AuSDaT
AUSTRALIAN STROKE DATA TOOL

Policies and Procedures

Australian Stroke Coalition

Version 5.1 October 2022

Contents

Introduction

The Australian Stroke Coalition (ASC) has identified that improving quality of care for stroke in Australia will be facilitated if we can improve existing data systems and better use data collection to inform quality improvement activities. The ASC has endorsed a vision for ‘standardised, funded, mandated data collection driving quality improvement’.

A major piece of work occurring as part of this collective action was the development of the Australian Stroke Data Tool (AuSDaT). This online integrated data management system facilitates centralised collection of standardised data across multiple programs for patients hospitalised with stroke or transient ischaemic attack (TIA) in Australia. The intent is to support existing and future programs that monitor health care and improve pre-hospital, acute and rehabilitative care. The result is improved health outcomes for patients from a reduction in unwarranted variations in care. The AuSDaT will also provide the benefit of facilitating efficient data collection for research purposes.

The Stroke Foundation and Australian Stroke Clinical Registry (AuSCR) jointly own and manage the AuSDaT in accordance with the terms and conditions outlined in the Relationship Deed.

Participating AuSDaT programs

These programs fall into two types: permanent programs (listed below) and time-limited programs.

Time-limited programs are short term projects or research trials which may wish to collect data, but not on an ongoing basis, and would benefit from the efficiencies in utilising this infrastructure.

Four permanent programs along with the ASC have contributed to the development of the AuSDaT. All groups are committed to maintaining a central web platform for stroke data collection in Australia. The four permanent programs are:

- The Stroke Foundation audit program (clinical and organisational audits) (https://www.strokefoundation.com.au/what-we-do/treatment-programs/stroke-data-collection/)
- The Australian Stroke Clinical Registry (AuSCR) (http://www.auscr.com.au)
- The Safe Implementation of Treatments in Stroke (SITS) (https://sitsinternational.org/)
- The International Stroke Perfusion Imaging Registry (INSPIRE) (http://www.inspire.apollomit.com/)

Aims of the AuSDaT

The ASC and the AuSDaT programs agree that the aims of the AuSDaT are to:

- Standardise the collection of stroke data using the same data definitions to maximise the utility and comparability of the data across programs, hospitals and time periods.
- Reduce the data entry burden through centralised data entry for multiple programs, where variables overlap.
- Reduce duplication of effort between programs now and into the future.
- Where possible, have a common system that can import data from existing hospital patient information systems.
- Enhance the quality (accuracy and reliability) of data collected through having consistent data logic checks and rules.

- Provide a system for hospitals to collect data of interest to them and enable them to export the data that they enter.
- Provide a range of real-time web-based summary reports based on the core national data collected and benchmarked against national performance.
- Have consistent data for use in publications and presentation of results, where relevant.

Further AuSDaT information

Further information about the AuSDaT including the aims and objectives, governance, participating programs, and data dictionary can be found at http://australianstrokecoalition.com.au/ausdat/.

Overview and interaction of policies

The policies related to the AuSDaT have considerable overlap and readers are encouraged to cross reference the relevant policies as noted in the following table.

	Communications	Complaints	Consumer and community participation	National stroke data dictionary operations	Publications	Data request	Data security	Intellectual property	Patient follow up	Quality assurance and data management	New program	Data custodian and inter-program data sharing
Communications				X	X							
Complaints			X									
Consumer and community participation		X					X					
National stroke data dictionary operations	X								X	X	X	X
Publications	X					X		X		X		X
Data request					X		X					X
Data security			X			X						X
Intellectual property					X							X
Patient follow up				X						X	X	X
Quality assurance and data management				X	X				X			X
New program				X					X			X
Data custodian and inter-program data sharing				X	X	X	X	X	X	X	X	

List of key acronyms

ABS	Australian Bureau of Statistics
AIHW	Australian Institute of Health and Welfare
ASC	Australian Stroke Coalition
AuSCR	Australian Stroke Clinical Registry
AuSDaT	Australian Stroke Data Tool
AWS	Amazon Web Services
HREC	Human Research Ethics Committee
INSPIRE	International Stroke Perfusion Imaging Registry
ISO/IEC	International Organisation for Standardisation/International Electrotechnical Commission
MDL	Master Data List
METeOR	Metadata Electronic Online Repository
NDI	National Death Index
NHMRC	National Health and Medical Research Council
NSDD	National Stroke Data Dictionary
QA	Quality assurance
QI	Quality improvement
SITS	Safe Implementation of Treatments in Stroke
TIA	Transient ischaemic attack
TLS	Transport Layer Security
USB	Universal Serial Bus

1. Communications Policy

Purpose and scope

The purpose of this Communications Policy is to provide guidelines to whom, and how, information about the AuSDaT is communicated.

The aims of this policy are to support effective communication with stakeholders, especially users, to reduce the likelihood of mixed messages and to ensure efficient use of resources across programs.

This policy should be read in conjunction with the AuSDaT Publications Policy.

Background

There is an agreed commitment to effectively collect, use and disseminate (within ethical and legal boundaries) findings from the data collected via the AuSDaT. Communication between the AuSDaT programs is fundamental to the aims and objectives of the AuSDaT, particularly to that of reducing duplication of effort.

Communications in this policy relates to any exchange of information, in various formats, with stakeholders who include program coordinators, central AuSDaT staff, hospital users, patients and their family/relatives, the general public, researchers, media and government stakeholders.

Guidelines and responsibilities

- The AuSDaT Coordinator, in conjunction with the AuSDaT Coordinating Committee, and where appropriate, the program coordinators and ASC, will develop and circulate communications to relevant stakeholders, as required e.g. when new features become available on the tool.
- Any communication will include references to the relevant programs and the AuSDaT as the tool used to collect data.
- Individual program coordinators are responsible for communication with respect to matters relating to their own program. Consideration should be given to other programs and the impact on the hospital coordinators in particular, given the potential overlap between programs.
- Where media releases or enquiries relate to more than one program, they will be forwarded to, and managed by, the AuSDaT Coordinator. The AuSDaT Coordinator will consult with the relevant programs to gather the agreed data and messages, draft communications and gain sign off from involved programs, the AuSDaT Coordinating Committee or the ASC as relevant. Media releases relating to more than one program will be included in the communications register.
- Communications relating to the AuSDaT generally (e.g. requests for changes to the National Stroke Data Dictionary, uptake and changes to functionality) will be coordinated by the AuSDaT Coordinator with assistance where required from the AuSDaT Data Manager. These communications may involve relevant program coordinators and will include any agreed timeframes for data cleaning and the availability of clean data for use in reporting.
- Each program is responsible for the reports and publications they produce (refer to the AuSDaT Publications Policy) using data that are cleaned and approved for public reporting by the AuSDaT Data Custodian (in consultation with the program data custodians).
- Communication with government will be the role of the AuSDaT Coordinating Committee via a nominated spokesperson. Representation to government for funding of the AuSDaT and other support for the AuSDaT will involve the Florey Neurosciences

Institute (as the AuSDaT Data Custodian) and the Stroke Foundation liaising with the AuSDaT Coordinating Committee prior to undertaking these activities, as appropriate. Efforts in this regard will be coordinated and avoid duplication.

Table 1. Functions and delegations

Position	Delegation/Task
ASC	Ensure compliance with Communications Policy. Contribute to internal and external communication strategies and activities. Advise and, where relevant, approve media releases (or delegating responsibility to the AuSDaT Coordinating Committee or AuSDaT staff) and recommend appropriate spokesperson to talk to media regarding AuSDaT issues.
AuSDaT Coordinating Committee	Ensure compliance with Communications Policy. Contribute to internal and external communication strategies and activities. Assist AuSDaT staff to draft media releases that apply across programs. Endorses draft media releases where delegated from ASC. Assist with AuSDaT communications.
AuSDaT Coordinator (and other AuSDaT staff)	Ensure compliance with Communications Policy. Contribute to internal and external communication strategies and activities. Actively contribute/write articles and collate items of interest for the AuSDaT's communications. Keep a register of media linked to the AuSDaT which is available to all programs.
Program Coordinators	Ensure compliance with Communications Policy. Contribute to internal and external communication strategies and activities. Coordinate media releases or respond to media requests that are related to their specific program. Assist AuSDaT staff to draft media releases that apply across programs (as part of the AuSDaT Coordinating Committee).

Related AuSDaT policies

National Stroke Data Dictionary Operational Policy

Publications Policy

2. Complaints Policy

Purpose and scope

This Complaints Policy provides guidelines for responding to, and dealing with, complaints associated with the AuSDaT and/or its associated permanent or time-limited programs.

What is a complaint?

A complaint is an expression of dissatisfaction or concern about a service. Complaints related to any aspect of the AuSDaT and its associated programs may be made by, or on behalf of, a patient or their family/carer, data collector/user based at a hospital, hospital executive, other health administrator (e.g. ethics or governance officers) or other individual/organisation. Complaints may be made in person, by telephone, email, or letter. It is possible some consumers may complain through their treating hospital. People may complain in order to prevent an incident or its recurrence, or to receive an apology.

What is resolution?

Resolution is the desired outcome of a complaint. It is a responsive process that seeks to address a person’s concerns and any accompanying emotions. The process involves complaints being acknowledged, assessed, responded to, and resolved.

Procedures for investigating complaints

Each Program will have their own internal complaints management policy or process and all complaints will be managed accordingly.

A complaint directed to the AuSDaT Coordinator, or received by a program coordinator who believes the complaint relates to the AuSDaT or another program is to be managed as follows:

- The complaint is to be registered on the Complaint Action Form and reviewed to determine if it relates to a single program or more than one program. This process will be undertaken by the AuSDaT Coordinator.
- If the complaint relates to a single program, it is to be forwarded to the relevant program coordinator and dealt with in accordance with the specific complaints management policy of that program.
- If the complaint relates to more than one program, it is to be forwarded to each of the relevant program coordinators. The AuSDaT Coordinator and, if appropriate, the AuSDaT Data Manager will facilitate a meeting (face to face or via teleconference) and document the actions agreed to for resolving the issue/s. If consensus cannot be reached in this forum, the AuSDaT Data Custodian will be informed, and the matter will be referred to the AuSDaT Coordinating Committee for resolution.
- There may be occasions where internal meetings will be insufficient, and a meeting may be required with an external body or the complainant. These meetings will be coordinated by the AuSDaT Coordinator.

