



*Request for Proposals*

# **MIDWEST STRATEGIC PHARMA-ACADEMIC RESEARCH CONSORTIUM AWARDS PROGRAM**

A JOINT INITIATIVE SPONSORED BY

INDIANA CLINICAL AND TRANSLATIONAL SCIENCES INSTITUTE

AND

OHIO STATE UNIVERSITY CENTER for CLINICAL TRANSLATIONAL SCIENCE

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SCIENCES

AND

THE UNIVERSITY OF CHICAGO

AND

ELI LILLY and COMPANY

AND

TAKEDA PHARMACEUTICALS INTERNATIONAL INC.

**ELECTRONIC RECEIPT DATES**

**LETTER of INTENT (LOI): MARCH 18, 2016 (Email: [ictsi@iu.edu](mailto:ictsi@iu.edu))**

**FULL APPLICATION: JUNE 17, 2016**

**[\(https://www.indianactsi.org/grants/\)](https://www.indianactsi.org/grants/)**

## INFORMATION FOR APPLICANTS

### Purpose

The Academic and Industry Members desire to participate in and conduct pharmaceutical related projects in the non-competitive intellectual property space, including but not limited to, early translational medicine and potential identification of therapeutic targets in the area of human Autoimmune Diseases with the following goals:

- To improve the definition of autoimmune diseases (in particular, to move towards molecular classification rather than clinically-defined syndromes) and to devise biomarkers that will predict response to therapy and enable early monitoring of the response to therapy. Studies that include longitudinal sample collection from well-characterized patients are particularly encouraged.
- To increase patient-focused research to understand mechanisms driving chronic inflammatory disease in order to improve and tailor therapies.

### Types of Projects

#### **In Scope:**

1. Underserved but relatively common autoimmune diseases, such as fibrotic diseases (e.g., scleroderma, IPF, primary biliary cirrhosis), progressive Multiple Sclerosis, Sjögrens syndrome, celiac disease, etc.
2. Rare or low prevalence inflammatory diseases: either as a 'direct' interest in pathogenesis or as a means to better understanding the biology of autoimmune disease or of the immune system in general (e.g., Common Variable ImmunoDeficiencies, myasthenia gravis, Neuromyelitis Optica, pemphigus, etc.)
3. Defined subpopulations of higher-prevalence diseases such as rheumatoid arthritis, type 1 diabetes, multiple sclerosis, inflammatory bowel disease, lupus, atopic diseases, or respiratory diseases if the population can provide new insights; e.g., a unique group of RA patients with an unusual genetic background or a particular complication etc.
4. The microbiome: understanding how microbiome/host molecular/biochemical interactions may be involved in pathogenesis or affect the phenotype and/or severity of autoimmune diseases in specific, in-scope patient populations.

#### **Out of Scope:**

1. Type 2 diabetes
2. Cardiovascular diseases
3. Osteoarthritis
4. Studies which replicate or significantly overlap with other/larger existing consortia (e.g., AMP program; large NIH initiatives etc.)
5. Exclusively animal models based research proposals, with the exception that certain patient-driven animal research such as human/mouse chimeric models may be considered

SPARC expects to support projects that meet the following criteria: (1) research is in the non-competitive space of mutual interest (see In Scope / Out Of Scope definitions above) that address scientific and technological research challenges confronting the pharmaceutical industry; (2) project is to be executed with the network of Academic Members; (3) study is designed to further the understanding of disease biology, potentially leading to the identification of novel therapeutic targets; (4) to promote an improved definition of autoimmune disease according to molecular taxonomy rather than as clinical syndromes; and/or (5) to improve the prediction of response to therapy and the early detection of response / non-response in autoimmune diseases where this is not apparent at a clinical level.

To be considered, the proposed project should demonstrate the followings:

1. Have at least **two (2)** Project Specific Personnel from different Academic Member institutions for which such institutions agree to contribute the requisite cost share funding for the research proposal.
2. Address the non-competitive space of mutual interest to the Members and scientific and technological research challenges confronting translational research.
3. Include the Research Plan and related budget for the study proposal.
4. Agrees to the maximum indirect cost rate of 20%.

Consortium members include:

Industry:

1. Eli Lilly and Company
2. Takeda Pharmaceuticals International, Inc.

Academic Institution:

1. Indiana Clinical Translational Science Institute (ICTSI)
2. Ohio State University Center for Clinical Translational Science (OSU-CCTS)
3. Northwestern University Clinical and Translational Science (NUCATS)
4. Washington University in St. Louis Institute of Clinical and Translational Sciences (WUSTL ICTS)
5. The University of Chicago Institute for Translational Medicine (UC-ITM)

### **Funding Amount**

Applications to this program are limited to a total of **\$400,000 with a 2-year maximum** for all collaborating member institutions.

