



COPE-AKI Consortium

Information Session #2

August 12th, 2026

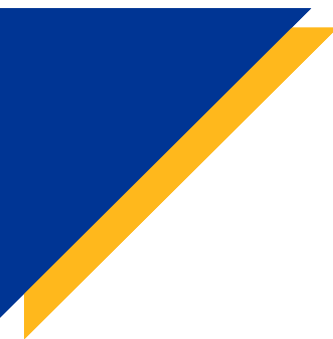


University of
Pittsburgh

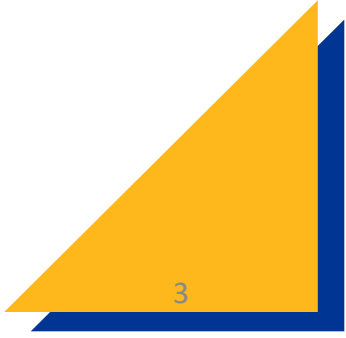


Outline

1. Overview of the COPE-AKI Consortium (20 min)
2. Clinical Center Application Process (20 min)
3. Q&A (20 min)



Protocol Synopsis





Study Description

- Phase III, randomized, pragmatic, parallel-arm trial comparing a multimodal intervention to usual care on hospital-free days through 90 days of study follow up.
- Primary hypothesis:
 - patients randomized to the intervention will have more hospital-free days through 90 days (primary) compared to those randomized to usual care.
- Secondary hypotheses will investigate the impact of the intervention on:
 - rates of hospital readmission
 - major adverse kidney events
 - patient-reported outcomes, such as global- and AKI-specific health reported quality of life
 - ...many other secondary outcomes



Study Population and Setting

- N= 2145 participants (anticipated)
 - randomized 1:1 to the intervention or usual care
 - stratified by clinical site and presence of chronic kidney disease (defined by eGFR < 60)
 - accounts for 30% attrition at 90d
- Adults hospitalized with persistent stage 2 or 3 AKI (defined as meeting Stage 2+ AKI for 2 consecutive days with serum creatinine concentration measurements >12 hours apart)

COPE-AKI Consortium

**Data and Safety
Monitoring Board**

NIDDK

Cleveland Clinic



MetroHealth • CCF Weston (FL)

Johns Hopkins University



University of Maryland • Yale University

Vanderbilt University



University of Alabama at Birmingham • Tennessee VA Nashville

Patient Advisors

Scientific and Data Research Center
University of Pittsburgh

Central Laboratory
University of Minnesota

Primary and Key Secondary Endpoints

Primary Outcome

- Hospital-free days through day 90 defined as days alive and out of hospital between day of discharge from index hospitalization and post-hospital discharge day 90.

Key Secondary Outcomes

- MAKE-180 composite outcome of:
 - death within 180 days of index hospital discharge;
 - need for dialysis at 180 days after index hospital discharge; or
 - serum creatinine >2x baseline at 180 days after index hospital discharge
- MAKE-90 and MAKE-365 will be defined similarly
- Rates of recurrent AKI readmission at 180 days (also assessed at 90, and 365 days)

Key Secondary PROs (assessed at 30, 90, 180, and 365 days)

- Global HRQoL – assessed with 10-item PROMIS measure
- AKI-specific HRQoL – assessed with 6-item CKD-QoL
- Interaction with providers – assessed with 5-item PEPPI and 8-item CSQ
- Social support – assessed with 4-item emotional support and 4 item instrumental support PROMIS measures

