

Informational Webinar: Development and Validation of Non-Invasive Immune Imaging Technology to Accelerate the Development of Beta Cell Replacement Therapies

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Agenda

JDRF

- Introduction to JDRF
- Introduction to Cell Therapy project
- Overview of RFA
- Overview of Funding Mechanisms
- Administrative Aspects of Applying
- •Q&A

JDRF's Purpose

Our Vision:

A world without T1D

Our Mission:

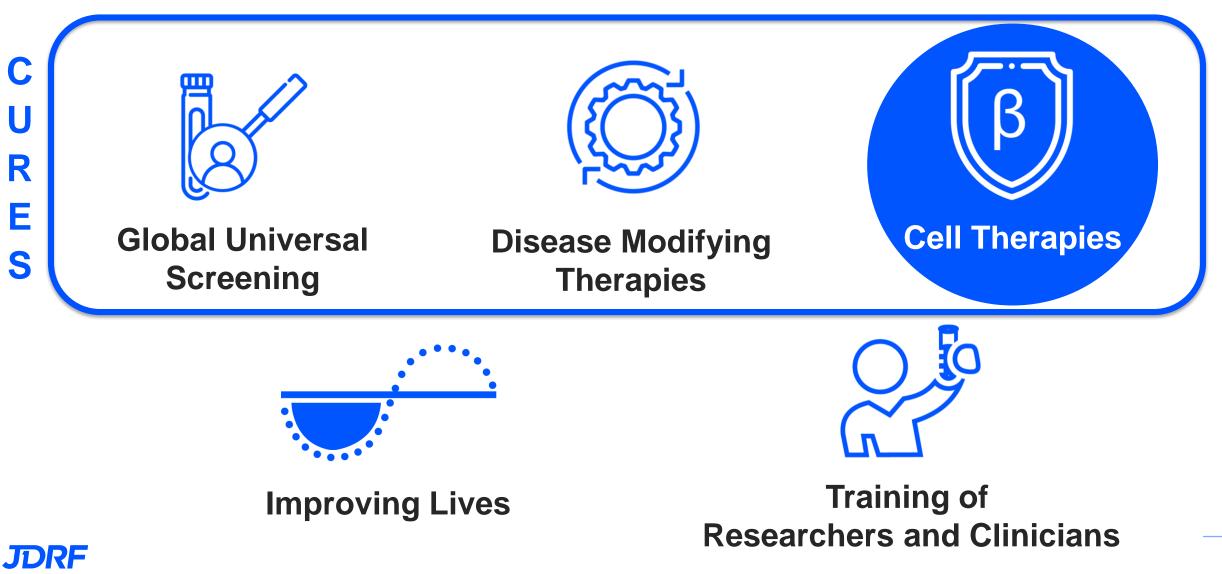
Improving lives today and tomorrow by accelerating life-changing breakthroughs to cure, prevent and treat T1D and its complications.



JDRF Affects Every Step in the Pipeline

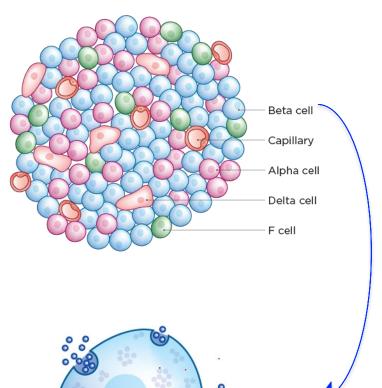


JDRF Research Priorities



What Are Cell Therapies?

- Therapies which use live cells to treat or reverse disease
- At JDRF: delivery of <u>externally</u> derived beta cells or islets to restore insulin independence and blood glucose control
- Requirement for Cell Therapy
 - Unlimited quantity of cells
 - Safe to place in humans
 - Able to survive after transplantation
 - Sense changes in glucose levels and secrete insulin appropriately



insulin

We Now Have Renewable Sources of Cells



Differentiation

A	Stage 1 3 d		Stage 2 3 d		Stage 3 1 d		Stage 4 5 d	Stage 5 7 d	Stage 6 >9 d
hPS	Act A CHIR	DE	KGF	PGT	KGF RA SANT1 Y LDN PdbU	PP1	KGF RA SANT1 Y Act A	RA SANT1 T3 XXI Alk5i Betacelluli	EN ESFM Cluster resize



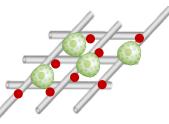
How to Deliver and Protect Cells

Encapsulation



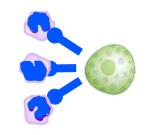
Strategy: Physical barrier blocks immune attack while ensuring cell survival and function

Scaffolds



Strategy: Use scaffolds that enable engineering of the local environment to keep the cells alive – multipurpose platform

Immune Modulation



Strategy: alter the immune response to the implanted cells and/or device, allowing cells to thrive

Gene Editing



Strategy: employ gene editing tools to enhance survival and function of implanted cells



Current Funding Opportunity & Goals of the RFA



Development and Validation of Non-Invasive Immune Imaging Technology to Accelerate the Development of Beta Cell Replacement Therapies

- Catalyze the development and in vivo validation of imaging and theranostic technology that enables the noninvasive in vivo monitoring and modulation of immune responses towards transplanted insulin-producing cells
- Leverage advances in immune imaging being pursued for oncology and inflammatory disease applications and apply them to T1D and transplantation.

