CARRA-Arthritis Foundation Large Grant

Grant Project Period Length: 2 years
Grant Funding Amount: $100,000
Grant Availability: up to 2 awards (1 specifically focusing on JIA and 1 focusing on other disease areas)
Application Deadline: March 15, 2024
Estimated Project Period: July 1, 2024 – June 30, 2026

CARRA's mission is to conduct collaborative research to prevent, treat, and cure pediatric rheumatic diseases.

This opportunity is available to support research projects in development.
The research project can be a pilot, continuation of ongoing research, or other projects that move forward clinical or translational research that furthers the CARRA mission under the 2023-2025 Strategic Plan and 2023-2025 Research Agenda.

Up to 2 grants will be awarded. At least one of the awards must focus on juvenile arthritis and areas identified in the 2023-2025 CARRA-Arthritis Foundation Inflammatory Arthritis Research Agenda. Special consideration will be given to applications addressing the specific topics listed below, which were considered among patients, caregivers and providers to be of critical importance:

- Precision medicine
    - Identifying diagnostic, prognostic, and predictive biomarkers
    - Uncovering factors that affect an individual's experience with starting and/or stopping medications
    - Identifying genetic, environmental, and/or lifestyle factors that impact overall safety and long-term medication use for individuals with juvenile inflammatory arthritis
- Long-term health outcomes
    - PROs, impact on health-related quality of life, health disparities, and other related issues
- Treatment-related issues
    - Safety and the impact of specific medications

Preference will be given to research that is collaborative in nature and/or will further develop the CARRA network of members.

New or early-career investigators are encouraged to apply.

Eligibility

- The project PI must be a CARRA member in good standing (up to date on membership dues and has ensured their membership information (location, contact information, and membership status) is current and accurate.
- The following current CARRA members are eligible to serve as Principal Investigators on CARRA-Arthritis Foundation Large Grants:
    - Pediatric Rheumatologists
    - Other Physicians and Health Care Professionals*
    - Research professionals (research scientists, investigators, and coordinators) *

    - Fellows*
    - Residents*
    - Patient/Caregiver Associate Members*
        - **Must have a Pediatric Rheumatologist as a Co-I on the grant*
    - **Not eligible:** Medical and graduate students, Research professional members who are regulatory or data coordinators, Business and Industry Associate members, Nonprofit/Government Associate members, members of CARRA's Board of Directors. Emeritus members are not permitted to serve as PIs but can serve as key personnel.
- Awardees from previous grant cycles who wish to submit grant applications for the upcoming deadline must have all active CARRA-Arthritis Foundation grant projects completed, with no active No Cost Extensions (NCEs), and must have submitted a final progress report.
- Current CARRA grant awardees are not eligible to apply

Online Submission

CARRA uses an electronic grant submission process. All applicants must submit their full application packages through Proposal Central 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).
- Still need help with Proposal Central? Reach out to Proposal Central's Support Desk.

CARRA-Arthritis Foundation Large Grant Application Required Information:

Title Page

- Provide the Title of the project
- CARRA Registry & Data Use Assurances (if necessary)
  Grant applicants who intend to utilize the CARRA Registry or CARRA-related data and/or samples must receive approval from the CARRA Data, Sample, and Publications Committee (DSPC) prior to submitting their grant applications. Data and sample requests take approximately 4-6 weeks for review and approval. If you would like to know more about who can access CARRA data and biosamples, conditions of use, and the review process, please review our data and sample share policy on the CARRA website (https://carragroup.org/membership/policies/).

  For more information on requesting CARRA data and/or samples and to access the request form, please visit the Data and Sample Request page on the CARRA wiki. (https://wiki.carragroup.org/display/DSSC/CARRA+Data+and+Sample+Requests).

  In 2024, CARRA will only be accepting proposals that utilize the current CRFs and standard biosample collection kits. No proposals requesting supplemental data collection and/or via CARRA sites will be accepted.

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.

Applicant/PI:

- The applicant information will be automatically populated by Proposal Central. Please ensure that all information is accurate and updated.
- Enter % effort proposed for PI on this project.
- Indicate whether the PI is a new or early investigator

Institution & Contacts

- The institution information will be automatically populated by PC. 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

References & Recommendations

Please provide information on references used in the application

Abstract

- Lay Summary: Please provide a general audience lay summary below. Text only. No special characters or formatting. (up to 900 characters)
- Project Summary: Please provide a project summary for a technical audience. Text only. No special characters or formatting. (up to 1800 characters)
- Scientific Discovery Continuum: see menu on PC
- Continuum Stage(s): see menu on PC
- Scientific Discovery Theme: see menu on PC
- Disease Area: see menu on PC
- Program Area: see menu on PC

Project Aims

- Identify two to five aims that outline the central objectives of the project 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 each year

- All Primary Investigators (PI) are required to dedicate effort to their projects, and this effort must be noted on the budget table. Requesting salary support is optional. 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).
- Reasonable poster printing, publication, and travel expenses are permitted.
- Other expenses should be discussed with CARRA personnel prior to application submission.
- Total salary support for the Principal Investigator(s) and all Co-Investigator(s) must not exceed 60% of total project costs.
- 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 $100,000.

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 the names and organizational affiliations of all consultants, the services they will perform, the expected rate of compensation, 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.

