CARRA
Childhood Arthritis and Rheumatology Research Alliance

**CARRA-Arthritis Foundation Investigation of Representativeness in the CARRA Registry – Planning Grant**

**Grant Project Period Length:** 12 months
**Grant Funding Amount:** $ 75,000
**Grant Availability:** up to 1 award
**Application Deadline:** October 1, 2024
**Project Period:** December 31, 2024 – December 30, 2025

CARRA's mission is to conduct collaborative research to prevent, treat, and cure pediatric rheumatic diseases. CARRA was founded on principles of inclusivity and collaboration. CARRA remains committed to diversity and inclusivity in the CARRA Registry so we can ensure all communities are benefiting from the scientific advances from the Registry.

**Program Description**
This CARRA-Arthritis Foundation planning grant mechanism seeks innovative proposals to support the assessment of the representativeness of the CARRA Registry by comparing enrollment at CARRA Registry sites with broader populations. These broader populations could include Registry site cohorts that include non-registry participants, cohorts from sources such as large administrative databases including insurance claims, or other cohorts available to Principal Investigator(s).

The primary objectives of the CARRA Registry are to collect essential data from persons with childhood-onset rheumatic diseases prospectively, evaluate the safety of therapeutic agents, evaluate the outcomes associated with therapeutic agents, document drug treatment patterns and clinical course of patients, and evaluate factors other than drug treatments that are associated with clinical outcomes of interest including patient-reported outcomes (PRO).

The CARRA Registry is an observational Registry, a convenience sample, and not a population-based Registry, and by definition is not designed to define the epidemiology of each disease. However, it is critically important to better understand the representativeness of the currently enrolled Registry cohort to gain insight into the generalizability of research findings and to strive for diversity and inclusivity. This planning RFA seeks innovative methodology to begin to accomplish these goals.

The purpose of this funding is to develop a feasible and clear plan to assess representativeness in the CARRA Registry. Pilot data are welcome but not required. Furthermore, all applications must clearly detail how the study plan will lead to and support a larger grant application (e.g. such as PCORI, NIH, CARRA-AF grant, or other public funding, or private foundation). The funding source and grant mechanism must be named in the application.

All applications must focus on areas identified in the 2023-2025 CARRA-Arthritis Foundation Inflammatory Arthritis Research Agenda.

**Eligibility**
- The application must include JIA, though other diseases within the CARRA Registry can also be studied.
- The project PI must be a CARRA member in good standing (up to date on membership dues and member profile is current and accurate).

- The PI must have served as a principal investigator or co-investigator (CO-I) on a research study that has successfully used Registry data, completed the research, and published results. Obtaining approved data alone does not meet this requirement.
- In addition to the experience detailed above, the following current CARRA members are eligible to serve as Principal Investigators on this grant:
  - MD or equivalent degree Pediatric Rheumatologists
  - PhD scientists
  - Fellows, as long as their co-PI meets the eligibility criteria.

- At least one patient/caregiver must be represented on the study team. If a patient/caregiver cannot be identified, please get in touch with Vincent Del Gaizo (vdelgaizo@carragroup.org) who can assist with identification.
- While not eligible to serve as PIs, the following may serve as team members: Medical and graduate students, research professional members who are regulatory or data coordinators, business and industry associate members, and nonprofit/government associate members.
- CARRA Board members or those in Executive Leadership positions may not serve as study leadership.
- Previous and current CARRA awardees who wish to submit new grant applications must be up to date on all award deliverables.
- No data and sample request will be required prior to submission for this RFA.
- Applications utilizing existing data (EHR or claims data) with minimal data cleaning/manipulation will be accepted for this opportunity.

**Important Information**

Application deadline: October 1, 2024

- Applicants will be notified of funding decisions before December 30, 2024
- Funds will be provided to the awardee's institution and used by the principal investigator according to the project budget. For projects requesting budget support to cover Registry and Biorepository costs, CARRA will hold the requested funds and pay them to the appropriate vendor.
- If the PI is unable to complete the project, any unexpended balance must be returned to CARRA.
- Awardees are expected to submit an abstract and attend the CARRA Annual Meeting(s) until the project is complete/results have been presented.
  - Awardees must submit a final progress report by 45 days after the project period's end date.
    - A late submission may impact an applicant's eligibility for future CARRA grants.
    - Timely provision of progress reports is required to be eligible for future CARRA grants and data/sample requests.
  - All awardees must share study progress once a quarter to the Registry and Biobank Operations Committee (RBOC) during their regularly scheduled teleconferences (Thursdays 4-5PM EST)
  - All awardees of funding received through CARRA's Intramural Research must abide by the procedures outlined in the current CARRA Authorship, Publication, and Presentation Guidelines when presenting/publishing findings from their projects.
    - This includes submitting all abstracts and manuscripts to the CARRA Publications Committee for approval prior to submission and 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." includes submitting all abstracts and manuscripts to the CARRA Publications Committee for approval prior to submission and 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."

