# Alliance Cancer Control Program (CCP) Award Frequently Asked Questions

## **Application Process**

- Is there a link for the Research Funding Proposal (RFP)? The link for the CCP Pilot Project Award can be found on the left side of the Alliance awards webpage at:
  - https://www.allianceforclinicaltrialsinoncology.org/main/public/standard.xhtml?path=%2FPublic%2FInvestigator-Award.
- What are the steps to apply for a CCP Pilot Project Award? First, interested applicants must submit a completed Eligibility Form to Jill Oliveri (jill.oliveri@osumc.edu) by November 14, 2023 at 5:00 pm Eastern Time in order to confirm institutional and individual Alliance membership, as well as CCP committee membership. The Eligibility Form for Pilot Project Award applicants can be found [here]. Eligible applicants will then be invited to submit an application to be considered for award funding.

#### **Eligibility**

- Who can apply for the 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 an Alliance CCP committee.*
- Is there a separate Junior Faculty Award? No, there is not a separate Junior Faculty Award; however, early career investigators are strongly encouraged to apply for the CCP Pilot Project Award. Early career investigators who are Alliance members rostered with an Alliance institution are eligible to submit a proposal for this award. They may have either an instructor or assistant professor position within their institution and must be within 10 years of their first faculty appointment as of February 1, 2024. Post-doctoral fellows must maintain their fellowship for the entire one-year award period. Each applicant must work with a mentor throughout that time, allocating protected time to engage in training activities and conduct a research project in the field of cancer prevention and control (includes cancer prevention, risk assessment, screening, symptom intervention, surveillance, health outcomes research or specific population groups, e.g., minority and underserved, older adult, adolescent and young adult populations).
- Are non-US investigators eligible to apply for this award? *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

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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 an Alliance CCP committee; however, it is strongly encouraged that all co-PIs on the project be a member of an Alliance CCP committee.

- What are the membership requirements for award eligibility? *Applicants must meet these membership requirements:* 
  - o Institutional Alliance membership
  - Individual Alliance membership (applies to all Principal or Co-Principal Investigators and early career investigator mentor, if applicable)
  - Alliance CCP committee membership (contact Principal Investigator only for pilot project award applicants and either early career investigator <u>or</u> mentor for early career investigator applicants)
- Are retrospective studies permitted for this award? Yes, proposals involving analyses of existing Alliance or legacy data are permitted; however, they will be considered external data requests by the Alliance and are subject to compliance with the Alliance Data Sharing Policy. More information about these types of studies can be found here:

https://www.allianceforclinicaltrialsinoncology.org/main/member/cmsfile?cmsPath=/Public/Governance/files/Alliance-15-Data-Sharing-20130315.pdf

Data sharing requests must be submitted to the Alliance data sharing inbox: <a href="mailto:datasharing@alliancenctn.org">datasharing@alliancenctn.org</a>.

PLEASE NOTE: Fees may be charged for more complex datasets, and ample time should be allotted to prepare the data and fulfill any Mayo Clinic IRB requirements prior to data use. Please contact the NCORP Statistics and Data Center (SDC) at NCORPStats@alliancenctn.org and copy Dr. Sumithra Mandrekar (Mandrekar.Sumithra@mayo.edu) to determine 1) if a fee applies, and 2) the estimated timeline for preparing and receiving data for the proposal. Be sure to include that fee in the proposed budget, if applicable, and structure project timelines accordingly to include time estimated for preparation and receipt of data.

• Are biomarker studies permitted for this award? *Yes, please see the Specimen Bank Requests instructions found on the Concept Submission webpage:* 

https://www.allianceforclinicaltrialsinoncology.org/main/member/standard.xhtml?path=%2FMember%2FConcept-Submission

PLEASE NOTE: Requests for use of Alliance/legacy specimens may take several months up to a year or more to obtain the appropriate permissions to actually

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be allowed to use the specimens. Please contact Dr. Yujia Wen, the Director of the Alliance Translational Research Program, by e-mail (<a href="www.wen@bsd.uchicago.edu">www.wen@bsd.uchicago.edu</a>) or by phone (773-834-7973) with questions about obtaining Alliance specimens for your project <a href="prior to submitting your application">prior to submitting your application</a> to see if it will be feasible to access specimens and complete your project within the one year award period.

