



2011 Request for Proposals
Investigator-Initiated Grants
Program Guidelines & Application Instructions

Application Postmark Deadline: December 1, 2011

Awards administered by:



**AMERICAN COLLEGE OF RHEUMATOLOGY
RESEARCH AND EDUCATION FOUNDATION**

2200 Lake Boulevard NE
Atlanta, GA 30319
404-633-3777 (phone)
404-633-1870 (fax)
www.rheumatology.org/REF

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

PROGRAM GOALS

Within Our Reach is a multi-year research initiative which will fund over \$30 million to accelerate high-risk, high-reward research in inflammatory arthritis not normally funded by the National Institutes of Health or other peer reviewed funding sources. Advancing research in this important area will enhance the practicing rheumatologist's ability to recognize various causes of the disease, predict onset of disease, individualize treatment, prevent joint damage, and improve joint function.

Through this program, the REF seeks to support projects that address basic, translational and clinical aspects of inflammatory arthritis. Outcomes from these projects should lead to new insights into the etiology, pathogenesis and treatment of these diseases. All applications must be relevant to the purpose and goals of the *Within Our Reach* initiative described below. For this cycle, the REF is seeking applications for the following grant types:

- **Pilot Grants** (*see separate RFP for pilot grants*)
- **Investigator-Initiated Grants**

Expanding Opportunities for Scientific Research

For this next phase, the program will be expanded to include rheumatoid arthritis as well as other conditions where inflammatory arthritis is the major pathology. These include the spondylarthropathies (psoriatic arthritis, reactive arthritis, ankylosing spondylitis, and undifferentiated spondylarthropathy) and juvenile idiopathic arthritis.

The following conditions, which can include arthritis as a feature, **will not** be supported by this program, and include but are not limited to:

- Systemic Lupus Erythematosus
- Systemic sclerosis
- Polymyositis/Dermatomyositis
- Behçet's Disease
- Vasculitis
- Systemic Onset JIA/Adult-Onset Still's Disease
- Autoinflammatory Disorders (Familial Mediterranean Fever, CINCA/NOMID, TRAPs, etc)

In addition, studies that focus on predisposing conditions such as psoriasis, genitourinary infections, or inflammatory bowel disease will not be supported by this program.

If you have questions about the relevance of your proposal, please contact REF staff before preparing an application.

AWARD TERMS & FUNDING

The investigator-initiated grants are funded for two years at an amount of up to \$200,000 per year, including eight percent indirect costs. Total costs cannot exceed \$400,000 over the 2 years of the award. The number of grants awarded will depend on the quality of applications received and funds available.

APPLICATION POSTMARK	DECISION DATE	START OF AWARD TERM
December 1, 2011	May 1, 2012	July 1, 2012

TABLE OF CONTENTS

SECTION I: Description of Grants

- Program Goals 2
- Important Dates 3
- Description of Investigator-Initiated Grants 5
- Research Categories..... 5
- Award Criteria 6

SECTION II: Terms of Award

- Award Period 8
- Award Amount 8
- Benchmarks..... 8
- IRS Provisions..... 8
- Equipment 8
- Scientific Conduct/IRB Approval..... 9
- Principal Investigator Assurance..... 9
- Cancellation..... 9

SECTION III: Submission & Review Process

- Submission Requirements 10
- Cover Letter..... 10
- Application Packet..... 10
- Supplemental Information..... 11
- Rating of Applications 12
- Review/Notification 12

SECTION IV: Conditions of Award

- Percent Time and Effort..... 13
- Meetings..... 13
- Award Receipt Requirements..... 13
- Financial Disbursements..... 14
- Reporting Requirements..... 14
- Publications..... 15
- Patent and Intellectual Property Policy..... 16

SECTION V: Application Instructions

- General Instructions (format and pagination)..... 19
- Specific Application Information..... 21
 - Face Page..... 21
 - Project Description (Abstract), project sites, key personnel..... 24
 - Table of Contents..... 25
 - Budget Summary..... 25
 - Budget Justification..... 27
 - Biographical Sketch..... 27
 - Resources..... 27
 - Research Plan..... 27
 - Benchmarks..... 30
 - Appendix..... 30

SECTION I: DESCRIPTION OF GRANTS

INVESTIGATOR-INITIATED GRANTS

It is anticipated that these projects will be carried out primarily by a single investigator / laboratory over a two-year period. These grants are not meant to provide support for the compression of a three year research project into a shorter time period, for career development, or for educational activities other than research. Projects may include the development/validation of biomarkers using patient-derived material; studies to understand human disease pathophysiology; and studies to improve diagnosis, prognosis or treatment of human subjects. The principal investigator is required to devote a minimum of 20 percent full-time professional research effort to the project.

RESEARCH CATEGORIES

Innovative Basic Science

Innovative basic science research grants are focused on fundamental biologic mechanisms, are not required to utilize human materials and may incorporate animal models.

These awards provide support for investigators to conduct exploratory research on new issues or approaches for which there is currently an insufficient theoretical or empirical basis for a competitive research project application. In contrast to research projects, research proposed in innovative basic research applications may be formative in nature and need not be designed to produce definitive results.

The innovative basic research grant is intended to appeal to investigators with research experience in rheumatic disease and those who are interested in exploring a new scientific question and to investigators without such experience but who are interested in applying their knowledge or methodologic skills from another research area to a scientific question in rheumatoid arthritis, or a related area (see above).

Innovative grants may have very little or no preliminary data. Applicants should focus on the newness of the proposed idea and ability to change the field. In addition, applicants should be aware the “innovative grant” mechanism is not for mature research projects or studies addressing a scientific question that can only produce a small, incremental advance in knowledge. The program is designed for truly novel proposals.

Investigators are encouraged to submit research proposals that are highly innovative or represent a special opportunity to address unique research questions. Research proposals may involve substantial experimental risks with the potential for highly significant outcomes. For example, an investigator may have evidence that a novel pathway mediates the loss of bone in patients with arthritis, or that an unanticipated type of cell or soluble mediator is centrally involved in the development of inflammation. These early studies in many instances can lead to promising breakthroughs in understanding the cause of inflammatory arthritis and in the development of novel drugs.

