

# JDRF REQUESTS LETTERS OF INTENT FOR: NOVEL ADJUNCTIVE THERAPEUTIC STRATEGIES TO IMPROVE METABOLIC CONTROL IN TYPE 1 DIABETES

## PURPOSE

JDRF is committed to the development of novel therapies to improve metabolic control in people with type 1 diabetes (T1D). Toward this goal, JDRF invites applications to pursue preclinical or clinical studies to identify or validate novel targets for T1D metabolic control. Additionally, we invite applications to pursue clinical investigation of T1D pathophysiology toward the future identification and validation of novel targets.

## BACKGROUND

T1D is characterized by the loss of insulin-producing beta cells and consequential metabolic sequelae induced by high levels of blood glucose. Insulin therapy, while absolutely essential, is insufficient for most people with T1D to achieve optimal glycemic control and other metabolic outcomes. Thus, adjunct therapies that complement insulin action are critical. Although some validated type 2 diabetes (T2D) drugs (such as GLP-1 receptor agonists and SGLT inhibitors) show clinical efficacy in T1D, additional therapies designed specifically for T1D pathophysiology promise further advances in metabolic control. This RFA is intended to advance the development of adjunctive therapies rooted in T1D biology.

## OBJECTIVES

Letters of intent (LOI's) are sought from academic or industry applicants with innovative approaches to 1) identify novel targets for therapeutics to improve metabolic control in T1D, 2) validate novel targets for therapeutics to improve metabolic control in T1D, or 3) perform clinical research on T1D pathophysiology (including studies on selected human tissues) that will facilitate the discovery or validation of novel targets in future studies.

Projects with the highest relevance to T1D will be given priority; relevance to T2D may be a plus. JDRF will support target identification and validation in either preclinical or clinical models. Among validation studies, JDRF encourages validation of targets supported by clinical evidence (e.g. reverse pharmacology approaches). Studies on T1D pathophysiology must be clinical to be considered for funding.

Examples of research appropriate for this RFA include, but are not limited to:

- Phenotypic or expression screens in preclinical models to identify novel targets for glycemic control
- Evaluation of potential targets or pathways selected by hypotheses based on literature or unpublished data
- Preclinical model validation of targets for metabolic control previously discovered in preclinical or clinical studies
- Clinical research to investigate how metabolic pathways are altered in T1D in liver, fat, muscle, and other tissues
- Clinical research to investigate how the circadian clock or dietary subtypes influence T1D metabolism.

This RFA will not support applications primarily focused on the following areas that are being funded by JDRF by other mechanisms:

- Preventing or delaying T1D onset
- Beta cell regeneration or survival
- Immune modulation
- Restoration of normal alpha cell function
- Novel insulin drugs or formulations

Applicants are encouraged to consult with JDRF Scientific Staff to discuss the alignment of their proposal to this RFA and to develop the projected study concept.

## MECHANISM

In response to this announcement, LOI's can be submitted to JDRF's **Strategic Research Agreement (SRA)** or **Industry Discovery and Development Program (IDDP)** grant mechanisms. For more information on these mechanisms, please refer to our website:

- Strategic Research Agreements: <http://grantcenter.jdrf.org/information-for-applicants/grant-mechanism-descriptions/strategic-research-agreements/>
- Industry Development and Discovery Program: <http://grantcenter.jdrf.org/industry-partnerships/>

Each application may request up to \$200,000 per year (including up to 10% indirect costs), for up to two years. Applicants should discuss with JDRF Staff (see below) when proposing projects with increased scope (time, budget), especially in the case of clinical research.

Applications that are not funded through this RFA may be resubmitted to other JDRF grant mechanisms according to the deadlines and guidelines described on the JDRF website: <http://grantcenter.jdrf.org/rfa/>

## ELIGIBILITY

Applications may be submitted by domestic and foreign non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of state and local governments, and eligible agencies of the federal government. Applicants must hold an M.D., D.M.D., D.V.M., Ph.D., or equivalent and have a faculty position or equivalent at a college, university, medical school, or other research facility. Please note that applications from for-profit entities or industry collaborations with academia may be submitted to this RFA; however, additional information will be requested from for-profit entities if a full application is invited.

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.

## LETTER OF INTENT

Prospective applicants should submit a LOI online via RMS360 (<http://jdrf.smartsimple.us>) to be considered for a full proposal request. The LOI template provided on the RMS360 website must be used to complete the application. Applicants will be notified approximately eight weeks after the LOI deadline date if they have been approved to submit a full application.

Please see below for complete instructions. Letters of intent should use the template provided and include the following information:

- Background/rationale, published or preliminary data, hypotheses, specific aims, deliverables of project, collaborative framework if applicable
- Description of potential for translating project deliverables into therapies, including short and long-term development goals
- Indication of whether research will include human subjects
- Intellectual property or commercial efforts associated with the current application
- Estimated budget (total and yearly)

## PROPOSAL

**An approved LOI is required prior to submission of a full proposal.** Upon notification of a request for a full proposal, the application must be completed using the templates provided on the RMS360 (<http://jdrf.smartsimple.us>). Proposal section templates in MS Word [**10 page maximum**] should be type-written, single-spaced and in typeface no smaller than 10-point font and have no more than six vertical lines per vertical inch. Margins, in all directions, must be at least ½ inch. Complete information should be included to permit review of each application without reference to previous applications.

Note that 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:

[http://grantcenter.jdrf.org/wp-content/uploads/2012/12/JDRF\\_Scientific\\_Guidelines\\_final-Aug20151.pdf](http://grantcenter.jdrf.org/wp-content/uploads/2012/12/JDRF_Scientific_Guidelines_final-Aug20151.pdf)

## ANNOUNCEMENT INTRODUCTION AND PUBLIC Q&A

JDRF will hold an announcement introduction meeting via web and teleconference on **September 12, 2018 at 10:30 am** US Eastern Standard Time, to which all interested prospective applicants are invited. JDRF scientists will give an overview of the goals of this initiative, explain the application process and answer initial questions on applications.

**Click here to [Join WebEx meeting](#)**

Meeting number: **738 828 664**

Meeting password: **JDRF2018**

### Join by phone

Dial in (US): **1-650-429-3300**

Dial in (International): [Global Call in Numbers](#)

Conference Code: **738 828 664**

## DEADLINES

- |   |                          |
|---|--------------------------|
| • <b>RFA release date</b>                         | <b>August 23, 2018</b>   |
| • <b>LOI deadline</b>                             | <b>October 1, 2018</b>   |
| • <b>Notification of full application request</b> | <b>October 17, 2018</b>  |
| • <b>Application deadline</b>                     | <b>November 28, 2018</b> |
| • <b>Response to applicants</b>                   | <b>April 2019</b>        |
| • <b>Earliest anticipated start date</b>          | <b>June 2019</b>         |

## SUBMISSION INSTRUCTIONS

Applicants should register and submit their completed LOI in RMS360 (<http://jdrf.smartsimple.us>).

## REVIEW CRITERIA

Applications will be evaluated based on JDRF's standard confidential award policy and according to the following criteria:

- Significance
- Relevance to T1D
- Approach
- Innovation
- Investigator experience
- Environment

## CONTACTS

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If you have any grant-specific questions as you work within RMS360, please contact the administrative contact listed above.

For any **non-grant-specific** inquiries or issues, please contact SmartSimple Support Services via email support@smartsimple.com or phone (866) 239-0991. Support hours are Monday through Friday between 5:00am and 9:00pm US Eastern Standard Time.