

# Australian Poisoning Surveillance Initiative

Data governance and access policy

## Contents

1. Background information .....	3
1.1. Australian Poisoning Surveillance Initiative .....	3
1.2. The APSI databank .....	3
1.3. APSI program of research .....	3
2. Policy overview .....	4
3. Definitions .....	4
4. Roles and responsibilities.....	5
4.1. PIC data custodians .....	5
4.2. APSI Data custodian/Program principal investigator.....	5
4.3. APSI data manager .....	5
4.4. APSI investigators.....	5
4.5. External investigators.....	6
4.6. APSI collaborating institutions .....	6
4.7. APSI executive committee .....	6
4.8. APSI scientific review committee.....	6
4.9. APSI data governance committee.....	6
5. Data and IP ownership .....	8
6. Eligibility and access to APSI data .....	8
6.1. Eligible applicants and eligible purpose.....	8
6.2. Ineligibility.....	8
7. Access rules.....	8
7.1. Access to simple aggregated datasets .....	9
7.2. Access to case listing data under the standing HREC approval .....	9
7.3. Access for case listing data not covered by standing HREC approval.....	9
8. Conditions of use of APSI data .....	9
9. Publication policy.....	10
9.1. Presentations and publications.....	10
9.2. Data.....	10
10. Data request procedure .....	10
11. Relevant legislation and policies.....	13

## 1. Background information

### 1.1. Australian Poisoning Surveillance Initiative

Australian Poisoning Surveillance Initiative (APSI) is a joint initiative of the four Australian Poisons Information Centres (PICs), based in NSW, QLD, VIC and WA (that together handle all calls to the Australia-wide 13 11 26 poisons information line), and the University of Sydney with support from the Australian Research Data Commons. The aims are to:

- Establish a high-quality national poisoning database (APSI databank) for research and surveillance purposes
- Establish a national program of research

APSI goals:

1. To provide high quality data on Australian poisonings to facilitate toxicosurveillance and toxicovigilance research and public health surveillance
2. to streamline and facilitate poisoning research and public health activities
3. to facilitate rapid translation of toxicosurveillance and toxicovigilance research findings into policy and practice through collaborative research efforts, thereby ensuring better health outcomes for the Australian public

### 1.2. The APSI databank

The APSI databank is a cloud-based database, derived from databases of calls logged by poisons specialists in the four Australian PICs during routine clinical operations. These involve answering calls from the public and healthcare professionals and providing advice on management of poisoning. The PICs collect data on each call, which is entered in real-time into a purpose-built relational database. This includes basic demographics (age, sex, postcode), exposure details (substance, dose, time, intent), details of clinical features and advice provided.

The APSI databank consists of regular submissions of a standardised national minimum poisoning dataset from each PIC. These data are the best source of general poisoning information in Australia as no government programs conduct regular toxicovigilance activities in the general population.

### 1.3. APSI program of research

The APSI dataset will be used to support the APSI research program. The APSI program of research has the following overall research objectives:

- A. Characterising poisoning epidemiology in Australia
- B. Identifying emerging trends and new substances present in poisoning
- C. Evaluating the effect of public health, legislative and clinical practice interventions on poisoning rates
- D. Facilitating access to the dataset for research purposes, to better inform policy and practice.

For a detailed description refer to the APSI protocol approved by Sydney Children's Hospital Network Human Research Ethics Committee (HREC) on behalf of the participating jurisdictions under the National Mutual Acceptance (NMA) scheme.

## 2. Policy overview

This policy defines the APSI data access pathways and procedures, roles, responsibilities, and the conditions governing its use. The policy includes a list of eligible recipients, the criteria and conditions for data, reports and analyses, and the procedures for requesting access. The policy also outlines the conditions governing the dissemination of research using APSI data to ensure adequate acknowledgment of the APSI and those contributing to its ongoing success.

