AUSTRALASIAN DIABETES DATA NETWORK

ADDN
Publication and Data Access Policy

**Accepted and approved by the ADDN Project Management group:
25 November 2022 Version 2.0**

Version History

Version	Date	Description	Name	Title
0.1	01/07/15	Initial draft for comment	H. Phelan	Program Manager
0.2	06/08/15	Draft post ADDN Steering Committee changes	H. Phelan H. Clapin	Program Managers
0.3	17/08/15	Draft post ADDN Project Team feedback	H. Phelan H. Clapin	Program Managers
0.4	5/09/15	Draft post ADDN Steering Committee feedback and request to extend policy to include investigators external to ADDN Study Group.	H.Phelan H.Clapin	Program Managers
0.5	16/09/15	Draft post ADDN meeting 11th Sept 2015	H.Phelan	Program Managers
1.0	28/09/15	Promoted to v1.0		
1.1	08/12/17	Inserted Section 2.2 Data Access; revised Sections 3.1, 3.4, 4 and 9.1; removed Appendices A-D; amended Section 3.3 following Steering Committee feedback; inserted EOI for ADDN and international collaborations in s 6)	MT Mok	Program Manager
1.2	20/04/18	Feedback from Steering Committee, clarifying ADDN Study in s 5; rewording of s 7; insertion of ICJME recommendations on authorship guidelines (s 10); and rewording of acknowledgment to JDRF (s 9.1); and calling for an EOI (s6.1)	MT Mok	Program Manager
2.0	01/12/22	Revised document following recommendations from PIs and Project Management team	B Waddell M Craig	Program Manager Medical Director

Associated Documents

	Description
1	ADDN Data Dictionary
2	ADDN Governance
3	ADDN Data Access Guide
4	ADDN Research Data Enquiry SOP
5	ADDN Research and Data Enquiry Form
6	ADDN Data Extract Request Form
7	ADDN Project Proposal Form
8	ADDN Data Access Agreement

Acronyms and Abbreviations

	Description
ADC	Australian Diabetes Council
ADDN	Australasian Diabetes Data Network
ADS	Australian Diabetes Society
ANZSPED	Australian and New Zealand Society of Paediatric Endocrinology and Diabetes
ARC	Australian Research Council
JDRF	Juvenile Diabetes Research Foundation
ICMJE	International Committee of Medical Journal Editors
NHMRC	National Health and Medical Research Council
T1D CRN	Australian Type 1 Diabetes Clinical Research Network

Definitions

ADDN data refers to the current ADDN dataset and data dictionary as approved by the ADDN Steering Committee.

ADDN website refers to the website in the public domain.

ADDN registry refers to the secure password enabled online site available only to authorised ADDN participants and users including the database.

Table of Contents

1   Purpose and Guiding Principles

The general philosophy of the ADDN Study Group is one of inclusion and collaboration. The ADDN Study Group aims to facilitate access to data from a broad range of investigators and to pursue collaborative research to drive scientific output.

The underlying premise of this policy is that ADDN data must be secure, strictly managed and comply with current ethics approval under the National Mutual Acceptance (NMA) and other jurisdictions. However, the processes to access the data must be efficient and timely to ensure the ADDN resource meets the aims of increasing person-centred research and improving the lives of people affected by diabetes.

The purpose of this document is to describe the processes for accessing multi-centre data within the ADDN registry, managing data requests, and the writing and authorship of abstracts, presentations, and publications. The finalised document will form the basis for abstract and manuscript proposal forms and procedural documentation.

2   Background

This document has been adapted from the T1D Exchange Clinic Network 'Analyses, Abstracts and Manuscripts using Clinic Registry Data General Policy and Procedures', the Australian Longitudinal Study on Women's Health 'Policy and Procedures for Data Access, Analysis and Publication', and BioGrid Australia 'How do I access Data'. Feedback has also been obtained from the ADDN Study Group.

