National Transfusion Dataset

Data Access Request and Publication Policy

Version: 2.0, 30 September 2024

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1. Introduction

1.1 Preface

Interested parties may request a data extract or an analysis of data for the purposes of academic research, clinical review, planning, or scientific investigation. Applications for data use will be accepted from a wide variety of requestors including registry participants, non-registry participants, researchers, industry and governmental organisations.

Access to data collected and collated by the National Transfusion Dataset (NTD) is guided by protocols and procedures to maintain privacy and confidentiality. Provision of data to the registry is subject to the study protocol, which has been approved by Human Research Ethics Committees (HRECs)/ Institutional Review Boards (IRBs) in each jurisdiction, and the relevant Research Governance Offices of participating hospitals (a hospital with ethics and governance approval for registry participation). In particular, specific measures have been put in place to maintain the confidentiality of personal identifying information.

Data access requests are subject to the approval of the NTD Management Group and/or the NTD Steering Committee and may be subject to conditions in project-related agreements and/or research ethics approvals depending on the nature of the data access request.

This policy includes the criteria and conditions for provision of data for research activities and procedures for data request applications. It also outlines the cases in which fees for such access might be applicable, and highlights associated acknowledgement and publishing responsibilities.

1.2 Project Overview

The NTD forms the first integrated national database of blood usage in Australia. The NTD aims to collect information about where, when, and how blood products are used across all clinical settings.

The NTD was formed through the incorporation of the established Australian and New Zealand Massive Transfusion Registry (ANZ-MTR) and a pilot Transfusion Database (TD) project. The ANZ-MTR has a unique focus on massive transfusion and contains over 10,000 cases from 41 hospitals across Australia and New Zealand. The TD was a trial extension of the registry that collated data on all (not just massive) transfusions on >8000 patients from pilot hospitals. The NTD will integrate and expand these databases to provide new data on transfusion practice, using novel approaches to collect data on clinical outcomes. The NTD will link datasets of blood utilisation including prehospital, clinical and registry data, with the aim of closing the vital haemovigilance loop.

1.3 Custodianship

All collective registry data and data management systems operate under the custodianship of Monash University. A participating hospital can access data they contributed to the Registry. Site Investigators/ Study Coordinators/ Data Managers can export a full copy of the dataset for their site.

1.4 Eligible applicants

Researchers, clinicians and pharmaceutical professionals working at research institutions, hospitals, private entities, government or other health services within Australia, overseas and industry are eligible to request access to data held within the registry. All requests for data are noted in the Steering Committee minutes and logged.

1.5 Governance

Access to data held by the NTD is governed by the NTD Management Group and the NTD Steering Committee. When considering the approval of access to NTD data, the NTD Management Group and Steering Committee will seek to balance the public health interest from the proposed research whilst prioritising the importance of security and information privacy.

When considering a data access request, the 5 Safes model will be consulted. The internationally recognised approach provides a framework that considers the risks associated with data sharing and release including privacy, security and ethics. The 5 Safe dimensions to consider are described briefly below.[1]

Safe projects	Is this use of the data appropriate?
Safe people	Can the researchers be trusted to use it in an appropriate manner?
Safe data	Is there a disclosure risk in the data itself?
Safe settings	Does the access facility limit unauthorised use?
Safe outputs	Are the statistical results non-disclosive?

1. Ritchie, Felix. (2016). Five Safes: designing data access for research. 10.13140/RG.2.1.3661.1604.

1.6 Fees

The provision of data may be subject to a fee-for-service on a cost recovery basis unless in line with existing funding agreements between registry funders/supporters. Fees will be at the discretion of the Steering Committee and will be based on the complexity and estimated time taken to complete the request.

2. Data held by the NTD

Data for adult patients (⩾18 years of age) transfused with any type of blood component will be captured from prehospital, hospital and ICU databases, and patient registries participating in the NTD. Data captured include:

- Demographic details
- Clinical context (acquired from ICD-10-AM codes) including diagnosis, procedures and complications.
- Laboratory results
- Transfusion records
- Adjunctive therapies
- Clinical outcome (i.e. mortality, hospital length of stay)

3. Levels of data access

The NTD is ethically approved to collect personal identifiers to permit longitudinal follow up of participants, however, it has adopted methods to reduce the risk of identification during analysis and storage of data and when presenting and publishing research results. The NTD will release the least sensitive level of data that is practicable for the requirements of the study proposal submitted.