Documenting the complaint and its management

All complaints are to be documented by the AuSDaT Coordinator on the Complaint Action Form. This form is designed to track the progress of individual complaints and provides a record of any communication and actions in relation to the complaint, including dates of receipt, related actions and resolution of the complaint. All Complaint Action Forms should be kept in an Issues Register maintained by the AuSDaT Coordinator.

If the response is related to a single program, the program coordinator is responsible to document and submit to the AuSDaT Coordinator the response/resolution taken in order to update the register (or close the issue).

Improving AuSDaT processes and procedures to avoid future complaints

The AuSDaT Coordinating Committee will review all complaints and related resolution, as required , and determine whether the resolution will ensure the same problem(s) do not arise in the future. The sharing of complaints will aid in improving individual programs and the whole initiative. It is important that there is an opportunity to learn from each other about issues and solutions as they arise.

The AuSDaT Coordinator will provide a copy of the Complaints Register to the ASC to be tabled as part of their regular meetings. Program coordinators may be requested to attend these meetings to discuss the nature of the complaint and the response/resolution undertaken.

Related AuSDaT policies

Consumer and Community Participation Policy

AuSDaT COMPLAINTS REGISTER

Date received	Complainant category	Source Eg ph call, email	Hospital	Issue/complaint	Action taken	Outcome	Date resolved	Staff involved

Complaint Action Form

Details of receipt of complaint

Date of complaint: ______________________________ Time: ___________________________

Complaint received by: ____

Method by which complaint made:

☐ Phone ☐ In person ☐ Letter ☐ Email ☐ Other (details)_______________________________

Details of the person/organisation making the complaint

Name:

____

Address:

____

____

Phone: _________________ Mobile:_________________ Email: ______________________________

Details of complaint

Brief description of event/complaint (attach email or letter for full details)

____

____

____

____

Was the complaint registered in the Issues Register? ☐ Yes ☐ No Date: ____________

Complaint type (tick which applies):

☐ Single program? Program: ______________________

☐ Multiple program? Programs: _____________________

☐ General complaint (not program specific)

Complaint acknowledgement emailed: Date: ____________ Time: ___________

Action

Placed on agenda for the next AuSDaT Coordinating Committee meeting: ☐ Yes ☐ No

Program coordinator/s contacted: ☐ Yes ☐ No Date/s contacted: ___________

Action deemed necessary: ☐ Yes ☐ No

Other:____

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3. Consumer and Community Participation Policy

Purpose and scope

This Consumer and Community Participation Policy outlines how consumer participation in the AuSDaT is encouraged and managed.

This policy should be read in conjunction with the AuSDaT Complaints Policy and the Data Security Policy.

Definitions

The term ‘consumer’, in relation to stroke, can mean different things to different people. The following definition was used for the purposes of this policy:

> *A consumer is a person who has experienced a stroke (or TIA), or is a caregiver, family member or friend of a person with stroke, or is a member of a community organisation representing stroke consumers’ interests (e.g. local stroke support groups). A consumer is able to voice the consumer perspective, from the position of a patient who has experienced a stroke or TIA.*[1]

The main attribute that these people share is that they are not usually a researcher or health professional. Their main experience of stroke is as a health consumer or community member.

Consumer and community participation include consumer and community involvement in policy formation, and relevant advocacy. The AuSDaT uses both *participation* and *consultation* as methods of including consumer and community involvement.

Participation is about being part of the process. It is about more than observing and commenting on processes but comprises actual involvement in committees or forums, written contributions to documents or the development of policies.

Consultation is when consumers are asked for their view or opinion from the perspective of the group, they state they are representing. Consultation is a level of participation in which people are offered to make contributions about choices on what is to happen but may not be involved in developing additional options or actions.

Consumer and community participation in the AuSDaT

The AuSDaT collects consumer (patient) information and protection and management of this data is paramount (refer to the Data Security Policy). Where programs collect identifiable data, consent may be requested, or an ethics approved opt-out or waiver of consent may be in place. Depending on the program there may be the opportunity to request that personal data is not stored within the database. There will also be a process available for participants and their family/carer if they are dissatisfied with their involvement (refer to Complaints Policy).

The ASC and AuSDaT Coordinating Committee believe that direct consumer participation aids the development and maintenance of a high-quality and relevant data system. Consumers work in collaboration and partnership with the ASC and the AuSDaT Coordinating Committee, who use both participation and consultation to engage consumers in the following potential ways:

- Consumer representative membership on the ASC and AuSDaT Coordinating Committee: at least one consumer representative member on each committee who voices the consumer perspective and participates in the decision making process on behalf of consumers.

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[1] AuSCR Statement on Consumer and Community Participation Version 2.1–Approved 29 August 2012

- Consumer consultation on relevant aspects of the AuSDaT operations including documentation such as patient consent and information forms, reports or other publications.
- Links to “consumer” version of documents will be available on the AuSDaT page of the ASC website. These will include:
  - Outlines of each program using the AuSDaT with reference to the benefits provided, and any risks involved, in the applicable programs;
  - One page summaries of national reports; and
  - Summaries of research projects using data from the AuSDaT.

Each program will encourage and manage consumer and community participation according to this policy and any individual program policy or procedures.

Consumer interest

People who have expressed interest in being involved in consumer participation and/or consultation for the AuSDaT, may be contacted by the AuSDaT Coordinator from time to time. Additionally, the ASC or AuSDaT Coordinating Committee may source consumer representatives to join one or both groups as appropriate. The collection and/or storage of any personal information about consumers who are involved, or are interested in becoming involved, will meet the relevant privacy legislation requirements.

Where consumers seek to receive regular information from programs involved in the AuSDaT, individual programs should have their own policies/processes in place to meet that demand.

Related AuSDaT policies

Complaints Policy

Data Security Policy

New Program Request Policy

4. National Stroke Data Dictionary Operational Policy

Purpose and scope

The National Stroke Data Dictionary (NSDD) provides standardised definitions, codes, and recording guidance for data items collected in the AuSDaT, to ensure that variables are interpreted consistently, and to maximise the quality of the data collected. This approach is to ensure the usefulness and comparability of the data across programs and hospitals. The NSDD lists all the endorsed data elements available in the AuSDaT, their definitions and recording advice/help notes, and nationally agreed indicators for stroke care. Variables are endorsed by the AuSDaT Coordinating Committee and ASC if they are deemed to be valid and clinically relevant. The NSDD Operational Policy provides guidance regarding the addition and modification of data elements within the AuSDaT. This policy applies to all permanent and time limited programs and should be read in conjunction with the AuSDaT Data Custodian and Inter-program Data Sharing Policy, Patient Follow Up Policy, and the Quality Assurance and Data Management Policy.

Selection of existing NSDD elements

Program coordinators will be able to select the data elements from the Master Data List (MDL), which lists all of the variables available in the AuSDaT, to be collected through their program as agreed (refer to the AuSDaT Data Custodian and Inter-program Data Sharing Policy).

Implementing new NSDD elements or changes to the NSDD

- The NSDD will be reviewed annually and any agreed changes applied during this process. Changes outside this review may be considered only in special circumstances at the discretion of the AuSDaT Coordinating Committee or ASC.
- Any programs or groups wishing to propose any changes or additions should allow significant lead time (e.g. at least six months) in order to accommodate any ethics changes or requirements, development, testing and deployment.
- Addition of new variables and changes to data elements and/or definitions will only be made after careful consideration of the impact of such changes including costs associated with the change and the ability to compare data across jurisdictions, programs, and/or time periods.
- Proposed new data elements should aim to be compliant with the Australian Institute of Health and Welfare (AIHW) or the Australian Bureau of Statistics (ABS) standard definitions if available (e.g. National Health Data Dictionary or the National Data Standards -METeOR (Metadata electronic Online Repository) : www.meteor.aihw.gov.au/).
- Where a request to change or add data elements is made, costs will be borne by the program requesting the change or addition (or as otherwise agreed in writing).

Data analysis and nationally agreed indicators

- It is the responsibility of individual programs to share information on how data analyses using common variables are undertaken so indicators are derived in the same way and can be compared between programs, regions etc. – refer to the Quality Assurance and Data Management Policy).
- Agreed national indicator details (including what is included in numerator and denominator) will be published within the NSDD to ensure consistency.
- Consideration of collective national data analysis will be undertaken in the future (e.g. reporting of the AuSCR and Stroke Foundation audit data, national SITS data) using agreed standardised analysis methodology and processes as noted above.

Procedure for adding or modifying a data element

- Any potential change should be initially discussed with the AuSDaT Coordinator and/or AuSDaT Data Manager who will advise on the next annual review date for the NSDD. The procedure for review along with governance of the process should be outlined during this initial discussion.
- Should a change or addition be made, the program or group will submit a *Request to change the AuSDaT Master Data List* form, electronically to the AuSDaT Coordinator.
- The AuSDaT Coordinator will manage referral of change requests to the AuSDaT Coordinating Committee and flag with the relevant program coordinators (those programs using these data elements) who will be required to consult with their own program's data custodian and governance committees.
- The request will be considered by the AuSDaT Coordinating Committee who will decide if a proposed data element should be added or changed in the AuSDaT and the feasibility of adding/changing the data element. The Committee will consider factors such as cost, degree of difference, impact on comparing to historical data, and overall risk of change.
- Once agreed to by the AuSDaT Coordinating Committee the request will be presented to the ASC for consideration and final approval. Further consultation with programs or external groups/organisations may be required before final approval.
- The decision of the ASC will be communicated to the requesting program coordinator or group. If approved, the AuSDaT Coordinator and/or AuSDaT Data Manager will coordinate the required changes in the AuSDaT.
- Each program and other users of the AuSDaT will be informed of any changes to the MDL.

