



ARTHRITIS FOUNDATION INVESTIGATOR AWARD PROGRAM GUIDELINES

Effective: June 17, 2013
Application Deadline: August 30, 2013

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Mission

The mission of the Arthritis Foundation is to improve lives through leadership in the prevention, control and cure of arthritis and related diseases.

**ARTHRITIS FOUNDATION INVESTIGATOR AWARD
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ARTHRITIS FOUNDATION INVESTIGATOR AWARD PROGRAM

DESCRIPTION OF ARTHRITIS FOUNDATION INVESTIGATOR AWARD

Arthritis Foundation Investigator (AFI) awards provide support for an outstanding established investigator with innovative, creative ideas that have the potential to move arthritis research toward better treatments and a cure. These AFI awards are for the support of research investigations that can be accomplished within a period of up to 5 years. The awards may provide salary and/or research support. This support is available to sustain individuals committed to a pioneering career dedicated to finding better treatments and a cure for arthritis.

Focus

- Rheumatoid arthritis
- Osteoarthritis
- Juvenile arthritis

Eligibility Criteria

Candidates must have a demonstrated commitment to arthritis research as indicated by prior publication history and scientific accomplishments.

- Each applicant must hold an MD, PhD, DO, DVM, or equivalent degree and a university faculty position at the associate professor level or above.
- Evidence of independence is required.
- The applicant *must* hold or have held in the past 12 months an NIH R01 or equivalent award (such as VA Merit, DOD, etc.) at the time of application.
- Individuals employed by the NIH and CDC are not eligible to apply.
- The most important criteria for selection are the productivity of the PI and potential of the project to yield groundbreaking results that impact the direction of research toward arthritis treatment, prevention or cure.
- Although applicants may apply for both an Innovative Research Grant and an Arthritis Foundation Investigator Award, an awardee may not be the principal investigator on more than one Arthritis Foundation Grant at any time.

Citizenship

- Applicants must be U.S. citizens or have permanent residence at the time of application.
- Awards may not be transferred out of the country.

Obligations

- This is a 5-year award based on approval of annual progress reports, following the template provided.
- One peer-reviewed renewal will be required before starting the 3rd award year.
- The award recipient is expected to speak on behalf of the Arthritis Foundation at least once per year and attend at least one fundraising event per year, at the request of Arthritis Foundation staff.
- Recipients are expected to demonstrate good stewardship of Arthritis Foundation funds.
- The award recipient is expected to serve on a peer-review panel for the Arthritis Foundation for at least 2 years, at the request of Arthritis Foundation staff.

TARGETED PROPOSALS

Applications will be accepted for novel projects with the potential for advances that will impact people with osteoarthritis, rheumatoid arthritis or juvenile arthritis. Proposed projects must not be a continuation of currently funded work, but may take that work in groundbreaking directions. Original investigations unrelated to current projects are encouraged.

Research areas of interest include but are not limited to:

- Understanding the disease pathogenesis of juvenile arthritis, including developmental biology, the developing immune system and environmental triggers.
- Understanding the human genetic, molecular, immunologic or environmental factors that initiate or drive the early progression of disease in patients with rheumatoid arthritis.
- Increasing knowledge of how normal joint homeostasis is disrupted in osteoarthritis by metabolic, inflammatory, and mechanical stresses that affect cartilage, subchondral bone, and/or synovial tissues and ways to detect and monitor the trajectory to joint failure.

ABBREVIATED PROPOSALS

The AFI Award proposal format is not the same as those used for traditional individual NIH research grants (R01). The proposal shall describe past research accomplishments, the potential of the AFI to provide new directions and innovations, and broadly discuss projected research studies; the application should not contain detailed protocols or focus heavily on the design or interpretation of individual experiments. The applicant should clarify how the proposal differs from other currently funded projects in their laboratory, or how these funds will be used to expand upon existing projects in unique ways. As part of good stewardship of Arthritis Foundation funds, all awardees will be required to submit additional details for the project plan including, milestones and a budget that must be approved before the disbursement of funds.

