

Australian Type 1 Diabetes Clinical Research Network

Request for Applications: Letters of Intent

Innovation Award

LOI Application Opens	April	15	2016	
LOI Application Deadline	July	22	2016	17:00 AEST
Invitation to Full Submission	August	31	2016	
Full Submission Deadline*	October	26	2016	17:00 AEDT
Notification to Applicants	January		2017	

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



Australian Government
Australian Research Council

A Special Research Initiative funded by the ARC

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1 INTRODUCTION

1.1 EXECUTIVE SUMMARY

The principal goal of the Type 1 Diabetes Clinical Research Network (T1DCRN), a Special Research Initiative funded by the Australian Research Council (ARC), is to positively impact the lives of people with type 1 diabetes in Australia through the support and promotion of clinical research, focussing on at-risk populations, new onset populations and individuals with established type 1 diabetes. The T1DCRN is a national collaborative network led by JDRF Australia supporting the most promising research projects, promoting and retaining outstanding scientists and attracting new researchers to the field of type 1 diabetes research. The network enables the efficient and effective delivery and adoption of clinical research, and invests in and builds long-term research capacity in Australia. The T1DCRN also forges national and global partnerships to leverage existing domestic and international expertise and resources in type 1 diabetes research.

The intention of this Request for Applications (RFA) “*Innovation Award*” is to advance promising innovation that if successful would improve the lives of people with type 1 diabetes. Accelerating world-class diabetes research in Australia and optimising access to novel medical therapies available to the type 1 diabetes community is a core aim of the T1DCRN.

1.2 REQUEST FOR APPLICATIONS: LETTERS OF INTENT

JDRF Australia is soliciting Letters of Intent (LOI) that describe breakthrough, cutting-edge innovation that falls outside current type 1 diabetes research paradigms expected to make good progress towards achieving high impact on the field and eventually the lives of people with type 1 diabetes.

The proposed research must describe either the discovery or advancement of innovation along the pipeline to implementation. Innovation is defined by:

- the generation of a novel idea;
- extending existing knowledge into a new and distinct area or application;
- the novel use of research tools or technologies; and/or
- the novel use of clinical tools, therapies, or strategies;

that addresses a critical barrier and/or will accelerate progress towards preventing, treating or curing the disease.

Letters of Intent (LOI) will be assessed as per the review process outlined in Section 8. Only shortlisted LOIs will progress to the second round “Invitation to Full Application”. Information relating to the Full Application and subsequent review processes will be provided to successful applicants at the time of notification of the LOI outcome.

1.3 PURPOSE

Advancing innovation across Australia has become a national priority, with the Australian Government recently releasing the [National Innovation and Science Agenda](#)¹. This report outlines the dedication of the Australian Government to increase collaborative, innovative research across academia and industry, and to invest in commercialising innovation through the CSIRO Innovation Fund and a Biomedical Translation Fund.

JDRF Australia has designed the “*Innovation Award*” described in this RFA to support exceptionally innovative collaborative research that will drive future life-changing breakthroughs in preventing, treating or curing type 1 diabetes and its complications.

Traditional funding mechanisms tend to drive peer review and funding decisions toward well-established research pathways supported by significant preliminary data, causing a shift away from investments in bold, transformative discovery research. Investing in innovative research is essential for the discovery of new medicines, technologies and approaches to improve the health and lives of people with type 1 diabetes and their carers, and to eventually cure and prevent the disease.

The RFA “*Clinical Centres and Concept Proposals*” released in 2014 resulted in large-scale clinical programs being funded through the Australian Type 1 Diabetes Clinical Research Network (T1DCRN). These programs are investigating research pathways in areas of glucose control, treating diabetic kidney or eye disease, and islet survival, with the aim to bring the experimental devices and therapies closer to market.

The T1DCRN is now focussing on addressing key challenges and complex questions to develop and advance innovation in the field. Australia is globally recognised as driving research innovation². With this current RFA the T1DCRN aims to ensure that innovation in type 1 diabetes research continues to be supported and driven by creative thinkers across Australia and is accelerated along the pathway of developing novel applications.

