Strategic Research Agreements

Summary (Single-, Multi-, and Clinical SRA Projects)

Description

Designed to provide research funding for single or multiple investigators to address critical gaps and challenges and potential breakthroughs in Type 1 diabetes research

Submission Process

1. **Project Concept**
   Approved Project Concept, submitted to the JDRF **Project Concept Call in RMS360**, required prior to submission of a full application
2. **Application**
   Access and submit full applications (including research plans) via **RMS360**. The research plan cannot exceed 12 pages, including figures and tables, unless otherwise specified on the research plan document. Citations and PI Assurance are an addition to this page limit.

Institutional Eligibility

Domestic & foreign non-profit organizations; public & private universities, colleges, hospitals, laboratories; units of state & local governments; eligible agencies of the federal government

Applicant Eligibility

Required: MD, DMD, DVM, PhD, or equivalent and faculty position or equivalent

Human Subjects Research

For a project proposing Human Subject Research, please review the **Human Subject Research Guidelines**

Upcoming Deadlines

Please see the **Submitting an Application** section below for project concept deadlines

Description

JDRF's Strategic Research Agreements provide research funding for single or multiple investigators to address critical gaps and challenges and potential breakthroughs in Type 1 diabetes research. The Strategic Research Agreement is a partnership between Investigator(s) and JDRF Scientists to help address roadblocks and accelerate JDRF's mission through support of cutting-edge scientific investigation. Further, this mechanism embodies cooperative development of a research plan, interim quarterly reporting on milestones and interaction with JDRF scientists prior to and during the award period. The budget and duration of funding are variable and continued funding is based on

budget and duration of funding are variable and continued funding is based on satisfactory effort and quarterly progress on milestones. Submission of an application requires permission from JDRF and is initiated with a Project Concept submitted to the JDRF **Project Concept Call in RMS360**

Successful Project Concept applicants will be contacted for further project development by JDRF personnel.

Eligibility

Applicants must hold an MD, DMD, DVM, PhD, or equivalent and have a faculty position or equivalent at a college, university, medical school, company, or other research facility. Applications may be submitted by domestic and foreign non-profit organizations, public and private, such as colleges, universities, hospitals, laboratories, units of state and local governments, and eligible agencies of the federal government. Ordinarily, for-profit organizations will not be considered, except under special circumstances. See the **Industry Discovery & Development Partnerships** section for a description of special programs for for-profit entities. There are no citizenship requirements for this program. To assure continued excellence and diversity among applicants and awardees, JDRF welcomes applications from all qualified individuals and encourages applications from persons with disabilities, women, and members of minority groups underrepresented in the sciences.

Submitting an Application

Step 1: Project Concept

An investigator interested in pursuing a research opportunity with JDRF must submit a Project Concept through JDRF's **Project Concept Call in RMS360**. Project Concepts are selected on the basis of programmatic fit and robustness of the concept. In addition, projects that hold a prospect for transformative breakthroughs that prevent, treat or cure Type 1 diabetes will be given top priority.
Project concepts are due at 5 PM ET on the deadline date. No extensions will be granted.

To view upcoming deadlines, click **here**.

Step 2: Full Application

If the applicant's Project Concept is approved by JDRF, the applicant will be invited to submit a full research application. The applicant will be authorized to access and electronically submit the completed application via **RMS360**.

1. The JDRF Scientific Personnel works collaboratively with the investigator or investigator team to develop a full application in accordance with JDRF strategic objectives.
2. All research applications are submitted and reviewed using RMS360.
3. The complete and submitted application is reviewed by scientific experts and written critiques are received by the staff, generally in 4-8 weeks.
4. The reviewers' critiques will be shared with the applicant. The applicant may submit a rebuttal that addresses the concerns raised by the reviewers.
5. The entire application and review materials are evaluated amongst JDRF staff and reviewers, and final approval is made by the Research Committee.

Note: For a project proposing Human Subject Research, please review the **Human Subject Research Guidelines**.

Terms of the Award

Available funding for the Strategic Research Agreement will be reviewed on a per-application basis. Projects will be milestone-driven, require teleconferences with the Scientific Staff to discuss project progress and research findings on a quarterly basis. In addition to quarterly reports, an annual progress report will be due 2 months prior to the anniversary date of the award, except in the final year, in which the progress report is due 75 days following the close of the award. Projects are no more than 3 years duration. Support beyond 3 years will be determined based on a detailed scientific review of the accomplishments and future plans of the Project. Decisions on continued funding are made by the Program Director in consultation with Senior Management based on progress on milestones. Indirect costs cannot exceed 10% of direct costs (direct costs do not include equipment costs, fee-for-services, consultants, or subcontract costs).

