JDRF REQUESTS LETTERS OF INTENT FOR:
3D BIOPRINTING AND BIOFABRICATION OF RATIONALLY DESIGNED ENGINEERED TISSUE CONSTRUCTS AS THERAPEUTIC PRODUCTS FOR TREATMENT OF TYPE 1 DIABETES (T1D)

BACKGROUND & PURPOSE

JDRF is committed to the development of a functional cure for T1D through beta cell replacement therapies that restore glycemic control and eliminate the need for exogenous insulin administration. Pancreatic islet transplantation has been efficacious in improving metabolic control, preventing severe hypoglycemia, and improving quality of life in patients with medically unstable T1D. However, the use of chronic systemic immune suppression and reliability on organ donors preclude its application to a broader T1D population. Significant progress has been achieved in the development of alternative renewable sources of insulin producing cells from human stem cells and porcine islets and strategies to deliver these cells and protect them from the recipient's immune response. One key development that could accelerate the translation of cell therapies into the clinical management of T1D and the commercialization of these combination products is the establishment of reproducible processes for integrating cells, biomaterials, and other components into complex engineered tissue constructs for implantation which are amenable to large scale manufacturing.

3D bioprinting is at the cutting edge of the field of regenerative medicine and at the forefront of the intersection between tissue engineering and biofabrication. By employing and adapting methods used in traditional 3D printing to combine cells, growth factors, and biomaterials into defined structures, 3D bioprinting enables the fabrication of tissues that can be used as in vitro models for research or therapeutic products to treat disease. This technology can drastically reduce the variability of tissue engineered products by allowing the precise and reproducible integration of various components in 3D space. Rational design of such constructs could ensure optimal cell survival and integration with the host upon implantation. Moreover, using these advanced methods of biofabrication can enable automated scaled up production of these constructs thus drastically reducing costs. All of these attributes make 3D bioprinting an attractive approach for fabrication of therapeutic products. Therefore, JDRF wishes to support research on the rational design and fabrication of engineered tissue constructs via 3D bioprinting that ensure optimal islet survival and integration with the host upon transplantation and lead to long-term graft function.

OBJECTIVES

Letters of intent (LOI's) are sought for proposals on preclinical and/or clinical studies from academic or industry applicants working on the development and optimization of engineered tissue constructs fabricated via 3D bioprinting destined for use as therapeutic products to accelerate clinical translation and enable scaled up manufacturing of beta cell replacement products. Only projects with relevance to T1D will be considered. Investigators with no background in T1D research collaborating with investigators experienced in T1D research are encouraged to apply.

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

- Development of technology necessary to enable the automated manufacturing of engineered tissue constructs for treatment of T1D and verification of process output matching input design specifications (i.e. integration of different bioprinting modalities or additional functionalities). Specific construct design must justify such work.

- Development of novel bioinks and ancillary components (i.e. bioinks functionalized for monitoring, factor or drug delivery, oxygen generation, immunomodulation), incorporation into new or already optimized and validated constructs, and validation in animal models and/or clinical studies

- Validation of constructs that integrate all the components required to generate a beta cell replacement product in preclinical models (special consideration given to design/geometry to enhance islet loading, packing density, cell survival, and integration with the host)
• Clinical testing of engineered constructs already validated in preclinical model (consideration to manufacturing process)
• Addition of new components into constructs previously validated through preclinical and/or clinical testing for improved performance

This RFA will not support applications focused on:
• 3D bioprinting of individual islets
• Production of construct via a means other than 3D bioprinting which are not amenable to scaled up manufacturing

Investigators may choose to focus solely on construct integration with the host and use immunosuppression as a first generation product, with a line of sight for future incorporation of immune protection strategies. Applicants are encouraged to consult with JDRF scientific staff to discuss the alignment of their proposal to this RFA and to develop the project concept. More details on the Beta Cell Replacement Program Strategy and Research Priorities can be found at the following website:


MECHANISM

LOI’s can be submitted to JDRF’s Strategic Research Agreement (SRA) or Industry Discovery and Development Program (IDDP) grant mechanisms in response to this announcement. 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/

Each application may request up to total $250,000 USD per year (including up to 10% indirect costs) for up to 2 years. The level of funding will vary depending on the scope and overall objectives of the proposal. Project proposals of up to 36 months duration and/or higher budget may be considered. Applicants should discuss with JDRF Staff (see below) when proposing longer timelines or higher budgets to determine the suitability of the proposal.

Pilot and feasibility studies without significant preliminary data may also be submitted and can request up to total $150,000 USD per year for one year (including 10% indirect costs).

For-profit entities interested in submitting an IDDP LOI are requested to contact Dr. Jaime Giraldo (jgiraldo@jdrf.org) prior to submitting an LOI. The IDDP application entails additional requirements including matching funds from the company and administration of the award by contract agreements. Projected timelines for IDDP submissions will be determined ad hoc by JDRF and communicated to the Principal Investigator at the time of invitation to submit a full IDDP proposal.

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 a faculty position or equivalent at a college, university, medical school, industry setting 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. Submissions from for-profit entities or collaborations involving for-profit entities will be reviewed by the JDRF T1D Fund (t1dfund.org) in addition to JDRF Research.

For clinical studies, applicants must hold an appointment or joint appointment in a subspecialty of clinical medicine, and conduct human clinical research.
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 Letter of Intent (LOI) online via RMS360 (http://jdrf.smartsimple.us) to be considered for a full proposal. The LOI template provided through RMS360 must be used to complete the application. Applicants will be notified if they have been approved to submit a full application in accordance with the timeline listed below.

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

- Background/Rationale and Specific Aims of overall project
- Uniqueness about the approach and advantages over other approaches explored in the field
- Overview of hypotheses, goals, deliverables, and collaborative framework if applicable
- Impact of the expected deliverables of the proposed study with potential next steps
- Timelines/timetable
- Intellectual Property or commercial efforts associated with the current application
- Estimated total and annual budgets
- Biosketches for all Principal Investigators

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 portal (http://jdrf.smartsimple.us). Proposal section templates in MS Word [12 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

ANNOUNCEMENT INTRODUCTION AND PUBLIC Q&A

JDRF will hold an introductory meeting via web teleconference on Wednesday, August 28th, 2019 from 11:00am-12:00pm 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. A brief introduction on JDRF’s grant application portal (RMS360) will also be given.

Click here to Join WebEx meeting
Meeting number (access code): 736 461 474
Meeting password: 346JQmaN

Join by phone
Dial in (US): 1-866-469-3239
Dial in (International): Global call-in numbers
DEADLINES

- Letter of Interest (LOI) Deadline
- Notification of Full Application Request
- Application Deadline
- Response to Applicants
- Earliest Anticipated Start Date

- Monday September 16, 2019
- Thursday October 10, 2019
- Thursday November 14, 2019
- April 2020
- June 2020

REVIEW CRITERIA

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

- Significance
- Relevance to T1D and alignment with the call
- Approach
- Innovation and level of differentiation
- 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.