- May I submit multiple, but separate, proposals for consideration for a CCP award in a given year? *No, an applicant may only be a PI (or Co-PI) on one proposal for consideration for a CCP award.*
- If I have previously received a CCP pilot project or CCP junior faculty award, may I submit another proposal? Yes, provided that you have at least completed enrollment or closed the study to accrual of a clinical trial <u>or</u> submitted and received approval for the final progress report of a retrospective study by the end of this current grant year (i.e., July 31, 2023).

# Alliance and Cancer Control Program 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.AllianceforClinicalTrialsinOncology.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 this 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 Grant Administration inbox at <a href="mailto:ResearchAdministration@AllianceNCTN.org">ResearchAdministration@AllianceNCTN.org</a>, 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 <u>must be</u> Alliance members. Mentors of early career investigator applicants <u>must also be</u> 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 <a href="Membership@AllianceNCTN.org">Membership@AllianceNCTN.org</a>.

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

- If my primary institution is not an 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 I need to be an Alliance CCP committee member? All pilot project award applicants <u>must be</u> a member of an Alliance CCP committee. Alliance CCP committee membership is required for early career investigator applicants if their mentor is <u>not</u> a member of an Alliance CCP committee. However, all early career investigator applicants are encouraged to become a member of the appropriate committee relevant to their proposal, if funded, even if their mentor is already a CCP committee member. The CCP committees are: Cancer in the Older Adult, Community Oncology, Health Disparities, Health Outcomes, Prevention, or Symptom Intervention. Please contact the CCP Program Manager, Niveditha Subbiah (<u>niveditha@AllianceNCTN.org</u>), and CCP Project Coordinator, Colleen Coady (<u>ccoady@AllianceNCTN.org</u>) for more information.
- Which Alliance CCP committee should I request membership from? *You should request membership on the committee most closely aligned with your proposal.*
- Do all investigators listed on the proposal need to be Alliance members? *Yes, all Principal or Co-Principal Investigators and the early career investigator's mentor, if applicable, need to be Alliance members.*
- Do all investigators need to be Alliance CCP committee members? *No. The* contact principal investigator does need to be an Alliance CCP committee member (for pilot project award applications), and either the early career investigator or the mentor need to be an Alliance CCP committee member (for early career investigator applicants).
- Does my mentor need to be a member of the Alliance? *Yes, all early career investigator mentors* <u>must be</u> members of the Alliance.
- Does my mentor need to be an Alliance CCP committee member? *No, but to mentor appropriately, mentors must have expertise relevant to the proposed application and be an Alliance member. If the mentor is not an Alliance CCP committee member, the early career investigator <u>must be</u> a member of an Alliance <i>CCP committee.*

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• How do I know if I am a member of an Alliance CCP committee? You can check CCP committee member status in the Alliance Directory under the Committee tab:

https://allianceforclinicaltrialsinoncology.org/main/member/apps/directory/directory/directory query.xhtml?firstName=b\*&lastName=moore&institution=0&nciId=&city=&personRole=none&coopGroup=6461&state=

• If I am not currently a member of an Alliance CCP committee, but am planning to apply for membership, may I submit an award application? Yes, however, Alliance CCP committee membership requests must be submitted to the CCP Program Manager, Niveditha Subbiah (niveditha@AllianceNCTN.org), with a copy to Colleen Coady ccoady@AllianceNCTN.org, and must have a confirmed membership status no later than the Eligibility Form deadline.

