



COPE-AKI Clinical Center Application Frequently Asked Questions

Q. Does the Nurse Navigator do one visit on days 2-3?

A. Study visits with the nurse navigator will occur via telemedicine, telephone or in-person based on patient preference. The visits will occur at hospital discharge, again within 2-3 days after hospital discharge, and then at 7-10 days post-discharge. After these initial visits, study visits will occur every two weeks for the next 2 months (3wks, 5 wks, 7wks and 9wks).

Q. For the intervention arm, are the nurse navigator and pharmacist at the local sites or centrally through the consortium?

A. At the local site.

Q. Does the pharmacist see patients or just meet with the team and review medication?

A. Pharmacists do meet with the patients and also with the study team.

Q. Does Clinician mean Primary Care Physician?

A. Clinician refers to the Study Principal investigators and Co-Investigators.

Q. What are the barriers for activities during days 2-7 encountered so far?

A. The primary barrier during the 7-day period post-discharge has been the study participant disposition. While the majority are discharged to their homes, roughly a quarter are discharged to acute rehab facilities (or similar) which can impact delivery of the intervention. Additional barriers have included delayed discharges, particularly unexpected discharges that impact the research team.

Q. Are the NN visits virtual or at patient residence or both?

A. The first NN visit is in-person while the participant is in the hospital. Subsequent visits are telemedicine and in-person clinic visits.

Q. Do you have Spanish consents?

A. Yes. Study materials and patient informational flyers have also been translated into Spanish.

A copy of the English and Spanish consent templates is posted on the Application portal homepage.



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Q. Are patients provided with monetary incentives for visits? Is this part of the site budget?

A. Participants are compensated \$50 per visit, being the total compensation of \$250 (for 5 visits: enrollment, 1 month, 3 months, 6 months and 12 months).

Q. Are you also looking to increase recruitment of other Races that are underrepresented?

A. We are mostly focusing on increasing representation of Hispanic/Latino patients; however, we are not limiting participation of any racial or ethnic groups.

Q. Do you require an institutional official to countersign an application or provide a letter for uploading into the letters of support section?

A. The clinical center applications do not require an institutional official to sign or submit the application. Letters of support are highly encouraged but optional.

Q. How many sites are you planning on funding?

A. The plan is to fund at least 1 site.

Q. Will this application count towards NIH cap for applications per PI per year?

A. No.

Q. Any particular PI you are looking for?

A. We are looking for PI/team that has experience with clinical trials in the AKI setting. Furthermore, we want a team that can demonstrate ability to integrate into an ongoing clinical trial.

Q. Are you specifically looking for Nephrologist Investigator as PI? Can these be: hospitalists, PCPs, etc.?

A. A Nephrologist as the Site Lead PI is encouraged.

Q. Is this a U.S. based research site, or do you anticipate including international sites?

A. U.S. only.

Q. Is this project approval through a central IRB, which we can cede to?

A. The University of Pittsburgh currently serves as the single IRB.



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Q. How many total estimated patients are you planning to recruit from the new site?

A. We expect the new site to contributed at least 1-2 participant enrollments per week.

Q. Where can applicants find information about the central lab and coordination with the lab (a key topic listed in the approach content guidance)?

A. The information is included in our protocol and standard operating procedures.

Q. What is the total budget for the site submission?

A. COPE-AKI site awards are designed to support enrollment across affiliated enrollment sites. Applicants should plan for a budget in the range of **\$350,000–\$700,000 in total costs per year**. Budget for needed resources to conduct the study. Not to exceed 700,000 total costs annually.

Q. As for pharmacist and nurse educator, are folks at the lead sites using specific staff?

A. The Nurse Navigators are usually part of the clinical research department; however, the pharmacist usually does clinical work as well.

Q. How many participants do you estimate will be recruited at the new site?

A. 104