Frequently Asked Questions for CUSP2CT (U01 and U24)

SEE RELATED NOTICES:

1. A Multilevel Approach to Connecting Underrepresented Populations to Clinical Trials (CUSP2CT; U01 Clinical Trial Optional) https://grants.nih.gov/grants/guide/rfa-files/RFA-CA-21-063.html
2. Data, Evaluation and Coordinating Center for: A Multilevel Approach to Connecting Underrepresented Populations to Clinical Trials (CUSP2CT) (U24 Clinical Trial Not Allowed) https://grants.nih.gov/grants/guide/rfa-files/RFA-CA-21-058.html

RFA-CA-21-063 (UO1)

1. Does the reissued CUSP2CT U01 FOA have the same mechanism (U01), objectives and research scope? YES, the FOA mechanism will still be a U01 and all objectives and scope remain the same.

2. Any advice for investigators who have prepared a LOI in response to RFA-CA-21-057? Please note that the only item of the RFA that has changed is the clinical trial optional designation, thus your current pre-planning considerations should not be affected. We value all of the hard work that each potential applicant puts into these applications and want to ensure that our specifications in the FOA align with the expectations of the program. Please continue your preparation.

3. Do we need to specify studies, or can we pivot to different studies with a certain population group based upon a focus on a specific cancer site (i.e. breast cancer)? The requirement is a focus on NCI supported trials and underrepresented minority population(s). Studies and population must be specified. Tracking and evaluation are critical.

4. Can we focus on screening, symptom management and supportive care trials or only therapeutic trials? Any NCI supported clinical trial. However, an application that does not include any therapeutic trials may not be considered as competitive as an application that does include therapeutic trials

5. Can we address multiple populations (with similar barriers and disparities) with the setting being the common factor for a level of intervention (i.e. faith-based)? Yes

6. Can we focus on multiple cancer sites with the interventions addressing a specific population (i.e. breast and prostate)? It's not a cancer site that should be the focus, it is the capability to increase referral of underrepresented minorities to NCI supported clinical trials

7. Can I apply if I am not an investigator with a NCI-supported clinical trial: YES. However, your U01 sites must have active enrollment to NCI-supported CTs from one or more of NCI's clinical trial networks (NCTN, NCORP, and ETCTN).

Please note that applicants must include letters of support from collaborating entities (e.g., hospitals, clinics, health departments, community-based organizations, etc.).

8. Will the U01 have a planning phase? No. We expect that U01 applicants will already have the appropriate infrastructure in place, along with established partnerships from relevant organizations (e.g., Cancer Centers and community-based organizations, minority-serving institutions), although establishing new partnerships is encouraged.

9. Does the trial need to be currently active, or can it include also trials approved as concepts by NCI in the process of protocol writing and that will activate in the next 9-12 mo (given that the award duration is 5 years)?
Yes, NCI approved concepts in process of protocol writing with expected activation in the next 9-12 months can be included.

10. Can trials that are earlier in development be included in the proposal? No, only NCI approved concepts or trials can be included.

11. Can we submit more than one proposal from our NCORP Research Base? The team needs to identify the most appropriate strategy to address the aims of the FOA within the proposed network. Yes, your NCORP base can submit two proposals, however you should be cautious of overlapping aims, organizations or key personnel, as only one might be funded.

12. Assuming proposals score competitively, is it possible that more than one proposal per NCORP Research Base will be funded? Please note that the scientific peer review will identify most meritorious applications. However, if two well-scored applications had overlapping aims, organizations, or key personnel, it is likely that only one would be funded.

13. Can we request costs associated with enrollment to our proposed trial, such as capitation payments, for reimbursement to participating sites, or would this be expected to be covered as part of the NCORP Research Base or individual NCORP grants? Costs associated with referral might be appropriate to support interventions, however enrollment is considered a subsequent step and the FOA is centered on referral.

14. Is my understanding correct that the focus of this grant is to identify CTs that might be impacted by efforts to reduce R/E disparities and then monitor them as we perform different methods to address the disparities? Please keep in mind that applicants responding to this FOA must propose multilevel interventions intended to improve **referral and ultimately, accrual of R/E minority patients to NCI-supported CTs**. While increasing referral of R/E minorities may serve to reduce disparities downstream, the current interventions are solely centered on

referral and accrual of patients into clinical trials. SEE RESEARCH SCOPE SECTION OF THE FOA

15. Are there particular theories that are felt would be especially appropriate for the theory- based interventions, particularly with respect to the various types that are proposed in the RFA that range from intervening at the level of community members, to patients, to providers? While we are not prescriptive on the types of interventions, we expect that applicants will propose theory-based research designs culturally tailored to R/E minority populations might include Individually Randomized Studies, Group Randomized Studies (e.g., matched clinics randomly assigned to either an experimental or control group) or Quasi-experiments (e.g., pre-post and/or matched control designs). When appropriate, building upon attributes developed for the Clinical Trial Assessment of Infrastructure Matrix (CT AIM) may be proposed

16. Is the expectation that we do research studies on the actual efforts to increase the representation of R/E minorities or just that we make these efforts and then monitor the data in the NCI supported Clinical Trials that our institution is performing? This FOA supports research to **test, refine, and examine** the impact of a multilevel intervention on rates of CT participation of R/E minority patients to NCI-supported CTs. This FOA encourages the submission of applications to **implement and evaluate** multilevel and culturally and linguistically tailored outreach and education interventions with the primary goal of increasing referral of racial/ethnic (R/E) minority populations to NCI-supported CTs.

RFA-CA-21-058 (U24)

17. Will the DECC be primarily responsible for Data Analysis or will that be the responsibility of the U01 sites? The U01 Project scientists will be responsible for much of the data analysis and interpretation of study findings. However, the DECC will provide technical support to sites as needed while also unifying the collaborative efforts. Ultimately, proposing a process for the development and conduct of trans-CUSP2CT research studies (e.g., validation of newly developed measures, identification of best practices).

18. What exactly is the learning collaborative responsibility for the DECC? The DECC will assist awardees with identifying shared resources that can support needs across the sites and maximize the collaborative nature and impact of the program. For example, helping to identify common metrics and measures, and identification of evaluation measures and metrics.

19. What are the Budgets for the U01 and U24 respectively?

a. Up to four (4) U01 Grantee Sites will be awarded. The project period is for 5-years, with $450K direct costs ($765K total costs)/award/year. The budget will encompass Fiscal Years 2022-2026.
b. One (1) U24 grant will be awarded. The project period is for 5-years, with $350K direct costs ($595K total costs)/year.