Summary of Patron / Data for Decisions

For researchers to submit with ethics applications that include a request to access data from the Patron primary care data repository.

July 2025

THE UNIVERSITY OF MELBOURNE

1. **Program name:** Known variously as Patron; Data for Decisions; the Data for Decisions research initiative; Data for Decisions and the Patron program. Patron: A safe haven for primary care data (as per The University of Melbourne ethics application ID number 23358).
2. **Patron Chief Investigators:** Prof Douglas Boyle (Data Steward), Prof Jane Hocking, Prof Lena Sanci (Data Custodian), A/Prof Kylie Vuong.
3. **What Patron / Data for Decisions is:**

The Patron Program is an initiative of The University of Melbourne. The Patron primary care repository contains deidentified data from general practice primarily in Victoria, Australia (interstate practices can also participate). It is part of the Data for Decisions research initiative: www.gp.unimelb.edu.au/datafordecisions The aim of the dataset is to facilitate research which will improve patient care in general practice and to benefit the community overall.

4. **The Patron program has ethics approval to:**
   a. Recruit general practices (with legal agreement and consent form) and extract non-identifiable patient data from these general practices' Electronic Medical Records (EMRs) using GRHANITE® data extraction tool. Explicit patient consent is not required, but participating practices are required to keep information about their participation in Data for Decisions on display for patients. Patients can withdraw from having their data extracted.
      i. As per good practice, GRHANITE® has function for general practices to re-identify patients using their unique re-identification key. This can be used for additional studies (not covered by Patron ethics) that practices are involved in when practices recruit patients with certain characteristics to be part of studies. Patron-related researchers do not have access to the re-identification key.
      ii. **Restriction participation:** Some practices contribute data to the Patron repository for use only for a specific research project. Those practices can convert to full participation at any time.
   b. Store encrypted data on a secure server physically located within The University of Melbourne environment. The data are actively managed by the Department of General Practice and Primary Care, HaBIC R^2 in conjunction with The University of Melbourne IT Services.
   c. Link patient data from general practices with other datasets, such as hospital, Medical Benefits Scheme and Pharmaceutical Benefits Scheme data.
   d. Share data with researchers (Data Applicants) who have ethics and Patron Data Governance Committee (DGC) approvals for a specific project. Each new project requires new ethics and DGC approvals.
      i. Researchers with explicit consent from practices to access data stored in the Patron repository relevant to their study do not require DGC approval. Ethics approval must always be obtained and there are processes to work through to access the data (see 4-a-ii – Restricted participation).
   e. Have standard/routine University of Melbourne research ethics applications to access Patron data expedited as a Project within Program ethics application process (Note: Project-Within-Program ethics applications no longer apply with the new ethics system).

5. **Ethics applications:** Patron is a rich repository of general practice clinical data that can be linked to other datasets, including hospital, government, police and social datasets. This provides a unique opportunity to address a wide range of research and policy questions from diverse fields including population health, health economics, health policy, general practice, pharmacoepidemiology, education and social science. Projects within the Patron program share similarity in their use of general practice data but are anticipated to vary in terms of data linkage requirements and research focus. Other Patron projects may include clinical trials or studies involving additional data collection (e.g. qualitative, surveys or pathology) or patient re-identification.

6. **Patron Partner Practices:** General Practices, primarily in Victoria, submit data from electronic medical records to Patron. Recruitment for Patron is ongoing. At present around 120 general practice contribute data from metropolitan and regional Victoria. There is no maximum number of general practices that will be approached or recruited to the Patron repository. Informed consent and legal agreement are gained from each participating practice. Recruitment of partner practices is opportunistic and voluntary. Partner practices do not receive payment for their participation.

7. **Methodology:** General practices are recruited to provide data from electronic medical record systems to Patron. This data is extracted using the privacy protecting tool GRHANITE®. The data is curated and made available to researchers following appropriate ethics clearances and review by the independent Patron DGC. DGC review includes

review of Recipients' data storage and security as outlined in Recipients' Data Risk Management Plans. Data security must be appropriate for sensitive health data.

