

Participant Information

1. What is the 'Join Us' research register about?

'Join Us' is a national electronic research register for people aged 18 years or over who are interested in taking part in health research. The register will:

- Collect and hold your personal details and Medicare number if provided;
- Match this information to your health-related records;
- Allow us to contact you about research projects that you might be interested in joining; and
- Enable us to use your de-identified health data to try and answer future research questions. 'De-identified health data' means health data that do not have your personal details attached to them and that cannot be used to identify you.

Who manages the register?

The Register is managed by The George Institute for Global Health (The George Institute), a non-for-profit medical research institute based in Sydney in collaboration with the University of New South Wales. The Chief Investigator is Professor Bruce Neal and the Co-Investigators are Doctor Clare Arnott, Professor Louisa Jorm, Ms Angela Hehir, Dr Duong Tran and Dr Xingzhong Jin. The register is funded jointly by The George Institute and the University of New South Wales.

2. Do I have to participate in the 'Join Us' register?

You are eligible to join 'Join Us' if you are an adult aged 18 years or over and are currently living in Australia.

Is my participation voluntary?

Your participation in the 'Join Us' register is completely voluntary and there will be no cost to you. If you do not want to take part in the 'Join Us' register you do not have to. You should feel under no obligation to participate. Choosing not to take part will not affect your current or future medical care in any way.

What do I need to do to participate?

If you decide to take part in the 'Join Us' register, you will be asked to provide consent for:

- Your personal details, including your Medicare number if provided, to be stored and matched with health-related records so that we can contact you about research studies you might be interested in. Up to four invitations could be sent a year, with each initial invitation being followed by one reminder if you don't get back to us. This will be a maximum of 8 messages a year.

AND/OR

- Your de-identified health-related records to be disclosed to the 'Join Us' register by the Australian Institute of Health and Welfare, Services Australia or by the agencies or providers of the Commonwealth government, State governments or Territory governments;

AND/OR

- Your de-identified health-related data to be held within the 'Join Us' register for approved research studies.

To participate you will need to:

- Read this Participant Information Statement and complete the Consent Form at the end;
- Give us some information about yourself, including your first name, last name, sex, date of birth, email address, street address and post code. We will also ask for your Medicare card details but this is optional as is provision of your telephone number. If you are not able to provide your Medicare card details at sign up we will send you a request in the weeks after sign up.
- After joining you will be asked to complete a brief optional survey that will help us match you to appropriate research studies.

You will receive a regular electronic newsletter with updates about the 'Join Us' register but you can unsubscribe from receiving newsletters if you wish to.

3. Can I withdraw from the 'Join Us' register?

You are under no obligation to continue with the 'Join Us' register if you join. You may change your mind at any time. People withdraw from studies for various reasons and you do not need to provide an explanation.

If you withdraw from the register, you will be able to choose whether the register will destroy or retain the information it has collected about you already. A withdrawal request will apply from the time you notify us. It may not be possible to withdraw information already used for research or publication but you will no longer be contacted about research opportunities. Your decision to withdraw from the register will not affect your relationship with The George Institute or the University of New South Wales and will not affect your healthcare or disadvantage you in any way.

4. What information is being collected in the 'Join Us' register and how is it being used?

What type of health information does the register collect?

The 'Join Us' register will link to a variety of information sources that will allow researchers to better understand factors influencing your health and the health needs of the community. Your personal details (first name, last name, email address, street address, post code, date of birth,

sex and Medicare number if provided) will be regularly matched to records relating to your current and past health treatments, procedures, and use of health services.

Linked data sources will include but are not limited to: the Medicare Benefits Scheme; the Pharmaceutical Benefits Scheme; the National Death Index; the Registry of Births, Deaths and Marriages; admissions to hospitals; attendances at emergency departments; and pathology services. The ability to do data linkage is expanding and we may expand future data collection to records that are not currently available. For example, it is not currently possible to link data from the electronic health record held by your general practitioner, but this might soon be possible. Before we link data from any additional source we will seek approval from a Human Research Ethics Committee. You can see approved data sources currently being accessed here. www.joinus.org.au/your-privacy.

How are my data to be used to match me to a research study?

Researchers wanting help with recruiting participants to their research study will discuss their study with the 'Join Us' team. The 'Join Us' team will check that the study has its own human research ethics approval and then search data held within the 'Join Us' register for people who may match the study requirements – for example people aged between 40 and 60 who have high blood pressure. A list of potentially eligible people will be generated and the 'Join Us' team will send an invitation to people in the list with information about the study. You can then consider whether you are interested in taking part. Importantly, the invitation is sent by the 'Join Us' team and we do not share your personal details or health information with the researchers. The researchers will only know that you have been invited if you get back to them.

How will my de-identified health data be used to try and answer health research questions?

Researchers wanting to try and answer health research questions using de-identified health data will discuss their study with the 'Join Us' team. Once again, before accessing your data for this purpose, the 'Join Us' team will check that the study has its own human research ethics approval. For a study with approval, the 'Join Us' team will provide the researchers with access to the 'Join Us' database to do analyses. Importantly, the access provided to the researchers is only to de-identified data that cannot be linked to personal information such as your name or email address.

