# **Innovative Research Award for Community Practitioners**

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

The Rheumatology Research Foundation (Foundation) recognizes the unique potential for research performed by rheumatologists and rheumatology professionals in community-based environments to advance our understanding of rheumatic diseases, their treatment and how to improve patient outcomes.

**Award Purpose:** Through our innovative research program, the Foundation is committed to funding research ideas that are essential to improve understanding of rheumatic diseases, including their causes and optimal treatments. The Innovative Research Award for Community Practitioners will enable research that has the potential to improve treatment of rheumatic diseases, patient outcomes, and/or quality of care.

This award is targeted to community practitioners who, in addition to being engaged in patient care, conduct or are interested in conducting research. Projects submitted for this award should be relevant to the mission of the Foundation and can include, but are not limited to:

- Health services research
- Outcomes-based research
- Observational studies
- Practice supply and demand analysis
- Cost-benefit analysis or value-based studies
- Patient communications studies

Annually, the Foundation's Scientific Advisory Council will choose one outstanding recipient of this award to receive the special designation of the **Norman B. Gaylis, MD Clinical Research Award.** This designated award was established in 2015 with a generous commitment from Norman B. Gaylis, MD.

Award Amount: \$50,000 - \$200,000 per year, for up to two years

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: https://proposalcentral.com/.

Letter of Intent Due	Application Deadline	Notification
June 1, 2021	August 2, 2021	December 6, 2021

**Notification and Funding:** Applicants will be notified about the status of their application in December 2021. Funding will begin July 1, 2022.

**Mentorship:** With advanced notice (at least 6 weeks) the Foundation can connect applicants to mentors from the rheumatology community. These mentors can provide objective guidance and feedback on proposals when requested. If you would like to be connected with a mentor, please contact the Foundation at <a href="Foundation@rheumatology.org">Foundation@rheumatology.org</a> or 404-365-1373. A mentor's comments will reflect their own independent assessment of the proposal and are not reflective of the view of the Foundation or peer review panel.

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

# **Award Eligibility and Guidelines**

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, DO, PhD, DNP, PsyD, EdD);
- Have a current license to practice medicine or other interprofessional specialty and be in good medical standing;
- > Be employed in a community practice setting including:
  - Solo practice
  - Single specialty group practice
  - Multi-specialty group practice
  - Hospital system-based practice
- Have the ability to manage a grant award administratively and fiscally,
- > Demonstrate certification of training in human subjects research and the ability to obtain human subjects research approval and oversight for the proposed research for the duration of the award;
- Meet citizenship and other eligibility requirements as outlined in the Awards and Grants policies.

## Please note the following:

- Applicants are highly encouraged to partner with a Co-investigator at an academic center or research-oriented institution. The partners may work collaboratively in all phases of the research project, including:
  - Identifying of the research question
  - Writing and submitting the application
  - Designing and carrying out the research
  - Analyzing the research findings
  - Preparing reports to the Foundation
  - Disseminating the results to community and scientific audiences
- ➤ Community practices receiving this award bear the responsibility of properly reporting the award income, determining tax impact, and paying any resulting taxes. Upon award receipt, the practice will provide the Foundation the most recent Form W-9. The Foundation will issue a Form 1099 if deemed necessary.

- Practices receiving this award assume all responsibilities and obligations to comply with relevant laws and applicable regulatory requirements (e.g., Good Clinical Practice).
- Scientific and/or budgetary overlap between Foundation grants and other funding sources (including Pharmaceutical funding and other foundations) is not permitted.
- > Individuals may not apply for more than one Foundation research grant per cycle.
- 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.

## **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 <a href="Strategic Plan">Strategic Plan</a> are particularly encouraged.

#### **Peer Review Process**

Your application will be reviewed in the Foundation's Innovative Research: Health Services Research study section. This study section is made up of a panel of community practitioners and academic investigators.

**Independent Reviews:** Your application will be assigned to two community practitioners and one academic investigator for review. Each of these assigned reviewers will provide preliminary scores for your application and full written critiques.

