DATA MANAGEMENT POLICY AND PROCEDURES

National Transfusion Dataset (NTD)

Version 3.0, dated 26 September 2024

Important Note:

The National Transfusion Dataset (NTD) collects identifiable patient data for the purpose of 'data linkage' as outlined in chapter 3.2 of the NHMRC National Statement on Ethical Conduct in Human Research (2007) (updated May 2015). Additionally, as the NTD dataset is extracted from several hospital databases that do not share common identification numbers, it is necessary to retain names and dates of birth in order to identify patients with repeat admissions in different hospitals. The identifiable data is not of scientific interest to the Chief Investigators of the NTD and will not under any circumstances be disclosed, reported or published.

Background

It is an ethical and data custodian requirement that identifiable data be handled (i.e. transferred or accessed) and stored in a secure manner. The NTD Data Management procedures have been developed in accordance with the Monash University "Electronic Information Security Policy" (https://www.monash.edu/__data/assets/pdf_file/0004/784057/Electronic-Information-Security-Policy.pdf). Data collected for the NTD will be managed according to guidelines stipulated by the NHMRC National Statement on Ethical Conduct in Human Research and the Australian Code for the Responsible Conduct of Research (2007) and conforms to Commonwealth and State privacy principles.

NTD Data Management Policy and Procedures

All Monash University staff and researchers involved in the handling of identifiable patient data collected for the NTD are required to adhere to the specified requirements and procedures detailed.

1. The chief investigator(s) of the NTD is/are the data "owner(s)". This person(s) will be listed as the chief investigator(s) on all ethics and data custodian communications.
2. NTD staff, including the project manager, database manager and project officer will have access to data to verify completeness and accuracy of data extracted by hospital data custodians.
3. The NTD statistician will have access to the data to assist with development of the database and analysis of data.
4. Monash University's Clinical Data Management Systems (CDMS) will have access to the data for the purpose of data importation, conversion and linkage and the overall management and security of the NTD database. A representative from CDMS will act as the NTD database administrator.
5. All identifiable data must be provided to the NTD database manager using the secure file transfer service Windows Secure CoPy (WinSCP) program. Further information on WinSCP is detailed in the 'Data Transfer Procedures' section below. Once the data is received, CDMS will upload the data into the MTR database (Figure 1.).
6. Identifiable data must only be used for linkage of data sets and for maintaining the integrity of the NTD database. Analysis of data collected for the NTD must be conducted in accordance with the aims and methods described in ethics applications. As such, researchers are not permitted to interrogate or analyse data for purposes outside of that described in ethics applications.
7. Identifiable data must not be stored by researchers on portable devices including USBs, CD/DVDs, external hard drives or laptop internal hard drives.

Data Transfer Procedures

The data custodian(s) at participating sites with Human Research Ethics Committee (HREC) approval to contribute data to the NTD will be responsible for transferring data for inclusion on the NTD database using WinSCP, a Secure File Transfer Protocol (SFTP) client for Microsoft Windows. Any file transferred to this server will automatically be 128-bit encrypted using Secure Socket Layer (SSL). This ensures the secure transfer of identifiable information between participating hospitals and dedicated Monash University owned servers.

Data Storage of Identifiable Data

Raw hospital data containing identifiable information as well as the NTD database will be permanently stored on a secure, Monash University owned server located at the Clayton Data Centre (Melbourne, Australia). Data stored on this server are backed up nightly and also mirrored on to the server located at the Noble Park Data Centre (Melbourne, Australia).

Data Access and Usage

Identifiable Data

Access to identifiable data collected for the NTD is restricted to the NTD chief investigators, project team, NTD statistician and Monash University's CDMS. Persons not listed on the ethics application will not be given access to identifiable data.

Identifiable data will only be used for the purpose of "Linkage" of data sets as outlined in chapter 3.2 of the NHMRC National Statement on Ethical Conduct in Human Research, and to identify patients with admissions in different hospitals.

Re-identifiable Data

For the purpose of data analysis patients will be given a unique registry identification number to allow distinction of individuals within the database without the use of identifiable information.

Analysis and Reporting

Re-identifiable datasets will be available to the named NTD chief investigators, project team and the NTD statistician for the purposes of developing aggregate data reports and analysis. Reports containing non-identifiable aggregate data will be provided to the NTD Steering Committee, to participating institutions, or used for preparation of scientific manuscripts. Data will not be used in a way that will allow individual patients to be identified. Publication will be restricted to statistical tabulation of aggregate data only.

References

Monash Policy "Electronic Information Security Policy "(https://www.monash.edu/__data/assets/pdf_file/0004/784057/Electronic-Information-Security-Policy.pdf)

NHMRC (2007). *National Statement on Ethical Conduct in Human Research*, Commonwealth of Australia, Canberra. Chapter 3.2; Databanks.
http://www.nhmrc.gov.au/publications/synopses/e72syn.htm

NHMRC (2007). *Australian Code for the Responsible Conduct of Research*, Commonwealth of Australia, Canberra. Section 2; Management of Research Data and Primary Materials.
http://www.nhmrc.gov.au/publications/synopses/r39syn.htm

Relevant links

WinSCP
http://winscp.net/eng/docs/introduction

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History of changes to ANZ-MTR/ NTD Data Management Policy and Procedures

Version	Date	Author	Summary of Revisions
1.0	28/06/11	Dr Amanda Zatta	MTR Data Management Policy and Procedures document finalised and locked (pdf version)
2.0	08/08/12	Ms Naomi Aoki and Dr Amanda Zatta	Updated to reflect changes to the transfer of identifiable data using SFTP
2.1	20/03/18	Dr Rosemary Sparrow Dr Cameron Wellard	Updated
3.0	26/09/2024	Ms Kirsten Caithness	Updated to reflect changes to the Project Outline (Version 3.0) including name change from ANZ-MTR to NTD