The entry, use, and sharing of information contained in the APSI databank is governed by strict protocols and procedures to protect its security, privacy, confidentiality, and intellectual property rights. All information will be handled in accordance with the Commonwealth Privacy Act 1988, the Privacy and Personal Information Protection Act 1998 (NSW), the Health Records and Information Privacy Act 2002 (NSW), similar legislation applicable to other Australian states, and any code of practice or guidelines made under these Acts (see section 11).

## 3. Definitions

Australian Poisoning Surveillance Initiative (APSI)	a joint initiative of the four Australian Poisons Information Centres (PICs), based in NSW, QLD, VIC and WA (that together handle all calls to the Australia-wide 13 11 26 poisons information line), NSW Ministry of Health and the University of Sydney with support from the Australian Research Data Commons.
Australian Poisoning Surveillance Initiative (APSI) databank	a national database of deidentified poisoning information consisting of the national minimum poisoning dataset collected and contributed by Australian PICs.
National minimum poisoning dataset	a core set of harmonised data specifications developed by the Australian PICs. The collection of this data will be implemented at all Poisons Information Centres. These data will be contributed to the APSI databank.
Toxicovigilance	the active process of identifying and evaluating the toxic risks existing in a community, and evaluating measures taken to reduce or eliminate them.
Toxicosurveillance	the analysis of poisons centre data to identify whether there are specific circumstances or agents giving rise to poisoning, or certain populations suffering a higher incidence of poisoning.
Approved APSI protocol	Scientific protocol approved by the approved by SCHN Human Research Ethics Committee (HREC) on behalf of the participating institutions under the National Mutual Acceptance (NMA) scheme.

## 4. Roles and responsibilities

This section describes roles and responsibilities of institutions and individuals within APSI. The APSI organisational structure is summarised in Figures 1 and 2.

### 4.1. PIC data custodians

PIC data custodians are persons responsible for the operational calls database at each Australian PIC. The custodians are responsible for:

- ensuring that the PIC collects the national minimum poisoning dataset in accordance with the agreed procedures.
- Ensuring the provision of the national minimum poisoning dataset to the APSI databank
- Approval of data release originating from their jurisdiction

The custodians are:

<b>Data custodian</b>	<b>Parent health organisation</b>
Operations Manager, NSW Poisons Information Centre	Sydney Children's Hospitals Network, NSW Health
Pharmacist Consultant (Poisons Information), QLD Poisons Information Centre	Children's Health Queensland Hospital and Health Service
Manager, Vic Poisons Information Centre	Austin Health
Head of Department, WA Poisons Information Centre	Sir Charles Gairdner Osborne Park Health Care Group North Metropolitan Health Service, WA Health

### 4.2. APSI Data custodian/Program principal investigator

The data custodian of the APSI databank is responsible for:

- the governance and management for the databank and for ensuring all legal, regulatory and policy obligations are met with respect to the APSI databank.
- ensuring that all research and operational activities associated with the databank comply with the approved APSI protocol and associated legislation.

### 4.3. APSI data manager

The APSI data manager is responsible for day-to-day management of the APSI databank and data requests.

### 4.4. APSI investigators

APSI investigators are investigators who are either listed in the approved APSI protocol or endorsed by a listed investigator from their institution. APSI investigators are expected to participate in APSI-initiated collaborative research efforts in line with goal 3 (section 1.1).

APSI investigators listed in the approved APSI protocol can endorse other investigators from their institutions for access to APSI data under the standing ethics approval. Endorsing APSI investigators are not required to review or contribute to project proposals or data requests prior to request submission. When the request is submitted, they will be asked by the APSI data manager to confirm that the applicant is affiliated with their organisation and confirm they are suitable applicant (e.g.,

they have the necessary knowledge, skills, resources and/or supervision to appropriately use the requested data).

#### 4.5. External investigators

An external investigator is a researcher who is not listed as an investigator on the approved APSI protocol and is not an endorsed staff member/formal affiliate of an APSI investigator's institution.

