

Advancing Treatment | Finding Cures

# **Innovative Research Award (IRA)**

The mission of the Rheumatology Research Foundation is to advance research and training to improve the health of people with rheumatic diseases.

**Purpose:** Supporting innovative research ideas is essential to better understanding rheumatic diseases, their cause, and the best way to treat them. The Innovative Research Award provides independent academic investigators with the funding they need to pursue ideas that could lead to important breakthroughs in discovering new treatments and, one day, a cure. This award provides essential support for innovative studies focused on generating new insights into the cause, progression, treatment, and outcomes of rheumatic and musculoskeletal diseases.

Award Amount: Up to \$400,000 for two years (maximum \$200,000 per year).

We require a non-binding letter of intent to be submitted no later than June 1, 2021.

All applications must be submitted by 5:00 pm ET on the deadline day through ProposalCentral at: <u>https://proposalcentral.com/</u>.

If you have any questions about your eligibility or submitting your application, please contact Award & Grants staff at 404-365-1373 or <u>Foundation@rheumatology.org.</u>

Letter of Intent Deadline			
June 1, 2021			
Application Deadline			
July 1, 2021			
Notification			
December 6, 2021			
Award Term Begins			
July 1, 2022			

All award recipients must abide by Foundation Awards and Grants Policies at all times.

Eligibility: To be eligible for this award, the applicant must:

- > Be a member of the ACR or ARP at the time of submission and for the duration of the award,
- Hold a doctoral-level degree (MD, PhD, DO, MBBS or equivalent),
- Have a faculty appointment (instructor, assistant professor, etc.) at an academic center or research institution at the time of application and for the duration of the award,
- > Must exhibit evidence of research independence, scientific productivity and career accomplishments,
- > Be able to devote a minimum of 20% full-time professional research effort to the project (see details below\*),
- > Meet citizenship and other eligibility requirements as outlined in the Awards and Grants policies.

#### **Please Note:**

- \*A total of 20% full-time professional research effort is required for the Principal Investigator, although lower FTE may be allowed in some circumstances such as when an arrangement a Co-PI has been made.
- > Principal Investigator(s) may not apply for more than one Foundation Innovative Research Award per cycle.
- Principal Investigator(s) may not hold two active Foundation grants simultaneously unless the grants are for two distinct purposes (ex. training award and innovative research award).
- Two projects are not eligible for concurrent funding under the same mechanism (ex. Individual may not have two different Innovative Research Awards at the same time).
- The Foundation does not allow resubmission of grant applications. This means formal responses to the previous year's critiques will not be accepted. Applicants may apply as many times as they wish; however, all grant applications will be reviewed as new applications.
- Scientific and/or budgetary overlap between Foundation grants and other funding sources (including NIH, VA, and other foundations) is not permitted.
- > Individuals employed at the NIH, FDA and CDC are not eligible to apply.
- Investigators from outside the United States may serve as co-investigators with a PI who is based in the U.S. and who may sub-contract grant support to co- investigators.

Investigators interested in using data from the ACR's RISE registry as part of their proposed research project need to get their data use request approved before applying for funding. Please visit <u>RISE for Research</u> for more information on RISE data. RISE data requests should be submitted at least 2 months prior to the Foundation's application deadline.

If you have questions about your eligibility, please inquire by email to <u>foundation@rheumatology.org</u> or 404-365-1373 before preparing your application.

#### **Foundation Strategic Plan**

The Foundation seeks to support the best basic, translational, clinical, and epidemiologic research in rheumatic and musculoskeletal diseases. Applications directly addressing the current <u>Strategic Plan</u> are particularly encouraged.

# **Review Criteria**

Reviewers will be asked to evaluate applications based on the likelihood that the proposed research will have a substantial impact on the mission of the Foundation. The scientific peer review group will address and consider each of the following criteria in assigning the application's overall score:

- Novelty: Does the project employ novel concepts, approaches or methods? Are the aims original and innovative?
- Investigator: Is the investigator appropriately trained and well suited to carry out the planned studies? If the investigator is in the early stages of an independent career, do they have appropriate experience and training? If established, has the investigator demonstrated an ongoing record of accomplishments that have advanced the field? If the investigator does not have specific experience in the topic of the grant, are there appropriate collaborative arrangements with experts in this area?
- Relevance to Foundation's mission: Is the proposed project relevant to the Foundation's mission and applicable to the strategic plan?