Tertiary/Exploratory Endpoints

Clinical Outcomes

- Hospital readmission rates (30-, 90-, 180-, and 365-day)
- Urine albumin to creatinine ratio (90-, 180-, and 365-day)
- Composite outcome of death or first rehospitalization
- Survival (90-, 180-, and 365-day)
- Need for dialysis (90-, 180-, and 365-day)
- MAKE-90 eGFR (and -180, -365) composite outcome of:
 - death prior to day 90 (scored as eGFR=0)
 - dialysis dependence at day 90 (scored as eGFR = 10); or
 - eGFR at day 90
- Alternative MAKE-90 (and -180, -365) composite outcome of:
 - death within 90 days of index hospital discharge;
 - need for dialysis at 90 days after index hospital discharge; or
 - serum creatinine >2x baseline at 90 days after index hospital discharge (*using pre-enrollment SCr*)
- eGFR (90-, 180-, and 365-day)
- CKD Stage (90-, 180-, and 365-day)



Tertiary/Exploratory Endpoints

PRO Outcomes

- Impact of AKI – assessed with 3 items from UPitt pilot study
- AKI-related symptoms – assessed with 10 items from UPitt pilot study
- Functional status – assessed with 4-item physical and 4-item cognitive PROMIS measures
- Psychosocial status – assessed with 4-item depressive affect and 4-item anxiety PROMIS measures
- AKI knowledge – assessed with 15-item objective knowledge and 5-item perceived knowledge scales from adapted KiKs
- Self-efficacy – assessed with 4-item symptom management and 4-item medications management PROMIS measures
- Healthcare utilization – assessed with 16-item Health Services Utilization Scale
- Frailty – assessed with the 16-item RAI-C
- Social determinants of health – assessed with 6 selected/modified items from the ACH Health-Related Social Needs Screening Tool



Tertiary/Exploratory Endpoints

Process of Care Measures

- Completion of virtual visit with nurse navigator/clinical pharmacist within 7 days (*Intervention Only*)
- Completion of PCP or nephrologist visit within 30 days, 90 days, 6 months, 12 months
- Blood pressure control at 90 days, 6 months, 12 months
- Medication use at 30 days, 90 days, 6 months, 12 months
 - Diuretics
 - RAS blockade
 - SGLT2i

Safety Endpoints

- Rate of adverse drug events through 12 months
- Rate of medication errors through 12 months

Study Assessments

Assessment	Enrollment (Prior to Hospital Discharge)	Day 30 (±7 days)	Day 90 (±14 days)	Month 6 (±14 days)	Month 12 (±14 days)
Demographic and Clinical Data					
Demographics	X				
Brief Confusion Assessment Method (bCAM)	X				
Vital Signs (weight, height, BP, HR)	X		X	X	X
Presence of edema	X		X	X	X
Medication List (e.g. dose; OTC; supplements)	X	X	X	X	X
Vital status		X	X	X	X
Hospital admissions		X	X	X	X
Assessment of visits with PCP		X	X	X	X
Assessment of visits with nephrologist		X	X	X	X
Dialysis Dependence		X	X	X	X
Laboratory Testing					
BMP (glucose, calcium, sodium, potassium, bicarbonate, chloride, blood urea nitrogen, creatinine)	X		X	X	X
Cystatin C	X		X	X	X
Urine panel (albumin, creatinine, protein)	X		X	X	X
Serum for banking	X		X	X	X
Urine for banking	X		X	X	X
Patient Reported Outcomes	X	X	X	X	X



Study Arms

- A multimodal process-of-care intervention that includes:
 1. study physician oversight and follow up care recommendations at the time of hospital discharge
 2. involvement of a nurse navigator to provide kidney-disease related education, coordinate care, and assess symptoms
 3. pharmacist-led medication reconciliation and review.
- Participants in the usual care arm will be provided information about their kidney disease, nephrotoxins to be avoided, and the importance of follow up with a physician will be emphasized.

Usual Care

- Participants will receive written info regarding:
 - their kidney disease
 - nephrotoxins to be avoided
 - importance of and need for follow up with physician

Kidney Fast Facts

- 1. Located in the Lower Back
- 2. Filters blood 40 times in 24 hours
- 3. Uses 25% of Blood From Every Heartbeat
- 4. About 1 in 10 people have some form of Chronic Kidney Disease
- 5. Acute Kidney Injury can occur after major surgery or with heart problems

Keeping Your Kidneys Healthy

- 1. Drink Water
- 2. Exercise Regularly
- 3. Don't Smoke
- 4. Eat a Healthy Diet
- 5. Maintain a Healthy Weight
- 6. Reduce Salt, Processed Food, & Sugar Intake
- 7. Medical Follow Up After AKI

Why Are Kidneys So Important?