1.4 BACKGROUND OF THE T1DCRN

The volume of type 1 diabetes research in Australia is rapidly expanding and its quality is recognised world-wide³. However, efficient study development and optimised uptake or delivery of research outcomes are hindered by including regulatory impediments, scarce long-term funding awards, and fragmentation of resources⁴. To improve type 1 diabetes clinical activity and capacity in Australia, the [Type 1 Diabetes Clinical Research Network](#) (T1DCRN) was launched by JDRF in June 2010 through a \$5 million grant from the Australian Government. With this initial investment the T1DCRN funded 12 clinical projects including three national multi-centre clinical projects and nine Pilot & Feasibility

¹ Commonwealth of Australia, Department of the Prime Minister and Cabinet, *National Innovation and Science Agenda*.

² Report by the House of Representatives Standing Committee for Science and Innovation “Pathways to Technological Innovation” June 2006

³ Australian Research Impact Analysis
<http://jdrf.org.au/research/type-1-diabetes-global-research-impact-analysis>

⁴ The Australian Type 1 Diabetes Research Resource Map
<http://jdrf.org.au/research/type-1-diabetes-research-resource-map>

projects, and nurtured the next generation of research leaders through five Mentored Clinical Researcher Fellowships.

Thanks to support from JDRF advocate families, T1DCRN has retained and extended government confidence and support in the form of a *Special Research Initiative* for \$35 million from the Australian Research Council (ARC). The initiative will enhance and expand on previous initiatives and further develop the national collaborative network of researchers, creating a more connected and cohesive clinical research system. The T1DCRN intends to accelerate strategic solutions to the above-mentioned barriers to research, and to leave a legacy by building lasting research capacity that extends beyond the current five year funding period.

In April 2015 the T1DCRN held its annual meeting attended by 43 key opinion leaders in type 1 diabetes research in Australia. One of the key recommendations arising from the meeting was that Project Grant schemes prioritised for funding by the T1DCRN should be targeted towards Innovative research.

1.5 OBJECTIVES OF THE T1DCRN

The T1DCRN is founded on the following operating principles, which underpin the delivery of the program objectives and are taken into account through the eligibility criteria in Section 4.2 and the selection criteria in Section 8.1. They are:

1.5.1 Patient-focused

Ultimate patient benefit is the goal that underscores all the activities of JDRF. The engagement of the type 1 diabetes community (research and public) is critical to the operation of this initiative.

1.5.2 Collaborative

A collaborative approach will be required for clinical research in the initiative. Research teams will be assembled based on the expertise needed and ability of participants to solve complex issue of type 1 diabetes.

1.5.3 Leveraged and connected

The initiative will build partnerships to benefit from the existing international and domestic expertise and resources and leverage prior investments in Australia by JDRF and other funders.

1.5.4 Information sharing

With the intention of creating a long-term research legacy, the initiative will capture valuable research information and invest in secondary analysis of outcomes and data generated.

1.5.5 Productivity-driven

JDRF will actively support and engage in the management of clinical trials, with assistance directed towards ensuring research performance meets budgets and timelines.

2 OBJECTIVES AND SCOPE OF CALL

2.1 OBJECTIVES

The objective of this *Innovation Award* is to support bold, innovative research, delivered by collaborative and cross-disciplinary research teams. These studies are expected to provide benefit for the T1DCRN, strengthening and expanding the skill set, knowledge base, and capacity in Australian type 1 diabetes research.

Applicants must address the following objectives when preparing their application (see Eligibility Criteria at section 4.2 and the Selection Criteria at section 8.1):

- significance and innovation of the proposed research
- collaboration: across multiple research organisations and/or with industry
- inclusion of early-mid career and established researchers in the leadership group
- inclusion of at least one experienced researcher who works outside of the field of type 1 diabetes
- provision of external support (e.g. additional sources of funding; in-kind contributions)

2.2 RESEARCH PRIORITY AREAS

JDRF has identified [Research Priority Areas](#) as current areas of need.

JDRF also welcomes applications that address an area of need outside of these Research Priority Areas that is yet to be identified and will deliver significant benefit to type 1 diabetes.

