



## Special Research Initiative for Type 1 Diabetes Program Guidelines



**Australian Government**  
**Australian Research Council**

A Special Research Initiative funded by the ARC

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## 2 EXECUTIVE SUMMARY

Following the 2013 federal election, the Commonwealth government committed an additional \$35 million of funding for further Type 1 Diabetes research to be administered through the Australian Research Council (ARC). This new Special Research Initiative (SRI) funding will be used to extend and expand the Clinical Research Network (CRN), including through a series of competitive and targeted grants to fund clinical research in key priority areas and build research capacity in the field of type 1 diabetes. The initiative will be a national collaborative network led by JDRF supporting research projects, promoting and retaining outstanding scientists and attracting new researchers to the field of type 1 diabetes. The initiative will enable the efficient and effective delivery and adoption of clinical research, and will build long-term clinical research capacity in Australia. The initiative's core function will be to deliver progress towards finding a cure for type 1 diabetes by focussing on the at-risk population, new onset patients and individuals with established type 1 diabetes.

Projects in this initiative will have a long-lasting impact on Australia's capacity to support and drive clinical research, beyond the lifetime of the ARC Special Research Initiative funding. The *SRI for Type 1 Diabetes* has an important role in adding to the mentoring and training of the next generation of clinical researchers in type 1 diabetes who can in turn grow to become independent investigators and future leaders. The initiative will also bring together a diverse range of other stakeholders important to clinical research progress, as well as actively partnering with international networks and clinical groups to better leverage their investments in clinical research and to promote and make globally visible the activities of the *SRI for Type 1 Diabetes*.

This document provides guidelines in relation to JDRF's *SRI for Type 1 Diabetes* program implementation and processes:

1. Research Priority Areas
2. Operating Principles
3. Initiative Goal
4. Competitive Schemes
  - a. Eligibility, Selection and Exclusion Criteria
5. Career Development Schemes
  - a. Eligibility, Selection and Exclusion Criteria
6. Targeted Schemes
  - a. Priorities and Specific Criteria
7. Terms of Reference for the Competitive Selection Panel
8. Approval Processes

These processes may be internally reviewed and amended throughout the program. Review and amendments will be documented and advised to applicants where it is appropriate to do so.

## 3 RESEARCH PRIORITY AREAS

The Research Priority Areas have been identified as current areas of need and may be updated from time to time. Applicants should note that the research priority areas will change over time to reflect developments in the field of type 1 diabetes and that this may potentially result in an application becoming overall less competitive when it occurs during an RFA process.

Current Research Priority Areas have been developed with regard to areas of research strength in Australia that can best contribute to the understanding of, and current knowledge gaps in, type 1 diabetes identified with the guidance of JDRF's global connections and may be subject to re-evaluation throughout the initiative:

### 3.1 AT-RISK POPULATIONS

- Studies that help with better characterization of heterogeneity of risk of type 1 diabetes
- Studies that help with understanding the factors that affect the rate of progression including identification and validation of biomarkers
- Exploratory clinical research studies (including mechanistic) focused on arresting progression, including combinations of therapeutic agents and repositioning of agents from other diseases

### 3.2 NEW ONSET POPULATION

- Better prediction of rate of progression, identification and validation of biomarkers
- Exploratory mechanistic clinical research studies focused on measures that indicate markers of disease progression
- New onset trials to arrest progression and preserve residual beta cell function including single or combination therapies

### 3.3 INDIVIDUALS WITH ESTABLISHED TYPE 1 DIABETES

- Improving metabolic control with devices
- Improving metabolic control with drugs (repurposed and new)
- Characterisation of clinical heterogeneity to enable trial participant stratification and characterise basis of preservation of residual beta cell function
- Clinical studies to compare effectiveness of two or more therapeutic agents
- Approaches to prevention of hypoglycaemia
- Improving residual beta cell function and/or *de novo* regeneration of beta cells
- Targeted strategic clinical trials for diabetic eye or kidney disease for early intervention to prevent progression of disease stage

- Prevention of complications and interventions to reduce complications
- Studies measuring impact of type 1 diabetes on neurologic and cognitive function
- Discovery and validation of clinical biomarkers of nephropathy or retinopathy for disease staging and therapeutic response to facilitate shorter clinical trials
- Clinical mechanistic studies testing agents for tolerance induction
- Clinical studies testing encapsulation modalities and cell therapy to replace beta cell function
- Approaches to continuous care throughout the life cycle e.g. transition care, pre-conception and perinatal care, aged care

## 4 OPERATING PRINCIPLES

The initiative is founded on the following operating principles, which underpin the delivery of the program objectives. They are:

### 4.1 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.

### 4.2 COLLABORATIVE

A collaborative approach will be required of 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.