1. Regulate Salt & Water in Your Body
2. Remove Waste Products From Your Blood into Your Urine
3. Regulate Blood Pressure
4. Keep Bones Healthy
5. Create Erythropoietin to Control Red Blood Cell Production
6. Removes Many Drugs

Symptoms of Kidney Problems

- Shortness of Breath
- Nausea/Vomiting
- Change in Urination Frequency
- Swelling/Numbing of Hands/Feet
- Tiredness
- Frequent Headaches
- Itchy Skin
- Muscle Cramps
- Change in Skin Tone
- Sleep Problems
- Loss of Appetite

What Can I Do to Protect My Kidney After AKI?

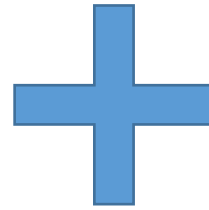
- 1. Avoid OTC Medications Harmful to Your Kidney (Nephrotoxic)
- 2. Avoid Too Much Salt
- 3. Discuss Medications with Your Doctor
- 4. Control Your Blood Pressure
- 5. Follow Up With Your Doctor to Review Your Kidney Function
- 6. Call Your Doctor if You Have Shortness of Breath, Increased Swelling, Nausea, & Vomiting

Questions to Ask Your Doctor About AKI

1. What is my current kidney function?
2. Are my medications OK for my kidneys?
3. Are there any other medications I should be taking to protect my kidneys?
4. Are there diet changes I should make?

Intervention

- Participants will receive written info regarding:
 - their kidney disease
 - nephrotoxins to be avoided
 - importance of and need for follow up with physician