Translational Research

Translational research grants will focus on the direct study of patients and patient-derived materials to improve our understanding of inflammatory arthritis.

Basic research into the mechanisms of disease has accelerated in recent years, but the knowledge gained has been slow to reach the clinic and be applied to patient care. Both the translation of basic research knowledge into improved patient care and the translation of clinical insights into hypotheses that can be validated in the laboratory are important to accelerating research in inflammatory arthritis.

The translational research grants support the two-way transfer between work at the laboratory bench and patient care. For example, an investigator(s) may have a novel way to identify genes that cause this disease or find environmental exposures that influence the development of inflammatory arthritis. Another example is the search for novel blood markers (biomarkers) that identify patients at risk for complications of the disease or its treatment. Translational research includes the mechanistic studies of the joint and its cells and tissues in inflammatory arthritis using newly developed methods in proteomics, genomics and systems biology. Translational research also includes proof-of-principle studies of novel treatment modalities.

Clinical Practice

Clinical practice grants will focus on translating recent advances in the prevention and treatment of rheumatoid arthritis and the pre-defined related conditions (see above) into clinical practice for individuals and communities at risk.

This program seeks applications for clinical or behavioral studies to develop improved methods of health care delivery to patients with inflammatory arthritis or at risk for developing it. Examples include studies of improved methods of management of arthritis using pharmacological and/or non-pharmacological strategies or cost-effective community-based strategies to identify individuals who are at-risk. Clinical practice grants may also focus on issues that directly affect the quality of care in clinical practice of rheumatology and patient access. For example, improving our understanding of the health economics and benefits of current therapies will increase appropriate access to novel therapies. Projects evaluating factors that may affect quality of life or treatment for individuals with inflammatory arthritis are also appropriate. Addressing disparities in health care access for patients with inflammatory arthritis is another important research topic that may improve the overall health of the patient population.

AWARDS CRITERIA

Eligibility

The principal investigator must be an ACR or ARHP member at the time of application and for the duration of the award period. Individuals with doctoral degrees (MD, PhD, DO or equivalent) at the assistant professor level or higher at any nonprofit U.S. institution are eligible to apply. Evidence of independence is required. Independence is demonstrated by holding a leadership position within an existing research program, demonstrating scholarly productivity, or providing evidence of other applicable experience attesting to a strong record of scientific productivity and accomplishments. The principal investigator is required to devote a minimum of 20 percent overall full-time professional effort to the project. Previous recipients of *Within Our Reach* grants may apply, but must propose a new project. Continuations of previously funded projects are not allowed, but previous recipients may apply for funds that translate promising pre-clinical studies to human inflammatory arthritis. *Individuals at the NIH, FDA and CDC are not eligible to apply.*

Citizenship

At the time of application, and for the duration of the award period, the Principal Investigator must be a citizen or non-citizen national of the United States, or be in lawful possession of a permanent resident card. Non-citizen nationals are generally persons born in outlying possessions of the United States (e.g., American Samoa and Swains Island). Individuals on temporary (J1, H1) visas 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.

Relevance

Outcomes from these grants should lead to new insights into the etiology, pathogenesis and treatment of inflammatory arthritis. For the purposes of this research program, inflammatory arthritis includes rheumatoid arthritis as well as other conditions described on page 2 of this RFP.

Applications will be considered highly relevant if the research proposal includes some or all of the following attributes:

- dedication to a research question in the pre-defined area of inflammatory arthritis
- production of results with direct applicability to our understanding of human disease
- stimulation of a real interchange across disciplines leading to advances in the prevention, control and cure of inflammatory arthritis

All applications must be relevant to the purpose and goals of the *Within Our Reach* initiative.

SECTION II: TERMS OF AWARD

AWARD PERIOD

Grants will be awarded for a two-year period and are not renewable.

AWARD AMOUNT

Funding for the two year period will be up to \$200,000 per year -\$400,000 total- including indirect costs that must not exceed eight percent of the total award amount. The total salary requested must be based on a full-time, 12-month calendar year appointment, and the Principal Investigator is required to devote a minimum of 20 percent overall full-time professional effort to the *Within Our Reach* grant.

BENCHMARKS

Any individual accepting an award from the ACR Research and Education Foundation will be required to provide benchmarks of progress toward the specific aims of the funded project and an estimated timeline for completion of those benchmarks. This information will be used to facilitate communication about projects to the Scientific Advisory Council and to assess progress. Renewal of the award in year two is contingent on submission of an annual progress report showing substantial accomplishment and progress toward benchmarks specified in the original application. Failure to meet benchmarks in a timely manner may result in delayed funding or award cancellation.

IRS PROVISIONS

Personnel compensated in whole or in part with funds from the ACR Research and Education 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.

EQUIPMENT

Title to all equipment purchased with ACR Research and Education Foundation funds shall vest in the Sponsoring Institution provided that, for the duration of the research grant and for the period not to exceed sixty days from the termination date of the grant, the ACR Research and Education Foundation may, at its option, direct the Sponsoring Institution to transfer title to a new Sponsoring Institution.

SCIENTIFIC CONDUCT/IRB APPROVAL

The ACR Research and Education 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 Sponsoring Institution and subject to the institution's medical and scientific policies.

Ethical Standards: All research involving human subjects, laboratory animals, and recombinant DNA techniques must show documented compliance with NIH guidelines, the same as provided by the Sponsoring Institution's clinical and research review board. Awardees must assure compliance with regulations promulgated by the US Department of Agriculture under amendments of the Animal Welfare Act, public law 99-198. In addition, all activities supported by an REF research award must comply with all applicable US Department of Health and Human Services regulations with respect to the rights and welfare of human subjects.

Malpractice Disclaimer: The REF is not responsible for any malpractice suit arising from any activity supported by the award. The award recipient and Sponsoring Institution agreed to hold the REF harmless from any claims arising from such programs.