- If awarded these grant funds, the PI will be paired with Registry leadership to offer guidance and ensure the project goes smoothly.
- Applications will be peer-reviewed by the Registry and Biobank Operations Committee, a patient/caregiver, and a member of the DEIA workgroup.
- Scoring and review information can be found in the CARRA Research Portal and as a pdf on the CARRA ProposalCentral site.

**Online Submission**

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 here.
- Click here for Proposal Central's guide on how to set up an account.
- Click here for Proposal Central's Frequently Asked Questions (FAQ's).

**Required Application Information**

**Download Template and Instructions**

Download all the attachments you need to have in your submission in Proposal Central.
Text should be Arial, Times New Roman, Palantino Linotype, Courier New, Georgia, or Helvetica, 11-point font or higher. Margins should not be less than 0.5" on standard letter paper (8 ½" x 11").

**Enable Other Users to Access this Proposal**

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.

**Institution & Contacts**

- The institution information will be automatically populated by Proposal Central. Please ensure that the institution's information is correct.
- Enter the email address for institution contacts:
    - Signing Official
    - Financial Officer
    - Technology Transfer Officer

**Other Key Personnel**

Add information for Key Personnel participating in the project

**Abstract**

- Lay Summary: Please provide a general audience summary. Text only. No special characters or formatting. (up to 900 characters)
- Project Summary: Please provide a summary for a technical audience. Text only. No special characters or formatting. (up to 1800 characters)

**Project Aims**

- Identify two to five aims that outline the project's central objectives within the full funding period. Each aim should also be referenced and fully described within the main Research Proposal document. When inputting the short description of the aim in section 8, please start with the aim number (e.g., 'Aim 1:

Description of aim'). Enter a short description of your Specific Aim and Associated Milestone. Explain how this aim relates to CARRA's mission and vision.

**Milestones and Deliverables**

- Provide a brief description of at least one milestone (timepoint that delineates a key phase in a project schedule) and at least one deliverable (final outputs) per aim. Deliverables may include but are not limited to, the development of new models, knowledge generation, publications and other knowledge mobilization activities, technical advancements, provisional patents filed etc.
- Input a brief description (one or two sentences) for each milestone/deliverable. Click the + icon to add rows for each additional milestone/deliverable.

**Budget Period Detail**

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

- All Principal Investigators (PI) are required to dedicate effort to their projects, and this effort must be noted on the budget table. A letter of support from the division chief of the applicant 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 will be limited to a base-salary cap of $200,000 but can include payment of local fringe rates (in addition to salary cap).
- Total salary support for the Principal Investigator(s) must not exceed 60% of total project costs.
- Reasonable poster printing, publication, and travel expenses are permitted.
- Other expenses should be discussed with CARRA personnel prior to application submission.
- CARRA will allow up to 8% F&A (indirect) costs, which must be incorporated into the project budget. If indirect costs are requested, total costs for this project must not exceed $75,000

**Budget Summary & Justification**

- Present items in the same order as they are in the budget. Explain how the cost of items was arithmetically determined. Provide all consultants' names and organizational affiliations, the services they will perform, the expected compensation rate, travel, per diem, and other related costs. Provide the purpose and destination of each trip and the number of travelling. List all individuals/organizations with whom consortium or contractual arrangements have been made. List all consortium personnel, percent effort and roles on the project.
- Note: Please be sure to research, accurately reflect, and explain data extraction costs (if proposed).

**Organization Assurances**

- Applicants are expected to provide an IRB approval letter, a copy of the IRB application, or an exemption letter.

**Required Attachments**

**NIH Biosketch**

In this section, the applicant can upload documents for the application. NIH-formatted Biosketches for all Principal Investigator(s), Co-Principal Investigator(s), and all Co-Investigator(s) (limit 5 pages per biosketch; please combine all biosketches into one PDF with the PI(s) biosketch listed first). Applicants should highlight any past CARRA Registry publications in their biosketch.

**Research Plan**

Formatting guidelines: Use Arial 11pt OR Times New Roman 12pt font. The page limit is eight pages, single-spaced. Margins should be 0.5" on all sides. Organize the Research Plan in the specified order using the instructions provided below. Start each section with the appropriate heading.