#### 4.6. APSI collaborating institutions

APSI collaborating institutions are institutions that contribute financially and in-kind (including data) to APSI operations, capacity-building, and research governance, and are party to the APSI data sharing and governance agreement.

#### 4.7. APSI executive committee

The APSI executive committee comprises representatives of the collaborating institutions (or their delegates), the APSI data custodian and chair of the APSI scientific review committee. The APSI executive committee may invite other members to provide advice and expertise. The APSI executive committee is responsible for governance oversight. The executive committee is chaired by the APSI data custodian or another member of the APSI executive committee. The APSI executive committee is responsible for the following activities:

- Oversee the operations of APSI in accordance with the APSI data sharing and governance agreement
- Develop and review criteria and processes for approval of data requests.
- Manage ongoing ethics and governance approvals for the APSI, including annual reports.
- Review and approve (if appropriate) proposed changes to the APSI databank structure and function, including changes to the national minimum poisoning dataset.
- Select and approve appointment of staff providing administrative and technical support (e.g., data manager).
- Form sub-committees and advisory groups that may be needed in assisting with the management of the APSI.
- Approve changes to the list of collaborating institutions.
- Ensure coordinated research and surveillance efforts by facilitating research collaborations and minimising duplication

#### 4.8. APSI scientific review committee

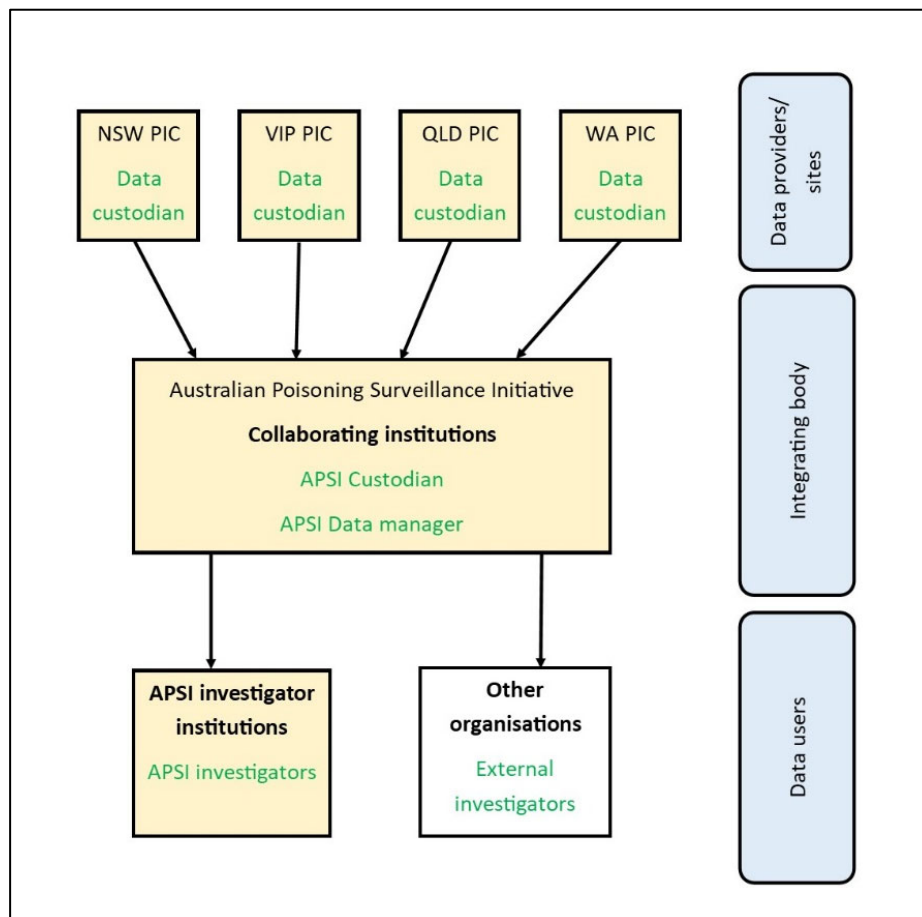
The scientific review committee membership comprises APSI investigators who wish to contribute to the governance of APSI. The APSI scientific committee may invite advisors to provide advice and expertise. The scientific review committee reviews submitted research protocols ensure that the proposed project is well designed and falls within the research objectives of APSI. The scientific review committee makes recommendations for approval to the APSI data governance committee. Members of the scientific review committee may engage in research capacity building activities for APSI.

