



**2012 Request for Proposals  
Clinical Trials**  
*Program Guidelines & Application Instructions*

**Letters of Intent Due: March 1, 2012**  
**Application Postmark Deadline: May 1, 2012**

**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](http://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 disease.*

## **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 National Institutes of Health or other peer reviewed funding sources. Accelerating RA research will enhance a practicing rheumatologist's ability to characterize various causes of the disease, predict onset of disease, individualize treatment based on a patient's characteristics, prevent joint damage and improve joint function.

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
- Clinical Trials Planning Grants
- Clinical Trials

**>> This Request for Proposals is relevant to Clinical Trials only.**

### **AWARD TERMS & FUNDING**

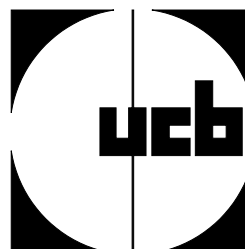
Trials will be funded for three years at up to \$1,000,000 per year, including eight percent indirect costs. Total costs cannot exceed \$3,000,000 for the entire award period.

<b>LETTERS OF INTENT DUE</b>  March 1, 2012	<b>APPLICATION DEADLINE</b>  May 1, 2012	<b>FUNDING BEGINS</b>  September 1, 2012
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### **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 CLINICAL TRIALS

This Request for Proposals invites applications that propose investigator-initiated clinical trials. The proposed trials must be hypothesis-driven, milestone-defined, related to the research mission of the *Within Our Reach* campaign and considered high priority by the Foundation. Investigators are encouraged to visit the REF website at [www.rheumatology.org/REF](http://www.rheumatology.org/REF) for additional information about the campaign. The total number of awards will depend upon the quality of the applications received; however the Foundation anticipates that a maximum of two trials will be funded.

It is expected that these clinical trials will include prospective studies designed to answer questions about biomedical or behavioral interventions, e.g., investigational drugs or investigational medical devices, new ways of using known treatments relevant to RA, management of treatment complications, or mitigation of co-morbidities. It is hoped that these trials will determine whether new biomedical or behavioral interventions are safe, efficacious, and effective.

Clinical Trials must be completed over a three-year period. No extensions will be granted. These grants are not meant to provide support for the compression of a longer research project into a shorter time period or for career development or for educational activities other than a clinical trial.

For purposes of the *Within Our Reach* program, the term ‘clinical trial’ refers to a broadly based prospective clinical investigation involving a large number of human subjects for the purpose of evaluating an experimental intervention in comparison with a standard or control intervention or comparing two or more existing treatments. Often, the aim of such investigation is to provide evidence leading to a scientific basis for consideration of a change in health policy or standard of care. The definition includes pharmacologic, non-pharmacologic, and behavioral interventions for disease prevention, prophylaxis, diagnosis, or therapy. Community- and other population-based intervention trials also are included.

Receipt of a *Within Our Reach* Clinical Trial Planning Grant is not required in order to apply for the clinical trial grant. However, one of the criteria for evaluation of the clinical trial application will be the readiness of the investigative team and the timely availability of study resources (documents, assessments, study populations, etc.). Therefore, recipients of the clinical trial planning grants may have an advantage.

### **PI Qualifications and Experience**

The PI must have the necessary experience and expertise to conduct clinical studies involving human subjects. Previous participation in large-scale studies or clinical trials should be detailed including name of study, role in study and number of patients recruited; participation in studies where recruitment was unsuccessful should also be included. An appropriate time commitment is expected from the principal investigators and co-investigators. The Principal investigator must commit at least 10 percent full-time professional effort to the clinical project and management of the program.

### **Study Population**

Applicants should demonstrate access to a sufficient number of patients to accomplish the protocol by providing specific, objective sources of data on the size of the available population. This can include documentation of participation in previous clinical trials of similar patients.

Patient access may be accomplished by establishing links with other groups in addition to the applicant's institution. It is strongly recommended that at least two recruiting centers with a demonstrated record of successful subject recruitment and retention be included in each trial. If links with other groups are anticipated, the application should include a plan with appropriate letters of support that describes (1) how the applicant will link to and operate with the other groups and (2) how the PI will monitor the quality of the other group's performance (recruitment and data quality).

