



Principal Research Fellow: Population Screening Pilot

POSITION DESCRIPTION AND APPLICATION PROCESS

1 SUMMARY OF POSITION

Type 1 diabetes (T1D) is a life-long autoimmune disease that likely begins in childhood but can be diagnosed at any age, affecting over 120,000 people in Australia. The autoimmune process destroys the insulin-producing beta cells within the pancreas, leading to insulin insufficiency, elevated blood glucose levels and a lifelong requirement for insulin therapy. Glucose control is difficult despite insulin therapy, placing many people at risk of developing serious complications, including blindness and kidney failure.

Only 10% of people newly diagnosed with T1D have an affected first-degree relative. Therefore, most at-risk individuals would only be identified by general population screening. There is a growing body of evidence internationally that earlier detection of T1D through antibody screening offers benefits, including a reduction in disease onset-related morbidity such as diabetic ketoacidosis and reduced psychological stress for families, provided the screening is followed by ongoing monitoring and treatment if required¹. Earlier detection of T1D, and reducing complications and improving quality of life among people with T1D, have been identified as two of the key goals of the <u>Australian National Diabetes Strategy 2016-2020</u>². Identification of individuals during the first stage of T1D, where the autoimmune process has begun but are pre-symptomatic, will ultimately allow for effective interventions to prevent progression to clinical diabetes, either through clinical trials or when such therapies have been demonstrated to be effective.

To progress these goals, JDRF Australia recently led workshops with key stakeholders to discuss feasibility of implementing population-based T1D screening in Australia, including challenges and strengths. A key recommendation arising from these workshops was to recruit a *Principal Research Fellow* who, in close consultation and partnership with an Expert Advisory Committee, JDRF Australia and key stakeholders, will lead and manage the design, implementation and evaluation of a pilot screening program to successfully identify and monitor individuals at risk of T1D in the general population. This pilot must be guided by and aligned with the criteria and key principles outlined in the <u>Population Based Screening Framework</u>³.

³ Population Based Screening Framework 2018. ISBN: 978-1-76007-370-1



¹ Steck AK et al. Residual beta-cell function in diabetes children followed and diagnosed in the TEDDY study compared to community controls. Pediatr Diabetes. 2017 Dec;18(8):794-802. doi: 10.1111/pedi.12485

² Australian National Diabetes Strategy 2016–2020.

The *Principal Research Fellow* and pilot program activities will be initially funded for three years by the <u>Australian Type 1 Diabetes Clinical Research Network</u> (T1DCRN), a Special Research Initiative of the Australian Research Council and led by JDRF Australia.

2 PROGRAM AIMS, SCOPE AND DELIVERABLES

The aim of this Request for Applications "Principal Research Fellow: Population Screening Pilot" (RFA) is to advance the emerging priority of a national screening program for T1D risk in Australia through an initial pilot, in collaboration with relevant existing infrastructure and research initiatives.

The pilot is expected to contribute to generating evidence in the context of T1D such as effectiveness and benefits of screening required by decision-makers regarding the implementation of screening embedded within the Australian health system, as outlined in the Population Based Screening Framework⁴. Additionally, screening could identify at-risk individuals who may be eligible for ongoing or future prevention trials. Accelerating world-class diabetes research in Australia and optimising access to novel medical therapies available to the T1D community, including those at-risk, is a core aim of the T1DCRN.

The scope of the pilot is to recruit children from the general population and identify those at an increased risk of T1D through the detection of persistent multiple islet autoantibodies. The scope will also include follow-up of the islet autoantibody positive children to monitor progression to T1D to determine whether screening and follow-up improves outcomes at diagnosis. The pilot protocol will be designed by the Fellow as part of the Prevention Strategic Plan, Budget and Evaluation Framework in Year 1 of the Fellowship. The Strategic Plan must include reasonings for the design of the pilot protocol such as choice of target population(s) and the proposed number of screened participants.

