

University of Colorado Cancer Center

K12 Paul Calabresi Career Development Award for Clinical Oncology (PCACO) Request for Applications

Intent: The purpose of this career development award is to increase the number of clinician-scientists trained in clinical and translational cancer research, and to promote their career development as cancer researchers.

This funding opportunity announcement seeks to appoint Scholars proposing to serve as the lead investigator of an independent clinical trial; or proposing a separate ancillary study to an existing trial or gain research experience in a clinical trial led by another investigator as part of their research and career development.

Eligibility: Clinical scientists who hold a full-time faculty appointment at the level of Instructor or Assistant Professor are eligible. Candidates also must have completed their clinical training, including specialty and, if applicable, subspecialty training, prior to receiving an award. However, candidates may submit an application prior to the completion of clinical training (Senior fellows with a planned faculty position pending). K12 Scholar will hold a clinical degree, including but not limited to, an MD, DO, DDS, DMD, OD, DC, PharmD ND and DVM. Individuals with a PhD or other doctoral degree in clinical disciplines, such as medical physics, clinical psychology, nursing, clinical genetics, speech-language pathology, or rehabilitation are also eligible. Non-clinically trained PhDs or PhDs without clinical/patient responsibilities are not eligible.

Scholars must be US citizens or non-citizen nationals of the US or have been lawfully admitted for permanent residence at the time of application. Individuals from under-represented minorities in medicine are encouraged to apply.

The candidate Scholar is expected to be in a mentored research environment. Current and former PDs/PIs on NIH research project (R01), program project (P01), center grants (P50), other individual career development awards (e.g., K01, K07, K08, K12, K22, K23, K25, K76, K99/R00), or Project Leads of program project (P01) or center grant (P50) sub-projects, or the equivalent are not eligible. Current and former PDs/PIs of an NIH Small Grant (R03), Exploratory/Developmental Grant (R21), Planning Grant (R34/U34), Dissertation Award (R36), or SBIR/STTR (R41, R42, R43, R44) remain eligible.

The Scholar will propose a research project that will include a clinical trial or correlative work to be done in conjunction with a clinical trial. Projects using only human cell lines or samples with no direct human clinical research contact are not eligible under the PCACO.

Award details: The PCACO K12 appoints Scholars for a two-year time of support. The award will provide \$100,000/year in salary support and up to \$25,830 in benefits costs. The Scholar is expected to spend 75% of their time to their health-related research with the remaining effort devoted to activities related to the development of a successful research career. Surgeon scientists with surgical duties are required to have at least 50% effort to their research and career development, with clear justification provided for being less than 75%. The award will also provide \$30,000/year in research and development funds (R&D), which may include supplies, equipment, technical support; tuition and fees related to career development courses and activities; travel to scientific meetings or training courses for career development; statistical support services.

Scholars will be required to attend the monthly Oncology-K ("OK-Club") meeting which has been scheduled for the 3rd Wednesday of each month from 4-5 pm (the timing is subject to adjust/change throughout the grant). Scholars will be required to present twice per year, the first being a brief overview of the scholar's project and subsequent presentations will cover project updates and progression. Other various instructional topics will be covered throughout the 2-year appointment period.

Mentorship requirements: Before submitting the application, the candidate must identify a mentor who will supervise the proposed career development and research experience. The mentor should be an active investigator in the proposed research and be committed both to the career development of the candidate and to the direct supervision of the candidate's research. The mentor must document the availability of sufficient research support and facilities for high-quality research. Candidates are encouraged to identify more than one

mentor, i.e., a mentoring team, if this is deemed advantageous for providing expert advice in all aspects of the research career development program. In such cases, one individual must be identified as the primary mentor who will coordinate the candidate's research. The candidate must work with the mentor(s) in preparing the application. The mentor, or a member of the mentoring team, should have a successful track record of mentoring individuals at the candidate's career stage. When feasible, candidates are encouraged to seek diverse mentors to serve as role models.

The mentor or mentoring team must demonstrate appropriate expertise, experience, and ability to guide the candidate in the organization, management and implementation of the proposed research and clinical trial.