#### 4.9. APSI data governance committee

The APSI data governance committee comprises the PIC data custodians and the APSI data custodian (or their delegates). The data governance committee makes the final decision about approval for release of data in response to a data request after review by the scientific committee, and makes the

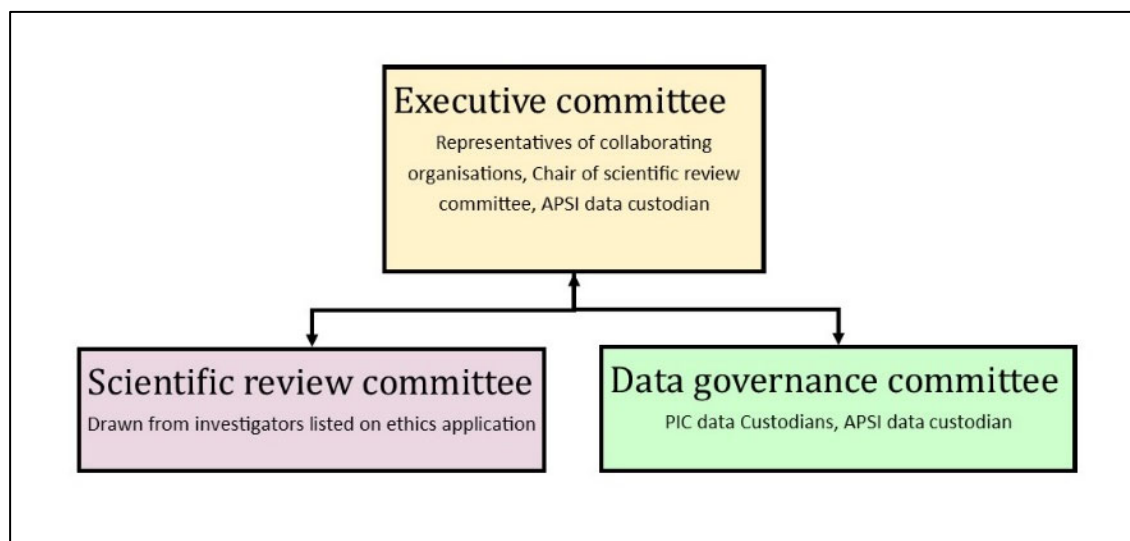
final decision on proposed changes to the national minimum dataset where such change will impact on operational processes.

**Figure 1. APSI organisational structure**



Yellow shapes - APSI investigator institutions listed on ethics approval; black text - institutions; green text— people/roles

**Figure 2. APSI committees**



## 5. Data and IP ownership

The calls dataset curated and held at each PIC is the intellectual property of the PIC and their parent organisation. The data custodians of these datasets are the PIC Managers/Heads of department.

The intellectual property rights resulting from the PICs contributing de-identified data to the APSI databank is governed by the data sharing and governance agreement between the core collaborating partners.

Any further or bespoke data and/or IP ownership arrangements may be agreed between the parties to the APSI data sharing and governance agreement in accordance with the terms of that document.

## 6. Eligibility and access to APSI data

### 6.1. Eligible applicants and eligible purpose

Eligible applicants include:

- APSI investigators (section 4.4 above)
- External investigators (section 4.5 above)

In addition, when requesting individual case listings, the investigator must be affiliated with one of the following institutions and must provide evidence that this institution has the infrastructure for appropriate storage of the data:

- Australian government entities
- An Australian approved research institute (ARI)
- An Australian non-for-profit organisation

The purpose of the request must align with the research objectives A-C (section 1.3). The use of the data must be legal, ethical, and ultimately aim to deliver a public benefit.