### **Feasibility**

Feasibility is an important aspect of these applications. Applicants must demonstrate the ability to enroll the required numbers of patients. Patient availability and a record of successful subject recruitment and retention at consortia proposed to assist with enrollment must also be documented. Additional recruiting site(s) are highly recommended. If an IDE or IND is required, applicants will be required to provide evidence of FDA approval at the time of award. Current possession of an FDA approved IND at the time of application for the Clinical Trial grant will be considered in the review process.

### **Communication**

Communication in this translational program is essential. Applicants must propose a plan to describe how communication and interactions will be maintained between clinical sites and study personnel. If projects or recruitment sites reside at separate institution, any costs for meetings and teleconferences should be included in the budget.

### **Relevance to Rheumatoid Arthritis**

Outcomes from these grants should answer questions about biomedical or behavioral interventions, e.g., investigational drugs or investigational medical devices, or new ways of using known treatments relevant to RA. These trials should determine whether new biomedical or behavioral interventions are safe, efficacious, and effective. Applications will be considered highly relevant if the research proposal includes some or all of the following attributes:

- dedication to a rheumatoid arthritis project
- stimulation of a real interchange across disciplines leading to advances in the prevention, control and cure of rheumatoid arthritis
- proposes work on projects with a demonstrable relationship to rheumatoid arthritis

**All applications must be relevant to the purpose and goals of the *Within Our Reach* program. If you have questions about relevance or eligibility, please contact REF staff BEFORE preparing an application.**

## **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 should the award be made. 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 10 percent overall full-time professional effort to the clinical trial. Individuals at the NIH and CDC are not eligible to apply.

### **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.

### **Cost Sharing**

It is expected that recipients of REF *Within Our Reach* clinical trial grants will include a cost sharing plan if costs for the anticipated trial are expected to exceed the \$3,000,000 cap. Allowable cost sharing plans include the following scenarios:

1. A company donates the drug but is not involved in the trial design. The donating company should be recognized for the monetary value of their contribution.
2. The NIH or other funding agency or foundation supports a set of mechanistic studies to accompany the proposed REF funded trial.
3. Matching funds from the sponsoring institution are allowable.

Co-funding of the trial will not be allowed unless the additional funds are used for mechanistic extension studies or to pay for the drug. Duplicate efforts that have already secured outside funds will not be funded through the REF clinical trials funding mechanism.

## **SECTION II: TERMS OF AWARD**

### **Award Period**

The clinical trial grant will be awarded for a three-year period—September 1, 2012 – August 30, 2015— and is not renewable.

### **Award Amount**

Funding for the three-year period will be up to \$3,000,000— including indirect costs that must not exceed eight percent of the total award amount. All unexpended funds must be returned to the REF at the close of the award. All contractual documents must be received and compliant documents signed before financial disbursements will be made. The disbursement schedule is as follows:

Year 1:	September 2012	\$500,000	March 2013	\$500,000
Year 2:	September 2013	\$500,000	March 2014	\$500,000
Year 3:	September 2014	\$500,000	March 2015	\$500,000

### **Protected Time**

The Awardee must agree to devote a minimum of 10 percent of their overall professional effort to this project. Effort should be based on a full-time 12 month professional appointment. The grantee institution agrees to guarantee 10% of the Awardee’s professional time to activities related to the REF funded project.

### **Benchmarks**

The PI must provide annual updates on benchmarks for progress toward the specific aims of the funded project and an estimated timeline for completion of those benchmarks. This information is used to facilitate communication about projects to the Scientific Advisory Council and to assess progress. In addition, summaries of research that are translatable to a lay audience will be periodically required.

### **IRS Provisions**

Personnel compensated in whole or in part with funds from the REF are not considered employees of the Foundation. Grantee Institutions shall be responsible for issuing the appropriated IRS tax filings for all individuals receiving compensation from REF’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 REF funds shall vest in the Grantee 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 Foundation may, at its option, direct the Grantee Institution to transfer title to a new Grantee Institution.

### **Scientific Conduct and 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 Grantee Institution and subject to the institution's medical and scientific policies.

