



2009 Request for Proposals
Collaborative Grants
Program Guidelines & Application Instructions

Application Postmark Deadline: December 1, 2009

Awards administered by:



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

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

*The mission of the **ACR Research and Education Foundation** is to improve patients' lives through support of research and training that advance the prevention, treatment, and cure of rheumatic diseases.*

WITHIN OUR REACH: FINDING A CURE FOR RHEUMATOID ARTHRITIS

Within Our Reach is a multi-year fundraising campaign to raise a minimum of \$30 million, which seeks to advance the future of rheumatologic research by accelerating rheumatoid arthritis research not normally funded by the National Institutes of Health or other peer reviewed funding sources. Accelerating RA research will enhance a practicing rheumatologist’s ability to identify contributing factors to the disease, predict onset of disease, tailor therapy based on a patient’s characteristics or a laboratory biomarker, prevent joint damage, and reduce disability.

The following Within Our Reach grants have been developed to assist the ACR Research and Education Foundation in its goal to accelerate RA research.

- **Investigator-Initiated Grants**
- **Collaborative Grants**

>> *See separate Request for Proposals for the Investigator-Initiated grants.*

AWARD TERMS & FUNDING:

Each collaborative grant is funded for three years at up to \$400,000 per year, including eight percent indirect costs. Total costs cannot exceed \$1,200,000.

APPLICATION POSTMARK	DECISION DATE	START OF AWARD TERM
December 1, 2009	May 1, 2010	July 1, 2010

SOURCES OF SUPPORT

Funding for these awards is made possible by the generous support and donations received for the *Within Our Reach: Finding a Cure for Rheumatoid Arthritis* campaign.

Pinnacle Donors of the *Within Our Reach* campaign include:



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SECTION I: DESCRIPTION OF GRANTS

COLLABORATIVE GRANTS

These larger awards are meant to support collaborative networks of investigators who propose multidisciplinary and/or multi-center projects. These projects may include studies of disease mechanisms, validation of biomarkers, proof-of-concept clinical trials, and investigation of the delivery and effectiveness of care to patients with rheumatoid arthritis. Applications must be translational or clinical in nature. Basic science applications will not be accepted.

Applicants must assemble a multidisciplinary and/or multi-center research team.

- A multidisciplinary team includes members with research interests and expertise arching across several established fields of study such as rheumatology, immunology, endocrinology, pulmonary medicine, bioinformatics, epidemiology, health services research, health economics, etc.
- A multi-center team includes two or more performance sites with a linked protocol in order to increase the amount of available patient data and create a more diverse patient population.

This collaborative grant mechanism will focus on innovative approaches to increase our understanding about the etiology, prevention, diagnosis and treatment of RA. These new approaches must hold the promise of leading to new research findings that improve patient care and ultimately lead to finding a cure for RA.

This mechanism is intended to lay the foundation and prepare investigators for submitting a subsequent application for more substantial and longer duration support through other funding mechanisms.

Collaborative studies are appropriate to address research questions that are beyond the capacity of any investigation conducted at a single institution. Considerations such as increased sample size, representation, and diversity may all support the need for multi-site studies, as do considerations of the need for collaboration between sites with varied expertise and/or perspectives.

The following are examples of the types of studies that can be supported under this mechanism—these are meant to be illustrative only and are not intended to be exclusive or exhaustive.

- Large scale, public health oriented intervention studies (prevention, etiology, diagnosis, treatment, or rehabilitation) using pharmacologic or holistic approaches individually or in combination, including studies that examine the balance between efficacy and safety, studies that compare cost-effectiveness of alternate approaches, and studies that employ novel designs to test personalized treatment options
- Studies within the context of clinical trials that assess population pharmacokinetics or identify other candidate biomarkers that, in combination with sociodemographic and clinical information, enhance prediction of treatment response