**Study Section Review:** Your application will be introduced to the entire review panel by the primary reviewer at a face-to-face meeting. An overview of the project will be provided as well as a summary of strengths and weaknesses. Secondary and tertiary reviewers will provide supplemental information prior to opening your project up for group discussion. After general discussion, all reviewers at the meeting privately submit overall impact scores for your project. Applications will be ranked by average impact score.

**Post Review:** The Foundation's Scientific Advisory Council will review the ranked slate of awards from the study section and will create a formal recommendation for funding to present for Board of Directors approval. All applicants (funded and unfunded) will receive a report including all written critiques in addition to their funding notification in December.

#### **Review Criteria**

Reviewers will be asked to evaluate applications based on the likelihood that the proposed project can be conducted with appropriate scientific rigor by the applicant and will have a substantial impact on the mission of the Foundation. The study section will address and consider each of the following criteria in assigning the application's overall score:

## Project Design, Methodology and Feasibility

O Do the aims answer the overall goal of the project? Are the aims interdependent of each other? Is the framework of the project appropriately designed to answer the question? Are there appropriate confounding or moderating variables accounted for? Is there appropriate scientific rigor in statistical analysis plan? Are there power calculations to determine adequate sample size? Is there adequate protection of human subjects?

#### > Qualifications and Expertise of Investigator(s) and Key Personnel

o Is the investigator/personnel appropriately trained and well suited to carry out the planned studies? Has the investigator/personnel 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 or methodological approaches, are there appropriate collaborative arrangements with experts in this area?

#### Timeline and Environment

O Does the environment in which the work will be performed contribute to the probability of success? Has the practice demonstrated that the proposed project could be conducted in the practice setting (e.g., collection of data, practice flow, etc.)? Is the proposed timeline adequate for completing the project?

#### Relevance to the Foundation's Mission and Strategic Plan

- o Is the proposed project relevant to the Foundation's mission and applicable to the <u>strategic plan</u>? Specifically, will this project build a foundation for or impact one or more 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

## > Overall Significance and Impact on the Field of Rheumatology

O Does the project challenge existing paradigms or develop new methodologies or technologies? 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?

# **Award Terms and Funding**

Funding for this grant will begin on July 1, 2022 and extend through June 30, 2024. Grants will be awarded for a two-year period and are not renewable. Applicants may request a total annual budget ranging from \$50,000 - \$200,000 per year. Funding for the two-year period will be up to a maximum of \$400,000 total. Financial support will be provided as outlined below (Awards of smaller amounts will be provided similarly in 25% increments):

Date	Amount		
July 2022	Up to \$100,000		
January 2023	Up to \$100,000		
July 2023	Up to \$100,000		
January 2024	Up to \$100,000		

Indirect Costs: Indirect costs are capped at 8% of the total budget.

**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.

#### The Foundation will not compensate for the following:

- Support for ongoing clinical programs that are part of an organization's routine operations
- Purchases of equipment unrelated to the proposed study
- Construction and new facilities
- Hiring or reimbursing of staff who are not directly dedicated to the proposed study

# **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 online.

**Investigator Meetings:** The Foundation sponsors an annual 2-day Investigators Meeting where all current investigators share progress updates on their funded projects. Attendance is required for all funded investigators. 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 an annual progress report (template provided) identifying progress towards the aims of the proposal. Failure to submit required reports by the deadline may result in penalties, including funding delays and/or grant cancellation. Progress reports will be due in March 2023 and March 2024.

**Final Report:** At the close of the award term, the recipient must provide the Foundation with a final report (template provided) describing completion of deliverables. In addition, the final report must contain a final financial reconciliation indicating how funds were allocated and whether any unexpended funds remain. Final reports will be due in September 2024.

**Award Evaluations:** To help the Foundation track the outcomes and impact of all awards, recipients may be asked to complete periodic online evaluations for up to 5 years after the award end date. This information is vital to improve and modify the existing award structure for future recipients.

