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 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 better understanding rheumatic diseases, their causes and the best way to treat them. The Innovative Research Award for Community Practitioners will help 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, Research Award for Rheumatologists in Community Practice.* This designated award was established in 2015 with a generous commitment from Norman B. Gaylis, MD.

Award Duration: 2 Years

Award Amount: \$50,000 - \$200,000 per year

Application Submission: All applications must be submitted through WizeHive by 5:00 PM EST on the deadline.

Letter of Intent Due	Application Deadline		
June 1, 2018	July 2, 2018		

Letters of Intent should be submitted at: https://app.wizehive.com/webform/loicp

Applications should be submitted at: https://app.wizehive.com/apps/ira_cp

Notification and Funding: Applicants will be notified about the status of their application in December 2018. Funding will begin July 1, 2019.

Mentorship: The Foundation is able to 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 Foundation@rheumatology.org or 404-365-1373. Note that the 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.

Award Eligibility and Guidelines

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

- > Be a member of the ACR at the time of submission and for the duration of the award;
- ➤ Hold a doctoral-level degree (MD, DO);
- Have a current license to practice medicine 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
- Must have the ability to administratively and fiscally manage a grant award;
- 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. If such partnership is chosen, the partners may work collaboratively in all phases of the research project, including:
 - Identification 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 with 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.

If you have questions about your project idea or eligibility, please contact Awards and Grants staff at foundation@rheumatology.org or 404-365-1373 before preparing your application.

Relevance: All applications must be relevant to the Foundation's mission of advancing research and training to improve the health of people with rheumatic disease. Outcomes from these grants should lead to improved treatment of rheumatic diseases, patient outcomes, and/or quality of care.

Review Criteria

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

- Project design and methodology
- Qualifications and expertise of Investigator(s) and Key Personnel
- > Feasibility and timeline
- Relevance to the Foundation's mission and strategic plan
- Overall significance and impact on the field of rheumatology

Award Terms and Funding

Funding for this grant will begin on July 1, 2019 and extend through June 30, 2021. 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. Funding for the two-year period will be up to a maximum of \$400,000 total. Financial support will be provided as outlined below for a \$400,000 total award amount. (Total awards of smaller amounts will be provided similarly in 25% increments):

Date	Amount		
July 2019	Up to \$100,000		
January 2020	Up to \$100,000		
July 2020	Up to \$100,000		
January 2021	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 funds to build new facilities
- Hiring or reimbursement 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 April 2020 and April 2021.

Final Report: At the close of the award term, the recipient must provide the Foundation with a final report (template provided) describing completion of applicable 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 2021.

Award Evaluations: In an effort 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 will be vital to help 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 abstracts, papers, etc.

Letter of Intent

In order to help recruit the most appropriate peer reviewers and assist with study section assignments, applicants are required to submit a brief <u>non-binding</u> letter of intent to the Foundation by **June 1, 2018.**

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

- Name of applicant(s) and sponsoring organization(s)
- Listing of all key personnel
- Disease area
- Hypothesis/es
- Goals of project stated in 2-3 sentences
- Brief description of proposed methods in 2-3 sentences

LOI should be submitted at: https://app.wizehive.com/webform/loicp

Application Instructions

The Foundation will be accepting applications for all awards via electronic format only. Applications should be submitted electronically through WizeHive. All applications must be submitted by 5:00 PM EST on July 2, 2018.

If you have questions about your application or need assistance in preparation, please contact Awards and Grants staff at foundation@rheumatology.org or 404-365-1373.

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

Application Information

Applicant Information: This section collects contact information regarding the applicant and the administrative official to be notified if a grant is awarded. You will be asked to upload your curriculum vitae (CV) or biographical sketch in this section. A CV template has been provided if needed.

General 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 (approximately ½ 1 page in length): This is meant to serve 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.

- Project Narrative (2-3 sentences): 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 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
- **Keywords:** Choose three keywords that accurately describe the project. If the application focuses on a specific disease, please include it as a keyword.
- Performance Site(s): Indicate where the work will be conducted. If there is more than one performance site, list all the sites.
- ➤ **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."
- Curriculum Vitae: This section must contain the curriculum vitae (CV) or biographical sketches of all key personnel and other significant contributors, including consultants, following the order as listed in sections above. A CV template has been provided if needed. All CV/biosketch information should be compiled into one document and uploaded as a PDF.

