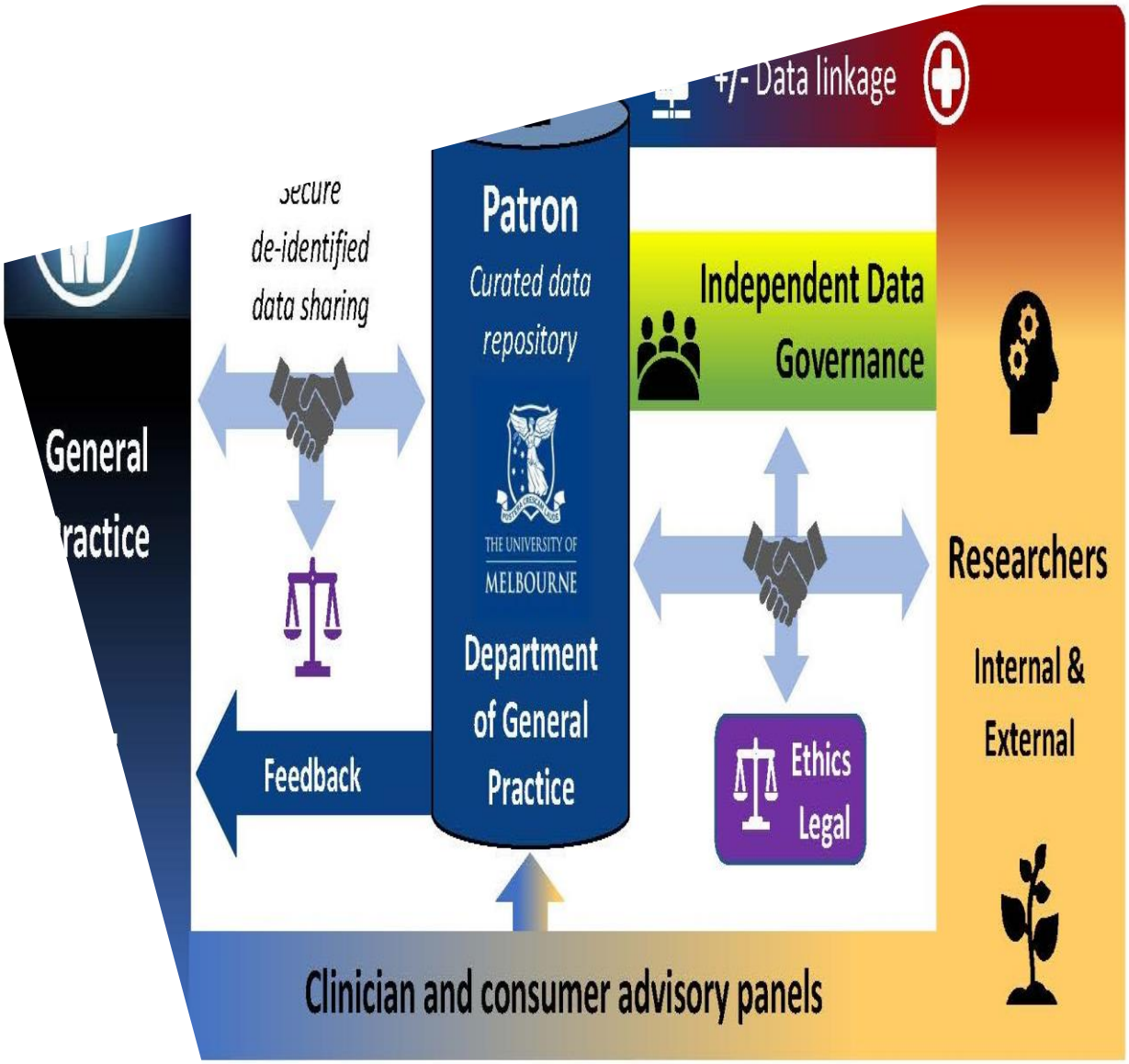
Department of General Practice
Faculty of Medicine, Dentistry & Health Sciences

Patron Data Governance Framework

Part of the Data for Decisions research initiative

15 March 2019



We acknowledge the Traditional Owners of the land on which we work, and pay my respects to the Elders, past and present.

This Data Governance Framework document will change over time to remain fit for purpose. Please check the website for the latest version.

Patron Data Governance Framework v.1

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Department of General Practice
The University of Melbourne
200 Berkeley Street, Carlton, Victoria, 3053, Australia
CRICOS: 00116K

www.gp.unimelb.edu.au/datafordecisions
https://doi.org/10.26188/5c52934b4aeb0

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1. Introduction

Secondary use of health data, including general practice medical records, for research can potentially provide significant public health gains through the identification of population health patterns and by informing evidence-based healthcare education, policy, practice and service delivery. The University of Melbourne, through its Department of General Practice,[1] manages the *Data for Decisions* research initiative which incorporates the Patron program of work. The Patron program aims to work in partnership with general practices to make better use of existing primary care data to improve knowledge, medical education, health care policy and the way care is delivered. General practices and other eligible primary care practices (**Practices**) may choose to participate in the Program by contributing de-identified data extracted from patient records to the Patron primary care data repository (Patron data repository). The University-developed and controlled GRHANITE™ data extraction tool (software) is used to transfer the primary care data to the University. Researchers apply to the Patron Data Governance Committee for access to de-identified data for research, teaching or policy development. This document is the governance framework for the Patron program of work. Figure 1 outlines components of the Patron program. Appendix 1 defines terms and acronyms, Appendix 2 provides a Program synopsis, and Appendix 3 provides the Program's organisational structure. See also www.gp.unimelb.edu.au/datafordecisions

