

JDRF REQUESTS LETTERS OF INTENT FOR: USER-CENTRIC INSULIN PUMPS

PURPOSE

JDRF is a longstanding supporter of artificial pancreas (AP) systems, also known as automated insulin delivery (AID) or hybrid closed loop (HCL) systems. Despite demonstrated benefits of AP systems for glucose control, there are significant barriers to widespread adoption, including user burden associated with insulin pump use. JDRF invites letters of intent to develop insulin pumps with improved form factor and other “user-centric” features that improve user experience so as to enable greater adoption of pumps and AP systems.

BACKGROUND

Today there are multiple AP systems commercially available in the United States and abroad. AP systems, which are comprised of an insulin pump, a continuous glucose monitor (CGM), and a control algorithm, improve HbA1c, increase time-in-range, and reduce time spent in hypoglycemia. AP systems also have the potential to improve quality of life by reducing the burden of disease management; however, for many this benefit is stymied by the on-body burden of wearing an insulin pump, which results in some people with T1D choosing not to take advantage of AP system technology despite the proven clinical benefits. This RFA is intended to solicit projects to develop “user-centric” pumps that impose less physical and psychological burden on people with T1D as well as people with type 2 diabetes who use insulin.

OBJECTIVES

Letters of intent (LOIs) are sought from academic or industry applicants to develop user-centric pumps.

Examples of research appropriate for this RFA include, but are not limited to, development of pumps with the following features:

- Decreased size (for example, due to novel pumping mechanisms) or other improvement in form factor for better user experience
- Reduced propensity to cause pain and/or dermatological complications
- Discreet appearance
- Combined insulin infusion and glucose sensing
- Simpler or otherwise improved user interactions with device
- Low cost

We will consider support for user-centric pumps at any stage of development, up to and including pivotal trials and regulatory submissions.

Examples of research not covered by this RFA include:

- Development of algorithms for automated insulin delivery
- Development of either CGM or infusion sets, except for combined insulin infusion and glucose sensing
- Implantable pumps

Deliverables

- Projects should be designed to achieve key inflection points appropriate to project duration, budget, and initial stage of development

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

CRITICAL CONSIDERATIONS

- JDRF strongly encourages applications from industry
- JDRF supports collaborative approaches, including between academic applicants and industry partners
- JDRF encourages proposals that seek to leverage existing or planned projects (e.g. proposals that add resources to projects with funding from other sources)
- Compatibility with concentrated insulins should be incorporated into miniaturized pump development plans as appropriate
- Product prototypes in advanced development may consider human factor testing to demonstrate user-centric attributes

CLINICAL STUDIES

- JDRF follows the U.S. National Institutes of Health (NIH) guidelines for studies including human subjects, including the common rule changes:
<https://nexus.od.nih.gov/all/2019/01/07/nih-implementation-of-the-final-rule-on-the-federal-policy-for-the-protection-of-human-subjects-common-rule/>

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: <https://grantcenter.jdrf.org/industry-discovery-development-partnerships/> For IDDP applications, applicants are required to contact the JDRF scientific contact below prior to submitting a LOI.

Each application may request up to a total of \$4,500,000 over a maximum of three years. SRAs allow up to 10% indirect costs; IDDP applications do not permit indirect costs. JDRF may consider applications with increased scope (time, budget) where there is a strong justification, and applicants interested in such should discuss with the JDRF scientific contact below. Note that the above budget is a maximum, and JDRF will also consider projects with substantially smaller budgets, including early-stage innovative approaches. In all cases, the level of requested funding should be commensurate with the studies proposed, stage of product development, and non-JDRF resources (funds, personnel, other) available to successfully complete the project.

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 according to the timeline below if they have been approved to submit a full application.

Letters of intent should use the template provided and include the following information:

- Background/rationale, preliminary data and references to relevant publications, specific aims, project deliverables, collaborative framework if applicable
- Description of how proposed pump will be differentiated from pumps currently on the market and soon to be available
- Development plan with timeline for advancing the pump through pre-clinical and clinical development
- Intellectual property or commercial efforts associated with the current application, including a list of existing business partnerships relevant to the proposed work
- 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 RMS360 (<http://jdrf.smartsimple.us>). 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

DEADLINES

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| • RFA release date | Tuesday, March 15, 2022 |
| • LOI deadline | Tuesday, May 10, 2022 |
| • Notification of full application request | Tuesday, May 31, 2022 |
| • Application deadline | Wednesday, July 13, 2022 |
| • Response to applicants | February 2023 |
| • Earliest anticipated start date | April 2023 |

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
- Approach
- Innovation

- Investigator experience
- Environment

CONTACTS

SCIENTIFIC

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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.