### 4.3 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.

### 4.4 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.

### 4.5 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.

## 5 INITIATIVE GOAL

The goal of the Type 1 Diabetes Clinical Research Network, the *SRI for Type 1 Diabetes* funded by the ARC, is:

**To positively impact the life of people with type 1 diabetes in Australia through the support and promotion of clinical research.**

## 6 COMPETITIVE GRANT SCHEMES

The majority of the *SRI for Type 1 Diabetes* budget will be directed towards funding type 1 diabetes competitive grants. Competitive grants will include support for research programs and projects as well as support for career awards. As part of JDRF's commitment to support researchers at different stages of their careers, build Australia's research capability, expand and enhance collaborations, and develop Clinical Centres of excellence, the competitive grants program comprises two main schemes:

- **Research Project Grants:** building Research Excellence through the impact of the highest-quality clinical research in Australia, leading to the discovery of new ideas and the advancement of knowledge in preventing, treating and curing type 1 diabetes
- **Career Support Grants:** building Australia's Research Capacity through support for the training and skills development of the next generation of Early-to-Mid-Career researchers, and attracting outstanding researchers new to the field of type 1 diabetes.

### 6.1 PRIORITIES FOR COMPETITIVE GRANT SCHEMES

The priorities for Competitive Grant Schemes are outlined in Table 6-1.

**Table 6-1 Scheme-Specific Priorities for Competitive Grants**

<b>Research Project Grants – Research Excellence</b>	
<b>Scheme</b>	<b>Priorities</b>
Research Grants	Funding the most promising high impact clinical studies to cure, treat or prevent T1D <ul style="list-style-type: none"> <li>▪ Hypothesis-driven/researcher-initiated clinical programs</li> <li>▪ Australian participation in existing multinational trials</li> </ul>
	Drive clinical innovation, discovery and adoption <ul style="list-style-type: none"> <li>▪ Enhance the scale and focus of research</li> </ul>
	Fund emerging novel areas of clinical research
Pilot and Feasibility/Innovative Grants	Expand Australia's knowledge base and research capability <ul style="list-style-type: none"> <li>▪ Support Proof of Concept and exploratory projects as catalysts for further clinical research studies</li> </ul>
<b>Career Support Grants – Research Capacity</b>	
<b>Scheme</b>	<b>Priorities</b>
Mentored Clinical Researcher	Enable research and research training in high quality and supportive environments
Clinical Career Development	Support the most promising emerging researchers
	Protect and retain outstanding scientists through their career transitions e.g. to return to Australia, cover during parental leave
	Protect and retain outstanding scientists on their career trajectory
	Attract new outstanding researchers to the field of T1D research

## 6.2 COMPETITIVE SELECTION PROCESS

Details of the proposed competitive selection process for competitive grants are given in Table 6-2. Timelines are provided as a guide only. Records of the assessment and decision-making processes for each competitive scheme will be maintained and will be open to scrutiny by the probity adviser, if required.

**Table 6-2 Proposed Competitive Selection Process. Timelines are indicative only and may be subject to change.**

<b>Timeline</b>	<b>Process</b>	<b>Stage</b>	<b>Who</b>
Week 0	RFA	1. Prepare <i>Request for Applications</i> (RFA)	JDRF
		2. Public release of approved RFA	JDRF
<b>Letter of Intent (LOI): For large grants only.</b> For smaller grant programs or Career Awards, LOIs will not be applicable. Applicants respond to the RFA with a full application.			
Week 10	Submission	3. a. Initial Submission: Letters of Intent (LOI) submitted through RMS360	APPLICANT

		b. LOIs certified in RMS360	Administering Organisation
Week 11	<b>Competitive selection</b>	c. LOIs assessed for eligibility and compliance. Briefs for the Competitive Selection Panel may be prepared where required on international relevance, alignment, and potential for duplication. Briefs will include Australian context for international members	JDRF
Week 12		d. LOIs merit ranked against the selection criteria as outlined in the RFA including alignment with research priorities and goals	Competitive Selection Panel
Week 20		e. Successful applicants invited for Final Submission: full application	JDRF
<b>Full Application</b>			
Week 31	<b>Submission</b>	4. Full application submitted through RMS360	APPLICANT
		5. Full applications certified in RMS360	Administering Organisation
Week 32	<b>Competitive Selection</b>	6. Full application assessed for eligibility and compliance. Proposals not meeting the eligibility criteria or providing incomplete, inaccurate or misleading information will be excluded	JDRF
		7. Briefs for the Competitive Selection Panel (CSP) may be prepared where required on international relevance, alignment, and potential for duplication. Briefs will include Australian context for international members	JDRF
Week 33		8. Full application is assessed, scored and ranked against selection criteria including alignment with research priorities, goals and budget. This may include an interview process with shortlisted applicants for some RFAs.	Competitive Selection Panel
		9. De-identified feedback from panel is provided to applicants	JDRF
Week 40		10. Recommendations are submitted to the JDRF Board CRN Subcommittee for consideration	JDRF
	<b>Approval</b>	11. The Board CRN Subcommittee approves grants for funding and high level budget for the project.	JDRF Board CRN Subcommittee
Week 48	<b>Notification</b>	12. JDRF notify ARC of the funding allocations	JDRF
		13. Funding announcement is made	JDRF
Week 52-70	<b>Activation</b>	14. a. Projects undergo budget calibration with Principal Investigators (PIs).	JDRF