**Communication of Findings:** The Foundation will require a commitment by the investigator to disseminate the findings in an appropriate, transparent, and timely manner. The support of the Foundation should be acknowledged in presentations, abstracts, papers, etc.

# **Letter of Intent**

In order to help provide feedback prior to formal application submission, 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 will be reviewed by Foundation staff and members of the Scientific Advisory Council. After review of the letter, Foundation representatives may reach out with additional feedback and resources.

Please fill out the online form including applicant name, sponsoring institution and listing of research collaborators, partners and key personnel.

The letter of intent should be no more than 2 pages and uploaded as a pdf. The letter of intent should address the following:

- Proposed title of project
- Hypothesis/es
- Goals of project
- Brief description of project design and methodology, including an estimation of time required (e.g. for patient recruitment, data analysis, etc.)
- Composition of the study team (Note: community physicians are encouraged to partner with academic-based investigators)

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 this link 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.

If you have questions about your application or need assistance in preparation, please contact Awards and Grants staff at <a href="mailto:foundation@rheumatology.org">foundation@rheumatology.org</a> or 404-365-1373.

The following sections outline the information that will be collected within the application site. The site will collect information via drop downs, free text boxes and uploads. A checklist is included in the online application highlighting each individual upload that you will need to submit your application successfully.

# **Applicant/Principal Investigator**

This section collects information regarding the applicant and eligibility. You will be asked to upload your curriculum vitae (CV), a template has been provided if needed. **Each CV may not exceed five pages in length.** 

# **Abstract/Project Information**

The section collects general information about the application 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 (2000 characters): The abstract serves as a succinct and accurate description of the proposed work when considered separately from the application. The abstract should present the essential meaning of the proposal and should summarize the significance (need) of the work, the hypothesis and major objectives of the project, the procedures to be followed to accomplish the objectives, and the potential impact of the work.
- Relevance to the 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 disease. Specifically, please explain how your project will build a foundation for or 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
- > 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. If there is more than one performance site, list all the sites.

## **Key Personnel/Other Significant Contributors**

All Key Personnel and Other Significant Contributors should be listed in this section, including any Co-Principal Investigators (Co-PIs). A curriculum vitae (CV) or <u>biographical sketch</u> is required for each individual listed. **Each CV or biographical sketch may not exceed 5 pages in length.** 

- ➤ **Key Personnel:** In addition to the principal investigator, 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.
- ➤ 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.

## **Budget & Justification**

Applicant should outline an itemized budget not to exceed \$200,000 per budget period, including fringe.

## **Direct Costs can Include:**

#### Personnel:

Starting with the principal investigator(s), list the names of all individuals 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.

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.

#### Consultant/Contractor 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:

Describe all supplies and expenses needed for the execution of the proposed project including any administrative costs associated with the startup and maintenance of your proposed project (administrative costs may include institutional review fees, communications, data access, publication costs, etc.).

## > Equipment:

This may include any equipment needed to carry out the project. Purchases of equipment unrelated to the proposed study are not allowed. 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 "supplies."

#### > Travel:

Include the cost associated with attending the annual Investigators' Meeting (2 days) and any other travel related to the proposed project. Be sure to include an estimate for airfare, ground transportation, accommodations, and per diem.

#### **Indirect Costs**

Also known as, "Facilities and Administrative Costs" and/or "overhead costs". Indirect costs are capped at 8% of the total budget.

#### **Budget Justification**

Include a Budget Justification that includes each of the following details as applicable:

- **Personnel:** Describe the specific function of each individual receiving salary support. Also include the total time they will allocate to this proposed project.
- **Consultant/Contractor Costs:** Describe the services to be performed and include the number of days of anticipated consultation, the expected rate of compensation, travel, per diem, and other related costs.
- > Supplies and Expenses: Describe all supplies and expenses needed for the execution of the proposed project including any administrative costs associated with the startup and maintenance of your proposed project (administrative costs may include institutional review fees, communications, data access, publication costs, etc.).
- **Equipment:** This may include any equipment needed to carry out the project. Purchases of equipment unrelated to the proposed study are not allowed.
- > Travel: Include the cost associated with attending the annual Investigators' Meeting (2 days) and any other travel related to the proposed project. Be sure to include an estimate for airfare, ground transportation, accommodations, and per diem.

