School of Public Health and Preventive Medicine,
Monash University

National Transfusion Dataset (NTD)

Data Access and Publication Policy

Version 1.0
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Preface

The National Transfusion Dataset (NTD) encourages the use of its data for a variety of purposes such as quality improvement, research and clinical planning. This 'data access and publications' policy defines how data from the NTD may be accessed and conditions regarding publication arising from data obtained. The policy includes the criteria and conditions for provision of aggregate data or de-identified 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 any associated acknowledgement and publishing responsibilities.

The management of data collected and collated by the NTD is guided by strict protocols and procedures to ensure the security, privacy and confidentiality of all information collected and stored in the dataset. All patient and stakeholder information will be handled in accordance with the *Commonwealth Privacy Act (1988),* the *Privacy and Data Protection Act 2014 (Vic)* and the *Health Records Act 2001 (Vic)* and any code of practice or guidelines made under these Acts.

Monash University is custodian of the NTD. Further information about Monash University's Privacy Compliance Framework is available at: https://www.monash.edu/privacy-monash

Project Information

Purpose of the NTD

The purpose of the NTD is to collect clinical and laboratory data on all adult (≥18 years of age) recipients transfused with any type of blood component in order to:

- Expand transfusion data coverage to create the first comprehensive national dataset of transfusion practice linked with transfusion laboratory data and clinical outcomes.
- Strengthen data quality.
- Streamline workflows for data collection to ensure an ongoing up-to-date resource.
- Improve access to transfusion data for stakeholders and researchers.
- Improve Australian transfusion research capacity and efficiency.
- Create new research opportunities (e.g. data for health economics analyses) to inform national transfusion policy and practice, improve blood utilisation and patient management and outcomes.

Project Overview

The NTD will provide valuable observational data regarding the types and frequency of conditions that require transfusion of various types of blood components, variation in practice across different services, hospitals and jurisdictions, incidence of adverse events, and alignment with PBM guidelines.

The NTD will provide information to inform the stewardship of precious resources, help inform policies at government, Blood Service, specialist society, specialist College and institutional levels, in Australia and internationally, and be a resource for the broader community.

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 to be 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)

Access to Data held by the NTD

NTD data is stored centrally within Monash University as Data Custodian. Access to data is subject to applicable privacy laws and principles, and ethics approvals. Specific measures have been put in place to maintain the confidentiality of personal identifying information.

Data access is subject to the approval of the NTD Steering Committee. When considering the approval of access to NTD data, the Steering Committee will seek to balance the importance of privacy protection and the significant public health interest from the proposed research.

Access to the data is subject to the Data Access Request Process outlined in this Section.

Eligible Applicants

Researchers, medical professionals and pharmaceutical professionals working at research institutions, hospitals, private entities, government or other health services are eligible to request access to data held within the database for research purposes. Requests for data are noted and logged in the report tabled at the NTD Steering Committee meetings.

Conditions of Use

1. Only staff within the NTD Project Team, and Monash University biostatisticians associated with the NTD have direct access to the dataset. For operational purposes Monash University IT staff directly involved in supporting database systems have access for new data import, upgrades and break fixes, and are bound by Monash University confidentiality agreements.
2. All other access to NTD data, in whatever context, must receive prior approval from the NTD Steering Committee and/or NTD Project Manager.
3. Data access may be subject to conditions in agreements or research ethics approvals.
4. Individually identifiable data will not be available to parties other than NTD authorised personnel.
5. The provision of data may be subject to a fee for service. Section 3.5 contains the fee for service schedule. Research collaboration with investigators associated with the database will not incur a fee.

6. 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. As a general rule, requests for data will take 2-4 weeks to complete. Requests must first be made to the NTD Project Manager who will consult with the NTD Steering Committee for consideration of the request. Data cannot be extracted until approval is given, relevant ethics approval from participating institutions are in place and any fees-for-service paid, where required.
7. All data must only be used for the purposes outlined in the written request, and as approved by the NTD Steering Committee or NTD Project Manager.
8. No data may be passed onto other researchers, clinicians or any other person not explicitly mentioned in the written data request.
9. Data security and storage remains the responsibility of the NTD Data Custodian. In order to maintain data security and integrity, all raw and/or identifiable data will remain under the custodianship of the NTD Project Team and will remain on the Monash University server.
10. Any material or manuscript to be published using NTD data must be submitted for review by the NTD Steering Committee prior to submission for publication. The NTD, and Partner Organisations should be acknowledged in all publications. Preferred wording for the acknowledgement will be provided with the data. The NTD reserves the right to dissociate itself from conclusions drawn if it deems necessary.
11. If the data is the primary source for a report or publication, the source of the data must be acknowledged, along with a statement that the analysis and interpretation are those of the author, not the NTD. Where an author analysing the data is a member of an organisation formally associated, or partnered with the NTD, the NTD should be acknowledged as a secondary affiliation. Where the author is a member of the NTD Project Team, then the primary attribution should be the NTD. The NTD reserves the right to dissociate itself from conclusions drawn if it deems necessary.
12. Requests must be made in accordance with the data access policy and provide full disclosure in the request form for proposed access and usage of the data. Data access and usage must comply with all conditions in the approval given for data access.

NTD Specific Access Guidelines

Below are additional access guidelines specific to the NTD:

1. Requests to access data must be submitted in writing to the NTD Project Manager using the form provided in this document.
2. Request for access to de-identified patient-level data for an entity to perform their own analysis can be provided in a secure isolated environment (safehaven) managed by Monash. All files will require approval by the data custodian before they can be exported, and only aggregate data (tables, graphs etc) will be approved for export.
3. Request for access to de-identified patient-level data to supplement an existing data set held by a third party may be considered, and if approved will be transferred securely (SFTP).
4. Where only summary data is requested, approval can be provided by the NTD Project Manager. A record of all such requests will be kept, and provided to the NTD Steering Committee on a quarterly basis.