Disclosure of Potential Conflict(s): For disclosure purposes, any relationship with industry that the applicant or sponsoring institution might feel would be a potential conflict of interest should be noted in a letter from the institution.

PRINCIPAL INVESTIGATOR ASSURANCE

Research performed under REF grants is the sole responsibility of the Principal Investigator of that grant and the Sponsoring Institution. The Principal Investigator and Sponsoring Institution are both responsible for ensuring that all research activities are conducted in a safe, responsible, and ethical manner.

CANCELLATION

Any grant may be terminated or cancelled by the REF upon written notice to the Awardee and the responsible Administrative Official at the Grantee Institution if in the sole discretion of the REF: (1) the Awardee is unable to carry out the research for any reason, (2) the Awardee or any member of his or her research team is found by an institutional investigation to have committed scientific misconduct or fraud, (3) the Awardee has failed to comply with any of the terms and conditions of this award, (4) the REF concludes that the Awardee has received overlap funding for the award or that the funds are not being used for the purposes originally outlined in the research protocol or (5) the IRB approval for the grant has been rescinded.

Scientific and/or budgetary overlap between REF grants and other funding sources (including NIH, CDC, and other foundations) is not permitted. Recipients must supply details regarding other support each year in their progress report. In addition, recipients must notify the REF upon Notice of other Award(s) if there is potential overlap. The REF Scientific Advisory Council will decide whether significant overlap exists and may cancel or reduce the amount of the REF award accordingly.

SECTION III: SUBMISSION & REVIEW PROCESS

SUBMISSION REQUIREMENTS

Forward the complete application packet (see below for details) to the address below. It is highly recommended that applicants send the application packet via a method with a tracking number (e.g., FedEx, UPS, etc.). All application packets must be postmarked no later than December 1, 2011. Send complete applications packets to:

Within Our Reach Grants Program
ATTN: Mary Wheatley, Sr. Director, Research
ACR Research and Education Foundation
2200 Lake Boulevard NE, Atlanta, GA 30319

APPLICATION PACKET

- Submit one hard copy of the application, including the signed **original** face page with signatures in blue ink, the full appendix and additional items as outlined below.
- Submit the following materials in one package:
 - **Cover Letter** - An electronic copy of the cover letter should be included on the CD in the 'ADMIN' folder (see below). The letter should contain the following information:
 - Application title
 - Type of grant being requested and applicable category (e.g., Investigator-Initiated Innovative Basic Science Research Grant)
 - Brief description (two to three sentences) of grant proposal
 - List of people who should not review your application and why (e.g., conflict of interest, collaborators, competitors)
 - Disciplines involved, if multidisciplinary
 - Principal Investigator percent effort budgeted
 - Names of Co-Investigators and percent effort budgeted
 - *A response to previous reviews may not be included. It is not appropriate to state this is a resubmission of an application from a prior cycle.*
 - **Original Application** - must be single-sided, with an authorized organization official's signature on the Face Page in blue ink. Assemble the pages in the order specified in the Table of Contents. Include full appendix.
 - **One CD of the application** - Each required application item 1-10 listed on the Table of Contents (See Form Page 4) must be saved as a separate PDF file (without security restrictions using Windows file system media), and labeled accordingly. Item 11, the Appendix, may include several separate PDF files. Each PDF file should then be organized into four separate folders to be included on the CD as follows:

- 1) **FirstInitialLastName_ADMIN** (example: 'JSMITH_ADMIN'), to include the following files: Cover Letter, Face Page (limit to one page), Table of Contents, Project Description, Performance Sites and Key Personnel, each labeled appropriately (e.g., 'Facepage.pdf').
- 2) **FirstInitialLastName_BUDGET**: includes Budget Summary, Budget Justification, Biosketch and Resources, each labeled appropriately (e.g., 'Budget.pdf').
- 3) **FirstInitialLastName_RESEARCH**: includes Research Plan and Research Project Benchmarks, each labeled appropriately (e.g., 'Benchmarks.pdf').
- 4) **FirstInitialLastName_APPENDIX**: includes all Appendix materials, if applicable any consortium/contractual budget sheets, each labeled appropriately (e.g., 'Appen1.pdf').

SUPPLEMENTARY INFORMATION

Unless specifically required by these instructions (e.g., vertebrate animals verification), do not send supplementary or corrective material after the submission date unless REF staff directly solicits this information.

RATING OF APPLICATIONS

Reviewers will be asked to evaluate applications based on the likelihood that the proposed research will have a substantial impact on the mission of *Within Our Reach* initiative. The scientific peer review group will address and consider each of the following criteria in assigning the application's overall score, weighing them as appropriate for each application.

Investigator: *Is the investigator appropriately trained and well suited to carry out the planned studies? If the investigator does not have experience in inflammatory arthritis, are there appropriate collaborative arrangements with experts in this area?*

Relevance to Inflammatory Arthritis: *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 inflammatory arthritis research?*

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?*

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? Is the proposed research feasible within the term of the award?*

Potential impact on the field: *Does the project challenge existing paradigms or develop new methodologies or technologies?*

REVIEW/NOTIFICATION

All grant applications will be peer-reviewed by study section(s) constituted by the REF. The REF Board of Directors will make all final funding decisions. Applicants will be notified of funding decisions by **May 1, 2012**.

SECTION IV: CONDITIONS OF AWARD

Upon acceptance of the *Within Our Reach* grant, the Principal Investigator and Sponsoring Institution will be required to sign a Conditions of Award agreement outlining in detail the various requirements of the grant. In addition to the administrative items, there are certain responsibilities that will be expected of the Principal Investigator and Sponsoring Institution, including a minimum effort requirement and attendance at annual *Within Our Reach* Investigators' Meetings.

PERCENT OF TIME AND EFFORT

The Principal Investigator is required to devote at least 20 percent overall full-time professional effort to the *Within Our Reach*-funded project. Percent effort should be calculated based on a full-time 12-month calendar year appointment at the Sponsoring Institution.