Specifically, does your project will build/lay the foundation for or directly address at least one of the following:

- Increase patient access to care,
- Lead to future treatments and/or cures,
- Demonstrate or improve the value of rheumatology care,
- Expand the impact of rheumatology,

Does this study address an important problem? What will be the effect of these studies on the concepts or methods that drive the field of rheumatic disease research forward?

- Feasibility: Does the scientific environment in which the work will be performed contribute to the probability of success? Do the experiments proposed take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support? Is the proposed research feasible within the term of the award?
- Methods: Are the conceptual framework, design, methods, and analyses adequately developed, well integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?
- Potential impact on the field: Does the project challenge existing paradigms or develop new methodologies or technologies?

Grants will be awarded for a two-year period and are not renewable. Funding for the two-year period will be up to \$400,000 total. Financial support will be provided as outlined below:

Year 1	Amount	Year 2	Amount
July 2022	\$100,000	July 2023	\$100,000
January 2023	\$100,000	January 2024	\$100,000

Salary: The Foundation operates under the same salary cap restrictions as the NIH.

**Indirect Costs:** Indirect costs cannot exceed **8%** of the total direct costs. This includes any indirect costs in line with consortium/contractual costs.

**Unexpended Funds:** All unexpended funds must be returned to the Foundation at the close of the award term. Requests for no-cost extensions will be considered on an individual basis and granted or denied at the discretion of the Foundation Scientific Advisory Council.

# **Award Requirements**

Awards and Grants Policies: All award recipients must abide by Foundation awards and grants policies at all times. A list of current policies is available <u>online</u>.

**Investigator Meetings:** The Foundation sponsors an annual Investigators Meeting where all current investigators share progress updates on their funded projects. **Attendance is required for all funded investigators both years.** Failure to participate may result in grant cancellation. Travel costs to attend this meeting must be included as a line item in the grant budget.

**Progress Report**: The recipient must provide the Foundation with a progress report identifying progress towards the aims of the proposal. Format and exact due date of all reports will be provided at least 30 days prior to the due date. Failure to submit required reports by the deadline may result in institutional penalties, including funding delays and/or grant cancellation. Failure to comply may also affect the awardee and sponsoring institution's eligibility to receive future Foundation funding.

**Final Report:** At the close of the award term, the recipient must provide the Foundation with a final report describing completion of applicable deliverables. In addition, the final report must contain a final financial reconciliation by cost category indicating how funds were allocated and whether any unexpended funds remain. This financial report should be prepared by your Grants and Contracts/Sponsored Projects Office and attached to the final report. In accordance with Foundation policy, failure to submit required reports by the deadline may hinder awardee's eligibility to receive future Foundation funding.

**Award Evaluations:** To help the Foundation track the outcomes and impact of all awards, recipients may be asked to complete periodic online evaluations. This information will be vital to help improve and modify the existing award structure for future recipients.

#### **Letter of Intent**

To help recruit the most appropriate peer reviewers and assist with study section assignments, applicants are required to submit a brief non-binding letter of intent to the Foundation by **June 1, 2021.** 

The letter of intent is an online form and includes the following:

- Project Title
- Name and contact information of Applicant and Institution
- Listing of all Key Personnel and Other Significant Contributors
- Disease Area (100 characters)
- Goals of project stated in (500 characters)
- Indication of Human Studies or Animal Studies
- Science Category
- Research Category
- Primary Study Method/Area
- Research Classification
- Primary Biomedical/Health Research Category

LOI should be submitted online at this link.

# **Application Instructions**

# Before starting the online application, you will be required to create a Professional Profile in ProposalCentral, if you have not already. To do so, visit <u>this link</u> to begin creating your account.

**Note:** The Foundation does not require official signature from an authorized institutional research office at the time of application. However, many institutions require an application to be reviewed prior to submission. Please check with your research office for your institution's requirements.

#### Applicant/Principal Investigator

You will be asked to confirm your eligibility and provide contact information in this section. In addition to the applicant information requested above, you will be asked to upload the following document:

#### **Applicant Biosketch in NIH Format**

Limit to 5 pages; should include any pending support and follow NIH guidelines. Download NIH format Biographical Sketch template by clicking <u>here.</u>

# Abstract/Project Information

The information in this section is general information about the grant submission.