APPLICATION INSTRUCTIONS

Remember: Online Application Submission is Required

The Arthritis Foundation requires applications to be submitted electronically, through proposalCENTRAL (<https://proposalcentral.altum.com>). You must begin your application submission process by creating a proposalCENTRAL account or by logging in with your current proposalCENTRAL account if you have previously been issued one as either a reviewer or applicant.

Instructions and application forms should be downloaded from the proposalCENTRAL website. Once you have converted the completed MS Word templates to PDF files, return/attach them through proposalCENTRAL along with the rest of your application, so that it can be transmitted electronically to the Arthritis Foundation.

For help with the electronic application process, please contact the help desk for proposalCENTRAL:

by e-mail: pcsupport@altum.com
by phone (toll-free): 1.800.875.2562

Deadline

The deadline for online submission is: **August 30, 2013, 5:00 PM Eastern Time.**

Do not submit your application electronically before obtaining the required institutional signatures.

You MUST ALSO PRINT AND MAIL the original Signature Page with all signatures to:

**Arthritis Foundation
Research Department
1330 West Peachtree St. NW, Suite 100
Atlanta, GA 30309-2904.**

DO NOT mail the entire application to the Arthritis Foundation; just the Signature Page.

*The original signed Signature Page must be postmarked by **August 30, 2013** and received by the Arthritis Foundation Research Department within seven business (7) days after the electronic submission deadline. If the deadline falls on a weekend or national holiday, use the first postal workday following the deadline as the submission/postmark day.*

Late or Incomplete Applications

An application will not be reviewed if: (1) it arrives after the deadline, (2) is incomplete, (3) the principal investigator is ineligible; (4) it exceeds the page limit, or (5) uses a printer font smaller than standard type size. If you are uncertain about your eligibility, contact the Research Department for clarification. An application will be considered incomplete if it fails to follow the instructions or if the material presented is insufficient to permit an adequate review without the solicitation of a substantial amount of additional information. The principal investigator bears the responsibility for submission of a complete application. **No award can be made** until evidence of the IRB/IACUC approval has been submitted. Unless specifically required by these instructions (e.g., IRB or IACUC approvals, change in other support), do not send supplementary or corrective material pertinent to an application after the receipt date without its being specifically solicited or agreed to by prior discussion with the staff.

Change of Application Status

Should your application status change after submission including a withdrawal of application, a change of address, etc. you should notify the research department via e-mail immediately at GrantSupport@arthritis.org.

REVIEW PROCESS

ADMINISTRATIVE AND PEER REVIEW

All applications will first be administratively reviewed for eligibility and responsiveness to the research focus specified in this RFA. Applications that do not meet eligibility or responsiveness requirements will be administratively withdrawn and will not be reviewed or scored. Proposals that do meet the requirements will undergo a national peer review process in which proposals are scored according to scientific merit and responsiveness to the RFA. Each grant will be reviewed by at least three experts in the field. Applicants will be provided with a very brief critique listing reasons for the assigned score.

Rating of Applications

To judge the merit of the application, reviewers will comment on the following criteria. Please be sure that you fully address these in your proposal. Generally the candidate, the innovativeness of the science, and responsiveness to the RFA are being evaluated. The most important criteria for selection are the productivity of the PI and potential of the project to yield groundbreaking results that impact the direction of research toward arthritis treatment, prevention or cure. The

remaining factors enter into the deliberations, but the relative weight given to each may differ from case to case.

- **Demonstrated commitment to arthritis research:** Has the research program of the candidate focused on basic or applied science related to arthritis research? Does the applicant indicate a clear commitment to arthritis research in the proposed study? Does the proposed study illustrate this commitment?
- **Investigator Independence:** Independence is assessed by publications and research funding as a principal investigator. Is the candidate established as an independent investigator?
- **Prior or current independent national-level awards:** Does the candidate's track record regarding funding provide evidence for independence, excellence and potential for future success? Has the candidate held independent national awards, such as an NIH R01 and/or equivalent? (e.g., VA Merit Award, NSF Grant, or PI of a project on a Program Project Grant from NIH). NIH "K" series awards are not considered equivalent to R01.
- **Innovative, novel research direction:** Described in the abbreviated application. Is the research direction described by the candidate likely to lead to significant contributions? Does the candidate pose an innovative research direction that challenges existing paradigms or critical barriers to progress in the field? Does the candidate propose to develop or employ novel concepts, approaches or technologies? Does the proposed research direction address one of the topics described in the RFA?
- **Environment:** Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed studies benefit from unique features of the scientific environment, or subject populations, or employ useful collaborative arrangements? Is there evidence of institutional support?