All research involving human subjects and recombinant DNA techniques must show documented compliance with NIH guidelines, the same as provided by the Grantee Institution's clinical and research review board. In addition, all activities supported by a REF research award must comply with all applicable U.S. Department of Health and Human Services regulations with respect to the rights and welfare of human subjects.

The Grantee Institution acknowledges that the Foundation does not direct, supervise or control the activities supported by this grant and will not be liable or otherwise responsible for such activities. Therefore, the Foundation is not responsible for any malpractice suit arising from any activity supported by the award.

### **Resource Sharing**

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.

### **Awardee Assurance**

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

The Principal Investigator must be an ACR or ARHP member for the duration of the award period. The Principal Investigator is required to devote a minimum of 10 percent overall full-time professional effort to the project.

### **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

#### LETTER OF INTENT

Letters of Intent are due online via the REF website no later than March 1, 2012. Each applicant intending to submit an application for a *Within Our Reach* Clinical Trial must submit a letter of intent via the REF website by the deadline above. The letter must include the following:

1. Names of Principal Investigator and Co-Investigators, along with a brief description of why this team is uniquely qualified to conduct the proposed trial
2. List of participating institutions/sites
3. Assurance that PI meets eligibility criteria as outlined in the RFP
4. Descriptive title of the study
5. Brief description of the proposed trial (200 words or less) - Succinctly describe the hypothesis to be tested, along with the aims and expected results.
6. Cost sharing plan – Briefly describe how the trial will be funded (e.g., solely by the REF, or cost-shared with sponsoring institution, etc.). See cost sharing policy on page 6.

#### APPLICATION PACKET

Submissions must contain the cover letter, original application with original signatures in blue ink, one set of the appendix materials, and one CD containing the completed application files as detailed below. Submission packets must be postmarked no later than May 1, 2012. Applicants are strongly encouraged to send submissions via UPS or FedEx in order to track receipt of the application files.

**Cover Letter** - Applicants are required to include a cover letter with the application. 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
- Brief description (two to three sentences) of proposed trial
- 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

**Original Application** – Applicants must submit the original application as a single-sided document on 8 ½ X 11 inch paper, 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. Original application must include all appendix materials.

### **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 saved in the appropriate folder as follows:

- 1) **FirstInitialLastName\_ADMIN** (e.g., 'JSMITH\_ADMIN'): to include the following files: Cover Letter, Face 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 Strategy section and Trial Benchmarks, each labeled appropriately (e.g., 'Benchmarks.pdf').
- 4) **FirstInitialLastName\_APPENDIX**: includes all Appendix materials, if applicable, including any consortium/contractual budget sheets, each labeled appropriately (e.g., 'App1.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 or incorrect 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. Late applications will not be accepted and will be returned without being considered for review. The PI and CO listed on the face page will receive e-mail confirmation within 24 hours of receipt of the application.

### **SUPPLEMENTARY INFORMATION**

Supplementary information will not be accepted. Unless directly instructed by REF staff, do not send supplementary or corrective material after the submission date.

**All applications must postmarked no later than May 1, 2012.** Applicant will receive e-mail confirmation within 24 hours of receipt. 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, Senior Director  
ACR Research and Education Foundation  
2200 Lake Boulevard NE, Atlanta, GA 30319

## 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* program. 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(s):** Is the primary investigator(s) appropriately trained and well suited to carry out the proposed trial? If the investigator does not have RA experience, are there appropriate collaborative arrangements with experts in RA? Is the assembled research team appropriate for the scope of the proposed trial?

**Relevance to Rheumatoid Arthritis:** Does the proposed trial address an important problem? What will be the effect of these trials on the concepts or methods that drive the field of RA research?

**Novelty:** Does the proposed trial employ novel concepts, approaches or methods? Are the aims original and innovative?

**Need:** Does the application have an appropriate justification for the proposed trial? Are the proposed activities appropriate given the scope of the project?

**Feasibility:** Does the scientific environment in which the work will be performed contribute to the probability of success? Does the proposed trial take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support? Are the proposed activities feasible within the term of the award? Are recruitment goals feasible within the start and ending times proposed?

**Methods:** Are the activities related to the proposed trial adequately developed, well integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

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

## REVIEW/NOTIFICATION

All grant applications will be peer-reviewed by a study section constituted by the REF. The REF Board of Directors will make all final funding decisions. Applicants will be notified of funding decisions by August 15, 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. These responsibilities include a minimum effort requirement and attendance at annual REF Investigators' Meetings.