		b. Funding Contract negotiation including timing of milestones and payments	JDRF with Institution
		c. JDRF and Institution sign Funding Contract and other essential documentation as required	JDRF with Institution
		d. Activate Award	JDRF

### 6.3 ELIGIBILITY CRITERION – INITIATIVE GOAL

The Initiative Goal (Section 5) will be included as an eligibility criterion in each *Request for Applications* (RFA).

All applications for funding received in response to **competitive grant schemes and targeted grant schemes** i.e. all schemes providing funding for research and/or for researchers 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**

### 6.4 SELECTION CRITERIA FOR ALL COMPETITIVE GRANT SCHEMES

Selection criteria will be used to rank and assess applications and will be included in each *Request for Applications* (RFA).

Selection criteria for **all competitive grant schemes** providing funding for research and/or for researchers within the *Special Research Initiative for the Type 1 Diabetes Clinical Research Network* will include:

1. A criterion relating to quality and innovativeness of research. This will include consideration of the extent to which the application aligns with the Research Priority Areas (Section 3) or is otherwise innovative and addresses a need within the T1D clinical research field.
2. Alignment with the operating principles (Section 4) as a selection criterion.

### 6.5 SCHEME-SPECIFIC SELECTION CRITERIA

*In addition* to Research Priority Areas (Section 3) and Operating Principles (Section 4), **competitive grant schemes** will have additional scheme-specific selection criteria. Selection criteria will be selected and weighted by JDRF to ensure the applications received are aligned with the priorities of each scheme (priorities are listed in Table 6-1). Each *Request for Applications* (RFA, and application templates where applicable) will contain all weighted selection criteria that will be considered during assessment and merit ranking processes.

#### 6.5.1 Selection Criteria - Clinical Centres and Concept Proposals (as specified in RFA released August 18, 2014, with weightings and descriptions)

##### Clinical Centres

##### 6.5.1.1 Type 1 Diabetes Research Programs – quality and innovation

Prior experience and current ability of the Clinical Centre in performing research studies in type 1 diabetes.

- i. Trial participant recruitment and retention
- ii. Experience in type 1 diabetes clinical research

#### 6.5.1.2 Investigators

- i. Investigators and key personnel
- ii. Institution and environment

#### 6.5.1.3 Outcomes and Linkages

- i. Management of collaborating sites (if applicable)
- ii. Collaborations with type 1 diabetes clinical trial networks

### **Concept Proposals**

#### 6.5.1.4 Type 1 Diabetes Research Program – quality and innovation and alignment with research priority areas

- i. Statement of need
- ii. Concept rationale, objectives and design

#### 6.5.1.5 Urgency and ability to lift burden of type 1 diabetes

- i. Anticipated outcome(s)
- ii. Translational potential of research

#### 6.5.1.6 Feasibility of implementation and alignment with aims of the CRN

- i. Requirements for successful delivery
- ii. Budget and duration estimates
- iii. Alignment with aims of the T1DCRN
  - Efficient use of resources
  - Cohesive, connected, collaborative

### **6.5.2 Selection Criteria – Competitive Research Project Grants**

JDRF may release further **RFAs** for Competitive Research Project Grants (such as Innovative Grants, Pilot and Feasibility etc) in the future. These RFAs may have additional selection criteria consistent with goals of each RFA. Each RFA (and application templates where applicable) will contain all weighted selection criteria that will be considered during assessment and merit ranking processes. **Core** selection criteria are as follows, with potential for additional selection criteria to be selected and weighted.

#### 6.5.2.1 Investigator(s)

- i. Research opportunity and performance evidence (ROPE); and
- ii. Time and capacity to undertake the proposed research.

#### 6.5.2.2 Program Quality and Innovation (Research)

- i. Type 1 Diabetes Research Program – quality and innovation
- ii. Is the conceptual/theoretical framework genuinely innovative and original?
- iii. Will the aims, concepts, methods and results advance knowledge and provide outcomes?