Assignment for Scientific Review

To assist with the review, applicants are asked to self-select an area of science most applicable to proposed projects and to identify the form of arthritis to which the study most closely applies. This information will be used to assist assignment of reviewers. Please indicate from the following fields of science where reviewers of your application might best be able to assess the quality of your proposal.

1. **Biochemistry:** studies at a molecular level.
2. **Cell Biology:** studies at a cellular level.
3. **Cellular Immunology:** studies focused mainly on cellular mechanisms of immune responses.
4. **Clinical Immunology:** studies focused mainly in the field of clinical immunology.
5. **Clinical/Therapeutics/Outcomes:** studies that involve Epidemiology, Health services research, Quantitative research and quality of life research, and clinical effectiveness research, and other evaluation research (including educational programs).

6. **Genetics:** studies of genetic associations with OA, RA, and JA.
7. **Inflammation:** studies are designed to understand inflammation including endothelial cell biology and leukocyte endothelial adhesion, Fluid phase mediators of inflammation such as complement, chemokines, and acute phase reactants, and the biology of cytokines including their production and actions, but not the lymphocyte-related aspects of cytokine biology.
8. **Molecular Biology and Gene Regulation:** studies that are designed to clone and sequence genes relevant to rheumatic disease, evaluate genetic structure, understand gene regulation; expand knowledge of genetic epidemiology, and to identify disease susceptibility genes.
9. **Molecular Immunology:** studies are designed to understand at a molecular level the immune system.
10. **Technologies/Biomechanics:** studies of biomaterials; biomechanics, computing and medical informatics, and medical technology (diagnostic and treatment).

Notification

Peer review will take place during the months of September through November. Award notices will be available December 2013. The Research Department will send score information, critiques and award notifications via email.

Source of Funds

Funds of the Arthritis Foundation are obtained principally from public donations collected through local offices of the Foundation. The amount available for grants and awards each year is determined by the success of the fundraising efforts. Funds for grants are also derived from partnerships established by the Arthritis Foundation with other groups with interest in research topics funded in the Arthritis Foundation portfolio of grants. To disseminate information about the Foundation research program to our volunteers and to the public, grantees are expected to occasionally give brief presentations of their research to professional audiences or the general public.

TERMS OF AWARD

Start Date

Funded awards may begin on the first of any month between January 2014 and March 2014. The grant may not begin before January 1, 2014.

Award Period/Amount of Award

- Funding is provided up to a level of \$100,000 per year for no more than 5 years.
- The award amount includes indirect costs not to exceed 8% per year.
- These grants can cover the salary and fringe benefits for the principal investigator or other essential personnel, consumable supplies, equipment, travel and other items to conduct the proposed research.
- No more than 3 grants will be awarded per year.

IRS

Personnel compensated in whole or in part with funds from the Arthritis Foundation are not considered employees of the Foundation. Institutions shall be responsible for issuing the appropriated IRS tax filings for all individuals receiving compensation from Grantor's funds hereunder, and shall be responsible for withholding and paying all required federal and state payroll taxes with regard to such compensation.

Scientific Conduct and IRB Approval

The Arthritis Foundation does not assume responsibility for the conduct of the investigation or the acts of the investigator since both are under the direction and control of the grantee institution and subject to the institution's medical and scientific policies. Grantee institutions must safeguard the rights and welfare of individuals who participate as subjects in research activities by reviewing proposed activities through an Institutional Review Board (IRB) as specified by the National Institutes of Health (NIH) Office for Protection from Research Risks (OPRR). In addition, institutions must adhere to current U.S. Department of Health and Human Services guidelines regarding financial conflict of interest, recombinant DNA, biohazards, research misconduct, and vertebrate animals.