Documents outlining governance of ADDN, data access requests, and the data dictionary are available from the ADDN Project Management Team and should be read in conjunction with this policy.

2.1   ADDN Data and Governance Structure

De-identified data collected by participating ADDN centres are aggregated in the ADDN registry. At present ADDN is transitioning from collecting de-identified data to identified data, as approved by the Monash Human Research Ethics Committee (HREC). However, it is recognised that some centres may continue to submit only deidentified data due to local HREC requirements. These data are continually being added and can be used repeatedly without diminishing their future availability or value. As such, ADDN has the potential to reduce research costs and increase person-centred research. The aim of the ADDN registry is to capture data on all people with diabetes, and to understand how to improve the treatment and management of T1D across their lifespan.

The database underlying the ADDN registry is hosted by the University of Melbourne and is regularly updated as each of the participating centres extract and upload data from local hospital/centre sources, currently twice-yearly in March and September. Details relating to the data set collected in ADDN can be found in the ADDN Data Dictionary.

All centres contributing data to ADDN are considered ADDN investigators. It is a prerogative of the centres to advise the ADDN Program Manager of the names of the individuals who are considered ADDN investigators for that centre. These individuals will be listed on the main HREC applications and local governance. Changes in ADDN investigators will be reviewed frequently by the ADDN Project Management Team.

ADDN has relationships with JDRF Australia, the Australian Type 1 Diabetes Clinical Research Network (T1DCRN), the Australian Diabetes Society (ADS), the Australian and New Zealand Society of Paediatric Endocrinology and Diabetes (ANZSPED; formerly known as APEG), the Environmental Determinants of Islet Autoimmunity (ENDIA), the Australian Type 1 Diabetes National Population Screening Pilot, Type1Screen, Australasian T1D Immunotherapy Collaborative (ATIC) and the Global

Centre of Excellence (CoE) in Diabetes Research. The roles of and relationships with each of these entities can be found in the 'ADDN Governance' document.

ADDN data are protected and governed according to the overarching ADDN governance arrangements. Contributing centres have ownership of their own centre's data and can access this data via the ADDN interface to produce general and customised reports. All centres that contribute data to ADDN can access the ADDN National Benchmarking reports and aggregated data via the ADDN website (requires login), as well as personalised interactive reports for their centre(s).

2.2   ADDN Data Access

More detailed information and forms used to access ADDN data can be found in the following documents:

- ADDN Research Data Enquiry SOP
- ADDN Data Access Guide
- ADDN Research and Data Enquiry Form
- ADDN Data Access Guide
- ADDN Data Extract Request Form
- ADDN Project Proposal Form
- ADDN Data Access Agreement

3   Types of Publications and Reports

3.1   ADDN National Benchmarking Reports

National de-identified benchmarking reports are produced bi-annually, and sites can access their reports and review data by logging into the ADDN Registry. Anonymised data snapshots are also available to the public through the ADDN website. These reports are authored by the ADDN Project Management Committee led by the ADDN Principal Investigators (PIs) with acknowledgement of individuals who have participated in producing the reports. The ADDN Project Management Committee approve national benchmarking reports prior to public disclosure.

3.2   Abstracts, Publications, Presentations and Reports

The ADDN Study Group undertake analyses of multi-centre data, including benchmarking, outcomes of Continuous Glucose Monitoring (CGM), and to address specific research questions. These data are submitted as abstracts to scientific meetings, published in scientific journals, included in presentations to stakeholders, and provided in government reports. Researchers external to the ADDN Study Group can request access to the ADDN data as part of a collaborative or independent research project. Publications arising from access to the ADDN data must acknowledge the ADDN Study Group as authors and/or as a source of data (depending on the circumstances as detailed below). All publications should acknowledge JDRF as funders of ADDN, as detailed in Section 9.