Multi-Project SRA Details

Description

The JDRF Strategic Research Agreement for multiple projects provides a mechanism to stimulate new collaborations between clinical and basic scientists and/or between scientists from diverse backgrounds as a means to conceive and develop new approaches to major challenges, potential breakthroughs, or persistent obstacles to progress along the various paths to

prevent, treat or cure Type 1 diabetes and its complications.

A central theme highly relevant to the priority areas of research for JDRF is required and must include a set of clearly defined goals that can be met within a 3-year period. In most cases, Multi-Project SRAs will focus on basic or pre-clinical research that seeks to impact the treatment or prevention of Type 1 diabetes and its complications. However, clinical studies meeting the other criteria for Multi-Project SRAs will be considered. Multi-Project SRAs may be composed of 3-6 projects and 1-3 cores, with component projects being highly interactive and benefiting from the use of common cores. In general, the component projects will have interdependent outcomes. An overall Project Principal Investigator is required. Generally, administration of the Project will rely on mutually agreed-upon leadership and common consent of the individual project principal investigators. In many instances, an administrative core will not be necessary, and any budget requests for administrative support must be strongly justified in the Multi-Project SRA application.

Application Guidelines

Upon approval of the Project Concept, the Multi-Project SRA overview application will become available. The Principal Investigators of Individual Projects & Cores must complete separate online applications on RMS360 for each Multi-Project SRA Individual Project/Core. JDRF Staff will make the Multi-Project SRA Individual Project/Core application templates available to the PI of each Individual Project/Core.

Application Title

The titles for each Individual Project/Core application MUST begin with the last name of the Multi-Project SRA Director (even if some Projects and Cores have different PIs) followed by its component. For example:

- Strategic Research Agreement – Multi-Project Overview title: DOE Overview: Cure T1D
- Strategic Research Agreement – Multi-Project Project 1 title: DOE Project 1: Beta Cell
- Strategic Research Agreement – Multi-Project Project 2 title: DOE Project 2: Immune
- Strategic Research Agreement – Multi-Project Core A title: DOE Core A: Mouse Core
- Strategic Research Agreement – Multi-Project Core B title: DOE Core B:

- Strategic Research Agreement – Multi-Project Core B title: DOE Core B: Admin Core
- RMS360 Composite Budget Detail Example

Each Individual Project/Core should complete and submit its own budget within its individual application, and all Individual Project/Core budgets should be entered into the Composite Budget within the Overview Application for each year. Within the Composite Budget of the Overview Application, click the Add Project/Core button to enter subtotals for each Project/Core for each year. Please contact the appropriate JDRF Pre-Award Staff for more information on completing the Composite and each Individual Project/Core Budget.

Evaluation

The overall application and each individual project/core will be evaluated by the review committee. Reviewers will be asked to: 1) assess each project on its own merits; and 2) assess each project as part of the overall Project and whether it should be included. Reviewers will be provided with the full application to assist them in their evaluation. As with the Single-Project, reviewer comments will be shared with the Investigator team and given an opportunity to respond to the commentary.

The relationship and contributions of each individual research project and core to the overall theme of the Multi-Project SRA application will be evaluated by the review committee and scored using the JDRF scoring guide. Assessment of the overall application is conducted after all individual research projects have been reviewed and rated. Reviews will be performed by an appropriate review group. The following criteria are among those which will be considered by the review committee:

- Potential to develop and prove principle of new approaches to unsolved problems, critical gaps and challenges, or novel paradigms in Type 1

  diabetes
- Relevance to the objectives and research emphasis areas of JDRF
- Scientific, technical, or medical significance of the Strategic Research Agreement – Multi-Project
- Scientific merit of the Strategic Research Agreement – Multi-Project as a whole, as well as that of the individual research projects
- Appropriateness and adequacy of the experimental approach and methodology
- Innovation

- Innovation
- Synergy:
    - Will there be a team of investigators with various types of expertise undertaking
    - Collaborative multidisciplinary research in the health sciences in various institutions
    - Will there be research components, each scientifically meritorious, which together form an integrated research program able to address issues which could not readily be approached were the components to be funded separately?
- Evaluation of the cohesiveness of the Strategic Research Agreement – Multi-Project and the coordination and interrelationships of individual projects and core(s) to the common theme. What are the relative priorities of the various projects; is there a chronological relationship; and should they all be included in the Strategic Research Agreement – Multi-Project?
- Investigators:
    - Assessment of the leadership and scientific ability of the principal investigator
    - His or her ability to develop a program of integrated research projects with a well-defined central research focus
    - His or her commitment and ability to devote adequate time and effort to the program.
    - What is the role of each investigator as part of the Strategic Research Agreement – Multi-Project: time commitment and who is going to do what?
    - Will each investigator be able to devote adequate time and effort to the program?
- Core facilities: Each core must provide essential facilities or services for two or more individual research projects. Review criteria for scientific cores consist of the following:

