

REQUEST FOR LETTERS OF INTENT (LOI):

CLINICAL AND PRECLINICAL STUDIES TO PREVENT OR TREAT HYPOGLYCEMIA UNAWARENESS

PURPOSE

JDRF is committed to facilitating the discovery and translation of promising targets or therapeutics to prevent or treat hypoglycemia unawareness in individuals with Type 1 Diabetes (T1D). To this end, JDRF is soliciting letters of intent for research with the potential to translate into novel drug-based approaches or the repurposing of approved drugs that will maintain or restore the awareness of potentially life-saving hypoglycemia warning symptoms in individuals with T1D.

BACKGROUND

Iatrogenic hypoglycemia is responsible for 4-10% of the mortality rate in people with T1D and is the chief barrier to optimal glucose control. Frequent hypoglycemia has been shown to reduce the glucose level that elicits the counterregulatory response needed to restore euglycemia during a subsequent hypoglycemic episode (hence, “hypoglycemia begets hypoglycemia”). As a result, some individuals develop hypoglycemia-associated autonomic failure (HAAF) and do not experience and respond to the potentially life-saving warning symptoms, and are at increased risk of seizures, coma and death. The JDRF Artificial Pancreas project holds great promise for the mitigation and ultimate elimination of hypoglycemia with recent clinical studies showing an absence of severe hypoglycemia events with systems that suspend insulin delivery in response to low blood glucose levels. JDRF seeks to complement this progress with drug-based therapeutic approaches in order to provide the broadest range of treatment alternatives to people with T1D.

OBJECTIVES

JDRF is seeking letters of interest from investigators with innovative approaches to discover and translate targets and pathways relevant to hypoglycemia unawareness and HAAF. Approaches might include, but are not limited to:

- Clinical and preclinical studies to support the repurposing of existing FDA-approved drugs
- Mechanistic studies to facilitate the discovery and translation of targets and pathways

Preference will be given to clinical study proposals or applications linking a pathway or target to hypoglycemia unawareness.

MECHANISM

Projects may request up to \$250,000 USD of funding per year, including a maximum of 10% indirect costs, for up to 2 years. Funded projects would be subject to quarterly progress reporting and recruitment based milestones for clinical trials.

ELIGIBILITY

Applications may be submitted by for-profit entities as well as nonprofit organizations, public and private universities, colleges, hospitals, laboratories, units of state and local governments. There are no citizenship requirements.

EXPRESSION OF INTEREST

An approved LOI is required prior to submission of a full proposal. Please see below for complete instructions.

DEADLINES

- Request for LOI Release Date:November 25th 2013
- *Intent to apply*.....December 6th 2013
- LOI Submission Deadline:January 13th 2014
- LOI Notification:January 27th 2014
- Application Receipt Date:March 3rd 2014
- Response to Applicants Date:May 2014
- Earliest Anticipated Start Date:July 2014

SUBMISSION INSTRUCTIONS

Please note that JDRF has transitioned to a new online grants management system called [RMS360](#). Accordingly, please follow these instructions carefully to insure your LOI is submitted by the January 13th deadline.


1. Please confirm your intent to apply to this initiative via email to Dr. Marlon Pragnell by **6th December 2013** (mpragnell@jdrf.org) by including the following information: Working Project Title, Principal Investigator Name and Email.

REVIEW CRITERIA

JDRF will review and select LOIs to be developed into full proposals. Please direct queries about the suitability of your proposal to the scientific contact below.

SCIENTIFIC CONTACT


Marlon Pragnell, Ph.D.
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ADMINISTRATIVE CONTACT

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