Organization Assurances

- Human Subjects
  Applicants are expected to provide an IRB approval letter, a copy of the IRB application, or an exemption letter.
    - Does the proposed project involve Human Subjects?
    - If Yes, Status of IRB Approval
    - Approved or Pending Date
    - If Exempt, Type
    - Human Subjects Assurance Number (OHRP)
    - Human Subjects Assurance Date
    - Upload IRB Approval or filing documents.
- Vertebrate Animals
    - Does the proposed project involve Vertebrate Animals?
    - If Yes, status of IACUC approval
    - Approved or Pending Date

        - Animal Welfare Assurance Number (OLAW)
        - AWAN Date
        - AAALAC Accreditation Date
        - USDA Inspection Date
        - Upload IACUC Approval or Copy of Filing
- Recombinant DNA
        - Does the Proposed project involve Recombinant DNA?
        - If Yes Status of Approval
        - Approved or Pending Date
        - Approved Agents
        - Approval Date
- Does the project require review for activities that have possible national security implications? If yes, explain. (up to 50 characters)
- Are hazardous materials used or produced in the project? If yes, explain. (up to 50 characters)
- Are genetically engineered organisms used or produced in the project? If yes, explain. (up to 50 characters)
- Are Historical sites affected by the project? If yes, explain. (up to 50 characters)
- Is human fetal tissue used in the project? If yes, explain. (up to 50 characters)

Research Plan

Formatting guidelines: Use Arial 11pt OR Times New Roman 12pt font. The page limit is 5 pages, single-spaced. Margins should be 0.5" on all sides. Organize the Research Plan in the specified order and using the instructions provided below. Start each section with the appropriate heading.

Background

Describe/Include the following:

- Establish current status of the field/significance of problem
- Reference and discuss work of experts in the field
- Indicate how project will advance knowledge in the field
- Discuss prior work, if applicable.

Impact and Significance

Describe the impact and wider implications of the project. Specifically:

- If this project leverages the CARRA network?
- How does this project positively impact the pediatric rheumatology scientific community?
- How will this project advance CARRA's Research Agenda?
- If this project advance health equity?

Methods/Activities

Describe/Include the following:

- Study population
- Study Design
- Sample size
- Study sites
- Study schedule
- Primary and secondary outcomes
- Thoroughly describe the project activities and feasibility

- Methods for solving the problem and possible pitfalls
- Timeline for the project activities

Analysis and Statistical Plan

Describe/Include the following:

- Qualitative and quantitative analysis plan for project
- Provide justification for sample size

Environment

Describe/Include the following:

- Scientific environment
- Institutional support
- Physical and other resources available to complete the project

Dissemination & Data Sharing:

- Present a plan for sharing results of project through a variety of mediums
- Describe how/when data sets will be shared with CARRA to be available for future research

Sustainability Plan

If applicable, present a plan for continuing project beyond period of award and future funding plans. Describe whether this project will be used to apply for future funding opportunities. If this is not applicable to your project, indicate with "N/A."

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.).

Letters of Support

- Required for budgets that include investigator salary/effort. A letter of support from the division chief of the applicant must be submitted documenting that the % effort is available and confirming the investigator salary. If the PI is the division chief, a letter from the Department Chairperson is required.
- Letters of support from collaborators, mentors and institutions are highly recommended.

PI Demographic Info.

The applicant should provide basic demographic information in this section:

- Gender
- Race
- Primary Race
- Ethnicity
- Citizenship

Required Signature Page

Here, the applicant and Institutional Signature Official can sign the application. The application must be signed before it can be submitted.

CARRA Staff is available to assist with the application process and to answer questions. Contact us by emailing grants@carragroup.org.

Important Information for Large Grant Submissions

- Application deadline for the CARRA-Arthritis Foundation Large Grant: March 15, 2024.
- Applicants will be notified of funding decisions in June 2024.
    - Funds will be provided to the awardee's institution to be used by the principal investigator according to the project budget. There will be several payments over the project period tied to reporting. Release of Year 2 funds may be contingent on IRB annual re-approval.
- For projects requesting budget support to cover Registry and Biorepository costs, requested funds will be held by CARRA and paid 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/final results have been presented.
- This funding mechanism is not intended for projects that are already eligible/appropriate for extramural funding.
- If the project is not completed within the project period, the award recipient may request 1 no-cost extension (NCE) for up to 12 months. Requests for NCEs must be made up to 90 days prior, but no less than 30 days prior to the project period end date. An interim progress report must be submitted with the NCE Request Form. Please use grants@carragroup.org to submit the no-cost extension request.
- Awardees must submit a year-1 progress report 30 days prior to the end of the first year of the project period to request the release of year 2 funds.
- Awardees must submit a final progress report no later than 45 days after the end date of the project period. 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-Arthritis Foundation grants.
- All awardees of CARRA-Arthritis Foundation funding 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."

Applicants who have questions or need additional information can contact grants@carragroup.org for assistance.

Review and Review Criteria Background

Grant Application Review Criteria

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 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. Are 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. Would you fund this grant if you were responsible for CARRA funding decisions?
10. 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 make a suggestion 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 parent 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 parent input? Are patients and families on the study team? Is there a plan for patients and families to access/receive study results?