Australian Type 1 Diabetes Clinical Research Network (JDRF) Policy on Intellectual Property, Commercialisation and Royalties.

1 APPLICATION OF POLICY

This Policy on Intellectual Property, Commercialisation and Royalties is made for the purpose of, and supplements, the Clinical Trial Research Agreement between JDRF and the Institution ("Clinical Trial Research Agreement"). Capitalised terms not otherwise defined in this Policy have the same meaning as in the Clinical Trial Research Agreement.

The Institution is required to comply with this Policy and the:

I. National Principles of Intellectual Property Management for Publicly Funded Research;

II. Australian Code for the Responsible Conduct of Research;

III. National Statement on Ethical Conduct in Human Research; and

IV. Australian Research Council (ARC) Open Access Policy,

as amended from time to time, and other relevant Australian codes of conduct and standards for responsible research practices.

2 POLICY ON DATA AND BIOSAMPLE SHARING

JDRF's Policy on Data and Biosample Sharing forms part of this Policy.

3 PURPOSE

The Australian Type 1 Diabetes Clinical Research Network ("Network") was established by JDRF with funding from the Australian Government to better bridge the gap between basic research and full scale clinical product development in Australia for type 1 diabetes therapies and technologies.

It is the purpose of the policy to maximise public benefit, whether generally or specifically directed towards Australia, from Studies receiving funds as part of the Network with the intention of accelerating the translation of research results, amplifying the effort and funding outcomes.

4 INTELLECTUAL PROPERTY POLICIES AND SYSTEMS

The Institution is required have policies and systems in place on Intellectual Property which enable it to comply with the following in respect of Intellectual Property in Study Materials ("Study IP"):

i. recording, managing and reporting on the Study IP held by Institution;

ii. implementing licensing and accessibility arrangements for Study IP which allow its most valuable use, such as:

    a. making it openly accessible to allow for its use and re-use, including potentially for commercial exploitation; or

    b. providing exclusive opportunities to undertake commercial exploitation;

iii. providing assistance to Personnel involved in the Study to identify Study IP that may be protected or commercialised, or to assess any existing third party Intellectual Property which is likely to affect the Study;

iv. making clear to Personnel involved in the Study their responsibilities in relation to management of Study IP including, where appropriate, the maintenance of research records (including e-lab books and field notebooks) and the handling of research results prior to promoting or disseminating the Study IP or obtaining protection for the Study IP;

v. having agreements with Personnel involved in the Study on ownership of Intellectual Property in Study Materials which are consistent with this Policy and the Clinical Trial Research Agreement;

vi. the requirements regarding collection and storage of data set out in JDRF's Policy on Data and Biosample Sharing;

vii. providing incentives to Personnel involved in the Study to foster compliance with this Policy and the Clinical Trial Research Agreement in relation to Study IP;

viii. providing guidance on potential conflicts between protection and commercialisation of Study IP and dissemination of Study IP required by JDRF's Data and Biosample Sharing Policy

ix. providing guidance on licensing of copyright included in Study IP, including in particular the criteria for publishing under the terms of open access licences;

x. if relevant, taking into account the different circumstances for ownership of IP by students who are involved in the Study in the course of their study, research or training, and if any student involvement in the Study would affect the Institution's ability to comply with the its obligations under this Policy or the Clinical Trial Research Agreement, the Institution must obtain JDRF's consent for that student's involvement; and

xi. If relevant, addressing cases where Study IP impinges, or potentially impinges on the cultural or spiritual or other aspects of indigenous peoples.

5 INVENTION DISCLOSURES

Institution shall disclose within 60 days to JDRF all potentially patentable inventions that are conceived or first reduced to practice by Institution or any of the Investigators during the course of carrying out any research using funding provided directly or indirectly, in whole or in part, by JDRF (each an "Invention"). Institution shall make such disclosure using JDRF's standard Invention

Disclosure Form (Appendix A). In each disclosure, Institution shall advise JDRF whether it intends to seek patent protection for the disclosed Invention.