Available funding from program sponsors will allow for approximately 2-4 awards to be made under the SPARC mechanism each year.

### **Application Process and Requirements**

Application is a two stage process:

(1) An initial one-page scientific summary of the proposal with a one page list of participating scientists in the form of a letter of intent is required to be submitted via email to [ICTSI@iu.edu](mailto:ICTSI@iu.edu) by **FRIDAY, MARCH 18, 2016**. These initial proposals will be triaged by the SPARC Scientific Committee for the strength of the research and collaboration. It is important to state clearly the goals of the research and collaboration. The initial proposal must have at least two collaborating academic members from the SPARC Consortium. Applicants will be advised by **MONDAY, APRIL 4, 2016** whether the proposal has been accepted for progression to submission of a Full application for the second round of review.

(2) If selected for the second round, the FULL application due date is **FRIDAY, JUNE 17, 2016– ONLINE** at <https://www.indianactsi.org/grants>. Applications are considered one time per year. Applicants must use the application forms that are provided and specified on the CTSI website noted above.

**FULL APPLICATIONS WILL FOLLOW THIS SEQUENCE:** (Application forms available on the [www.indianactsi.org/grants](http://www.indianactsi.org/grants) website.)

**1.** Face pages, which specifies the title of the proposal, principal investigators and his/her affiliation, collaborator(s) and affiliation, where work will be performed, and the total budget. Department / School support must be indicated by completion of all signatures on the face page(s). As submission will be electronic only, facsimile or electronic signatures are appropriate.

2. Budget page listing all costs. This page may be duplicated and a separate budget page included for each performance site / collaborating institution. An Excel budget template is provided on CTSI grant software website noted above.

- Proposals must reflect a sharing of budget and effort between the collaborating consortium members.
- Supplies and other costs must relate directly to performance of the project.
- Travel beyond that which is necessary between the institutions / campuses for purposes related directly to the Project will require justification.
- All costs should be specifically justified and expenditures for each participating partner clearly denoted. Limit the budget justification to 1 page.

3. Research Plan should have **1/2 inch margins** and is not to exceed **5 single-spaced pages** Arial 11-pont font, not including the references.

Requests for funds will be assessed on the following criteria:

- The fit with the scope outlined above.
- The strength of the research.
- The strength of the collaboration.
- The strength of a defined plan for future extramural support and/or IP.

The Research Plan narrative should be structured in accordance with the following format:

- A. **Objectives of the current proposal:** State the overall objective or goal of the proposed research. Describe the collaborative research program that exists or that will develop from the collaboration and the nature of the complimentary expertise that will promote synergism.
- B. **Specific Aims and methods of the current proposal:** Communicate the scientific significance and innovation of the proposed collaboration.
  - a. Describe the specific aims of the proposal, the methods of procedure, how the complementary expertise contributes to those aims, and the rationale behind the chosen approach to the problem. Include a discussion of pitfalls that might be encountered and the limitations of the procedures proposed.
  - b. Indicate the reason for the selection of a particular model system, if not using human or conventional animal model (or explain why this is not applicable).
- C. **Description of Joint Research Program:** Briefly review the current status of research in the field and the PI / co-PI contributions to that field. Document with references. Describe any preliminary work the investigators have performed which led to this proposal, alone or in collaboration. Explain how synergy will be achieved.
- D. **Significance:** What is the potential importance of the proposed collaboration? What is its potential impact on human health and/or how may it be translated to impact human health concerns in the future? Specifically describe its relevance and translational potential. Discuss any novel ideas or contributions the collaboration offers. Make clear the potential importance of the proposed collaboration for further investigation and future research on the different campuses.
- E. **Potential for Biomarker Development:** Studies that include acquisition of clinical samples from well-characterized patients are valued as these will aid the discovery and development of biomarkers to predict and monitor treatment response. Except where there are very specific patient-centric reasons, the Informed Consent Forms should include explicit provision for retention of samples and for de-identified samples to be used by 'third parties' including the Industry partners, other institutions within the consortium, and institutions outside the consortium as required for particular markers. Plans for sample acquisition, and any limitations on the use of such samples, should be explicitly described.

**Project timeline:** The following (or a similar) table should be completed and inserted at the end of the research plan.