#### 6.5.2.3 Feasibility and Benefit

- i. Is the design of the Project and the expertise of the participants sufficient to ensure the Project can be completed within the proposed budget and timeframe?
- ii. Is there an existing, or developing, supportive and high quality research environment for this Project?
- iii. Are the necessary facilities available to complete the Project?
- iv. Are there adequate strategies to encourage dissemination, commercialisation, if appropriate, and promotion of research outcomes?
- v. In circumstances where this application is a request for renewal of funding, has the progress of the Project been satisfactory?
- vi. Will the Project be value for money?

## 6.6 EXCLUSION CRITERION

If JDRF or the Competitive Selection Panel deems a proposal to:

- i. be duplicative; or
- ii. overlap significantly

with a current or planned Project (in Australia and/or overseas) the proposal will be excluded from funding. This exclusion criterion will be included in each RFA.

## 7 CAREER DEVELOPMENT SCHEMES

The *SRI for Type 1 Diabetes* will support projects that have a long-lasting impact on Australia's capacity to support and drive clinical research, including after the non-renewing ARC funding is completed. The initiative will coordinate interdisciplinary teams of outstanding Australian researchers to successfully address clinical type 1 diabetes research priorities.

The initiative has an important role in adding to the mentoring and training of the next generation of researchers in type 1 diabetes to become independent investigators and future leaders. As referred to in earlier documentation from JDRF as "Research Excellence", **Research Capacity** will be cultivated through salary and project support to outstanding early and mid-career researchers, providing increased training and career development for early and mid-career researchers and mentoring opportunities for physician scientists.

### 7.1 ELIGIBILITY CRITERION – INITIATIVE GOAL

The Initiative Goal (Section 5) will be included as an eligibility criterion in each *Request for Applications* (RFA).

All applications for funding received in response to **competitive research schemes and targeted research schemes** i.e. all schemes providing funding for research and/or for researchers 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**

### 7.2 SELECTION CRITERIA FOR ALL CAREER DEVELOPMENT SCHEMES

Selection criteria will be used to rank and assess applications. Each *Request for Applications* (RFA), and application templates where applicable, will contain all weighted selection criteria that will be considered during assessment and merit ranking processes.

Selection criteria for **all competitive grant schemes** providing funding for research and/or for researchers within the *Special Research Initiative for the Type 1 Diabetes* Clinical Research Network will include:

3. A criterion relating to quality and innovativeness of research. This will include consideration of the extent to which the application aligns with the Research Priority Areas (Section 3) or is otherwise innovative and addresses a need within the T1D clinical research field.
4. Alignment with the operating principles (Section 4) as a selection criterion.

### 7.3 SELECTION CRITERIA – CAREER SUPPORT GRANTS

*In addition* to Research Priority Areas (Section 3) and Operating Principles (Section 4), **career development schemes** will have additional scheme-specific selection criteria consistent with goals of each RFA. These will be included in each *Request for Applications* (RFA) and considered during assessment and merit ranking processes.

Each RFA (and application templates where applicable) will contain all weighted selection criteria that will be considered during assessment and merit ranking processes. **Core** selection criteria are as follows, with potential for additional selection criteria to be selected and weighted.

### **7.3.1 Investigator**

- i. Research opportunity and performance evidence (ROPE); and
- ii. Time and capacity to undertake the proposed research.

### **7.3.2 Project Quality and Innovation (Research)**

- i. What is the potential for the research to contribute to the Research Priorities or emerging areas?
- ii. Will the aims, concepts, methods and results advance knowledge?

### **7.3.3 Research Environment**

- i. Is there a supportive and collaborative research environment for the Project?
- ii. Will the Project provide the EMCR with the capacity and opportunity to develop an independent record of innovative, high quality research?
- iii. Are the necessary facilities available to complete the Project?
- iv. What resources will be provided to support the EMCR during her/his fellowship and after the end of the Grant?
- v. Are there adequate strategies to encourage dissemination, commercialisation, if appropriate, and promotion of research outcomes?

### **7.3.4 Feasibility and Benefit**

- i. Are the design of the project and the expertise of the participants sufficient to ensure the Project can be completed with the proposed budget and timeframe?
- ii. Will the completed project produce innovative benefit to the Australian and international community?
- iii. Will the Project be cost-effective and value for money?
- iv. In circumstances where this application is a request for renewal of funding, has the progress of the Project been satisfactory?

## **7.4 EXCLUSION CRITERION**

If JDRF or the Competitive Selection Panel deems a proposal to:

- iii. be duplicative; or
- iv. overlap significantly

with a current or planned Project (in Australia and/or overseas) the proposal will be excluded from funding. This exclusion criterion will be included in each RFA.

