

2023 Rheumatoid Arthritis Research Request for Proposals (RFP)

I. RFP Overview

Participating Organization	The Arthritis Foundation (AF), Science Department
Expert Advisors	Medical and Scientific Advisory Committee (MSAC); MSAC RA Working Group
Funding Opportunity Title	Optimizing Response of Rheumatoid Arthritis (RA) to Therapeutic Agents: Request for Proposals on Treatment- focused RA Research
Announcement Type	New
Funding Opportunity Announcement Number	RFP-RA-2023
Funding Opportunity Purpose	This Request for Proposals (RFP) invites applications that seek to better understand and predict the varied responses patients have to RA medications, including projects that aim to characterize disease control, remission, flare, and non-response, as well as ideas for potential novel interventions that could improve treatment response and control disease. The long-term goal of this AF research program is to improve therapeutic outcomes for individuals living with RA. The funding for this initiative will be provided by the 2023 Arthritis Foundation's Science Budget. For more information on our work, please visit: www.arthritis.org/science
Posted Date	02.15.2023
Open Date (Earliest Submission Date)	02.15.2023
Letter of Intent Due Date	05.17.2023
Application Due Date	07.19.2023 All applications are due by 5:00 p.m., Eastern Time Zone.
Award Announcement	11.15.2023
Earliest Project Start Date	01.01.2024
Expiration Date	This RFP will expire after 'Application Due Date' above.
Informational Webinar Dates	03.16.2023 3-4 p.m. ET and 04.11.2023 12-1 p.m. ET Register: https://cvent.me/zdXA3

II. RFP Information

1. RFP Purpose and Objectives

This RFP invites research proposals of two types:

- A. **Pilot Research Award:** Projects aim to investigate a novel hypothesis with no preliminary data requirements. Budget of up to \$75,000 per year for 2 years (up to \$150,000 total per award), or
- B. **Large Research Award:** Projects require preliminary data. Budget of up to \$150,000 per year for 3 years (up to \$450,000 total per award).

Proposed budget can include up to 8% indirect expenses, if needed.

Research proposals should focus on understanding and improving treatment response for patients with RA. Research studies using clinical samples and/or clinical data are strongly encouraged. Animal studies are not allowed.

Proposed research may include, but is not limited to:

- Identifying determinants of treatment response and/or non-response to currently approved therapies;
- Development of predictive biomarkers for response, remission, flare, non-response, and de-escalation of currently approved therapies;
- Uncovering underlying mechanisms of disease flare and/or remission;
- Identifying novel therapeutic interventions; and
- Uncovering social determinants of health and their association with response and/or lack of response to treatment in RA patients.

For proposals including clinical studies, the incorporation into the design of assessment of patient-reported outcomes is highly encouraged. Awardees will become a part of a cohort of investigators that will regularly communicate with other investigators funded by AF as part of the RA Research Portfolio our Foundation supports.

For all proposals, the Arthritis Foundation strongly encourages the inclusion of patient advocate(s) who are meaningfully engaged in the research project. We define meaningful engagement as active and collaborative interaction between patient(s) and researchers across all stages of the research process from conception to results distribution, where research decision making is guided by patients' contributions as partners, recognizing their specific experiences, values, and expertise.

The long-term goal of this funding mechanism is to support research that would improve the lives of patients with RA.

2. Background

The Arthritis Foundation (AF) has previously supported ground-breaking research that led to the development of early biologics used in the treatment of RA. In 2021, the AF

Medical and Scientific Advisory Committee formed an [Expert Working Group](#) of academic and government RA experts to prioritize the unmet medical needs and potential research areas of interest for funding in RA research. Based on their recommendations, AF is releasing this RFP, which is open to investigators affiliated with US academic institutions and hospitals who are committed to improving the outcomes of the RA patient community through biomedical (translational, clinical) and/or health outcomes research.

3. Why Focus on Understanding and Improving Treatment Response in RA?

Patient responses to currently approved therapies vary widely and may change over a person's lifetime. The reasons for such variation in outcomes are not well understood but are most likely the result of a combination of factors. Recent advances in development of experimental tools and approaches applicable to the study of blood and tissue of RA patients, along with availability of clinical and demographic data linked to biologic data, provide an opportunity to gain novel insights. These insights have the potential to reveal the underlying causes of therapeutic response, non-response, remission, and flare, as well as shed light on novel drug targets.

III. Award Information & Eligibility Criteria

The Arthritis Foundation encourages applications from a diverse pool of investigators with respect to race, gender, sexual orientation, ethnicity, national origin, and disability. The Arthritis Foundation recognizes that a diverse and inclusive workforce is critical for ensuring that the most creative minds have the opportunity to contribute to realizing our research goals and to ensuring more equitable health outcomes for patients living with arthritis

Multiple awards are expected to be made, with project durations of 2-3 years, depending on the mechanism.