Types of data include:

Aggregate/summary data

Requests for aggregated/summary data are requests where the data may be stratified by non-identifiable data elements, including age (or age group), sex, drug, and diagnosis year(s). The level of aggregation would be sufficiently high so as to prevent the indirect identification of any individual. To assist with this, the NTD may suppress any data with few cases.

De-identified individual unit record

Requests for de-identified individual unit record information are requests where the dataset would not contain any identifying details. That is, they would not include database registration ID, name, full date of birth, or any data items that either singly or collectively may identify an individual.

If a researcher discovers that it is possible to re-identify a participant in the provided dataset, the researcher must immediately notify the NTD Management Group and take the reasonable steps required by the NTD Management Group to mitigate risk or harm to the participants.

Identifiable unit record information

Access to individually identifiable data, where the identity of a specific individual can be reasonably ascertained, will not be granted.

4. Types of data access requests

Specific analyses/ study proposals:	Applicants may request the NTD to undertake specific analyses of data in which the NTD would provide de-identified aggregate/summary data reports only. Steering Committee approval is required before data is made available. Applicants may also request de-identified individual unit record data to perform their own analyses for study proposals. These requests require Steering Committee approval and HREC/IRB approval. Approved applicants will be provided a de-identified dataset on the Monash Secure e-Research Platform (Monash SeRP) where access is limited to approved users only. (See Section 7.1 Monash Secure e-Research Platform).
Analysis of combined datasets:	For projects that require data linkage, a data linkage plan will be developed with the applicant with the overarching requirement that the privacy of individual hospitals and participants is maintained. Identifiable data will not be provided. Steering Committee approval, HREC/IRB approval and a Data Sharing Agreement or other legal agreement between the custodians of the included datasets will be required. Participant identifiers will be removed once data linkage is complete. For data requests requiring linkage to a third-party dataset, applicants may be charged a fee for service to undertake and access the linked data. For data requests requiring datasets to be combined, the NTD may require data to be provided for the purpose of carrying-out the linkage process.
Hospital-specific Data	If a hospital, or its representative, makes a specific request for its own performance data, beyond that available on the Hospital Data Report, a request must be submitted to the NTD Project Manager (PM). At the discretion of the PM, depending on the complexity and extent of the request, the request may be further reviewed and approved by the NTD Management Team.

5. Conditions of use

1. Requests must be made in accordance with this Data Access Request Policy and applicants must provide the full project scope including project rationale, research questions and intended use in the request form. The NTD holds the rights to reject or revoke access if the terms of this Policy are not adhered to.
2. Hospitals contributing data to the NTD may have access to their own patient level data without charge.
3. Data cannot be provided until all required approvals have been obtained, ethics approval from relevant HRECs/IRBs are in place, and any fees-for-service paid, where required.
4. Data access and usage must comply with all conditions of approval and contractual arrangements where applicable.
5. All acquired data must only be used for the specific research question(s) outlined in the written data request and study proposal, and as approved by the NTD Steering Committee and/or NTD Management Group. Secondary use or publication of the acquired data set will require a separate HREC/IRB approval.
6. Data provided by the NTD may not be disclosed to any person other than those explicitly listed in the written data request.
7. Applicants should make no attempt to re-identify individuals in the de-identified data set provided.
8. Applicants are encouraged to complete their research in a timely manner. If there has been no or little progress within 12 months from the data request approval date without valid reason, the NTD Management Group will consider the research as abandoned. Applicants with projects that have exceeded 24 months in duration or exceeded the expected completion timeframe, will not have new projects considered unless sufficient progress in the existing projects has been demonstrated.
9. For study proposals, the applicant will be asked to provide an update as to the progress of the study at least every 6 months from the data request approval date or as requested by the NTD
10. It is a condition of use of NTD data that in publications the registry is recognised as the/a data source and the NTD will be acknowledged in accordance with the NTD authorship and publication guidelines in any presentation of the data. A copy of any publication or presentation containing NTD data must be provided to the NTD Management Group prior to submission.