NOTE: Requests from commercial entities for access to aggregated APSI data for purposes aligned with research objectives A-C in section 1.3 may be accepted. Examples of potentially acceptable requests include pharmaceutical companies requesting aggregated data for pharmacovigilance purposes.

### 6.2. Ineligibility

- Access to APSI data for commercial exploitation will not be granted.
- Overseas investigators will not be eligible for access to individual case data for analysis outside Australia. Overseas investigators will be encouraged to collaborate with an APSI investigator on international multi-site studies.

## 7. Access rules

The APSI data custodian and data manager will have ongoing access to all data held within the APSI databank for the purposes of ongoing database administration, processing of data access requests, and administration of modifications to the database following approval by the APSI governance committee. The PIC data custodians (Section 4.1) will have access to data held within the APSI databank where the call originated from their jurisdiction. All other access will be via data extractions.



### 7.1. Access to simple aggregated datasets

Access to simple aggregated datasets (except those already publicly available), falling under the standing approval 8.3.2 (ii) of the approved APSI protocol (Access to aggregated data), will be provided without the need for APSI scientific committee review, with approval from the APSI data governance committee.

All access to data not already publicly available must be granted via the data request procedure (section 9). The APSI data governance committee may implement standing approvals for recurring data requests.

### 7.2. Access to case listing data under the standing HREC approval

Requests for access to case listing data under the approved APSI protocol must meet the following criteria:

- Fall within the scope of APSI project objectives A-C defined in section 5 of the approved APSI protocol and section 1.3 of this document
- Undergo APSI scientific committee review and data governance committee approval
- Be led by an APSI investigator (as listed in the APSI protocol) or a staff member/formal affiliate of an APSI investigator's institution who has been endorsed for access to the dataset by an APSI investigator from that institution
- Comply with terms of use outlined in section 8 Use of APSI data
- Involve retrospective analyses of routinely collected PIC data

APSI investigators are encouraged to collaborate with each other on research studies with national coverage, in line with APSI core objective 3 (1.3) and investigators' roles and responsibilities (section 4.4).

### 7.3. Access for case listing data not covered by standing HREC approval

When case listing access requests are not covered by the standing approvals, or it is not clear if they are covered, the APSI data custodian should consult the SCHN HREC regarding additional approvals that might be required.

## 8. Conditions of use of APSI data

- The recipient of APSI data is to make no attempts to re-identify individuals
- APSI data may not be combined with data from other sources into a single dataset unless specific HREC approval to do so has been granted
- The recipient of APSI data must use it exclusively for the purpose described in the data access application. Any further use of data is subject to an additional Access Request.
- The data set is not to be shared outside the individuals described in the data access application.
- When publishing or presenting outcomes related to the approved use of data, recipients must acknowledge the APSI and use Persistent Identifiers (IDs) according to guidelines in section 9.
- Recipients must provide a copy of the manuscript to the APSI executive committee prior to submission to the journal, to ensure that the data is appropriately represented, interpreted and acknowledged.
- Recipients must comply with relevant federal and state legislature and policies including but not limited to: the NHMRC National Statement on Ethical Conduct in Human Research,

Australian Code for the Responsible Conduct of Research, 2018, Commonwealth Privacy Act 1988, state and institutional data management and retention policies.

- Recipients are to comply with any additional conditions specified by the institution of the receiving party, by a reviewing HREC, or as otherwise specified in the data access agreement.

## 9. Publication policy

### 9.1. Presentations and publications

Inclusion as a named author on resulting publications must comply with standard authorship requirements outlined in the Australian Code for the Responsible Conduct of Research.

<https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018>

APSI must be acknowledged in any presentation or publication arising from projects using APSI data. Example statements include:

‘This research study was made possible by access to data held in the Australian Poisoning Surveillance Initiative (APSI) databank’

‘This research study was conducted in collaboration with the Australian Poisoning Surveillance Initiative (APSI)’

DOI of the dataset should be included in the publication either in the body (e.g., methods section) or in an appropriate information field that is published with the article.