## **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)
  - o 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 Pilot Project Award proposals? No, letters of support should not be included for the Pilot Project Award proposals. However, one letter of support is permitted for each participating institution of a multiinstitutional study. If additional letters of support are included with Pilot Project Award proposals, they will be removed prior to distribution to the review committee. A letter of support from the mentor <u>is required</u> for early career investigator applicants.
- 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

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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 approval by any other entity (other than an IRB) needed? If stored/archived specimens are to be used, approval for the use of the archived specimens must be obtained from the entity that owns the specimens and a letter authorizing specimen use must be included with the application. For example, if stored cooperative group specimens will be requested for the project, then approval will need to be obtained from NCI. Since obtaining approval can be a lengthy process, this approval from NCI must be obtained prior to submitting the application and the approval for use of the specimens should be included with the application. For projects requesting the use of archived cooperative group specimens, contact the Alliance Translational Research Program (TRP) Director (Dr. Yujia Wen, <a href="ywen@bsd.uchicago.edu">ywen@bsd.uchicago.edu</a>) for additional information or visit these Translational Research Program webpages at:

https://www.allianceforclinicaltrialsinoncology.org/main/member/standard.xht ml?path=%2FMember%2FTranslational-Research-Program OR

 $\frac{https://www.allianceforclinicaltrialsinoncology.org/main/member/standard.xht}{ml?path=\%2FMember\%2FConcept-Submission}.$ 

• 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 Alliance investigators and early career investigators. See other questions below and the relevant 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

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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 pilot project award, 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 the pilot project award.*
- As an early career investigator applicant, may I request salary support for myself (the PI)? Yes, you may request up to 10% of your salary plus the fringe on that salary. For example, if your salary is \$50,000, and your fringe rate is 25%, you may request \$5,000 in salary plus an additional \$1,250 in fringe (total of \$6,250) as part of the \$150,000 budget limit.
- As an early career investigator applicant, may I request salary support for my mentor? *No, salary support for mentors is not permitted.*
- 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.
- Are there any special considerations for proposals involving retrospective analyses of Alliance data? Yes, investigators should review the Alliance Data Sharing policy, which can be found at the link below. Refer to Section 15.7(Fees) when preparing the budget.
  - https://www.allianceforclinicaltrialsinoncology.org/main/member/cmsfile?cms Path=/Public/Governance/files/Alliance-15-Data-Sharing-20130315.pdf
- 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*

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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:

o *For clinical trials*, the special reporting requirements are:

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- 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
- <u>For retrospective or biomarker studies</u>, the special reporting requirements are:
  - Notification of IRB approval (or exemption approval)
  - 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.
- How many applications will be selected for funding? Only one CCP award will be selected in 2023 – either a pilot or an early career investigator award. Early career investigators are strongly encouraged to apply; however, a separate award for early career investigators is not being offered this year. If applying as an early career investigator, the applicant must include a mentor and a detailed training plan in the application.

#### Submission

- What is the application deadline? *December 11<sup>th</sup> 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 Dr. Jill Oliveri* (jill.oliveri@osumc.edu).
- 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
  - Detailed description of training activities (early career investigator applicants only)
  - o Letter of support from mentor (early career investigator applicants only)
  - o Budget (not to exceed \$150,000 total costs) in PHS 398 format
  - Budget justification
  - Biosketch of PI(s)
  - o Biosketch of mentor (early career investigator applicants only)
  - Documentation of Other Support for PI(s)

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 Documentation of Other Support for mentor (early career investigator applicants only)

Click [here] for a submission checklist for Pilot Project Award proposals.

#### 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 proposals will be* reviewed by Alliance CCP committee chairs, co-chairs and vice chairs, as well as relevant Alliance disease-specific committee chairs 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 either the relevant CCP committee chair(s) or the CCP Program Manager.
- Do publications resulting from the project need to follow the Alliance Publications Policy? Yes, awardees must adhere to the Alliance Publications Policy (10 Publications (allianceforclinicaltrialsinoncology.org)) 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).

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