- Large-scale human genetic studies, in which pedigree recruitment and ascertainment must occur in parallel fashion across multiple sites
- Smaller scale studies of unique clinical populations or low base rate outcomes that would be difficult to recruit from a single clinical setting
- Large scale studies of risk factors (including genetic, biological, and environmental factors).
- Studies that enhance enrollment in clinical trials through, for example, optimizing procedures for assessing eligibility and obtaining informed consent, investigating methods to enhance recruitment, participation and retention of ethnically diverse participants
- Health services research to identify mutable factors that impact access, utilization, quality, and outcomes of healthcare services to inform or test patient-, provider-, organizational-, or policy- level services and treatment.
- Studies of knowledge translation including diffusion strategies (i.e., dissemination and implementation) to improve adoption of evidence-based treatments in practice settings (These can include patient, provider, or organizational level targets.)
- Studies that will aid in the development of novel therapies for RA; identify mechanisms and processes (genetic, biological, and/or environmental) that confer risk for or protection from RA; improve the phenotypic characterization and refine standardized assessment tools that are sensitive to developmental change, cultural diversity, and variation in functioning; develop, test, and validate biologically based markers for diagnosing or detecting risk/vulnerability, onset, progress, and/or severity of disease; and identify mechanisms underlying sex differences in, and gender influences on disease.

In addition to multi-site collaborations, this program aims to support multidisciplinary research - that is, research that brings together researchers from different disciplines to focus on a circumscribed problem. Combining particular aspects of different disciplines to develop entirely new ways to approach disease targeted research is increasingly important in order to create and apply new knowledge to the field of RA.

If the application proposes the creation of novel patient cohorts or the creation of a repository for clinical data and/or Biospecimens, applicant(s) must include a detailed Resource Sharing Plan for distribution and maintenance of these resources following completion of REF funding.

RESEARCH GRANT CATEGORIES

TRANSLATIONAL

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

Basic research into the mechanisms of disease has accelerated in recent years, but the knowledge gained has been slow to reach the clinic and 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 RA research.

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 that there are environmental exposures that influence the development of RA. 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 RA using newly developed methods in proteomics, genomics and systems biology. Translational research also includes proof-of-principal studies of novel treatment modalities.

CLINICAL PRACTICE

Clinical practice grants will focus on translating recent advances in the prevention and treatment of rheumatoid arthritis 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 or at risk of rheumatoid arthritis. Examples include studies of improved methods of RA management 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 the clinical practice of rheumatology, including patient access. For example, improving our understanding of the health economics and benefits of current therapies will increase appropriate access to novel therapies. Addressing disparities in health care access for patients with RA is necessary to improve the overall health of the patient population.

No basic science applications will be accepted.

AWARDS CRITERIA

Eligibility Criteria

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, a distinguished publication record or other applicable experience, which signifies scientific leadership. 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 previous translational or clinical projects are not allowed, but previous recipients with basic science projects may apply for funds that translate promising pre-clinical studies to human RA. NIH or CDC employees may participate in a team as collaborators or consultants, but may not serve as a Site Leader, or receive funds from this program. These investigators must obtain appropriate clearances and include documentation in the application along with a letter of commitment, and current curriculum vitae.

An individual scientist or a single institution may be proposed as the Principal Investigator in only one application. However, an individual scientist may be a Site Leader in more than one application, or a PI and a Site Leader on separate applications. If a scientist appears on more than one application, it is the responsibility of the PI to demonstrate in their applications that there are no scientific or budgetary overlaps or proprietary conflicts with each individual's proposed activities. Likewise, individuals currently receiving funding via contracts, grants, gifts, commercial arrangements, or Cooperative Agreements may be funded under this RFP providing that there is no scientific or budgetary overlap or proprietary conflict in funded activities.

Citizenship

At the time of application, 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 United States and who may sub-contract grant support to Co-Investigators.

