



## FUNDING OPPORTUNITY ANNOUNCEMENT

We are seeking applications for a special grant opportunity under the College's Community and Academic Allergists Partnership in Education and Research (CA<sup>2</sup>PER) program. We will fund collaborative research focused on practice-based translational research that addresses clinically relevant questions conducted by a team of academic and private practice allergists in the US and Canada. A total of \$100,000 in grant support will be awarded in 2025.

#### **Submission Deadlines:**

Letter of Intent (LOI): December 1, 2024

Full Proposals (by invitation only): January 31, 2025

All requests for funding under the CA<sup>2</sup>PER program must be submitted via a <u>Letter of Intent (LOI)</u>. A selected number of applicants will then be invited to submit a full proposal.

We strongly recommend that applicants carefully review our program areas of focus, criteria, and funding restrictions before submitting the LOI.

#### I. Areas of Focus

We will consider proposals that address research questions of relevance to clinical practice (either directly or indirectly) that are ultimately important for improving A/I care. The program is designed to enable College members to initiate research where other sources of funding would be challenging to obtain due to lack of preliminary data. This may include comparative efficacy studies of similar therapies for specific clinical conditions (such as biologics in asthma), generating preliminary data necessary to secure funding for a larger study. Proposals for innovative studies that have a "proof of concept" component are welcomed.

<u>Proposed projects must be limited to translational research with emphasis on T2-T4 research as defined below.</u>

T2 (translation to patients) research assesses the value of applying clinical trial research and establishes evidence-based guidelines. T3 (translation to practice) research primarily focuses on dissemination and implementation while T4 (translation to communities) research evaluates the real-world health outcomes of population health, and can include policy analysis and evaluation, cost-benefit analysis, and surveillance studies.

### Project examples include, but are not limited to:

- Comparative efficacy study of specific FDA-approved therapies in similar patient populations with an emphasis on characterizing the patient groups that optimally responded to specific products.
- Testing the validity of clinical assumptions in a pristine, hypothesis-driven research design. As an
  example, the research could explore the role of skin pigmentation in serum vitamin D levels.
  Specifically, to see whether lower vitamin D levels in people of color represent their normal levels
  or are truly associated with clinical deficiency/insufficiency.
- An interventional trial focused on the impact of stress management on clinical control measures and mechanism-based biomarkers in patients with CSU, MCAS or asthma who have a history of stress, anxiety and/or depression.
- Identification of biomarkers to predict response to therapeutic interventions in a given disease state using different mechanism-based therapies.

### Projects Focusing on Adult Onset Allergic (Mast Cell-Mediated) Diseases

This round of funding for the CA<sup>2</sup>PER Program will give special consideration to proposals that provide new insights into what factors (genetic, environmental, life choices) predispose susceptible adult patients to develop new onset of IgE- and/or non IgE-mediated mast cell diseases.

Examples include but are not limited to:

- Identification of novel biomarkers for the diagnosis of adult onset allergic (MC) diseases.
- Creation of diagnostic and treatment algorithms based on studies to identify factors that can lead to improved management pathways in late onset allergic (MC) diseases.
- Discovery of new genes or genetic variants that are associated with adult onset allergic (MC) diseases.
- Identification of risk factors that lead to poor prognosis in autoimmune or autoinflammatory disorders, such as lifestyle, exercise, diet, specific biomarker profiles, and others.
- Elucidation of new biomarkers that help optimize treatment in patients with adult onset allergic (MC) diseases or identifying pathogenic mechanisms that will lead to improved selection of personalized treatment options.
- Use of Artificial Intelligence in the diagnosis, treatment and management of adult onset allergic (MC) diseases.

## II. Program Criteria

The proposed project should meet one or more of the following criteria:

- Be focused on a research question that is germane to patient care and can be addressed in a translational format.
- Outline a scientifically valid research plan that can answer a clear research question.
- Be hypothesis-driven unless it can be clearly identified that the project is hypothesis generating.
- Have the potential to improve the future system of care for allergy and asthma patients.
- Result in the potential for national/large-scale applicability.

NOTE: Proposed projects must be limited to translational research with emphasis on T2 (translation to patients), T3 (translation to practice) and T4 (translation to communities). See the definitions under Areas of Focus above. Generally, T0 (basic research) and T1 (translation to humans) research proposals will be considered nonresponsive to the RFP and will not be reviewed. Quality improvement projects will also be considered nonresponsive to the RFP and will not be reviewed.

