

Alliance Cancer Care Delivery Research (CCDR) Committee

Pilot Project Awards

Frequently Asked Questions

Application Process

- Is there a link for the Research Funding Proposals (RFPs)? *Links for the CCDR Pilot Project Award can be found on the left side of the Alliance awards webpage at:*
<https://www.allianceforclinicaltrialsnoncology.org/main/public/standard.xhtml?path=%2FPublic%2FInvestigator-Award>.
- What are the steps to apply for a CCDR Pilot Project Award? *First, interested applicants must submit a completed [Eligibility Form](#) to the Alliance CCDR Committee Manager (abarber@facs.org) by November 14, 2023 at 5:00pm Eastern Time in order to confirm institutional and individual Alliance membership, as well as CCDR Committee membership. Eligible applicants will then be invited to submit an application to be considered for award funding.*

Eligibility

- Who can apply for the CCDR Pilot Project Award? *Alliance members rostered with an Alliance institution are eligible to submit a proposal for this award. Applicants must also be a member of the Alliance CCDR Committee.*
- Are non-US investigators eligible to apply for these awards? *Yes, as long as they are an Alliance member rostered with an Alliance institution.*
- Can multiple investigators be listed on the application? *Yes. However, one person must be designated as the contact Principal Investigator. This person will be the primary contact for all communications related to the application, including the person who will be named on the sub award, if the project is selected for funding. All co-PIs must be an Alliance member rostered with an Alliance institution. Only the contact PI must be a member of the Alliance CCDR Committee; however, it is strongly encouraged that all co-PIs on the project be a member of the Alliance CCDR Committee.*
- What are the membership requirements for award eligibility? *Applicants must meet these membership requirements:*
 - *Institutional Alliance membership*
 - *Individual Alliance membership (applies to all Principal or Co-Principal Investigators)*
 - *Alliance CCDR Committee membership (contact Principal Investigator only)*

- If I have previously received a CCDR pilot project, may I submit another proposal? *Yes, provided that you have at least completed enrollment or closed the study to accrual by the end of this current grant year (i.e., July 31, 2023).*

Alliance Cancer Care Delivery Research Committee Membership

- How can I determine if my institution is an Alliance member? *To see if your institution is an Alliance member, please check under the “about” tab → “member institutions” on the Alliance website (www.allianceforclinicaltrialsnoncology.org).*
- Can members of affiliate institutions apply? *Yes, members of affiliate institutions, as long as the affiliate institution is an Alliance member institution, are eligible to apply for an award.*
- If I transfer to another Alliance institution, can my award also be transferred? *Most likely yes; however, the request to transfer the award should be made as soon as possible. The request should be sent to the Alliance CCDR Committee Manager (abarber@facs.org) and a final determination will be made. You will be notified of the decision in writing.*
- If I transfer to a non-Alliance institution, can my award also be transferred? *No, your award cannot be transferred to a non-Alliance institution. Your options include transferring the project to someone else located at the originating Alliance institution or shutting down the study.*
- Do I need to be an Alliance member? *Yes, all applicants must be Alliance members.*
- How do I become an Alliance member? *The link for becoming an Alliance member is provided below and questions can be directed to the Alliance membership coordinator at membership@AllianceNCTN.org.*

<https://www.allianceforclinicaltrialsnoncology.org/main/public/standard.xhtml?path=%2FPublic%2FIndividual-Participation>

- If my primary institution is not Alliance member, but I hold an appointment at an Alliance member institution, am I eligible? *Yes. The fact that you hold an appointment at an Alliance member institution should be made clear in your application. Please note, however, the funds will be awarded to the Alliance institution where you hold an appointment.*
- Do all investigators listed on the proposal need to be Alliance members? *Yes, all Principal or Co-Principal Investigators need to be Alliance members.*

- Do I need to be an Alliance CCDR committee member? *All CCDR Pilot Project Award applicants must be a member of the Alliance CCDR Committee. Please contact the CCDR Committee Manager, Anne Barber (abarber@facs.org), for more information on CCDR Committee membership.*
- Do all investigators need to be an Alliance CCDR committee member? *No. The contact principal investigator does need to be an Alliance CCDR committee member.*
- How do I know if I am a member of the Alliance CCDR committee? *You can check CCDR Committee member status in the Alliance Directory under the Committee tab:*

https://allianceforclinicaltrialsnoncology.org/main/member/apps/directory/directory_query.xhtml?firstName=b*&lastName=moore&institution=0&ncid=&city=&personRole=none&coopGroup=6461&state=

