JDRF Australia's Policy on Data and Biosample Sharing

1 PURPOSE AND APPLICATION OF POLICY

JDRF Australia fosters openness, inclusion and scientific collaboration among T1D researchers. The sharing of Project Materials such as data and biological samples ("biosample") facilitates the transfer of knowledge among researchers, helps to avoid unnecessary duplication of resources and establishes a long-term legacy and resource for the research community. It aims to stimulate ongoing research and allows for new ideas to be generated from existing resources.

JDRF Australia expects research data and biosample generated as a result of its funding to be made available with as few restrictions as possible in a timely and responsible manner to the scientific community for subsequent research. This Policy on "Data and Biological Sample Sharing" is made for the purpose of, and supplements, the JDRF Funding Agreement between JDRF and the Institution ("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 Research Agreement.

Biosamples include any human or non-human biological specimen collected in the course of a Project, including but not limited to:

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

Data in this Policy means Project Materials. 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 Project will be handled, disseminated and shared with others both during the Project and after the Project is completed.

Repository means "databank" defined in the *National Statement on Ethical Conduct in Human Research 2007* as a "systematic collection of data 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 Project Materials, the custodian of the Repository, or a third party, subject to approval by relevant authorities.

3 PROVISION AND SCOPE

3.1 DATA

The Institution is required to maintain or provide systems to:

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

ii. support the management of such Data, including Data which constitutes Intellectual Property 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 Project Materials, in accordance with JDRF's Policy on Intellectual Property, Commercialisation and Royalties referred to in Section 1 above.

3.2 DATA SHARING

3.2.1 Methods for Sharing Data

Data sharing is also subject to the requirements of the 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.

3.2.2 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 Project 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 Project

In the instance that any of the above does not occur, justifications for non-compliance must be included in the Final Report or promptly notified to JDRF if the time for compliance is after the Final Report date.

3.2.3 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.

3.3 BIOSAMPLE SHARING

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

4 DATA SHARING PLAN

4.1 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 website.

4.2 POST-AWARD

After an award is made, the awardee must comply with its Data Sharing Plan as approved by JDRF, with amendments agreed from time to time. Interim 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 pursuant to any nominated embargo periods.

5 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
P: +61 2 9020 6100
E: 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	Type and format of data expected to be generated?
	Storage?
	Who will have ongoing custody of data or research outputs, including any intellectual property ownership?
	Will guidelines for health and medical research under section 95 of the Privacy Act (1988) be adhered to?
Governance of data	State procedures for managing and for maintaining the confidentiality of the data to be shared
	State roles and responsibilities of Project or institutional staff in the management and retention of research data
	Have participants consented to their data being shared?
	Do you plan to share any individual research results obtained during this project to the participants? If so, explain how participant confidentiality will be ensured.
	Will data be aggregated for variables with less than five cases?

Data Access	Will data be made available to other organisations for research purposes if requested?
	What steps will be taken to ensure the security of data?
	Method of data sharing (e.g., provided by the Principal Investigator, through a data archive)
	Expected timeframes for data sharing?
	Any circumstances that prevent all or some of the data from being shared
	Prioritising data access?
	Will a fee be changed for providing data to other institutions for research purposes?
	Will any restrictions be placed on data if shared?
	Are there any restrictions or embargos from the data is collect until institutions can obtain the data?

Collaborations, publications	How will publication, authorships and acknowledgements be managed
Implementation of the data sharing plan	Does your site have a data sharing agreement? If so, please provide
	How will the data sharing plan be implemented?

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)	