### III. Human Subjects Protection (IRB Approval)

Proposals that generate data from identifiable human research participants will require Institutional Review Board (IRB) approval. The review may be conducted by the academic Pl's institution or an independent IRB. Projects that utilize data derived from completely deidentified databases will not require IRB approval, but applicants must provide a full description of the database and how it is deidentified in the proposal.

### IV. Eligibility

Applicants must meet the following eligibility criteria:

- Use a multiple principal investigator (MPI) model consisting of at least one academic allergist PI and at least one community/private practice allergist PI. The academic PI must have a faculty (teaching/research) appointment at an academic institution and dedicate at least 80% of their time to activities in an academic setting. The community practice PI must dedicate 80% of their time to clinical activities in a private/community practice setting.
- Pls must contribute at least 10% of their time for the oversight of the project. Pl time dedicated to the project must be 'in kind.'
- Both PIs must be members of the ACAAI (in good standing) residing in the US and Canada.
- Fellows-in-Training (FITs) cannot serve as PIs, but may serve on the research team.

## V. Partnership Requirements

A strong partnership between academic and community-based allergists is at the core of the CA<sup>2</sup>PER program. Below is what's expected of participating organizations and research teams:

- **Equal collaboration:** A full commitment by the principal investigators (at least one academic and one community-based) who will collaborate equally in directing the research project and share credit.
- Rotating responsibilities: Duties can be rotated, but the PIs will remain equal partners.
- Shared tasks: Pls will share tasks such as experimental design, resource allocation, supervision of staff, financial management, data sharing, and timely submission of publications.
- Co-presentation and co-publication: Pls agree to co-present and co-publish the research.
   Annals of Allergy, Asthma, and Immunology will be given first right of refusal to publish the research findings.
- **Investigative goals:** Pls will participate in composing and delivering the investigative goals that are consistent with CA<sup>2</sup>PER and Good Clinical Practice guidelines.
- Regular communication: Frequent and consistent communication should be maintained between the PIs to keep the project on track.

Administrative contact: Each grantee will need to designate an administrative contact who
will manage all communications between the College, Pls, research teams and participating
organizations (e.g., university pre-/post-award office and the private/community A/I practice).

## **VI.** Grantee Support

The CA²PER program is dedicated to offering grantees the resources and guidance they need to successfully launch their research. Each applicant selected to submit a full proposal will be assisted by members of the Task Force who will be available to answer questions about the grant opportunity to enable the applicant to write a strong grant application. Once selected for funding, grantees will be asked to complete an online assessment that will help us identify additional resources to assist them in the conduct of their study.

#### VII. Letter of Intent

All applicants are required to submit a <u>Letter of Intent</u> (online) by **Dec. 1, 2024**. LOIs submitted after the deadline will <u>NOT</u> be considered. You will be asked to provide the following information in the online LOI form:

- Descriptive title of proposed research and proposed start and end date;
- Estimated amount of funding needed (not to exceed \$100,000);
- Designated contact person for all communications related to the proposal, including their name, email address and telephone number;
- Names, email addresses and CVs (in <u>NIH biosketch format</u>) of the principal investigators;\*
- A brief description of partnership between participating institutions (academic and community-based A/I practice), including roles and responsibilities and the research team's qualifications;
- A description of your proposed project (in 1,000 words or less). You will need to list your specific aims, describe your general strategy, and specify how your project will benefit the field of allergy and immunology. You will also need to indicate if an IRB approval is needed for your research.

\*Note: At least one academic allergist PI and one community allergist PI are required; see the Eligibility and Partnership Requirements sections above for additional details.

Once we receive your LOI, we will determine if your research is a good fit for the CA<sup>2</sup>PER program. If selected, you will be invited to submit a full proposal within 45 days of the notification. If not selected, you may be advised about other relevant opportunities or concerns worth addressing before you apply again in the future.

# VIII. Full Proposal

If your LOI is selected for a full proposal submission, you will be asked to describe the proposed research in more detail, stating its significance and how it will be conducted. You will be required to submit the following: 1) Project Narrative, 2) Itemized Budget and Justification, and 3) NIH-style Biosketches for all key investigators. You will find additional details on what's required on pages 5 and 6 below.

