Patron database
Data Access Agreement Summary & Checklist

Program Aim

To make better use of existing primary care data to improve knowledge, medical education, health care policy and the way medical care is delivered, and so ultimately improve the health of Australians.

History

Data for Decisions and the Patron database has been planned to ensure that national and international best practice guidelines are incorporated. The first general practices consented to participate in late 2017.

Due Process

Researchers using data from Patron must gain approval from an NHMRC approved ethics committee, the independent Data Governance Committee, and commit to a legal agreement stipulating terms of data use.

Researchers

Prof Jon Emery

Prof Lena Sanci

Prof Jane Hocking

A/Prof Douglas Boyle

A/Prof Jo-Anne Manski-Nankervis

This document is for prospective and current Patron Data Recipients. It outlines areas covered by the *Data Access Agreement* (legal agreement) and provides a Checklist for Data Recipients of the steps to access data and meet obligations once data has been received.

The Patron program of work: In a nutshell

1. The Patron program uses GRHANITE® software to de-identify and collect information from general practice patient records from consenting practices.
2. Individual patients can 'withdraw' if they choose and participating practices should ensure that practice staff agree to the data collection.
3. Patient **and** practitioner data are de-identified. The de-identified data is curated and stored within the Patron primary care data repository (the Patron database).
4. An independent Data Governance Committee oversees the appropriate storage and use of the data, assessing all applications for use of data.
5. Researchers apply to access the data to undertake clearly defined studies. Researchers must meet strict legal and ethical standards and agree to make available plain language summaries of their research findings.
6. Data providers can have opportunity to choose whether to be involved in additional research or clinical trials that might arise relating to *Data for Decisions* and the Patron program of work.
7. Get more information at www.gp.unimelb.edu.au/datafordecisions

Data access legal agreement

Why is a legal agreement needed?
The legal agreement is so Patron data recipients and the University of Melbourne both have a clear understanding of the terms under which the data is shared.

Why do I also need ethics committee approval?
Gaining approval to access Patron data from an NHMRC recognised Human Research Ethics Committee is part of your ethical obligation to the people and general practices that contribute information to the Patron data repository. Patron data will not be provided if ethics committee approval has not been gained.

Reading the legal agreement
The legal agreement summarises some of the obligations of data recipients. At the end a glossary defines the terms used. Data recipients may wish to seek their own independent legal advice prior to signing the Data Access Agreement.

Who should sign the legal agreement?
One **Data Access Agreement** needs to be completed and returned by a representative from each data recipient organisation. For example, if 6 researchers from 2 organisations external to the University of Melbourne are accessing Patron data, then 2 Agreements need to be returned. Each individual data recipient should sign a **Data Access Acknowledgement for Individuals** (Appendix B to legal agreement).

What the legal agreement covers

The legal agreement contains a section called Contract Details. This is where the terms of the agreement are captured. Terms can include whether Data Recipients agree to provide Project Derivatives back to the University of Melbourne (such as data scripts, data fields, methods and code, or other agreed project outputs).

The legal agreement spells out the obligations of both the Data Recipients and the University of Melbourne. It includes details about:

- Supply of Patron data
- Timing of supply
- Support provided to the data recipients
- How data change requests are handled
- Permitted use of Patron data
- Recipients' obligations around publication of research outcomes arising from Patron data
- Payment
- Intellectual property rights
- Warranties
- Recipient obligations around data privacy, security and access
- Confidentiality
- Limitations, liability and indemnity
- Termination of contract
- Insurance obligations of data recipients
- Conflicts of interest
- Resolution of disputes
- Audit and inspection of recipient's records relating to its use of Patron data and compliance with the legal Agreement
- Definitions

University of Melbourne staff

Memorandum of Understanding (MOU)

University of Melbourne approved Patron Data Recipients cannot sign the *Data Access Agreement* because the University cannot execute a legal agreement with itself. Lead University of Melbourne Patron Data Recipients sign an MOU which outlines largely the same terms and obligations as the legal agreement. Individual researchers working under the Lead Recipient should also sign the ***Data Access Acknowledgement for Individual Researchers*** (University of Melbourne version).

IF UNCERTAINTIES OR QUESTIONS ARISE WHILE WORKING WITH PATRON DATA CONTACT OUR TEAM IMMEDIATELY

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www.gp.unimelb.edu.au/datafordecisions

To Do List for Data Recipients

- [ ] Have an idea? Check the Patron Databook on the website to determine whether the Patron dataset contains information you need
- [ ] Talk with Department of General Practice (DGP) to determine project feasibility
- [ ] If feasible, complete a Patron *Data Access Application form* and an initial *Data Risk & Management Plan* (DRMP)
- [ ] Submit your application, DRMP and any other requested items (e.g. ethics application) to vicren-enquiries@unimelb.edu.au

Your application is assessed by the independent Patron Data Governance Committee. If approved…

- [ ] Provide a copy of your full ethics application & work with DGP to develop a *Project Plan* and your *Data Specification Requirement*
- [ ] Return your signed and witnessed Data Access legal agreement (one per organisation) and/or MOU (for University of Melbourne)
- [ ] Project Leader collects signed *Data Access Acknowledgements* from all individuals (Appendix B of legal agreement / MOU)
- [ ] Personnel accessing Patron data must undertake appropriate data security awareness and incident prevention training
- [ ] Provide updated DRMP to DGP (you comply with your DRMP as per the Privacy & Security clause in the legal Agreement)
- [ ] Within 30 days, check received data for accuracy and completeness
- [ ] Return *Data Delivery Receipt* within 30 days of data delivery indicating data received as agreed
- [ ] Notify us immediately if you find a privacy breach in the data (i.e. person identifiable information)
- [ ] Notify us within 3 days if you become aware of a security breach – e.g. unauthorised access to or loss of Patron data
- [ ] Notify us if you find an anonymisation inaccuracy e.g. '[Anonymised] cyst' rather than 'Baker's cyst'
- [ ] Become a member of the Patron Data Users group and benefit from the data coding bank
- [ ] 1 month prior to disclosing outputs (journal article, conference, etc), provide DGP with relevant sections for checking to safeguard against inaccurate data interpretation
- [ ] When research personnel change: Update your DRMP and have new researchers sign a *Data Access Acknowledgement*
- [ ] Provide DGP with annual progress reports
- [ ] Provide DGP with plain language summaries of findings for dissemination
- [ ] Provide DGP with Project Derivatives if contractually agreed to do so