



Australian Type 1 Diabetes
Clinical Research Network

JDRF Australia Pilot and Innovation Awards 2021

Request for Applications: Letters of Intent

Applications Open	Wednesday	02 September 2020
LOI Deadline[†]	Tuesday	20 October 2020
Invitation to Full Application[^]	Thursday	03 December 2020
Full Application Deadline* [†]	Tuesday	16 February 2021
Earliest Start[^]		May 2021

*Applicants must note that the Research Office of each Administering Organisation is required to certify full applications submitted to JDRF in RMS360 and may have an internal closing time which precedes this deadline.

[^]Subject to change.

[†]Deadlines are at 11:59 pm AEST/AEDT

[Click Here to Apply](#)

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1. Introduction and Purpose of this RFA

The JDRF Australian [Type 1 Diabetes Clinical Research Network](#) (T1DCRN) provides a national framework to support the most promising type 1 diabetes (T1D) research and clinical trials in Australia. The T1DCRN has a strong track record of supporting outstanding pre-clinical research activities that have made stellar contributions to our understanding of T1D pathogenesis and in advancing translation of basic research towards clinical care. However, JDRF recognises there is a clear need for funding for early-stage projects in T1D as they are increasingly getting difficult to support through traditional funding mechanisms in Australia. As such, the aim of the “*Pilot and Innovation Awards 2021*” is to support the best research activities that can provide new and innovative research directions to accelerate the mission of JDRF and the T1DCRN.

This Request for Applications (RFA) “*Pilot and Innovation Awards 2021*” solicits Letters of Intent (LOIs) from investigators affiliated with Australian institutions with the aim of funding *Pilot* and *Innovative* projects in high-impact areas of T1D research. Research projects should clearly articulate potential for a significant benefit to people with T1D.

The purpose of this initiative is to support:

- Pilot projects that typically involve developmental or early stage work, including pilot data acquisition and proof-of-concept studies
- Innovative and/or high-risk projects that address key research questions and have the potential to lead to a change in current paradigm or conventional approaches to T1D diagnosis, management or treatment
- Ancillary studies that involve secondary analysis or derivation of data from existing cohorts, clinical databases, data networks and repositories.

This RFA will focus on attracting talented new investigators from within and outside of the field of T1D as well as embracing experienced investigators in T1D to develop promising ideas. To benefit the field, proposals submitted must include at least one experienced researcher from outside of the field of T1D and must also include an early to mid-career researcher in the leadership group. The submission of new collaborative projects between investigators who are basic scientists and those who are clinicians or clinical scientists is encouraged. This RFA also aims to create collaborative projects between Australian and international investigators to leverage domestic and international expertise and resources to advance T1D research.

2. Goals and Objectives of this RFA

The main goal of the *Pilot and Innovation Awards 2021* is to support early-stage and innovative research by collaborative and cross-disciplinary research teams. Proposed research should have a strong potential for translation and ultimately to reduce the burden of T1D. LOIs submitted in response to this RFA will need to strongly articulate this vision and align closely with the following objectives:

2.1 Support Pilot and Innovative Research

LOIs submitted in response to this RFA must fit into one of the following three categories:

- i. **Pilot projects** that are:
 - Small-scale exploratory and/or implementation studies to prove the viability of a new project idea and de-risk future investment in the approach being tested
 - An application of an existing approach from the research outside the field of T1D and directed to illuminate scientific exploration in T1D
 - Small-scale data acquisition for proof of concept and validation studies.
- ii. **Innovative projects** that involve:
 - The generation of data to support or define a novel idea
 - Extending existing knowledge into a new and distinct area or application
 - The novel use of research tools or technologies
 - The novel use of clinical tools, therapies or strategies.
- iii. **Ancillary studies** that:
 - Support secondary research using existing resources including clinical data, human biosamples and/or registries
 - Allow the collection of novel data to ongoing clinical studies (e.g. CGM, imaging)
 - Explore knowledge gaps specific to T1D patients affected by COVID-19, including studies intended to obtain clinical data from outside Australia. With the current COVID-19 pandemic there is a scarcity of empirical evidence on susceptibility to and effects of COVID-19 for people with T1D. Therefore, proposals exploring knowledge gaps in COVID-19 infection in T1D patients are encouraged.