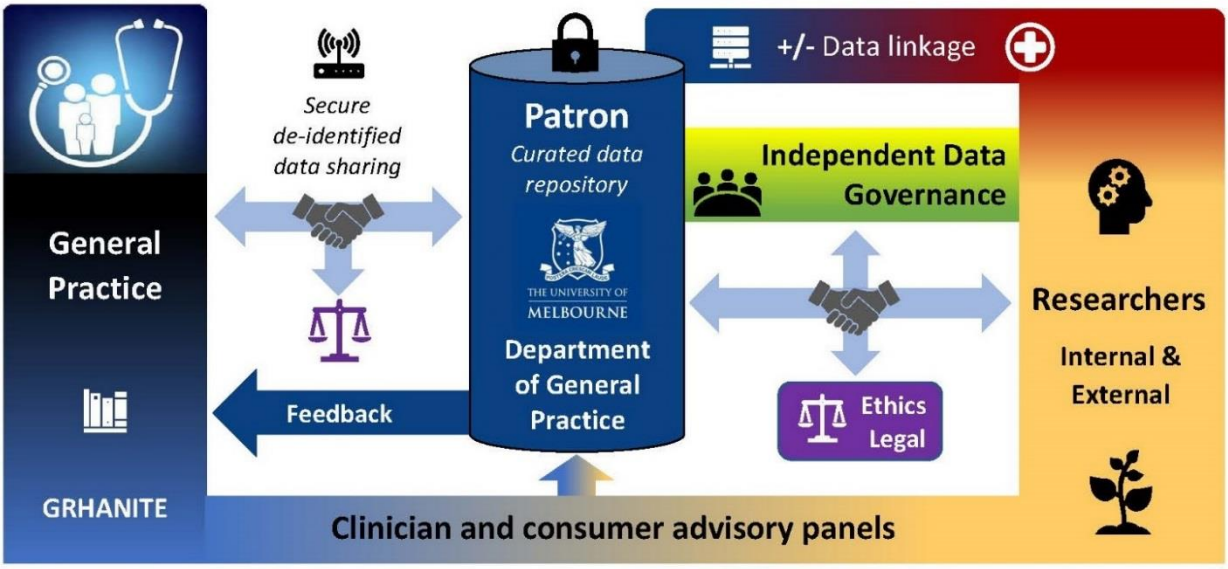

Figure 1. Main components of the Patron program of work

1.1. Data for Decisions and the Patron program of work

The Patron program (**the Program**) is underpinned by commitments in relation to ethics, transparency, privacy protection and data security, building knowledge and connectedness across disciplines (Table 1). Within the Program, data are collected and used for purposes such as research (including audit and quality improvement), education and teaching and policy development. As part of the program, the University manages the Patron data repository in which de-identified primary care data derived from electronic medical records are stored (e.g. GP clinical records). Independent data governance and advisory panels work to ensure that the best interests of healthcare providers and consumers are kept central to the research program.

The Patron program operates in accordance with relevant Privacy Laws and all other relevant legislation and has been granted the necessary Ethics approvals by the University of Melbourne. Consent and legal agreement is received from the participating Practices prior to data extraction. No data within the practice electronic medical record systems known to normally contain personally-identifiable information relating to patients, practices, general practice staff or referring practitioners are extracted from general practices. The Program incorporates a low tolerance to risk and uses the 'Five Safes' framework to assess risk dimensions associated with data recipients' access to sensitive data.[2]

[1] The Department of General Practice, University of Melbourne, specialises in co-designed health services research and implementation in the complex, multidisciplinary primary care environment.

[2] The dimensions in the Five Safes framework are: (1) Safe Projects - Is the use of the data appropriate?; (2) Safe People - Can the researchers be trusted to use it in an appropriate manner?; (3) Safe Data - Is there a disclosure risk in the data itself?; (4) Safe

Table 1. Guiding principles: Patron program of work

Ethics and transparency
- **To ensure collection, monitoring and use of data is transparent, ethical and in partnership with primary care practice and consumers.**

Privacy protection and data security
- **To ensure that international good practice data security standards and proactive risk mitigation strategies are employed when collecting or handling data to protect privacy (as per Australian legal and regulatory requirements).**

Knowledge building
- **To enable generation of meaningful knowledge to answer consumers', clinicians', policymakers' and researchers' questions to advance primary care and improve health services and health outcomes.**

Connectedness
- **To connect disciplines and de-identified datasets to build understanding of health systems and the patient journey.**

1.2. Aims

Data for Decisions is a primary care focused research initiative that aims to make better use of existing primary care data in order to grow research capacity and improve:

- data quality
- health and medical knowledge
- medical education
- healthcare policy, and
- the way medical care is delivered.

The Patron program of work is a key component of the *Data for Decisions* program.

1.3. Objectives

The objectives of the Patron program are to:

- Create a research program that will advance medical research and public health through creation and use of an enduring, professionally curated repository of primary care data.
- Contribute to evidence-based development of healthcare-related policy, tools and practices.
- Provide leadership in the management and use of primary health care data for research, teaching and policy development through transparent processes and proactive mechanisms for data management, privacy, security, program monitoring and evaluation.
- Address relevant research gaps, develop innovative research methodology and increase primary health care research capacity and data quality.
- Plan for and promote the long-term prospects of the program.

1.4. Program accountability

The Data Custodian and the Program Principal Investigator, as representatives of The University of Melbourne, share accountability for the Patron data repository and its data.

Settings - Does the access facility limit unauthorised use?; (5) Safe Outputs - Are the statistical results non-disclosive? See Desai, T., Ritchie, F. and Welpton, R. (2016) Five Safes: Designing data access for research. Working Paper. University of the West of England. Available from: http://eprints.uwe.ac.uk/28124 Accessed March 2019.

1.5. Framework purpose

This Data Governance Framework (the Framework) is dynamic and will change over time to remain fit for purpose. The Framework outlines the Patron program's governance procedures, the legal and ethical environment within which the Patron program operates and provides a framework for the identification and management of privacy risks during the life of the Patron program. This Framework has been developed to inspire and maintain trust in the conduct and operation of the Patron program in the public interest.

This Framework is overseen by a Data Governance Committee that is independent of (but supported by) The University of Melbourne in accordance with the *Patron Data Governance Committee Terms of Reference.*

Two other key documents relating to the Patron program of work can be referred to for detailed information, they are the:

- *Program Protocol for the Patron Program of Work;*
- *Patron Program Standard Operating Procedures.*

1.6. Audience

This Framework is a public document designed to inform all parties who may have an interest in the governance of the Program – including the public, health care consumers, government, University and research organisations, Primary Health Networks, General Practices and other primary healthcare providers.

This framework is not intended to be legal advice. Readers should consider getting their own independent legal advice in relation to their potential involvement in the program.

