



REQUEST FOR APPLICATIONS:

OPTIMIZATION AND CLINICAL VALIDATION OF ISLET AUTOANTIBODY ASSAYS FOR SCREENING FOR TYPE ONE DIABETES RISK

PURPOSE

JDRF is soliciting applications for the optimization and/or clinical validation of existing islet autoantibody (AAb) assays. Several newly developed islet AAb assays provide a platform for general population screening for type 1 diabetes (T1D) risk. JDRF intends to support investigators and organizations with assays that have the potential to alter the current islet AAb screening paradigm and have plans to commercialize or distribute their assay for wide-spread adoption and use.

BACKGROUND

The ability to screen for risk and stage of T1D prior to the onset of disease-related symptoms presents a valuable opportunity to delay, and ultimately prevent, stage 3 T1D. Several screening protocols initially focused on screening individuals who have close relatives with T1D, but only about 10% of people who develop T1D fall into this category. JDRF believes that screening all children for islet AABs, which are prognostic biomarkers for progression to stage 3 T1D, during well-child visits is feasible and should be implemented as part of public health policy. This will not only enable enrollment into T1D prevention trials, but in the short-term, aims to reduce hospitalization and life-threatening diabetic ketoacidosis (DKA) incidents at onset of stage 3 T1D. Current AAb detection assays are not a viable option for T1D risk screening in the general population due to high cost, blood volume requirements and various assay platform considerations. Therefore, new approaches that minimize cost and sample volume requirements are needed to facilitate implementation of general population screening for T1D.

Several new approaches to detect islet AABs have been developed, which not only increase the sensitivity and specificity of AAb detection, but are poised to support general population screening for T1D risk due to their relatively low cost and minimal blood volume requirement. JDRF has actively supported the development of several of these assays and is dedicated to supporting the continued optimization of such assays.

In order to advance these assays to wide-spread research and ultimately clinical use, validation in real-world clinical research studies is necessary. Therefore, in addition to supporting optimization of the assays, this RFA intends to support clinical research teams already invested in screening populations for T1D AABs to investigate the utility of the existing assays.

OBJECTIVES

Applications are sought from investigators who seek to **optimize existing islet AAb assays** and/or **perform clinical validation studies using islet AAb assays**. Assays should consider the following criteria for general population screening, which may include childhood-based screening methods:

- Selectivity, specificity, and sensitivity as assessed through the Islet Autoantibody Standardization Program (IASP).
 - As per the FDA Bioanalytical Method Validation Guidance for Industry Section III.A, the outlined guiding principles should be considered when submitting an application for this call: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/bioanalytical-method-validation-guidance-industry>
- High-throughput capacity and ability to be multiplexed in order to screen multiple islet AABs in the same sample

- Use of sample that avoids venipuncture for screening in children (e.g., finger prick, dried blood spots, saliva, urine)

This RFA **will not** support the development of novel technologies or assays.

Proof of timely access to clinical samples is encouraged with submissions and **will be required** prior to JDRF grant activation. For assays that have demonstrated acceptable optimization and initial validation, JDRF will facilitate larger-scale clinical validation. Investigators applying for support for clinical validation must show proof that their university/organization laboratories are GLP compliant and comply with all federal and state regulatory qualifications.

For assays that have participated in the IASP, **historical IASP data are required to be included as part of the application** in the Additional Attachments section.

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.

Letters of Intent (LOI) from for-profit entities or industry collaborations with academia may also be submitted to this RFA; however, additional information will be requested from 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.

MECHANISM

- Applications responding to this RFA 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-discovery-development-partnerships/>

Non-profit organizations, public and private universities, colleges, hospitals, laboratories, units of state and local governments may apply under JDRF's **Strategic Research Agreement (SRA)** funding mechanism. Under the terms of the SRA grant application, regular written reports will be required from the funded investigator with evidence of progress toward achieving research milestones as a basis for continued support.

For-profit entities may apply under JDRF's **Industry Discovery & Development Partnership (IDDP)** funding mechanism, which entails additional requirements including matching funds from the company. The IDDP application process **requires** a LOI, and IDDP awards are administered by contract agreements. Timelines for awards administered by contracts are typically longer than those listed at the end of this RFA, and will be determined ad hoc between JDRF and the Principal Investigator at the time of invitation to a full IDDP proposal. Please note that submissions from for-profit entities or collaborations involving for-profit entities will be reviewed by the JDRF T1D Fund (<http://www.jdrf.org/about/t1dfund/>) in addition to JDRF Research. Applicants interested in submitting an IDDP LOI in response to this RFA are required to contact JDRF program staff prior to submitting the LOI.

Each application may request up to \$250,000 per year (including up to 10% indirect costs), for up to two years. Applicants should discuss with JDRF program staff if proposing projects with increased scope (time, budget), especially in the case of clinical research. IDDPs require matching funds from the company.

In addition to a research proposal, all SRA applicants should consider including a business plan describing the path to commercial launch of their assay. A business plan template can be found in the Additional Attachments section of the application. Letters of support or identification of collaborators with relevant expertise who will help investigators to continue to develop business plans during the project may be submitted. In the business plan, please **consider** including:

1. Value of the project, assay, expected outcomes and impact
2. Market, customer, and competitive landscape analysis
3. Specific milestones on the plan to move from clinical validation to commercialization/widespread adoption of assay, including any plans to achieve marketing authorization from regulatory authorities
4. Analysis of the assay cost (goods and services) at scale
5. Financial Plan (How will this venture be funded, assuming JDRF is unable to provide support?)
6. Intellectual Property (IP) Protection
7. Production & Marketing Plan (if applicable)

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/>

DEADLINES

- **Release Date:** July 10, 2019
- **SRA Application Due Date:**..... September 12, 2019
- **IDDP LOI Due Date:** September 12, 2019
- **IDDP Notification of LOI Outcome:**..... TBD
- **SRA Response to Applicants Date:** January 3, 2020
- **SRA Earliest Anticipated Start Date:** March 1, 2020

SRA PROPOSAL

The application must be completed using the templates provided on the [RMS360](https://jdrf.smartsimple.us) website (<https://jdrf.smartsimple.us>). The research 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. Business plans can be submitted as a supporting document and should follow the same formatting instructions (also a 10 page maximum; no page minimum) as the research proposal.

IDDP LETTER OF INTENT

Prospective applicants should submit a Letter of Intent, [**2 page maximum**] online via [RMS360](https://jdrf.smartsimple.us) (<https://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.

SUBMISSION INSTRUCTIONS

Applicants must register as an applicant and submit their application in response to this RFA using JDRF's online research management system, [RMS360](https://jdrf.smartsimple.us) (<https://jdrf.smartsimple.us>).

REVIEW CRITERIA

Applications will be evaluated based on JDRF standard review policies including to the following criteria

- Background & Significance to T1D
- Proposed Research & Approach
- Investigator/Team Credentials
- Environment
- Commercial Feasibility & Assay Development Potential

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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 technical 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.