Support projects that:

- Enhance imaging sensitivity and specificity
- Enable non-invasive multimodal imaging
- Enable non-invasive multiplexed imaging
- Develop theranostic technologies

Other Considerations

- Multi-disciplinary collaborative projects combining the resources and capabilities of multiple research groups with relevant expertise are strongly encouraged and will be prioritized.
- Implications of mechanisms of probe clearance, site of implantation, and ability to image immune responses must be considered.
- Technologies with a direct path to clinical translation will be prioritized.
- In vivo validation of technology should be done in the context of models of islet/beta cell transplantation and rejection.
- Impact of probes on targeted cell viability and function and ability to accurately assess immune responses or impact of other immune targeted interventions.
- Ability to discern immune responses specific to cell graft versus others (i.e. infection).



Out of Scope

- Projects focused immune imaging to assess T1D onset, progression, and prevention.
- Projects focused on imaging the beta cell graft.

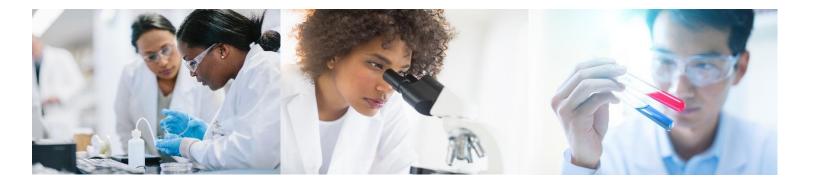
Applicant Eligibility

Investigators, collaborative teams, organizations, and companies with demonstrated expertise to carry out the proposed research

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. Domestic and foreign non-profit organization, public and private, such as universities, colleges, hospitals and laboratories; units of state and local governments and eligible agencies of the federal government; for-profit entities; or industry collaborations with academia

JDRF welcomes applications from all qualified individuals and encourages applications from members of groups underrepresented in the sciences.

No citizenship requirements for this program.





Funding Mechanism

Strategic Research Agreement (SRA)

- Intended to support research activities at non-for-profit entities such as academic institutions.
- Research funding for single or multiple investigators.
- Continued funding is based on satisfactory effort and semi-annual progress on milestones.

Industry Discovery & Development Partnership (IDDP)

- Intended to support research and development activities at for-profit entities.
- Potential IDDP partners must reach out to JDRF Scientific Staff prior to submitting an LOI.
- Additional information will be required upon submission of full proposal.
- Please visit our website for additional information: <u>https://grantcenter.jdrf.org/industry-discovery-</u> <u>development-partnerships/</u>

This Award:

- Meant to support projects up to \$750,000.00 USD, including 10% indirect costs., over 3 years
- The level of funding will vary depending on the scope and overall objectives of the proposal.

If project exceeds 3yrs/\$750,000.00, you must discuss with JDRF scientists prior to submitting an LOI.



Submission/Award Timeline

LOI Deadline	Notification of LOI Outcome	Full Proposal Deadline	Award Notification	Earliest Anticipated Start Date
August 30, 2022	September 14, 2022	October 12, 2022	April 2023	June 2023

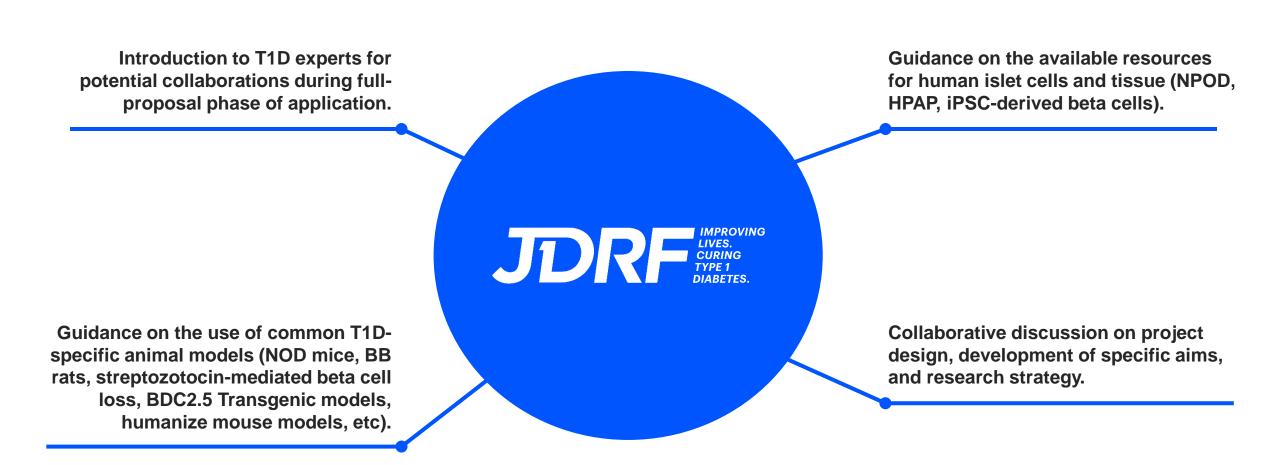
Tips for Success



Development and Validation of Non-Invasive Immune Imaging Technology to Accelerate the Development of Beta Cell Replacement Therapies

- Describe what is innovative and unique about your approach
- **Demonstrate feasibility of completing work proposed**
 - Expertise in imaging and probe development
 - Expertise with and access to models of islet/beta cell transplantation
 - Methods established/validated
- Clearly describe success criteria and deliverables
- Describe how the studies proposed will move the technology forward through development pipeline and next steps

New to T1D?



JDRF



Any Questions?

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https://grantcenter.jdrf.org