Proposals using animal studies are not eligible for this funding mechanism.

Eligible institutions include:

Higher Education Institutions, including:

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education
- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Non-domestic (non-U.S.) Entities (Foreign Institutions) and Non-domestic (non-U.S.) components of U.S. Organizations are not eligible to apply.

Eligibility Criteria for Applicants:

- All proposed research projects must be led by a Principal Investigator (PI) who holds a doctorate (e.g., Ph.D., M.D., or equivalent degree).
- Applicants who hold the rank of full Professor (or equivalent) are **excluded** from applying for these opportunities.

- *For Pilot Awards:* PIs must hold a full-time faculty/staff appointment up to and including the rank of Associate Professor (or equivalent), be a clinical fellow, or be an experienced postdoctoral fellow at an academic or other non-profit research institution within the United States. Applicants holding non-tenure track, full-time, independent faculty-level positions with titles such as Instructor or Assistant Research Professor are eligible to apply.
- *For Large Awards:* PIs must hold a full-time faculty/staff appointment up to and including the rank of Professor (or equivalent) or above. Applicants holding non-tenure track, full-time, independent faculty-level positions with titles such as Instructor or Assistant Research Professor are eligible to apply. Postdoctoral fellows and clinical fellows *are not* eligible to apply for this award type.
- For purposes of this RFP, an experienced postdoctoral fellow is an individual who holds a doctoral degree (Ph.D., M.D., or an equivalent degree), has completed a minimum of two years of full-time postdoctoral research at the time of application, and who is engaged in a temporary period of mentored research for the purpose of acquiring the professional skills needed to pursue a career path of their choosing. Postdoctoral fellows must have at minimum 90% protected research time.
- For the purposes of this RFP, clinical fellows are individuals who are in, or have recently completed, subspecialty fellowship training and are working at an eligible institution (see above criteria). The end date of your fellowship must fall between June 30, 2023 – July 1, 2025, and you must have at minimum 75% protected research time.
- If previously funded by the Arthritis Foundation, applicant must be up to date on all reporting requirements.
- Individuals currently holding the role of PI on an active RA Research Program award are not eligible to apply.
- Multiple applications will be accepted from a single institution, provided that each application has a different applicant PI and represents a distinct hypothesis.

Arthritis Foundation funds are primarily obtained from individual donations. The amount available for scientific awards each year is determined by the success of the fundraising efforts. Funds for awards are also derived from partnerships established by the Arthritis Foundation, with other nonprofit and private sector organizations that share common interests. Funds for subsequent years of a project, after the first, even if initially approved, are contingent upon adequate scientific progress and available funds, and are therefore subject to change.

IV. General Proposal Application and Submission Information

1. Submission

All LOIs and applications should be submitted using the Arthritis Foundation online portal for this program, available at <https://proposalcentral.com/>. All applications should be submitted by 11:59 PM Eastern time on the deadline date. Please expect that any

application submitted after deadline, incomplete, or failing to otherwise adhere to instructions will be administratively declined.

2. Letter of Intent (LOI)

Submit LOIs through Proposal Central at <https://proposalcentral.com/> by 11:59 p.m. ET on May 17, 2023. The LOI, 2 pages maximum in length, should describe the fit of your idea to the overarching goals of this program, include a hypothesis and specific aims, and summarize at a high level the impact you expect from the work.

LOIs will be evaluated administratively to confirm each applicant's eligibility for subsequent application submission. The information provided will allow AF Staff to estimate the potential review workload and plan the review.

3. Formatting and Page Limits

For both the LOI and the proposal submission, please follow the format requirements. Margins should be greater than or equal to 1/2" on all sides. Font size should be no less than 11 points. Applications must be written in English and formatted such that, if printed, would print to 8.5" x 11" paper. PDF file formats are preferred. Editing permissions must not be restricted and files must not be password protected.

Proposals need to adhere to a strict limit of:

- 5 pages single space for the pilot proposals
- 10 pages single space for the large grant proposals

The page limits do not include the additional biosketches, references, letters of support, and table of contents that will also be a part of all proposals.

4. Instructions for Full Application

4.1 Title page: Enter project title. Select award type (Pilot or Large Grant).

4.2 Download Templates & Instructions: Download RFP

4.3 Enable Other Users to Access this Proposal: Allow others (e.g., institutional administrators or collaborators) to view, edit, or submit your proposal. Electronic signatures are required to submit the application for submission. The Signing Official from the applicant's institution must be provided at least 'Edit' access on this screen to be able to sign. Please review the Signature Page to confirm the signature roles required and add as appropriate on this page.

