CARRA-Arthritis Foundation Data Analysis Support Grant Application Checklist and Instructions

This checklist is provided as support for applicants to have a successful grant submission to CARRA. Refer to the application instructions for more detailed information.

Formatting guidelines: Use of the templates provided on the CARRA website is REQUIRED. Use Arial 11pt OR Times New Roman 12pt font. Margins must not be less than 0.5” on all sides.

Contact the CARRA Research Administrator, with any questions about your application and/or submission process at grants@carragroup.org.

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Data Analysis Support Grants
The CARRA-Arthritis Foundation Data Analysis Support Grant funding opportunity is available to researchers to support qualitative or quantitative data analyses on existing CARRA datasets from collaborative research projects. Limited funds (up to $10,000 in total costs) may be requested to complete a fixed set of tasks that will result in timely publication of results. The investigator should have the necessary data in hand at the time of the application submission. It is anticipated that funds will be used for statistician effort/fee for service to support database cleaning and/or statistical analyses. Funds are not to be used for collecting additional data, investigator effort for drafting manuscripts, publication or printing costs. This grant mechanism is not for collecting data but rather for analyzing and publishing data that already exists. This mechanism ONLY supports the analysis of CARRA-related datasets. Any proposed work using datasets outside of CARRA are not eligible.

Eligibility
- The project PI must be a current CARRA Member who is in good standing and up to date on both membership dues and membership information (location, contact information, and membership status).
- MD applicants must be at a faculty level.
- Pediatric Rheumatologist Members, Sponsored Voting Members, Emeritus Members, Associate Physician Members, Associate Health Care Members, and Research Coordinator Members are eligible to submit proposals.
- Fellow Members, Trainee Members, members of the CARRA Executive Committee and Board of Director members are not eligible.
- Priority will be given to new and/or early investigators.

Page Limits

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Contact the CARRA Research Administrator, with any questions about your application and/or submission process at grants@carragroup.org.

Application Instructions
Log into the online submission system through the CARRA website. Complete the following sections of the online application:

Section 1: Applicant Information
- Provide current PI and institution information.
Section 2: Project Details
- Principal Investigator – Provide contact information for the PI
- Check the box indicating that you are the PI for this application
- Check all that apply:
  o First CARRA grant submission
  o Received prior funding – check all the sources that apply
  o Early Investigator (within 7 years of completion of rheumatology fellowship training and at the rank of Instructor or Assistant Professor (or equivalent at your institution) but no higher
- Project Details – Provide title, total budget requested
- Indicate if this application is a resubmission
- Primary Performance Site – list the applicant organization name and address
- Project/Performance Site Locations – list performance sites in addition to primary site that apply to this application

Section 3: Applicant Institution Information
- Payee Name – If this project is awarded, provide payee name of applicant institution (name to indicate on check for payment), address and any additional contact information required.
- Institutional Personnel – Institutional personnel are associated with the applicant’s institution. These personnel will not need to provide supporting documentation for the application.
  Provide contact information (name, email and phone number) for the following:
  • Grants/Sponsored Programs contact
  • Finance Contact
  • Immediate Supervisor

Section 4: Key Personnel
- List all Co-Investigators for this project – provide name, institution and project role
- List all Key Personnel for this project – provide name, institution and project role

Section 5: Additional Information
- Reviewer Conflicts – Check the Scientific Review Committee roster provided on the CARRA website for any conflicts of interest. List all conflicts and a brief description in the textbox provided.
- Select all that apply to this project:
  • JDM
  • JIA
  • PAIN
  • SLE
  • SVARD
    o If SVARD, specify disease
  • Basic Science Research
  • Clinical Trial
  • Translational Research
  • Utilization of CARRA Registry
  • Collaboration with more than one CARRA site

Section 6: Application Component – Summaries
Project Summary/Abstract (300 word max)
Enter the project summary/abstract in the textbox provided in the online application.