## 8 TERMS OF REFERENCE FOR COMPETITIVE SELECTION PANEL

### 8.1 TITLE

The JDRF Special Research Initiative Competitive Selection Panel (CSP)

### 8.2 PURPOSE AND SCOPE

The role of the CSP is to assist JDRF in providing independent and expert assessment of the scientific merit and feasibility of the applications submitted for funding via the competitive selection process. The CSP will assess applications against provided priorities and selection criteria. Briefs for the Competitive Selection Panel may be prepared by JDRF staff where required on international relevance, alignment, and potential for duplication. Briefs will include Australian context for international members.

### 8.3 REPORTING RELATIONSHIP

Final recommendations of the Competitive Selection Panel are submitted to the JDRF Board CRN Subcommittee for approval.

### 8.4 MEMBERSHIP

A CSP will be formed for the purpose of assessment of applications submitted to each competitive *Request for Applications* (RFA). A CSP will be convened for each competitive RFA with membership and Terms of Reference adapted to reflect the objectives of that particular RFA. Size and quorum of each CSP will be proportionate to the complexity of the granting activity. It is desirable that the majority of Panel members are retained throughout the RFA process. In some instances, further specialist expertise may be required as identified by CSP members or by JDRF to ensure application assessment is performed by the most appropriately qualified experts.

Membership will consist of recognised leaders in type 1 diabetes with proven expertise in successful implementation of clinical research, and/or as needed to provide in-depth assessment of grants as determined by objectives of the RFA. Members will be required to read and agree to comply with JDRF Conflict of Interest and Confidentiality Policies prior to receiving any proposals. The panel will be appointed by JDRF based on “best fit” according to each RFA with consideration of recommendations from ARC; the research interests of the panel will span the broad field/s of the research projects they are asked to assess, or they will be experts in the specific field of a proposed research project.

Membership of each CSP will be assembled with consideration of the following composition principles:

- broad expertise in their relevant fields with international standing;
- international representation;
- gender balance;
- specific disciplinary knowledge; and

- a high level of experience in managing selection processes in the clinical research sector.

#### **8.5 THE PROPOSED PROCESS FOR COMPETITIVE SELECTION IS AS FOLLOWS:**

- i. The RFA closes;
- ii. Review of applications by JDRF to determine breadth of professional knowledge and expertise required for CSP);
- iii. Selection of potential assessors giving consideration to above requirements;
- iv. Assessors invited to become CSP members by JDRF;
- v. CSP Members agree to the Confidentiality Statement managed through online grant management platform;
- vi. For complex RFAs, an initial teleconference may be coordinated to brief the CSP Members on the process;
- vii. Applications allocated to CSP Members through grant management platform;
- viii. CSP Members declare Conflicts of Interest against applications through grant management platform;
- ix. Allocated applications are released to CSP Members through grant management platform that have declared no conflicts of interest or have declared low or medium-level conflicts of interest that have been appropriately managed and documented by JDRF;
- x. CSP Members evaluate applications against selection criteria and provide scoring, managed through online grant management platform; and
- xi. Face-to-Face meeting of CSP may be coordinated for more complex grants, or to clarify scoring and feedback of applications if required.

## 9 TARGETED RESEARCH SCHEMES

Separate to the competitive grants scheme, JDRF can issue funding via **targeted** partnerships and grants, designed to achieve the aim of building national capacity to leverage existing international and domestic expertise and resources in type 1 diabetes and clinical research and specifically address urgent gaps in research priorities.

The objective of targeted schemes is to support superior-quality research which will assist in building Australia's research excellence, extending its global competitiveness via strategic partnerships and deliver benefits to type 1 diabetes communities. This extends, but is not limited, to supporting research-related activities in strategically important areas and/or in response to emerging opportunities or changing priorities.

Specifically, targeted scheme funding supports excellent collaborative research activities that would be unlikely otherwise to occur, including:

- i. establishment of partnerships to leverage investments in funds and/or expertise;
- ii. development of national and international linkages, enhancing research collaboration and connectivity;
- iii. development and/or extension of innovative research or infrastructure that will deliver national benefit(s);
- iv. activities aimed at building the scale and focus of excellent research and research training; and
- v. other activities that JDRF judges to be consistent with the scheme's objectives.

### 9.1 PROCESS FOR IDENTIFYING AND PRIORITISING INITIATIVES

JDRF, takes a proactive role in identifying specific initiatives to be supported in targeted schemes. Initiatives must fill gaps in clinical knowledge or care, respond to an emerging research priority, or leverage existing opportunities to further progress innovative research. Initiatives may be identified and prioritised by JDRF in consultation with institutions, professional organisations and/or peak bodies representing type 1 diabetes communities. Initiatives may result from strategic reviews, from internal reviews of competitive scheme outcomes or from other reviews or reports of a similar nature.

