

Data for Decisions Data Sharing Agreement Summary

Project 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 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

A/Prof Jo-Anne Manski-Nankervis

Prof Jon EMery

Prof Lena Sancu

Prof Douglas Boyle

Prof Jane Hocking

Welcome

This leaflet provides a summary of *Data for Decisions*, the *Agreement for the Provision of Data*, and other information about the project for General Practitioners.

Our Commitment

We are committed to protecting privacy and we de-identify both **patient AND practitioner**-related information. Data re-identification is only possible within the practice by the practice using a re-identification key.

Data for Decisions is not-for-profit and adheres to the ethical principles in the *National Statement on Ethical Conduct in Human Research*. We are committed to making research outcomes accessible and to publishing research findings. We work with a GP network to design research studies and to facilitate practice improvements and innovation. Curated data is held only within University controlled, on-shore, secure data storage facilities. The project is not compatible with 'cloud'-based clinical practice software.



Data for Decisions research initiative: In a nutshell

1. *Data for Decisions* uses a University of Melbourne developed and controlled software program (GRHANITE®) to securely de-identify and collect information from general practice patient records from consenting practices.
2. Because the information is de-identified, patient consent is not required, but patients can easily 'withdraw' if they choose. Participating practices need to 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. They must meet strict legal and ethical standards and agree to make available plain language summaries of their research findings.
6. GPs can choose, at their discretion, whether to be involved in additional research or clinical trials that might arise relating to *Data for Decisions* and the Patron data repository.
7. You can access more information at www.gp.unimelb.edu.au/datafordecisions

Agreement for the Provision of Data - Summary

Why is a legal agreement needed?

The legal agreement is so that The University of Melbourne and the general practice sharing data both have a clear understanding of the terms under which the data is shared.

Why is there a consent form?

The consent form is part of our ethical obligation to you. It tells us you have read the plain language information statement and that you have had a chance to ask questions so that you fully understand the project. You can also indicate whether you do not wish for your practice data to be accessed by commercial entities or used in research funded by commercial entities.

Reading the legal agreement

The grey boxes in the Agreement explain each section in plain language. At the end a glossary defines the terms used (Part G). If you feel it is necessary, please seek independent legal advice, and do not hesitate to contact us with any questions.

Who should sign the legal agreement?

Like the Consent form, the legal Agreement should be signed by Practice Principals or someone else authorised to sign on behalf of all staff.

What the legal agreement covers

Part A: Installation and licence of data sharing software

This part details what you agree to when you 'accept' the License Agreement on your practice computer when GRHANITE® is installed. It outlines promises made between you and The University of Melbourne regarding GRHANITE®.

Part B: Collection of Data

This is the longest part of the Agreement. It suggests that practices should attempt to maintain the quality of their data; outlines information about communication with patients about the project, including the patient withdrawal form; outlines the permission you give for The University of Melbourne to extract and transmit de-identified data from your practice records; explains the terms under which the University can use and share the data; and how practices might be invited to participate in optional data validation studies and/or interventional studies including clinical trials. It also outlines the circumstances under which de-identified data might be re-identified (this can only be done by the practice using a re-identification key).

Part C: Privacy and Security

The University of Melbourne will comply with all privacy laws. It outlines how demographic data about practice staff is de-identified (a special feature of this program). It also sets out General Practice and University responsibilities related to consent, data breaches and complaints.

Part D: Training, Support and Feedback

This part describes how your practice may benefit from participating in *Data for Decisions*, including opportunities to receive training and customised practice feedback.

Parts E & F: General Provisions & Miscellaneous

These parts set out general provisions regarding compliance, intellectual property, terms of the Agreement and its termination, confidentiality, publicity related to the program, and miscellaneous 'standard' contractual provisions that do not fit elsewhere within the Agreement (e.g. about partnerships, variations to the contract, being covered by governing laws).

What you need to do

- ✓ Read the information about the project and ask questions:
 - *Information for General Practices*
 - *Consent to Participate for General Practices*
 - *Agreement for the Provision of Data*, and see our website.
- ✓ Discuss the project with your practice staff (you will be signing for all practice staff so it is important that current and new staff understand this).
- ✓ The Practice Principal(s) or other designated person(s) sign the consent form and the legal Agreement.
- ✓ Department of General Practice staff will liaise with your practice to install GRHANITE®.
- ✓ Keep the practice computer with GRHANITE® installed turned on (data sharing occurs overnight).
- ✓ Display information about *Data for Decisions* in your waiting area (that we will supply).
- ✓ If you wish, keep abreast of research associated with *Data for Decisions* through our newsletters and our website.
- ✓ If you wish, join our General Practice Advisory Panel and have input on the research undertaken.

Get in touch

www.gp.unimelb.edu.au/datafordecisions

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