MEETINGS

The REF sponsors an annual *Within Our Reach* Investigators' Meeting. All *Within Our Reach* grant recipients are required to attend this meeting to share the status of their funded research. This meeting will be limited to Principal Investigators, REF leadership, and invited guests of the REF Board of Directors and Scientific Advisory Council. All materials/presentations of the meeting will be held in strict confidence. Investigators will be provided advance notice as to the dates and locations of these meetings. Failure to participate may result in grant cancellation.

Travel costs to attend this meeting must be included in the grant budget for each year.

>> Save the date! The 2012 Within Our Reach Investigators' Meeting will be held January 19, 2012 in Santa Fe, New Mexico.

AWARD RECEIPT REQUIREMENTS

The following information must be submitted after receiving notification of funding decision in order for funds to be awarded to your institution:

- Current Other Support (Use the sample format from NIH) – Please be reminded that a minimum of 20 percent overall full-time professional effort per year is required for this award.
- Certifications if Human Subjects are involved - Please provide the institution assurance type and number and the certification date of IRB review and approval. Pending approvals are acceptable; however IRB approval must be submitted within 60 days of receipt of funding.
- If Vertebrate Animals are involved -Please provide the institution assurance number, verification of IACUC approval with date, and any IACUC imposed changes. Pending approvals are acceptable; however IRB and/or IACUC approval must be submitted within 60 days of receipt of funding.

- Human Subjects Education for grants involving Human Subjects - Provide certification that each person identified under Key Personnel involved in human subjects research has completed an educational program in the protection of human subjects. A letter with the key personnel listed stating this HSPR certification from your institution's IRB will suffice.

FINANCIAL DISBURSEMENTS

Funding for the two-year period will be up to \$200,000 per year-\$400,000 total-**including indirect costs not to exceed 8 percent of the total award amount.**

All contractual documents must be received and compliant documents signed before financial disbursements will be made. The disbursement schedule is as follows:

Year 1:	July 2012	\$100,000	January 2013	\$100,000
Year 2:	July 2013	\$100,000	January 2014	\$100,000

Budget reconciliation is also required after the first year of the grant. The reconciliation must be submitted by September 1, 2013. Upon successful completion of the two-year grant, investigators must submit a final report and a final budget reconciliation of their research project. This report is due no later than September 1, 2014.

****All unexpended funds must be returned to the REF 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 REF Scientific Advisory Council.

REPORTING REQUIREMENTS

Award Evaluation Metrics

In an effort to help the REF 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.

Annual Progress Reports

The recipient must provide the REF with a progress report identifying progress towards benchmarks of your proposal. Recipient must report on the following: project outcomes, progress and updated benchmarks, submitted or published articles and abstracts, patents and other grants obtained. Format and exact due date 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 grant cancellation. Failure to comply may also affect the applicant and sponsoring institution's eligibility to receive future REF funding.

Benchmarks

Recipients are required to provide benchmarks of progress toward the specific aims of the funded project and an estimated timeline for completion of those benchmarks. This information will be used to facilitate communication about projects to the Scientific Advisory Council and to assess progress. Renewal of the award in year two is contingent on submission of an annual progress

report showing substantial accomplishment and progress toward benchmarks specified in the original application. Failure to meet benchmarks in a timely manner may result in delayed funding or award cancellation.

Publications

It is expected that the results of research supported by the ACR Research and Education Foundation shall be published as rapidly as possible in the open literature, consistent with the high standards of scientific excellence and rigor. The responsibility for publication lays exclusively with the Principal Investigator and his/her collaborators and the result of any work supported by the ACR Research and Education Foundation may be published without prior review of the REF. Any publication arising in whole or in part from a research grant funded by the REF shall acknowledge funding support by the ACR Research and Education Foundation. Recommended language for acknowledging the ACR Research and Education Foundation is as follows: **Funding for this research was made possible by the American College of Rheumatology Research and Education Foundation *Within Our Reach* initiative.**

As soon as a manuscript is accepted for publication-whether during the term of the grant or after it has expired-a copy of the publication along with the name of the journal and expected date of publication should be forwarded to the REF. As soon as reprints are available, two copies of the reprint should be forwarded to the REF.

AWARD POLICIES

Anyone accepting an award or grant from the ACR Research and Education Foundation must comply with published award policies at all times. A full list of current policies may be found online at http://www.rheumatology.org/ref/awards/recipient_policies.asp.

PATENT AND INTELLECTUAL PROPERTY POLICY

The following Patent and Intellectual Property Policy of the American College of Rheumatology Research and Education Foundation (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 Foundation.
2. The term "**Grantee Institution**" as used in this policy shall mean the tax-exempt sponsoring institution by which the Awardee is employed or its assignee or the for-profit employer of the Awardee or its assignee, 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 this policy.
3. The term "**Awardee**" as used in this policy means the Principal Investigator or primary recipient identified in a Foundation award, grant or contract.

II. TERMS AND CONDITIONS

4. Notifications, Cooperation and Confidentiality

All notices hereunder shall be delivered to the Foundation by notifying the Executive Director. The Grantee Institution or its assignee and Awardee will notify the Foundation at the earliest practical time of any Foundation Supported Intellectual Property and will further notify the 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 Foundation may have concerning such patent application or copyright protection and agrees to the provisions as stated in paragraph 5, below. The Foundation agrees to keep all such patent application or copyright protection information confidential and not to release any non-public information relating to such patent application or copyright protection while prosecution is pending. The Grantee Institution or its assignee shall take all reasonable steps to pursue patent or legal protection of any Foundation Supported Intellectual Property within a reasonable time following discovery and, in no event shall delay publication of related data for more than 6 months.

5. Ownership Rights

The Foundation understands that many Grantee Institutions may have patent or intellectual property policies or procedures that require employees, private contractors or agents to assign their ownership rights to the Grantee Institution or its assignee, and that such policies or procedures are binding on the Awardee. In such instances, the Grantee Institution with which the Awardee is associated shall own the intellectual property rights in, and may pursue patent or other protection for, any Foundation Supported Intellectual Property, subject to the rights of the Foundation specified or referenced below. In the event that an Awardee or Grantee Institution wishes to assign, license, or otherwise transfer any of its rights in REF Supported Intellectual Property, it must obtain the prior written consent of Foundation to any such assignment, license or transfer.