2.2 Nurture Talent and Collaboration: Attract and retain talent of highest quality to T1D research, and facilitate multidisciplinary collaboration amongst researchers including:

- Early to mid-career researchers who are seeking independent research directions and may have not previously received substantial independent funding
- Established investigators already active in the field of T1D proposing a new direction (i.e. whose proposed project is different from their previous work) or progressing existing work to proof-of-concept studies
- Investigators outside of T1D research from other fields (e.g. T2D, oncology, immunology, modelling/data science, applied sciences) interested in embarking on a T1D related project for the first time to explore new directions
- Investigators aiming to advance critical early stage research such as proof-of-concept studies or market opportunity validation, which may lead to commercialization
- Investigators aiming to collaborate across multiple Australian states and territories as well as internationally
- Investigators aspiring to collaborate with industry partners (e.g. small biotech and pharmaceutical companies).

2.2 Improve translatability to impact human T1D: Despite recognizing that pilot and innovative research projects may be at an early stage in their development, applications must have a strong focus on the translatability of the proposed study to impact human T1D. Studies using pre-clinical animal models should articulate a clear line of sight to

human relevance. Where possible the use of human bio-specimens and/or existing clinical databases, data networks and repositories should be considered.

3. Eligibility

All LOIs submitted in response to this RFA must demonstrate that they meet the following eligibility criteria.

- i. Principal Investigators (PI) and Co-PIs must hold Ph.D., M.D. or an equivalent academic degree to be eligible to apply for this Award. PIs must be affiliated with an Australian university, hospital, research institute, or other comparable institutions which may include a for-profit entity.
- ii. Applications must be submitted by an Australian institution affiliated with the PI. Co-PIs and/or other collaborators may be affiliated with institutions outside of Australia.
- iii. The application must involve collaboration with researchers from at least one research organisation separate to and independent of the research organisation of the lead Principal Investigator; or at least one industry partner.
- iv. Early to mid-career researchers should also be included in the leadership group to provide opportunity for the EMCRs to develop their leadership experience.
- v. At least one experienced researcher from outside of the field of T1D must be included to bring capacity and knowledge from other areas that will benefit the field as well as the proposal. Researchers from outside the T1D field are defined as individuals who have not previously held a substantial T1D-related national or international research grant.
- vi. There are no citizenship requirements for this program however, awardees must be eligible to work in Australia for the length of the proposed project. To assure continued excellence and diversity among applicants and awardees, applications are welcomed from individuals with disabilities, and members of minority groups underrepresented in the Australian T1D research landscape.

4. Exclusion Criteria

4.1 Duplication of research

If at any time during the assessment process JDRF or the review panel deems the scientific objectives of a proposal to either duplicate or significantly overlap with the scientific objectives of a current or planned project (in Australia or overseas) the proposal will be excluded from further consideration.

4.2 Applications not suited for this RFA

If at any time during the review process JDRF decides that an application falls within one of the following exclusion criteria the application will be deemed ineligible and will be excluded from further consideration:

- i. Applications that propose to carry out a clinical trial other than a small proof of concept or mechanistic study
- ii. Applications that lack a clearly articulated vision of steps to translation, accepting that the end-point of this vision may extend beyond the period of time that this funding scheme supports, and that by definition early stage projects will contain inherent risk and may have go/no-go decision points. Examples of endpoints include (but not limited to) eventual commercialisation, changing health care practice, implementing a new approach to imaging, identifying biomarkers, or identifying aetiological factors
- iii. Applications that describe exploratory blue-sky research purely for the acquisition of data
- iv. Applications that contain harmful or high-risk elements that are inadequately managed or would be unlikely to be viable approaches to treating, preventing or curing T1D due to the harm-benefit ratio e.g. complete immune ablation.

5. Overview of the Application Process

Prospective applicants are required to register/login to JDRF's Online Grants Management Platform RMS360 (<http://jdrf.smartsimple.us>) to access the RFA, supporting documents and templates. At the initial step in the application process, applicants submit LOIs to provide a brief overview of their research plan. Please see Section 6 for requirements for preparing an LOI.