Related AuSDaT policies

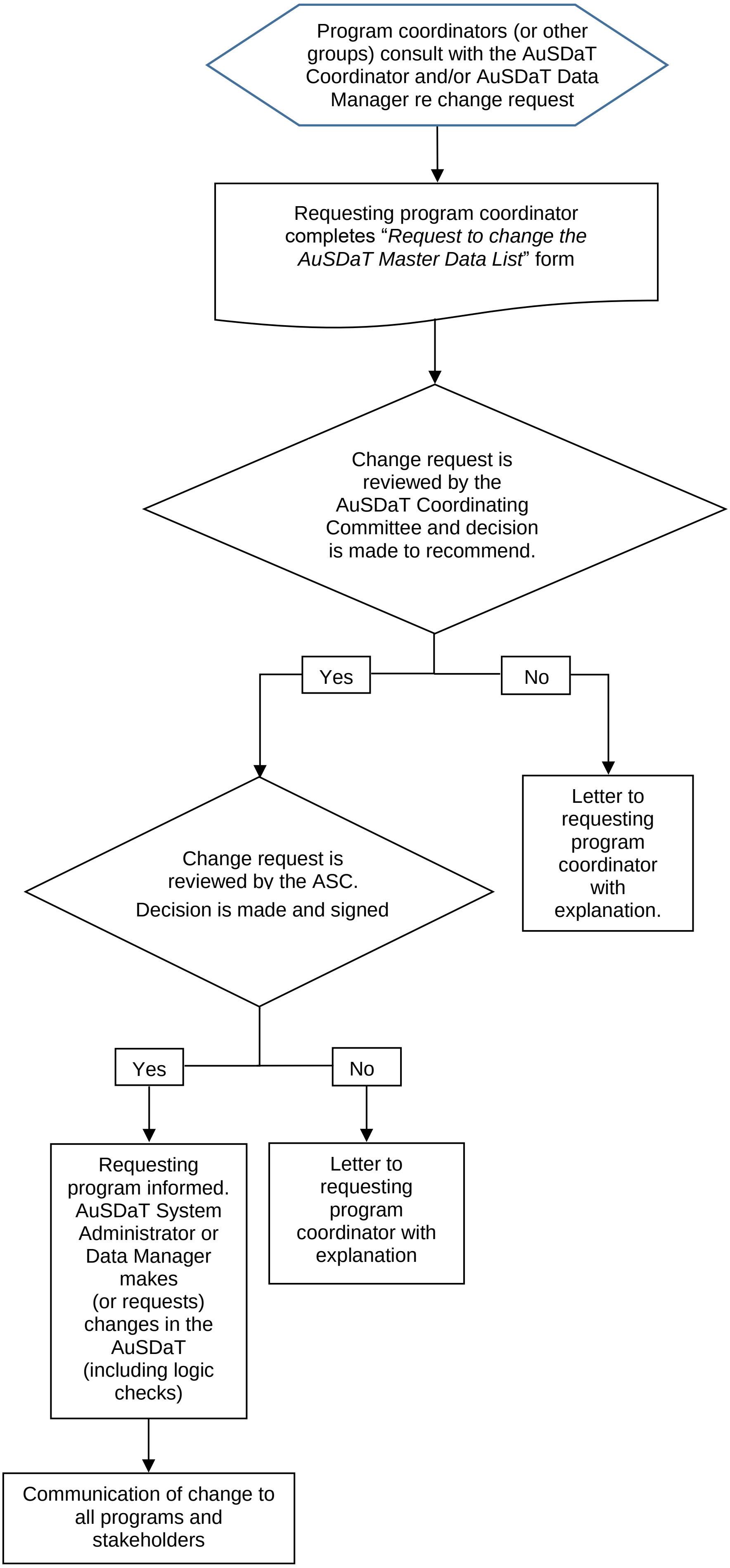
Communications Policy

Data Custodian and Inter-program Data Sharing Policy

Quality Assurance and Data Management Policy

Patient Follow up Policy

Flow chart for decision making regarding requests to modify the NSDD



Request to change the AuSDaT Master Data List

Program/project name: ______________________

Principal investigator name: ______________________

Organisation name: ______________________

Principal investigator ph number: ______________________

Principal investigator email: ______________________

Date request submitted: ______________________

Type of change to data element (please tick) ☐ Addition ☐ Modification

AuSDaT reference number for data element: __________ N/A (new element) ☐

Name of new data element: ______________________

Rationale/justification of change:

____

____

____

Source of data (e.g. METeOR or program source):

____

____

Change requested by date: ______________________

Additional information (e.g. implications for other programs etc):

____

____

____

Please submit this request via email to AuSDaT@florey.edu.au

AuSDaT office staff use only

Date reviewed by AuSDaT Coordinating Committee: ______________________

Comments/recommendations (including cost implications):

____

____

____

Date considered by the ASC: ______________________

Comments (if applicable):

____

____

____

Final decision: ☐ Approved ☐ Not approved Date applicant informed: ______________________

5. Publications Policy

Purpose and scope

This Publication Policy provides guidelines for the publication of the data collected in the AuSDaT. This policy applies to AuSDaT staff, members of the ASC, the AuSDaT Coordinating Committee, staff and investigators associated with the AuSDaT permanent and time limited programs, and any other individual or group requesting access to data collected in the AuSDaT.

This policy should be read in conjunction with the AuSDaT Data Request Policy, Quality Assurance and Data Management Processes Policy, and Intellectual Property Policy.

Appropriate acknowledgement of the AuSDaT

All publications relating to a single program will be managed by the relevant program coordinator/program team and restricted to data and analysis associated with that program.

Any publication using data from more than one program will need to gain approval as per the Data Request Policy. The publication in this instance must acknowledge the program/s which contributed data and in accordance with the Data Sharing Agreement.

All publications will acknowledge the AuSDaT as the data collection tool used.

One of the following two referencing styles should be used where information about the AuSDaT is being used to describe the tool:

1. Reference the website: Australian Stroke Data Tool https://australianstrokecoalition.org.au/projects/ausdat/ access date

2. Reference the fact sheet e.g. AuSDaT Coordinating Committee, AUSTRALIAN STROKE DATA TOOL (AuSDaT) INTRODUCTORY FACT SHEET, Florey Institute of Neuroscience and Mental Health, version 11 November 2016, Melbourne, Australia.

If a publication is acknowledging the AuSDaT as the data collection tool, the following format can be used:

> Data presented in this report for “Program Name” were obtained using the Australian Stroke Data Tool (https://australianstrokecoalition.org.au/projects/ausdat/).

The relevant program coordinator is responsible for reminding researchers to include the appropriate reference and acknowledgement of the AuSDaT in their publications.

If a publication is using data from more than one program, the AuSDaT Coordinator will provide this reminder.

All publications will include a statement of the date that data were extracted from the AuSDaT by the relevant program and the date range of data contained within a publication or presentation.

Plans for disseminating AuSDaT information

Sharing AuSDaT data with the general scientific community is encouraged. A draft of the full publication will be reviewed and noted by the AuSDaT Data Custodian on behalf of the AuSDaT Coordinating Committee. This review is to ensure the authors have correctly acknowledged the use of the AuSDaT data collection tool, the program/s which contributed data, and the extraction and data analysis date contained within a publication, according to this publication policy.

All publicly available publications derived from the AuSDaT will be promoted on individual program websites as appropriate and/or on the Florey or ASC websites. The relevant program and researchers authoring the publication will be clearly acknowledged. Journal publications that have copyright restrictions will be available on the website in the manner that is permissible by that publisher e.g. web link.

Related AuSDaT policies

Communications Policy

Data Request Policy

Quality Assurance and Data Management Processes Policy

Intellectual Property Policy

Data Custodian and Inter-program Data Sharing Policy

6. Data Request Policy

Purpose and scope

The Data Request Policy defines how data, collected through authorised participating programs, can be obtained by third parties for secondary purposes. This policy includes the criteria, conditions, and limitations for procedures to be followed when requesting data extracts from the AuSDaT programs, and the fees for providing these services by the coordinating office. The aims of this policy are to streamline and centralise administration of all requests for archived data available from the AuSDaT.

This policy should be read in conjunction with the AuSDaT Publications Policy and the AuSDaT Data Custodian and Inter-program Data Sharing Policy.

Requests and ethical requirements

The underlying principle of the AuSDaT is that data collected should be used wherever possible to promote improved stroke care. However, irrespective of whether an activity is for quality improvement (QI), evaluation, or research, the activity must be conducted according to ethical principles and guidelines (NHMRC, 2014[2]).

All requests for data by a third party usually need to be assessed by an ethics committee as either requiring a full, low risk, or exemption approval process.

Triggers for consideration of different types of ethical review include (NHMRC, 2014[2]):

- Where the activity potentially infringes the privacy or professional reputation of participants, providers or organisations.
- Secondary use of data - using data or analysis from QI or evaluation activities for another purpose (e.g. research projects by external researchers).
- Gathering information about the participant beyond that which is collected routinely. Information may include bio specimens or additional investigations.
- Testing of non-standard (innovative) protocols or equipment.
- Comparison of cohorts.
- Randomisation or the use of control groups or placebos.
- Targeted analysis of data involving minority/vulnerable groups whose data are to be separated out of that data collected or analysed as part of the main QI/evaluation activity.

Any research request or a request that triggers the need for formal ethical review (i.e. it has one or more of the triggers listed above) for data will only be considered where all the relevant documentation is provided as outlined in this policy (see requirements for requests for data for research or evaluation purposes, section below). It is recommended that any initial consideration for requested data be discussed with the relevant program coordinator or the AuSDaT Coordinator before preparing an ethics application.

Confidentiality of information

Information held by the AuSDaT is confidential. All applicants who have requests for data approved will be required to sign the *Conditions of Release of Data* form (see below). This document will outline what the researcher or other party requesting data (e.g. state clinical

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[2] National Health and Medical Research Council (NHMRC) 2014. Ethical Considerations in Quality Assurance and Evaluation Activities.

networks) can and cannot do with the data, and ensures a process for review of any publications using data from the AuSDaT (including the use of hospital level data).