Deliverables for the *Principal Research Fellow* over the three year funding period include but are not limited to:

Year 1

- in consultation with JDRF, finalise membership and terms of reference of the Expert Advisory Committee to participate in and provide guidance and advice on planning, implementation and evaluation of the pilot, including development of final recommendations;
- assess the available evidence and resources to support cost-effective screening, including but not limited to screening tests, target groups, recruitment strategies and call/recall mechanisms, uptake, and registry requirements;
- identify and consult with multiple stakeholder groups;
- by end of Q2 Year 1, develop and begin implementing a 3 year Prevention Strategic Plan, Budget and Evaluation Framework (in consultation with and approved by JDRF) to progress towards a sustainable, national screening program of type 1 diabetes risk in Australia, integrated into existing prevention initiatives/infrastructure where possible;

⁴ Population Based Screening Framework 2018. ISBN: 978-1-76007-370-1

Years 2 and 3

- support the collection of pilot data on antibody screening and monitoring of at-risk individuals, specific for the local Australian context and contributing to global efforts;
- identify important determinants, challenges and opportunities of feasibility and acceptability in diverse target populations and in a range of clinical/community settings;
- identify evidence gaps that would need to be addressed beyond the current pilot; and
- by end of Q4 Year 3, complete evaluation of pilot including key recommendations.

This work will inform future efforts to implement and monitor the effectiveness of a national type 1 diabetes screening program.

3 DECISION-MAKING, REPORTING REQUIREMENTS AND FUNCTIONAL RELATIONSHIPS

The *Principal Research Fellow* is responsible for program management, including operational decision-making, and the development and implementation of agreed deliverables.

The *Principal Research Fellow* will be assisted by the Expert Advisory Committee who will provide the Fellow with access to skills and expertise, with clear terms of reference. The Expert Advisory Committee will also be responsible for regular review of the progress and appropriateness of the program activities.

The role must:

- Consult with the Expert Advisory Committee and JDRF staff on any decision that will substantially alter the outcomes or timeframe of the Prevention Strategic Plan and Evaluation Framework;
- Provide reports to the JDRF Australia staff and Board on progress and achievements, including significant developments, issues or conflicts that may impact national screening decision-making or strategic planning.

This initiative is being funded by the T1DCRN and administered by JDRF Australia. As such, the JDRF Australia Board will be the binding authority for all direction-setting and decision-making regarding the use of funds for this initiative.

4 FUNDING

Funding of up to \$1.3M for a period of 3 years, subject to sufficient funding being available and continued satisfactory progress. This includes:

- Salary: Up to \$600,000 for 3 years inclusive of on-costs (0.6 to 1 FTE and dependent on experience and qualifications);
- Project Costs for Year 1: Up to \$20,000 for travel, supplies and other costs supporting Year
 1 deliverables; and
- Project Costs for Years 2 and 3: Totalling up to \$680,000 for costs such as personnel, travel and supplies, subject to approval of the Prevention Strategic Plan, Budget and Evaluation Framework by the JDRF Board.

JDRF Australia reserves 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 Australia through the T1DCRN are listed on the <u>Australian</u> <u>Competitive Grants Register</u>. As such, indirect costs may be recovered through Research Block Grant (**RBG**) funding and JDRF Australia will <u>not</u> provide funding for indirect costs, including basic facilities and equipment, organisational overheads and/or infrastructure costs.

5 ELIGIBILITY AND ESSENTIAL SELECTION CRITERIA

5.1 ELIGIBILITY CRITERIA

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

- Once appointed, the fellow must be located at an Australian institution (e.g. an Australian university, college, hospital, laboratory, unit of state or local government, or an eligible Commonwealth government agency), and must legally reside predominantly in Australia for the duration of the pilot
- The applicant must have a doctoral degree (PhD, MD or equivalent) in a research discipline relevant to general population screening (e.g. clinical epidemiology, public health research, health policy, biostatistics, health economics)

5.2 FORMATTING REQUIREMENTS

JDRF Australia will only consider complete applications that meet the formatting requirements as specified in Appendix 1 Applicant Statement. An application is considered to be completed if it includes all the documents listed in Section 6.1. Incomplete applications or incorrectly formatted applications will be deemed ineligible and declined without further assessment.