If the Grantee Institution does not have such policies or procedures, if the Awardee is not employed by or affiliated with Grantee Institution, or if the Grantee Institution or its assignee chooses to suspend or abandon for any reason the pursuit of a patent or other legal protection of, 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 to the Foundation 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. In such event, 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. If the Foundation Supported Intellectual Property results in part from federally-sponsored research, and any such assignment to the Foundation requires the prior approval of the federal granting agency, the Grantee Institution shall not be required to assign such inventions and rights to the Foundation in the absence of such approval. If other sponsors have been involved with such Foundation Supported Intellectual Property, Grantee and Foundation will in good faith work with all parties involved to arrive at an appropriate disposition of such property.

The financial rights and obligations of the Foundation, the Awardee, and the Grantee Institution will be in accordance with the following terms:

- a) Costs of prosecution of any patent application or copyright protection shall be borne by the party prosecuting same.
- b) The Foundation waives the receipt of income until the gross receipts from the Foundation Supported Intellectual Property exceeds \$1,000,000.
- c) Once the cumulative gross receipts (including any revenue from licensing) of Foundation Supported Intellectual Property exceeds \$1,000,000, the Grantee Institution shall pay the REF annually a portion of the gross receipts earned from the Foundation Supported Intellectual Property that is proportionate to the Foundation's financial support for the research and development that resulted in the commercialization of the Foundation Supported Intellectual Property. Such payment shall be accompanied by an appropriate statement of account detailing the amount and showing the calculation of gross receipts due the Grantee Institution during the relevant period. The Foundation shall have the right to audit at its own expense the

Grantee Institution's books and records annually, in order to verify the gross receipts derived annually from any Foundation Supported Intellectual Property.

- d) The percentage of gross receipts due the Foundation from a Foundation Supported Intellectual Property shall be determined by the parties within 90 days of the date the Foundation is notified by the Grantee Institution that a Foundation Supported Intellectual Property has been commercialized (can be extended by mutual agreement of both parties). The Grantee Institution shall notify Foundation within 30 days of grant of a license, sublicense, lease or other revenue generating agreement involving the Foundation Supported Intellectual Property.

6. 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 is diligently pursuing the [Foundation Supported Intellectual Property].

7. Publicity

The Foundation reserves the right to publicize Foundation supported research. The REF will provide the Grantee Institution and the Awardee prior notice and an opportunity for comment on any such public acknowledgment. This is not intended to include the use of the name of the grantee or institution in connection with commercial purposes or use in product promotion or product endorsement. The Foundation name and logo, however, may not be used in association with any REF Supported Intellectual Property without prior approval of the Foundation.

8. Use by REF

The REF 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 2 above, notwithstanding the grant of any exclusive license under paragraph 3 above, without payment of royalties or fees, but solely for use within the Foundation for research and noncommercial purposes by Foundation Awardees via materials transfer agreement or confidential disclosure agreement.

SECTION V: APPLICATION INSTRUCTIONS

Read these instructions thoroughly prior to preparing your application.

These instructions pertain to the compilation of *Within Our Reach* research grant applications. Read and follow the instructions carefully to avoid possible return of an incorrect or incomplete application.

>> ***Be sure to submit a complete and correct application.***

Contact REF staff ahead of time at 404-633-3777 or REF@rheumatology.org if you have questions or need assistance. Incomplete or incorrect applications may be returned to the applicant without being considered for review. An application may be returned if it is illegible, if the instructions were not followed, or if the material presented is insufficient to permit an adequate review. All applications must be complete and accurate at the time of submission. Late applications will be returned without being considered for review.

The REF Scientific Advisory Council has the responsibility to make the final determination of legibility and the authority to return applications. This decision is final and not subject to appeal. Inquiries should be directed to REF Senior Director of Research at 404-633-3777.

GENERAL INSTRUCTIONS

Forms & Format

- Prepare the application using the MS Word forms and format pages as provided. You will need to convert to PDF for final submission on CD.
- *Format pages* are intended to assist you in the development of specific sections of the application.
- Font sizes on some form pages vary due to field or space limitations. The Form Pages as provided are acceptable to REF. All other sections of your application (e.g., Biographical Sketch, Introduction, if necessary; Literature Citations, and the Research Plan) must conform to the font requirements stated below.
- **Follow font and format specifications. Otherwise, application processing may be delayed, or the application may be returned to the applicant without review.**
- Adherence to font and margin requirements is necessary for several reasons. No applicant should have an advantage over other applicants by providing more content in his/her application by using smaller, denser type. Small type sizes may also make it difficult for reviewers to read the application.

Font

- Use an *Arial typeface 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.)
- Type density, including characters and spaces, must be no more than 15 characters per inch.
- Type may be no more than six lines per inch.
- Use black ink that can be clearly copied.

- Print must be clear and legible.

Page Format

- Size: Use standard size (8 1/2" x 11") sheets of paper.
- Margins: The margins of your text should be at least 1/2 inch all around, unless a form with different margins is supplied in the application document.
- Columns: Since a number of reviewers will be reviewing applications as an electronic document and not a paper version, applicants are strongly encouraged to use only a standard, single-column format for the text. Avoid using a two-column format since it can cause difficulties when reviewing the document electronically.
- Spacing: The application must be single-sided and single-spaced.
- Page Numbering: Consecutively number pages throughout the application. Do not use suffixes (e.g., 5a, 5b). Do not include unnumbered pages.

Figures, Diagrams, Charts, Tables, Figure Legends and Footnotes

- A smaller font size may be used for figures, graphs, diagrams, charts, tables, figure legends, and footnotes, but this type must follow the font typeface requirement and be readily legible.
- A symbol font may be used to insert Greek letters or special characters; the font size requirement still applies.