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2. Ethics and Legal Framework

2.1. Ethical framework

Data for Decisions and the Patron program of work adhere to the ethical principles in the National Statement on Ethical Conduct in Human Research.[3]

2.1.1. Ethics approval (University of Melbourne)

The Patron program of work (the Program) commenced with its successful ethics approval by the University of Melbourne Human Research Ethics Committee (HREC) on the 12th December 2016 (application 1647396). Ethics approval is granted until September 2021 at which time an application will be submitted to renew the program for the next five-year term. The terms of the ethics approval are as follows:

- People in a general practice, authorised to consent on behalf of their Practice, can give permission to the University to collect de-identified data extracted from their patient record system.
- A waiver of patient consent is in place in accordance with the NHMRC Statement on Ethical Conduct in Human Research.[4]

[3] Australian Government, National Health and Medical Research Council (NHMRC), *National statement on ethical conduct in human research*. 2007 (Updated 2018), Australian Government, National Health and Medical Research Council: Canberra. https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018

[4] A waiver of patient consent has been granted because the Human Research Ethics Committee has been satisfied that the Program meets the NMRC National statement on ethical conduct in human research guidelines for such a waiver. These include: that involvement carries no more than low risk, the benefits from the research justify and risks of harm associated with not seeking consent, it is impracticable to obtain consent from all participants, there is sufficient protection of participant privacy). See the Program Protocol document for more information. Australian Government, National Health and Medical Research Council (NHMRC), *National statement on ethical conduct in human research*. 2007 (Updated 2018), Australian Government, National Health and Medical Research Council: Canberra.

- GRHANITE™ software, installed on a general practice computer by the Department of General Practice technical team, facilitates extraction of de-identified patient and practitioner data.
- The Patron program's technical team curate the data centrally in the Patron data repository.
- Potential Data Recipients, within and outside of The University of Melbourne, apply to access a subset of Patron data for the permitted purposes of research, education / teaching, quality improvement, and policy development.
- In some instances of research, the de-identified Patron data can be linked with de-identified data from other datasets (e.g. hospital data). Any combining of primary care and other datasets happens in accordance with legislation and only after approvals from the Data Governance Committee and an appropriate ethics committee. The Patron program employs privacy-preserving linkage techniques to support such linkage utilising non-reversible mathematically derived statistical linkage keys.
- The Patron database itself will not hold datasets other than from primary care practices.

2.1.2. Ethical processes

Detailed information about practice recruitment is provided in the *Program Protocol for the Patron Program of Work.* All practice staff should agree to participate. When data are extracted, they are drawn from all healthcare providers and staff working within the practice who contribute to the electronic medical record (EMR). The data fields extracted from the practice EMR do not include those known to normally contain individual identifying information about health providers, practice staff or patients.[5]

In accordance with the NHMRC Statement on Ethical Conduct in Human Research (National Statement), the collection and storage of de-identified patient data in the Patron database has been approved by the University of Melbourne's Human Research Ethics Committee (HREC) on the basis of a waiver of consent model. This requires Practices to consent to the extraction and storage of de-identified patient data in the Patron databases on behalf of their patients.

The Program Consent form[6] enables practices to indicate whether they consent for their practice data to be accessed for research undertaken or funded by commercial entities, and whether they consent for their practice to be named on the *Data for Decisions* website. Participating Practices can change their consent options or withdraw their consent to participate at any time, without prejudice.

In addition to the Consent form, each participating practice signs a legal agreement (*Agreement for the Provision of Data*) with the University of Melbourne (see **Error! Reference source not found.**).

Despite operating under an ethics committee approved waiver of patient consent, the Program requires participating practices to display Program information for patients including on how patients can withdraw (see 2.1.3).

To ensure transparency, all lead recipients of Patron data should be named on the *Data for Decisions* website (www.gp.unimb.edu.au/datafordecisions). Data Recipients are required to provide the Program Management Group with plain language 'community reports' of research findings that can be made openly available on the *Data for Decisions* website, with excerpts included in regular newsletters to Practices participating in the Program.

2.1.3. Right to withdraw

Patients: All patients have a right to withdraw. Withdrawal will not affect clinical care. Participating Practices agree to display posters and leaflets informing patients about the Program and their right to withdraw. Participating practices also agree to action requests by patients to withdraw from the Program by completing the relevant 'consent denial' form within the GRHANITE™ software (see the Agreement for the Provision of Data).

General Practices: A participating Practice may request to withdraw from the Program at any time by providing written notice to the University. Upon receipt of such notice, the University will disable GRHANITE™ software as soon as reasonably practicable (within 14 days). (see the Agreement for the Provision of Data).

[5] Individual identifying information not collected includes: names, full dates of birth or death, Medicare numbers, provider, prescriber or other identifying numbers, most free text fields over 30 characters.

[6] Signed by practice principal(s), CEO, Director, or other designated person(s).

2.1.4. GP and practice staff data

Using GRHANITE™ software, the University collects and stores in the Patron data repository de-identified information about health care providers and practice staff where these individuals have contributed to patient data that is collected by the Program. The software generates a code for each health professional or practice staff member, but this does not enable the University to personally identify any clinical or non-clinical practice staff. As outlined at 2.2.1, some personal information of practice staff is collected for administrative purposes. The collection and handling by the University of this personal information is separate from Patron and is subject to the Privacy and Data Protection Act (Vic) IPPs. Unless health professionals give their explicit consent, there will be no onward collection or disclosure of personal information about GPs in any circumstances.

2.2. Legal framework and guiding policies

The Program has been designed to comply with all Australian legislation and with all relevant University of Melbourne Policies. The Patron program of work is guided by and adopts processes aimed at adhering to:

- Health Records Act 2001 (Vic) and the Health Privacy Principles (HPPs) in the Act
- Privacy and Data Protection Act 2014 (Vic) and the Information Privacy Principles (IPPs) in the Ac
- Commonwealth Privacy Act 1988
- University of Melbourne Privacy Policy (MPF1104) – incorporating obligations under the Freedom of Information Act 1982 (Vic)
- University of Melbourne's Conflict of Interest Guidelines in the Research Integrity and Misconduct Policy (MPF1318)
- University of Melbourne Management of Research Data and Records Policy (MPF1242)
- University of Melbourne Information Security Policy (MPF1270)

General practitioners' professional obligations under the *Health Practitioner Regulation National Law Act 2009* (Vic, Health Practitioner National Law) and codes of conduct in relation to medical records have been given consideration. It is not considered that these obligations will have any impact on the way that doctors handle medical records for the purpose of the Program. However, it is up to participating Practices to seek their own legal advice in relation to this if they wish.

2.2.1. Privacy principles

University of Melbourne and Practices aim to comply with all relevant Privacy laws. Research conducted using the Patron data repository adopts good practice for the protection of privacy of personal information and complies with University of Melbourne Privacy Policy (MPF1104). The ethical research requirements in the NHMRC Statement on Ethical Conduct in Human Research (National Statement) underpin the privacy obligations.