5.3 ESSENTIAL SELECTION CRITERIA

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

5.3.1 Investigator

- Outstanding performance in research and/or translating research into policy and practice, relevant to this Fellowship
- Evidence of leadership and influence relative to opportunity
- Advanced program management expertise throughout the program life cycle from concept to closure
- Capacity to achieve the specified deliverables on time and to budget, including identifying milestones, monitoring progress and determining appropriate actions in advance of delays
- Advanced analytical skills to draw conclusions from the pilot evaluation and to identify potential remaining evidence gaps, as well as identify opportunities for prevention initiatives

- Engagement with multiple stakeholder groups to maximise probability of success of the
 pilot in contributing to evidence, such as effectiveness and benefits of screening, required
 by decision-makers regarding the implementation of a national screening program
- Demonstrated expertise in designing and implementing a population-based study

5.3.2 Feasibility and Research Environment

- Sufficient time and capacity to undertake the proposed activities and deliverables of the Fellowship
- Evidence of necessary facilities and resources to undertake the Fellowship (e.g. infrastructure, office space/equipment/furniture)
- Evidence of additional resources and support available to the Fellow throughout the Fellowship

6 SUBMISSION AND SELECTION PROCESSES

The information in this document is underpinned by the Program Guidelines. Please review the Program Guidelines on the <u>T1DCRN website</u> before preparing the application.

6.1 SUBMISSION INSTRUCTIONS

Applications must be completed and submitted to crn@jdrf.org.au. 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 applications must include the following documents combined into a single PDF document:

- Applicant Statement (see Appendix 1 Applicant Statement)
- Written Evidence (see Appendix 2 Additional Attachments)
- Current Biosketch. The Biosketch template is provided for download on the <u>T1DCRN</u> website.
- Letter of Support from Administering Institution (see Appendix 3 Letter of Support)

6.2 SELECTION PROCESS

JDRF Australia will consider each application to determine if it satisfies the eligibility criteria. JDRF Australia will assign all eligible applications to a selection panel (Recruitment Advisory Committee; RAC) of assessors from a range of organisations. The RAC will assess the application against the essential selection criteria in Section 5.3 and provide written comments supporting their assessment.

Please ensure your application complies with eligibility criteria as outlined in Section 5. Only eligible applications will progress to the next stage of assessment – interview with the RAC. Shortlisted applicants will be provided with the RAC's written assessments prior to interview.

Shortlisted applicants will be advised by JDRF Australia in writing of the proposed dates and times of their interview and of the process and format for the interviews at least one week prior to interview.

Interviews will take place in Sydney. Videoconferencing may be available if required. Applicants are reminded that JDRF Australia will not fund any part of the application process, including participation in interviews.

Following the interviews, the panel will consider the shortlisted applications and form their final recommendations for funding in accordance with the process set out in the <u>Program Guidelines</u>. Please refer to the <u>Program Guidelines</u> for information regarding approval processes.

7 KEY DATES

Applications Open	Monday	May	6	2019
Application Deadline	Wednesday	July	3	2019
Earliest Start Date	September			2019

8 CONTRACTUAL REQUIREMENTS

This funding will be administered by JDRF. The award recipient will be required to sign a JDRF Funding Agreement with JDRF Australia (Agreement). JDRF will endeavour to provide a template of the Agreement to applicants within ten business days of the RFA Release Date or as soon as practicable thereafter. A condition of application to this RFA is provision of certification of the Fellow and their Organisation to have read and agree to abide by the terms of the Agreement ("Written Evidence"; please see Appendix 2 Additional Attachments for further information).

JDRF has no obligation in respect of this RFA or the pilot screening program, including any funding, unless and until JDRF and the successful applicant(s) have signed a formal Agreement.

The template Agreement 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 Fellow; and
- b) an obligation to comply with the Australian Type 1 Diabetes Clinical Research Network (JDRF) Policy on Intellectual Property, Commercialisation and Royalties - Version August 2016 and the Australian Type 1 Diabetes Clinical Research Network (JDRF) Policy on Data and Biosample Sharing - Version August 2016 ("IP Policies"), including in relation to data sharing and biosample sharing and Open Access referred to in section 8.1,

as further detailed in the template Agreement.

JDRF reserves the right to require changes to the template Agreement to address the particular circumstances of an application.