Sections include:
Background, Impact and Significance, Methods/Activities, Analysis and Statistical Plan Environment, Dissemination & Data Sharing, Sustainability Plan

**References & Recommendations**
Please provide information on references used in the application.

**Contact Information**

Program or Administrative Questions:
Emily Klein, Senior Manager, Grants & Awards, CARRA
grants@carragroup.org

Technical Questions:
ProposalCENTRAL
pcsupport@altum.com, 800-875-2562

**Review and Review Criteria Background – provided only as reference/pdf. on Proposal Central and Research Portal. It will not be a part of the application pdf.**

**Grant Application Review Criteria**

Unlike other CARRA grants, these applications will be peer-reviewed by the Registry and Biobank Operations Committee, a patient/caregiver, and a member of the DEIA workgroup.

CARRA has procedures for assessing the technical and scientific merit of applications to provide for an objective review and to assist you in understanding the standards against which your application will be reviewed. CARRA has indicators for each review criterion to assist you in presenting pertinent information related to that. Generally, at least 2 scientific reviewers and one patient/caregiver reviewer will assess every application that passes the initial administrative review. Below are the criteria that reviewers use to assess applications.


## Scientific Review Committee Grant Scoring Criteria

| Score | Descriptor | Additional Guidance on Strengths/Weaknesses |
|---|---|---|
| 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 weakness |
| 6 | Satisfactory | Some strengths but also some moderate weaknesses |
| 7 | Fair | Some strengths but with at least one major weakness |
| 8 | Marginal | A few strengths and a few major weaknesses |
| 9 | Poor | Very few strengths and numerous major weaknesses |

**Review Criteria**

1. Overall Impact of this proposal. This score should reflect your assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following scored criteria, and additional review criteria. An application does not need to be strong in all categories to be judged likely to have major scientific impact. Comments should be provided that explain scores of 8 or 9.
2. Provide critique of the Experimental Methods, Design and Scientific Merit of the research project as detailed in the Research Proposal. Is the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Have the investigators included plans to address weaknesses in the rigor of prior research that serves as the key support for the proposed project? Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? Are potential problems, alternative strategies, and benchmarks for success presented?
3. Are the PI(s), collaborators, and other researchers well suited to the project? If Early-Stage Investigators or those in the early stages of independent careers, do they have appropriate experience and training? If

established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance, and organizational structure appropriate for the project?

4. Does the proposal show relevance to rheumatology, specifically arthritis or other rheumatic diseases?
5. How well does this proposal meet the goals of the RFA?
6. Likelihood this research will lead to additional funding or operational success within CARRA. This criterion is not score-driving.
7. Budget Justification: This criterion is administrative and not score-driving. Please provide specific recommendations about the budget should this project be funded or any specific concerns that you may have.
8. Feasibility of performing the proposed research within the allotted time frame. This criterion is not score-driving.
9. Should this applicant be assigned a mentor by the Scientific Review Committee?

**Strengths and Weaknesses of the Proposal**

1. Please provide comments regarding any strengths of this proposal
2. Please provide comments regarding any weaknesses in this proposal. If you have identified any major weaknesses, please suggest how to aid the proposal

**Caregiver Reviews**

Caregiver reviewers use the same scoring as the scientific reviewers and review the aspects of the grant applications as outlined below:

Your response represents a global impression of the application and need not reflect the average of all the categories.

Feasibility

Are there possible ethical issues for patient families that would choose to participate in this study? Is there a plan for families to access/receive study results? Will patient families be overly burdened by participating? As you evaluate, consider whether patient families were consulted in the development of the study and if there is patient family oversight along the entire study life cycle. Will patient families be willing to enroll in this study? What barriers or concerns might prevent family participation? Will patient families understand the purpose of the study? Is there consideration for health literacy for all communications to patient families? As you evaluate, consider whether patient families are on the study team and if they will help draft study materials. Enter "N/A" if the study will not be enrolling patients.

Relevance

Does the application address an important priority for patient families? As you evaluate, consider whether patient families were involved in selecting the topic or if the topic is based on an issue widely known to be of importance to patient families. Will knowledge gained from the proposed study provide important information to patient families in managing their care or making treatment decisions? Are outcome measures appropriate/important to patient families? Will patient families be involved in helping to select measures?

Patient Centeredness Strengths

Include “patient centeredness” in your strengths and weaknesses comments. Was the study designed with patients and families? Were outcome measures selected with patient and caregiver input? Are patients and families on the study team? Is there a plan for patients and families to access/receive study results?

Patient Centeredness Weaknesses:
Include “patient centeredness” in your strengths and weaknesses comments. Was the study designed with patients and families? Were outcome measures selected with patient and caregiver input? Are patients and families on the study team? Is there a plan for patients and families to access/receive study results?