6. Requesting Data Access

6.1 Data Access Request form

Prior to seeking HREC/IRB approval, we encourage applicants to seek approval from the registry steering committee to ensure project feasibility. If the project is deemed feasible, a letter of support from the Steering Committee will be issued to support the applicants HREC/IRB application. The latest version of the Data Access Request Form can be found here: https://redcap.helix.monash.edu/surveys/?s=CK9TYXPMLTCRWPDM

6.2 *Documents required to support request for access*

The documents that need to be included in your submission are:

- The specific categories of data required for analysis
- Where relevant, HREC/IRB application and approval letter

6.3 *Review Process*

1. Applicants are encouraged to discuss the application with the NTD Project Manager/Coordinator before preparing/submitting the Data Access Request Form and prior to seeking HREC/IRB approval.
2. All requests should include the following information: Study background, aims and objectives, methods and detailed statistical analysis plan, data type and request (see section 3 and 4 above), contact details of the applicants and their supervisors, anticipated timeline, source of funding and proposed publication/presentation plan.
3. All data requests are considered on a case-by-case basis and will undergo an initial review by the NTD Management Group for feasibility, duplication, complexity and scientific merit.
4. Data requests supported by the NTD Management Group (see point 3), will be sent to the NTD Steering Committee for review and approval. The Steering Committee is given 2 weeks to review and provide feedback.
5. If approved, the applicant must submit a copy of the HREC/IRB approval and subsequent annual HREC progress reports must be to the NTD.
6. The NTD Management Group will confirm the anticipated timelines for approved request completion, costing estimate (if needed), feedback from the Steering Committee, and any specific conditions of use including HREC/IRB approval requirements if the request is outside the scope of the ethics approval held by the NTD for its routine operations and purpose. Registry staff will notify the applicant if additional approvals are required
7. Any material to be presented or published must be sent to the NTD Management Group at least 2 weeks prior to presentation or submission for review to ensure accurate interpretation of registry data and acknowledgement of the NTD. Approval from the NTD prior to presentation or publication is required.
8. Applicants will be required to complete a progress report every 6 months or upon request.

6.4 *Terms of release*

All requests for access to the NTD data will be processed in a timely manner, but are undertaken in addition to the routine NTD workload.

Access to data will generally be provided on a non-exclusive “first come-first served basis”. However, the following factors may be taken into consideration when prioritising access:

- Data availability,
- Technical feasibility or complexity of project,
- Resource availability, or
- Urgency of request if required for a time-sensitive event (e.g. conferences).

As a general rule, requests for aggregated data will take 6-8 weeks to complete after approval.

Where a data request for publication purposes is already the subject of another approved data request, priority will be given to the original request. If deemed appropriate by the NTD Management Group, the NTD may put both applicants in touch with each other for collaboration.

To accommodate data requests for abstract submissions to scientific meetings, the Data Access Request form must be received no less than 60 days prior to the abstract submission deadline. This timeframe is required to allow a thorough analysis and result discussion for all approved requests.

7. Data storage and sharing

7.1 Monash Secure File Transfer Protocol (SFTP)

In most cases, data will be transferred via Monash University's Secure File Transfer Protocol. The de-identified data is encrypted and stored on a server that is accessible only to approved and authenticated researchers.

7.2 Monash Secure e-Research Platform (Monash SeRP)

Where appropriate, access to Monash SeRP may be provided to applicants who wish to conduct their own analysis of unit record data and for data linkage studies.

The Monash SeRP allows a subset of data to be analysed remotely on Monash University servers in a controlled manner and with an appropriate level of security. Individual unit record data may not be removed from this server, only aggregated research outputs can be exported upon approval by the data custodian.

Data will be provided either as labelled .dta files (Stata format) or as .csv files. Within Monash SeRP, researchers can access commonly used statistical software including Stata, SPSS, and R.

7.3 Data security and storage

People accessing NTD data are responsible for ensuring appropriate security for the storage of any material, confidential or otherwise, held in any format including on computing systems.

No identifiable **or potentially re-identifiable** research data and/or health information should ever be stored on local machines or sent via email or fax or transported on a portable disk or disk drive.

On completion of analysis, users will be required to download their analysis software/code and store as per their local institution guidelines. The de-identified unit record data will be archived for 7 years after the date of publication. For unpublished research, data will be kept for 7 years post the final report.