    - Justification and usefulness of the core facilities to the various research projects
    - Relationship of each core to the central focus of the overall Strategic Research Agreement – Multi-Project
    - Quality of relevant facilities or services provided by the core (including procedures, techniques and quality control) and criteria for prioritization and usage
    - Qualifications, competence and commitment of the Core leader and key personnel

key personnel

- Organization and Communication:
  - Organizational aspects of the Multi-Project
  - Assessment of the plans for meetings, other interactions, and exchange of data, material and techniques
  - Effect of geographical distribution of the members
- Institutional and other sources of support:
  - Institutional commitment
  - Impact of the project on the institutions involved in terms of research priorities of the institution, financial support, time protection, and laboratory space and equipment
- Other sources of financial support for the request:
  - Cost-sharing arrangements with the sponsoring institution(s)
  - Industry (keeping in mind that university-industry collaborations are encouraged)
  - Other agencies
  - Estimates of institutional expenditures involved in upgrading or constructing laboratory facilities; estimates of indirect institutional support such as provision of services and computing resources; user fees

Clinical SRA Details

Description

JDRF Clinical SRAs are are intended to support research programs that qualify under the JDRF clinical review process. This funding mechanism is intended to support early-stage clinical trials to test therapeutic approaches as well as non-interventional patient oriented studies that are intended to lead to the development of clinical interventions and monitoring tools (such as markers) for diabetes and its complications. Applications for Strategic Research

Agreement – Clinical must be goal oriented and closely focused on the JDRF mission.

Clinical Application Guidelines

All applications involving human subject research must include supplemental information to address subject safety, study design and investigational product information. More details can be found in the **Human Subject Research Guidelines**. All applications that receive a funding recommendation after scientific review will undergo clinical review where a subsequent review of the

scientific review will undergo clinical review where a subsequent review of the study protocol and supporting documents will be performed.

Outcomes Beyond A1C Resources

The Steering Committee of the T1D Outcomes Program has defined the following outcomes: hypoglycemia, hyperglycemia, time-in-range, and diabetic ketoacidosis (DKA). JDRF requires that all newly funded clinical studies incorporate the appropriate outcomes. Further, outcomes incorporated into a study should be consistent with the definitions from the publication, and we recommend their usage as endpoints in all T1D studies. Protocols that include measurement of these outcomes that are not defined per the publication must provide justification prior to grant approval. Please see relevant resources- **fact sheet** and **video**.

Evaluation

Clinical SRAs will be – Clinical will be evaluated for scientific merit, clinical standards of care for the proposed patient population and adherence to Good Clinical Practice. The scientific review criteria include:

- Potential to prove principle of new approaches to unsolved problems of type 1 diabetes
- Relevance to the objectives of JDRF
- Scientific, technical, or medical significance of the research proposal
- Innovative quality of the proposed study
- Soundness of the clinical study design
- Availability of sufficient pre-clinical data to justify the proposed clinical study
- Qualifications and research experience of the principal investigators and collaborators

- Consideration of the potential benefits and risks to patients who will be involved in the research, plans to limit risks, and other ethical considerations
- Availability of resources and facilities necessary for the study
- Appropriateness of the proposed budget in relation to the proposed research

Clinical Trial Management

The mission of this group at JDRF is to facilitate execution of high quality

The mission of this group at JDRF is to facilitate execution of high quality clinical trials. Please click the link for the current **Human Subject Research Guidelines** with a few additions as listed below.

- Pre-award: an application for funding can be submitted for bundled studies, pre-clinical and clinical piece, etc but if deemed appropriate by the CTM, the below funding structures may apply requesting updated split budgets for each phase as applicable. No new application required.
  - multipart funding structure for clinical trial set up and execution phase, if applicable
  - if bundled trials within a single proposal, multipart funding structure
- Post-award: assigned JDRF-CTM will provide active management of clinical trial grants via site calls to understand the study progress, as applicable.
- In some cases, it may be necessary for the CTM to perform a site visit either in advance of study initiation or during study conduct.

*Please speak with your proposal/study assigned **JDRF-CTM** if you have any questions or need clarifications.*

Additional information

- **Grant Mechanism Descriptions**
- **How to Apply**
- **Applicant Guidelines**
- **Application Checklists**
- **Contact Us**

Funding Opportunities and Deadlines

Grant Mechanism Descriptions

Strategic Research Agreements

Postdoctoral Fellowships

Advanced Postdoctoral Fellowships

Career Development Awards

Early-Career Patient-Oriented Diabetes Research Awards

Innovative Grants

Conference Grants

Industry Discovery & Development Partnerships

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