Pre-receipt Webinar for Caring for OutPatiEnts after Acute Kidney Injury (COPE-AKI) Research Consortium Funding Opportunity Announcements (FOAs)

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) hosted the Pre-receipt Webinar for COPE-AKI Research Consortium FOAs with the purpose of bringing together investigators in the AKI field who are interested in applying for these funding opportunities and answering their questions. The COPE-AKI FOAs will establish three to four Clinical Centers (CCs) (RFA-DK-20-011) to work collaboratively with a Scientific and Data Research Center (SDRC) (RFA-DK-20-012) in a consortium. The NIDDK is interested in improving clinical and patient-centered outcomes of survivors of AKI. The COPE-AKI Consortium will develop and test interventions that aim to reduce morbidity compared with the usual care in patients after hospitalization with stages 2 and 3 AKI. Approximately 55 participants attended the Pre-receipt Webinar via Zoom on August 18, 2020.

Links to the FOAs

https://grants.nih.gov/grants/guide/rfa-files/rfa-dk-20-011.html

https://grants.nih.gov/grants/guide/rfa-files/rfa-dk-20-012.html

Questions and Answers Discussed during the Webinar

1. **Has the NIDDK chronic kidney disease (CKD) eCare plan been developed, and will it be available for use in the study? How do we access it?**

   Information can be obtained at the following link: https://ecareplan.ahrq.gov/collaborate/. For questions, please contact—

   Jenna M. Norton, M.P.H.
   Kidney and Urologic Science Translation Program Manager, NIDDK
   Email: jenna.norton@nih.gov

2. **Does the SDRC have to propose a specific clinical trial design in the application?**

   Yes. As stated under the Research Strategy section of the FOA, an application for the SDRC must propose a late-hospitalization and/or outpatient intervention study that incorporates an innovative strategy, analytical approach, and power analysis to accomplish the goals of the FOA to illustrate how the SDRC will operate.

3. **The Request for Applications (RFA) states the first-year budget for direct costs is $500,000. Is this the annual amount for the SDRC, or will it increase in subsequent years and, if so, to what amount?**

   This budget is expected to be the annual amount for subsequent years, with a maximum of 5 years.

4. **Will the NIDDK be receptive to a single center applying as both an SDRC site and a clinical site? Is there any concern about this (assuming the principal investigators [PIs] would be different for each application)?**

   Yes, but there must be no scientific, budgetary, or effort overlap.

5. **May investigators who are listed on CC proposals also have a role in an SDRC?**

   Yes, but there must be no scientific, budgetary, or effort overlap.

6. **The RFA allows multiple PIs. Will the NIDDK be receptive to a clinical site submission recruiting from multiple sites?**

   Yes. Multiple local or out-of-state sites are allowed.

7. **What is the application deadline?**

   The application due date is November 4, 2020.

8. **Is the final protocol anticipated to address a single intervention or possibly multiple interventions?**

   The PI can propose any type of trial that is within the confines of the FOA budget; however, it is important for applications to focus on the clinical design presentation. Designs should be generalizable and effective and should consider the size of the consortia. The final protocol will be determined by the Steering Committee composed of successful PIs and will be reviewed and approved by the Data and Safety Monitoring Board and the NIDDK. Given the funds for this FOA, a single randomized clinical trial is likely.

9. **How should the SDRC budget for the proposed project?**

   The budget should reflect the scope of work being done by the SDRC, which includes coordinating data flow, analyses, meetings, etc. Applicants are encouraged to focus on the typical work of the SDRC in coordinating a large clinical trial.

10. **Should clinical sites budget for biomarker and/or other outcome studies (electrocardiogram, echocardiogram, etc.), or is this for the SDRC?**

    Decisions are generally made on a consortial basis. Clinical sites should outline what they anticipate the costs of the tests to be. These costs are important to detail because every site will propose a different trial.

11. **What is the expectation in terms of preliminary/feasibility data?**

    Any preliminary data presentation in the application should be applicable to the RFA. Applicants are advised to show preliminary data for the intervention, if available, in AKI patient studies. In addition, applicants should proficiently demonstrate the feasibility of carrying out this type of study.

12. **Are patients who have undergone a kidney transplant included?**

    Reviewers are looking for generalizable populations and those that are useful to the broader community. Applicants are encouraged to submit studies involving patients who develop AKI during a hospitalization stay, rather than patients who have undergone a kidney transplant since that could be within the mission scope of the National Institute of Allergy and Infectious Diseases.

13. **For clinical site applications, including different institutions, do we need single PI or multi-PI applications?**

    Both multi-PI and single PI applications may be submitted. Multi-PI plans should be well justified.

14. **The SDRC will cover the cost of transport of the biological samples from the CCs to the SDRC Repository.**

    a. **Will the government FedEx rate be available to the SDRC as it was for ASSESS-AK**I?

       The NIDDK will work with consortia to apply the government FedEx rate for SDRC resources.

    b. **Who covers the cost of transporting biosamples to the Central Repository?**

       This is a function of the SDRC.

    c. **Who covers the cost of sample collection and shipping supplies?**

       This is negotiated at the time the consortium starts, unless stipulated by the RFA.

15. **When will we be notified of a successful application?**

    Applications will be reviewed in February through March 2021, and awards will be made after the May Advisory Council meeting.

    PIs who are interested in applying are strongly encouraged to speak with Drs. Ivonne Schulman and Paul Kimmel. A one-page summary of the proposal may be submitted for program staff review for comments and advice.