Australian Type 1 Diabetes Clinical Research Network (JDRF) Policy on Data and Biosample Sharing.

1 APPLICATION OF POLICY

This Policy on Data and Biosample Sharing is made for the purpose of, and supplements, the Clinical Trial Research Agreement between JDRF and the Institution ("Clinical Trial Research Agreement"), and forms part of JDRF's Policy on Intellectual Property, Commercialisation and Royalties.

2 DEFINITIONS

Capitalised terms not otherwise defined in this Policy have the same meaning as in the Clinical Trial Research Agreement.

Biosamples include any Biological Samples collected from Study Participants in the course of a Study, including but not limited to:

- blood and blood products
- urine
- saliva
- exhaled breath
- buccal cells
- breast milk
- faeces
- tissue
- keratinised tissue (hair and nails)
- ossified tissue (teeth and bone)
- organ(s)
- cadaveric material

Data in this policy means Study Material. For the purposes of this policy, Data does not include Biological Samples ("Biosamples").

Data Sharing Plan is a formal document that outlines how research Data resulting from the Study will be handled, disseminated and shared with others both during the Study and after the Study is completed.

Repository means "databank" defined in the *National Statement on Ethical Conduct in Human Research 2007* as a "systematic collection of data ("Study Material") whether individually identifiable, re-identifiable or non-identifiable". A Repository must manage content and metadata in a sustainable and well-controlled way for the purpose of future use by the owner of the Study Material, the custodian of the Repository, or a third party, subject to approval by relevant authorities.

3 PURPOSE

The Australian Type 1 Diabetes Clinical Research Network ("Network") fosters openness, inclusion and scientific collaboration among Network participants. The sharing of Study Materials such as Data and Biosamples facilitates the transfer of knowledge among researchers, helps to avoid unnecessary duplication of resources and establishes a long term legacy and research resource for the entire Network's community. It aims to stimulate ongoing research and allows for new ideas to be generated from existing resources.

4 PROVISION AND SCOPE

4.1 DATA

The Institution is required to maintain or provide systems to:

i. identify where Data, including datasets and databases, constitute IP; and

ii. support the management of such Data, including Data which constitutes IP and Data which does not, in order to maximise the benefits from the research, including the documentation and safe storage for future use.

Data sharing does not discourage patent applications and appreciates the need for researchers and Institutions to appropriately protect Intellectual Property in Study Materials, in accordance with JDRF's Policy on Intellectual Property, Commercialisation and Royalties.

4.2 DATA SHARING

4.2.1 Methods for Sharing Data

Data sharing is also subject to the requirements of Clinical Trial Research Agreement and any other applicable requirements under relevant state and federal laws and ethics committee and regulatory approvals, including but not limited to duty of confidentiality and protection of privacy. The Institution must ensure that all participants have provided informed consent prior to their Data and personal information being made available to researchers and the scientific community.

Examples of Data sharing methods may include by Publication or direct transfer of Data from the Investigator to the requester.

4.2.2 Timeframe for Sharing of Data

It is understood that the timing of Data availability may vary according to the timelines for publication and analysis of research results. JDRF expects a commitment to share Data within the following timeframes:

- Studies that meet the SHO/ICMJE 2008 definition of a Clinical Trial must be entered in an authorised public register at the trial's inception prior to the start of participant enrolment
- Clinical research protocols must be submitted for publication in the form of a manuscript prior to initiating recruitment of participants
- Statistical Analysis Plans must be submitted for Publication within 12 months of initiating recruitment of participants
- Any restricted publication arising from a Study must be deposited in an open access institutional repository within a twelve month period from the date of publication. Data related to publications must be submitted to a repository within twelve months after publication in an open access institutional repository
- Unpublished Data must be submitted to a repository within two years from end of the Study

In the instance that any of the above does not occur, justifications for non-compliance must be included in the Final Report.

4.2.3 Data Sharing Protection and Access

JDRF appreciates the need for shared Data to be protected and appropriately governed. The Principal Investigator(s) will be required to submit a Data Sharing Plan (refer to Section 5) to adequately address the governance and framework on how Data protection and Data access including who can request access.

4.3 Biosample Sharing

4.3.1 Methods for Storing and Sharing Biosamples

Biosamples stored for the purpose of future use that could be shared subject to approval by relevant authorities (such as ethics committees) must be deposited in a standardised manner in a secure, well-controlled Repository. All Repositories must comply with relevant state and federal laws regarding privacy protection, duty of confidentiality and appropriate consent procedures. The Institution must ensure that standardised methods are developed regarding Biosample collection, processing, storage, access/distribution, tracking and disposal.

Interim Progress Reports and the Final Report must include details on Biosamples collected during the Study and deposited or planned to be deposited in a Repository.

5 DATA SHARING PLAN

5.1 Pre-award

All applicants seeking funding will be required to submit a Data Sharing Plan as part of their funding application. JDRF is available for consultation during this process.

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 are considered. A guide to developing a Data Sharing Plan is provided on the JDRF T1DCRN website.

5.2 POST-AWARD

After an award is made, the Institution must comply with its Data Sharing Plan as approved by JDRF, with amendments agreed from time to time. Interim Progress Reports must provide information on the progress of Data management and any deviations from the Data Sharing Plan.

The Final Report must include the final Data Sharing Plan for public release by the JDRF T1DCRN pursuant to any nominated embargo periods.

6 ENQUIRIES

In the first instance, researchers should direct general enquiries regarding Intellectual Property, Data sharing and Biosample sharing to the Grants Management Office of their Institution. For any queries relating directly to this Policy or the development of a Data Sharing Plan please contact:

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

Appendix A
Data Sharing Plan Template

Please consider each of the following core elements as thoroughly as possible.
If you need additional space for any question, please attach additional sheets to this template.

Description of data	i.	Type and format of data expected to be generated
	ii.	Storage
Governance of data	i.	Procedures for managing and for maintaining the confidentiality of the data to be shared
	ii.	Roles and responsibilities of Study or institutional staff in the management and retention of research data
Data Access	i.	Method of data sharing (e.g., provided by the Principal Investigator, through a data archive)
	ii.	Expected timeframes for data sharing
	iii.	Any circumstances that prevent all or some of the data from being shared
	iv.	Prioritising data access
Collaborations, publications and authorship	i.	How will publication, authorships and acknowledgements be managed
Implementation of the data sharing plan		

Certification	
I hereby certify that the information I have provided in this Research Data Sharing Plan is true and complete to the best of my knowledge.	
Investigator's Signature	Date:
Printed name	
Institution's Signature	Date:
Printed name (Authorised Representative)	