Research Plan

Instructions: This section should be prepared as 3 separate documents and uploaded as PDFs.

- Upload 1: Research Plan- 10 page limit (sections A-F below)
- Upload 2: Research Benchmarks- template provided (section G below)
- Upload 3: Literature Cited no page limit (section H below)
- Use a font size of 11 points or larger. A smaller font may be used for tables, graphs, figures, diagrams, charts, legends, etc.
- Margins should be at least ½ inch all around.
- Line spacing should be not less than 1 (please do not use "exact" spacing).
- The research plan 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.

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. **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?
 - Is there an existing body of knowledge to support this project or is the intent to fill current 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 the following questions:
 - What do you intend to do?
 - How will you accomplish the work?
 - What is 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?
 - Do you foresee any challenges? If so, how will you handle these challenges?
 - How will the data be collected, 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 identification, contact, and recruitment 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.
- 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 be reflective of 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.

Budget

Download and complete the budget template to prepare your budget for entry into the online application. Budget should be uploaded as a PDF. The budget justification section (below) provides more detail on what should be accounted for in each section of the budget.

Direct Costs can include:

- > Personnel: Complete budget table A for each person receiving salary support.
- Consultant/Contractor Costs (if applicable)
- Supplies and Expenses: Add lines as needed to itemize
- > Equipment: Add lines as needed to itemize
- Travel: Include travel to annual Investigators' Meeting

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

Prepare and upload a budget justification that provides each of the following details as applicable:

- **Personnel:** Describe the specific function of each individual receiving salary support. Also include their total time to be allocated 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 things like institutional review fees, communications, data access, publication costs, etc.).

- **Equipment:** This may include any equipment needed to carry out the execution of this 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.

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.

Checklist of Uploads to be Submitted through WizeHive

Each of the following should be prepared as a separate PDF and uploaded into the correct place in WizeHive:

	Applicant's Curriculum Vitae or <u>Biosketch</u> (more info on page 5)
	Curriculum Vitae or <u>Biosketch</u> for Key Personnel and Contributors (more info on page 6)
	Research Plan (more info on page 6)
	Research Benchmarks (template provided and more info on page 7)
	Literature Cited (more info on page 7)
	Budget (template provided and more info on page 7)
	Budget Justification (more info on page 8)
П	Appendix (more info on page 8)

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.

Metrics for Success (Projected end points)	Expected completion (Specific dates or months into project)
	(Projected end points)

INNOVATIVE RESEARCH AWARD BUDGET	YEAR 1 (7/1/2019 - 6/30/2020)	YEAR 2 (7/1/2020 - 6/30/2021)
DIRECT COSTS		
PERSONNEL: Salaries & Fringe Benefits		
(Please specify personnel, institution and percent effort on Budget Table A)	\$0.00	\$0.00
CONSULTANT COSTS		
SUPPLIES & EXPENSES		
EQUIPMENT ¹		
TRAVEL- SCIENTIFIC MEETINGS ²		
DIRECT CONSORTIUM/CONTRACTUAL COSTS ³		
DIRECT COSTS SUBTOTAL	\$0.00	\$0.00
INDIRECT COSTS		
PRIMARY INSTITUTION INDIRECT COSTS⁴		
INDIRECT CONSORTIUM/CONTRACTUAL COSTS 3,4		
INDIRECT COSTS SUBTOTAL	\$0.00	\$0.00
TOTAL COSTS ⁵	\$0.00	\$0.00

¹Equipment 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."

Complete Budget Table A for each person receiving salary support. The personnel subtotal will pre-populate into the table above.

BUDGET TABLE A				
PERSONNEL NAME & INSTITUTION	% Effort**	YEAR 1	YEAR 2	
PERS	\$0.00	\$0.00		

^{**}PI must devote a minimum of 20% effort to this project each year.

Personnel - 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.

Salary – The Foundation operates under the same salary cap restrictions 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.

Joint University and Department of Veterans Affairs Appointments - 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.

²Must include travel costs to the Investigators' Meeting.

³Consortium detailed budget must be submitted as noted in instructions.

⁴Indirect costs are limited to 8% of the direct costs.

⁵Maximum duration is two years and the total costs (Direct + Indirect) may not exceed \$200,000 per year.

CURRICULUM VITAE

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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)