3.3   Scientific Journal Publications and Scientific Abstracts arising from data that are in ADDN but where the ADDN Investigator seeks to publish separately from ADDN

The contribution of data to ADDN does not preclude contributing centres from publishing their own centre's data independently from ADDN. When practicable, members of the ADDN Study Group should inform of potential competitive publications to those in development by ADDN as they are in a privileged position, overseeing national data. It would be courteous for centres that intend to publish their own data independently from ADDN to communicate their intentions with the ADDN Project Management Team. This is particularly relevant for collaborations with international registries, since it is preferable to include nationally representative data, or data from more than one site, if available.

In circumstances where data requested are available from only one ADDN centre, the ADDN Study Group who have requested the data will consider, in consultation with the ADDN Project Management Team, whether this will constitute an ADDN Study Group publication in which procedures as set out in Section 6.1 below will apply. If this is deemed not to be an ADDN Study Group publication, then procedures in Section 6.3 should be followed.

3.4   Summary Reports that describe the ADDN Cohort

Researchers can request multi-centre data describing the ADDN cohort to inform study feasibility and grant applications, for clinical trials and other activities. Summary reports in aggregate, which do not identify individuals, centres, or states/territories, will be produced by the ADDN Program Administrator, ADDN Data Analyst and ADDN Program Manager with oversight from the ADDN Project Management Team. The ADDN Study Group need to be notified and informed of any publication of summary reports. The source of the ADDN data and the role of JDRF as funders should be stated.

4   Analysis Proposals

The **Research and Data Enquiry Form** is available on the ADDN website (https://www.addn.org.au/contact-us). Each submission of this form is allocated a unique enquiry number (in the format ADDN_####_ENQ) for use in initial correspondence.

The ADDN PIs will review and prioritise submitted proposals in accordance with the ADDN Research Data Enquiry Standard Operating Procedures document.

Proposals will be received by the ADDN Data Analyst, who will prepare a summary that includes availability of ADDN registry data and overlap with other approved or planned studies. A preliminary review of each proposal will be presented to the ADDN PIs to determine if the data are available and adequate to address the objective(s) of the proposal. The ADDN PIs will also discuss and suggest any adjustments to the proposal. It is anticipated that most proposals will request deidentified data. Those requesting identifiable data will require additional discussion with the ADDN PIs, as well as adequate ethics approval allowing identifiable data to be released.

The ADDN PIs will review and prioritize proposals. For each proposal, a decision will be made to approve, request further information, or decline the proposal with an option to resubmit. Based on the requested data, the PIs will confirm whether the proposal constitutes an ADDN study, whether it requires additional local institutional ethics approval (the majority of studies will require this), and whether an Expression of Interest will be called (see 4.3 and 5.1).

When considering data requests, the ADDN PIs will assess whether each proposal should proceed, based on the following criteria:

- Are data available and adequate to address the objective(s)?
- Does the proposal overlap with any existing or planned studies?
- Are the aims of the proposal consistent with the overall aims of ADDN?
- Is the proposal seeking to use data from all ADDN centres or only some?
- Is the analysis feasible with respect to involvement of a skilled statistician and realistic timelines to publication?
- Will the outcomes of the analysis be scientifically valid, with respect to generalizability of the sample and issues such as statistical power?
- Is the proposed study in the best interest of ADDN participants?

The ADDN Data Analyst will contact the researcher to communicate the outcome of the preliminary review. Where additional information is requested by the ADDN PIs and the Project Management Team, the ADDN Data Analyst will request any outstanding information not provided in the proposal.

4.1   Approvals, Data Extracts, and Deferrals

Where a proposal is approved by the ADDN PIs, the ADDN Data Analyst will perform a complete data review. Approved proposals will be assigned a unique project number (in the format of PRO_###) for use in all future correspondence. At this stage, researchers will be asked to complete an **ADDN Data Extract Request Form** including all ADDN Registry data fields required for the project, and any inclusion/exclusion criteria. Requests for specific data fields should align with the research question(s).

On receipt, the ADDN Data Analyst will extract all requested fields from the most recent data load and will summarise any issues with the quality and completeness of available data at each participating site.

