

Instructions for CARRA-Arthritis Foundation ABC Award

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, 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, 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 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

- Importance of the Proposed Biosample Collection:
 - Describe the significance of the proposed biosample collection (Up to 300 words).
 - Why should biosamples be collected from the study population?
 - How will this project advance the CARRA mission?
 - How will studying the proposed biosamples impact patients?
- The ABC Award is designed to allow the collection of biosamples in the CARRA network that will be used immediately for hypothesis-generating research or that will enable investigators to apply for non-CARRA funding to conduct ongoing research. It is important that the applicant provides evidence of feasibility-that the research team is able and qualified to conduct the proposed translational research.
 - Describe the future study that will use the collected biosamples (Up to 300 words):
 - Background, significance/innovation
 - Any supporting preliminary data
 - Research methods (including sample size and statistical plan)
 - Expected outcomes
 - Timeline- Include a proposed timeline for the recruitment and sample collection.
- Provide the number, type(s), and volume of samples that the research team would like to be reserved for your research project (Up to 300 words).
- Future Funding:
 - Describe how future research activities will be funded (Up to 300 words).
 - How will obtaining these biosamples impact the research team's ability to acquire funding from other sources?

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 PI'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 1st 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>, and <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
 - 5 (Good) = Strong but with at least one moderate weaknesses
 - 6 (Satisfactory) = Some strengths but also some moderate weaknesses
 - 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

This funding opportunity supports biosample collection within the CARRA network to advance CARRA translational research. The goal is to collect biosamples from patients enrolled in the CARRA Registry, to be used by CARRA investigators for future hypothesis-based research.

ABC grants should be **primarily** scored based on the importance and feasibility of the biosample collection. Review of the proposed future science project is secondary. Further, the proposed scientific project may be somewhat preliminary as it is being proposed for future research after the biosamples are obtained and will be funded by the investigator through a different mechanism (not the ABC grant).

Review the proposal and provide a score and comment on each section below.

Review Criteria:

1. Overall rating of the proposed biosample collection: Your response represents a global impression of the proposal and need not reflect the average of all the categories. Please provide additional explanation for scores of 8 or 9.

SCORE: COMMENTS:

- Significance, originality, and scientific merit of collecting the proposed biosamples from the proposed study population.
 SCORE: COMMENTS:
- Feasibility to collect biosample from the CARRA Registry patients within the allotted time frame.
 SCORE: COMMENTS:
- Likelihood that the collected biosamples will lead to new translational research projects, additional funding, or operational success within CARRA SCORE: COMMENTS:
- Feasibility that the study team has the experience and capabilities to perform the proposed future research project with the collected biosamples.
 SCORE: COMMENTS:
- 6. Likelihood that the study team has or will be able to obtain funding for the future research project that will be performed with the collected biosamples. SCORE: COMMENTS:
- How well does this proposal meet the goals of the RFA? SCORE: COMMENTS:
- Budget Justification SCORE: COMMENTS:

- 9. Would you fund this grant if you were responsible for CARRA funding decisions? Yes No
- 10. Should this applicant be assigned a mentor by the Scientific Review Committee? Yes No

Strengths and Weaknesses of the Proposal

Please provide comments regarding any strengths of this proposal:

Please provide comments regarding any weaknesses in this proposal. If you have identified any major weaknesses, please make a suggestion to aid the proposal:

Contact Information: <u>Program or Administrative Questions</u>:

Emily Klein Senior Manager, Grants & Awards grants@carragroup.org

Technical Questions:

proposalCENTRAL pcsupport@altum.com 800-875-2562

Appendix A

Biosample Collection Form

Please provide details about the samples that will be collected using the table below.

Disease/Cohort and Eligibility	# Patients	Sample Type	Kit Type (see kit types described below) or Tubes	Spin Requirements (e.g., spin/no spin)	Time points

CARRA Standard Kits

Type I Kit	Type II Kit
CARRA Study Sites that are <u>able</u> to centrifuge prior to shipping to the CARRA Central Biobank	CARRA Study Sites that are <u>unable</u> to centrifuge prior to shipping to the CARRA Central Biobank
P100 (8.5cc)	EDTA (6.0cc)
SST (3.5cc)	Tempus (3.0cc)
aCPT (8.0cc)	
Tempus (3.0cc)	