Relevance to Rheumatoid Arthritis

Outcomes from these grants should lead to new insights into the etiology, pathogenesis and treatment of RA. Applications will be considered highly relevant if the research proposal includes some or all of the following attributes:

- Focus on human rheumatoid arthritis
- Scientific knowledge to be gained is highly significant
- Integration of scientific investigation across disciplines in a way that uniquely advances the prevention, control and cure of rheumatoid arthritis

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

SECTION II: TERMS OF AWARD

AWARD PERIOD

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

AWARD AMOUNT

Funding for the three year period will be up to \$400,000 per year - \$1,200,000 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

Anyone accepting an award from the ACR Research and Education Foundation must 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. In addition, summaries of research that are appropriate for a lay audience will be periodically required.

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 by mail the cover letter, original application with original signatures in blue ink, two copies of the complete application, and one CD containing the completed application files as detailed below *postmarked no later than December 1, 2009* to:

Within Our Reach - RA Grants
ATTN: Mary Wheatley
ACR Research and Education Foundation
2200 Lake Boulevard NE
Atlanta, GA 30319

COVER LETTER

Applicants are required to include a cover letter with the application. The letter should contain the following information:

- Application title
- Type of grant being requested (Translational or Clinical)
- 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.

APPLICATION PACKET

Number of Copies & Packaging

- Submit the **original and two** exact, legible, single-sided photocopies of each application.
- Submit five copies of any materials that cannot be photocopied, including glossy photographs.
- **Submit one CD of your application.**

Submit the following materials in one package:

- **Cover Letter** - please briefly describe the proposal in two to three sentences and indicate for which grant category the application is being submitted. See preceding section for complete information. An electronic copy of the cover letter should be included on the CD in the 'ADMIN' folder (see below).
- **Original Application** - must be single-sided, with an authorized organization official's signature on the Face Page. Assemble the pages in the order specified in the Table of Contents (Form Page 4).

- **Two exact, single-sided copies of the original application** - Make the copies after an authorized organizational official has signed the Face Page so that the official's signature is present on the copies.
- **Two collated sets of appendix material** - Items should be stapled or bound where appropriate and each marked with the name of the Principal Investigator. A summary sheet, listing all of the items included in the Appendix is required (see appendix section instructions). Appendix material can be two-sided as appropriate. While the font requirements imposed in the rest of the application do not apply to the Appendix, all material must be clearly legible. **Please submit five copies of any materials that cannot be photocopied including glossy photographs.**
- **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 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').

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 applications will be returned to the applicant without being considered for review. An application will 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 and late materials will not be accepted.

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 the Director, Awards and Grants 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* campaign. 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 RA experience, are there appropriate collaborative arrangements with experts in RA?*

Collaborative Team: *Is the assembled research team appropriate for the scope of the project? Has the PI assembled a multi-site or multidisciplinary team in accordance with the program requirements? Will each member and/or site contribute significant resources to accomplish the proposed aims?*

Relevance to Rheumatoid 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 RA 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?*

Resource Sharing Plan: *If the application proposes the creation of novel patient cohorts or the creation of a repository for clinical data and/or Biospecimens, does the applicant include a detailed plan for distribution and maintenance of these resources?*

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, 2010**.

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.

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* RA 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.**

The 2010 *Within Our Reach* Investigators' Meeting will be held June 4-6 in Forth Worth, Texas.

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 three-year period will be up to \$400,000 per year-\$1,200,000 total-**including indirect costs that 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 2010	\$200,000	January 2011	\$200,000
Year 2:	July 2011	\$200,000	January 2012	\$200,000
Year 3:	July 2012	\$200,000	January 2013	\$200,000

Budget reconciliation is also required after the first year of the grant. The reconciliation must be submitted by September 1, 2011. Upon successful completion of the three-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, 2013.

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 or abstracts other grants obtained and invited reviews. Format and exact due date for the progress report will be provided within 60 days of the due date. Failure to submit a progress report by the deadline may result in funding delays and may result in grant cancellation and hinder applicant's eligibility to receive additional REF funding.

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 lies 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: Finding a Cure for Rheumatoid Arthritis* campaign.**

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.