8. Publishing and Dissemination of research results

All research requests must comply with the Acknowledgement and Authorship guidelines outlined in this policy.

The NTD expends significant time, effort and other resources in collecting, cleaning and preparing the data for research. Because the dataset comes from multiple centres, the investigators connected to the NTD are also exclusively positioned to take responsibility for the quality and accuracy of the data. For these reasons, consistent with the ICMJE authorship criteria, it is expected that any manuscript arising from an NTD research data extract includes a minimum of two authors from the NTD. The NTD contributors to be named would depend on the actual input to the particular data exercise and should conform to the Australian Code for the Responsible Conduct of Research (http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/r39.pdf) and Monash University Research Outputs and Authorship Policy (http://policy.monash.edu.au/policy-bank/academic/research/research-outputs-and-authorship-policy.html). Applicants are encouraged to discuss the authorship requirements with the Registry PM and will be advised on the appropriate acknowledgement statement.

To ensure that the data and any limitations in scope or quality of the data provided has been properly understood by the applicants, pre-publication drafts of any derivative works must be submitted at least 4 weeks prior to submission for NTD Management Group review and comment on data interpretation.

Any material or manuscript to be published using NTD data must contain appropriate acknowledgements of the NTD. Preferred wording for the acknowledgement will be provided with the data.

Applicants should seek a template and/or logo from the registry for presentations and they are provided on the condition that individual slides are not altered in any way (including background) prior to use.

NTD maintains a record of all requests for NTD data and its subsequent use as a means of monitoring the value of the project to the wider clinical community.

9. Fees

Requests for data will be considered on a case-by-case basis and may be subject to a fee. If a fee is charged, an agreement in writing from the requesting party must be received prior to data being extracted.

In general, requests for data from contributing clinicians, hospitals, and academic organisations will either be waived or calculated on a cost recovery basis that is dependent on the complexity and feasibility of the request/study proposal.

10. Use of NTD Data for Presentations or Publications

1. Where the NTD data is the primary source of data for a report or publication and/or the interpretation of the data is central to the data request, a copy of the manuscript must be submitted to the NTD Management Team and Steering Committee for review at least thirty (30) days prior to the date of proposed submission.
2. The source and treatment of the data should be made clear in the "Methods" section. Preferably the abstract (and keywords if applicable) should also include "National Transfusion Dataset" which would allow for searching project publications.
3. Any potential publication should be circulated to co-authors for review. Any comments should be received within two (2) weeks of initial correspondence for consideration.
4. Individual patients and institutions must never be identified or identifiable by inference in de-identified data unless HREC approval and agreement from the individuals or institutions identifiable in the potential publication has been received.
5. Once accepted for publication, the NTD Management Team must be notified by email (sphpm.ntd@monash.edu), advising of the reference details.
6. The NTD requires that you provide (to the address above) a copy of any document or presentation in which data, figures, or PowerPoint slides are used. The NTD maintains a record of all requests for NTD data and its subsequent use as a means of monitoring the value of the project to the wider clinical community.

11. Use of NTD Slides

Any PowerPoint Slides supplied from the NTD for presentations are provided on the condition that individual slides are not altered in any way (including background) prior to use. The NTD will provide a PowerPoint presentation template for the presentation of all NTD data at conferences and presentations.

12. Acknowledgements

Where the NTD data is the primary source of data for a report or publication, and/or the interpretation of the data is central to the data request:

1. The use of NTD data is to be acknowledged, along with a statement that the analysis and interpretation are those of the author(s), not the NTD.
2. It is expected that at least two members of the NTD Management Team, Steering Committee, Project Manager and/or Principal Investigators are named as a co-author on any publication arising from the use of requested data. The actual contributor(s) to be named would depend on the input to the particular data exercise.
3. Where an author is an NTD representative, authorship should be cited in the following manner: "*John Doe for the National Transfusion Dataset*". This allows for the NTD to be a searchable term in search engines.
4. Authors should use the phrase "*National Transfusion Dataset, Monash University, Melbourne, Australia*" within the research output (manuscript or otherwise) when stating the location of the originating institution.
5. Publications should include information on sources of financial support for research.

