Issued March 1, 2016

Rheumatology Research Foundation
Advancing Treatment | Finding Cures

Innovative Research Award

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

Purpose: The Innovative Research Award provides essential support for innovative studies focused on generating new insights into the cause, progression, treatment, and outcomes of rheumatic diseases.

Annually, the Foundation's Scientific Advisory Council chooses an outstanding recipient of the Innovative Research Award who is a community-based rheumatologist conducting health services research to receive the Norman B. Gaylis, MD, Research Award for Rheumatologists in Community Practice. The award's intent is to support community practice physicians, who, in addition to being engaged in patient care, initiate research, including but not limited to, health services research or outcome studies, practice supply and demand, and/or patient communications. This designated award was established in 2015 with a generous commitment from Norman B. Gaylis, MD.

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

We are requesting a non-binding letter of intent be submitted no later than June 1, 2016. Note that this is not required but STRONGLY ENCOURAGED to help aid in recruitment of appropriate peer reviewers.

All applications must be submitted by 5:00 PM EST on the deadline through WizeHive at https://app.wizehive.com/apps/IRAward

Letter of Intent Deadline
June 1, 2016
Application Deadline
July 1, 2016
Notification
December 1, 2016
Award Term Begins
July 1, 2017

Guidelines

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

- Be a member of the ACR or ARHP 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; **OR** be employed in a clinical practice setting with the ability to administratively and fiscally manage a grant award and obtain human subjects research oversight 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 percent 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% FTE is required for the PI, although lower FTE may be allowed in some circumstances such as when an arrangement for Co-PIs has been made.
- Individuals may not apply for this award and another Foundation research award (Scientist Development Award, Investigator Award) during the same cycle.
- Individuals may not hold two active Foundation grants unless the grants are for two distinct purposes (ex. career development award and innovative research award).
- 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, CDC, 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 principal investigator who is based in the U.S. and who may sub-contract grant support to co-investigators.
- Clinical practices receiving this award bear the responsibility of properly reporting the award income, determining tax impact, and potentially paying resulting taxes. Upon receipt, the practice will provide the Foundation with the most recent Form W-9. The Foundation will issue a Form 1099 if deemed necessary.

If you have questions about your eligibility, please inquire by email to 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 new insights into the cause, progression, treatment, and outcomes of rheumatic diseases.

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:

- **Investigator:** Is the investigator appropriately trained and well suited to carry out the planned studies? If the investigator is in the early stages of 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 mission:** Is the proposed project relevant to the Foundation's mission and applicable to the strategic plan? Specifically, will this project: a) increase patient access to care, b) lead to future treatments and/or cures, c) demonstrate or improve the value of rheumatology care; and/or d) 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?
- **Novelty:** Does the project employ novel concepts, approaches or methods? Are the aims original and innovative?
- **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?

Award Terms and Funding

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:

Date	Amount	Date	Amount
July 2017	$100,000	July 2018	$100,000
January 2018	$100,000	January 2019	$100,000

Salary: The Foundation operates under the same salary cap restrictions as the NIH. Effective January 2016, the Executive Level II salary cap is **$185,100**.

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 applicants and 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 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. The recipient must report on the following: project outcomes, progress and submitted or published articles and abstracts, patents and other grants obtained. 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 applicant 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 applicant's eligibility to receive additional Foundation funding.

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. This information will be vital to help improve and modify the existing award structure for future recipients.

Letter of Intent

In order to help recruit the most appropriate peer reviewers and assist with study section assignments, applicants are encouraged to submit a brief non-binding letter of intent to the Foundation by **June 1, 2016.**

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

- Name of PI and Institution
- Listing of all Key Personnel and Institutions (in order to identify potential conflicts)
- Disease Area
- Goals of project stated in 2-3 sentences
- Indication of Human Studies or Animal Studies
- Primary Study Material and Method

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

Application Instructions

Before starting the online application, please read the Instructions for All Awards.

The Foundation will be accepting applications for all awards via electronic format only. Applications should be submitted electronically through WizeHive.

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 Information

This section collects contact information regarding the principal investigator and the administrative official to be notified if a grant is awarded.

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 **81 characters**, including the spaces between words and punctuation.
- **Abstract:** 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.

- **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: a) increase patient access to care, b) develop future treatments and cures, c) demonstrate or improve the value of rheumatology care; and/or d) expand the impact of rheumatology. In this section, be succinct and use plain language that can be understood by a lay audience. The Project Narrative is made public for all awarded grants and used by the Foundation for marketing efforts.

- **Primary Study Material and Method:** Please select one or more of the checkbox options in the online application. This will be used to assign your application to the appropriate study section.

- **Research and Classification:** Information provided in this section will help to ensure each application is assigned to the most appropriate study section.