PLEASE MAKE SURE TO GRANT ACCESS AHEAD OF TIME TO YOUR INSTITUTION'S SIGNING OFFICIAL TO AVOID ANY LAST-MINUTE ISSUES WITH SIGNING AND SUBMITTING YOUR APPLICATION.

4.4 Applicant/PI: Key information about the applicant PI.

4.5 Institution & Contacts: Key information about the PI's institution, including name and email address of the financial officer and the signing official who, in addition to the PI, will be contacted if the award is selected for funding. If your institution has a ROR (Research Organization Registry ID), please include.

- 4.6 Other Key Personnel:** List and provide contact information for key persons. Include everyone except the applicant who will contribute to the scientific development or execution of the project in a substantive, measurable way whether they receive salaries or compensation under the grant. Applicants who are postdoctoral or clinical fellows must name an individual who will serve as their mentor for the project. Mentors must hold a full time, faculty position at the rank of Assistant Professor (or equivalent) or higher. They need not be at the same institution as the applicant but should have expertise in the subject matter proposed.
- 4.7 Abstracts:** Provide a general audience abstract (non-technical) and a technical abstract (2,000 characters, including spaces, maximum each). Please note: the general audience abstract will become public if the award is selected for funding, therefore, it should not contain any proprietary information.
- 4.8 Budget Period Detail:** Enter budget detail for each 12-month award period requested. Up to 8% of the total budget may be dedicated to indirect costs (F&A). Fringe benefits for personnel salaries are allowable. Include any costs associated with sharing of resource outputs. The total cost of salary and fringe support must not exceed 75% of total project costs. Requests for salary and fringe support beyond 75% may be considered but require a letter of justification for why this is necessary for the goals of the project to be achieved.
- 4.9 Budget Summary & Justification:** A summary of the budget detail will be shown in this step. In addition, provide a detailed explanation for each budget category for the evaluation of the major portions of the budget that are being requested. If more space is required than is provided in the Proposal Central forms (2,000 characters), applicants may upload the budget justification in document form in step #14.
- 4.10 Other Support:** Please list all current and pending support for the Applicant and Co-Investigators. Any overlap of current or pending support with the Arthritis Foundation proposal must be described and explained. Current and pending support can be added to your (and other Key Personnel's) Professional Profile on Proposal Central by clicking on the 'Professional Profile' tab and going to Step #10: Other Support. To add your entries, please click on the "+" link and all entries previously saved in your Professional Profile will show. Please select the applicable support and save. For other Key Personnel, if they have granted you at least 'View' access to their profile, you can select Other Support from their profile as well. If they have not provided you 'View' access, upload a list of their current and pending support and any overlap in a separate document in step #14 of the application.
- 4.11 Data & Resource Sharing Plan:** While not strictly required, data and resource sharing are an expected outcome from grants funded by the Arthritis Foundation. Provide requested information as to how the data and other resources generated as part of the research project will be shared.

- 4.12 Organization Assurances:** IRB approvals, if applicable.
- 4.13 PI Demographics:** Please enter your ORCID ID and other requested demographic information. If you do not have an ORCID ID, you can register for one here: <https://orcid.org/register>. Please note that requested demographic information will NOT be shared with reviewers or used by the Arthritis Foundation in any way during the selection process. The Arthritis Foundation collects such data to better understand the demographic make-up of its applicant and awardee pools and detect and address any inequities identified.
- 4.14 Proposal & Supporting Documents:** Upload the following:
1. Research Proposal: Applicants are encouraged to use the suggested layout below
 - *Project Summary*: A paragraph that emphasizes the key attributes of the proposed program at the start of the proposal.
 - *Scientific Background and Research Plan*: This section summarizes the overall importance of the proposed work, including the problem statement, hypothesis and when available, the preliminary results, plus a list of the Specific Aims, Proposed Approach and Specific Methodology, including a Statistical Plan, a detailed study timeline, Alternative Hypotheses & Pitfalls, and Rationale and Fit with RFP Purpose & Objectives.
 - *Description of Key Personnel*: Proposed PI, and proposed team governance structure, how patient advocate(s) will be incorporated into research team.
 - *Additional Information*: Any additional information relevant to the Review Criteria listed above.
 2. NIH Biosketches: For Applicant/PI and relevant Key Personnel (Co-Investigator, Collaborator, and Mentor roles only).
 3. Current and Pending Support: For the Applicant and any Co-Investigators only. Upload here ONLY when this information cannot be entered in the Other Support section of the application.
 4. Budget Justification: 5 pages maximum. Only provide if more space is needed than what is provided in the Budget Summary & Justification section of the application.
 5. Letter from Applicant's Division Chief: Documents that % effort is available and confirming Applicant's salary.
 6. Letters of Support (optional).
- 4.15 Validate:** Check for any missing information.
- 4.16 E-Signature: Before submitting the application**, an electronic signature is required from both the Applicant/PI and a Signing Official from the applicant's institution. Type your name in the text box and click the green 'Sign' button. A date and time stamp will appear next to the button indicating that the electronic signature was successful. To give the Signing official access to sign this application, enter their information in Step #3:

“Enable other users to access this proposal” and grant them at least “Edit” access.