FUNDING SOURCES AND DISCLOSURE

Funding for these awards is made possible in part through the financial support of the American College of Rheumatology Research and Education Foundation *Within Our Reach* campaign, and the following Pinnacle donors: Abbott Immunology, American College of Rheumatology, Bristol-Meyers Squibb, and UCB.

TRANSFER POLICY

Awards may not be transferred between individuals. Requests to transfer awards between institutions will be considered on a case-by-case basis. Formal requests should be made using the Award Transfer Request Checklist and submitted to the REF along with the required supporting documentation. Requests are reviewed and granted at the discretion of the Scientific Advisory Council.

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. 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.

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 applications will be returned to the applicant without being considered for review. An application will 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 and late materials will not be accepted.

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 Director of Awards and Grants 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.**

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.

Photographs and Images

- Do not include photographs or other materials that are not printed directly on the application page in the body of the application. Pictures or other materials that are glued or taped onto application pages are incompatible with the current duplication/scanning process.
- You may include black-and-white or color images in the two (2) submitted copies provided such images are printed directly on the application page and are critical to the content of the application.

Copies

- Provide the signed original—signed by an authorized organizational official—and two exact, legible, single-sided photocopies.
- Do not use photo reduction. The application must contain only material that reproduces well when photocopied in black and white.
- Glossy photographs, or other materials that cannot be photocopied, must be submitted in **five** collated sets as appendices. *Note:* Full-sized glossy photographs may be included in the appendix; however, a photo copy of each must also be included within the page limitations of the Research Plan.

Grantsmanship

- 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.

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-F). The remaining items (G-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 three years of support. If the full 36-month project period is being requested, the period of support will be July 1, 2010 through June 30, 2013.

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 \$1,200,000 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* research program. 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* campaign. 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 full-time 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)

- Investigators must submit an overall budget for the entire project. Separate itemized budgets must be prepared for each subcontract and/or collaborating institution. If parts of the costs of the project are to be borne by sources other than the REF, these contributions

must be presented in detail in the budget justification along with supporting letters signed by individuals who have the authority to commit the institution. Funding for the other institution(s) must be requested via a subcontract to be administered by the Sponsoring Institution. When submitting a detailed budget, the Sponsoring Institution should submit its budget using the Budget Summary sheet. All other institutions should complete their individual budgets separately using the Consortium / Contractual Costs Budget Sheet. See below for further instruction regarding the use of the Consortium / Contractual Costs Budget Sheet.

Start and End Dates

If the full 36-month project duration is being requested, start and end dates should be as follows:

Year 1:	July 1, 2010 – June 30, 2011
Year 2:	July 1, 2011 – June 30, 2012
Year 3:	July 1, 2012 – June 30, 2013

Maximum duration is three years and the total costs direct plus indirect may not exceed \$1,200,000 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, 2009, the Executive Level I salary level cap is \$196,700. 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

- The application must describe any sub-contracts or service agreements for personnel or facilities and include in the application documentation of their commitment, co-signed by a business official and the scientific director at the participating center. Any site that contracts out some portions of this work should clearly state this and provide a full description of the nature, purpose and oversight of this contractual arrangement. This documentation should be included in the Appendix section designated for ‘letters of collaboration.’
- 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 Page three 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 should not be included in your application. It is not appropriate to state this is a resubmission of an application from a prior cycle.**

The Research Plan must describe all aspects of the project across research sites and/or team members of the collaborative effort. Investigators should use this section to describe the research procedures or protocol, the study population from which samples are drawn, resources, data analyses, and any other characteristics that support each site and/or team member’s importance to the overall project

The formation of the team, submission of the application in response to this RFP, and the overall management of the team will be the responsibility of the PI and the PI’s institution in accordance with REF policies. Only one application per collaborative team may be submitted. It is expected that each participant will contribute an essential component to the overall study. There are likely to be elements unique to some sites (e.g., data coordination, fidelity assessment, statistical analyses). Each site and/or team member’s specific contributions should be noted in the proposal.