The project summary/abstract is a succinct and accurate description of the proposed work and should be able to stand on its own (separate from the application). This section should be informative to other persons working in the
same or related fields and understandable to a scientifically literate reader. Avoid both descriptions of past accomplishments and the use of first person. Please be concise.

State the application’s broad, long-term objectives and specific aims. Describe the research design and methods for achieving the stated goals. Be sure that the project summary reflects the key focus of the proposed project so that the application can be appropriately categorized. Do not include proprietary confidential information or trade secrets.

_Lay Summary (150 word max)_
Enter the lay summary in the textbox provided in the online application.

Describe the research project using plain language that can be understood by a general, lay audience. CARRA requests the release of the lay summary for use, at CARRA’s discretion, should the proposal be funded. All grants are reviewed by parent/patient representatives and information will be used on CARRA and Arthritis Foundation websites to communicate to the public. Do not include proprietary confidential information or trade secrets.

**Section 7: Application Component – Scientific Uploads**

Upload the following application components in this section.

_Resubmission Modification, if applicable (Limit 1 page)_

(Use of the template provided on the CARRA website is REQUIRED. Formatting guidelines: Use Arial 11pt OR Times New Roman 12pt font. Margins must not be less than 0.5” on all sides.)

This document should include:
- Specify significant changes made in response to major comments/criticisms from the scientific critiques.
- Explain how the application has been strengthened or modified (additions, deletions, revisions).

_Specific Aims (limit 1 page)_

(Use of the template provided on CARRA website is REQUIRED. Use Arial 11pt OR Times New Roman 12pt font on the template provided. Margins must not be less than 0.5” on all sides. Figure legends can use a smaller font size as long as it remains legible. Tables and figures count towards page limits.)

Relate the aims of the project to CARRA’s mission and vision. State concisely the goals of the proposed research and summarize the expected outcome(s) including the impact that the results of the proposed research will exert on the research field(s) involved as well as how it will impact CARRA. List succinctly the specific objectives of the research proposed, e.g. to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology.

_Research Plan (limit 3 pages)_

(Use of the template provided on CARRA website is REQUIRED. Use Arial 11pt OR Times New Roman 12pt font on the template provided. Margins must not be less than 0.5” on all sides. Figure legends can use a smaller font size as long as it remains legible. Tables and figures count towards page limits.)

Organize the Research Plan in the specified order and using the instructions provided below. Start each section with the appropriate heading.

1. **Background**
   - Briefly describe the study and what data have been collected. Provide more complete details of this in the methods/activities section below.
   - Indicate if you have the all data in hand that is needed to complete this project.
   - Note any collaborations and previous funding.
   - Briefly justify why funds are needed.
(2) Impact and Significance
- 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?

(3) Methods/Activities
- Study population
- Study design
- Sample size
- Study sites
- Primary and secondary outcomes
- Thoroughly describe the project activities and feasibility
- Methods for solving the problem and possible pitfalls
- Timeline for the project activities

(4) Analysis and Statistical Plan
- Describe qualitative and quantitative analysis plan for the project
- Provide justification for sample size

(5) Environment
- Include description of scientific environment, institutional support, physical and other resources available to complete the project

(6) Dissemination & Data Sharing Plan
- Present a plan for sharing 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

(7) Sustainability Plan
- Present a plan for continuing the project beyond the 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 the project, indicate so.

References Cited (no page limit)

(Use of the template provided on the CARRA website is REQUIRED. Formatting guidelines: Use Arial 11pt OR Times New Roman 12pt font. Margins must not be less than 0.5” on all sides.)

List all literature citations for the Research Plan. Citation references should be limited to relevant and current literature; be concise and select only those references cited in the Research Plan. Standard abbreviations are acceptable with two exceptions: full titles and full paging must be provided.

Each reference must list the:
- Authors in the same order as they appear on the paper
- Title
- Name of the book or journal
- Volume number
- Page numbers
- Year of publication
Section 8: Application Component – Budget Uploads
Upload the following application components in this section.