## A. Project Narrative (Full Proposal)

The Project Narrative (research plan) is limited to <u>6 pages</u> (11 pt font Arial or equivalent, single spaced and margins set to no less than half an inch) and must be submitted in either Microsoft Word (DOC/DOCX) or PDF file format.

Your Project Narrative will need to outline the rationale for the proposed research and specify the following: goals and objectives, research methodology, responsibilities of each participating organization (e.g., academic institution and private/community A/I practice), and qualifications of the research team. (See the proposal review criteria below on what your proposal needs to address.) Key references should be included in the project narrative, but will not count toward the 6-page limit.

### B. Budget

Applicants may request up to \$100,000, though the individual award(s) may vary in size depending on the scope of the research and number of projects selected for funding under this program. You will need to supply an itemized budget and justification for all direct and indirect expenses if invited to submit a full proposal.

Typical direct expenses include study personnel expenses (excluding salary for PIs and key investigators), equipment or equipment rental, participant incentives, materials and supplies, data management fees, data analysis support (or other consultant services), human subjects protections (e.g., external IRB fees), etc. Indirect expenses (paid to the principal investigator's institution for the administration of the grant) may not exceed 10% of the proposed budget.

#### **Restrictions: What We Don't Fund**

- Direct Salary support for PIs and investigators (their time dedicated to the project must be in-kind.) Technical/clinical staff and/or data management/analysis support will be considered if appropriately justified.
- Indirect cost of more than 10% of the grant amount
- Projects that are already fully funded through another source
- Scholarships
- Religious or political organizations, lobbying, etc.
- Fundraising organizations/activities

## C. NIH-style Biosketches

Applicants will need to complete the <u>NIH-style biosketch</u> for all key investigators. Please be sure to combine them into two separate PDF files (one for your academic team and one for your community team) before you upload them to the online form.

## IX. Proposal Review Criteria

Significance: Does the project address an important problem/challenge faced by allergists?
 Does it clearly meet the above stated program criteria? Does the proposal achieve clear, reasonable, and measurable goals and objectives to advance this field?

- **Innovation**: Does the project challenge and seek to shift current clinical practice paradigms by utilizing novel concepts, approaches, or interventions?
- Approach: Are the overall strategy, methodology, and evaluation well-reasoned and appropriate to accomplish the specified goals and objectives? Does the proposal address potential barriers and present alternative strategies to ensure the project's success? Can the project reasonably be expected to be completed within the one-year funding period?
- **Environment:** Does the environment in which the project will be conducted contribute to its success? Are the resources that have or will be secured sufficient? Is there evidence of institutional/community support? Does the project adhere to nondiscriminatory policies within the program/workplace?
- Budget: Is the budget realistic and adequately justified?
- **Partnership:** Does the proposal follow an MPI model (with at least one academic and one private/community A/I practice PI) and demonstrate adequate distribution of responsibilities between academic and community-based researchers?
- Project Team: Does the research team have appropriate expertise? Are individual members of the project team qualified to carry out their specified role in the project?

## X. Application Process and Timeline

- Letter of Intent deadline December 1, 2024
- Applicants meeting grant criteria invited to submit full proposal December 16, 2024
- Full proposal deadline January 31, 2025
- Award notifications February 28, 2025
- Project start April 1, 2025 (projects involving human subjects will require IRB approval)
- Initial progress report October 1, 2025
- Final report May 30, 2026
- Abstract submission July 2026

## XI. Reporting, Publication and Acknowledgement of Support

Grant recipients will be required to:

- Submit a progress report (every 6 months of the project start date) and a final report (within 2 months of completion).
- Submit an abstract for presentation at the first ACAAI Annual Scientific Meeting at the completion of the project.

NOTE: Annals of Allergy, Asthma and Immunology will be given first right of refusal to publish the findings as a submitted manuscript. Any additional publication or presentation (including a poster or oral abstract presentation) of the material based on or developed under this project must include an acknowledgement of the College's CA<sup>2</sup>PER grant support.

# XII. How to Apply

If you believe that your proposed project meets the scope of the program, eligibility and program criteria, we encourage you to submit a <u>Letter of Intent</u> no later than December 1, 2024. LOIs submitted after the deadline will not be considered.

Questions? Contact Katerina Barcal, MPH, at <a href="mailto:katerinabarcal@acaai.org">katerinabarcal@acaai.org</a> or 847-725-2283.