All manuscripts arising from APSI data should be submitted to the APSI executive committee for endorsement prior to publication.

APSI Investigators will obtain an ORCID and use this in any publications resulting from studies using APSI data.

### 9.2. Data

Data may only be published or presented (ie. publicly released) in aggregated form, if there is no reasonable likelihood of identifying any individual.

When data is published, the dataset’s digital object identifier (DOI) assigned by the APSI must be published with the data.

## 10. Data request procedure

Data request procedure is summarised in Figure 3 and detailed below:

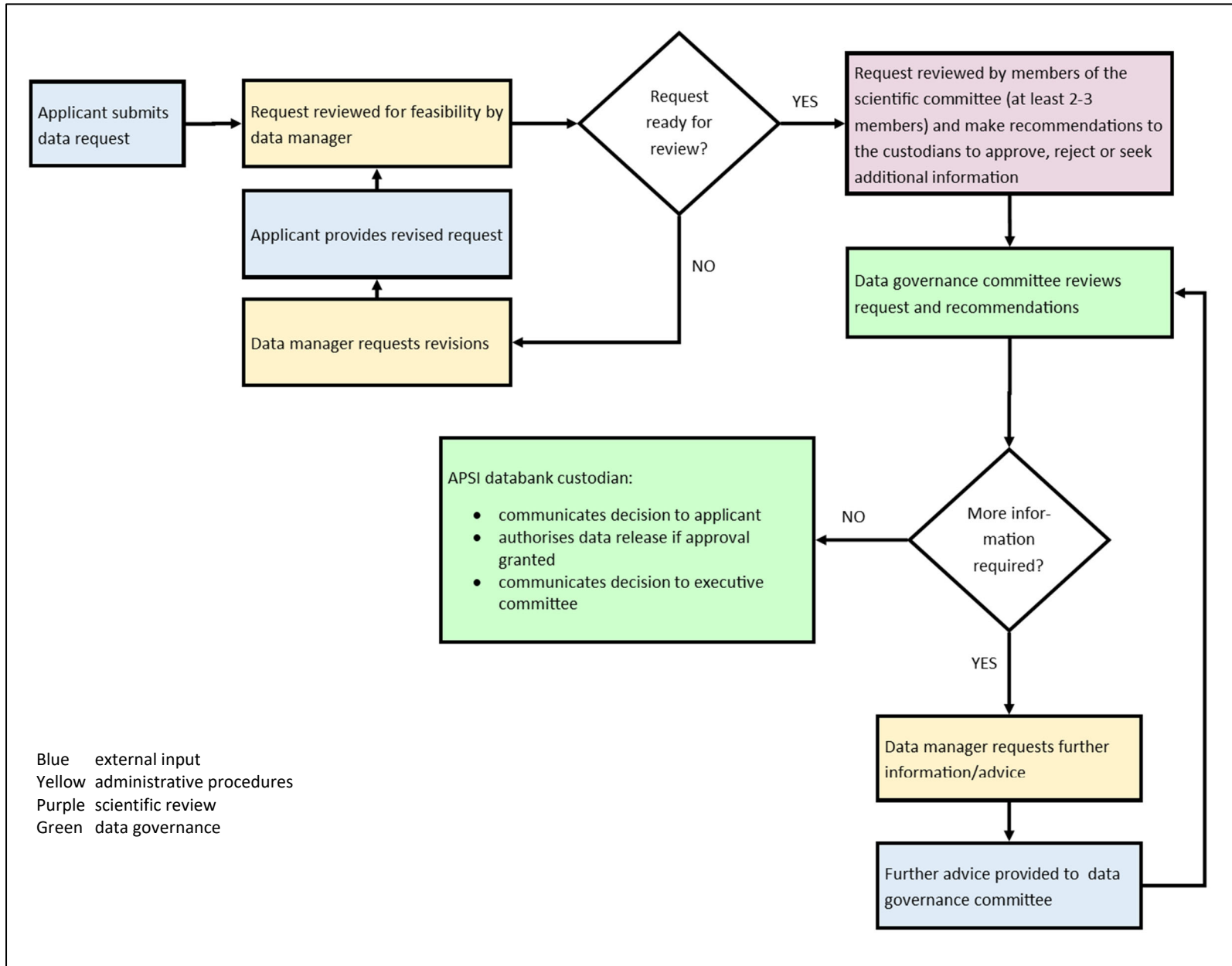
1. Requests for data are to be made using an electronic request form according to instructions published on the submission web page [insert URL]. Investigators intending to submit a request should review APSI information including data dictionaries to ensure feasibility of their studies.
2. The APSI data manager will conduct an initial eligibility check and a feasibility assessment of the study given available data and will work with the requesting investigator to refine the