Grantsmanship

- Read all the application instructions before beginning your application. If you have questions, contact REF staff immediately.
- All applications must be written in English, and you should avoid jargon and abbreviations.
- If terms are not universally known, spell out the term the first time it is used and note the appropriate abbreviation in parentheses. The abbreviation may be used thereafter.
- Be concise. Just because a certain number of pages are permitted does not mean they must be used!

Page Limitations and Content Requirements

- All applications and proposals for REF funding must be self-contained within specified page limitations.
- Font and margin specifications must be followed; if not, application processing may be delayed or the application may be returned to the applicant without review.
- Prepare a succinct Research Plan. There is no requirement for applicants to use the maximum allowable pages allotted to the Research Plan (see section Content of Research Plan, Items A-D). The remaining items (E-L) of the Research Plan have no maximum allowable pages, but should be succinct.

SPECIFIC INSTRUCTIONS

Face Page (Form Page 1)

The Face Page (Form Page 1) must be printed on a single page. The information provided on the Face Page of the application and the fiscal information, including the calculation of project costs (item 6), must be verified by the official signing for the applicant organization.

Item 1. Title of Project

Do not exceed 81 characters, including the spaces between words and punctuation. Choose a descriptive title that is specifically appropriate.

Item 2. Principal Investigator(s)

Name of Principal Investigator. Name the one person responsible to the REF for the scientific and technical direction of the project. REF staff will conduct official business only with the Principal Investigators and Institutional Officials named here.

- **Item 2a. Degree(s):** Indicate up to three academic and professional degrees or other credentials, such as licenses (e.g., RN).
- **Item 2b. Position Title:** Provide the academic or professional title of the Principal Investigator. If more than one title, indicate the one most relevant to the proposed project (e.g., Professor of Biochemistry, or Chief of Surgical Service).
- **Item 2d. Mailing Address:** Provide complete information (including room number, building, and street address) necessary for postal delivery. All mailed communications with the Principal Investigator will be sent to this address.
- **Item 2c. Department, Service, Laboratory, or Equivalent:** Indicate your organizational affiliation, such as Department of Medicine, Materials Research Laboratory, or Social Sciences Institute.
- **Item 2e. Telephone and Fax Numbers:** Provide a daytime telephone number and, if available, a fax number.
- **Item 2f. E-Mail address:** For electronic mail, enter the appropriate e-mail address and not a Web site URL.

Item 3. Human Subjects Research

All human subjects research funded by the REF must be conducted according to the Common Rule (45 CFR 46) and guidance from the Office of Human Research Protections. Any research that involves obtaining private information or human biological specimens-such as blood and tissue samples-that can be linked by the investigator(s) to living individuals is considered human subjects research. Research that involves only coded private information/data or coded biological specimens may or may not constitute human subjects research under 45 CFR 46.

If research activities involving human subjects or coded information/specimens are planned at any time during the proposed project period, either at the applicant organization or at any other performance site or collaborating institution, then your answer is "Yes" even if the research is exempt from regulations for the protection of human subjects.

Following REF peer review, applicants and their institutions will be notified of the need for IRB review of the protocol. IRB approval of the proposed research is not required before peer review, but will be necessary once a final funding decision is made. The term "IRB approval" includes all decisions including expedited review, review at a full convened meeting, or determination that the research is either exempt from review, or not human subjects research.

Item 4. Vertebrate Animals

- Check “No” if activities involving vertebrate animals are not planned at any time during the proposed project period. The remaining parts of Item 4 are then not applicable.
- Check “Yes” if activities involving vertebrate animals are planned at any time during the proposed project period, either at the applicant organization or at any other performance site or collaborating institution. Note that generation of custom antibodies constitutes an activity involving vertebrate animals.
- Following REF peer review, applicants and their institutions will be notified of the need for IACUC review and verification for the proposed animal activity and Animal Welfare Assurances.
- By checking “Yes” and by the signing on the Face Page, the applicant organization is declaring that it will be submitting an Animal Welfare Assurance and verification of IACUC approval when requested.

Item 5. Dates of Proposed Period of Support

Request no more than two years of support. Award payments will be disbursed on July 1 and January 1 of each award year.

Item 6. Costs Requested for Proposed Period of Support

- Enter the exact figure as calculated (“total costs”) in the budget summary (Form Page 5).
- Total costs (Direct + Indirect) cannot exceed \$400,000 for the entire project period.

Item 7. Applicant Organization

Name the one organization that will be legally and financially responsible for the conduct of activities supported by the award.

Item 8. Entity Identification Number

- Enter the complete name of the organization. University Systems should include location information as part of the name (i.e. University of California – Los Angeles)
- Enter the complete 12-digit Entity Identification Number assigned to the applicant organization by the Department of Health and Human Services Payment Management System for payment and accounting purposes. This number is an expansion of the 9-digit EIN assigned by the IRS.
- If the institution has not yet been assigned a number, enter either (1) the organization’s Internal Revenue Service employer identification number (nine digits) or (2) the words *Applied for* to indicate that the organization does not have an EIN but has applied to the local office of the IRS for one.

- **DO NOT ENTER THE PRINCIPAL INVESTIGATOR'S SOCIAL SECURITY NUMBER** as it is not appropriate for this item.

Items 9-10. Administrative Official to be Notified if Award is Made

Name the applicant organization administrative official to be notified if an award is made. Provide a complete address for postal delivery and the telephone, fax, and e-mail address for the administrative official.

Item 11. Official Signing for Applicant Organization

Name an individual authorized to act for the applicant organization and to assume the obligations imposed by the Federal laws, requirements, and conditions for a grant or grant application, including the applicable Federal regulations. Provide a complete address for postal delivery and the telephone, fax, and e-mail address for the signing official.