POLICY

Name: **Use of Animals in Biomedical Research**

Recommended by: **Research Advisory Council**

Adopted/Revised: **November 17, 2007**

Approved by: **Board of Directors**

The Arthritis Foundation is committed to the support and encouragement of biomedical research in order that new knowledge may be discovered, which will lead to more effective treatment and diagnosis and eventually to the cure and prevention of all forms of arthritis and the rheumatic diseases.

The Arthritis Foundation recognizes the absolute necessity to use animals in medical research in order to avoid the direct testing of new research on humans, before safety and effectiveness have been established by biological models. The advantages provided by animals include models of disease processes, great variability, genetic control, rapid reproduction of generations, and large numbers of subjects, which can be economically kept. The Foundation strongly opposes excessive and inflexible restrictions of the use of laboratory animals in research.

Prior to supporting the research in which animals are used, the Arthritis Foundation must be assured of adherence to the following principles and conditions.

1. Animals shall be used in biomedical research only when no other means of obtaining scientifically sound, valid and useful results are available.
2. The minimum number of appropriate animals required to obtain and validate results shall be used.
3. The acquisition, care and use of animals must be in accordance with all applicable federal, state and local laws and regulations.
4. Certifications must be received from research facilities prior to being approved for a research grant that the facility(ies), its researchers and employees adhere to the Animal Welfare Act, National Research Council *Guide for the Care and Use of Laboratory Animals*, and any appropriate U.S. Department of Agriculture or National Institutes of Health regulations and standards.
5. In cases requiring the death of an animal, only the most appropriate and humane form of euthanasia shall be used consistent with the purpose of the research.

POLICY

Name: **Patent and Intellectual Property**
Recommended by: **Research Committee**
Adopted/Revised: **November 16, 1996**
Approved by: **Board of Trustees/House of Delegates**

The following Patent and Intellectual Property Policy of the Arthritis Foundation will be adhered to by, and is binding on, all Grantee Institutions, their assignees, and Awardees as defined herein. Acceptance of the award by the Grantee Institution and Awardee constitutes acceptance of the terms and conditions outlined herein.

I. DEFINITIONS

1. The term "Foundation Supported Intellectual Property" as used in this policy means all data, information, inventions, formulas, techniques, processes, concepts, systems, protocols, programs or devices (electrical, electronic or mechanical), whether or not patentable, or subject to copyright or trade secret protection, that are created, made, developed, or perfected by the Grantee Institution, its assignee, or Awardee with support by the Arthritis Foundation.
2. The term "Grantee Institution" as used in this policy means the parent institution in which the Awardee holds a position, which is responsible for administering the award, and is signatory for all matters relating to the award, including use of human subjects, animals, recombinant nucleic acid, safety, and Patent and Intellectual Property Policy of the Arthritis Foundation.
3. The term "Awardee" as used in this policy means the principal investigator or primary recipient of an Arthritis Foundation award or grant.

II. TERMS AND CONDITIONS

4. Notification, Cooperation and Confidentiality

The Grantee Institution or its assignee and Awardee will notify the Research Department of the Arthritis Foundation at the earliest practical time of any Foundation Supported Intellectual Property and will further notify the Arthritis Foundation whether the Grantee Institution or its assignee intends to pursue patent application or copyright protection of the Foundation Supported Intellectual Property. The Grantee Institution or its assignee will consider seriously and in good faith, any comments or objections the Arthritis Foundation may have concerning such patent application or copyright protection and agrees to the provisions as stated in paragraph 9, below. The Foundation agrees to keep all such patent application or copyright protection information confidential and not to release any information relating to such patent application or copyright protection while prosecution is pending.