6. Where relevant, publications should also include the acknowledgement(s) required by the contributing organisations, including, but not limited to, the ARDC, MRFF, NHMRC Blood Synergy, and individual hospitals.
7. Where relevant, the authors should acknowledge other data sources used for the report or publication according to the source's respective guidelines.

Where NTD data is only a minor portion of the work, it may be more appropriate to acknowledge the NTD explicitly in the "Acknowledgements" section.

13. Authorship Criteria

All persons who make substantial contributions to the manuscript should be offered authorship. Authorship should be discussed openly among investigators as soon as it becomes apparent that the data obtained may be suitable for publication.

Based on the comments received on the draft version(s) of a manuscript the first and last authors will decide together who qualifies for authorship. This decision should conform to the *Australian Code for the Responsible Conduct of Research* and *Monash University Research Outputs and Authorship Policy*.

As a guide, authorship is based on substantial contribution to two or more of the following criteria (as outlined by the International Committee of Medical Journal Editors - ICMJE):

- Conception and design of the research or acquisition of data;
- Analysis and interpretation of the data;
- Drafting of the manuscript, or revising it critically for important intellectual content; and/or
- Final approval of the version for publication.

The use of NTD data is to be acknowledged, along with a statement that the analysis and interpretation are those of the author(s), not the NTD.

14. Declaration of Interests in Research Output

Authors must be aware that perceived or real conflicts of interest (for example, sources of funding or other commercial interests or affiliations) may interfere with the perceived integrity of the research findings of the NTD and Monash University. Therefore, in the confirmation of authorship, all authors must take responsibility for declaring any potential or actual conflict of interest.

15. References

Monash University Research Data Protection and Privacy Collection Statement: https://www.monash.edu/__data/assets/pdf_file/0010/1595269/Research-Data-Management-and-Privacy-Collection-Statement.pdf

Australian Code for the Responsible Conduct of Research: http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/r39.pdf

Monash University Research Outputs and Authorship Policy: http://policy.monash.edu.au/policy-bank/academic/research/research-outputs-and-authorship-policy.html

16. Version History

Date	Document Version	Document Revision History	Author/Reviser
23/05/2018	1.0	Initial Version Release. Approved by the ANZ-MTR Steering Committee on 10/5/2018	ANZ-MTR project staff
30/09/2024	2.0	Revised version updated based on TRU Master Data Access Plan. Updated to NTD project.	Kirsten Caithness and Naomi Aoki

17. Data Request Form – Researcher

Please return your completed application to: **sphpm.ntd@monash.edu**

Part A: Requester Details

Date of Request:			
Type of data request	☐ De-identified aggregate/summary data ☐ De-identified Individual Unit record data		
Short title of data request:			
Principal Requester:		Title:	
Other Investigators:		Titles:	
Affiliation/Organisation:			
Address:			
Telephone/Mobile:			
Email:			
Are you a student	☐ Yes ☐ No		
If YES, what degree are you working towards?			
Name and contact details of your supervisor			
Is this a funded research project?	☐ Yes ☐ No		
If YES, who has funded the project?			
Was the NTD formally involved in the grant application?	☐ Yes ☐ No		
Will the data be used as part of a collaborative project with industry partners?	☐ Yes ☐ No		
Does your project require ethics approval?	☐ Yes ☐ No *If NO proceed to PART B		
If YES have you applied for ethics approval?	☐ Yes ☐ No		
If YES, to which organisation did you submit the application?			
Have you received ethics approval?	☐ Yes ☐ No *If YES, please attach a copy of your approval certificate, a full copy of your application and any other relevant documents such as participant information sheets and consent forms etc.		
What is the anticipated date for project completion?			

Part B: Project Details

Reason for data request. Please note that approval will only be given for the project described in this application. Use of data for any other purpose will require an **additional** request.

Title of project	
Background and rationale for the project (500 word maximum plus key references)	
Hypothesis and specific research questions	
Possible outcomes and clinical significance of this research (250 word maximum)	
Methodology of project (500 word maximum)	

Inclusion and Exclusion criteria	
Statistical plan	
Means of data transfer	
Anticipated timeline for completion or important dates for consideration	
Publication plan	
Have you read the authorship and publication guidelines?	

Part C: Data Fields Required

Please contact the NTD for a list of data fields available.

Data item required	Justification