Under the terms of the Program 'Agreement for the Provision of Data' (legal agreement), participating Practices give permission to the University of Melbourne to extract patient data using GRHANITE™ software. Key functions of GRHANITE™ software are its ability to de-identify patient and health professional data before it leaves the clinic computer, assign a unique digital signature to each patient and health professional in place of person identifying information, facilitate encrypted transmission of data, and enable re-identification of data in the confines of the clinic computer from which the data was transmitted. These functions mean that data collected and stored in the Patron data repository are securely sent and not personally identifiable for the purposes of the Health Records Act 2001 (Vic) and the Health Privacy Principles (HPPs) in the Act. Re-identification may only happen within the confines of, and with permission of, the practice where the data were collected. The University must at all times comply with the Health Records Act 2001 (Vic) and the Health Privacy Principles (HPPs) in the Act, and in the event that any other identifiable information is held (see 1.2.4 'Purposes, including data linkage and re-identification').

For the purpose of engaging with Practices as part of the Program, under the terms of the Agreement of the Provisions of Data, Practices give permission to the Program technical staff to collect some personal information of practice staff. This administrative information is not stored in the Patron database. The University of Melbourne complies with the

Privacy and Data Protection Act 2014 (Vic) and the Information Privacy Principles (IPPs) in the Act in relation to the personal (identifiable) information it collects about practice staff.

To enhance privacy of people whose data are contained in the Patron repository, the Program has adopted a data minimisation principle to limit unnecessary sharing of Patron data fields with Data Recipients. Data minimisation is the principle that only as much data should be captured and/or shared as is required to efficiently and effectively accomplish a given task.

2.2.2. HPP and IPP obligations

The University has obligations under the Health Records Act 2001 (Vic) and the Health Privacy Principles (**HPPs**) in the Act when collecting and handling of personal information that has NOT been deidentified (e.g information for administrative purposes not shared with Data Recipients). It must also comply with the Privacy and Data Protection Act 2014 (Vic) and the Information Privacy Principles (**IPPs**) in the Act in relation to personal information it collects about GPs. The most directly relevant principles are in relation to the project data's:

1. collection and notice (IPP1 and HPP1);
2. use and disclosure including outside Victoria (IPP2 and HPP2, IPP9 and HPP9);
3. data quality (IPP3 and HPP3);
4. data governance and transparency (IPP5 and HPP5);
5. data security and destruction (IPP4 and HPP4)
6. access and correction (IPP6 and HPP6);

The HPPs and IPPs contain many similar rules, but the HPPs impose some additional obligations which afford health information of patients, compared to personal information of doctors, a higher level of protection.

2.2.3. Legal Agreements

Agreement for the Provision of Data: Practices that agree to participate in the Program enter into an 'Agreement for the Provision of Data', a legal agreement with the University of Melbourne. The purpose of the legal agreement is so that The University of Melbourne and the general practice both have a clear understanding of the terms under which data are shared. The terms of the agreement are explained to potential participating practices. Data are not collected until this agreement is in place.

Practices have the right to terminate this agreement at any time. The University may also terminate the Agreement and cancel the participation of the Practice in the Program and its access to GRHANITE™ software.

Data Access Agreement (for Data Recipients): Access to Patron data is only permitted after Data Recipients have gained approval of the Data Governance Committee, ethics approval from an NHMRC recognised ethics committee, and signed a legally binding 'Data Access Agreement' with the University. Internal University of Melbourne researchers are obliged to sign an equivalent Memorandum of Understanding (MOU). The Data Access Agreement and the MoU stipulate the terms under which researchers can access, use and manage Patron data, and their legal obligations around privacy, security, confidentiality and publication of findings.

Individual researchers working under a Project Leader sign a *Data Access Acknowledgement for Individuals*. The purpose of the Data Access Acknowledgement is to ensure that each researcher accessing Patron data has a clear understanding of the terms under which data are provided.

2.2.4. De-identified patient data

The GRHANITE™ data extraction tool applies de-identification techniques to both patient and practice staff information within the practice. In addition to limiting data extraction to non-individual identifying fields (see Footnote 5), a privacy filter is applied to the data prior to its inclusion within the Patron dataset.

Under the Privacy and Data Protection Act 2014 (Vic), and the Commonwealth Privacy Act 1988, 'de-identified' is defined in relation to personal information as meaning: *personal information which no longer relates to an identifiable individual*

or an individual who can be reasonably identified. The Australian Government Office of the Australian Information Commissioner states that "information that has undergone an appropriate and robust de-identification process is not personal information and is therefore not subject to the Privacy Act 1988. Information will be de-identified where the risk of an individual being re-identified in the data is very low in the relevant release context (or data access environment)."[7](p.3)

De-identified (including health) information that is collected and held by the University in the Patron data repository is de-identified to the extent that the University cannot identify or cannot reasonably identify an individual patient from the patient data alone, and controls and safeguards are in place in the data warehouse environment to prevent re-identification. Under the Privacy Act (1988), de-identified data is not considered personal information.[7]

2.2.5. Purposes, including data linkage and re-identification

Before any Data Recipient gains access to data held within the Patron data repository, Data Recipients and their proposed use of the data will be subject to due diligence by the University and the Data Governance Committee (see also Section 5).

The de-identified data supplied to a Data Recipient may only be used for the specific, agreed purposes contained within in the Data Access Agreement. Activities supported under the Data Access Agreement are very specific and aligned to the requirements of the project being undertaken and approved by ethics. As per the Program's ethics approval, permitted purposes for Patron data are: research, education, quality improvement, and policy development. For example, research relating to medication safety, disease patterns, prescribing patterns, health economics and public health. The data may be used in conjunction with other datasets during the course of such activities where the 'Data Access Agreement' permits it.

In limited and defined circumstances, it may be necessary for the Practice, using the GRHANITE™ software that it has installed on a practice computer, to re-identify data that has previously been de-identified.[8] To do so, the Practice's instance of GRHANITE™ software contains the key for re-identification. The University will not have access to that key.

In relation to its collection and handling of re-identified data, the Practice must comply with the Health Privacy Principles and the Australian Privacy Principles and all other applicable Privacy Laws.

If any de-identified research outputs deriving from Patron data are given to participating practices in a form that the practice would have the ability to re-identify patient data that is linked to individual patients, the research outputs may need to be regarded by the practice as personal information.

2.2.6. Intentional re-identification of individuals

The Data Custodian, associated Department of General Practice technical team, and researchers have no means to re-identify patients. For privacy and security reasons the de-identification and processing of patient and practice staff data occurs at the practice. A mapping to the identity of patients and practice staff is retained by the general practice (within their GRHANITE™ software) to allow re-identification by practice staff should the need arise. The patient and staff re-identification feature may be called on under three conditions:

1. Practices involved in internal quality improvement or similar processes have the ability to re-identify staff and/or patients.
2. When a research project has been granted specific ethics approval to re-identify individuals within the Patron dataset. This requires additional consent mechanisms from the practice and the patients – for example, a general practice consent to be involved in an approved intervention study that utilises patient opt-in consent.
3. When a direct risk to a patient's welfare is identified in a Patron research project.