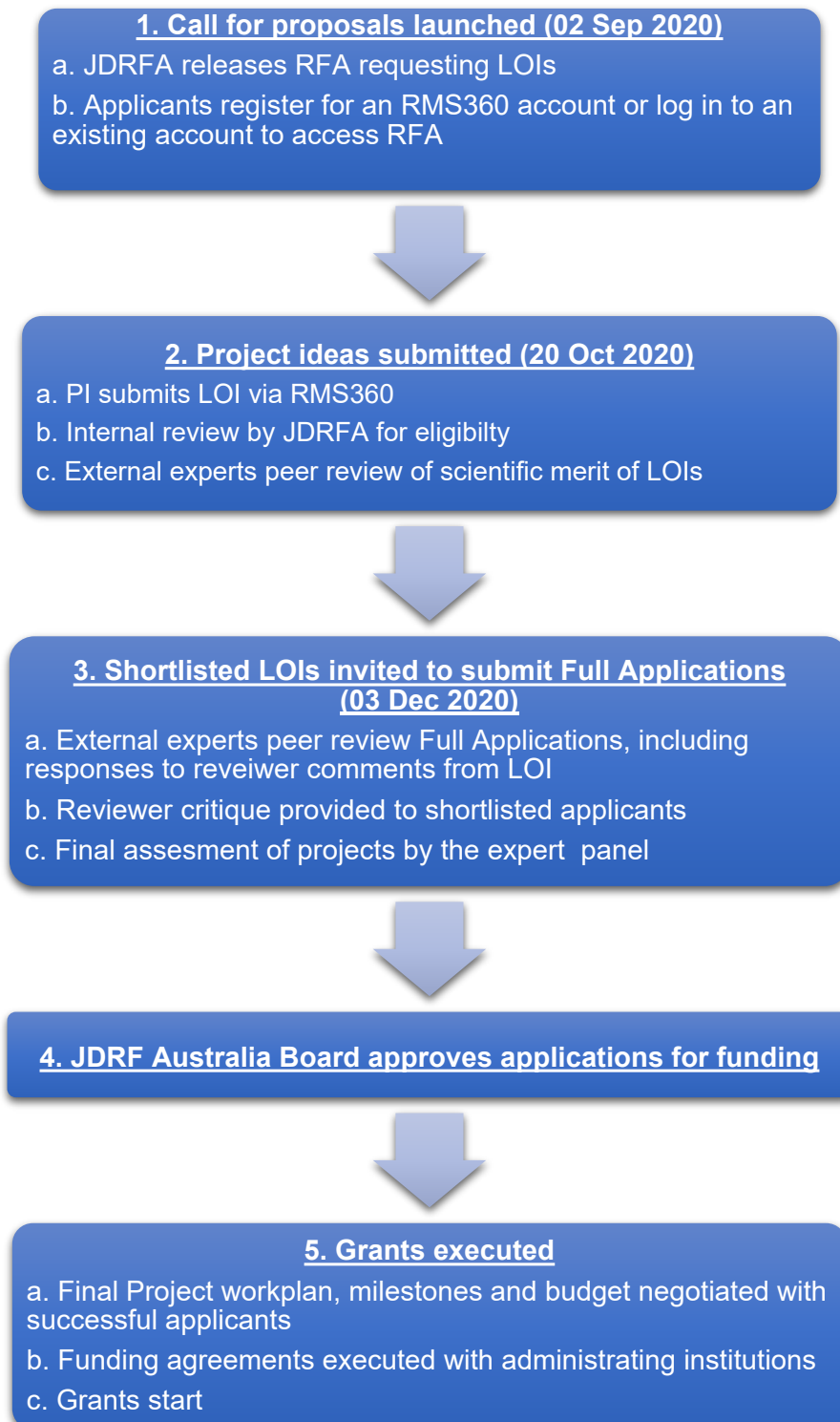
JDRF will check applications for compliance with eligibility (Sections 3 and 4). A review panel of national and international experts will then assess LOIs for the quality and originality of the proposed research and its potential to advance knowledge and opportunities for T1D research and clinical care as well as its relevance to the mission of JDRF and the T1DCRN.