Procedure for all requests for data from the AuSDaT

Requests for data extracts from the AuSDaT, where data from more than one program are requested, must be submitted to the AuSDaT Coordinator using the *“Expression of Interest to Request Access and Use of Data collected via the Australian Stroke Data Tool (AuSDaT)”* form (refer below).

The AuSDaT Coordinator will screen the Expression of Interest (EOI) form and determine if the request relates to one program only or involves data from more than one program.

a) If the request relates to data from a single program only, the EOI form will be directed to the relevant program coordinator who will manage the request in accordance with that program’s policies and procedures.

b) If the request relates to data that is from more than one program and is not overlapping, the AuSDaT coordinator will request that the applicant provides further details by completing the *“Application for Access and Use of Data collected via the Australian Stroke Data Tool (AuSDaT)”* form. Once received, this application will initially be reviewed by the AuSDaT Coordinator to ensure all requested information (including ethics clearances) is included. If all relevant information is present, the AuSDaT Coordinator will confirm receipt of the application and then proceed to process the request with all relevant program coordinators. If there are not additional clarifications required from any of the individual programs and it is approved at that level; then the application is progressed to the AuSDaT Coordinating Committee for final approval and ratification.

Data export and provision of data will be coordinated by the AuSDaT Data Manager in accordance with the AuSDaT Data Security Policy.

Only data that have been cleaned, locked and made part of the AuSDaT archive database will be provided unless exceptional circumstances apply.

Any requests for data made by a third party located outside of Australia will require the Florey’s and Stroke Foundation’s review and approval before releasing the relevant data to this third party. The AuSDaT coordinating committee will also be required to review the request, in line with the relevant AuSDaT policies and procedures.

Requirements for requests for data for research or evaluation purposes

All requests for access to the AuSDaT must be made in writing and include the following information (refer to template of application below):

- Project title
- Principal investigator/co-investigators
- Project description (not to exceed two (2) pages, including references and tables).This information should be provided in the form of an extended abstract, including purpose, specific aims or research questions/hypotheses, background, methods including approach to the data analysis, source of funding, and dissemination plan (i.e. publication outlets, presentations) and should discuss the following items:

    - A 100 word summary, in lay terms, that also describes how consumers may benefit from the research.

  - The final list of variables and their NSDD/MDL codes to be used in the analysis, and where relevant, a description of how the risk-adjusted outcome analysis will be undertaken.
  - The format of the dataset to be supplied including any analytic software specific requirements.
  - The resources available for the project at the investigator/s institution/s.

- List details of the Human Research Ethics Committee (HREC) approval or exemption and attaching copies of the letters of approval or exemptions.
- Detail the requirements of the AuSDaT support that will be required to complete the project. This may include support provided for data extraction or statistical analyses that the investigators anticipate will be necessary from the AuSDaT staff. This should be discussed prior to submission, so a quote can be prepared by the AuSDaT Coordinator in consultation with the AuSDaT Data Custodian and the details included in your submission.
- Detail the desired timeframe for receipt of the data and when the project is anticipated to be completed, including journals the results might be submitted for potential publication.

Review Criteria

A review process will be conducted to determine: that the request for data has relevant approvals and governance clearance; there are sufficient resources available to fulfil the objective of the request within the desired timeframe; the source of the request for data (i.e. industry or academic); the intended use of the requested information and results derived from the data; and whether there is any overlap with other projects using the archived data obtained from the AuSDaT, will be taken into consideration.

Review Process for all requests requiring consideration

See diagram below for review and decision making process.

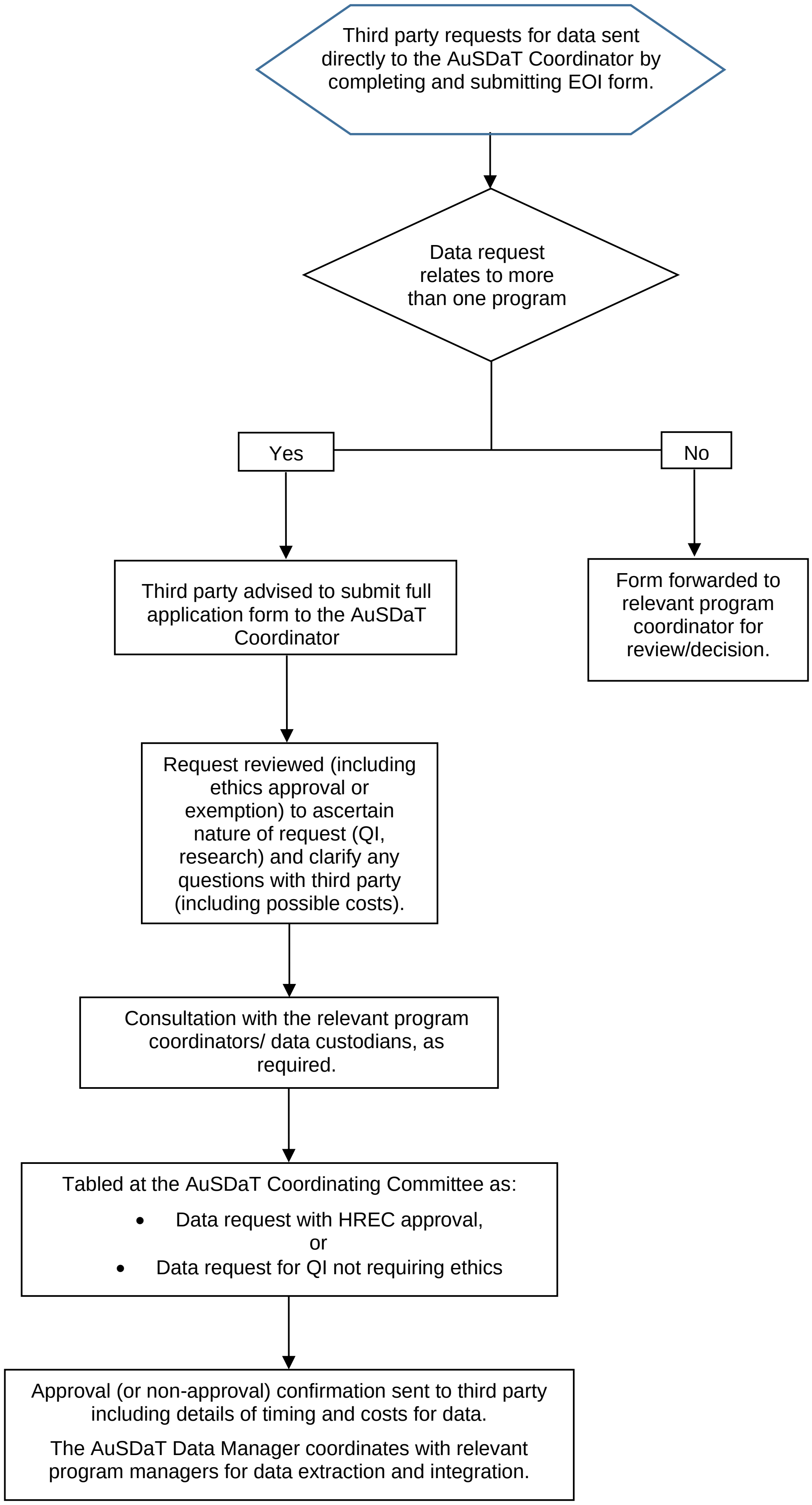
Related AuSDaT policies

Publications Policy

Data Security Policy

Data Custodian and Inter-program Data Sharing Policy

Decision making process regarding requests for data from the AuSDaT



AuSDaT
AUSTRALIAN STROKE DATA TOOL

Expression of Interest for Access and Use of Data Collected via the Australian Stroke Data Tool (AuSDaT)

Applicant Information	Ref no.	Date

Applicant's name:	Title:
Principal investigator/s;	
Position:	Department:
Mailing address:	Organisation:
Phone(s):	Fax:
Email:	Pager:

Project and Data Request Details

Project title

AuSDaT data required:

All applicants should review the Master Data List, highlight the variables that they require, and attach this to the completed Expression of Interest form.

Signatures

This project has been approved by my organisation / supervisor ☐ **No** ☐ **Yes**

Applicant's signature:	**Date:**
Supervisor name:	**Position:**

Email completed EOI form and Master Data List to
AuSDaT@florey.edu.au

Application for Access and Use of Data Collected via the Australian Stroke Data Tool (AuSDaT)

Section 1: Applicant Information	Ref no.	Date
Applicant’s name:	Title:	
Principal investigator/s:		
Position:	Department:	
Mailing address:	Organisation:	
Phone(s):	Fax:	
Email:	Pager:	

Section 2: Overview of Project & Request

Project title

Project description including references and tables (no more than 2 pages in total). Please provide in abstract format (background, aims and objectives, methods, source of funding and dissemination plan.

Please provide a final list of variables and the corresponding Master Data List codes available in the NSDD (as an attachment). Describe the planned data analysis methodology and methods for any risk-adjusted outcome analyses. Indicate if support for this or other aspects of the work is to be undertaken with input by the AuSDaT team or a third party (e.g. consultant statistician).

Data start date:	Data end date:

List intended uses of the data / information (including anticipated publications, reports, presentations, analyses etc.):

Add (or attach) a 100 word lay summary of project:

Date by which data / information / records are required:

Date anticipated completion of project:

Detail the expected hours of AuSDaT support that will be required:

Section 3: Ethics (if applicable)

List details of the Australian Health Research Ethics Committee(s) approval(s) and include the protocol number(s):

Please attach copies of letters of approvals and all correspondence (including any conditions imposed).

Section 4: Data Security Requirements

I agree that when using the data I receive, I will:
- use the information only for the research purpose stated in their application
- store the information in a secure manner and only for an agreed time period related to the purpose of the research
- not provide the information to any other person other than the associate researchers nominated in the application
- not seek to identify individual patients by any process, including by attempting linkage with another data set.