### **I. PERCENT TIME AND EFFORT:**

The Principal Investigator is required to devote at least 10 percent overall full-time professional effort to the trial. Percent effort should be calculated based on a full-time 12-month calendar year appointment at the Sponsoring Institution.

### **II. INVESTIGATOR MEETINGS:**

The REF sponsors an annual Investigators' Meeting. All *Within Our Reach* grant recipients are required to attend this meeting to share the status of their funded research. This meeting is 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.

### **III. 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 10 percent overall full-time professional effort per year is required for this award.
- Human Subjects Certifications - Provide the institution assurance type and number and the certification date of IRB review and approval. Pending approvals are not acceptable; IRB approval must be submitted prior to receipt of funding.
- Human Subjects Education - 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.

## **IV. REPORTING REQUIREMENTS:**

### **Progress Reports**

The PI must provide the REF with progress reports at 6, 18, and 30 months identifying progress towards benchmarks of the proposal. Recipient must report on the following: project outcomes, progress and updated benchmarks, submitted or published articles or abstracts as well as additional funding received. Continued funding will be contingent upon progress demonstrated in these progress reports, including patient recruitment. Format and template for the progress report will be provided within 30 days of the due date (see below for schedule). Failure to submit a progress report by the deadline may result in funding delays and may hinder applicant's eligibility to receive additional REF funding.

April 1, 2013	6 month progress report due
April 1, 2014	Annual progress report due
April 1, 2015	Annual progress report due

### **Financial Reconciliations**

Annual financial reconciliations will be due by September 1 each year. These reports should be prepared by the sponsoring institution's Grants and Contracts/Sponsored Projects office. The report must contain the grant account balance as of June 30, as well as the carryover amount (if applicable). The report must contain reconciliation by cost category indicating how funds were allocated and whether any unexpended funds remain for the year. If the carryover exceeds 20 percent, a written explanation must be submitted by the PI explaining the reason for the excess carryover and how funds will be spent the following grant year. Assurance must be provided by the preparing officer stating they have reviewed the report and the financials for the project and award and found it to be true and accurate.

### **Final Report**

At the close of the award term, the recipient must provide the REF with a final report describing completion of project benchmarks as well as applicable deliverables. The format and template for the final report will be provided within 30 days of the due date. Final reports will be due by December 1, 2015. In accordance with REF policy, failure to submit required reports by the deadline may hinder applicant's eligibility to receive future REF funding.

### **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.

## **V. 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.

## **VI. 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-Myers Squibb Company, and UCB.

## **VII. 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.

## **VIII. 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**

#### **1. 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.

#### **2. 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

Foundation 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 Foundation 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.

### 3. 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].

#### 4. Publicity

The Foundation reserves the right to publicize Foundation supported research. The Foundation will provide the Grantee Institution and the Awardee prior notice and an opportunity for comment on any such public acknowledgment. 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 Foundation Supported Intellectual Property without prior approval of the Foundation.

#### 5. Use by Foundation

The Foundation may have the use of any Foundation Supported Intellectual Property, the ownership of which was retained by the Grantee Institution or its assignee under paragraph 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* clinical trial 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.

It is the applicant's responsibility 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 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 Mary Wheatley 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 Strategy section) 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.
- Print must be clear and legible.

## **Page Format**

- Size: Use standard size (8 ½" 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.

## **Photographs and Images**

- Black-and-white or color images may be included, provided such images are inserted directly into the application page and are critical to the content of the application.
- Do not include photographs or other materials that are not inserted 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.
- Do not use photo reduction. The application must contain only material that reproduces well when printed in black and white.

## **Grantsmanship**

- All applications must be written in English, and 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, the application may be returned to the applicant without review.
- Prepare a succinct research strategy section, items A-D. There is no requirement to use the maximum allowable pages allotted to the section. The remaining items (E-J) of the Research Strategy section 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 2c. Department, Service, Laboratory, or Equivalent:* Indicate your organizational affiliation, such as Department of Medicine, Materials Research Laboratory, or Social Sciences Institute.
- *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 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*

Must check 'Yes.' 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. 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 exempt from review.