8.1 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/arc-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.

8.2 REPORTING

Progress reports will be required bi-annually, or as outlined in the 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 at any time as required.

9 ABOUT THE T1DCRN

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.

10 PROGRAM CONTACTS

Inquiries concerning this program are encouraged and should be directed to:

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Head of Research Development, JDRF Australia

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Appendix 1 Applicant Statement

Applicant Statement Formatting

- The Applicant Statement 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 (except where otherwise specified) before converting to PDF format and must be legible to assessors. Avoid scanning.
- Paper must be white A4 size with at least 2cm margin on each size and at top and bottom.
- 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 Header.
- The Applicant Statement must be no more than two pages in total.
- The Applicant Statement must be uploaded as an unlocked PDF document without password protection.

Applicant Statement Template

The Applicant Statement should be organised using the suggested section headings provided in the table below. Do not repeat information provided in your Biosketch (see Additional Attachments). The RAC will assess the application against the Essential Selection Criteria in Section 5.3 on the basis of the information set out in the Applicant Statement. Applicants need to ensure that detailed information provided in the Statement appropriately addresses these Essential Selection Criteria. Ensure the significance of your achievements is relevant to general population screening.

Sec	tion Heading	Gu	ide
1.	Applicant Name and Administering Institution		
2.	Research performance	a.	Provide a brief summary of your most significant contributions to research and/or translating research into policy and practice. Pay particular attention to achievements demonstrating research independence and innovation. Include any career interruptions.
		b.	Provide evidence of peer recognition of your achievements.
3.			Outline any achievements demonstrating yourself as a leader and influencer in the field, such as contributions to research training, policy development, clinical/public health leadership and/or services delivery.
		b.	Comment on the trajectory of your research career relevant to general population screening, including a statement of current and future career goals. Include

			evidence that demonstrates your national and international standing.	
4.	Advanced Program Management Expertise and Analytical Skills	a.	Describe a complex program you have led, and how you approached designing, managing, and evaluating this program.	
		b.	Comment on how you delivered a complex program on- time and to budget, including risk management approaches.	
		C.	Describe your advanced analytical skills and how you have applied them in evaluating a complex program, including how you approached the development of key recommendations arising from the evaluation.	
5.	Stakeholder Engagement	a.	Provide details of how you have previously engaged and consulted with diverse stakeholders to support evidence-based decision-making and evaluation.	
		b.	Describe how you would approach identifying and consulting the stakeholders that may be required to maximise probability of success of this initiative.	
6.	Feasibility and Research Environment	a.	You are expected to spend a minimum of 0.6 FTE (60 per cent of Full Time Equivalent) of your time on research activities related to the Fellowship. Discuss how you will balance the Fellowship with any and all other existing and planned professional responsibilities and activities, including honorary or non-remunerated positions.	
		b.	Describe the available resources, facilities and support that will be made available to you by your Administering Institution throughout the Fellowship.	

Appendix 2 Additional Attachments

Additional Attachments are limited to the following documents, no other attachments may be considered:

- Current Biosketch. The Biosketch template is provided for download on the <u>T1DCRN</u> website.
- JDRF Australia is required to obtain written evidence from the Fellow and their organisation. The template for Written Evidence is provided for download on the <u>T1DCRN</u> website.
- A Letter of Support from the administering organisation. This letter must specify commitment of the department to support the applicant and the initiative, including provision of resources and facilities and be signed by a senior representative such as the CEO, Deputy Vice-Chancellor (Research) or equivalent of the organisation. See Appendix 3 Letter of Support for requirements.

Appendix 3 Letter of Support

A Letter of Support **of no more than 2 A4 pages** from the administering organisation must be submitted as part of the application.

Formatting Requirements

- The Letter of Support 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.
- The official letterhead of the organisation must be included.
- The Letter of Support must be uploaded as an unlocked PDF document without password protection.

Content Requirements

The Letter of Support must include the following:

- a brief profile of the organisation and alignment with the initiative;
- commitment to provide detailed resources, facilities and support to the applicant for the duration of the Fellowship; and
- signed by the Chief Executive Officer, Deputy Vice-Chancellor (Research), or delegate.