac MRI Core Results Form # 723 – COMBINE

This form is completed and key entered into the study database by Cardiac MRI Core personnel.

1. Identification Number PID	2. Alphacode AC	3a.Visit Type	3b. Visit Number (Month)	3b. Visit Number (Week)	4. Cardiac MRI Date: (mm/dd/yyyy) VISIT_DT	5. Study STUDY
						C

6. Date this cardiac MRI read (mm/dd/yyyy) ..... __ __/__ __ /__ __ __ __READ_DT

During data entry, items in grey will be calculated and displayed on the screen.
Report Incidental Pathology findings on the incidental findings forms (Forms 711/712).

Global Left Ventricular Function

7. Left ventricular ejection fraction (%) ..... __ __.__LVEF
8. a. Left ventricular end-diastolic (ED) volume (ml)..... __ __ __.__ __LVEDV
   b. Left ventricular ED volume indexed to BSA (ml/m²)..... __ __ __.__ __LVEDVI
9. a. Left ventricular end-systolic (ES) volume (ml)..... __ __ __.__ __LVESV
   b. Left ventricular ES volume indexed to BSA (ml/m²) ..... __ __ __.__ __LVESVI
10. a. Left ventricular stroke volume (LVSV) (ml) ..... __ __ __.__ __LVSV
    b. Left ventricular stroke volume indexed to BSA (ml/m²) ..... __ __ __.__ __LVSVI
11. a. Cardiac Output (l/min) ..... __ __ __.__ __CARD_OUTPUT
    b. Cardiac Index (l/min/m²)..... __ __ __.__ __CARD_INDEX

Left Ventricular Mass

12. a. Left ventricular mass at ED (g)..... __ __ __.__ __LVEDM
    b. Left ventricular mass at ED indexed to BSA (g/m²) ..... __ __ __.__ __LVEDMI

Left Atrial Function

13. a. Left atrial ED volume..... __ __ __.__ __LAEDV
    b. Left atrial ED volume indexed to BSA (ml/m²) ..... __ __ __. __ __LAEDVI
14. a. Left atrial ES volume ..... __ __ __.__ __LAESV
    b. Left atrial ES volume indexed to BSA (ml/m²) ..... __ __ __ . __ __LAESVI

15. a. Left atrial output (l/min) ..... __ __ __.__ __ LA_OUTPUT

    b. Left atrial index (l/min/m²) ..... __ __ __.__ __ LA_INDEX

Flow Assessment at Mitral Valve

16. a. E Velocity (cm/s) ..... __ __ __.__ __ MV_EV

    b. A velocity (cm/s) ..... __ __.__ __ MV_AV

    c. EA ratio ..... __.__ __ __ MV_AE_RATIO

17. Forward Flow (ml/cycle) ..... __ __ __.__ __ MV_FFLOW

18. Reverse Flow (ml/cycle) ..... __ __ __.__ __ __ MV_RFLOW

19. a. Net Flow (ml/cycle) ..... __ __ __.__ __ MV_NFLOW

    b. Net Flow indexed to BSA (ml/cycle/m²) ..... __ __.__ __ MV_NFLOWI

Wall Thickness (mm)

		Anterior	Anterolateral	Inferolateral	Inferior	Inferoseptal	Anteroseptal	Slice Position
20.	ED Wall thickness at Base	ANT_BASE __ __ __.__ __	ANT_LAT_BASE __ __ __.__ __	INF_LAT_BASE __ __ __.__ __	INF_BASE __ __ __.__ __	INF_SEP_BASE __ __ __.__ __	ANT_SEP_BASE __ __ __.__ __	SLICE_BASE_CHAR SLICE_BASE __ __ __ __ . __ __
21.	ED wall thickness at mid-ventricular level	ANT_MID __ __ __.__ __	ANT_LAT_MID __ __ __.__ __	INF_LAT_MID __ __ __.__ __	INF_MID __ __ __.__ __	INF_SEP_MID __ __ __.__ __	ANT_SEP_MID __ __ __.__ __	SLICE_MID_CHAR SLICE_MID __ __ __ __ . __ __

		Anterior	Lateral	Inferior	Septal	Slice Position
22.	ED wall thickness at Apex	ANT_APEX __ __ __.__ __	LAT_APEX __ __ __.__ __	INF_APEX __ __ __.__ __	SEP_APEX __ __ __.__ __	SLICE_APEX_CHAR SLICE_APEX __ __ __ __ . __ __

197. Username of MRI Core staff member completing MRI tracings ..... __ __ __ __ __ __ __ TRACE_USER

198. Username of MRI Core staff radiologist reading the MRI ..... __ __ __ __ __ __ __ READ_USER

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

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

MRI Core Lab Use Only

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

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

Pilot Clinical Trials in CKD
Ix Ancillary Plasma Results Form # 800 – COMBINE

UW Core Lab results are entered at visits B, F3 and F12.

																				C	

1. Identification Number PID
2. Visit VISIT
3. Date plasma drawn (mm/dd/yyyy) VISIT_DT
4. Study STUDY

5. Immutopics FGF-23 (RU/mL) ..... __ __ __ . __IMMUTOPICS
6. Comments Imm FGF-23 ..... _____COMMENTS_IMM
7. 1,25 (OH) 2 D2 ..... __ . __ __V125OH2D2
8. 1,25 (OH) 2 D3 ..... __ __ . __ __V125OH2D3
9. 23 (S),25(OH)2D3 and/or 25,26 (OH)2D3 ..... __ . __ __V23S25OH
10. 24,25(OH)2 D3 ..... __ . __ __V2425OH
11. 25(OH)D2 ..... __ . __ __V25OHD2
12. 25(OH)D3 ..... __ __ . __ __V25OHD3
13. Comments Vit D ..... _____COMMENTS_V

14. Load date ..... __ __/__ __/__ __ __ __LOAD_DT

Pilot Clinical Trials in CKD
Ix Ancillary Serum Results Form # 801 – COMBINE

UW Core Lab results are entered at visits B, F3 and F12.

1. Identification Number PID	2. Visit VISIT	3. Date plasma drawn (mm/dd/yyyy) VISIT_DT	4. Study STUDY
			C

5. Ferritin (ng/mL) ..... __ __ __ . __FERRITIN
6. IL-6 (pg/mL) ..... __ __ . __ __IL_6
7. C-RP (mg/L) ..... __ __ . __CR_P
8. Iron (ug/dL)..... __ __IRON
9. Transferrin (mg/dL) ..... __ __ __TRANSFERRIN
10. Notes_IL6 ..... _____NOTES_IL6

11. Load date..... __ __/__ __/__ __ __ __LOAD_DT