The ADDN Data Analyst will confirm if the researcher wants to proceed. If the current data are deemed insufficient by the ADDN PIs or the researcher, the project may be placed on-hold. Deferred projects may be reopened (for a period of up to 2 years) to allow for the inclusion of additional data loads. In these cases, the researcher may consider working with the ADDN PIs and investigators to facilitate improved collection of certain data fields at some or all centres prior to repeat review.

4.2   Data Agreements

Once the data are deemed sufficient and the researcher has chosen to proceed, the ADDN Data Analyst will provide the data, specific to the analysis described in the proposal, including any reasonable and minor changes and additions that arise during the work.

Prior to the provision of data, researchers will be required to sign a **Data Access and Publication Agreement** relating to use of data (only for the purposes for which they applied, agree to not attempt to identify individuals, nor to release data to others). This agreement is to be signed by all persons associated with the project, including those who present results and those whose name will appear on publications arising from the project, including students.

It includes acknowledgement that the project leader/guarantor takes responsibility for ensuring:

- ethics and privacy principles are adhered to;
- adequate facilities and resources to enable the project to progress in a reasonable manner;
- the de-identified data are used specifically for the analysis described in the application. If there are to be any substantial changes to the nature of the analysis or the topic to be addressed a new application should be submitted.

4.3   Study Definitions and Requirements for Data Access

Proposals for use of ADDN data that do not involve linkage with external data and are considered as Quality Assurance (QA)/Quality Improvement (QI) projects, undertaken by ADDN for ADDN, do not require separate ethics committee approval, as this is covered by the existing ADDN ethics NMA. All other studies, including analysis of ADDN data for research purposes as well as linkage with other data sources, must demonstrate HREC approval before data are released from ADDN. Most studies that do not involve linkage will usually require low-risk ethics approval. The definition of an ADDN project is one that is primarily led by any investigator that is a member of the ADDN Study Group, and not by an external entity. A project conducted under the governance of another research group is not defined as an ADDN project.

QA/QI projects are defined as those where the primary purpose is to monitor or improve the quality of service delivered by an individual or an organisation. When requesting access to ADDN data, applicants should specify whether their project is a QA/QI activity, according to the Australian Commission on Safety and Quality in Health Care, Framework for Australian clinical quality registries (https://www.safetyandquality.gov.au/publications-and-resources/resource-library/framework-australian-clinical-quality-registries).

The ADDN PIs will review the submission and determine whether the proposal/project is a QA/QI activity. QA/QI projects that are not undertaken by ADDN will require ethics approval. Any project that does not meet these criteria, whether it is led by ADDN investigators or not, requires ethics approval.
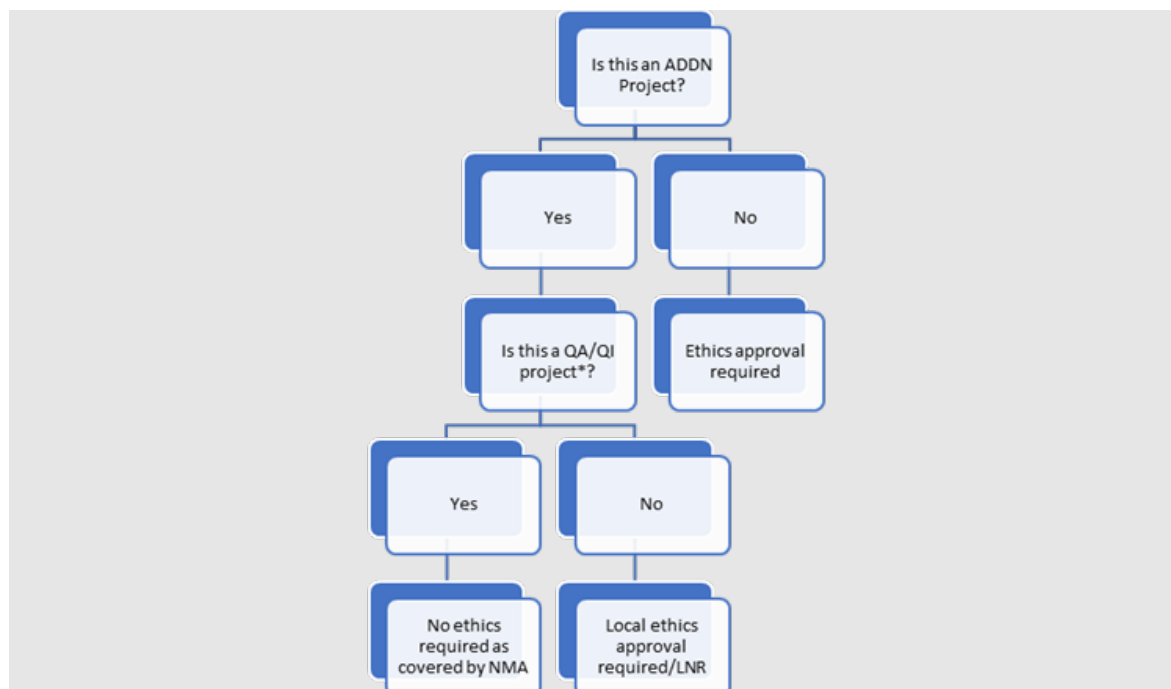
*as defined above.