The reviewers will assess LOIs through a scoring system based on the Selection Criteria outlined in Section 7. Scoring of application is done individually by each expert reviewer, and any reviewer with a conflict of interest is excused from scoring on a specific proposal. Only the highest-quality, highest impact Projects will be invited to proceed to a Full Application. These applicants will be provided with written critiques from the reviewers which must be addressed in their Full Application. Further information about this process will be provided to applicants who are invited to submit a Full Application.

Full Applications will also be assessed and scored by a panel of expert reviewers. If recommended for further consideration, applicants will be provided with written critiques from the reviewers and invited to respond in writing. The Panel will consider the scientific merit of the applications and provide appraisal of scientific merit and ranking of the application against the selection criteria. The JDRF Australia Board has the responsibility to approve grants for funding and allocation of the final budget.

JDRF or the review panel may suggest changes to the research plan and budget at any stage during the course of the review process.

Successful awardees will be notified, and a Funding Agreement will be executed with the applicants administrating institution. After a grant is awarded, JDRF monitors the progress of the Project.



6. Letters of Intent

Applicants must submit LOIs via RMS360 (<http://jdrf.smartsimple.us>) to be considered for a Full Application. The following materials need to be submitted at the LOI stage using templates provided in RMS360:

6.1 Proposal Synopsis (*2 pages maximum, use template*) Summary outlining the area of research, main objectives of the project, key personnel and institutions, and check for eligibility.

6.2 LOI Research Plan (*3 pages maximum excluding references, use template*) that provides the following information:

- Significance and impact for proposed research
- Rationale for proposed research including aims
- Description of research design and methods
- If applicable, advantages over alternative approaches
- Future plans and potential translational impact
- Projected deliverables (if successful).

6.3 Bio-sketch (*4 pages maximum, use template*) of the Principal Investigator (PI) and Co-investigators must be provided. Applicants must have relevant experience and must have the ability to lead investigations and perform proposed research activities.

6.4 LOI Proposal Budget (*Use template*) A concise indicative budget for each grant year with a brief justification for the use of funds. Please note, a more detailed budget and justification will be requested if an LOI progresses to a Full Application.

7. Selection Criteria

All LOIs that meet the eligibility criteria (Section 3) will be assessed by an independent panel for merit based on the following selection criteria. Applicants must ensure that adequate information is provided in a concise and focused manner for reviewers to assess their LOI application against each of the weighted selection criteria:

- **Significance and Impact (20%)**
 - How significant the project's impact will be on advancing T1D research and/or improving lives of people with T1D? LOIs should address the importance of the problem or critical barriers to progress and the impact the proposed project will have in the field
 - How the proposed project will improve scientific knowledge, diagnostic capability, and/or clinical practice
 - How the project will change concepts, methods, technologies, treatments or preventive interventions that drive T1D research
 - Clear focus on translation towards clinical care including future clinical trials and development of assays for early diagnosis of T1D
 - Expansion of skill sets, knowledge base and overall capacity and quality of Australian T1D research

- **Innovation and Novelty (20%)**
 - Extent to which the proposed work is original and innovative, supported by convincing argument with appropriate citations
 - How the proposed work challenges and seeks to shift current research or clinical practice
 - Scope of novel concepts, approaches or methodologies to be developed or used, and any advantage over existing alternatives
 - Scope of any refinements or improvements of existing concepts, approaches or methodologies
- **Study Design and Research Methods (30%)**
 - Quality of the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project
 - Clarity of how the data will be collected, analysed, and interpreted as well as the scope of resource sharing
 - Foresight of potential problems, alternative strategies and benchmarks for success anticipated to achieve the aims
- **Team Expertise and Environment (20%)**
 - Expertise of the PI and Co-PIs and core members of the team (refer to selection criteria)
 - Level of collaboration, cross-disciplinary expertise
 - Provision to institutional resources, infrastructure and other support mechanisms
- **Feasibility (10%)**
 - Appropriateness of proposed timeline and budget
 - Likelihood of obtaining ethical approval if needed
 - Potential and clear plan for future steps including obtaining larger funds from other sources and progressing to end-users

8. Funding

The *Pilot and Innovation Awards 2021* will fund studies over a maximum of two years, subject to sufficient funding being available and continued satisfactory progress of the study. The level of funding for individual projects will vary depending on the scope and overall objectives of the project. Applicants should propose budgets that are well justified and strongly commensurate with project scope.