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[7] Office of the Australian Information Commissioner, *De-identification and the Privacy Act*. 2018, Office of the Australian Information Commissioner: Canberra. p. 18.

[8] An example of when patient or practitioner re-identification might occur is if the practice agrees to participate in an intervention, validation, clinical trial or other additional research study where identification is necessary. Whether or not the practice agrees to participate in any activities that require such intervention is entirely at the practice's discretion. The intervention will require its own, additional ethics and Data Governance Committee approvals, and practice and patient consents (as relevant).

In this third condition, the GRHANITE™ re-identification capability gives a practical means for a GP to address a patient-specific risk to a participant's welfare that has been identified by research. This is aligned to the NHMRC guidelines in the National Statement on Ethical Conduct in Human Research 2018, section 2.3.10: 'in case the results have significance for the participants' welfare there is, where practicable, a plan for making information arising from the research available to them'.[9]

2.2.7. Non-intentional identification of individuals

By utilising routinely collected data there is risk that clinical or non-clinical practice staff may have inserted into the EMR person-identifiable information in a field where it would not normally be expected (e.g. a person's name in the reason for visit field). It is impossible then to absolutely guarantee that all patient data collected is de-identified in all cases. The *Standard Operating Procedures* outline the mechanisms to actively address this through technologies and ongoing review of the data, including further scrutiny before it is released to researchers. Any breach of these procedures must be escalated to Ethics and the Data Governance Committee. Incident Reporting Procedures are outlined in the *Patron Program Standard Operating Procedures*.

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3. People and Responsibilities

The Data Custodian and the Program Principal Investigator share ultimate accountability for the Patron data repository and its data. People and responsibilities refers to those individuals and groups with a role in Patron data governance.

3.1. Data Governance Committee

A Data Governance Committee independently oversees adherence with this Data Governance Framework and the Standard Operating Procedures, in accordance with University of Melbourne Ethics approval and any legal requirements. The Data Governance Committee operates in accordance with the established *Terms of Reference*. The Committee is responsible for reviewing and approving Patron data access requests (after feasibility assessment by the Program technical team) and providing oversight and advice to the Data Custodian, the Principal Investigators and the Data Steward as per the *Patron Data Governance Committee Terms of Reference*. Technical and operational (secretariat) support is provided to the Data Governance Committee by the Patron Program Management Group.

To maintain independence in advice and opinion, the Chair of the Committee may not be an employee of The University of Melbourne. The *Patron Data Governance Committee Operational Instructions and Guidelines* should be consulted, alongside the *Patron Data Governance Committee Terms of Reference* for rules around the function, membership, structure and operation of the committee.

The Data Governance Committee are not legally responsible for the Patron primary care data repository. Legal responsibility remains with The University of Melbourne. The Data Custodian, in consultation with the Head of the Melbourne Medical School and the Associate Dean of Research, Faculty of Medicine, Dentistry and Health Sciences retain discretionary powers to overturn a decision of the Data Governance Committee if they believe the decision is not in the best interest of the University, participating general practices, or consumers whose de-identified data are contained in the Patron data repository.

[9] Australian Government, National Health and Medical Research Council (NHMRC), *National statement on ethical conduct in human research*. 2007 (Updated 2018), Australian Government, National Health and Medical Research Council: Canberra.

3.2. Data Custodian

The Data Custodian is the Head, Department of General Practice and is ultimately responsible for the data contained in the Patron data repository in compliance with relevant University policies and Australian laws and regulations. The Data Governance Committee advises the Data Custodian and the Principal Investigator.

The Head, Department of General Practice, appoints the Chair of the Data Governance Committee, in consultation with the Head of the Melbourne Medical School and the Associate Dean of Research, Faculty of Medicine, Dentistry and Health Sciences, The University of Melbourne.

3.3. Data Steward

The Data Steward is the Director of the Health and Biomedical Informatics Unit Research Information Technology Unit (HaBIC R^2) – a unit based within the University of Melbourne, Department of General Practice with extensive experience in data security management and curation. The Data Steward has the delegated responsibility to manage the security and other data curation activities of the Patron data collection on behalf of the Data Custodian.

3.4. Principal Investigator

The Principal Investigator is as named on the Patron ethics application (HREC ID 1647396). The Data Governance Committee advises the Principal Investigator and the Data Custodian. The Principal Investigator is responsible for the preparation, conduct and administration of the research program in compliance with relevant University policies and Australian laws and regulations.

3.5. Patron Program Management Group

A Program Establishment Group comprising the named Patron researchers and other experts developed and administered the Patron program since its inception until the establishment of the Patron Data Governance Committee. On establishment of the Patron Data Governance Committee the Program Establishment Group became the Patron Program Management Group. The Program Management Group, including the Data Steward, the technical and operations teams, and the researcher group, is responsible for technical and administrative program operations, program development, and feasibility assessment of researchers' data access request applications.

3.6. Advisory panels

General practice and consumer advisory panels can be utilised to capture community perspectives on the use and governance of Patron data. Tasks of such panels might include reviewing research concepts and protocols, assessing the relevance of research questions, and reviewing information sheets and consent forms of Patron-related studies. One general practice panel representative and one consumer representative should be a member of the Patron Data Governance Committee.

3.7. Researchers

Researchers accessing Patron data have responsibilities to comply with ethical, legal and regulatory obligations related to privacy, data management and data security.

4. Data Processes and Management

4.1. Data quality

Unmodified, original data are key to good epidemiological practice. GRHANITE™ provides data in as close to the original data recording structure (as found in the general practice computer systems) as possible, but with person identifying information removed. Quality assurance of data includes routine assessment of Patron data for completeness, continuity and plausibility of electronic recording in key areas at the practice level.

4.2. Data security

The Patron program and repository must comply with The University of Melbourne, Information Security Policy (MPF1270), and all relevant Australian laws and requirements. Refer to the Patron Program *Standard Operating Procedures.* The University also has obligations to have appropriate data security measures under privacy and health records law, but these only relate to personal (identifiable) information.

GRHANITE™ technology is designed with the aim of de-identifying and encrypting all data, from the instant it leaves the general practice clinical software environment until it arrives at the Patron primary care data repository. Internationally recognised encryption mechanisms are used to protect data in transit (i.e. site specific encryption keys that are themselves encrypted, and 'end-to-end' encryption with endpoint authentication). Additional information about GRHANITE's technical and data security features can be found at: www.grhanite.com

4.3. Data warehousing and management

The Program must comply with The University of Melbourne's Management of Research Data and Records Policy (MPF1242) and implement the Procedures and Guidelines for the Management of Research Data and Records. Refer also to the Patron Program Standard Operating Procedures – section 3 Data Management, for procedures in place for data management.