6 PATENTS

As between JDRF and Institution, Institution will have the first right to pursue patent protection for Inventions. If JDRF reasonably determines that Institution is not diligently pursuing patent protection for any Invention, or in the event that Institution chooses not to pursue patent protection for any Invention, or abandons or intends to abandon a patent application or an issued patent claiming any Invention, then at JDRF's request Institution shall assign all patent and other rights in such Invention to JDRF. In such event, Institution shall cooperate with JDRF (at JDRF's expense) and shall execute or cause to be executed such documents and take or cause to be taken such other actions as reasonably may be requested by JDRF in order to effectuate such assignment in a timely manner. After the effective date of the assignment of any such patent to JDRF, as between Institution and JDRF, JDRF shall be solely responsible for all costs associated with filing, prosecuting and maintaining such patent. In the event that JDRF commercialises a product the making, use, sale or import of which would infringe any valid claim of any such patent had it not been assigned to JDRF, JDRF shall negotiate in good faith with Institution a reasonable royalty rate that will be payable to Institution based on sales of such product.

Institution shall notify JDRF of its intention to abandon any patent application claiming an Invention or any issued patent claiming an Invention at least ninety (90) days in advance of any deadline that would cause such application or patent to be abandoned or otherwise lapse, and of its intention not to pursue patent protection for any Invention at least ninety (90) days in advance of any statutory bar that would prevent JDRF from obtaining patent protection for such Invention.

7 COMMERCIALISATION

Upon the issuance of any patent claiming an Invention, or at such earlier time as may be commercially reasonable, Institution shall take appropriate steps to commercialise such Invention in a timely fashion, either itself or through one or more licensees, in the field of diagnosing, treating, curing and/or preventing diabetes and its complications. Institution shall ensure that all licenses of commercial rights in or to any Invention require the licensee to diligently pursue commercialisation of such Invention and specify objective milestones and benchmarks so that the licensee's progress toward commercialisation can be assessed and monitored. If JDRF determines in good faith that Institution has not itself or through one or more licensees diligently pursued commercialisation of any Invention in the field of diagnosing, treating, curing and/or preventing diabetes and its complications within a commercially reasonable time, then at JDRF's request the Institution shall assign all patent and other rights in such Invention to JDRF, unless Institution can show reasonable cause as to why it should retain title to such Invention. In the event of an assignment, Institution shall cooperate with JDRF (at JDRF's expense) and shall execute or cause to be executed such documents and take or cause to be taken such other actions as reasonably may be requested by JDRF in order to effectuate such assignment. After the effective date of the assignment to JDRF of any patent claiming such an Invention, as between Institution and JDRF, JDRF shall be solely responsible for all costs associated with filing, prosecuting and maintaining such patent. In the event that JDRF commercialises a product the making use, sale or import of which would infringe any valid claim of any such patent had it not been assigned to JDRF, JDRF shall negotiate in good faith with Institution a reasonable royalty rate that will be payable to Institution based on sales of such product.

Institution's obligations under this policy apply in respect of each jurisdiction in which patent protection may be sought for an Invention, and, to the extent that Institution has not done

something in respect of one or more jurisdictions, JDRF's rights will arise in respect of each of those jurisdictions.

8 ROYALTIES

In acknowledgement of JDRF's provision of funding, net royalties resulting from commercialisation of discoveries made with JDRF financial support must be shared with JDRF. The portion of royalties to be shared with JDRF shall be determined on a case-by-case basis in accordance with the policies of Institution and will be based on the relative contribution of JDRF funding to the overall project. Net royalties shall mean gross royalties and other licensing payments less administrative, licensing, legal, and other reasonably related expenses. Institution will provide to JDRF, upon request, financial information adequate to establish and document the amount of net royalties received.

JDRF also shall have the right to audit Institution's books and records annually in order to verify the net royalties. Institution's obligation to pay royalties to JDRF shall survive the termination or expiration of the Clinical Trial Research Agreement. Institution's obligation to pay royalties to JDRF as set out in other agreements shall survive the provisions of the Clinical Trial Research Agreement.

9 REPORTING

Institution shall report to JDRF within 30 days the filing of any patent application claiming any Invention, the issuance of any patent claiming any Invention, and the execution of any agreement granting any third party the right to use or practise any Inventions or other Study IP (whether for research, development, commercial or other purposes). Institution's obligation to report to JDRF shall survive after the termination or expiration of the Clinical Trial Research Agreement.