The approval from ADDN for data access is valid for a period of 2 years from date of receipt of data. If at the end of 2 years, the project is not completed and/or no publications have been submitted the researcher can apply to the ADDN PIs for an extension of approval or the data must be destroyed as per NHMRC guidelines. If the project is completed and/or publications have been submitted, the researchers must keep the data in accordance with NHMRC guidelines (https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018).

5   Authorship of ADDN Publications

5.1   Projects by ADDN Study Group

For each manuscript that utilises multi-centre data, and is deemed an ADDN Study by the ADDN PIs, an Expression of Interest (EOI) may be circulated to ADDN Study Group members and other researchers, if applicable. ADDN encourages early career researchers to participate. The lead and co-investigators will be designated by the ADDN PIs. Detailed processes regarding the EOI are covered in the ADDN Research Data Enquiry SOP document. The ADDN Program Manager will keep a record of those people who are interested in contributing to publications but were not selected so that they can be given another opportunity at a later date.

When an idea for a manuscript has been proposed by an individual from the ADDN Study Group, that individual will typically be given the opportunity to be the lead author or senior author. The senior author(s) will usually be the supervisor(s) of the lead author.

The nominated statistician for the project will work with the lead author to develop a statistical analysis plan. If the statistical analysis is performed by the authors, then statistical review of the data analysis and manuscript will be sought prior to submission.

The journal for submission will be determined by the lead and senior authors of the publication, in discussion with the ADDN PIs.

5.2 International collaborations

For international collaborations that are initiated by the ADDN Study Group, the processes described above will apply.

For international collaborations that arise from another registry, an Expression of Interest (EOI) will be called from ADDN Steering Committee members, as well as other researchers whereby a lead and co-investigators will be designated.

The lead investigator together with the ADDN PIs will designate individual(s) to represent the ADDN Study Group in adherence to project publication guidelines set together with international collaborators. Detailed processes regarding the EOI are covered in the ADDN Research Data Enquiry SOP document.

Individuals who are selected to represent ADDN on such publications will be required to sign a Data Access and Publication Agreement, which includes ensuring the ADDN Study Group are named in the author list and that funding by JDRF is acknowledged. The ADDN Program Manager should be included on all communication to ensure the publication guidelines are followed and to provide regular updates to the ADDN PIs. International publications often have a limit on the number of authors from each registry (typically no more than four) and this will be considered at the time of the EOI. ADDN encourages early career researchers to participate.

5.3 Proposals from investigators external to ADDN

Investigators external to ADDN are encouraged to apply for access to ADDN data and may choose to invite members of the ADDN Study Group as co-authors, however this is not a requirement of access to or use of ADDN data. However, the ADDN Study Group should always be acknowledged and, funding by JDRF stated clearly in the manuscript.