5. Requests for aggregate data require approval of the NTD Steering Committee.
6. Researchers may request the NTD to undertake specific analyses of data. In all cases, the researchers would subsequently be provided with resulting aggregate data only. Requests of this nature would require approval of the NTD Steering Committee.
7. A caveat and conditions of use statement will be provided with all data approvals.
8. If a researcher requires data from a particular hospital(s), registry or linked database, a specific Steering Committee or ethics application approval from that hospital(s), registry or database may be required before data is made available. This ethics approval should be made jointly with the NTD.
9. If a hospital or its representative requests its own data, beyond that available in the Hospital Data Report, this will be provided by the NTD. Data that could specifically identify a patient will be transferred in a secure manager (e.g. SFTP). Requests must be made in writing to the NTD. Whilst such data requests do not require NTD Steering Committee approval, the NTD Project Manager will notify the NTD Steering Committee of the requests.
10. Any party provided with NTD data must agree not to use the data to match, in whole or in part, with any other information for the purposes of attempting to identify individuals, hospitals or patient services, nor will any other attempt to identify an individual be made.

Data Access Request Process

1. All data requests must be formally lodged using the Request Data Application Form via email or post to:

   Email: sphpm.ntd@monash.edu

   Post: National Transfusion Dataset
   c/o Transfusion Research Unit
   Monash University
   553 St Kilda Road
   Melbourne VIC 3004
   AUSTRALIA
2. Upon receipt of the completed and signed form, the data request will be appraised by the NTD Project Team/Project Manager who will consult with the NTD Steering Committee for consideration of the request.
3. There are three possible outcomes of the data access request. The data access request may be approved, approved subject to amendment or declined. If the application is declined, a major revision and subsequent resubmission will be required. Approval subject to minor revision will not require a full resubmission.
4. Upon approval, the NTD Project Manager will liaise with the researcher(s) to undertake the data request.
5. Data provided to the researcher(s) will be accompanied by a statement of the conditions of its use, consistent with this policy.

Fee for Service Schedule

1. The minimum charge is AUD$150 plus 10% GST per hour. This fee is for basic tabulations and data extractions only.
2. Work time will be charged in hourly blocks.
3. Requests for more detailed data extractions, analyses or reports, the TD will provide a cost estimate. This will normally be within 2 weeks of receipt of the request. Those requesting data must agree to these costs (in writing) before any data request will be met.

REQUEST FOR ACCESS TO DATA – RESEARCHER

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

Part A: Requester Details

Date of Request:			
Type of data request	☐ Raw de-identified data ☐ Aggregate data ☐ Other, specify ……..		
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.		

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	

Part C: Data Fields Required

Please contact the NTD for a list of data fields available. NTD is required to maintain patient privacy. No data will be released that could potentially identify patients.

Data item required	Justification

Part D: Applicant's Signature

*I CERTIFY THAT I HAVE READ AND UNDERSTOOD THE NATIONAL TRANSFUSION DATASET (**NTD**) DATA ACCESS AND PUBLICATIONS POLICY. I AGREE TO COMPLY WITH THAT POLICY.*

I AGREE TO UNDERTAKE ALL ACTIVITIES DESCRIBED IN THIS REQUEST IN ACCORDANCE WITH THE RESEARCH PROPOSAL, RESEARCH APPROVAL OF THE REVIEWING HUMAN RESEARCH ETHICS COMMITTEE (HREC) AND ALL RELEVANT STATE AND COMMONWEALTH PRIVACY LEGISLATION RELATING TO PATIENT INFORMATION AND HEALTH RECORDS.

*I AGREE NOT TO USE THE **NTD** DATA TO MATCH, IN WHOLE OR IN PART, WITH ANY OTHER INFORMATION FOR THE PURPOSES OF ATTEMPTING TO IDENTIFY INDIVIDUALS OR HOSPITALS, NOR WILL ANY OTHER ATTEMPT TO IDENTIFY AN INDIVIDUAL BE MADE.*

*I AGREE TO ADHERE TO ALL THE CONDITIONS PLACED ON USE AND STORAGE OF THE DATA AS OUTLINED IN ANY **NTD** DATA ACCESS APPROVAL, WHICH WILL BE PROVIDED TO ME PRIOR TO COMMENCEMENT OF ANY RESEARCH ACTIVITY OR DATA ANALYSIS.*

*I AGREE THAT THE INFORMATION PROVIDED BY ME TO **NTD** IS TRUE, ACCURATE, COMPLETE AND WITHOUT MATERIAL OMISSION.*

*I ALSO AGREE THAT THE INFORMATION PROVIDED TO ME BY **NTD**, WHETHER IN THE FORM OF DATA, REPORTS, MODELS, SAMPLES AND REGARDLESS OF HOW COMMUNICATED OR RECORDED, IS CONFIDENTIAL AND CONFIDENTIALITY OF ALL INFORMATION AND COMMUNICATIONS WILL BE MAINTAINED UNLESS OTHERWISE AGREED BY BOTH PARTIES.*

Name (PRINT): _____

Signature: _____ *Date:* _____

FOR OFFICE USE ONLY:

REQUEST FOR DATA APPROVAL FORM

Short Title of Data Request:	
NTD Steering Committee decision	☐ Approved ☐ Approved subject to amendment ☐ Declined
If approved, subject to approval, list required changes:	
Approved by NTD Steering Committee Chairperson: Signature:_____ Date of approval:	

Document Version Control

Version	Date	Reason/Comments/Approvals
1.0	25/02/2021	Initial Version Release