Nephrologist



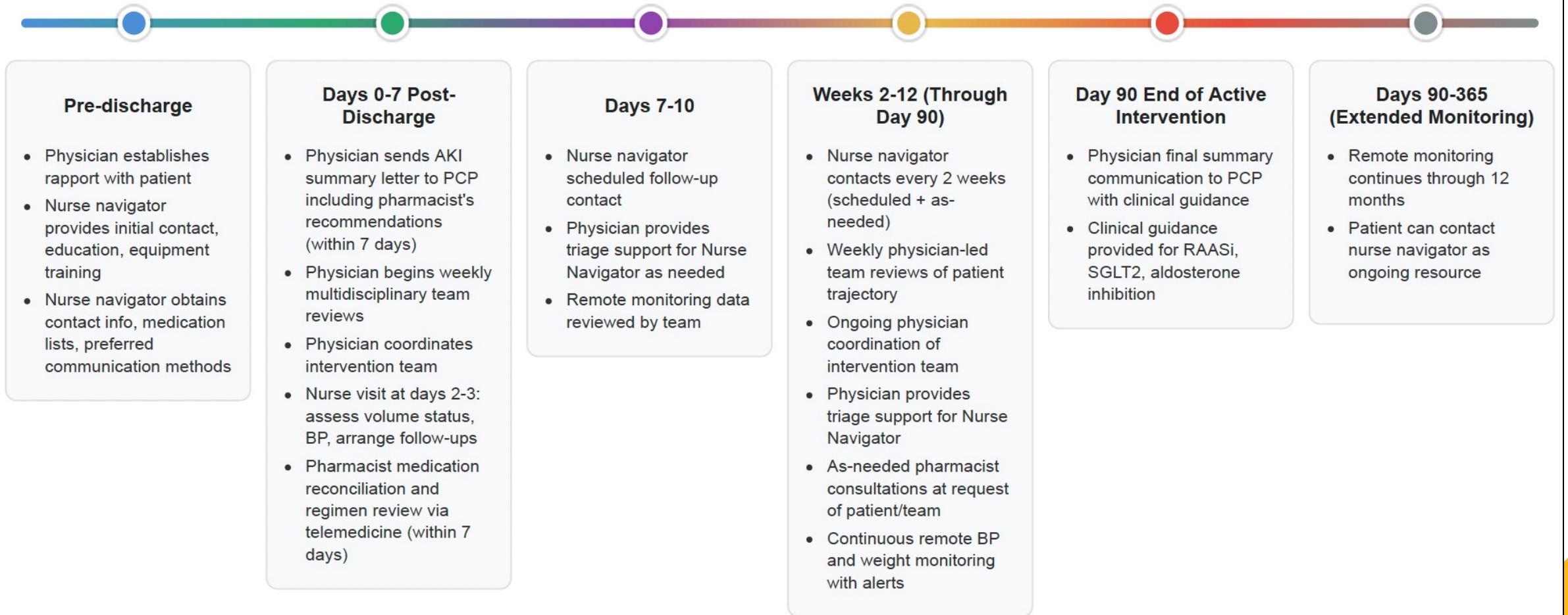
Nurse navigator



Pharmacist



Intervention Timeline



STANDARD OF CARE

RC/PRO

RC/PRO

RC/PRO RC/PRO

Discharge

3 Months

6 Months

12 Months



RANDOMIZATION & EDUCATIONAL
MATERIALS DISTRIBUTED

LEGEND

Study Participant Activity

Study Group Activity

SCM: Site Clinician Meeting with PharmD, Physician, & Nurse Navigator

RC: Research Coordinator PRO: Patient Reported Outcomes

CM: Consortium Meeting NN: Nurse Navigator

MULTIMODAL INTERVENTION

RC/PRO
NN & MD

SCM

SCM & CM

SCM

SCM & CM

SCM

RC/PRO
SCM & CM

RC/PRO RC/PRO

NN

PharmD

NN

NN

NN

NN

NN

NN

NN

NN

NN

Discharge

2-3 Days

5-7 Days

7-10 Days

2 Weeks

3 Weeks

1 Month

5 Weeks

6 Weeks

7 Weeks

2 Months

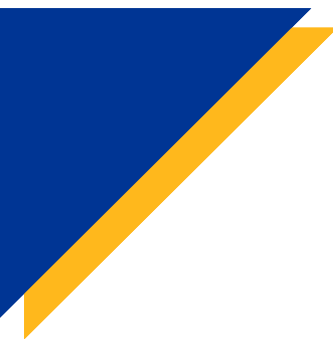
9 Weeks

10 Weeks

3 Months

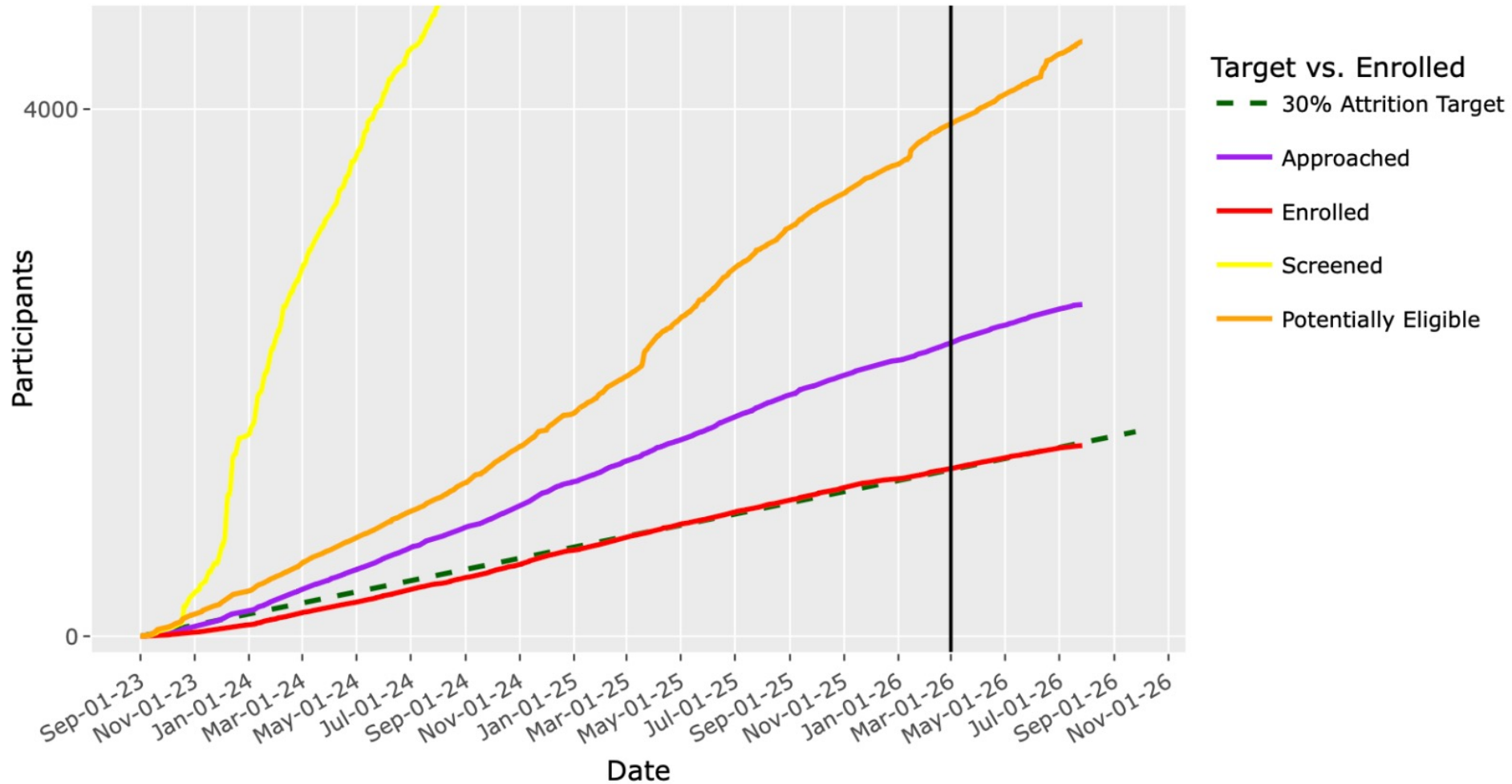
6 Months

12 Months



Enrollment Update

Total Enrollment



Current N = 1447 (99% of target)

Target = 10/week

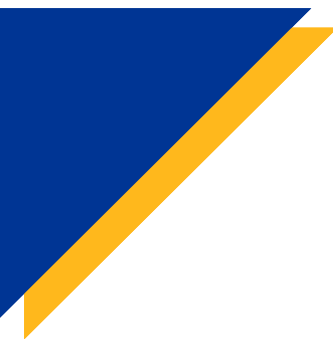
Screening Failure Table

Exclusion Criteria	Count
Metastatic malignancy or malignancy requiring active treatment (chemotherapy, immunotherapy)	1907 (17.32%)