Item 12. Applicant Organization Certification and Acceptance

Read this section carefully

- An original signature, in blue ink, is required. "For" signatures are acceptable; i.e., if the official designated to sign for the applicant organization is not available to sign, only another institutional official with formal delegated authority to act in his/her behalf may sign as "acting for" such official. The date of signature must be included. "Per" signatures (signing as the designated official or without the formal delegation) are not acceptable.
- ***In signing the application Face Page, the duly authorized representative of the applicant organization certifies that the applicant organization will comply with all applicable policies, assurances and/or certifications referenced in the guidelines and application.***
- The applicant organization is responsible for verifying its eligibility and the accuracy, validity, and conformity with the most current institutional guidelines of all the administrative, fiscal, and scientific information in the application.
- Deliberate withholding, falsification, or misrepresentation of information could result in administrative actions, such as withdrawal of an application, suspension and/or termination of an award, debarment of individuals, as well as possible criminal penalties.
- The signer further certifies that the applicant organization will be accountable both for the appropriate use of any funds awarded and for the performance of the grant-supported project or activities resulting from this application. The applicant organization may be liable for the reimbursement of funds associated with any inappropriate or fraudulent conduct of the project activity.
- Assurances and Certifications - Each application to the REF requires that the human subjects and animal welfare assurances and/or certifications be verified by the signature of the Official Signing for Applicant Organization on the Face Page of the application. These assurances and/or certifications may or may not be applicable to your project, program, or type of applicant organization.

Project Description, Performance Sites and Key Personnel (Form Pages 2-3)

Project Description (Abstract)

- Project Summary: 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 to the *Within Our Reach* initiative. Concisely describe the research design and methods for achieving the stated goals. This section should be informative to other persons working in the same or related fields and insofar as possible understandable to a scientifically or technically literate reader. Avoid describing past accomplishments and the use of the first person.

- Relevance: Using no more than two or three sentences, describe the relevance of this research to the goals of the *Within Our Reach* initiative. In this section, be succinct and use plain language that can be understood by a general, lay audience.
- Do not include proprietary, confidential information or trade secrets in the description section. If the application is funded, the project description will be entered into the REF database and will become public information.
- **DO NOT EXCEED THE SPACE PROVIDED**

Performance Site(s)

- Indicate where the work described in the Research Plan 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 on the Resources Page of the application.
- State whether a consortium/contractual arrangement is involved with one or more collaborating organizations for the conduct of a portion of the work described in the Research Plan.
- If a performance site is engaged in research involving human subjects, the applicant organization is responsible for ensuring that the performance site operates under an appropriate OHRP-approved assurance for the protection of human subjects and complies with 45 CFR Part 46 and other NIH human subject related policies.
- For research involving vertebrate animals, the applicant organization must ensure that all performance sites hold OLAW-approved assurances.

Key Personnel

- In addition to the Principal Investigator(s), 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.
- Typically, these individuals have doctoral or other professional degrees, although individuals at the masters or baccalaureate level should be included if their involvement meets the definition of Key Personnel. **Consultants should be included if they meet this definition.**
- Key Personnel must devote measurable effort to the project whether or not salaries are requested. "Effort of zero" or "as needed" are not acceptable levels of involvement for those designated as Key Personnel (see Other Significant Contributors). Percent effort should be calculated based on a full-time 12-month calendar year appointment at the Sponsoring Institution. The PI must devote a minimum of 20 percent overall professional effort to the proposed project. **Start with the Principal Investigator(s).** List the Principal Investigator's **last name first**. When multiple PIs are proposed, list the contact PI first, then all additional PIs in alphabetical order. Then all other Key Personnel should

be listed in **alphabetical order**, last name first. For each individual provide name, organization name (their institutional affiliation), and role on the project.

- Under “role on the project,” indicate how the individual will function on the proposed project. *Use additional consecutively numbered pages as necessary.*

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. Reviewers use these pages to address the "investigator" review criterion.
- However, if an award is to be made, Other Support information will not be required or accepted since considerations of overlap do not apply to these individuals.
- Should the level of involvement change for an individual listed in this category, they should be re-designated as "Key Personnel." This change should be made before any compensation is charged to the project.

Research Project Table of Contents (Form Page 4)

Provide the page number for each category listed on the Table of Contents. Place page numbers at the top of each page and consecutively number pages throughout the application. Do not include unnumbered pages and do not use suffixes, such as 5a, 5b, etc.

Budget Summary (Form Page 5)

Start and End Dates

If a 24-month project duration is requested, the start dates should be 7/1/2012 for Year 1 and 7/1/2013 for Year 2. **Maximum duration is two years and the total costs direct plus indirect may not exceed \$400,000 for the entire award period.**

Total Personnel Costs

- Budget Table A - Complete Budget Table A for each person receiving salary support. Enter the Personnel subtotal amount on line subtotal (line 3).
- 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 (Form Page 6).
- Salary – The REF operates under the same salary cap restrictions as the NIH. Effective January 1, 2011, the Executive Level I salary level cap is \$199,700. For the purposes of the salary limitation, the terms "direct salary," "salary," and "institutional base salary" have the same meaning and are exclusive of fringe benefits and facilities and administrative (F&A) expenses, also referred to as indirect costs. 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.

- Fringe Benefits – Fringe Benefits may be requested in accordance with institutional guidelines for each position provided the costs are treated consistently by the applicant organization as a direct cost to all sponsors.
- 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. Signature by the institutional official on the application 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.

Consortium/Contractual Costs

- For the applicant organization budget, list the sum of all consortium/contractual costs. Sub-contract budget details and letters of collaboration should be placed in the appendix.
- 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 Sheet (See Form Page 12).

Other Direct Costs

Enter separately the "Direct Costs" for each subcategory.

- 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. Justify each purchase on Budget Justification Form.
- Travel - Scientific meeting travel is capped at \$2,000/yr. Itemize travel requests and justify on Budget Justification Form. Provide the purpose and destination of each trip and the number of individuals for whom funds are requested. **This MUST include travel of at least one investigator to the annual *Within Our Reach* Investigators' Meeting.**

Indirect Costs

Indirect costs cannot exceed 8 percent of the total budget. This includes any indirect costs in line with consortium/contractual costs. In signing the application Face Page, the duly authorized representative of the applicant organization certifies that the applicant organization will be

accountable both for the appropriate use of any funds awarded and for the performance of the grant-supported project or activities resulting from this application.