Initiatives are expected to fall into the following two categories:

- **Targeted Contract Research Grants:** support for excellent research studies
- **Targeted Infrastructure Grants:** support for the development of infrastructure that builds long-term research capacity in Australia and raises the international value of the CRN

Applicants for each targeted initiative are eligible only when invited by JDRF. JDRF may invite applicants from one or more organisations (which may involve researchers, consultants or facilitators). Potential applicants will be identified by JDRF in consultation with institutions, professional organisations and/or peak bodies representing type 1 diabetes communities. The

identification of potential applicants may also result from CRN strategic reviews, from internal reviews of competitive scheme outcomes or from other reviews or reports of a similar nature.

## **9.2 ELIGIBLE APPLICANTS**

The process of selecting eligible applicant(s) to deliver a project will include internal documented assessment by the JDRF assessment team against the following selection criteria:

- i. The degree to which the project aligns with one or more of the Research Priority Areas (Section 4),
- ii. The degree to which the project and potential applicant(s) align with the Initiative Goal (Section 5),
- iii. The degree to which the potential applicant(s) and proposed delivery mechanism align with the Operating Principles (Section 4),
- iv. The degree to which the potential applicant(s), project and or proposed delivery mechanism align with any initiative-specific priorities as determined and documented by JDRF (including but not limited to Sections 9.3.1 and 9.3.2), and
- v. Value for money

## **9.3 PRIORITIES AND SPECIFIC CRITERIA FOR TARGETED RESEARCH SCHEMES**

Targeted research and infrastructure schemes will have additional scheme-specific criteria consistent with the goals of each initiative as described in 9.3.1 and 9.3.2.

Assessment for funding is undertaken by JDRF, which has the right to make recommendations for funding to the Board based on any number of assessments. JDRF will initially assess against the criteria and may recommend that an invited applicant that does not meet the requirements be deemed ineligible. This recommendation may occur at any stage during assessment and may result in non-progression through the assessment process.

Where peer review has been facilitated by an external national or international funding organisation, the protocol and peer review outcomes will be evaluated by JDRF to determine whether the assessment was satisfactory and further assessment would be required.

Where sufficient internal expertise is not available, or when additional assessment is required, JDRF will appoint external assessors to assess and report, and potentially provide written comments, against the assessment criteria. JDRF has policies and procedures in place for managing organisational and personal Conflicts of Interest for Board members, assessors and JDRF staff. These and their implementation will also be overseen and reviewed, as necessary and appropriate, by the probity adviser. The applicant may be given the opportunity for a rejoinder to assessors' written comments, and to provide any additional information requested by JDRF. Names of assessors will not be provided to the applicant. Please see Figure 9-1 for flow process.

### **9.3.1 Assessment Criteria - Infrastructure**

Two Targeted Infrastructure Grants are currently planned:

- i. Database; and
- ii. Biobank.

#### 9.3.1.1 Database Assessment Criteria

- Feasibility of expansion of current paediatric database to include adoption by additional centres
- Quality of plan for connection of the paediatric clinical database with adult databases
- Promotion and support for studies that utilise the collected datasets to test specific research hypotheses
- Value for money

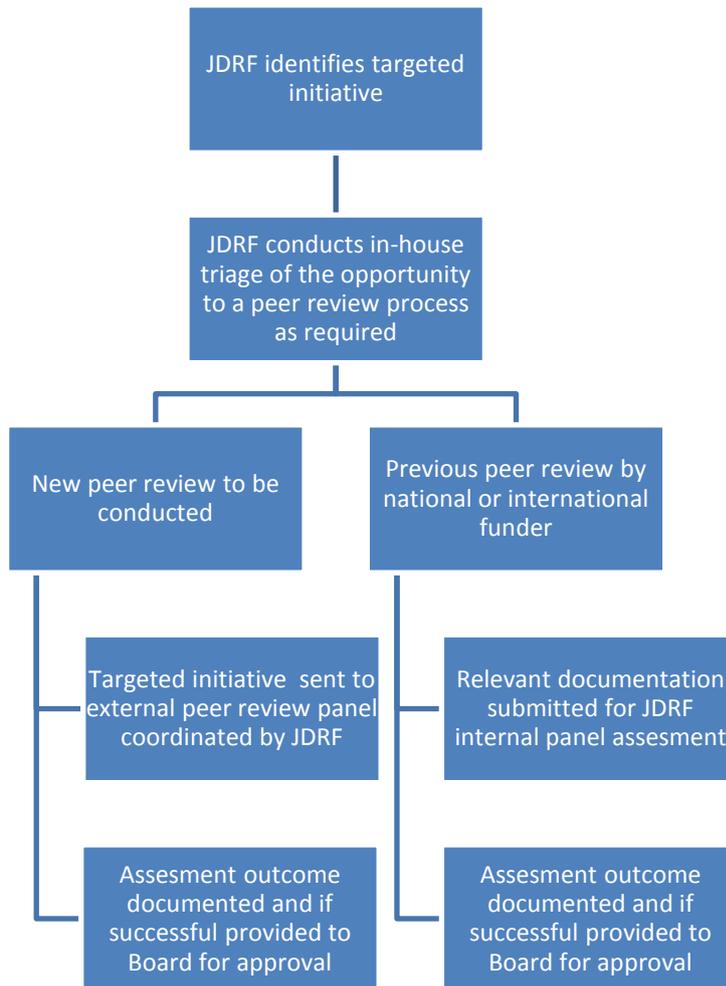
#### 9.3.1.2 Biobank Assessment Criteria