Inability to participate as determined by the research team at time of discharge based on disposition	1530 (13.89%)
Non-kidney end-organ failure	1000 (9.08%)
Inability to provide informed consent due to impaired cognition	990 (8.99%)
Diagnosis of end-stage kidney disease (ESKD) at the time of admission	830 (7.54%)
Primary goal of care is palliation	654 (5.94%)
Inability to participate in either in-person or remote visits	558 (5.07%)
Index hospitalization involving solid organ transplant or stem cell/bone marrow transplant	506 (4.59%)
Discharge to long-term acute care facility or other hospital-based location	463 (4.2%)
Continued dialysis dependence at time of discharge	422 (3.83%)
Acute urinary obstruction with rapid kidney function improvement following relief of obstruction	388 (3.52%)
Previous (within 6 months) or new referral to a nephrologist for care	187 (1.7%)
AKI due to primary glomerulonephritis, renal vasculitis, or thrombotic microangiopathy	181 (1.64%)
Persons incarcerated or institutionalized	129 (1.17%)
Concurrent enrollment in a separate greater than minimal risk interventional trial	104 (0.94%)
Index hospitalization involving nephrectomy	59 (0.54%)
Screened Patient is Pregnant	17 (0.15%)
Declined to participate in study	1087 (9.87%)
Total	11012