If the application is funded, the following information will be entered into the Foundation database and will become public. Do not include proprietary, confidential information or trade secrets in the description section.

- > **Project Title:** Do not exceed **200 characters**, including the spaces between words and punctuation.
- Abstract (limit to 2000 characters): This is meant to serve as a succinct and accurate description of the proposed work when considered separately from the application. State the broad, long-term objectives and specific aims, making reference to the relevance. Concisely describe the research design and methods for achieving the stated goals. This section should be informative to other persons working in the same or related fields and insofar as possible understandable to a scientifically or technically literate reader. Avoid describing past accomplishments and the use of the first person.
- Relevance to Foundation's Mission (1000 characters): Briefly describe how your proposed project is relevant to the Foundation's mission to improve the health of people with rheumatic diseases.

Specifically, please explain how your project will build/lay the foundation for or directly address at least one of the following:

- Increase patient access to care
- Develop future treatments and cures
- Demonstrate or improve the value of rheumatology care
- Expand the impact of rheumatology

In this section, be succinct and use plain language that can be understood by a lay audience. This information is made public for all awarded grants and used by the Foundation for marketing and or fundraising efforts.

- > Patient Impact (1500 characters): In what ways will your Foundation funded award ultimately impact patients?
- Keywords: Choose three keywords that accurately describe the project. If the application focuses on a specific disease, please include it as a keyword.
- The following questions will be used to assign your application to the appropriate study section. Please select one or more of the options in the online application.
  - Primary Research Material
  - Science Category
  - Primary Research Method/Area
  - Research Classification
  - Primary Biomedical/Health Research Category

# Institution

Institutional information and contacts should be included in this section.

**Performance Site(s)**: List the organization, city & state where the work will be conducted in the area provided. If there is more than one performance site, list all the sites, including Department of Veterans Affairs facilities and foreign sites, and provide an explanation in the resources section of the application.

# Key Personnel/Other Significant Contributors

All Key Personnel and Other Significant Contributors should be listed in this section, including any Co-Principal Investigators. A biosketch in <u>NIH format</u> is required for each individual and may not exceed 5 pages. In the other support section of the PI's biosketch, please identify any grants (current or pending) that may overlap with this submission and how you plan to address this issue if funded (i.e., relinquish overlapping grant, etc.).

- Key Personnel: In addition to the PI, key personnel are defined as individuals who contribute to the scientific development or execution of the project in a substantive, measurable way, whether or not salaries are requested. Consultants should be included if they meet this definition. Key personnel must devote measurable effort to the project whether or not salaries are requested. Percent effort should be calculated based on a full-time 12-month calendar year appointment at the sponsoring institution. For each individual provide name, organization name, and role on the project.
- Other Significant Contributors: This category identifies individuals who have committed to contribute to the scientific development or execution of the project but are not committing any specified measurable effort to the project. These individuals are typically presented at "effort of zero" or "as needed." Individuals with measurable effort cannot be listed as other significant contributors. Consultants should be included if they meet this definition.

# **Budget & Justification**

Applicant should outline an itemized budget not to exceed \$200,000 per budget period, including fringe. Principal Investigator or Co-Principal Investigators must devote a minimum of 20% effort to this project. The budget sections include:

#### **Direct Costs**

#### > Personnel Costs:

Starting with the principal investigator(s), list the names of all applicant organization employees who are involved on the project during the budget period, regardless of whether a salary is requested. Include all collaborating investigators, individuals in training and support staff. Describe their specific functions in the budget justification.

The Foundation operates under the same <u>salary cap restrictions</u> as the NIH. An individual's institutional base salary is the annual compensation that the applicant organization pays for an individual's appointment, whether that individual's time is spent on research, teaching, patient care, or other activities. The total salary requested must be based on a full-time, 12-month calendar year appointment.

Individuals with joint university and VA appointments may request the university's share of their salary in proportion to the effort devoted to the research project. The individual's salary with the university determines the base for computing that request. If awarded, must provide a signature by the institutional official which certifies that: (1) the individual is applying as part of a joint appointment specified by a formal Memorandum of Understanding between the university and the VA; and (2) there is no possibility of dual compensation for the same work, or of an actual or apparent conflict of interest regarding such work. Additional information may be requested by the awarding components.