Application instructions: Potential Scholars will submit a competitive proposal that is limited to 6 pages ARIAL 11, margins 0.5 inch. The following sections are required for a competitive proposal.

Candidate Information and Goals for Career Development

Candidate's Background (one page)

- Describe the candidate's commitment to an academic career in Patient-Oriented Research (POR). Describe all of the candidate's professional responsibilities in the grantee institution and elsewhere and describe their relationship to the proposed activities on the career award. If the candidate is already faculty, describe how their effort will change (if needed to) as a PCACO Scholar to accommodate the effort for the award. (i.e., Dr. Moo currently sees patients 2.5 days a week in clinic and this will be reduced to 1.5 days a week on the grant, or similar). Candidates with existing protected time that will be maintained should be described in detail.
- Present evidence of the candidate's ability to interact and collaborate with other scientists.
- Describe prior training and how it relates to the objectives and long-term career plans of the candidate.
- Describe the candidate's research efforts to this point in their research career, including any publications, prior research interests and experience.
- Provide evidence of the candidate's potential to develop into an independent investigator.
- If applicable, describe the candidate's prior clinical trials research efforts, prior research interests and experience. If these are extensive, describe what is different about the research to be conducted next that merits ongoing need for mentored support.

Career Goals and Objectives (one page or less)

- Describe a systematic plan that: (1) shows a logical progression from prior research and training experiences to the research and career development experiences that will occur during the career award period and then to independent investigator status; and (2) justifies the need for further career development to become an independent investigator. The PCACO scholar is expected to use their 2 years of support to bridge to the next step of their research plan and independence. This will vary depending on the candidate. A more scientifically experienced scholar may propose an R01 as the next step of their career. An earlier career candidate may propose applying for a K23 or similar national level career development award as the next step of their career.
- The candidate must demonstrate they have received training or will participate in courses such as: data management, epidemiology, study design (including statistics), hypothesis development, drug development, etc., as well as the legal and ethical issues associated with research on human subjects and clinical trials.

Candidate's Plan for Career Development/Training Activities During Award Period (one page)

- The candidate and the mentor or mentoring team are jointly responsible for the preparation of the career development plan. A career development timeline is often helpful.
- The didactic (if any) and the research aspects of the plan must be designed to develop the necessary knowledge and research skills in scientific areas relevant to the candidate's career goals. A table is often a good choice to illustrate the career development plan over the 2 years of the award by skill needed, mentor/mentor committee member to support, coursework or research skill to be mastered.
- Describe the professional responsibilities/activities including other research projects beyond the minimum required 9 person-months (75% full-time professional effort) commitment to the K12 award. Explain how these responsibilities/activities will help ensure career progression to achieve independence as an investigator.

Research Strategy (Two pages or less)

- The PCACO Scholar candidate will propose a plan of research that can be accomplished within two years.
- Provide a hypothesis and specific aims for the research plan proposed for the 2 years; include the novelty, significance, creativity, approach, and the feasibility of the candidate to carry out the research.
- The application must also describe the relationship between the mentor's ongoing research and the candidate's proposed research plan and how the candidate will move to independence from the mentor over time.
- While the focus of the K12 award is on POR, directly related translational laboratory research may be proposed in the application, if there is direct human subjects contact/connection proposed in the research or career development plan. Analysis of data from samples derived by others with no direct human subjects contact during the award time is not eligible.
- Applicants proposing a clinical trial, ancillary or feasibility study should describe the planned analyses and statistical approach and how the expected analytical approach is suited to the available resources, proposed study design, scope of the project, and methods used to assign trial participants and deliver interventions. Inclusion of a biostatistician or bioinformatics/data analyst to the mentorship committee is needed for projects that will be heavily data driven to be considered feasible unless the candidate has their own extensive background in this area.
- If proposing an ancillary clinical trial, provide a brief description of its relationship to the larger clinical trial.
- If proposing a clinical trial, describe how the two years will be used to set up the study and what are the plans for continuance of the trial if the timeline of completion will bridge to the next phase of the Scholar's career development.
- If proposing a 1-2 year feasibility study, to begin to address a clinical question, provide justification why this is warranted and how it will contribute to the overall goals of the career development and future research projects including planning and preliminary data for future, larger scale clinical trials.
- Provide a timeline for the proposed clinical trial, feasibility or ancillary study, including potential challenges and solutions (e.g., enrollment shortfalls or inability to attribute causal inference to the results of an intervention when performing a small feasibility study). Describe how the proposed clinical trial or ancillary study will test the safety, efficacy or effectiveness of an intervention that could lead to a larger study that could change clinical practice, community behaviors or health care policy. (This would not apply to a feasibility study).