**Budget Table (limit 1 page)**
*(Use of the template provided on the CARRA website is REQUIRED.)*

Complete the table with project costs listed in the appropriate field. This is a total costs award. If indirects are requested, they must be inclusive of the maximum funding amount of $10,000. Indirects may not exceed 8% and costs must be incorporated into the project budget and not exceed the advertised award amount. Salary support is not allowed for PI(s) and Co-I(s), but can be used for analytical support and for other personnel essential to the project. Salary support will be limited to a base-salary cap of $200,000 but can include payment of local fringe rates (on top of the $200,000 salary cap).

**Budget Justification (no page limit)**
*(Use of the template provided on the CARRA website is REQUIRED.)*

Justify all categories:

- **Personnel** – List all personnel (PI should be listed first), including names, institutions, roles and functions on the project, percent of effort, salary requested and fringe. Funds are NOT to be used to provide PI or Co-I salary support, but can be used to support other personnel essential to the project. Effort must be specified for all personnel, even when cost-sharing.
- **Consulting Costs** – Whether or not costs are involved, provide the names and organizational affiliates of all consultants. Describe the services to be performed for all consultants. Include the expected rate of compensation, travel, per diem, and other related costs.
- **Equipment** – List each item of equipment with amount requested separately and justify each purchase. (Equipment is defined as an item of property that has an acquisition cost of $5,000 or more and an expected service life of more than one year.)
- **Supplies** – Itemize supplies in separate categories, such as glassware, chemicals, radioisotopes, etc. Computers are allowed if it is necessary for the conduct of research. After a project has been completed, computers purchased with CARRA-Arthritis Foundation funds may remain as property of the institution to be used for further CARRA-related research.
- **Travel** – Note: Travel costs are NOT allowed under this award mechanism.
- **Consortium Costs** – List all individuals/organizations with whom consortium or contractual arrangements have been made. List all project personnel, including names, percent effort and roles on the project even if no salary is requested. List all costs for each organization as part of this project and provide a justification for each.
- **Other Expenses** – Note: CARRA does NOT allow funding for poster, presentation or publication costs. Other expenses should be discussed with CARRA personnel prior to application submission. Itemize any other expenses by category and unit cost. These might include institutional review board (IRB) submission costs, patient participation incentives, site payments, donor fees, computer charges, rentals and leases, equipment maintenance and service contracts.

Section 9: Application Component – Additional Uploads
Upload the following application components in this section.

**Biographical Sketches (limit 5 pages per biosketch)**
Provide NIH-formatted general biosketches for PI(s) and all Co-I’s. Blank templates and complete instructions are available online at https://grants.nih.gov/grants/forms/biosketch.htm. Combine all biosketches into one PDF with the PI(s) biosketch first. List your name, eRA Commons user name, position title, and education training in the provided table. Include the following sections:
A. **Personal Statement**
Briefly describe why you are well-suited for your role(s) in this project. Relevant factors may include aspects of your training; your previous experimental work on this specific topic or related topics; your technical expertise; your collaborators or scientific environment; and/or your past performance in this or related fields (you may mention specific contributions to science that are not included in section C). You may cite up to 4 publications or research products that highlight your experience and qualifications for this project (for a list of research product examples, see NIH instructions). If you wish to explain impediments to your past productivity, you may include a description of factors such as family care responsibilities, illness, disability, and active duty military service. Indicate if you have published or created research projects under another name. Figures, tables, and graphics are not allowed.

B. **Positions and Honors**
List in chronological order the positions you’ve held that are relevant to this application, concluding with the present position. List any relevant professional achievements and honors. Include present membership on any Federal Government public advisory committee. Junior Faculty should include scholarships, traineeships, fellowships & development awards (if applicable). Clinicians should include information on clinical licensure and specialty board certifications (if applicable).