#### Consultant/Contract costs:

Include the number of days of anticipated consultation, the expected rate of compensation, travel, per diem, and other related costs. Describe the services to be performed in the budget justification.

#### Supplies and Expenses:

Itemize supplies in separate categories, such as glassware, chemicals, radioisotopes, etc. Categories in amounts less than \$1,000 do not have to be itemized. If animals are to be purchased, state the species and the number to be used.

#### > Equipment:

Equipment purchases up to \$10,000 are allowed. Only include individual items greater than \$5,000. Any items less than \$5,000 must be purchased under the "supplies" budget category.

# > Travel:

Itemize all travel requests. Provide the purpose and destination of each trip and the number of individuals for whom funds are requested. All travel must be justified as to how it relates to the project. Travel must be included for one investigator associated with the project to attend the Foundation's Annual Investigator's Meeting.

# Direct Consortium/Contractual Costs:

List all Direct consortium/Contractual Costs with description. Consortium arrangements may involve personnel costs, supplies, and other allowable costs.

#### Indirect Costs:

All Indirect Costs associated with the Primary Institution and/or Consortium/Contractual agreements should be listed individually below with a brief description. Indirect costs are capped at 8 percent of the direct costs.

#### **Budget Justification:**

This section provides justification for each component included in the budget summary. At the very least, the budget justification should name each person to be supported by this grant, their percentage full time effort committed to the project, and their role in the project. This includes any "to-be-appointed" positions. No individual salary information should be provided. You should also explain the need for consortium/contractual arrangements and indicate whether the collaborating institutions are foreign or domestic and why they are uniquely qualified to contribute. Descriptions of equipment, major supply items and project – related travel should also be included in the justification.

# **Current & Pending Support**

Applicant should list all current and pending research support, including but not limited to grants and contracts. Indicate any current startup funds. For each entry specify the overlap between the other awards, applications, and/or sources listed in this application.

# **Organization Assurances**

The applicant assures that the proposal is in compliance with institutional guidelines as provided by the sponsoring institution's clinical and research review boards. All research proposals including human subjects, laboratory animals and recombinant DNA techniques must show documented compliance with institutional guidelines. Copies of approval notices by the institutions IRB, IACUC and/or biosafety committees must be provided as appropriate once awarded.

#### **Research Proposal & Literature Cited**

The research proposal should include enough information needed for evaluation of the project, independent of any other document (e.g., appendix, supplemental materials, etc.). A response to prior reviews of the proposal may <u>not</u> be included in your application. Each application is treated as a new submission.

The research proposal cannot exceed 10 pages. All tables, graphs, figures, diagrams and charts should be included within the 10-page limit.

While there is no character limit for Literature Cited, it is important to be concise and to select only those literature references pertinent to the proposed research.

#### **Contents of Research Plan:**

- A. Specific Aims (one page): List the broad, long-term objectives and the goal of the specific 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).
- B. Background and Significance (two pages are recommended):
  - Briefly describe the background leading to the present application, critically evaluate existing knowledge, and specifically identify the gaps that the project is intended to fill.
  - State concisely the importance and health relevance of the research described in this application by relating the specific aims to the broad, long-term objectives.
  - If the aims of the application are achieved, state how scientific knowledge or clinical practice will be advanced.
  - Describe the effect of these studies on the concepts, methods, technologies, treatments, services or preventative interventions that drive this field.
- C. **Preliminary Studies** (two pages are recommended): Provide an account of the PI's preliminary studies pertinent to this application, including his/her preliminary experience with and outreach to the proposed racial/ethnic group members (if applicable).
- D. Research Design and Method (five pages are recommended):
  - Describe the research design conceptual or clinical framework, procedures, and analyses to be used to accomplish the specific aims of the project.
  - Include how the data will be collected, analyzed and interpreted as well as the data- sharing plan as appropriate.
  - Describe any new methodology and its advantage over existing methodologies.
  - > Describe any novel concepts, approaches, tools or technologies for the proposed studies.

- Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims.
- Provide a tentative sequence or timetable for the project. Point out any procedures, situations or materials that may be hazardous to personnel and the precautions to be exercised.
- E. Literature Cited: List all references. Each reference must include the title, names of all authors, book or journal, volume number, page numbers and year of publication.

# Human Subjects/Vertebrate Animals Research

Although no specific character limit applies to this section of the application, be succinct.