For the LOI stage, budget amounts must be provided for each year of the project although are indicative of size and scope of the project only and do not form part of the review. If the application progresses to the full submission, budget amounts will be assessed during the peer review of the full submission.

JDRF or the reviewers reserve the right to recommend levels, duration and scope of funding which may differ from those requested in the application.

Please note: Grants awarded by JDRF through the T1DCRN are listed on the Australian Competitive Grants Register. As such, indirect costs can be recovered through Research Block Grants funding. JDRF will not provide funding for indirect costs including basic facilities and equipment, organisational overheads and/or infrastructure costs. These must not be included in the budget request.

9. Submission Instructions and Checklist

9.1 Instructions

Applications must be submitted online using JDRF's online grants management system RMS360 (<http://jdrf.smartsimple.us>). Information submitted as part of the application is collected and stored in accordance with the JDRF Australia's [Privacy Policy](#).

All parties involved in or associated with an application must declare at the date of submission any Conflict of Interest that exists or is likely to arise in relation to any aspect of the application.

JDRF will only consider complete applications that meet Application formatting requirements. Information must be typed single-spaced and in black typeface no smaller than size 11 points Times New Roman font or an equivalent size, including text within images and figures, before converting to PDF format and must be legible to assessors. Avoid scanning.

A submission is complete if:

- It includes all the documents listed in the submission checklist below
- All mandatory fields in the online grant management system RMS360 are completed

9.2 LOI Submission Checklist

- Proposal Synopsis (use template)
- LOI Research Plan (use template)
- Bio-sketch for each investigator (use template)
- LOI Proposal Budget with Justification (use template)

10. Contractual Requirements

10.1 Funding Agreement

This funding will be provided by JDRF and administered by the recipient's institution. The award recipient will be required to sign a Funding Agreement with JDRF Australia (Agreement). A condition of application to this RFA is provision of certification of the PI, Co-PI(s) and their organisations to have read and agree to abide by the terms of the Agreement.

JDRF has no obligation in respect of this RFA including any funding, unless and until JDRF and the successful applicant(s) have executed the formal Agreement. JDRF expects the Agreement to be executed prior to the grant start date, unless otherwise agreed by JDRF. The Agreement template will include, but is not limited to, the following:

- A payment schedule dependent upon the achievement of project milestones. JDRF will determine such milestones to be included in the Agreement in consultation with the relevant Investigators
- An obligation to comply with all relevant JDRF Policies as further detailed in the [Agreement template](#).

JDRF reserves the right to require changes to the Agreement template to address specific needs and circumstances of an application.

10.2 Consent to Combine Applications

The objectives of this RFA and the T1DCRN emphasise collaboration and encourage research that presents the greatest benefit to the T1D community. After the review of the LOIs, shortlisted applications from separate investigators may be invited to combine their applications into a single Full Application submission where such collaboration is deemed necessary to maximise benefit and avoid overlap.

In submitting an LOI in response to this RFA, applicants consent to information about their application being shared with other applicants for this purpose and acknowledge they may be asked to combine their application with another applicant as a condition of being invited to submit a Full Application. Applicants will be informed about this possibility prior to sharing any information, providing the opportunity for them to withdraw their application if required.

10.3 Consent to Co-funding

JDRF actively seeks co-funding opportunities with other funding bodies and partner institutions. In submitting an LOI in response to this RFA applicants consent to information about their LOI being shared with other funding bodies that are specifically interested in supporting the research and related activities generated through the T1DCRN.

10.4 Data and Resource Sharing

All applicants invited to Full Application will be required to submit a Data Sharing Plan. For more information please refer to the T1DCRN [Data and Biosample Sharing Policy](#).