*Item 4. Vertebrate Animals*

- Must check “No.” Activities involving vertebrate animals should not be planned at any time during the proposed trial period. The remaining parts of Item 4 are then not applicable.

*Item 5. Dates of Proposed Period of Support*

Request no more than three years of support. Award payments will be disbursed as detailed in Section IV.

*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 \$ 1,000,000 for the entire project period.

*Item 7. Applicant Organization*

- Enter the complete name of the organization that will be legally and financially responsible for the conduct of activities supported by the award. 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.

*Item 8. Organization Address*

Include the full address of the applicant organization, including building name, room number

*Items 9. 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 10. 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 11. Principal Investigator/Program Director Assurance*

The Principal Investigator’s original signature, in blue ink, is required.

## *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 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 Strategy section 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 Strategy section.

### 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 10 percent overall professional effort to the proposed trial. 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

The start date for Year 1 is 9/1/2012; the end date is 8/30/13, and so on. Maximum duration is three years.

### 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 December 24, 2011, the Executive Level I salary level cap is \$179,700. 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.

### 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.
- 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.
- Patient Care Costs: Indicate, in detail, the basis for estimating costs in this subcategory, including number of patients, the number of patient days, estimated costs per day, and cost per test or treatment.
- Travel - Scientific meeting travel is specifically restricted to cover expenses related to investigator travel to the REF Investigators’ Meeting only, and is capped at \$2,000. Meeting attendance is mandatory; this is a required line item for the grant budget. Travel funds for additional meetings relevant to the proposed trial are allowable, but should be listed as a separate line item. These costs must be included within the project budget. No additional funds will be provided.

### 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).

### Indirect Costs

**Indirect costs cannot exceed eight 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.
- Provide budget detail for per patient care costs.

### **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.

## Clinical Trial Research Plan (Form Page 9)

The Clinical Trial Research Plan section should include sufficient information needed for evaluation of the project, independent of any other document (e.g., appendix). The format for preparing this section is provided below. Be specific and informative, and avoid redundancies.

### Page Limitations

- Do not exceed 15 pages for Items A-C. 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-C of the Research Strategy section.
- All applications and proposals must be self-contained within specified page limitations. Internet Web site addresses (URLs) may not be used to provide information necessary to the review (Note: reviewers are under no obligation to view the Internet sites).

**A. Overview:** The overview will describe the significance and rationale of the proposed clinical trial. The potential for substantially changing clinical management must be addressed. (1 page limit)

**B. Clinical Protocol:** This section should include research aims, a rationale (*i.e.*, scientific and clinical practice justification for the proposed research), outcome measures (indicating appropriate objective and patient-centered measures for primary and secondary outcomes), study design. It is expected that all protocols will be performed in a manner consistent with NIH clinical research policies and the United States Food and Drug Administration guidelines. Evidence of FDA approval, or a plan for obtaining FDA approval should be provided and will be required at the time of award.

- *Specific Aims and Rationale*  
List the broad, long-term objectives and the goal of the specific trial 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. This section should also describe appropriate outcome measures (indicating objective and patient-centered measures for primary and secondary outcomes).
- *Background and Significance*  
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 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.

- *Clinical Trial 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. Provide a concise description of the overall strategy, methodology, and analyses to be used to accomplish the goals and specific aims of the trial, as well as a description of the intervention to be tested and the protocol to be followed in each arm of the trial, including a discussion of potential biases or challenges in the protocol and how they will be addressed. In addition, provide a description of the study organization and administration, including, but not limited to: a description of committee structures needed to manage the complexity of the trial; the role of any internal or external advisory committees; the oversight, responsibilities, and coordination of any sites or cores proposed; and the role of any subcontractors or service providers for personnel or facilities. Include how the data will be collected, analyzed and interpreted as well as the data-sharing plan as appropriate. This section should include a detailed statistical plan appropriate for the study design, including sample size and power calculations and the underlying assumptions (and data) used to link these calculations to the endpoints and to the hypothesis(es) being tested. 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 detailed communications plan between recruitment sites and co-investigators. Point out any procedures, situations or materials that may be hazardous to personnel and the precautions to be exercised, including stopping rules.

