

CARRA-Arthritis Foundation Health Equity Design (Planning) Grant

Grant Project Period: 1 year

Grant Funding Amount: \$100,000

Grant Availability: Up to 2 awards (1 focusing on JIA and 1 on any disease area)

Application Deadline: March 15, 2024

Estimated Project Period: July 1, 2024 – June 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, and we continue to promote our mission and vision with these core values. This CARRA-Arthritis Foundation grant mechanism was established to support design (planning) activities for researchers to develop research projects that address topics along the **health equity research spectrum**, including but not limited to:

- Research addressing treatment adherence, patient education, or self-management
- The identification and measurement of the root causes of health inequities in pediatric rheumatology;
- Strategies that improve engagement of diverse patient populations in CARRA;
- Research that aims to understand barriers and facilitators to the participation of specific minoritized/marginalized patient groups in CARRA Research
- Implementation science research designed to improve representation and participation of minoritized populations in the CARRA Registry, in PARTNERS, and in/or in workgroups
- Translational research that identifies how social determinants of health affect disease onset, severity, and outcomes; and/or
- Interventions designed to reduce or eliminate health disparities and/or address health inequities in pediatric rheumatology.

This grant provides support for the initial development and design (planning) of future health equity research projects. The research project can be a pilot, continuation of ongoing research, or activities that involve designing health equity projects that move forward clinical or translational research that furthers the CARRA mission under the 2023-2025 strategic plan (<https://carragroup.org/about/strategic-plan/>) and 2023-2025 [Research Agenda](#).

This program may support:

- establishment of the research team,
- development of tools for data management and research oversight
- development of a trial design or experimental research designs
- finalization of the protocol
- preparation of an operations/procedures manual
- pilot studies or collection of feasibility data for subsequent research projects

Renewal of applications are not allowed.

New or early-career investigators are encouraged to apply.

Up to 2 grants will be awarded. Priority will be given to projects that will design (plan) health equity research projects that focus on juvenile arthritis and reflect priority areas and knowledge gaps identified in the 2023-2025 CARRA -Arthritis Foundation Inflammatory Arthritis [Research Agenda](#).

Preference will be given to projects that seek to design (plan) research that is collaborative in nature and/or will further develop the CARRA network of members.

Special consideration will be given to applications seeking to design (plan) research projects 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

Eligibility

- The project PI must be a CARRA member in good standing (up to date on membership dues and 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 Health Equity 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, and 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 ProposalCentral 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 Health Equity Grant Application Required Information

Title Page

- Provide the Title of the project
- Please check one of the options below:
 - Research project
 - Design project

CARRA Registry & Data Use Assurances (if applicable)

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) via a data and sample request before submitting their grant applications. Applicants will be required to provide documentation of DSPC approval. The request must match the intended use outlined in the grant proposal. Failure to receive approval of the data and /or sample request before submission of the grant application will result in the administrative decline of the application.

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 accept proposals utilizing the current CRFs and standard biosample collection kits. No proposals requesting supplemental data collection will be accepted.

Enable Other Users to Access this Proposal

This section allows the PI to give other users access to the grant application. If electronic signatures are required for submission, signatories will need at least Edit access on this screen.

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 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 lay summary below. This should include a statement detailing 1) how the design (planning) process will lead to the development of a research project that addresses health equity in pediatric rheumatology and 2) the diversity of the research team in terms of the racial and ethnic composition of the team and/or DEI strategies the team will employ to increase diversity within the team. 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: menu to be provided in PC
- Disease Area: menu to be provided in PC
- Program Area: menu to be provided in 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, vision and strategic plan.

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.

- Use the dropdown box to select milestone/deliverable and then add the targeted start and completion date for each milestone/deliverable. 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) must dedicate effort to their projects, which 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 the 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. 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 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 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. (up to 8000 characters)

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

Impact and Significance

Describe the impact and wider implications of the proposed project. Specifically, discuss the following:

- How does this project address health equity in pediatric rheumatology?
- What is your approach to DEI practices/representation in the research team?
- How does this project leverage the CARRA network?
- How does this project positively impact the pediatric rheumatology scientific community?
- How will this project advance CARRA's mission?

Methods/Activities

Describe the activities to be undertaken. Please respond "N/A" to any that do not apply:

- establishment of the research team,
- development of tools for data management and research oversight
- development of a trial design or experimental research designs
- finalization of the protocol
- preparation of an operations/procedures manual
- pilot studies or collection of feasibility data for subsequent research projects

Environment

Describe/Include the following:

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

Sustainability Plan

Present a plan for applying for funding to support the planned research project:

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

- Letters of support are 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 investigator's 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 answer questions. Contact us by emailing grants@carragroup.org.

Important Information for Health Equity Grant Submissions

- Application deadline for the CARRA-Arthritis Foundation Health Equity Design (p lanning) Grant: March 15, 2024.
- Funds will be provided to the awardee's institution in two payments to be used by the principal investigator according to the project budget.
 - **Year 1** funding, as outlined in the budget justification, will be provided upfront.
- 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 cannot 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.

- 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 to 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."

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.

Criteria used by scientific reviewers



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 design (planning) activities 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? Are potential problems, alternative strategies, and benchmarks for success presented?
3. Does the design (plan) address an important problem or a critical barrier to progress in the field?
6. Does the proposal show relevance to rheumatology, specifically arthritis or other rheumatic diseases?
7. How well does this proposal meet the goals of the RFA?
8. Likelihood this research will lead to additional funding or operational success within CARRA. This criterion is not score-driving.
9. 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.
10. Feasibility to perform the proposed research within the allotted time frame. This criterion is not score-driving.
11. Would you fund this grant if you were responsible for CARRA funding decisions?
12. 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 categories' average.

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? Consider whether patient families were involved in selecting the topic or if the topic is based on an issue widely known to be important to patient families. Will knowledge gained from the 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/Weaknesses

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