- **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, including Department of Veterans Affairs facilities and foreign sites, and provide an explanation in the resources section of the application.

- **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. 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.

  List the principal investigator (PI) first. When multiple PIs are proposed, list the contact PI first, then all additional PIs in alphabetical order. All other key personnel should be listed in alphabetical order

- **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. A biographical sketch, including research support information, will be required for these individuals as this highlights their accomplishments as scientists.

- **Biographical Sketches:** This section must contain the biographical sketches of all key personnel and other significant contributors, including consultants, following the order as listed under

those sections. Each biographical sketch **may not exceed five pages** and must use the current NIH biographical sketch format. 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.).

Research Plan

The research plan should include sufficient 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 not be included in your application. Each application is treated as a new submission.

Instructions:

- These sections should be prepared as separate Word documents and uploaded as PDFs.
- Use an Arial, Helvetica, Palatino Linotype, or Georgia typeface, a black font color, and a font size of 11 points or larger. (A Symbol font may be used to insert Greek letters or special characters; the font size requirement still applies.) A smaller font or different font type may be used for tables, graphs, figures, diagrams, charts, legends, etc.
- Margins should be **at least 1 inch** all around.
- Line spacing should be not less than 1 (please do not use "exact" spacing).
- Separate uploads include (see Items A-J for additional information on each section):
  - **Upload 1: Research Plan (Items A-D) and Literature Cited (Item E)**
    - **Items A-D 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.
    - Item E: While there is no character limit, it is important to be concise and to select only those literature references pertinent to the proposed research.
  - **Upload 2: Human Subjects/Vertebrate Animals Research (Items F-G)**
    - Although no specific character limit applies to this section of the application, be succinct.
  - **Upload 3: Consortium/Contractual Arrangements (Item H)**
  - **Upload 4: Resource Sharing (Item I)**
    - Although no specific character limit applies to this section of the application, be succinct.
  - **Upload 5: Research Benchmarks (Item J)**
    - Use the template provided.

Content 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 sketch 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 principal investigator's preliminary studies pertinent to this application, including his/her preliminary experience with and outreach to the proposed racial/ethnic group members.

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.

F. 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.

G. 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.

H. 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.

I. Resource Sharing: 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.

J. 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 principal investigators 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.

Budget

Download and complete the budget template to prepare your budget for entry into the online application. Budget should be uploaded as a PDF. Budget sections include:

Direct Costs

- **Personnel:**
  - Budget Table A - Complete budget table A for each person receiving salary support.
  - 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. Effective January 2016, the Executive Level II salary cap is **$185,100**. 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/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 on budget justification form.

- **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. **This must include travel of one investigator to the annual Foundation Investigators' Meeting (only one investigator allowed to attend per award).**

Indirect Costs:
Indirect costs are capped at **8 percent** of the direct costs. This includes any indirect costs in line with consortium/contractual 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 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. This should be uploaded as a PDF.

Consortium/Contractual Costs Budget (if applicable)

If applicable, download and complete the consortium/contractual budget template to prepare your budget for entry into the online application. Budget should be uploaded as a PDF. Required budget sections include:

Consortium/Contractual Costs:

- For the applicant organization budget, list the sum of all consortium/contractual costs.
- Consortium arrangements may involve personnel costs, supplies, and other allowable costs including indirect costs.
- Contractual costs for support services, such as the laboratory testing of biological materials, clinical services, or data processing, are occasionally sufficiently high to warrant a similar categorical breakdown of costs.
- Each participating consortium/contractual organization must submit a separate detailed budget using the consortium/contractual costs budget template.

Consortium Budget(s) and Justification:
Download and complete the consortium/contractual costs budget template to prepare your consortium budget(s) for entry into the online application. You should complete as many templates necessary for each consortium/contractual arrangement. All budgets should be combined and uploaded as a single PDF. Provide justification for all consortium/contractual costs and upload as a PDF.

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. This should be uploaded as a PDF.

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.

Checklist of Uploads to be Submitted through WizeHive

- ☐ Principal investigator biosketch (current NIH format)*
- ☐ Key personnel/Other significant contributors biosketches (current NIH format, uploaded as one document)*
- ☐ Research plan (10 page limit, Items A-D) and Literature Cited (Item E)*
- ☐ Human subjects/Vertebrate animals research (Items F-G)
- ☐ Consortium/Contractual arrangements (Item H)
- ☐ Resource sharing plan (Item I)*
- ☐ Research benchmarks (Item J)*
- ☐ Budget template*
- ☐ Budget justification*
- ☐ Consortium/Contractual budget template
- ☐ Consortium/Contractual budget justification
- ☐ Resources*
- ☐ Appendix (20 page limit)

*denotes a required upload