**Human Subjects Research:** The following human subject information applies even if you are obtaining specimens from collaborators or if you are subcontracting the human research to another organization.

- Provide evidence that the investigators (or subcontractors) have current training in the protection of human subjects.
- Provide a detailed description of the proposed methods of identification, contact, and recruitment of potential research participants.
- > Justify the number of subjects to be included.
- Clearly identify study-related risks, including risks to privacy associated with identification and recruitment as well as risks of participating in the research.
- Identify steps that will be taken to protect participant privacy and confidentiality.
- > Identify steps that will be taken to minimize exposure to risks associated with study procedures.
- Provide a description of the specific inclusion/exclusion of women, minorities, and children, and a justification for the inclusion plan.

**Vertebrate Animals:** This section must be completed if research involving vertebrate animals will take place.

- Provide a detailed description of the proposed use of the animals in the work outlined in the research design and methods section. Identify the species, strains, ages, sex and numbers of animals to be used in the proposed work.
- Justify the use of animals, the choice of species and the numbers to be used. If animals are in short supply, costly or to be used in large numbers, provide an additional rationale for their selection and numbers.
- > Provide information on the veterinary care of the animals involved.

- Describe the procedures for ensuring that discomfort, distress, pain and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. Describe the use of analgesic, anesthetic, tranquilizing drugs and/or comfortable restraining devices, where appropriate, to minimize discomfort, distress, pain and injury.
- Describe any method of euthanasia to be used and the reasons for its selection. State whether this method is consistent with the recommendations of the Panel on Euthanasia of the American Veterinary Medical Association. If not, present a justification for not following the recommendations.

#### **Consortium/Contractual Arrangements**

If applicable, explain the programmatic, fiscal and administrative arrangements to be made between the applicant organization and the consortium organization(s). If consortium/contractual activities represent a significant portion of the overall project, explain why the applicant organization, rather than the ultimate performer of the activities, should be the grantee.

Attach appropriate letters here from all paid consultants confirming their roles in the project and rate/charge for consulting services. Do not place these letters in the appendix.

#### **Resource Sharing Plan**

Describe the resource sharing plan and how you will share results and/or reagents derived from this project. When resources have been developed with Foundation funds and the associated research findings published or provided to the Foundation, it is important that they be made readily available for research purposes to qualified individuals within the scientific community. The Foundation resource sharing policy is available online and plans to follow this should be detailed in this section. Applications that do not contain an appropriate resource sharing plan will be returned without review. Although no specific character limit applies to this section of the application, be succinct.

#### **Benchmarks for Success**

# Download, complete and submit the Benchmarks of Success template. See example of the template below.

Applications should include a list of milestones (expected status of the project at various points in time). These milestones will be used to evaluate progress and to facilitate communication between PIs and the Foundation Scientific Advisory Council. The milestones should reflect the specific aims of the proposal and be presented within the context of a pathway for determining or evaluating a potential target for treatment.

#### Resources

Specify the facilities (including laboratory, clinical, animal, computer, office and other) to be used for the conduct of the proposed research. Indicate the performance sites and describe capacities, pertinent capabilities, relative proximity and extent of availability to the project. If there are multiple performance sites, the resources available at each site should be described. In describing the scientific environment in which the work will be done, discuss ways in which the proposed studies will benefit from unique features of the scientific environment, or subject populations, or employ useful collaborative arrangements.

# Appendix

The appendix may not be more than **20 pages** in length. The appendix may not be used to circumvent the page limitations of the research plan. The research plan must be self-contained and understandable without having to refer to the appendix. While the font requirements imposed in the rest of the application do not apply to the appendix, all material must be clearly legible. Items to be included in the appendix include but are not limited to the following:

- Letters of Collaboration: Letters of support and/or commitment from collaborators stating they will provide research resources, etc. as proposed in the application. Letters from paid consultants must be included in Part H of the research plan.
- Supporting Materials: Supplemental tables and figures, relevant publications or manuscripts.

Benchmarks for Success					
The benchmarks (expected status of the project at various points in time) included in your original application will be					
used to evaluate progress. The milestones should reflect the specific aims of the proposal and be presented within the context of measurable outcomes.					
BENCHMARKS	Metrics for Success	Expected Completion			
(Should be listed chronologically)	(Projected end points)	(Specific dates or months into			
		project)			