3 FUNDING

Innovation projects may be applied for and awarded funding of up to \$1.5M for a period of two to three years, subject to sufficient funding being available and continued satisfactory progress of the study. All projects funded through this RFA must have an end date of no later than 31 January 2020, regardless of the commencement date for the funding agreement. JDRF Australia reserves the right to recommend levels, duration and scope of funding which may differ from those requested in the application.

3.1 BUDGET REQUEST

For the LOI stage, budget amounts must be provided for each year of the project, but 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.

Please note: Grants awarded by JDRF Australia through the T1DCRN are listed on the [Australian Competitive Grants Register](#). As such, indirect costs can be recovered through RBG funding and JDRF Australia 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.

4 ELIGIBILITY

4.1 ALIGNMENT WITH CRN GOAL

All applications for funding within the *Special Research Initiative* for the Type 1 Diabetes Clinical Research Network will only be eligible for funding if the application demonstrates that it is in alignment with the Goal i.e. **To positively impact the life of people with type 1 diabetes in Australia through the support and promotion of clinical research.** The *Innovation Award* is specifically designed to support frontier, discovery research which may take years to reach the clinic or market. To address this eligibility criterion the application must describe how this innovation, if successful, will eventually result in positive impact.

4.2 ALIGNMENT WITH RFA OBJECTIVES

All applications for funding submitted in response to this RFA will only be eligible for funding if the application demonstrates that it meets the following objectives of the RFA:

- The application must at a minimum involve collaboration with at least one industry organisation OR researchers from at least one research organisation separate to and independent of the research organisation of the lead Principal Investigator;
- Inclusion of both early-mid career (EMCR) and established researchers in the leadership group to provide opportunity for the EMCRs to develop their leadership experience under the mentorship of more senior researchers; and
- Inclusion of at least one experienced researcher from outside of the field of type 1 diabetes to bring capacity and knowledge from other areas that will benefit the field as well as the proposal. Researchers from outside the type 1 diabetes field are defined as individuals who have not previously competed successfully for a substantial diabetes-related national or international research grant.

4.3 FORMATTING REQUIREMENTS

JDRF Australia will only consider complete applications that meet the formatting requirements as specified in Appendix A – LOI Research Plan. An application is considered to be complete if:

- it includes all the documents listed in Section 7; and
- all mandatory fields in the online grant management system RMS360 are completed.

Incomplete applications or incorrectly formatted applications will be deemed ineligible and declined without further assessment.

5 EXCLUSION CRITERIA

5.1 DUPLICATION OF RESEARCH

If at any time during the assessment process JDRF or the review panel deems the scientific objectives of a proposal to:

- i. duplicate; or
- ii. overlap significantly with; or
- iii. be an extension of

the scientific objectives of a current or planned Project (in Australia and/or overseas) the proposal will be excluded from further consideration.

5.2 APPLICATIONS NOT SUITED TO THE INNOVATION AWARD

The *Innovation Award* is designed to support bold, innovative research, distinct from well-established existing programs, and delivered by collaborative and cross-disciplinary research teams. If at any time during the review process JDRF forms the view that an application falls within one of the following 6 exclusion criteria, the application will be deemed ineligible and will be excluded from further consideration:

1. Applications that describe a small/incremental step in an established research program.
2. Applications that lack a clearly articulated vision of steps to progress the innovation to the end-user, accepting that the end-point of this vision may extend beyond the period of time that this funding scheme supports, and that by definition innovative projects will contain inherent risk and may have go/no-go decision points. Examples of end-points include eventual commercialisation; changing health care practice; implementing a new approach to imaging, to identifying biomarkers, to identifying aetiological factors etc.
3. Applications that describe exploratory blue-sky research purely for the acquisition of data.
4. Applications that lack diversity from disciplines outside of type 1 diabetes in its leadership team; applicants that fail to build collaborations and bring external expertise into the field to drive innovation.
5. Applications that describe approaches or ideas that, even if successful, will have limited impact on the field or only incremental improvements in health.
6. 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 type 1 diabetes due to the harm-benefit ratio e.g. complete immune ablation.

6 POTENTIAL OVERLAP OF PROPOSED PROJECTS

The objectives of this RFA and the CRN emphasise commitment to encouraging collaboration within the type 1 diabetes research field and funding projects that will present the greatest benefit to the type 1 diabetes community. After the review of the LOIs, shortlisted applications from separate investigators may be invited to combine their applications into a single full submission where such collaboration is deemed necessary to maximise benefit and avoid overlap.