Budget Justification Form (Form Page 6)

- Name each person to be supported by this grant, their percentage FTE – 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.
- Explain the need for contractual arrangements. Indicate whether the collaborating institution is foreign or domestic. Sub-contract budget details and letters of collaboration should be placed in the appendix.
- Provide appropriate description of pieces of equipment, major supply items and project-related travel.

Biographical Sketch (Form Page 7)

- **Previously formatted NIH Biographical Sketch can be substituted for this form.**
- Follow the instructions on the Biographical Sketch format page. This section must contain the biographical sketches of all **Key Personnel and Other Significant Contributors**, including consultants, following the order as listed on Form Page 3 of the application.
- The Biographical Sketch may not exceed four pages (See Form Page 7). This four-page limit includes the table at the top of the first page.

Resources (Form Page 8)

- Specify the facilities 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.
- Under “Other,” identify support services such as machine shop or electronics shop, and specify the extent to which they will be available to the project. Use continuation pages if necessary.
- 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.

Research Plan (Form Page 9)

The Research Plan should include sufficient information needed for evaluation of the project, independent of any other document, e.g., appendix, supplemental materials, etc. The format for preparing this section is provided below. Be specific and informative, and avoid redundancies. **A response to prior reviews of the proposal may not be included in your application. It is not appropriate to state this is a resubmission of an application from a prior cycle. Each application is treated as a new submission.**

Page Limitations

- **Do not exceed 15 pages for Items A-D.** All tables, graphs, figures, diagrams and charts must be included within the 15-page limit.

- Be succinct and remember that there is no requirement to use all 15 pages allotted to Items A-D of the Research Plan.
- Full-sized glossy photographs of material such as electron micrographs or gels may be included in the Appendix; however, a photocopy of each must also be included within the page limitations of the Research Plan.
- All applications and proposals for REF funding must be self-contained within specified page limitations. Internet Web site addresses (URLs) may not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Moreover, reviewers are cautioned that they should not directly access an Internet site as it could compromise their anonymity.

The 15-page limit will be strictly enforced. If proposal exceeds the page limits, it will be returned to the applicant and will not be considered for review.

Content of Research Plan

The REF recommends the following format and page distribution. Organize Items A-D of the Research Plan to answer these questions: *What do you intend to do? Why is the work important? What has already been done? How are you going to do the work?*

A. Specific Aims (one page is recommended)

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 - three pages 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 (one - two pages recommended)

Extensive preliminary data is not required. Use this section to 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. This information will also help to establish the experience and competence of the investigator to pursue the proposed project.

D. Research Design and Methods

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. As part of this section, 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. 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.

For all research involving human subjects, a part of the peer review process will include careful consideration of protections from research risks, as well as the appropriate inclusion of women, minorities and children. The study section will assess the adequacy of safeguards of the rights and welfare of research participants, and the appropriate inclusion of women, minorities, and children, based on the information in the application. This evaluation will be a part of the Approach criterion. The evaluation of the inclusion plans will be factored into the overall score that the study section awards for scientific and technical merit of the application.

F. Vertebrate Animals

If you have marked Item 4 on the Face Page of the application “Yes,” create a section heading entitled “Vertebrate Animals.” Place it immediately following the Research Design and Methods section of the application or after Item E, if applicable.

Under the “Vertebrate Animals” heading, address the following five points. In addition, when research involving vertebrate animals will take place at collaborating site(s) or other performance site(s) provide this information before discussing the five points. Although no specific page limitation applies to this section of the application, be succinct.

1. 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.
2. 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.
3. Provide information on the veterinary care of the animals involved.
4. 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.
5. 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.

G. 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. The reference should be limited to relevant and current literature. While there is not a page limitation, it is important to be concise and to select only those literature references pertinent to the proposed research.

H. Consortium/Contractual Arrangements

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.

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 REF funds and the associated research findings published or provided to the REF, it is important that they be made readily available for research purposes to qualified individuals within the scientific community. The REF follows NIH policy and guidelines related to Resource Sharing.

J. Consultants

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

Benchmarks (Form Page 10)

Applications should include a list of benchmarks or milestones to indicate the expected status of the project at various points in time. 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 of inflammatory arthritis. These benchmarks will be used to evaluate progress and to facilitate communication between the Principal Investigator and the REF Scientific Advisory Council. Renewal of the award in year two is contingent on submission of an annual progress report showing substantial accomplishment and progress toward benchmarks specified in the original application.

Appendix (Form Page 11)

- **The appendix may not be more than 30 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.
- A cover page listing all of the items included in the Appendix is required (See Form Page 11).
- Appendix material can be two-sided as appropriate. Items should be stapled or bound where appropriate and each marked with the name of the Principal Investigator.

- 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 J of the Research Plan.
 - **Contractual Budget(s):** Include a “Consortium/Contractual Costs Budget Sheet” for each consortium/contractual arrangement.
 - **Supporting Materials:** Supplemental tables and figures, relevant publications or manuscripts.

REMINDER: SUBMISSION REQUIREMENTS

Each applicant must include the following items in their submission packet (See page 10 of this document for detailed submission instructions):

All applications must be postmarked no later than December 1, 2011.

Late applications will not be accepted and will be returned without being considered for review.

All submissions must be sent to:

Within Our Reach Grants Program
 ATTN: Mary Wheatley, Sr. Director, Research and Training
 ACR Research and Education Foundation
 2200 Lake Boulevard NE
 Atlanta, GA 30319

ABOUT THE REF

The American College of Rheumatology Research and Education Foundation was established in 1985 as a 501(c)(3) organization, with the mission of advancing research and training to improve the health of people with rheumatic diseases. The REF funds groundbreaking research resulting in better care and treatment for more than 50 million Americans affected by rheumatic diseases. As the largest private funding source of rheumatology research and training programs in the U.S., the REF has awarded over \$50 million to more than 1,000 recipients in the past five years. For more information about the REF and the Within Our Reach campaign, visit www.rheumatology.org/REF.