5. Ownership Rights

If the Grantee Institution has a patent or intellectual property policy or procedure that

requires employees, private contractors or agents to assign their ownership rights to the Grantee Institution or its assignee and such policy or procedure is binding on the Awardee, then the Grantee Institution may pursue patent protection for any Foundation Supported Intellectual Property. If the Grantee Institution does not have such a policy or procedure, if there is no Grantee Institution, or if the Grantee Institution or its assignee chooses to suspend or abandon the pursuit of a patent or other legal protection for any reason, or is unsuccessful in the commercialization of any Foundation Supported Intellectual Property, then the Awardee and the Grantee Institution or its assignee, as applicable, will assign, if the Arthritis Foundation requests such assignment in writing within 90 days of notification, all of whatever right, title and interest they may have in the Foundation Supported Intellectual Property and in any patents or patent applications or copyright protection thereon to the Arthritis Foundation, provided, however, that if the invention results in part from federally-sponsored research, any such assignments to the Foundation require the prior approval of the federal granting agency. In the absence of such approval, Grantee Institution shall not be required to assign such inventions and rights to the Foundation. However, the Awardee and the Grantee Institution or its assignee shall have a perpetual, royalty-free right to use Foundation Supported Intellectual Property for educational, research, and academic purposes. The costs of prosecution of any patent application or copyright protection shall be borne by the party prosecuting same.

6. Distribution of Income

If the Grantee Institution or its assignee obtains and retains the rights to the Foundation Supported Intellectual Property as stated in paragraph 5 above, then the distribution of any income derived from such property, including any equity dispositions, shall be according to the policies of the Grantee Institution. When income exceeds \$250,000, there shall be a distribution of income or equity distribution to the Arthritis Foundation reasonably related to the Foundation's proportion of support, unless such distribution is prohibited under applicable federal or state law. Whenever income is received by a Grantee Institution which would otherwise be sharable with the Arthritis Foundation under this Policy, but the Grantee Institution determines that distribution of such income is prohibited by applicable federal or state law, the Grantee Institute shall notify the Arthritis Foundation of (i) the amount of income received and the periods during which it has been received; (ii) the proportion of the Arthritis Foundation's support in the creation, etc. of the Foundation Supported Intellectual Property, or the Grantee Institution's most reasonable estimate thereof and the basis for such estimate; and (iii) the specific provision of federal or state law which the Grantee Institution believes prohibits distribution of a proportionate part of the income to the Arthritis Foundation.

7. Licenses

Any licenses made by the Grantee Institution or its assignee for any Foundation Supported Intellectual Property shall include terms similar to the following, as appropriate to the licensee, obligating the licensee to use its best efforts to commercialize any Foundation Supported Intellectual Property:

The licensee agrees to exert its best efforts to commercialize or cause to be commercialized the [Foundation Supported Intellectual Property] as rapidly as practical, consistent with sound and reasonable business practices and judgment. In the event that the licensee has failed to commercialize the [Foundation Supported Intellectual Property] within a number of years determined to be reasonable for the [Foundation Supported Intellectual Property], the Grantee Institution or its assignee upon conferring with the Foundation shall have the right to convert an exclusive license to a non-

exclusive license or to terminate a non-exclusive license. If the licensee has an ongoing and active research, development, manufacturing, marketing or licensing program as appropriately directed toward the production and sale of the [Foundation Supported Intellectual Property], the same would be deemed to be sufficient evidence that the licensee has commercialized the [Foundation Supported Intellectual Property].

8. Publicity

The Arthritis Foundation reserves the right to publicize Arthritis Foundation supported research. The Foundation will provide the Grantee Institution and the Awardee prior notice and an opportunity for comment on any such public acknowledgment. The Arthritis Foundation name and logo, however, may not be used in association with any Foundation Supported Intellectual Property without prior approval of the Foundation.

9. Use by Arthritis Foundation

The Arthritis Foundation may have the use of any Foundation Supported Intellectual Property the ownership of which was retained by the Grantee Institution or its assignee under paragraph 5 above, notwithstanding the grant of any exclusive license under paragraph 7 above, without payment of royalties or fees, but solely for use within the Foundation for research and non-commercial purposes by its Awardees via materials transfer agreement or confidential disclosure agreement.