Please note: A signed copy of the Covenant of Confidentiality must also accompany this application. This form must be signed by **all** persons who will have access to the data.

Section 5: Signatures

This project has been approved by my organisation / Supervisor ☐ ***Yes*** ☐ ***No***

Applicant's signature:	**Date:**
Supervisor name:	**Position:**

Conditions of Release of Data

This document outlines the conditions of release of information to ______________________

by ____(relevant AuSDaT program/s).

This involves (briefly state):

____

____

____

____

1. Ethical obligations

1.1 Undertake to follow ethical requirements in the use of the data.

This research proposal has gained approval from ____________________Human Research Ethics Committee (if applicable).

2. Other obligations

2.1 Only undertake analysis and reporting of the data as agreed.

2.2 No data will be used or shared beyond what is agreed to and all personnel working with the data are bound to maintain the confidentiality of all information disclosed to them within the agreed study.

2.3 Any information will be used within the agreed time period.

2.4 All reasonable steps will be undertaken to ensure that the information is kept confidential, including storing or disposing of all data, information, documents and associated correspondence in a secure manner.

2.5 Further approval must be obtained in writing from the AuSDaT Coordinating Committee if:
- Additional information is required, or if
- Further time is required, or if
- Additional individuals require access to this information as part of the approved research study.

2.6 Any presentation or publication must acknowledge the source of the data (as per publications policy).

3. Costs incurred

I acknowledge the request to access data will cost $_______.

I agree to pay this cost in the timeframe stipulated.

In signing this declaration, I declare that I will adhere to the obligations specified in this document.

…………………………….	……………………………	…../…../…..
[Name of Applicant]	[Signature of Applicant]	[Date]

COVENANT OF CONFIDENTIALITY

All personnel (both employed and volunteer or in-kind) who have access to data from AuSDaT records must sign this declaration.

I declare that it is necessary for me to access name-identified data held in the AuSDaT. I will preserve the confidentiality of the information released into my care and will adhere to the *AuSDaT Data Security Policy,* the relevant national and state privacy legislation, and all National Health and Medical Research Council guidelines on research as stated in the *National Statement on Ethical Conduct in Human Research 2007.* I understand that I cannot publish or release data during or after my engagement with ____________________________ program, including release to the media, without written permission from the appropriate AuSDaT governance group.

	DECLARANT	**WITNESS**
SIGNATURE		
POSITION		
NAME		
DATE		
SIGNATURE		
POSITION		
NAME		
DATE		
SIGNATURE		
POSITION		
NAME		
DATE		
SIGNATURE		
POSITION		
NAME		
DATE		

7. Data Security Policy

Purpose and scope

This policy describes the data security measures incorporated in the AuSDaT, including the collection, use of, and access to, data, all of which are conducted in accordance with legal, ethical, and national best practice guidelines or standards.
This policy should be read in conjunction with the Data Custodian and Inter-program Data Sharing Policy.

Security operating principles

All security measures will meet the national standards for clinical registries and relevant privacy legislation.

Secure data housing

Currently the AuSDaT is hosted by an independent, external provider (Amazon Web Services [AWS]) with the necessary infrastructure and processes including backup and disaster recovery procedures to meet national standards. Each of the services within the AWS cloud is designed to be secure and contain a number of capabilities that restrict unauthorised access or usage. AWS is certified as compliant with International Organisation for Standardisation/International Electrotechnical Commission (ISO/IEC) 27018:2014 (certificate date 1 October, 2015) and ISO/IEC 27001:2013 (certificate date 4 November, 2014). The hosting arrangements are managed by an expert consultant (currently ICM consulting [the AuSDaT software developers]) and are overseen by the AuSDaT Data Manager.

The appointed Data Custodian (currently The Florey Institute of Neuroscience and Mental Health) is responsible for the oversight and management of the data in the system, including authorising access to users and providing data to external agents with appropriate approvals. All future custodians must adhere to this Data Security Policy and related policies.

Secure transfer and messaging

All AuSDaT data are transmitted in a secure manner and access to data is only permitted to registered users and authorised persons after authentication is provided.

All AuSDaT data files transmitted electronically must be sent in a manner compliant with currently accepted ‘best practice’ e.g. secure cloud solution. Data flowing between the browser, web server, and the AuSDaT server is encrypted via Transport Layer Security (TLS).

When extracted from the AuSDaT, identifiable data (e.g. personal information such as name, addresses) must be stored only on a secure networked, password protected hard drive within an organisation with authority to hold these data and cannot be downloaded onto portable devices such as a USB or personal computer drives.

Ethics and privacy

AuSDaT programs and hospitals must have processes and procedures in place to ensure that the data they collect meets ethical and privacy standards.

In addition, collection, storage and transfer of the AuSDaT data will be compliant with the national Privacy Amendment Act 2012 (updated version March 2014) which, amongst other purposes, is aimed at maintaining security of data in relation to cross-border disclosure of personal information i.e. data being sent, or accessible, to *overseas* parties.

All AuSDaT operational staff are familiar with, and abide by, the requirements set out in Australian privacy legislation, the National Statement on Ethical Conduct in Human Research, and the Australian Code for the Responsible Conduct of Research.

All personnel involved in the AuSDaT (employed, volunteer or in-kind) who have access to name-identified data from the AuSDaT records, must sign the Covenant of Confidentiality to ensure their commitment to upholding the confidentiality and privacy of all participants.

Access to information

All information held in the AuSDaT database is confidential and access to data is restricted by role. Passwords for user accounts are encrypted using bcrypt which is a key derivation function which derives one or more secret keys from a password, or a passphrase using a pseudo-random function. Users are required to change their passwords every 4 months.

The procedure for making a request for data by a third party is outlined in the AuSDaT Data Request Policy. In brief, only anonymised data can be accessed by a third party for analysis if they have been authorised to receive the requested data.

Data linkage activity

In situations where the data custodians of datasets pertaining to individual programs held within the AuSDaT wish to link with government held routinely collected data, such as hospital morbidity data or National Death Index data to assess data quality or patient outcomes (e.g. deaths), the data linkage will be performed by authorised government data linkage units using best practice privacy preserving methods. In this circumstance, AuSDaT identifying data (but only at the level that the specific program collects) may be extracted and securely submitted by the relevant program data manager to the authorised data linkage unit for the purpose of approved data linkage. Secure data transfer protocols will be followed, and any ethical clearances obtained prior to any transfer of data.

Where data are to be updated in the AuSDaT (i.e. for those variables that are common to more than one program such as ‘Date of death’) an agreed overwriting rule will be determined amongst the relevant programs at the time, with documentation of who is responsible for updating the data and when the data updates occurred. When the task is completed, this information is to be submitted to the AuSDaT Coordinator. The AuSDaT Coordinator should be involved in the initial discussion with program coordinators/data managers, to ensure the process and overwriting rules accord with the AuSDaT policies and procedures. The data linkage unit or integrating authority will be unable to keep a record of the AuSDaT data beyond the timeframe specified in the application for data.

In the case of third party/external researchers, only anonymised content data can be provided by the AuSDaT to these researchers. If they require data linkage that necessitates the provision of identifiable information to a data linkage authority/unit, then the AuSDaT Data Manager would facilitate the process of secure data submission on behalf of the third party as specified, including the creation of privacy preserving project specific identifiers or statistical linkage keys (SLKs). The anonymised linked data would then be sent to the third party by the data linkage unit for merging with content data for analysis.

Person-level merging of datasets between different programs held within the AuSDaT will be performed by the program’s principal investigator (PI) requesting the linkage. The PI must obtain approvals according to the relevant governance requirements, HREC approvals, and program

SOPs, and request the linkage of records by the AuSDaT Data Manager. A unique project identifier will be created to be used as an SLK. The SLKs and content data from the other program will then be provided to the PI allowing them to merge the datasets.

Ongoing data access

In general, collected data will remain accessible within the AuSDaT i.e. the AuSDaT is a perpetual data repository.

Any disposal of data from a program (if applicable) will need to comply with the ethical requirements of that program and have no impact on any other program. To this end, it is envisaged that programs extract their required data for reporting or analysis processes, and this becomes their primary, cleaned dataset for a specified purpose that they then archive appropriately, and would dispose of, rather than doing so within the AuSDaT system.

Monitoring and responding to breaches

The AuSDaT Data Manager will monitor adherence to the Data Security Policy in conjunction with the AuSDaT Coordinator and Data Custodian. Program coordinators are responsible for alerting the AuSDaT Data Manager regarding any potential or actual breaches related to this policy within 24 hours of learning of the situation. Any breaches including transferring data insecurely or unauthorised access to data will be investigated and rapidly resolved. The AuSDaT Data Manager will follow up security issues related to hosting in conjunction with the software developer consultants (currently ICM Consulting), and make sure a resolution within minutes or up to maximum of a few hours depending on the nature of the issue is achieved.
Any actual or potential breaches of security will be discussed with the AuSDaT Data Custodian and then the AuSDaT Coordinating Committee including resolution or actions taken or required by each program. The AuSDaT Coordinating Committee will be apprised of any breaches that do occur and inform the ASC.

Review

AuSDaT security and access requirements will be reviewed annually by the AuSDaT Coordinating Committee in consultation with the AuSDaT Data Custodian, Data Manager, and Coordinator. The ASC will be apprised of, and ratify, any recommended changes. Any changes will be communicated to all programs, authorised users and relevant external stakeholders.

Related AuSDaT policies

Consumer and Community Participation Policy

Data Request Policy

Data Custodian and Inter-program Data Sharing Policy

8. Intellectual Property Policy

Purpose and scope

This policy details the permissions and ownerships regarding the AuSDaT intellectual property (IP). This policy should be read in conjunction with the AuSDaT Publications Policy and the Data Custodian and Inter-program Data Sharing Policy.

Background

The AuSDaT is a collaboration between many groups that have all committed significant amounts of time, intellectual skill, and know-how to improve stroke data collection processes in Australia. Given that the AuSDaT builds on existing programs, it is important to recognise and acknowledge this past effort, as well as provide clarity around future IP. The ongoing and productive sharing of knowledge is encouraged within the AuSDaT collaboration.