6 Abstracts

All abstracts using multi-centre data must be reviewed by the ADDN PIs. To meet abstract submission deadlines, authors should submit abstracts to the ADDN Program Manager at least two weeks prior to abstract submission deadline when planning a conference abstract. The ADDN Program Administrator will assist the presenter in drafting the abstract and with the submission process if needed.

7 Review and Approval of Manuscripts

7.1 Projects by ADDN Study Group

A final draft of the manuscript (or conference abstract) will be sent to the ADDN PIs for review, with a two-week deadline. The comments from the ADDN Study Group members will be sent back to the lead author to consider. The ADDN Program Manager will coordinate this. The ADDN Program Manager should be copied in all correspondence regarding manuscripts. The revised version of the manuscript will be sent to the ADDN Program Manager and ADDN PIs for final approval with a two-week deadline.

7.2 International collaborations

For international collaborations that are initiated by the ADDN Study Group, the processes described above will apply. For international collaborations that arise from another registry, the final draft of manuscript must be submitted to the ADDN PIs for approval prior to publication, to ensure that the manuscript adheres to publications policies and acknowledgement of funding.

7.3 Proposals from investigators external to ADDN

The final draft of the manuscript or abstract must be submitted to the ADDN Program Manager and PIs for approval prior to publication.

8 Publication

8.1 Manuscript and Abstract Approvals

All manuscripts (articles, papers, book, monograph, abstract, presentation, poster, or report) that include multi-centre data must:

- Acknowledge the ADDN Study Group, by including 'ADDN Study Group' in the author list;
- Acknowledge ADDN funders using the statement below:
    - "This research was conducted as part of the Australasian Diabetes Data Network. We are grateful to JDRF Australia, the Australian Research Council and to the children and young people with diabetes and their families who provided the data. This research was supported by JDRF Australia, the recipient of the Australian Research Council Special Research Initiative in Type 1 Juvenile Diabetes";
- Include the date of the data extract and list ADDN as the source of data used;
- Include an appendix listing the ADDN Study Group participants (manuscripts);
- Also acknowledge, where applicable:
    - other persons who have provided comments, advice, support or other input into the paper, who are not already listed as authors;
    - research assistants, technical officers, and 'non-authors' who contribute;
    - additional funding bodies.

The author must provide copies of manuscripts or reports and all correspondence to the ADDN Program Manager who will coordinate informing and obtaining approvals from the ADDN PIs when the project is submitted, reviewed, re-submitted and finally accepted, and that proper authorship (Section 10) and publication protocols (Section 9) are adhered to. A hard or electronic copy of the published paper/ abstract should be provided to the ADDN Program Manager who will also provide a copy to JDRF.

9 Authorship

For all manuscripts, the ADDN Study Group will be listed as named authors. Authors must meet the authorship criteria listed below. The senior (last) author(s) will usually be the supervisor of the lead author. For abstracts, the same policy will be followed if a writing committee exists and has been involved in preparation of the abstract. If not, the presenter and statistician will be listed followed by 'for the ADDN Study Group'.

Unless specifically referred otherwise, authorship guidelines (including conflicts of interests) are based on ICJME recommendations (http://www.icmje.org/icmje-recommendations.pdf).

9.1 Authorship Criteria (based on International Committee of Medical Journal Editors (ICMJE) requirements)

To qualify for authorship, each author must meet at least one criterion in each of the three categories:
1. Category 1
   a) Conception and design
   b) Acquisition of data
   c) Analysis and interpretation of data
2. Category 2
   a) Drafting of the manuscript
   b) Critical revision of the manuscript for important intellectual content (this does not include reviewing the manuscript for journal submission approval)
3. Category 3
   a) Statistical analysis
   b) Obtaining funding
   c) Administrative, technical, or material support
   d) Supervision
   e) Other (specify)