- If I am not currently a member of an Alliance CCDR committee, but am planning to apply for membership, may I submit an award application? *Yes, however, Alliance CCDR Committee membership requests must be submitted to the CCDR Committee Manager, Anne Barber (abarber@facs.org), no later than the Eligibility Form deadline, and “Pending CCDR Committee membership” should be noted clearly on the Eligibility Form.*

Application

- Is there a specific format to use for the application? *While there is no specific format, proposals should be written using 11 point font (or larger) in either Arial, Helvetica, Palatino Linotype or Georgia typeface (black font color) with at least 0.5 inch margins on all sides and should include the following:*
 - Title page (include address, phone number, and preferred email address for PI) (not included in page limit)
 - Background (include rationale and significance)
 - Study objectives
 - Study plan (include schema and eligibility criteria)
 - Data analysis plan
 - Feasibility (provide evidence that study can reach accrual goal within 12 months of the start of funding)
 - Description of how this pilot study will lead to an Alliance protocol in the future
 - Description of research environment
 - References (not included in page limit)
- Are references included in the page limit? *No, references are not included in the page limit.*

- Are letters of support needed for CCDR Pilot Project Award proposals? *No, letters of support are not needed for the CCDR Pilot Project Award proposals. However, one letter of support is permitted for each participating institution of a multi-institutional study. If letters of support are included with CCDR Pilot Project Award proposals, they will be removed prior to distribution to the review committee.*
- Does the application need to be signed by the institution's authorized official? *No, the application does not need to be signed. However, should funding be awarded, your institution's authorized official will need to sign the sub award. Please note, some institutions may require the institution's authorized official signature for the application. You are responsible for determining if your own institution requires an authorized official signature on your submitted application.*
- Does my study need to be approved by an IRB? *Yes, IRB approval or exemption from the contact Principal Investigator's institution is required and preferably before funding begins so research activities can begin as soon as possible after funding is awarded. Note: IRB approval is a required special reporting requirement deliverable.*
- Is a separate Other Support document required, or is the other support noted on the biosketch sufficient for this application? *Other support noted on the biosketch is sufficient for this application, but a separate Other Support document will also be accepted.*

Funding and Budget

- What is the level of funding? *Up to \$150,000 total costs (including institutional indirect costs totaling not more than 15%) for up to 18 months of funding will be awarded for CCDR Pilot Project Awards. See other questions below and the RFP for more detailed information.*
- What budget format should I use? *All applicants should use the PHS 398 budget format (i.e., both the Detailed Budget for Initial Budget Period AND the [Checklist Form](#) Page). The link for those forms is provided below. Be sure to include the checklist page (which will reflect the indirect rate, too, totaling not more than 15%).*

<http://grants.nih.gov/grants/funding/phs398/phs398.html>
- Are the budget pages included in the page limit? *No, the budget pages are not included in the page limit.*

- What indirect F & A rate should I use? *Applicants should use the federally negotiated rate for their institution, totaling not more than 15%.*
- For the CCDR Pilot Project Awards, may I request salary support for myself (the PI) and/or other investigators? *No, salary support for PIs and other investigators is not permitted for CCDR pilot project awards.*
- May I include a line item in the budget to reimburse participating sites for their collaboration on my proposal? *Yes, you may include a line item for this purpose; however, the collaborating institutions will not receive cancer control credit or per-case reimbursement for any participants enrolled on this trial. The Alliance NCORP Research Base will only issue one sub-contract (to the contact applicant's institution) per award. The contact PI will be responsible for payment to their collaborating institutions. Important note: When making arrangements with collaborating institutions, the applicant must take into consideration that if awarded, the applicant will not receive all of the funding upfront, but will receive funds via a cost-reimbursement agreement.*
- Can travel funds be included in the budget? *Yes, travel funds to conduct the research and/or attend an Alliance meeting to present final results are permitted and should be included in the budget. No additional Alliance funds will be available to assist with travel to an Alliance meeting to present your final results.*
- What other items cannot be included in the budget? *Funds for equipment cannot be requested because use of federal funds prohibits it.*
- May I request carryover funds? *Carryover funds may be requested, but they are not guaranteed. The proposal's scope and timeline should be realistic for an 18-month research period. If the project cannot be completed in an 18-month period, a back-up plan for supplemental funding should be in place as we cannot guarantee that carryover funds will be approved by NCI.*
- When will funding begin? *Funding can begin when the sub awards are fully executed. The sub award contracts will be sent to the recipient's institution in late January / early February 2024.*
- What will happen if I have difficulty activating and recruiting to my study? *If the study is not activated within the first 12 months after funding is awarded, the study will be shut down. Applicants are strongly encouraged to submit their proposal to their local IRB for approval at the time the application is submitted to reduce time to activation, if funded. Progress toward implementing recruitment strategies and increasing accrual will be evaluated as needed throughout the study period. Failure to accrue to the trial as planned may result in early termination of the study and forfeiture of remaining award funds.*