Plan for Mentor/Co-mentor(s) and mentorship committee: (one page)

- The candidate must name a primary mentor who, together with the candidate, is responsible for planning, directing, monitoring, and executing the proposed program. The candidate may also nominate co-mentors as appropriate to the goals of the program.

- The mentor should have sufficient independent research support to cover the costs of the proposed research project in excess of the allowable costs of this award.
- The primary mentor or co-mentors should provide a letter of support that includes a statement that the candidate will commit at least 9 person-months (75% of full-time professional effort) to the career development program and related career development activities.
- A strong letter from the mentor/co-mentors will include a statement providing: 1) information on their research qualifications and previous experience as a research supervisor; 2) a plan that describes the nature of the supervision and mentoring that will occur during the proposed award period; 3) a plan for career progression for the candidate to move from the mentored stage of his/her career to independent research investigator status during the project period of the award; and 4) a plan for monitoring the candidate's research, publications, and progression towards independence.
- The primary mentor/co-mentors must agree to attend regular meetings with the Scholar and participate in a 6-month full committee reviews with their Scholar, the mentoring team and the PCACO leaders. The mentor/co-mentors are also expected to participate in the activities of the PCACO K12 Award (~5 meetings per year -4 scholar based interactive meetings and one national annual meeting during the 2-year award period) and will be required to write and provide annual evaluations of the candidate's progress as required in the annual progress report.
- The mentor or mentoring team should be a complementary but not overlapping team of expertise, experience, and ability to guide the applicant in the organization, management and implementation of the proposed clinical trial, ancillary or feasibility study and help them to meet timelines.

Biosketch

- Provide NIH style biosketch. Follow the format of the NIH regarding biosketch requirements.

Letters of Support

- *Institutional Commitment to the Candidate's Research Career Development* (a letter from the department or division head or cancer center leader who is the senior direct report for the candidate)
 - The sponsoring division, department or program must provide a statement of commitment to the candidate's development into a productive, independent investigator and to meeting the requirements of this award. It should be clear that the institutional commitment to the candidate is not contingent upon receipt of this career award.
 - Provide assurances that the candidate will devote the required effort to activities under this award. The remaining effort should be devoted to activities related to the development of the candidate's career as an independent scientist.
 - Provide assurances that the candidate will have access to appropriate office and laboratory space, equipment, and other resources and facilities (including access to clinical and/or other research populations) to carry out the proposed research plan.
 - Provide assurance that appropriate time and support will be available for any proposed mentor(s) and/or other staff consistent with the career development plan.
- *Mentor Letters of Support*: Provide at least 2 additional letters of support: One should be from the primary mentor and at least one from a co-mentor or equivalent.

Application Submission and Deadline

- Applications are due no later than Monday, August 5, 2024.
- The full application (Face Page, Candidate's Background, Career Goals and Objectives, Career Development Plan, Research Strategy, Mentorship Plan, NIH style Biosketch and 3 letters) should be converted into a single PDF and submitted electronically [here](#).

- For more information, please reach out to Paige Diller at Paige.Diller@cuanschutz.edu.

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Application Face Page

Date:

Applicant Name and Degree(s):

Applicant Appointment Title:

Applicant Department/Division:

Mentor/s

Primary:

Secondary/Co-Mentor(s)/mentoring team:

Do you identify as an underrepresented minority? Information regarding URM can be found at the following link, :
<https://diversity.nih.gov/about-us/population-underrepresented>

Yes

No

To date, how many publications have you written? Of these, how many are you first author?

Have you previously received any grants?

Yes (If yes, please list the grant information below: sponsor, your role, award dates, and total funding amount)

No