

Summary of Data Access Agreement and researcher checklist



THE UNIVERSITY OF
MELBOURNE

Department of General Practice and Primary Care, Melbourne Medical School

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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 Lena Sancı

Prof Jane Hocking

Prof Douglas Boyle

A/Prof Kylie Vuong

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 <http://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**.

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

The University of Melbourne staff

Memorandum of Understanding (MOU)

The 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***.

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

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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 and Primary Care (DGPPC) to determine project feasibility
- If feasible, complete an online Patron *Data Access Application form*
- Submit your application and any other requested items (e.g. ethics application) via the Data for Decisions website

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

- Provide a copy of your full ethics application & work with DGPPC to develop your *Data Specification Requirement*
- Return your signed and witnessed Data Access legal agreement and/or MOU (for The University of Melbourne)
- Project Leader collects signed *Data Access Acknowledgement forms* from all individuals
- Personnel accessing Patron data must undertake appropriate data security awareness and incident prevention training
- Provide updated DRMP to DGPPC (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
- Ensure that any new use of the Patron data, within the approved ethics, is registered as a subproject
- 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 DGPPC with relevant sections for checking to safeguard against inaccurate data interpretation
- When research personnel change: Update your Data Access Application form and have new researchers sign a *Data Access Acknowledgement*
- Provide DGPPC with annual progress reports
- Provide DGPPC with plain language summaries of findings for dissemination
- Provide DGPPC with Project Derivatives if contractually agreed to do so