Funding Mechanism

- Who is the sponsor of this grant? *The National Cancer Institute (NCI) via a grant to the Alliance NCORP Research Base.*
- What is the Alliance NCORP Research Base grant number? *UG1 CA189823*
- How will the funds be awarded? *Funds will be awarded as a cost-reimbursement agreement from the Alliance NCORP Research Base grant to the contact PI.*
- Will funded proposals receive the entire award at the beginning of the funding period? *No, a cost-reimbursement agreement will be issued and the applicant will need to invoice for allowable costs incurred. The funding will be conveyed over an 18-month period, with a maximum of \$75,000 in total costs for the period February 2024 – July 31, 2024. The remaining funds will be conveyed in the second year of funding for the period August 2024 – July 31, 2025.*

In addition, there will be some special reporting requirements for the specified deliverables described below:

- *Notification of IRB approval (or exemption approval)*
 - *A written progress report to the Alliance in six months*
 - *Notification when participant enrollment reaches 50%*
 - *Notification participant enrollment is completed or study is closed to accrual*
 - *A written progress report at the completion of the funding period*
- Can sub awards be created for each institution participating in a particular trial? *No. Only one sub award will be issued per funded project from the Alliance NCORP Research Base to the contact PI of the award. Investigators should work with their own institution to determine if they are able to request an exception to their institution's policy to avoid charges incurred to set up subcontracts post-award.*

Submission

- What is the application deadline? *December 11, 2023 at 5:00 pm (Eastern Time). Submission deadlines will be strictly enforced.*
- How should I submit my proposal and supporting documents? *Complete applications should be emailed to Anne Barber (abarber@facs.org).*
- What do I need for my submission?

- *Complete application including title page, background, study objectives, study plan, data analysis plan, feasibility, likelihood of future Alliance protocol, references, description of research environment*
- *Budget (not to exceed \$150,000 total costs) in PHS 398 format*
- *Budget justification*
- *Biosketch of PI(s)*
- *Documentation of Other Support for PI(s)*

Other

- *Will the Alliance provide any regulatory management of my proposal? No, so please budget accordingly. The contact PI will be responsible for regulatory management at his/her own institution and working with collaborating institutions.*
- *Who will review these proposals? Eligible and complete CCDR proposals will be reviewed by CCDR Committee co-chairs and vice chairs as well as ad hoc reviewers with expertise in the subject matter who disclose no conflict of interest with the assigned protocol(s).*
- *Will there be any special reporting requirements regarding my project, if funded? Yes, awardees will be required to provide formal written updates every 6 months. In addition, they may be contacted periodically throughout the lifetime of the project to provide informal updates to the CCDR Committee Manager.*
- *Do publications resulting from the project need to follow the Alliance Publications Policy? Yes, awardees must adhere to the Alliance Publications Policy (<https://www.allianceforclinicaltrialsnononcology.org/main/member/cmsfile?cmsPath=/Public/Governance/files/Chapter%2010%20Publications%20clean%20January%201%202018.pdf>) and are required to submit all abstracts and manuscripts to the Alliance Publications Coordinator (publications@AllianceNCTN.org) prior to submitting to the meeting or journal. All publications must acknowledge support from the Alliance NCORP Research Base grant UG1 CA189823 (Contact PI: Electra Paskett, PhD).*