## **CARRA-Arthritis Foundation Team Science Planning Grant**

Grant Project Period Length: 12 months Grant Funding Amount: \$ 100,000 Grant Availability: up to 1 award LOI due: February 20, 2025 Application Deadline: August 22, 2025 Project Period: December 31, 2025-December 30, 2026

CARRA's culture of collaboration focuses on facilitating, accelerating, funding, and performing research driven by academicians, clinicians, scientists, patients and families to fulfill its mission: to conduct collaborative research to prevent, treat, and cure pediatric rheumatic diseases. CARRA's peer-reviewed Intramural Grant Program offers various funding opportunities to support investigators at all career levels and advance research that furthers our mission.

## **Program Description**

The CARRA-Arthritis Foundation Team Science planning grant aims to stimulate the development of high-quality, multi-investigator, multi-disciplinary program projects that advance to extramurally funded grant awards.

The goal of the funding award is to develop a mature project and plan for submission to a specific extramural funding source within 12 months of the conclusion of the planning grant period. Successful applications will clearly detail how the study plan will lead to and support an interdisciplinary, collaborative, highly synergistic team science grant application to an external public funding source such as PCORI or NIH, or a private foundation. The funding source and grant mechanism must be named in the application with a link to the notice provided.

A successful application will describe high-quality research projects focusing on inflammatory arthritis in children and adolescents, in areas identified in the 2023-2025 CARRA -Arthritis Foundation <u>Research Agenda</u>. Special consideration will be given to applications addressing the topics considered critical among patients, caregivers, and providers listed below. However, other topics will be considered if a compelling case is made for their significance in the research agenda.

- Precision Medicine
  - Diagnostic and prognostic biomarker identification
  - Starting/stopping medication

- Safety and the impact of use of specific medications (e.g., TNF-I in non-systemic JIA)
- Patient Outcomes and Outcome Measures
  - Patient Reported Outcome Measures (RROs), impact on health-related quality of life, health disparities and other related issues
  - Long-term outcomes; impact on childbearing, occupation, college, marriage, delays vs. peers, growth, and reproductive health
  - Transition
  - Health-related quality of life (HRQOL)
  - Environmental factors
  - Patient-reported outcomes (PROs)
  - Tools/outcome measure development, implementation, and ongoing validation
- Epidemiology
  - Use of the Registry (use of artificial intelligence or data science)
- Representativeness
  - Social determinants of health
  - Equitable participant representation in the Registry
- Treatment Development
  - Working with the Food and Drug Administration (FDA) to develop acceptable trial designs for pediatric patients
  - Evidence development (data linkage)
- Comparative Effectiveness Research
  - Consensus Treatment Plan (CTP) Program (development, revision, and implementation)

## Eligibility

- 1. The application must address inflammatory arthritis in children and adolescents, though other diseases can also be included.
- 2. The project PI must be a current CARRA member, who is up to date on membership dues and has ensured their membership information (location, contact information, and membership status) is current and accurate.
- 3. The PI must have served as a principal investigator or co-investigator (Co-PI) in one or more research studies with external peer-reviewed funding such as an R01 or equivalent, and must be:

- a. A Pediatric Rheumatologist with an MD or equivalent academic degree and hold a faculty position or equivalent at a college, university, medical school, or comparable institution.
- b. A PhD with a research emphasis on translational pediatric rheumatology research or a PhD psychologist with a history of treating patients with juvenile arthritis.
- 4. Applicants should have attended and/or viewed each of the CARRA Team Science webinars and completed the program evaluations. The webinars and evaluations can be accessed through the <u>CARRA Research Portal</u>.
- A team must consist of at least two but no more than 4 high effort co-Investigators (Co I). The team must be interdisciplinary and can represent one or more institutions.
- Patient engagement is critical. At least one parent/patient must be part of the study team. If a patient/parent cannot be identified, please contact Vincent Del Gaizo through the CARRA Research Support and Services Request Form at <u>https://carra.tfaforms.net/58</u> who will assist with identification.
  - a. More details can be found on the CARRA Research Portal here: https://research.carragroup.org/en/requests/research-support-services
- 7. While not eligible to serve as a PI, team members can include fellows, junior faculty, and students, research professionals who are regulatory or data coordinators, business and industry associate members, and nonprofit/government associate members.
- 8. CARRA Board members or those in Executive Leadership positions may not apply
- 9. CARRA grant awardees who are not up to date in their progress reports are not eligible.