Page Limitations

- **Do not exceed 20 pages for Items A-F.** All tables, graphs, figures, diagrams and charts must be included within the 20-page limit.
- Be succinct and remember that there is no requirement to use all 20 pages allotted to Items A-F 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 20-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-F 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. Description of Collaborative Team (one - two pages recommended)

Please describe the makeup of the assembled team, and how each Research Performance Site and/or team member has a unique role in the collaboration, such as data coordination, statistical analyses, etc. The composition of a collaborative team is envisioned as follows:

- The PI, in addition to providing scientific and administrative leadership, may serve as a Performance Site Leader, but is not required to do so. Performance Site Leaders will be directly responsible to the PI.
- If building a multidisciplinary team, include members with research interests and expertise arching across several established fields of study such as rheumatology, immunology, endocrinology, pulmonary, bioinformatics, epidemiology, health services research, health economics, etc.
- The composition of the team and its members and Performance Site Leaders depends on the talents required to accomplish its scientific and technical objectives as perceived by the investigators. The major consideration in structuring a team should be the maximum utilization of intellectual, physical, and financial resources to carry out the proposed research and capacity-building. If the team includes more than one Site Leader on a specific topic, each should be capable of contributing high quality, necessary, and non-overlapping expertise. Due to the varied talents and technologies available at any given institution, more than one team member may be derived from a single institution, however it is anticipated that the Site Leaders within a team will be derived from several different institutions.
- No prescribed number of Performance Sites is stipulated. However, the PI could experience difficulty in providing the desirable level of guidance, and team members might communicate and collaborate less efficiently, if the team were to contain more than five or six sites. In addition, to ensure the most effective use of budget resources and to minimize the burden of negotiating agreements and the management of data, the number of institutions collaborating should be considered carefully.
- The collaborating Performance Sites must share a specific protocol and be organized in such a way as to increase sample size, accelerate recruitment, or increase sample diversity and representation. In studies with a large number of sites, it is expected that one site will be submitted as a coordinating site for data management and/or other centralized administration. Each site must have a designated Site Leader who will serve as a Co-Investigator on the overall project, and is responsible for site coordination, quality control, database management, statistical analyses, and reporting.
- Clinical, data management, and laboratory facilities and required equipment should be described in detail for all participating institutions.

E. 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.

F. Management Plan for Collaboration (one page recommended)

In forming teams, potential PIs should remain cognizant of the need for communication, including regular meetings of members and transfer in a timely manner of data and materials to team members located in all the participating Performance Sites. Please present a plan for how the team will collaborate and how the efforts of the individual investigators will be coordinated. A plan for communication and material transfer, including all permits and other legal documents required to assure this transfer, must be supplied. Regular telephone and internet based conferences can yield significant efficiencies in this regard. For multi-site applications, PIs must describe a feasible mechanism for scientific integration of research procedures, overall managerial and administrative responsibilities, and cross-site comparability of training to assure reliability and quality control. Plans for ensuring access to data by all sites, analytic resources, publication and authorship rights, the possibility of public use research materials and data, or other means of distributing research materials to the wider scientific community, and a means of arbitrating disagreements on publication and other issues should be included in the application.

G. 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. These benchmarks will be used to evaluate progress and to facilitate communication between Principal Investigator and the REF Scientific Advisory Council. The milestones should reflect the specific aims of the proposal and be presented within the context of a pathway for determining or evaluating a potential target for RA treatment.

Appendix (Form Page 11)

- **The appendix may not be more than 40 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 L 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):

1. Cover letter from PI
2. Original application with original signatures in blue ink (face page)
3. Two copies of the complete application
4. One CD containing the complete application files

All applications must postmarked no later than December 1, 2009.

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

All submissions must be sent to:

Within Our Reach - RA Grants
ATTN: Mary Wheatley, Director, Awards and Grants
ACR Research and Education Foundation
2200 Lake Boulevard NE
Atlanta, GA 30319