In submitting an LOI in response to this RFA, you consent to information about your LOI being shared with other applicants for this purpose and acknowledge that you may be asked to combine your application with another applicant as a condition of being invited to submit a full proposal. You will be asked and informed about this possibility prior to sharing information, providing the opportunity for you to withdraw your application.

7 SUBMISSION INSTRUCTIONS

The information in this document is underpinned by the Program Guidelines which explain the selection processes in more detail. Please review the [Program Guidelines](#) before preparing the application.

Applications must be completed and submitted online, and certified by an authorised officer of the Administering Organisation, using JDRF Australia's online grants management system RMS360 (see *RMS360 User Guide* for further details). Information submitted as part of the application is collected and stored in accordance with the [JDRF 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 Australia's Network Conflict of Interest policy and management practices are available on the JDRF Website.

All asterisked fields in RMS360 must be completed, including "Objective and Preliminary Specific Aims" tab (maximum 300 words). All applications must include the following documents uploaded into RMS360:

- Research Plan (see Appendix A – Research Plan Template)
- Written Evidence (see Appendix A – Additional Attachments)

7.1 CONSENT TO BE CONSIDERED FOR COFUNDING

JDRF actively seeks cofunding opportunities with other funding bodies. With consent from the applicant, JDRF Australia may share the application and information about the results of assessment of the application with other funding bodies that are specifically interested in supporting the research and related activities generated through T1DCRN. Consent to disclose is included in the LOI Research template provided in RMS360. Refusal of the applicant to consent will not influence funding decisions made by JDRF Australia.

8 REVIEW PROCESS

The review process has been designed to emphasise to peer reviewers that the focus of the review will be on the significance and innovation of the hypothesis and/or methodology and the impact on end-users if successful.

JDRF Australia will consider each proposal to determine if it satisfies the eligibility criteria. JDRF Australia will assign all eligible proposals to a panel of independent assessors from a range of national and international organisations, who will assess the proposal against the selection criteria in section 8.1 and provide written comments supporting their assessment. The external panel of independent assessors will then merit rank each application relative to the others on the basis of these assessments and shortlist applications.

Only shortlisted applicants will progress to the next stage of assessment – invitation to full submission. The details regarding the process for full submission will be provided with the notification of decision of the LOI. Full submissions that meet the eligibility criteria will be assessed by the independent panel for value for money and merit against each of the selection criteria.

All applicants will be provided with reviewers' reports. Shortlisted applicants must consider reviewers' reports and comments from JDRF Australia when preparing their full submission.

8.1 SELECTION CRITERIA

All applications that meet the eligibility criteria will be assessed by an independent panel for merit based on the following selection criteria. Applicants must ensure that sufficient information is provided in a concise, focussed manner in the Research Plan for reviewers to assess the application against each of the weighted selection criteria.

Type 1 Diabetes Research Program – Innovation (40%)

- Extent to which the application is innovative and original, supported by convincing argument with appropriate citations
- Likelihood of innovation progressing to end-user (beyond the life of this grant) if the project is successful

Type 1 Diabetes Research Program – Significance (30%)

- If successful, will make a significant contribution to type 1 diabetes research

Research Team and Environment (20%)

- Collaborative, cross-disciplinary, qualified, well-resourced

Provision of external support (10%)

- E.g. additional sources of funding; in-kind contributions

9 DEADLINES

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

10 CONTRACTUAL REQUIREMENTS

This funding will be administered by JDRF. The award recipient will be required to sign a Funding Agreement with JDRF Australia, a template of the Agreement will be provided to shortlisted applicants with the notification of decision of the LOI. The payment schedule contained within the Agreement will be dependent upon the achievement of project milestones determined in consultation with the Principal Investigators. Part of the contractual requirement is the Principal Investigator must be aware of and comply with the T1DCRN JDRF [Policy on Intellectual Property, Commercialisation and Royalties](#) (“IP Policies”), including in relation to data sharing and biosample sharing.

