

# <u>Instructions for CARRA-Arthritis Foundation Clinical Management of JIA</u>

# **Required Application Information**

# **Full Application**

Completed application packages, with all required attachments and supportive documentation must be submitted through Proposal Central by 5:00PM Eastern Time on February 28, 2025. We will not accept hard copies.

All application text should be Arial, Times New Roman, Palatino 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").

#### **Other Key Personnel**

Add emails 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 300 words)
- Project Summary: Please provide a summary for a technical audience. Text only. No special characters or formatting. (up to 600 words)

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

- LOIs are due in Proposal Central January 15, 2025, by 11:59PM ET
- No separate data and sample request is required when applying for a CARRA Grant in 2025.
- 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.
- 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.

#### **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.

# **Patient Impact**

 Patient Impact Statement: Describe how your CARRA-funded award will ultimately directly or indirectly impact patients (limit 350 words).

# **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, other knowledge mobilization activities, technical advancements, provisional patents filed, etc.
- Input a brief description (one or two sentences) for each milestone/deliverable.

#### **Budgeting**

#### **Budget Period Detail**

The budget must indicate how funds will be allocated during the project period.

- All Principal Investigators (PI) are required to dedicate effort to their projects, which
  must be noted on the budget table. A letter of support from the applicant's division
  chief 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).
- 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 staff before 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 the amount awarded per year by the grant.

#### **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 amount of time spent traveling. List all individuals/organizations
with whom consortium or contractual arrangements have been made. List all
consortium personnel, the percentage of effort, and the roles in 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.
- Vertebrate Animals

- Recombinant DNA
- Assurances Questions

# **Application 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 (if applicable).

## **Research Plan**

# Background

Describe/Include the following:

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

# Impact and Significance

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

- 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 Research Agenda?

#### Methods/Activities

Describe/Include the following:

- Study question
- 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 the 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 the results of the 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 the project beyond the award period and future funding plans. Describe in detail how this project will be used to apply for future funding opportunities.

#### **References & Recommendations**

Please provide information on references used in the application.

## **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's salary. If the PI is the division chief, a letter from the Department Chairperson is required.
- Up to 2 letters of support from collaborators, mentors, and institutions are highly recommended. They must reflect the Pl's ability to lead this effort and complete the study.

## PI Demographic Info.

The applicant should provide basic demographic information in this section:

- Gender
- Race
- Primary Race
- Ethnicity
- Citizenship

## **Required Signature Page**

The applicant and Institutional Official must sign the application before it can be submitted.

# **Additional Grant Requirements**

- 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 cannot complete the project, any unexpended balance must be returned to CARRA.
- Awardees are expected to submit an abstract after the 1<sup>st</sup> year of the awards and attend
  the CARRA Annual Meeting(s) until the project is complete/results have been presented.
- Awardees must submit a final progress report no later than 45 days after the project period's end date.
  - A late submission may impact an applicant's eligibility for future CARRA grants and data/sample requests.

- All awardees of funding received through CARRA's Intramural Research Program must abide by the procedures outlined in the current <u>CARRA Authorship</u>, <u>Publication</u>, <u>and</u> <u>Presentation Guidelines</u> 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."

# Online Submission through Proposal Central

- 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

# **Research Survey Request**

All requests to distribute research surveys through CARRA's network must be submitted online using the <u>Survey Request Form</u>. As of January 1, 2025, CARRA will not provide staff support to program and distribute surveys. However, CARRA members can request access to CARRA email lists to distribute their surveys. Investigators will be responsible for programming and distributing their research surveys upon request approval and contingent upon receiving required documentation (including IRB approval/waiver).

# **Evaluation of Proposals**

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

Scientific Review Committee Grant Scoring Criteria

- Scored from 1-9
  - 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
  - o 5 (Good) = Strong but with at least one moderate weaknesses
  - 6 (Satisfactory) = Some strengths but also some moderate weaknesses
  - o 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
<a href="mailto:grants@carragroup.org">grants@carragroup.org</a>

**Technical Questions:** 

proposalCENTRAL pcsupport@altum.com 800-875-2562