- Level of improvement of linkages between existing sample collections
- Ability to support collection of samples linked to the Type 1 Diabetes Clinical Database
- Ability to support trial-specific collection of additional tissue and samples
- Value for money

#### **9.3.2 Assessment Criteria - Contract Research**

Assessment criteria for funding under contract research initiatives may include but are not limited to any of the following:

- Scientific quality and feasibility of the project, including past performance of the project where applicable
- Significance and/or innovation of the project and expected outcomes
- Track record and capacity of the team to undertake the research and deliver outcomes
- Collaborative gain and/or research connectivity on a national or international scale
- Long-term sustainability
- Overall value for money



**Figure 9-1 Flow process for assessment of targeted initiatives**

## 10 APPROVAL PROCESSES

### 10.1 BUDGET RECALIBRATION

JDRF staff will use in-house expertise and past experience of managing funded trials to evaluate the budget estimates in relevance to the project proposal. In the rare event that budget is more than requested, thorough documentation will be kept.

### 10.2 APPROVAL MECHANISM

As described in Table 6-2, funding recommendations are submitted to the JDRF Board for approval. The Board will be required to declare any and all Conflict(s) of Interest and maintain the confidentiality of information and material as part of this process.

### 10.3 FEEDBACK

The provision of feedback to unsuccessful applicants at the time of outcome notification will be in compliance with the *Commonwealth Grants Rules and Guidelines* and the *Grants Administration Better Practice Guide* of the Australian National Audit Office (ANAO). Feedback will vary from scheme to scheme in line with the proportionality principle e.g. it is not practical for JDRF to provide feedback to each unsuccessful applicant in the context of a scheme that received a high number of applications for low-value grants. The most efficient and effective method will depend on the nature of the granting activity and the resources available to deliver feedback.

Where written feedback for each unsuccessful applicant is considered practical, the type of feedback to be provided will be outlined in each RFA, will be provided to unsuccessful applicants at notification of grant outcome, and may include:

- For ineligible proposals - reason(s) the proposal was deemed to be ineligible
- For eligible yet unsuccessful proposals - reason(s) the proposal was considered uncompetitive including criteria the application performed poorly against

If written feedback is considered impractical, a feedback session for interested parties may be provided by JDRF and details of such a session would likely be provided at notification of grant outcome.

### 10.4 APPEALS PROCESS

In compliance with the *Commonwealth Grants Rules and Guidelines* of the Australian Government, the various competitive funding schemes dispersing funds from the ARC's Special Research Initiative awarded to JDRF make provision for an appeals process, whereby appeals will be considered against administrative process issues. The appeals process is designed to ensure that the applicant has been treated fairly and consistently in the context of the selection procedures.

JDRF will only consider appeals against administrative process issues and not against committee decisions, assessor ratings and comments or the assessment outcome.

The draft Appeals form is attached (Appendix A). The form must be lodged through the relevant Administering Organisation's research office and authorised by a Deputy Vice-Chancellor (Research),

Chief Executive Officer or equivalent. Appeals must be received within 28 days of date of the JDRF notification to the Administering Organisation of application outcomes.

