JDRF Request for Applications: Effectiveness and Implementation Trials to Address Mental Health in Type 1 Diabetes

October 2023

Summary

- JDRF is soliciting Letters of Intent (LOIs) from single investigators or groups of investigators to conduct effectiveness or implementation trials to address diabetes distress, anxiety, depression or disordered eating in type 1 diabetes (T1D).
- The goal of this funding opportunity is to encourage effectiveness and implementation research on T1D specific psychosocial interventions with previously demonstrated efficacy, for use with broader target populations or for use in clinical practice settings.
- This program will award grants up to $1,500,000.00 over 4 years. JDRF will consider applications with increased scope (time and/or budget) where there is a strong justification and interested applicants should discuss with the JDRF scientific contact.

Funding Opportunity Description

JDRF aims to support the implementation and integration of evidence based T1D specific behavioral and psychosocial interventions into clinical practice. Therefore, JDRF solicits applications for studies and clinical trials designed to test psychosocial treatment and preventive interventions for which there is already evidence of efficacy, for use in community and practice settings.

This RFA will support clinical trials of interventions that already have feasibility, acceptability and efficacy data and are ready to go onto effectiveness and implementation trials. Projects may also only have feasibility and acceptability data and seek to utilize novel trial protocols with hybrid designs with emphasis on effectiveness and implementation outcomes.

Applications might include research to evaluate the effectiveness or increase the clinical impact of behavioral and psychosocial interventions to prevent or treat diabetes distress, anxiety, depression and/or disordered eating in T1D. Projects around provider-, organizational-, or systems-level interventions to improve access, continuity, and quality will also be considered.

LOIs should clearly describe the intervention, the preliminary data including efficacy data and, if available, data on mediators and moderators, and define the population to be studied, including mental health issue, age, and other characteristics.

Proposals should take an implementation focused approach to intervention development and testing, acknowledging that many people with T1D will receive care from providers unaffiliated with specialty diabetes or specialty psychological centers. The goal is to ensure that the resultant interventions are scalable and implementable in clinical care.

Examples of pertinent deliverables include, but are not limited to:

- Effectiveness or effectiveness-implementation data for behavioral or multidisciplinary treatment interventions that improve psychological measures and glycemic outcomes in children, adolescents, and/or adults with T1D
- Evaluation of implementation strategies for bringing existing interventions into clinical practice
- Implementation strategies for existing outcomes measures and instruments for detection and screening of mental health issues in T1D
- Understanding resources needed in diabetes care settings to deliver psychosocial prevention strategies or interventions.
- Identifying and addressing barriers and facilitators to the uptake of evidence-based clinical psychosocial interventions.
- Health economics studies on the impact of T1D related mental health issues, in particular diabetes distress

Topics that are not covered by the RFA, include:

- Early development of new interventions
- Trials evaluating interventions with no previous feasibility, acceptability and efficacy data
- Trials evaluating interventions against issues other than diabetes distress, depression and anxiety and disordered eating

Other considerations:

- Priority will be given to projects that have the potential for broad-scale applicability across various geographies, cultures, or healthcare systems.
- Applications that include collaborative and multidisciplinary approaches are of particular interest.
- JDRF encourages assessment of the intervention's impact on glucose control in addition to mental health endpoints.

Background

Complex psychosocial factors influence living with T1D and achieving satisfactory clinical outcomes, quality of life and well-being. The behavioral research field in T1D is growing and interventions to address diabetes-related psychosocial difficulties are being developed. However, many of these interventions never reach the clinic. More effort is needed to address the research-practice gap, i.e., the lack of progression of evidence-based treatments from controlled research settings to clinical care.

The traditional research pipeline has a staged approach to evidence-based intervention development with feasibility and acceptability research, efficacy testing and subsequent effectiveness trials preceding translation into the real world setting and implementation. As a result, the time lag between development of an evidence-based intervention and routine uptake in the community can be very long.

This RFA is intended to support studies evaluating the effectiveness of approaches to improve mental health in T1D, studies that explicitly address how an intervention can be implemented in clinical practice and impact public health, and larger scale studies e.g., comparative effectiveness studies, pragmatic trials, etc.

The overall objective of this RFA is to advance new psychosocial and behavioral research in T1D, to implement effective interventions and to ultimately incorporate these new insights and interventions into clinical practice.

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., Psy.D. or equivalent and have a faculty position or equivalent at a college, university, medical school, or other research facility.
- 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.

Funding Mechanism

In response to this announcement, Letters of Intent (LOI) can be submitted under the following mechanism(s):

Strategic Research Agreement

For Strategic Research Agreements, proposed budgets for projects should not exceed $1,500,000 USD (including 10% indirect costs) total costs for up to four years. The level of funding will vary depending on the scope and overall objectives of the proposal. If your project budget exceeds $1,500,000, please discuss with JDRF staff (contact information below). For more information on the Strategic Research Agreement (SRA) grant mechanism please refer to our website.

Letter of Intent

Prospective applicants should submit an LOI, 2 pages maximum online via RMS360 to be considered for a full proposal request. The LOI template provided on the RMS360 website must be used to complete the application to be considered for a full proposal request.

Proposal

An approved LOI is required prior to the submission of a full proposal. Upon notification of a request for a full proposal, the application must be completed using the templates provided in RMS360. Proposal section templates in Microsoft Word, [10 pages 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 a 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.

JDRF follows the U.S. National Institutes of Health (NIH) guidelines for studies including human subjects, including the Common Rule changes.

Review Criteria

Applications will be subjected to confidential external scientific review evaluated on the following:

- Significance
- Relevance
- Approach
- Innovation
- Environment
- Resource sharing plan

Informational Webinar and Q&A

JDRF will hold an announcement introduction meeting via Zoom on **October 20, 2023, from 9-10 am** Eastern Time to which all prospective applicants are invited. JDRF scientist(s) will give an overview of the goals of this initiative, explain the application process, and answer initial questions on applications.

Registration for Webinar (please register by October 19, 2023):

https://jdrf.zoom.us/webinar/register/WN_syVi0tR4RGS7I-ITuC8s_w

**** The webinar will be recorded and available after October 20th for those unable to attend ****

Projected Timeline

Milestone	Date
Information webinar and Q&A	October 20, 2023; 9-10 am ET
LOI deadline	December 18, 2023
Notification of LOI Outcome	January 11, 2024
Full proposal deadline	February 20, 2024
Award notification	July 2024
Earliest anticipated start	September 2024

Program Contacts

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