- 4.17 Submit:** No proposals will be able to be submitted past their deadline. Technical support for the on-line application system is not available after 5:00 p.m. Eastern Time or on weekends.

V. Selection Process and Award Management

1. Review and Selection Process

Applications will be evaluated for scientific merit by an expert Scientific Review Group, convened by the Arthritis Foundation, and using the below stated review criteria. As part of the scientific peer review, all applications will receive a written critique in Proposal Central. Only those applications deemed to have the highest scientific and technical merit will be discussed and assigned an overall impact score. A final discussion of the review committee may be required to recommend a list of the final applicants to be considered for award. The following factors will be considered in making final AF funding decisions:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Relevance of the proposed project to program priorities and strategic importance for the Arthritis Foundation and patients with RA.
- Availability of funds.

A formal email notification will be provided to the applicant's organization for successful applications. An award notification is not an authorization to begin performance. Any costs incurred before receipt of the notice of award are at the recipient's risk.

2. Research Proposal Evaluation Factors

A. Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on optimizing treatment response for RA patients, in consideration of the review criteria below.

B. Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of the scientific merit and strategic importance of each proposal. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not original may be essential to advance the RA field. The list of evaluation factors is presented below.

- **Significance**
Does the proposal address an important problem or a critical barrier to optimizing treatment response in RA? How will successful completion of the project's aims improve treatment outcomes for RA patients?
- **Originality**
Does the proposed research project challenge and seek to shift current paradigms by utilizing novel concepts, approaches, or methodologies? Does the

design/research plan include original elements, as appropriate, that enhance its potential to advance scientific knowledge or clinical practice?

- **Approach**

Are the overall proposed strategy and methodology well-reasoned and appropriate to accomplish the specific aims of the project? Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? Is a robust statistical analysis plan included? Are potential problems, alternative strategies, and benchmarks for success presented?

- **Principal Investigator(s), Scientific Team, and Environment**

Do PI(s), collaborators, and other researchers have appropriate experience and expertise to carry out the project? Does the research team have complementary and integrated expertise; is their leadership approach, governance, and organizational structure appropriate for the project? Is the institutional support, equipment, and other physical resources available to the investigators adequate for the project proposed? If a clinical trial is proposed: Are the administrative, coordinating, enrollment, and laboratory/testing centers appropriate?

- **Protections for Human Subjects**

For research that involves human subjects but does not involve one of the categories of research that are exempt under 45CFR 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

- **Inclusion of Women, Minorities, and Individuals Across the Lifespan**

When the proposed project involves human subjects and/or clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals based on sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of individuals of all ages (including children and older adults) to determine if it is justified in terms of the scientific goals and research strategy proposed.

- **Study Timeline (for clinical trials only)**

Is the projected timeline feasible and well justified? Does the project incorporate efficiencies and utilize existing resources (e.g., CTSAs, practice-based research networks, electronic medical records, administrative database, or patient registries) to increase the efficiency of participant enrollment and data collection, as appropriate? Are potential challenges and corresponding solutions discussed (e.g., strategies that can be implemented in the event of enrollment shortfalls)?

- **Budget and Period of Support (unscored)**

Reviewers will consider whether the budget, staffing plan and the requested period of support are fully justified and reasonable in relation to the proposed statement of work. Indirect costs (F & A) must be 8% or less as per Arthritis Foundation policy.

3. Award Management and Reporting

AF Science Staff will have substantial programmatic involvement, beyond the normal stewardship role in this award. Awardees will be required to submit Annual Progress Reports and Annual Accounting Reports via Proposal Central in addition to a final report once the project is complete. Individual awards are based on the application submitted to, and as approved by, the AF and are subject to the specific terms and conditions identified in the notice of award (available upon request). Additional regulations that need to be observed include the registration of clinical trials within 21 days of protocol approval on ClinicalTrials.gov.

All awardees must acknowledge the support from this funding mechanism in all presentations and publications related to this project by including the following language: "The authors wish to acknowledge the Arthritis Foundation financial support for this work." Any publications supported in full or in part by this funding must also cite the award Digital Object Identifier ([DOI](#)) that will be assigned at the time of award activation.

4. Questions and Additional Information

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Two informational webinars about the RFP will be offered on the following dates:

March 16, 3 p.m. ET

April 11, 12 p.m. ET

Please register for the webinar here: <https://cvent.me/zzdXA3>

For general grants information and with questions regarding application instructions, application, and processes, please email:

AFscience@arthritis.org (preferred method of contact)

Scientific/Research Contact(s)

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