The Patron primary care data repository should be warehoused within a University of Melbourne controlled environment or other trusted and accredited facility. Data warehousing processes should, as far as possible, protect the data from privacy and security breach.

4.4. Privacy protection

The Patron Data Access Agreement sets out the general privacy and security rules that the Data Recipients agree to comply with on entering into the Agreement with The University of Melbourne.

Ensuring data are de-identified at all times is managed through the Patron Program Standard Operating Procedures and facilitated by the GRHANITE tool which enables privacy-protecting data extraction and record linkage. See section 2.2 of this document, and specifically section 2.2.1 - Privacy principles.

4.5. Incidents and breaches

The Privacy and Security clause in the Patron Data Access Agreement stipulates that Data Recipients agree that they must notify the University of Melbourne immediately after becoming aware of any actual or suspected data breach or suspected inaccuracy in any data.

All identified data privacy and security breaches (internal or as identified by Data Recipients) must be escalated to the patron Data Governance Committee. Refer to the *Patron Standard Operating Procedures*.

4.6. Data retention

The Patron data repository is designed to be an enduring dataset, but not all Patron data will be stored indefinitely. Data is to be retained in accordance with Program ethics approvals and University of Melbourne policies. The Patron program must comply with the Management of Research Data and Records Policy (MPF1242) and implement the Procedures and Guidelines for the Management of Research Data and Records. These procedures include guidance on data retention durations. Refer to Patron Program Standard Operating Procedures.

Patron data should be retained intact for a period of at least five years from the date of any publication based on the data, or longer if discussion of results continues. Data will be retained if there are regulatory or sponsor requirements, or if the data has historical or archival value, according to the University of Melbourne Code of Conduct for Research. Data supplied for Project-within-Program or separate ethics applications will be retained for the period required for the research type (e.g. a minimum of 15 years for a clinical trial). Data will be disposed of in keeping with University of Melbourne policy and procedures.

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5. Data Access and Conditions of Use

Resources related to this section include the:

- Patron Program Standard Operating Procedures;
- Patron Data Access Application form (refer to website);
- Researcher Data Access Flowchart - from application to receipt of data. Refer to website;
- Data Access Agreement for researchers external to the University of Melbourne; and

5.1. Permitted projects and scope

Data collected and stored in the Patron data repository is permitted to be used for (as per the approved ethics application) research (including audit and quality improvement), education and teaching, and policy purposes.

Projects that may be undertaken using Patron data are also restricted by the scope permitted by the Program's ethics approval, and under the terms of each prospective Data Recipient's project ethics approval. Scope is also shaped by any limits placed on Data Recipient's use of data by any limits place on the project by the Patron Data Governance Committee.

The extent of which fields of Patron data are shared, and how that data can be managed and used, are limited by the agreed terms of the Data Access Agreement or University of Melbourne MOU (including the Contract Details).

5.2. Ethics approval of Patron projects

Patron data are not to be shared with any Data Recipient without them first receiving ethics approval from a legally constituted NHMRC approved Australian Human Ethics Committee. Prospective Patron Data Recipients must provide a full copy of their ethics application to the Patron Program Management Group (specifically the Program Manager and the technical team) so that the Patron team can ensure that only fields of data that were approved by the ethics committee are shared, and that all persons named on the ethics application sign the relevant Data Access Agreement, MOU or Data Access Acknowledgement.

University of Melbourne employed prospective Data Recipients can apply for University of Melbourne Project within Program ethics approval.

Industry funded, for profit research will only be permitted (1) with data from practices who have consented for their patient data to be used for research undertaken by a commercial entity / funded by a commercial entity, and (2) only if the research project fulfils the due diligence investigation.

5.3. Governance committee approval

Patron data may only be utilised for projects approved by the Patron Data Governance Committee. No use outside of this scope is permitted. Re-use of the same Patron dataset for a new project requires new ethics and Patron Data Governance Committee approvals.

5.3.1. Access decisions

As per the Researcher Data Access Flowchart, a Project Feasibility Assessment is first undertaken by the Patron Program Management Group (initial assessment of data requirements, fees, timeline). Information to assess the proposed project against the Five Safes,[10] to assess risk dimensions associated with the Data Recipient's access to Patron data, is also gathered by the Patron Program Management Group. The Five Safes are:

1. Safe Projects - Is the use of the data appropriate?
2. Safe People - Can the researchers be trusted to use it in an appropriate manner?
3. Safe Data - Is there a disclosure risk in the data itself?
4. Safe Settings - Does the access facility limit unauthorised use?
5. Safe Outputs - Are the statistical results non-disclosive?

If feasible, the project data access application, ethics approval documentation, and information related to the Five Safes, are referred to the Data Governance Committee for consideration. **With regard to each application, the Governance Committee should consider:**

- the nature of a prospective Data Recipient's IT system;
- security systems and protections in place by the prospective Data Recipient to safeguard Patron data from corruption or tampering;
- the nature of the organisation and its objectives;
- proposed uses and disclosure of the data and whether there are commercial entities involved; and
- any previous contraventions of privacy laws or data breaches.

Each application will be assessed in terms of:

- Researchers' credentials (bona fide researchers)
- The scientific merit / quality of the project
- Relevance / importance of the research
- The potential for public benefit
- Risks
- Conflicts of interest

The Data Governance Committee may ask prospective Data Recipients to provide additional information if it is deemed needed to fulfil due diligence. On approval, prospective Data Recipients agree on a Project Plan and sign a contract / legal agreement prior to delivery of data. The legal agreement specifies the terms of access and obligations of the Data Recipient to:

- comply with applicable privacy and health records laws, record keeping and data management standards;
- keep the data confidential and report any actual or suspected data security breaches that could compromise the confidentiality of the data, the security of Patron, cause the data to be re-identified or misused;
- limit the purposes for which the recipients can use Patron data;
- prevent the recipient from attempting to re-identify the information; and
- be subject to audit to ensure compliance with the agreement.

The University of Melbourne retains the right to, itself or its nominated delegate, audit and inspect Data Recipients' records that relate to its use of Patron data and compliance with the legal Agreement.