# Important Information for CARRA-Arthritis Foundation Investigation Team Science Planning Grant

- 1. LOI due: February 20, 2025
  - a. If the LOI is accepted, the proposed PI(s) will be invited to present the proposed study plan to a panel of experts for feedback and guidance over either video conference or at the ASM in early April 2025. Date to be determined.
- 2. Applications due: August 22, 2025
- 3. Award: December 31, 2025
- 4. Funds will be provided to the awardee's institution and used by the PI according to the project budget.
- 5. If the PI cannot complete the project, any unexpended balance must be returned to CARRA.
- 6. Awardees are expected to attend the ASM yearly and submit an abstract once the grant period is complete

- 7. Awardees must submit a final progress report no more than 45 days after the project period end date.
  - a. Late report submission may impact an applicant's eligibility for future CARRA grants.
- 8. Awardee must keep CARRA informed about future plans, awards and add on funding for up to 3 years after the grant end date.
- 9. All successful applicants must abide by the procedures outlined in the current CARRA Authorship, Publication, and Presentation Guidelines when presenting/publishing findings from their projects. This includes:
  - a. Submitting all abstracts and manuscripts to the CARRA Publications Committee for approval prior to submission
  - b. Acknowledging the support of CARRA and the Arthritis Foundation by including the following language: "The authors wish to acknowledge CARRA and the ongoing Arthritis Foundation financial support of CARRA."

## New: Letter of Intent and Data/Sample Share Request: CARRA Registry and Biorepository

- LOIs are due in Proposal Central February 20 2025, by 11:59PM ET.
- Grant applicants who intend to utilize the CARRA Registry or CARRA-related data and/or samples must submit a Letter of Intent (LOI) for prior approval. This year, in an effort to streamline the user experience and improve operational workflow, we are combining the LOI and data /sample requests into one process.
- No separate data and sample request is required when applying for a CARRA Grant in 2025.
  - If you would like to know more about conditions of use, please review our data and sample share policy on the <u>CARRA Research Portal</u>.
  - CARRA will only accept proposals that utilize the current Registry CRFs and standard biosample collection kit. However, with CARRA approval, the subsequent extramural funding project plan may include plans for supplemental data collection.

## **Application Process**

Step 1: Letter of Intent/Data Request (Form on Proposal Central)

Letters of Intent (LOIs) are due in Proposal Central February 20 2025, by 11:59PM ET and must include the following information specific to the planning grant:

- Grant Program Name:
- Grant project title
- Names of all key personnel

- Study organizational chart outlining team member roles [can be an image /chart that is uploaded or list that is inputted in free text]
- Research plan that includes an outline of the background, objectives, significance, and innovation
- The "Contact PI" responsible for receiving communications about the project.
- Estimated timeline with milestones at every four months of the grant project period.
- Study aims
- Data and Sample Questions
  - $\circ$   $\;$  Does your project involve the use of CARRA Registry data and/or biosamples?
    - If yes to CARRA biosamples above: Data and Sample Request Questions
  - o Sample request details
    - Will the proposed biosample collection be open to all CARRA Registry sites or limited to a subset of sites? Desired sample timepoint [multiple choice]
  - o If yes to CARRA Registry data above: Data request details
  - Zip Codes (Note: Must provide an appropriate IRB approval letter if fullfull zip codes are requested. 5-digit zip codes require a limited data set) [multiple choice]

If the LOI is deemed responsive to the RFA, the team will be invited to present the proposed project for feedback to a panel of experts.