*Screening Failure Categories are not Mutually Exclusive

Enrollment Demographics

Measure	Value
Race	
N	1433
Alaskan	14 (1%)
Asian	9 (0.6%)
Black	506 (35.3%)
Haiwain	4 (0.3%)
White	841 (58.7%)
Other	41 (2.9%)
Prefer Not to Answer	23 (1.6%)
Unknown	16 (1.1%)
Ethnicity	
Hispanic	84 (5.9%)
Not Hispanic	1304 (91%)
Prefer Not to Answer	45 (3.1%)



Application Process



Application Portal

- URL = <https://cope-aki.pitt.edu/application/Applicant>
- Support = email DCWEB@pitt.edu
- Any questions (big or small)
 - email Susan Copelli (SJU1@pitt.edu) or Kaleab Abebe (kza3@pitt.edu)



Application Components

1. Applicant/Institution Info
2. Summary/Abstract (1pg)
3. Research Strategy (3pgs)
4. Budget
5. NIH Biosketch
6. Letters of Support (optional)
7. PI Attestation

Creating an Account

University of Pittsburgh

COPE-AKI-Application PortalYou are in test database.

APPLICANT LOGIN

Welcome to the COPE-AKI - New Clinical Center Application Portal. Here you will submit and manage all required information for your application to the COPE-AKI Scientific Research Data Center.

[COPE-AKI Study protocol \(most recent version\)](#)
[COPE-AKI Info Session PowerPoint Slides](#)
[COPE-AKI Info Session - FAQ's](#)
[COPE-AKI Informed Consent Form \(ICF\) template - English](#)
[COPE-AKI Informed Consent Form \(ICF\) template - Spanish](#)

To begin you will need to create an account using your primary email address as your user name and a password of your choice. You will have the ability to retrieve your password later if you lose it and you can save your work at any time using the save button at the bottom of each page. When you are finished you will use the submit button to finalize your application and lock it from further editing.

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E-mail:

Password:

Forgot your password? [Click here.](#)

Login

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Creating an Account

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COPE-AKI

COPE-AKI-Application Portal

You are in test database.

CREATE A NEW ACCOUNT
Use the form below to create a new account.
Passwords are required to be a minimum of 6 characters in length.

Account Information
E-mail:

Password:

Confirm Password:

[Login to Application Portal](#)
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Starting an Application

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NEW APPLICATION

The application has 10 sections: Institution, Principal Investigator, Co-Investigator, Summary/Abstract, Research Strategy, Detailed Budget, Budget Justification, NIH Biosketch, Letters of Support, and Signature.

You can move between sections with **Back** and **Next**, and each section is saved as you go. You may leave and resume at any time before submitting.

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APPLICATION 0BE4F5 (DRAFT)

[\[1. Applicant Information\]](#) · [2. Institution](#) · [3. PI / Co-I](#) · [4. Summary / Abstract](#) · [5. Research Strategy](#) · [6. Detailed Budget](#) · [7. Budget Justification](#) · [8. NIH Biosketch](#) · [9. Letters of Support](#) · [10. Signature](#)

Applicant Information

First Name

Last Name

Email

Phone

Next

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[1. Applicant Information](#) · [2. Institution](#) · [3. PI / Co-I](#) · [4. Summary / Abstract](#) · **[5. Research Strategy]** · [6. Detailed Budget](#) · [7. Budget Justification](#) · [8. NIH Biosketch](#) · [9. Letters of Support](#) · [10. Signature](#)

STEP 5 OF 10: RESEARCH STRATEGY

Research Strategy (3 pages)

Guidance: [View Research Strategy guidance.](#)

Add documents (PDF, Word, or image; max 25 MB each):

Choose Files

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Upload

UPLOADED DOCUMENTS

File	Size	Uploaded
No documents uploaded for this section yet.		