10.1 DATA SHARING

All applicants invited to full application will be required to submit a Data Sharing Plan. For more information please refer to the [Australian Type 1 Diabetes Clinical Research Network \(JDRF\) Policy on Data and Biosample Sharing](#).

JDRF acknowledges that Data Sharing Plans will differ according to the types of Data collected and does not prescribe 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 [Australian Type 1 Diabetes Clinical Research Network \(JDRF\) Policy on Data and Biosample Sharing](#) are considered.

10.2 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 ARC policy requirement on Open Access (http://www.arc.gov.au/applicants/open_access.htm). 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.

10.3 REPORTING

Progress reports will be required bi-annually, or as outlined in the Funding Agreement, and a Final Report at the end of the funding period. In line with the ARC funding rules for the Initiative, recipients may be required to participate in a Review of the Initiative in 2016 or at any time as required.

11 PROGRAM CONTACTS

We strongly encourage all researchers who are considering submitting an LOI to contact us prior to application.

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12 APPENDIX A – LOI RESEARCH PLAN

A Research Plan **of no more than six A4 pages** (excluding the cover page) must be uploaded as part of the application in RMS360 (<https://jdrf.smartsimple.us>). The LOI Research Plan template is provided on RMS360. Refer to the [RMS360 User Guide](#) for assistance.

The Research Plan should include all necessary information for peer review of the project. Be specific, informative and concise. Avoid using jargon.

Formatting Requirements

- The Research Plan must be type-written, single column, single-spaced and in black typeface no smaller than size 12 point Times New Roman font or an equivalent size before converting to PDF format and must be legible to assessors. Avoid scanning.
- Paper must be white A4 size with at least 2 cm margin on each side and at top and bottom.
- References only can be in 10 point Times New Roman font or equivalent and must be no more than one page.
- The Applicant's name (Last, First, Middle) must be provided as left-aligned text in the Header.
- Page numbers must be provided in the format "Page X of Y" as right-aligned text in the Footer.
- The Research Plan must be uploaded as an **unlocked PDF document** without password protection.

Research Plan Template

The Research Plan must be organised using the section headings provided in Table 1.

Reviewers will use the Selection Criteria (Section 8.1) to evaluate applications; applicants need to ensure that detailed information provided in the Research Plan addresses all Selection Criteria.

Please Note "Overall Objective of the Proposal and Preliminary Specific Aims" are submitted as free text directly into the required field in **RMS360**. This field is truncated at 300 words with the following guidance:

- a. State concisely the specific aims of the proposal.
- b. Specify the objectives and hypotheses to be tested.
- c. Summarise the expected practical outcomes.

Table 1. Research Plan Template.

Section Heading	Guide
1. Application title	The title of the application may be used in publicity if awarded; please ensure the title is descriptive without revealing confidential information
2. Innovation	Describe the rationale for proposed research, including existing knowledge and any preliminary and pilot data; explain why this proposal is innovative, and distinct from any related work that has been completed or is currently underway in the field. Detail the steps required to progress this innovation to end-users (beyond the life of this grant). Include possible barriers at any step.
3. Significance	Explain the importance of the problem that this proposal addresses, including the potential impact of expected research outcomes on people living with type 1 diabetes
Sections 1 -3 listed above must be no longer than 3 pages.	
4. Research Team and Environment	No more than one page. Describe the diversity of the team and how the team and research environment contain all necessary expertise and resources to deliver the research as described in sections 2 and 3.
5. Provision of external support	No more than one page. Describe current provision of and/or potential opportunities to receive additional external support for this project (e.g. additional sources of funding; in-kind contributions) if this application is successful.
6. References	No more than one page.
7. Consideration for cofunding	Applicants who wish to be considered for cofunding opportunities must tick the box to indicate their consent for JDRF to provide the application and information about the results of assessment of this application to other funding bodies.

Additional Attachments

Additional Attachments must be uploaded as unlocked PDFs without password protection.

Additional Attachments must be limited to the following documents, no other attachments will be considered:

- JDRF Australia is required to obtain written evidence of all the relevant persons (PI of the project and all PIs of subcontracted sites and collaborative centres) and their organisations. Written evidence must be uploaded into RMS360. The template for Written Evidence is provided for download in the “Additional Attachments” section of RMS360.