Task	Month	1-3	4-6	7-9	10-12	24
Task 1 – enter description and mark appropriate period(s)						
Task 2 – enter description and mark appropriate period(s)						
Task 3 - enter description and mark appropriate period(s)						
Task 4 - enter description and mark appropriate period(s)						
Task 5 - enter description and mark appropriate period(s)						
Task x – complete requisite progress reports			X		X	X

**4. Biographical sketch of the principal investigators (4-page maximum).**

The biosketch should be provided in the new NIH format available at <http://grants1.nih.gov/grants/funding/phs398/phs398.html>. It is limited to 4 pages in length and should include positions, honors, publications and selected research projects that are most relevant to the proposed project. For those unfamiliar with the NIH format, more information can be found within section 4.6 of the [PHS398 application instructions document](#).

**5. Biographical sketch of each co-investigator / collaborator (4-page maximum per collaborator). Same format and instructions as pages 9-12.**

6. Other support for the principal investigator and each co-investigator / collaborator, including detail on any overlap that this proposal has with active or pending awards. This information must be provided in NIH format. Links to the forms and instructions are provided above in ‘page 15-18’ section.

7. Letters of Collaboration

**RESTRICTIONS**

1. There is a maximum \$400,000 funding request per proposal.
2. The project period must have a start date of September 1, 2016 or after.
3. The requested grant funding period cannot exceed **24 months**. If necessary and deemed appropriate, no-cost extension (NCE) may be granted one time.
4. Faculty salary is allowed. However, the request for PI support is based on the NIH cap.
5. Request for the purchase of equipment (>\$5000) will not be considered.
6. Supplies and other costs are allowable, but must relate directly to performance of the project.
7. Travel beyond what is necessary for the performance of the project is not allowed.
8. Facilities and Administrative costs, or indirect costs, are allowed at a rate of 20%

## WHO MAY APPLY

All full-time faculty, regardless of tenure status, having a primary appointment within the institutions of the consortium members as Assistant Professor or Assistant Scientist and above. This includes those faculty appointed as part-time Assistant Professor or above, if they are geographically full-time. Faculty that hold the title of visiting rank are not eligible for funding.

## PEER REVIEW AND AWARD SELECTION

### Stage 1:

**Letter of Intent is due on FRIDAY, MARCH 18, 2016– E-mail to [ictsi@iu.edu](mailto:ictsi@iu.edu).**

### Stage 2: (Only selected applicants)

**Submission due date is FRIDAY, JUNE 17, 2016– ONLINE at <https://www.indianactsi.org/grants>.** Applicants must use the application forms that are provided and specified on the Indiana CTSI website noted above.

The number, size and scope of the final awards will be determined by the SPARC Executive Committee and announced in **AUGUST 2016**. Projects should have a start date no earlier than **SEPTEMBER 1, 2016**.

## CONTACT INFORMATION

For questions regarding scope or review of the proposal, please contact:

IU: Anne Nguyen ([ictsi@iu.edu](mailto:ictsi@iu.edu))

For financial issues related to budgeting and grant submissions, please contact:

IU: Indiana CTSI Office ([ictsi@iu.edu](mailto:ictsi@iu.edu) / 317-278-2874)

Navigators:

ICTSI: Anne Nguyen ([ictsi@iu.edu](mailto:ictsi@iu.edu))

NUCATS: Frume Yehiely ([yehiely@northwestern.edu](mailto:yehiely@northwestern.edu))

WUSTL ICTS: Jaimee Stagner ([jstagner@dom.wustl.edu](mailto:jstagner@dom.wustl.edu))

OSU-CCTS: Amy Dworkin ([Amy.dworkin@osumc.edu](mailto:Amy.dworkin@osumc.edu))

UC-ITM: Julian Solway ([Jsolway@medicine.bsd.uchicago.edu](mailto:Jsolway@medicine.bsd.uchicago.edu))

## POST AWARD REQUIREMENTS

1. All awards will be monitored for progress by the Central SPARC Administrative Office as required. Progress monitoring generally includes the following from all project PIs and, when appropriate, may be developed in consultation with SPARC Administration:
  - a. A milestone driven budget management plan developed cooperatively with SPARC.
  - b. Semiannual progress reports due in June and December that report status of milestone progress along with documentations of external grant submissions/awards, IP, publications, and/or presentations arising from the supported research. Project support and budget management discussions will occur if applicable.
  - c. Final report submission electronically to the Central SPARC Administrative Office within 60 days of the termination date.
  - d. Annual follow-up reports upon request for up to 3 years after the project ends, including but not limited to the following data:
    - i. External grant submissions and awards arising from the supported research

- ii. Intellectual property arising from the supported research including disclosures or patents filed
  - iii. Publications arising from the supported research
  - iv. Additional impacts of the award on your research and the collaboration
- 2. Grant recipients are reminded to acknowledge receipt of the NIH CTSA and SPARC support in any presentation or publication of work funded by the award.