JDRF acknowledges that resource sharing plans will differ according to the types of data and biosamples collected and does not prescribe the exact content or format. JDRF requests that at a minimum the core elements outlined in the Data Sharing Plan template in Appendix A of the JDRF Australian T1DCRN Data and Biosample Sharing Policy are considered.

10.5 Publications and Open Access

The T1DCRN is committed to the timely publication and dissemination of all information and materials developed under T1DCRN funding and must also comply with the [Australian Research Council Open Access Policy](#). Recipients of this award must also comply with this policy and must take steps to make available all generated project materials for publication and wider dissemination. The sharing of data will be supported by clear policies and guidelines, as well as mechanisms to satisfy this requirement.

11. Background on JDRF Australia and the T1DCRN

Type 1 diabetes (T1D) is a serious, chronic autoimmune condition that affects over 120,000 Australians¹. T1D is classically characterised by a sudden and pronounced onset in children, adolescents and young adults, requiring immediate and life-long dependence on exogenous insulin due to autoimmune destruction of pancreatic beta cells. It is now recognised that T1D initially progresses through a silent asymptomatic phase characterised by the persistence of circulating islet autoantibodies. This asymptomatic phase can last for months or years, until diagnosis of clinical T1D requiring carefully titrated exogenous insulin therapy². Underlying genetic predisposition or/and delayed trigger factors as well as the role of stressed and sick beta cells in necessitating an immune reactive pathway, are yet to be fully understood. Clinical manifestations and the disease evolving epidemiology of T1D globally remain overwhelming and unresolved.

JDRF is the world's biggest non-profit funder of T1D research with the ultimate goal to find a cure for T1D. Until a cure is found, our focus is on advances that ease the burden for those living with the disease. The key to treating, preventing, and ultimately curing T1D is the swift translation of Australian and global basic science and applied research outcomes into treatments and technologies that work effectively in people. Australian T1D research ranks highly on a global scale³, but adoption into clinical care remains a challenge⁴. Overcoming this challenge requires an important step out of the laboratory and the translation of research into human trials.

The Australian Type 1 Diabetes Research Clinical Research Network (T1DCRN), a JDRF initiative, is a national framework that supports the most promising T1D research and clinical trials. The network was informed by The Australian Type 1 Diabetes Research Agenda, developed through a broad consultation process with researchers, clinicians and patient representatives.

The T1DCRN was launched in June 2010, initially through a \$5 million, four-year grant from the Australian Government through the Department of Health and Ageing. In 2014, a further \$35 million over five years was provided by the Australian Government via the Australian Research Council.

The T1DCRN has established a highly successful research network bringing together world-class researchers, patients, industry and international partners to answer critical T1D clinical research questions, with a strong focus on patient benefit. In addition to fostering the most outstanding T1D research talent, the T1DCRN attracts exceptional scientists from other disciplines to broaden the scope of T1D research in Australia.

To date, the T1DCRN has invested \$95M in Australian research and attracted over US \$10M of direct financial leverage from international partners. T1DCRN initiatives have supported more than 250 researchers across 70 institutes, connecting approximately 2,500 Australians with the latest research, treatments and technologies. The sharp focus on patient benefit is a

¹ jdrf.org.au

² Diabetes Care Oct 2015, 38 (10) 1964-1974.

³ [The Australian Research Impact Analysis](#)

⁴ [The Australian Type 1 Diabetes Research Resource Map](#)

unique dimension of the T1DCRN and the patient-centric approach provides a platform to accelerate therapies and amplify research impact.

In 2019, the Australian Government committed a further \$25M to extend the T1DCRN for an additional five years to 2024. This new investment aims to build on prior achievements and increase the impact of T1DCRN via expansion of its scientific priorities. The new phase of the T1DCRN aims to:

- Increase the volume and impact of Australian T1D clinical research, while investing in large-scale prevention and screening initiatives
- Support “bench to bedside” research and ensure researchers have the required supporting tools and policy environment, and
- Nurture current and future research leaders in T1D while attracting bright new talent.

12. Program Contacts

Inquiries concerning this funding opportunity should be directed to:

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