## **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.

# **Required Documents/Uploads**

## **Research Proposal & Literature Cited**

The research proposal cannot exceed 10 pages. All tables, graphs, figures, diagrams and charts should be included within the 10-page limit. Note that the research plan must be self-contained and understandable without having to refer to the appendix.

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. **Introduction:** This section should describe the overall importance of the proposed research and introduce the main question (hypothesis) under investigation.
- B. **Specific Aims:** List the broad, long-term objectives and the goal of the proposed research project. The objectives should be clear and address the main question the project is trying to answer (hypothesis). Objectives should include the primary measures, any comparator groups, and the time point(s) of interest.
- C. **Background and Significance**: Discuss the overall significance (need) of the proposed research making sure to answer the following questions:
  - Why is the proposed work important?
  - What is the existing body of knowledge to support this project, and how will the project address existing knowledge gaps?
  - If the aims and objectives of this project are achieved how will clinical practice, patient care and/or the field of rheumatology be advanced?
- D. **Research Design:** Provide a full and detailed description of the study design and methodology. Be specific and informative. As you prepare this section, carefully consider and address the following questions:
  - What do you intend to do?
  - How will you accomplish the work within the two-year timeframe?
  - What are your study population and selection criterion (if applicable)?
  - Are there any potential biases/limitations associated with your design? If so, how do you propose to overcome or minimize them?
  - What is your study framework?

- What is your statistical plan?
- Do you foresee any challenges? If so, how will you handle these challenges?
- How will the data be collected, protected, stored, analyzed and interpreted?
- E. **Human Subjects Research (if applicable):** 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. Please include the following:
  - Evidence that the applicant(s) (and/or subcontractors) have current training in the protection of human subjects.
  - A description of the proposed methods of identifying, contacting, and recruiting of research participants.
  - Study-related risks, including risks to privacy associated with identification and recruitment as well as risks of participating in the research.
  - Steps that will be taken to protect participant privacy and confidentiality.
  - Steps that will be taken to minimize exposure to risks associated with study procedures.
  - A description of the specific inclusion/exclusion of women, minorities, and children, and a justification for the selection plan.
  - Note: if awarded, IRB approval must be provided to the Foundation.
- F. **Dissemination Strategy:** Clearly describe how these data will be disseminated by indicating where this information will be submitted for presentation or publication. Examples may include abstract submissions, manuscript submissions, and/or presentations at local/regional society meetings.
- G. **Research Benchmarks.** 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 the awardee and the Foundation's Scientific Advisory Council. The milestones should reflect the specific Aims of the proposal. (A research benchmarks template is provided.)
- H. **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.

#### **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.

# **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. 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.
- > Supporting Materials: Supplemental tables and figures, relevant publications or manuscripts.

# **BENCHMARKS OF SUCCESS**

The benchmarks (expected status of the project at various points in time) included in your original application will be used to evaluate progress.

Goals	Metrics for Success	Expected completion
(Should be listed chronologically)	(Projected end points)	(Specific dates or months
		into project)
1.		
2.		
2.		
3.		
4.		
5.		

CURRICULUM VITAE					
NAME:					
CURRENT POSITION:  EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)					
INSTITUTION AND LOCATION	DEGREE (if applicable)	Completion Date MM/YYYY	FIELD OF STUDY		
A. Employment History	' '	'			
B. Licensure					
C. Board Certification					
D. Membership in Professional Societies					
E. Honors and Awards (if applicable)					
F. Publications (if applicable)					
G. Oral Presentations (Continuing Medical Education, Local, Regional or National Meetings) (if applicable)					