request if necessary. The data manager will also notify the executive committee of the submission upon first receipt of the request.

3. Request forms and any supporting documentation will be distributed to the data governance committee and at least two to three APSI scientific review committee members assigned to review the request and provide feedback and approval recommendation to the APSI data manager. Requests will be assessed for alignment with APSI objectives, scientific feasibility and the NSW Health Five Safes framework for data sharing <https://data.nsw.gov.au/data-sharing-principles>. The scientific review committee will meet if discussion of the request is required or communicate via email if meeting is deemed unnecessary to provide a final recommendation. Scientific reviewers may recommend approval, rejection, seek additional information from the applicant through the data manager or recommend seeking of specialist advice.
4. APSI data manager will forward the scientific committee's recommendation to the APSI data governance committee who will review the request and recommendation and decide whether to approve the data release. The committee will meet if discussion of the recommendation is required or communicate via email if meeting is deemed unnecessary to provide final approval. Custodians may seek more information from the applicant and/or the scientific committee through the data manager if required or may seek the advice of an independent party, if necessary, such as the SCHN HREC, another HREC certified by the NHMRC, or an independent professional body.
5. If jurisdictional barriers arise (e.g., some custodians may not be able provide approval due to local restrictions), the data governance committee will be able to approve partial data release.
6. Rejection of the entire request has to be unanimous (that is all custodians agree that data cannot be provided) and be based on strong scientific, resourcing, ethical, legal, or other relevant grounds.
7. Once data governance committee decision is given, the APSI data custodian will formalise the request and notify the APSI executive committee and the APSI data manager.
8. Decision will be communicated to the applicant by the APSI manager within 30 days of receipt of the request.
9. Once approval is provided and any additional governance requirements met, including a Data Transfer Agreement if needed, the APSI data custodian will authorise the data manager to arrange for secure data transfer to the applicant.

Scientific committee members and data custodians will be required to declare any perceived or actual conflict of interest (whether financial or otherwise) relating to an application and these will be recorded. Where a conflict of interest is deemed to interfere with impartiality of members, the conflicted individual will not participate in the review. Custodians may nominate an impartial delegate from their institution.

Figure 3 Data request process



## 11. Relevant legislation and policies

Commonwealth Privacy Act 1988

Data.NSW Data Sharing Principles <https://data.nsw.gov.au/data-sharing-principles>

Health Records Act 2001 (VIC)

Health Records and Information Privacy Act 2002 (NSW)

Health Services Act 2016 (WA)

Information Privacy Act 2009 (QLD)

National Statement on Ethical Conduct in Human research (2007)

NHMRC guidelines approved under Section 95A of the Privacy Act 1988 (2014)

NSW Data & Information Custodianship Policy

Privacy and Data Protection Act 2014 (VIC)

Privacy and Personal Information Protection Act 1998 (NSW)

Public Health Act 2005 (QLD)

### VERSION CONTROL

Version	Date	Amendment (brief description)	Approved by
220831	31.08.2022	Version 1 as submitted for ethics approval	Project steering committee