## 11 ANTICIPATED FUNDING BREAKDOWN

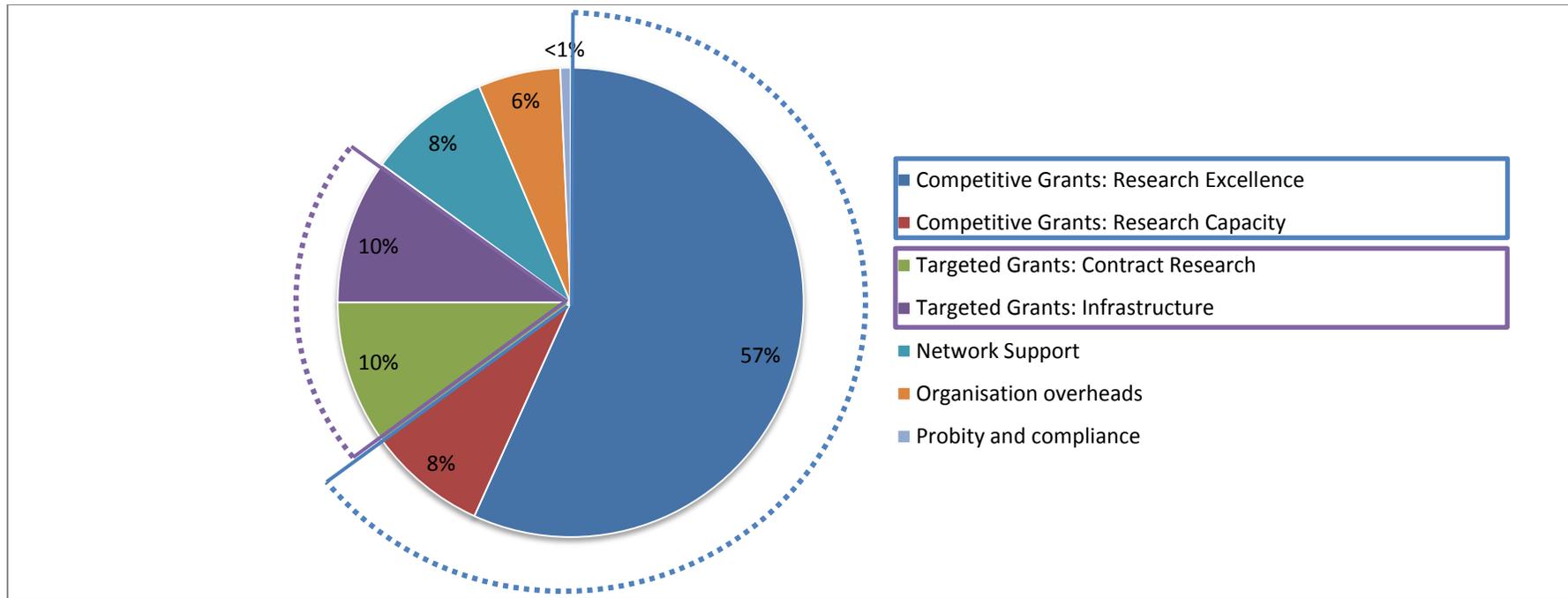
The anticipated funding distribution of funds from the ARC Special Research Initiative awarded to JDRF is given in Figure 11-1. The majority of investment will go directly into competitively selected research. Percentages are dependent on quality of applications received in response to *Request for Applications*. Should amounts not be reached within each funding scheme they will be reallocated.

*Competitive grants:* These will be of varying value, duration, scientific focus, and intention. They will include grants directly supporting clinical research and grants designed to build clinical research capacity. The exact breakdown of size, value, and duration of grants and balance between areas within competitive grants depends on nature and quality of applications received in response to RFAs/approaches for grants, matched against available budget and ongoing commitment tracking.

*Targeted grants:* Further funding will be allocated to investing in infrastructure and contract grant research with potential to leverage further investment into the CRN from national or international partners.

*Network support:* These are costs associated with network operations and network development such as meetings, symposia, clinical trials oversight, support with trials implementation, community involvement and sectorial leadership.

*Organisation overheads, and probity and compliance:* The initiative has been designed to minimise the administrative load overall, these cost are associated with grants administration, grant-making processes for development, implementation, media and promotions and progress review.



**Figure 11-1 Anticipated Funding Breakdown**

Appeals [crn@jdrf.org.au](mailto:crn@jdrf.org.au)  
The Australian Type 1 Diabetes Clinical Research Network  
c/o JDRF  
PO Box 183  
St Leonards NSW 1590

**JDRF Australian Type 1 Diabetes Clinical Research Network**

A Special Research Initiative Funded by the ARC

**APPEAL FORM**

**Scheme:** .....

**Project ID No.:** .....

**Proposal Title:** .....

**Appellant Organisation:** .....

**Investigator(s):** .....

**Grounds for Appeal:** Pursuant to the "Request for Applications" for the relevant funding round, appeals will be considered only against administrative process issues and not, for example, against committee recommendations or assessor ratings and comments.

**Details of Appeal:** Appellants should provide all the information necessary to enable the appeal to be considered without the need for further written or oral explanation or reference to additional material.

**Signature of Deputy Vice-Chancellor (Research) or equivalent:**

**Date:**

**Name and Position (please print):**