8. **Arrangements to document informed consent:** A waiver of consent for patients is applied. Patients are able to withdraw from having their data extracted. This is in keeping with NHMRC guidance (Chapter 2.3.9-2.3.10, 2.3.12, National Statement on Ethical Conduct in Human Research). This ethical approach is appropriate given that risk to patients through use of deidentified data is minimal (the benefits outweigh the risks), there is a transparent Data Governance Framework in place, it is not practicable to collect explicit consent from all patients and to do so would introduce bias into the data. Consistent with guidance, the Patron project is low risk. Patients have recourse to advise their general practice if they wish to withdraw; this is recorded at the practice directly into GRHANITE®. Once marked as withdrawn, no further data will be extracted for that patient. The Department of General Practice (HABIC R^2) removes from Patron data that was previously extracted for patients who withdraw but cannot do this for datasets that have already been provided to researchers.

9. **Risk or inconvenience to participant practices:** The Patron team do not anticipate any risks to general practices. GRHANITE® is designed to be seamless, invisible and to not interrupt clinical workflow and data extraction occurs outside practice hours. As a risk minimisation strategy, only practices with warranted IT hardware/infrastructure are eligible to participate, i.e. the computer allocated in the general practice for GRHANITE® installation meets minimum requirements to avoid issues of slow performance or disk saturation.

10. **Procedures for data privacy:** The HaBIC R^2 team and DGP have a procedure for the review of data on an on-going basis, they ensure:

- all data are scrutinized on a regular basis for any mistaken importation of identifiable information;
- data released to researchers has a second level of scrutiny to ensure data are de-identified and is in concordance with the ethics approval of the Recipient; and
- any breach of the above procedures are escalated to ethics and the Patron DGC by the Patron Chief Investigator.

If issues are found internally and no release of identifiable data has occurred, the program:

- Records such occurrences for consideration by the DGC (who may advise escalation to ethics committee)
- Permanently removes offending data
- Ensures immediate steps are undertaken to prevent any further offending data from being imported
- Introduces updates to the GRHANITE® automated screening systems where this is possible.

Data recipients are also required to show their awareness of their obligations around safe use and housing of the data

- Prospective data recipients provide a Patron Data Risk & Management Plan with their application indicating their knowledge and compliance with mechanisms and processes for use and storage of Patron derived data.
- Data Recipients enter into a legal agreement with the University of Melbourne (or MOU if University of Melbourne recipient) to ensure clear understanding of the terms under which Patron data are shared.
- Each user of Patron data completes a Data Access Acknowledgment for Individuals to confirm their understanding of their obligations around data use and reporting.
- A Patron Data Recipient compliance training module with quiz is planned, to be completed by all Patron data users to demonstrate their knowledge of the terms under which the data are shared.

11. **Risks to researchers:** There are no specific risks to researchers in this program of work.

12. **Limitation of the data:** Participant practices voluntarily contribute to the Patron dataset. Their interest in this project may mean that they are not representative of other practices, nor may their style of practice be representative of other practices. They are a non-random, convenience sample of the general practice population in metropolitan and regional Victoria, Australia (and elsewhere, if data from other states is included). Research that draws from this non-random sample is limited in the assumptions that can be made about the general population, even if the practices included in the Patron dataset represent a significant proportion of the total practices in an area.

13. **When requesting data of persons aged over a certain age, be explicit whether entire medical record, including when they were underage, will be requested.** You might use the following in your ethics (and Data Governance) application: "*We are requesting data for patients that are over 18 years of age as at xx/xx/xx. For these patients we are requesting their entire medical history, including records that may have been generated prior to being 18 years of age as some conditions may be persistent, medications ongoing or pathology results still relevant for the period after they have turned 18 and are therefore relevant for the research.*"

Further information on Patron/Data for Decisions is available here: http://www.gp.unimelb.edu.au/datafordecisions