**C. Human Subjects Research:** The 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. 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.

- *Clinical Protocol Synopsis* (1 page limit)

The clinical protocol synopsis should be included at the end of the Human Subjects section. Applications that lack the Clinical Protocol Synopsis will not be reviewed. The clinical protocol synopsis must include the following information:

- A description of the study population, including subject eligibility and inclusion/exclusion criteria;
- Sampling, recruitment and enrollment plans, including a discussion of the availability of subjects for the proposed study and the ability of enrollment center(s) to recruit and retain the proposed number of subjects;

- The process to be used for obtaining informed consent and, if applicable, assent;
- Approaches to be used for retention, cooperation and follow-up of subjects and to address any anticipated changes in the composition of the study population over the course of the trial;
- Methods of assignment of subjects to study groups and of randomization;
- If appropriate to the study, a description and justification for the selection of the dose, frequency and administration of the intervention(s);
- A description of each enrollment site and how data from the site(s) will be obtained, managed, and protected;
- Descriptions of all clinical, laboratory, physiological, and/or behavioral tests to enable the research questions to be answered; and
- A description of the data management and quality control plan, including methods for monitoring the quality and consistency of the intervention(s) and data collection; policies and methods for ensuring blinding of study results; and data confidentiality and subject privacy.
- Identification and qualifications of clinical trial site(s), pharmacies and laboratories
- Comprehensive Laboratory Plan
- Documentation of availability of study agents and support for acquisition and administration of study agent(s)
- Site Quality Management Plan

**D. 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.

**E. 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.

**F. 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. Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: 1) [Data Sharing Plan](#) and 2) [Genome Wide Association Studies](#).

**G. Consultants:** Attach appropriate letters here from all individuals acting as consultants on the project, confirming their roles in the project and rate/charge for consulting services. Do not place these letters in the Appendix. Letters of support from collaborators should be included in the Appendix unless they are receiving consulting fees for their services.

### **Research Project Benchmarks (Form Page 10)**

A detailed timeline for milestones in the study must be provided. This time line must account for IRB and DSMB approval, realistic goals for patient recruitment and follow up, and data analysis and preparation. Progress will be administratively assessed annually before the next year's disbursement is made. These benchmarks will be used to evaluate progress and to facilitate communication between principal investigators 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 20 pages in length.**
- **Note:** 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. Only those materials necessary to facilitate the evaluation of the research plan may be included.
- A summary sheet (see form page 11) of the application-listing all of the items included in the Appendix is required.
- 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 G of the Research Strategy*
  - 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.
- **The following additional documents MUST be included in the Appendix material and do NOT count against the page limit:**
  - Complete Clinical Protocol
  - Informed consent form(s) and, if applicable, assent form(s)
  - Copies of data collection forms, questionnaires or other relevant materials
  - Investigator’s Brochure or equivalent for the study products(s)
  - Table of Contents of the Manual of Procedures

## **REMINDER: SUBMISSION REQUIREMENTS**

### **Letter of Intent: Due online no later than March 1, 2012**

Each applicant intending to submit an application for an REF *Within Our Reach* Clinical Trial must submit a letter of intent via the REF website by the deadline above. The letter must include the following:

1. Names of Principal Investigator and Co-Investigators, along with a brief description of why this team is uniquely qualified to conduct the proposed trial
2. List of participating institutions/sites
3. Assurance that PI meets eligibility criteria as outlined in the RFP
4. Intent to apply for trial, along with proposed descriptive title
5. Brief description of the proposed trial (200 words or less) - Succinctly describe the hypothesis to be tested, along with the aims and expected results.
6. Cost sharing plan – Briefly describe how the trial will be funded (e.g., solely by the REF, or cost-shared with sponsoring institution, etc.). See cost sharing policy on page 6.

### **Applications: Must be postmarked no later than May 1, 2012**

Each applicant must include the following items in their submission packet (See pages 9-10 of this document for detailed submission instructions):

1. Cover letter from PI
2. Original application (hard copy) with original signatures in blue ink
3. One set of appendix materials
4. One CD containing the completed application files as detailed on pages 9- 10

Applicants will receive e-mail confirmation within 24 hours of receipt. 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, Senior Director  
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