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APPLICATION 0BE4F5 (DRAFT)
[1. Applicant Information](#) · [2. Institution](#) · [3. PI / Co-I](#) · [4. Summary / Abstract](#) · [5. Research Strategy](#) · [6. Detailed Budget](#) · **[7. Budget Justification]** · [8. NIH Biosketch](#) · [9. Letters of Support](#) · [10. Signature](#)

STEP 7 OF 10: BUDGET JUSTIFICATION

Budget Justification

Guidance: [View Budget Justification guidance.](#)

Add documents (PDF, Word, or image; max 25 MB each):

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Submitting an Application

Signature

Electronic applications do not need to be signed. Checking the box below is considered equivalent to your signature.

☐ I certify that the information provided on this application form and supporting documentation is accurate and correct. I understand that providing false and misleading information is just cause for disqualification for COPE-AKI application acceptance.

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My APPLICATIONS

Add New Application

Application #	Applicant	PI	Institution	Status	Created	Submitted	
0BE4F5				Application Drafted	07/27/2026	No	Edit Delete
53646D	Kaleab Abebe	Kaleab Abebe	University of Pittsburgh	Application Submitted and Under Review	07/21/2026	07/22/2026	View
8CF166				Application Drafted	07/21/2026	No	Edit Delete

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Withdrawing an Application

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[My Applications](#)>> Application 53646D

APPLICATION 53646D
Status: **In Review** | Submitted: **07/22/2026**

Applicant Information

Name: Kaleab Abebe

Email: kaleab.abebe@gmail.com

Phone:

Withdraw Application

Reason for withdrawal (optional):

Withdraw Application

[Back to My Applications](#)



Research Strategy

- CC applications must:
 1. demonstrate evidence of expertise and experience in the conduct of clinical trials in AKI
 2. demonstrate evidence of having and being able to recruit Hispanic patients that meet the inclusion/exclusion criteria of the study.



Research Strategy

- Key aspects to highlight:
 - Experience of the team in clinical trials
 - Plans for coordination of biosamples with the central lab and the SDRC
 - Track record of working collaboratively in multi-institution consortiums/studies
- Include:
 - Recruitment plans (including use of EHR to support)
 - Plan to delivery multimodal intervention in a bilingual fashion
 - Readiness of the investigative team (PI, Co-I, SC, NN, Pharm)



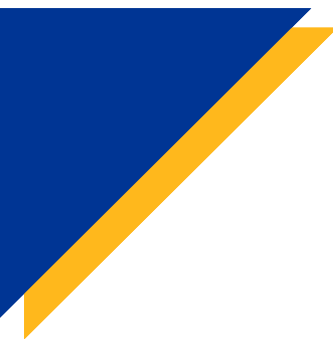
Budget

- \$1.4m in total costs allocated for 2 years
- Applicants should ensure they budget for the following:
 - Investigator effort (PI, Co-I)
 - Study Coordinator
 - Nurse Navigator
 - Study Pharmacist
 - Study participant costs (e.g. participant reimbursements; sample collection, processing and storage; etc.)
 - Travel for Annual Steering Cmte Meeting (typically at ASN)
 - Participant Advisory Committee honorarium



Anticipated Timeline

- Applications close Sept 18, 2026
- Applications will be reviewed on a rolling basis with PI notification by Oct 2, 2026.
- Clinical Center onboarding (e.g. regulatory, training, IRB) to occur in October and November
- Enrollment expected to commence before Dec 1, 2026



Questions