[10] Desai, T., Ritchie, F. and Welpton, R. (2016) Five Safes: Designing data access for research. Working Paper. University of the West of England. Available from: http://eprints.uwe.ac.uk/28124 Accessed March 2019

5.4. Legal agreement

Once a prospective project has been approved by the Patron Data Governance Committee, the applicable Data Access Agreement or Memorandum of Understanding must be fully executed prior to the sharing of Patron data (see **Error! Reference source not found. – Error! Reference source not found.**).

If circumstance dictate that an amendment of the terms in the Data Access Agreement or Memorandum of Understanding are required, the circumstance must be considered by the Data Governance Committee, in consultation with the Data Custodian, Principal Investigator, and University of Melbourne Legal Services.

5.5. Controls on data access (including for third parties)

Only individuals named on an approved Patron project ethics application may access and utilise data from Patron. Note that ethics review processes include the scrutiny of the suitability of researchers and organisations to be undertaking their research.

Access to data from the Patron data repository may be provided to researchers employed by the University of Melbourne after the signing of a Patron Data Access Memorandum of Understanding. Access to the data repository may be provided to third parties after the signing of a Patron Data Access Agreement. All data access is bound by the conditions of the Agreement / Memorandum.

Any changes to researchers involved in a project must be requested via an ethics amendment with access to data by new researchers prohibited until ethics approval has been granted and compliance under the MOU or Data Access Agreement has been confirmed.

5.6. International transfer of Patron data

The standard Data Access Agreement prohibits transfer or sharing of Patron data with any third party (researcher, funder, collaborator, etc) outside of Australia without the express written consent of the University of Melbourne. When in receipt of Data Access applications that include the express wish to transfer Patron data outside of Australia, the Data Governance Committee may consider these on a case-by-case basis, in consultation with University of Melbourne Legal Services and Privacy Office. If the University consents to data sharing outside of Australia, the relevant third party must sign an appropriate legal agreement with the University, that includes substantially similar terms to the standard Data Access Agreement.

5.7. Researcher obligations

Researchers external to the University sign a legal agreement with the University of Melbourne (*Data Access Agreement*) stipulating compliance with the ethical, legal and regulatory obligations related to privacy, data management and security. Researchers internal to the University sign a Memorandum of Understanding, similar to the legal agreement, stipulating compliance with the ethical, legal and regulatory obligations related to privacy, data management and security. The purpose of the agreement / Memorandum of Understanding is so that The University of Melbourne and the Data Recipients (i.e. researchers) have a clear understanding of the terms under which data are released.

5.8. Cost recovery

The Program is run on a not-for-profit, cost recovery model. Projects must be individually costed prior to their undertaking and the costs agreed with the Data Recipient prior to signing the Data Access Agreement (for researchers external to The University of Melbourne), or the Memorandum of Understanding (for researchers employed by The University of Melbourne).

Costs of running the Patron program of work include salary and non-salary costs associated with: recruiting primary care practices to share data; liaising with practices and installing GRHANITE™ software; keeping general practices in the feedback loop; data collection and warehousing; data repository maintenance; data cleansing and coding; security and risk assessment and testing; assessment of cost and feasibility of Patron data access requests; running costs of the independent Patron Data Governance Committee and Advisory Panels (e.g. secretariat support, member remuneration); program development and improvement; and university overheads.

5.8.1. Publication obligations

Unreasonable restrictions on publication may result in a Patron project request being refused. All projects must comply with the National Statement on Ethical Conduct in Human Research 2007 (Updated 2018) 'Element 6: Dissemination of project outputs and outcomes' (or later)

As stipulated in the Data Access Agreement, Data Recipients are asked to use their 'best endeavours' to complete the approved project and submit a paper of their findings for publication in a reputable journal. All publications utilising Patron data must include the acknowledgement provided Table 2.

Table 2. Acknowledgement text for publications relating to outcomes from patron data

This research used de-identified patient data from the Patron primary care data repository (extracted from consenting Practices), that has been created and is operated by the Department of General Practice, The University of Melbourne: www.gp.unimelb.edu.au/datafordecisions.

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6. Conflict of interest

All individuals involved in the operation, management and governance of the Patron Program of work must adhere to the University of Melbourne's Conflict of Interest Guidelines of the Research Integrity and Misconduct Policy (MPF1318). Conflicts may be actual, perceived or potential conflicts, direct or indirect, financial or non-financial.

Conflicts of interest must also be declared by prospective Data Recipients in the Data Access Application form.

A record of this declaration must be made and acted on accordingly.

If a declaration of conflict of interest is made by a Patron Data Governance Committee member, that member must not be present during any deliberations with respect to that matter, unless the Committee directs otherwise. The member is not entitled to vote on that matter (refer to Patron Data Governance Committee Operational Instructions and Guidelines).