Definitions

In this Policy, unless the contrary intention appears:

- “AuSDaT” means the Australian Stroke Data Tool.
- “National Permanent Programs” means the Australian Stroke Clinical Registry (AuSCR), the Stroke Foundation, Safe Implementation of Treatments in Stroke (SITS) and the International Stroke Perfusion Imaging Registry (INSPIRE) collectively.
- “Time-limited programs” means an authorised organisation that has user access permissions and privileges, for a limited period of time only, to manage data collection activities across all health services participating in their program.
- “Intellectual property” or “IP” means all statutory and other proprietary rights in respect of patents (whether registered or not), designs, trademarks, circuit layouts, software, algorithms, copyright, confidential information and know how (including trade secrets), and all other intellectual property rights defined in Article 2 of the Convention Establishing the World Intellectual Property Organisation of July 1967, and the right to apply for such rights.
- “Background IP” means any information, techniques, inventions, discoveries, methods, systems, know-how, software, and materials (regardless of the form or medium in which they are disclosed or stored) that is pre-existing or independently developed Intellectual Property made available by a Party for the purpose of the AuSDaT.
- “Confidential information” means all valuable information in whatever form and of whatever description which a Party claims is confidential to itself and over which it has full control and includes all other such information as may be in the possession of that Party. It excludes the interpretation, analysis and application of general information generally known to the public.
- “Coordinating committee” means the committee established to provide oversight and direction of the overall AuSDaT platform and use of data.
- “Steering committee” means the Australian Stroke Coalitions (ASC) which oversees the governance of the AuSDaT and maintains the confidence of all permanent parties and time limited parties involved.

Background Intellectual Property

Background IP remains owned by the permanent program or time-limited program that introduces it to the AuSDaT. Programs that use the AuSDaT, after its initial establishment (i.e. future programs that join), will retain ownership of any background IP they bring to the AuSDaT.

Each program warrants that it is the owner of, or is otherwise entitled to provide, the background IP which it makes available to the AuSDaT.

The programs grant to each other for the duration of each program's participation in the AuSDaT, a non-exclusive royalty-free licence to their background IP for the sole purpose of the carrying out of AuSDaT routine business. Discussion on ongoing access to IP after a time-limited program has concluded should occur and be agreed to prior to the program finishing.

The various programs must treat background IP as confidential in accordance with this policy unless it has been published or is in the public domain.

Each party agrees that it will:

a) Take all necessary steps to protect background IP introduced to the AuSDaT;
b) Give to the other programs prompt notice of any infringement of background IP that comes to its attention;
c) Seek permission to use another party's background IP prior to its use unless agreed to as part of any formal agreement between parties; and,
d) Give to the other programs, all assistance which is reasonably required in order to protect Background IP.

The AuSDaT programs or individuals involved in the programs (via the AuSDaT Coordinator and AuSDaT Coordinating Committee) may choose to document background IP that they introduce to the AuSDaT and any conditions associated with the provision of that background IP. This information will be stored by the AuSDaT Coordinator and be noted in the AuSDaT Coordinating Committee minutes.

Created Intellectual Property

- Ownership and use of any new IP created during the development and management of the AuSDaT will be governed by the terms of the AuSDaT Collaborative Services Agreement. Ownership of AuSDaT collaboration material and intellectual property in AuSDaT collaboration material will vest in the Party who created that AuSDaT collaboration material or, where the AuSDaT collaboration material is created by more than one party, by those parties jointly, as tenants in common in shares proportionate to those respective parties' contributions to the creation of that AuSDaT collaboration material.
- Each party grants to each of the other parties a perpetual, irrevocable, royalty-free and licence fee-free, world-wide, non-exclusive licence (including a right of sub-licence) to use, reproduce, modify, adapt, publish, perform, broadcast, communicate and exploit, but not to commercialise, the IP in the AuSDaT collaboration material.

Confidential information and publication

The various programs agree to treat as confidential and not disclose (without written consent of relevant party) any:

(a) Confidential information received by them while coordinating their relevant program within the AuSDaT;
(b) Personal information received by them from the AuSDaT; and,
(c) Background IP introduced to the AuSDaT.

Disclosure of information will adhere to the other AuSDaT Policies (i.e. Publications Policy, Data Request Policy, and Data Security Policy). Agreement/s between participating hospitals and the

AuSDaT Collaboration or individual programs will also cover confidentiality, publication and use of data in line with relevant AuSDaT Policies.

Any infringements of this policy will be reviewed by the AuSDaT Coordinating Committee and as needed the ASC.

Related AuSDaT policies

Publications Policy

Data Custodian and Inter-program Data Sharing Policy

9. Patient Follow Up Policy

Purpose and scope

The AuSDaT has been built to enable follow up to occur at time intervals set by a program's coordinator. This policy provides guidance on aligning follow up processes between programs in order to avoid duplication in follow up data collection and reduce burden on patients and data entry for data collectors.

This policy should be read in conjunction with the AuSDaT Data Custodian and Inter-program Data Sharing Policy.

Identifying programs with follow up

Programs involving follow up will be identified during the request to add a new program. Initially the AuSDaT Coordinator and Coordinating Committee will review all new programs and discuss planned follow up questions and timing. The following will be recommended:

- Programs requiring 3 month follow up are encouraged to include the AuSCR follow up data elements to encourage cross program collaboration (refer next point).
- Coordinators of the programs requiring follow up at the same time will liaise with each other to determine the feasibility of coordinating this process (one contact only using consistent methodology) and notify the AuSDaT Coordinator and Coordinating Committee of the arrangements.

Requirements of programs involving follow up and National Death Index (NDI) data

- Any follow up using the AuSDaT will require ethics approval to use the AuSDaT tool for data collection, with specific reference to the process of sharing of data collected on behalf of more than one program. This information will be included in the new program application and agreement for sharing of common data elements.
- Processes involved in coordinated follow up will be communicated to all relevant stakeholders including patients. .
- Costs associated with follow up will be negotiated between relevant programs and any costs (amount, timing, etc.) agreed in writing prior to data collection commencing.
- Where death and cause of death data subsequently are obtained from the NDI, AuSDaT programs are encouraged to share these data between programs where this is feasible and in accordance with ethical and AIHW clearances.
- Costs associated with obtaining NDI data should be agreed to between programs where this is shared.

Related AuSDaT policies

National Stroke Data Dictionary Operational Policy

Quality Assurance and Data Management Policy

Data Custodian and Inter-program Data Sharing Policy

10. Quality Assurance and Data Management Policy

Purpose and scope

The Quality Assurance and Data Management Policy provides guidance for the processes of data management, data cleaning, and systems to change data collected within the AuSDaT. This policy should be read in conjunction with the AuSDaT Data Custodian and Inter-program Data Sharing Policy, National Stroke Data Dictionary Operational Policy, Publications Policy, and Patient Follow up Policy.

Data Quality Assurance (QA) activities

Each Program using the AuSDaT is ultimately responsible for ensuring QA data management processes are undertaken by appropriately skilled staff for their own program.

These QA data management processes may include but are not limited to:

- appropriate documentation such as help notes and training resources
- spot audits
- reliability case
- appropriate statistical analyses of group data for annual reports
- data backup procedures

Where possible, data management practices should be shared between programs via discussions at the AuSDaT Coordinating Committee meetings and between individual program coordinators. Where efficiencies can be made between programs (e.g. spot audits) these should be implemented collaboratively to reduce data collection burden (as long as is permissible from a confidentiality and ethics perspective). Ideally, centrally coordinated (independent) reliability audits should be considered where practicable and agreement between programs documented including any costs. Review of the methods programs employ for tracking and reporting data quality, will be conducted as required by the AuSDaT Coordinating Committee.

The AuSDaT includes systems to maximise data quality. These include, but are not limited to, inbuilt data validation and logic checks, and the ability to double-enter reliability (spot audit) data.

Data management

Once entered, data can only be changed by authorised individuals as follows:

- A patient record for which data entry is complete and ‘closed’ by a hospital coordinator and is subsequently available as view only to data collectors, may be changed by the hospital coordinator by reopening records, editing and then closing them again.
- Patient record data that have been ‘locked’ i.e. data that is deemed “clean” and accurate, can be changed by the program coordinator when it is a program specific data element, or by the AuSDaT Data Manager if it a shared data element (collected by more than one program).
  Note: patient records with a date of admission within a calendar year, will be locked in approximately August of the following year, to allow sufficient time for analysis and reporting.
- Requests for change to a ‘locked’ data element (when it is shared data element) must be discussed with the relevant program coordinator who will then consult with the AuSDaT Data Manager.

The tracking of changes will be recorded in the tool (date last modified and modified by whom) for simple auditing, with other methods for tracking more complex changes undertaken as appropriate. These changes will be the responsibility of the AuSDaT Data Manager and include the reasons for the decision and when the change occurred.

Roles and responsibilities

All programs must have their own policy for QA activity and a commitment to implement the policy to ensure high quality (valid and reliable) data are collected. This includes reporting and feedback to sites where applicable to ensure standardised data collection between sites. Each program will report annually to the AuSDaT Coordinating Committee on their QA processes and future planned quality assurance activities to be undertaken to ensure there are no adverse impacts on other programs.

The AuSDaT Data Manager will:

- Oversee the AuSDaT QA processes and respond to related queries.
- Communicate these issues to the AuSDaT Coordinating Committee and if required the ASC.
- Resolve issues arising from such processes within the available resources.
- Maintain the AuSDaT system and oversee upgrades to the AuSDaT website, web tool, and data tables ensuring an appropriate audit trail and system backups are made.
- Be responsible for notification to AuSDaT programs, and users, when the system will be down e.g. for systems/software updates to maintain database integrity.

Communication related to QA

Where data quality issues at a particular site are noted by a program, this should be discussed within the specific program governance process first. This may include a tactful initial strategy (conversation from a key opinion leader to lead at site where the issue is found). If the problem continues, or if the issue is compromising multiple programs, the issue will be discussed at the AuSDaT Coordinating Committee and then if relevant, the ASC.