In addition, Institution shall submit Interim Progress Reports, as outlined in the Clinical Trial Research Agreement, to JDRF describing the status of JDRF-funded research, the Study IP (including a description of any Intellectual Property rights other than Inventions that have been developed), any publication relating to JDRF-funded research, Institution's efforts to seek patent protection for, develop and commercialise Inventions and other Study IP, and, if applicable, setting forth the net income from such commercialisation for such year. Such reports shall include the status of such development, the names of current or potential licensees, the relevant terms of any licenses that are in negotiation or have been executed granting any third party the right to use or practice any Inventions or other Study IP, and the receipt of any royalties and other consideration under such licenses. JDRF shall treat all such reports as confidential and shall not disclose the contents thereof to any third party, except as may be permitted under the Clinical Trial Research Agreement.

10 COOPERATION

As reasonably requested by JDRF, Institution shall from time to time consult with JDRF with respect to matters relating to JDRF-funded research, including matters relating to the patenting, development and commercialisation of Inventions. For example, if so requested by JDRF, Institution shall discuss with JDRF the ongoing progress of JDRF-funded research, critically assess the results of such research, identify and address any weaknesses or delays in research or commercialisation, and determine when and whether particular research or commercialisation targets are achieved.

11 PUBLICATION REQUIREMENTS

It is expected that researchers involved in JDRF-funded research will publish in relevant peer-reviewed scientific journals and provide information to the public on objectives, methodology and finding resulting from the JDRF-funded research, and Institution must ensure that its relevant

Personnel involved in the Study to do so. Institution must notify JDRF of any publication relating to JDRF-funded research. Copies of abstracts and journal articles should be included as a component of the Institution's Interim Progress Reports.

12 ENQUIRIES

For any queries relating directly to this Policy please contact:

Research Team
JDRF Australia
☎ +61 2 9020 6100
💻 crn@jdrf.org.au

I hereby certify that I have read and understand JDRF's policy on Intellectual Property, Commercialisation and Royalties, and I will comply with all provisions of that policy.
_____ Investigator's Signature Date: _____ Printed name _____ Institution's Signature Date: _____ Printed name

Appendix A

JDRF Invention Disclosure Form

Please complete all requested information as thoroughly as possible.
If you need additional space for any question, please attach additional sheets to this form.

1. Grant Number:
2. Name of Institution:
3. Name of Principal Investigator:
4. Title of Invention: (Please use technical terms and not proposed trademarks)
5. Describe, briefly, the nature of the Invention:
6. List all Inventor(s): Inventor Position Dept/Location & Phone E-mail address
7. Was this Invention developed with the use of any research grant or funding from a person or organisation other than JDRF? Please include in your answer any NMHRC or other funding. YES □ No □ If YES, please fill in the following Contract/Grant No. Sponsor (s) Project No. Principal Investigator
8. Dates of conceptible and if application, public disclosure[Note: should this be date of conception and if applicable public disclosure?] , . (Please indicate the date in the format MM/DD/YYYY, or N/A if inapplicable to the Invention.) State first date of: a. Conception b. Sketch or drawing c. Written description d. Completion of working model (or operational process) e. Disclosure to others (excluding employees of Institution) f. Printed publication g. Oral disclosure (e.g. seminars, conferences, etc.) h. Use for commercial purposes i. Offer for sale

9. Do you intend to pursue formal protection for this Invention? Yes □ No □
If so, please indicate the nature of those plans, e.g filing of a patent application.

10. If applicable, describe the advantages of the Invention over currently available technology and potential commercial applications of the Invention:

11. If applicable, list any businesses that may be interested in licensing or otherwise having rights to practice this Invention (provide as much detail as possible):

I hereby certify that I have read and understand JDRF's Policy on Intellectual Property, Commercialisation and Royalties and the Intellectual Property provisions of the Clinical Trial Research Agreement applicable to the Invention and I will comply with all provisions thereof relating to the Invention. I also certify that the information I have provided in this form is true and complete to the best of my knowledge.

IP Owner's Signature Date:	IP Owner's Signature Date:
Printed name	Printed name