Appendices

Appendix 1. Acronyms and definitions

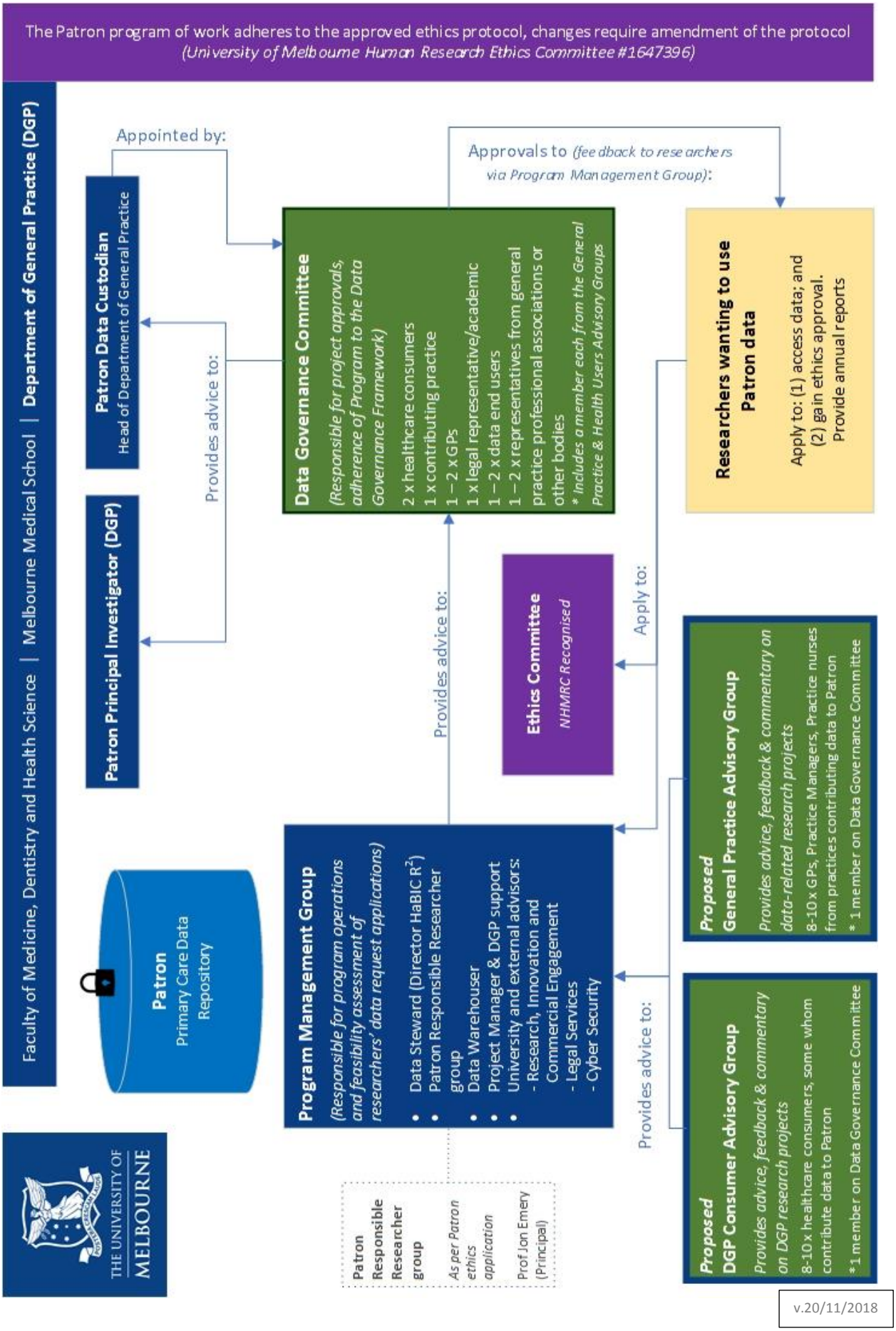
Term	Definition
Approved project	Project status once a request to access Patron data has been approved by the Patron Data Governance Committee
Data Custodian	The Data Custodian is the Head, Department of General Practice and is responsible for the data contained in the Patron data repository.
Data Governance Framework	A document that details data governance arrangements for the Patron data repository and the Patron program more broadly, including details on procedures related to the operation of the Data Governance Committee.
Data for Decisions	A research initiative within The University of Melbourne Department of General Practice that incorporates the Patron data repository and program of work.
Data Minimisation	The principle of data minimisation puts limits on the amount of personal data collected and stored, and limits unnecessary sharing of Patron data fields with Data Recipients.
Data Recipient	The recipient of Patron data may be an institution/organisation, or individual – normally a researcher
Data Steward	The Data Steward – the Director of HaBIC R^2 – has the delegated responsibility to manage security and other data curation activities of the Patron data repository.
EMR	Electronic Medical Record
Five Safes	Is a framework for assessing risk dimensions associated with researcher access to sensitive data (http://eprints.uwe.ac.uk/28124 accessed July 2018).
GP	General practitioner
GRHANITE™	A data software tool that enables the extraction, curation and delivery of sensitive data to data storage facilities. It was first developed in 2007 at The University of Melbourne by Douglas Boyle and Siaw Teng Liaw.
HaBIC R^2	Health and Biomedical Informatics Centre, Research Information Technology Unit
HPPs	Health Privacy Principles
HREC	Human Research Ethics Committee
IPPs	Information Privacy Principles
IT	Information Technology
MOU	Memorandum of Understanding
NHMRC	National Health and Medical Research Council
Patron data repository	A repository of de-identified primary care data housed within The University of Melbourne, it is part of the Data for Decisions research initiative. Patron is abbreviation of 'Primary care Audit, Teaching & Research Open Network'.
Patron Program Management Group	Provides advice and support to the Patron Data Governance Committee, including feasibility review of Data Access Applications, communicating with researchers seeking access to Patron data, and day to day operation of the Patron program.

Practices	General practices and other eligible primary care practices that participate in the Patron program.
Principal Investigator	The Principal Investigator is named on the Patron program ethics application (HREC ID 1647396).
Project Derivatives	Outputs derived from Patron data by an approved project – these may include data scripts, data fields, methods and code, reporting templates used to generate results and other agreed outputs
Risk Register	A tool developed to document, track and help manage risks as they arise.
Secondary use	Secondary use of data is using it for purposes other than what it was originally collected
Standard Operating Procedures	A set of procedures that form the basis for the management of Patron activities
the Program	The Patron program of work, part of the overarching Data for Decisions research initiative
the University	The University of Melbourne
UoM	The University of Melbourne
VicReN	Victorian primary-care practice-based Research Network

Appendix 2. Program synopsis

Title	The Patron Program of Work
Aim	To make better use of existing primary care data to increase research capacity and data quality and improve knowledge, medical education, healthcare policy and the way medical care is delivered.
Objectives	- Create a research program that will advance medical research and public health through creation and use of an enduring, professionally curated repository of primary care data. - Contribute to evidence-based development of healthcare-related policy, tools and practices - Use Patron data to address research gaps, develop innovative research methodology and increase primary health care research capacity. - Provide leadership in the best practice management and use of primary care data for research, teaching and policy development. - Plan and promote the long-term prospects of the program.
Design	A health informatics and research capacity building program of work featuring development of a practice-based research network, creation of an enduring repository of de-identified, curated primary-care data, and use of data for research and teaching purposes. An independent data governance committee oversees appropriate use of data and general practice and health user panels provide advice on the research program. Data has the potential to be linked to other administrative, hospital or laboratory data.
Methods	- Utilise a Learning Healthcare System approach. - Develop partnerships with consenting general practices. - Build a primary care data repository by using GRHANITE™ software to facilitate extraction of de-identified electronic medical record data. - Undertake data curation, cleaning and quality assurance exercises with the data in University of Melbourne data storage facilities. - Make de-identified data available to researchers who gain appropriate data governance and ethics committee approvals. - Provide research, education opportunities and feedback to staff at partnering practices. - Facilitate data linkage, where applicable, through appropriate accredited bodies.
Expected outcomes	- Increased research capacity around primary care in Australia. - Increased knowledge about general practice to contribute to medical education, healthcare policy, health service improvements, and improved patient care.
Study Duration	There is no time limit to this program of research.
Population	The current phase includes general practices in Victoria, Australia.

Appendix 3: Patron Program Organisational Structure



Department of General Practice, The University of Melbourne, 200 Berkeley Street, Carlton, Victoria 3053, Australia

www.gp.unimelb.edu.au/datafordecisions
https://doi.org/10.26188/5c52934b4aeb0