Use of data for publications

All reports and publications using AuSDaT data will include in the methods the date of data extraction and that a number of quality assurance processes have been undertaken to ensure reliable and valid data within the AuSDaT tool (refer to AuSDaT Publications policy).

Related AuSDaT policies

National Stroke Data Dictionary Operational Policy

Publications Policy

Patient Follow up Policy

Data Custodian and Inter-program Data Sharing Policy

11. New Program Request Policy

Purpose and scope

The New Program Request Policy provides guidance about the processes for requests by new programs (including individual health services) to use the AuSDaT to collect data.

For the purpose of this policy, a ‘program’ refers to any collection of data variables for a specified activity (including but not limited to QI monitoring or research) focussed on improving the understanding or management of stroke care and patient outcomes.

This policy should be read in conjunction with the AuSDaT Data Custodian and Inter-program Data Sharing Policy, National Stroke Data Dictionary Operational Policy, and Patient Follow up Policy.

Requests to use the AuSDaT

Requests for a new program (i.e. ‘permanent’ or ‘time-limited’) to join the AuSDaT will be submitted centrally via the AuSDaT Coordinator.

Each request will be initially considered by the AuSDaT Coordinating Committee and approved by the ASC. New program requests will be required to outline:

- A list of the data required, stating the specific names and codes from the NSDD and whether there is a requirement for any new data elements to be developed or derived (i.e. variables); any overlap with existing programs should be noted.
- The purpose, rationale, research questions, and methodology of the program or research project including time frame and any funding available to undertake the program.
- The program scope (geography, number of sites, setting [acute/rehab], etc.
- HREC and other governance approvals if required (based on criteria outlined in national documents and privacy legislation).
- Any background intellectual property the program brings to the AuSDaT.
- Patient outcome follow up requirements (including timing and data variables).
- Consumer benefits from the program (maximum one page description in lay terminology) that will be published on-line.
- Timeline for data collection and possible implications for other existing programs/projects using the AuSDaT system at the same venues or with the same patient groups.

If the program is located outside of Australia or intends to access the AuSDaT from outside of Australia, The Florey and Stroke Foundation must agree in writing to permit this activity.

Programs involved in the AuSDaT must consider relevant legislation (e.g. privacy), national standards for research and QI projects including ethical clearance, or other governance requirements.

The ethical obligations of programs will be based on the criteria outlined in the *NHMRC Ethical Considerations in Quality Assurance and Evaluation Activities*[3]*.* Assistance by AuSDaT staff and help notes on ethical requirements will be offered to potential new programs. Each program must

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[3] NHMRC 2014. Ethical Considerations in Quality Assurance and Evaluation Activities and NHMRC (2015) National Statement on Ethical Conduct in Human Research

have clear policies on the collection and use of data for their program and adhere to the AuSDaT Policies and Procedures as stipulated in the Collaborative Services Agreement.

The AuSDaT Coordinator will report bi-annually (or as otherwise agreed) to the ASC about all the time-limited programs using (or requesting to use) the AuSDaT. In addition, a link to the list of all health services or organisations undertaking various data collection programs within the AuSDaT will be included on the AuSDaT page of the ASC website.

Requests from individual health services or organisations using the AuSDaT

Requests from health services to use the AuSDaT to collect local data (in addition to existing program data variables to which they contribute) in either an ongoing or time-limited manner, will follow the same process outlined above for new programs. Health services or organisations will be required to sign a Health Services Participation Agreement for their individual ‘Program’.

Related AuSDaT policies

National Stroke Data Dictionary Operational Policy

Patient Follow up Policy

Data Custodian and Inter-program Data Sharing Policy

Publication Policy

Data Security Policy

12. Data Custodian and Inter-program Data Sharing Policy

Purpose and scope

The AuSDaT Data Custodian and Inter-program Data Sharing Policy provides guidelines and requirements for the:

- Overarching AuSDaT Data Custodian;
- Different data custodians for authorised programs responsible for the integrity and use of various data bundles contained in the AuSDaT; and,
- The use and management of data variables that overlap between programs.

This policy is central to the AuSDaT and all other policies related to the management and use of the AuSDaT.

Data custodianship

Custodianship reinforces the concept of one individual/agency being ultimately responsible and accountable for the information that others might use. This gives users confidence in the level of integrity, timeliness, precision and completeness of data, and consequently in the quality and soundness of decisions made based on the information.

The overriding philosophy in all AuSDaT activities should be that each program is responsible for its own data and has its own data custodian. However, because of the integrated system, there is a need to have an overarching AuSDaT Data Custodian acting on behalf of all programs and AuSDaT users. This is because, where variables overlap, they are jointly owned, and coordination for data cleaning decisions, access to data, and maintenance of agreed operational policies and procedures needs to be provided by one organisation to ensure a clear mechanism for accountability and decision making.

General principles and objectives of data custodianship for the national coordinating office and all programs authorised to use the AuSDaT:

- Data are consistently obtained and maintained.
- Duplication of effort is avoided.
- Cooperation is paramount and should be facilitated by regular communication between data custodians and program coordinators/data managers.
- The AuSDaT Data Custodian takes responsibility for the overall data quality decisions associated with agreed systems management; protection, documentation, and management of the data within the AuSDaT; and provides assurance for maintaining appropriate systems of backup and storage of electronic information, and any paper-based information related to administrative aspects of coordinating the overall AuSDaT system.

The objectives of data custodianship are to:

- Ensure data quality, protection, documentation, and management of the data including storage of any paper-based source documents and electronic data downloaded from the AuSDaT are according to agreed data collection policies and ethics approval requirements.
- Ensure the security, confidentiality, and privacy of data is consistent with the AuSDaT Data Security Policy, and any relevant national and state privacy legislation.

- Ensure all relevant policies for the AuSDaT are adhered to and communication between AuSDaT users on policy changes is timely.
- Ensure consistency of data collection and management practices so that goals for standardised and integrated information is achieved.
- Ensure certainty regarding accountability for data.
- Minimise collection of duplicate data over various programs and ensure these data are integrated based on agreed policies and procedures (see below).

Data custodian responsibilities

Authorised programs of data collection using the AuSDaT may differ in terms of the sites, where they collect data, the types of data collected, and the timing of data collection. Variables in the AuSDaT can only be collected once for an individual patient for a particular episode of care or time point. Therefore, some programs, and their data custodians, may be entirely responsible for their own set of data variables or will have a small or large proportion that has been collected through another program. As such, goodwill and trust are paramount in cooperation around data custodianship responsibilities. The following is an outline of how data custodianship responsibilities operate within this context and setting.

- The AuSDaT Data Custodian will be the current AuSCR Data Custodian.
- Individual program data custodianship will continue to be held by each program according to their program guidelines, ethical clearances, and their own policies and procedures for use of the data.
- The AuSDaT Data Custodian, in cooperation with the AuSDaT Data Manager, AuSDaT Coordinator and AuSDaT Coordinating Committee, oversee the hosting arrangements of the AuSDaT (currently via AWS, see AuSDaT Data Security Policy).
- All programs will have full access to their data within the AuSDaT.
- The responsibilities, obligations, and expectations of each permanent and time limited program participating within the AuSDaT is covered within the Collaborative Services Agreement.
- All users will be required to accept the Terms and Conditions for using the AuSDaT (see Appendix) which is done the first time they log onto the AuSDaT, or when a change is made to the Terms and Conditions. In addition, programs may have separate Organisation Participation Agreements between a program and a health service or other appropriate entity, and these will be consistent with the AuSDaT Policies and Terms and Conditions for Users.

The AuSDaT Data Custodian in conjunction with the AuSDaT Coordinator and the AuSDaT Data Manager will ensure:

- Individuals and programs will have appropriate level of access to the web tool and data variables as they are authorised to collect or have access to.
- Technical processes are maintained within the AuSDaT system to maximise data integrity and quality.
- Communication processes exist for data quality issues to be resolved in partnership with program data custodians.
- Technical controls are maintained to safeguard data in the AuSDaT.
- Versions of the Master Data List are maintained along with a history of changes.
- Maintenance of the integrated data management system are implemented according to best practice and with pre-notification of users for system upgrades.
- Data content and changes are recorded in the system archiving functions and can be audited, as requested.
- Data from programs to be linked to other external datasets should ensure separate roles and responsibilities so that merged data cannot be re-identified (see also Data Security

policy). To this end the AuSDaT Data Custodian and AuSDaT Data Manager will facilitate data linkage processes related to AuSDaT data being used for this purpose and will ensure record keeping and secure transfer of data in line with best practice standards. Administrative fees for such activities will be charged back on a cost recovery basis.

The AuSDaT Coordinating Committee will provide support and oversight to AuSDaT staff regarding these requirements.

Issue resolution

Where issues or infractions of data custodial rights and obligations arise regarding the AuSDaT dataset, resolution shall be attempted through each of the following escalation levels (beginning at the lowest level and proceeding one level at a time):

1. Program data custodians along with the AuSDaT Data Custodian
2. AuSDaT Coordinating Committee
3. ASC

The guiding principle in issue resolution must be to protect the privacy of those people registered in the AuSDaT dataset or the IP of various programs participating in the AuSDaT, or avoid duplication of effort or risk of patient responder burden. The escalation pathway should be guided by the significance of the issue.

Data sharing between programs

Programs using common data variables will agree to follow the national AuSDaT Policies & Procedures particularly the AuSDaT National Data Dictionary Operational Policy, Data Request Policy, Follow-up Policy, Publications Policy, and the Quality Assurance and Data Management Policy. A Data Sharing Agreement which ensures clarity of the use of shared variables and how contributors are acknowledged in publications arriving from the shared data will be included in the Collaborative Services Agreement.