## Step 2: Full Application

The full application should include a detailed description of the proposed planning grant project. Information required includes:

- 1. Title Page (no more than 1 page).
  - See the "Attachments and Descriptions" section for more information or see the template.
- 2. Research Plan (no more than 8 pages) must include:
  - Project goals
  - Interdisciplinary aspects and background
  - Relevance, innovation, and significance
  - Research approach and methods
  - $\circ$   $\;$  Description of the collaborative aspects of the team  $\;$
  - The funding agency and which funding mechanism(s) targeted for the team-based submission
  - $\circ \quad \text{Project implementation, coordination}$

- The role of mentorship for new or junior faculty
- Milestones and corresponding timeline in the development of the extramural grant proposal and how these funds will provide essential data for a future extramural grant application
- Plan to submit an extramural application.
- 3. Proposed budget and detailed budget justification (see below)

## **Budget Period Detail**

The budget provided must indicate how funds are to be allocated.

- All PIs must dedicate effort to the project, which must be noted on the budget table.
- A letter of support from each of the PIs' division chief(s) must be submitted, documenting that the % effort is available and confirming the investigator's salary. If the PI is the division chief, a letter from the Department Chairperson is required.
- Salary support should be calculated based on the current salary up to a cap of \$200,000 and fringe at the investigator's institutional rate. No cap on effort PIs, co-PIs or co-Is.
- CARRA will allow up to 8% F&A (indirect) costs, and these must be incorporated into the project budget. If indirect costs are requested, total costs for this project must not exceed \$75,000.
- Funds are only designated to support the proposal directly.
  - $\circ$   $\;$  Funds cannot be used for cost sharing or matching.
  - No computers or related hardware
  - o Publication costs are not permitted.

## **Budget Summary & Justification**

- Present items in the same order as in the budget. Explain how the cost of items was arithmetically determined.
- The funds must be designated for the direct support of proposal development activities, which can include consulting support, travel to a project specific meeting, hosting costs, pilot data collection and other needs identified in the application.
- If project-specific travel is included, please provide the purpose and destination of each trip and the number of team members traveling. List all individuals/organizations with whom consortium or contractual arrangements have been made. List all consortium personnel, percent effort and roles on the project.

## **Online Submission through Proposal Central**

CARRA uses an electronic grant submission process. All applicants must submit their full application packages through Proposal Central's online grants management system. Paper applications will not be accepted.

- All applicants must register as users on Proposal Central <u>here</u>.
- Click <u>here</u> for Proposal Central's guide on how to set up an account.
- Click here for Proposal Central's Frequently Asked Questions (FAQ's).
- Still need help with Proposal Central? Reach out to <u>Proposal Central's Support Desk</u>.
- Enable other users to access this proposal in Proposal Central
  - This section allows the PI to give other users access to the grant application.
    Signatories will need at least Edit access on this screen if electronic signatures are required for submission.
- Include institution and contacts
  - Proposal Central will automatically populate the institution's information. Please ensure that the institution's information is correct.
  - Enter the email address for institution contacts:
    - Signing Official
    - Financial Officer
    - Technology Transfer Officer

#### Attachments

- NIH Biosketch for PI, co-PIs and key members
- Proposed external application (PDF)
- Letters of Support
  - No more than 2 to support the planning grant application
- References

## **Evaluation of Proposals**

The NIH 9-point review system will be utilized, and all proposals will be reviewed by experts and one patient/parent reviewer.

Scientific Review Committee Grant Scoring Criteria

- Scored from 1-9
  - $\circ$  1 (Exceptional) = Exceptionally strong with essentially no weaknesses
  - 2 (Outstanding ) = Extremely strong with negligible weaknesses
  - 3 (Excellent) = Very strong with only some minor weaknesses

- 4 (Very good) = Strong but with numerous minor weaknesses
- 5 (Good) = Strong but with at least one moderate weaknesses
- 6 (Satisfactory) = Some strengths but also some moderate weaknesses
- 7 (Fair) = Some strengths but with a least one major weakness
- 8 (Marginal) = A few strengths and a few major weaknesses
- 9 (Poor) = Very few strengths and numerous major weaknesses

#### **Contact Information:**

Program or Administrative Questions:

Emily Klein Senior Manager, Grants & Awards grants@carragroup.org

Technical Questions:

proposalCENTRAL pcsupport@altum.com 800-875-2562