C. **Contribution to Science**
Briefly describe up to five of your most significant contributions to science. For each contribution: indicate the historical background that frames the scientific problem; the central finding(s); the influence of the finding(s) on the progress of science of the application of those finding(s) to health or technology; and your specific role in the described work. For each contribution, cite up to 4 papers accepted for publication or research products that are relevant to the contribution. Each contribution should be no longer than one half page including citations. These citations do not have to be authored by you. These contributions do not have to be related to this project. Figures, tables and graphics are not allowed. You may provide a URL to a full list of your published work (not required). This URL must be to a Federal Government website such as MyNCBI, My Bibliography.

D. **Research Support**
List both selected ongoing and completed research projects for the past 3 years (Federal or non-Federal support). Briefly indicate the overall goals of the project and your responsibilities. Do not include effort or direct costs. Research support highlights your accomplishments, and those of your colleagues.

**Letters of Support**
Letters of support from collaborators, mentors and institutions are highly recommended.

**Research Assurances**
Provide IRB approval letter for this project. If the IRB approval is pending, provide written confirmation that the IRB is in progress and will be approved by the project period start date. Funds awarded will be held until the approval letter is received. Awards will be relinquished if IRB approval is not received by 6 months after the project period start date.

**Appendix**
Do not use the Appendix to circumvent the page limits of the Research Strategy or any other section of the application for which a page limit applies. All information required for the peer review process must be contained within the application sections. Information that expands upon or complements information provided in any section of the application – even if it is not required for the review – in NOT allowed in the appendix unless it is listed in the allowed appendix materials below. Reviewers are not required to comment on appendix material in their reviews.

A summary sheet listing all of the items included in the Appendix is encouraged, but not required. When including a summary sheet, it should be the first page of the upload.
The only allowable appendix materials are:

- Blank data collection forms, blank survey forms, and blank questionnaire forms – or screenshots thereof
- Simple lists of interview questions
- Blank informed consent/assent forms
- Lists of additional key personnel or sites that do not fit in the space provided in the application sections

**NOTE:** In the blank forms and lists, do not include items such as: data, data compilations, lists of variables or acronyms, data analyses, publications, manuals, instructions, descriptions or drawings/figures/diagrams of data collection methods or machines/devices.

**Evaluation Process**

All CARRA-Arthritis Foundation grant applications undergo the same review criteria with the exception of the Publication Support grant mechanism. Applications will be administratively reviewed upon receipt. Applications that pass the administrative review round will be reviewed by the CARRA Scientific Review Committee (SRC), a representative from the Arthritis Foundation and parent/patient reviewers. After discussion with the SRC, the SRC Chair will further discuss/review applications with the CARRA Internally Funded Research Oversight Committee (IROC). The IROC makes the final decision regarding funding based on SRC recommendations, scientific merit, relevance to the CARRA mission, and the proposal budget.

**Awardee Expectations/Reporting Requirements**

- Awardees must sign and obtain an institutional signature and return the Award Acceptance Acknowledgement form to CARRA in order for project funds to be released.
- Awardees must supply their institution’s W-9 form in order for project funds to be released.
- All awardees of CARRA funding must abide by the procedures outlined in the CARRA Publications Policy when presenting/publishing findings from their projects, including acknowledgement of CARRA and the Arthritis Foundation. Refer to the current Publications Policy on the CARRA website for complete details.
- It is expected that awardees will complete analysis and submit a manuscript for publication based on the funded project within the project period, but no later than 6 months after the project end date.
- Awardees are expected to submit an abstract to CARRA and present their findings at the CARRA Annual Scientific Meeting(s) until funding is complete/final results are presented.
- Final Progress Reports are due no later than 45 days after the project period end date.
- If a project cannot be completed within the original project period, awardees are allowed to request a no-cost extension (NCE) for up to an additional 12 months of funding. NCE’s must be requested no more than 90 days prior, and no less than 30 days prior, to the project period end date. To submit the NCE request, complete the required request form and interim project report and submit to CARRA via the online submission system. Templates are available on the CARRA website.
- Awardees must provide a photo for CARRA and Arthritis Foundation for publication and communication purposes.