Coordination of patient follow-up data collection

Data custodians are responsible for ensuring that common variables used across programs are consistently collected and duplication of effort and responder burden is avoided. Program coordinators of the programs requiring follow up at the same time will liaise with each other to determine the feasibility of coordinating this process (one contact only using consistent methodology) and notify the AuSDaT Coordinator and Coordinating Committee of the arrangements (refer Patient Follow-up Policy). The AuSDaT Data Custodian ensures these efforts are coordinated in an equitable way to ensure minimal disadvantage to any one program whilst balancing the need for data quality to be maintained, patient responder burden to be minimised, financial implications to projects, and providing timely access to these data. If a clear cut solution through goodwill between programs is not found, the proposition and alternate options will be presented to the AuSDaT Coordinating Committee and ASC for assessment and resolution.

Related AuSDaT policies

National Stroke Data Dictionary Operational Policy

Publications Policy

Data Request Policy

Data Security Policy

Intellectual Property Policy

Patient Follow up Policy

New Program Request Policy

Quality Assurance and Data Management Policy

Appendix A: AuSDaT Terms and Conditions for Users

BACKGROUND

The Australian Stroke Data Tool (**AuSDaT**) is an online, integrated data management system for monitoring the quality of stroke care. The AuSDaT is operated by a collaboration of four organisations (the AuSDaT Collaboration) to enable shared responsibilities for the collaborative development and operation of the AuSDaT in accordance with an interparty agreement between the Stroke Foundation; the Florey Institute of Neuroscience and Mental Health; Hunter Medical Research Institute; and the Stroke Society of Australasia.

The initial build of the AuSDaT was funded by the Stroke Foundation with cash and in-kind contributions from the Florey Institute of Neuroscience and Mental Health (Florey). The Australian Stroke Coalition oversees the governance of the AuSDaT and maintains the confidence of all parties involved. The operation of the AuSDaT is managed by the AuSDaT Coordinating Committee whose members include representatives from the programs involved in using the AuSDaT. There is an appointed AuSDaT Data Custodian, Coordinator, Data Manager and Systems Administrator to conduct the day-to-day activities associated with the AuSDaT according to agreed policies and procedures.

User organisations will retain ownership of any of their data submitted to the AuSDaT and authorised users can access and export such data at any point using the functionality in the AuSDaT. User organisations agree to share, without restriction, their data submitted into the AuSDaT for the Agreed Purpose.

A Glossary is provided at the end of this document with definitions of terminology as used in these Terms and Conditions.

TERMS and CONDITIONS

You must not click “I agree” (or use the AuSDaT in any manner) unless you have been authorised by your organisation to be an authorised user who is able to agree to these Terms and Conditions.

By clicking “I agree” (and in consideration of the AuSDaT Coordinating Committee providing your organisation with the right to access and use the AuSDaT, as set out in this document), you agree to the Terms and Conditions set out below and must ensure you comply with these Terms and Conditions. Failure to comply with these Terms and Conditions may result in you, or your organisation, being excluded from further use of AuSDaT.

The AuSDaT Collaboration and User agree that:

1. These Terms and Conditions take effect on the date that they are accepted by clicking “I agree”, and continue until they are terminated in accordance with Clause 22.
2. The AuSDaT Collaboration owns all rights (including any intellectual property rights) in the AuSDaT and grants Users a right to access and use the AuSDaT for the Agreed Purpose only.
3. The User agrees that they will adhere to all relevant policies and procedures for the AuSDaT including the User Manual, National Stroke Data Dictionary (NSDD) and in activities related to data collection, data quality, data export and upload, use of live reports and analysis, and reporting of data extracted from the AuSDaT.
4. Data entered into the AuSDaT by a User may be used by the AuSDaT Collaboration for the Agreed Purpose and in accordance with AuSDaT, Program or Project policies and procedures and ethical clearances as required.
5. The AuSDaT is not intended to be used to make clinical decisions in place of primary source data (e.g. medical record) for individual patient care, and should not be used for this purpose by a User.

6. The User is responsible for ensuring that any data that they submit to the AuSDaT:
    a. satisfies any minimum data requirements reasonably specified in the NSDD and relevant AuSDaT policies for ensuring data quality;
    b. is correct, accurate, complete and up to date; and
    c. is submitted:
        i. according to governance clearances for the Programs or Projects to which your organisation is contributing; and,
        ii. otherwise in accordance with all applicable laws (including privacy laws).
7. Users must not knowingly, recklessly or negligently submit to, or amend, any data in the AuSDaT that is deliberately inaccurate, false or misleading.
8. The User agrees to provide all reasonable assistance requested by the AuSDaT Data Custodian or delegate to undertake data quality assurance activities as required to comply with Clause 6.
9. The User must at all times maintain the security and confidentiality of their AuSDaT account(s) and password(s) details, and otherwise take all reasonable steps to protect the AuSDaT from unauthorised access or use (including by any other individuals). The User is responsible for all activities that occur under their AuSDaT account(s) or password(s).
10. The AuSDaT Data custodian or delegate may, without any liability to the Organisation or its personnel, suspend any or all access to, or use of, the AuSDaT by a User if there is an actual, threatened or suspected breach of security, including any unauthorised access or use of a User's AuSDaT account or password.
11. A User must complete the Stroke Foundation Organisational Survey on first login (if not already completed), which will remain within the AuSDaT as a hospital's profile. If a hospital does not complete the survey, a hospital's user/s will not be able to access the tool to collect data for other Program/s or data collection Projects.
12. Users must collect data for the Agreed Purpose in a timely manner to ensure that no Program or Project is disadvantaged or data quality compromised (as per Clause 6).
13. A User agrees to be invited to participate in an evaluation of the AuSDaT if requested by the AuSDaT Coordinating Committee, the AuSDaT Data Custodian or delegate in order to assist with making improvements to the AuSDaT system.
14. The AuSDaT Coordinating Committee, the AuSDaT Data Custodian or delegate may suspend access to, and use of, the AuSDaT in order to coordinate or perform scheduled maintenance and upgrade work on AuSDaT. Subject to Clause 15, they will:
    a. use reasonable endeavours to ensure that planned system maintenance and upgrades are managed efficiently to minimise downtime; and,
    b. notify Users of scheduled maintenance and upgrade work through the AuSDaT Dashboard or alternative method.
15. The AuSDaT Coordinating Committee, the AuSDaT Data Custodian or delegate may interrupt or suspend all access to and use of the AuSDaT (without any liability to a Participating Organisation or Users) if urgent repairs or maintenance are required, or it is required to interrupt or suspend access by law (including where required by any lawful direction of a regulator, court or other authority). Where reasonable and practicable, Participating Organisations or Users will be provided with prior notice of any such interruption or suspension.
16. The AuSDaT Data Custodian will use reasonable endeavours to ensure that any data submitted by Users is stored in a secure environment that complies with all applicable state and national legal obligations regarding the collection and storage of data.

17. Programs collecting data via the AuSDaT will provide reasonable assistance to train and support Users in the use of the tool for the Agreed Purpose.
18. The AuSDaT Coordinating Committee, the AuSDaT Data Custodian or delegate will, from time to time, provide communication regarding any evaluation and resultant enhancements to the AuSDaT.
19. The AuSDaT will, unless otherwise notified, contain functionality to assist Users to maximise the usefulness of the data collected in informing quality improvement to address variations in clinical practice, including reviewing reports derived in the AuSDaT or exporting data for local use.
20. The User acknowledges that the AuSDaT is provided on an "as is" basis. The AuSDaT Collaboration makes no guarantees or representations:
    a. as to the availability or performance of the AuSDaT;
    b. about the completeness, accuracy or currency of any data that has been uploaded to the AuSDaT by third parties (such as other Users or Participating Organisations); or,
    c. that the AuSDaT will be error free.
21. The AuSDaT Collaboration (and each of their respective directors, officers, agents or employees) exclude all liability in contract or in tort (including in negligence) or otherwise for any liability, claims, cost, loss or damage (including indirect, special or consequential loss or damage) which may be suffered or incurred by Users as a direct or indirect result of their use of AuSDaT.
22. The AuSDaT Collaboration may, at any time, terminate these Terms and Conditions by giving the User 30 days' written notice and may also terminate these Terms and Conditions immediately if:
    a. the User commits a material breach of these Terms and Conditions and that breach is not capable of remedy;
    b. the User fails to remedy a material breach of these Terms and Conditions within 30 days after receiving written notice requiring the User to do so; or,
    c. the AuSDaT is discontinued for any reason.

    The User may terminate these Terms and Conditions at any time by giving the AuSDaT Collaboration 30 days' written notice.
23. Upon termination of these Terms and Conditions, the User must immediately cease all use and access of the AuSDaT.
24. These Terms and Conditions may only be varied or replaced by a document executed by the AuSDaT Data custodian or delegate on behalf of the AuSDaT collaboration.
25. These Terms and Conditions are governed by and are to be construed in accordance with the laws applicable in Victoria, and the AuSDaT Collaboration and the User irrevocably and unconditionally submits to the non-exclusive jurisdiction of the courts of Victoria.
26. The User may not assign any, or all, of his/her rights and obligations under these Terms and Conditions to any other party, except with the prior written consent of the AuSDaT collaboration.
27. These Terms and Conditions are not intended to create a partnership, joint venture or agency relationship between the AuSDaT Collaboration and the User.

GLOSSARY

Agreed Purpose:	Defined within an AuSDaT organisational agreement outlining the Programs or Projects or data variables, available from the National Stroke Data Dictionary, to which the User will be contributing.
AuSDaT:	Australian Stroke Data Tool
AuSDaT Collaboration:	Organisations that have signed the AuSDaT Interparty Agreement and hold the intellectual property and responsibility for the integrity of the system.
AuSDaT Organisational Agreement:	A separate agreement between the AuSDaT Collaboration and the Participating Organisation that outlines which Programs or Projects or local customised dataset to which the organisation will contribute as part of using AuSDaT.
Participating Organisation:	Health service, university, independent research institute or similar that will contribute data into AuSDaT for the Agreed Purpose.
Program:	Ongoing data collection as part of a recognised activity e.g. Australian Stroke Clinical Registry.
Project:	Time limited data collection as part of a recognised activity e.g. research project.
NSDD:	National Stroke Data Dictionary
User:	Authorised user of the AuSDaT who has been issued a password to use the system.