5. How do I give consent for linkage of my data to the Medicare Benefits Schedule, the Pharmaceutical Benefits Scheme and other databases?

You will sign the consent form at the end of this document authorising the 'Join Us' register to access your complete Medicare Benefits Schedule, Pharmaceutical Benefits Scheme and other data. Medicare collects information on your doctor visits and the associated costs, the Pharmaceutical Benefits Scheme collects information on

the prescription medications you have filled at pharmacies, and other service providers collect additional types of data. A copy of your consent form will be sent securely as required to relevant government providers (for example Services Australia) who hold your data confidentially, to show them that you have given us permission to access your data.

6. What will happen to my data?

How are my data stored and de-identified?

Your health data will be stored in the University of New South Wales E-Research Institutional Cloud Architecture (ERICA) Platform. ERICA is a secure cloud computing environment that has been approved by eHealth New South Wales for data security. Your personal details collected during the registration phase will be held within an industry standard, password protected, encrypted database designed to meet the privacy and security requirements of commercial, government and not for profit segments. Your data are physically located within Australian borders. If you have provided data to the register via the optional survey, this will be transferred to ERICA and purged from the register.

Your personal details (e.g. names, date of birth, sex, Medicare number, and email address) will be stored separate to your health data. The system will assign a unique identifying number to your personal details. That unique number (not your personal details) will be used to tag all records of your health data. Importantly, the database that contains your personal details linked to your unique identifying number is stored separately from your tagged health data. The database linking your personal details to your unique identifying number is only accessible to 'Join Us' team members with special security clearance. This arrangement ensures that no one knows which health data belong to which person.

You will not be identifiable in published study reports and no results for individual participants will be disclosed. Additionally, your data will not be used for an unspecified purpose outside of ethically approved studies..

How long will my data be stored and how will it be destroyed?

The 'Join Us' register is intended to be a long-term project and has no end date, with data intended to be stored indefinitely. Many health conditions take decades to evolve and treatments are often long-term, so years of data are required to answer many medical and health research questions. At any point you can request to stop having your data added to the 'Join Us' register or to have your data removed from the register. If you chose to have your data destroyed, the Join Us register administrator will delete your record in the register. All health records in ERICA will be disposed of in accordance with the [University of New South Wales standard Handling Research Material & Data Procedure](#).

Can I access my data?

The information you will provide is personal information regulated by the Privacy Act 1988 (Federal) and the Privacy and Personal Information Protection Act 1998 (NSW). You have the right of access to personal information held about you by 'Join Us', the right to request correction and amendment, and the right to make a complaint about a breach of the Information Protection Principles as contained in the Privacy and Personal Information Protection Act. Further information on how the University of New South Wales protects personal information such as that held by 'Join Us' is available in the [UNSW Privacy Management Plan](#).

7. Are there any risks involved?

Data security is a potential risk but privacy of information held within the 'Join Us' register is taken very seriously. 'Join Us' uses several strategies to maximise data security:

- The 'Join Us' register is managed by The George Institute Australia and the University of New South Wales who are both world-leading research facilities with comprehensive procedures in place to manage sensitive health data.
- The 'Join Us' register will store your data (personal identifiers and health information) in the E-Research Institutional Cloud Architecture (ERICA) Platform. ERICA has completed the full eHealth New South Wales Privacy Security Assurance Framework review and eHealth New South Wales has formally advised that ERICA is designed with adequate security to meet the requirements of New South Wales Health. The ERICA platform has comprehensive security protocols for storage, access, quality assurance, retention and destruction of data. All 'Join Us' team members and researchers with approval to analyse data through ERICA will receive specific and comprehensive training.
- The 'Join Us' participant personal details (e.g. names and email address) are stored separate from the health data. In addition, the health data held by 'Join Us' are de-identified and comprehensive privacy-preserve protocols are in place for procedures linking personal details to the central database of health and other information.

8. What are the possible benefits of taking part?

There is no guaranteed personal benefit for participating in this study, but your participation would be likely to make a contribution to the health of the larger Australian community. Other possible benefits may include the opportunity to take part in clinical trials investigating new treatments, and the opportunity to let your friends and relatives know about opportunities to take part in medical research.

You will not receive reimbursement for joining 'Join Us' but there is a potential for individual studies to offer reimbursement for costs such as travel.

9. What are the alternatives to taking part in the register?

'Join Us' is the only research register of its type in Australia. There are other disease registries for people with specific health problems but none that are trying to engage the broader Australian community in this way. You are welcome to join 'Join Us' even if you are already involved in health and medical research in another way.

10. How and when will I find out what the results of research I participate in through the register?

When the 'Join Us' team matches you to an approved research study and you agree to participate, you will be informed by the researchers responsible for that study about all details of the research you participate in. This will include finding out the results at the completion of the study.

11. What if I want to withdraw from 'Join Us'?

You may withdraw at any time. You can do so by:

- Completing the electronic 'Form for Withdrawal of Participation' which is provided at the end of this document;
- Calling us (02) 8052 4798; or
- Emailing us info@joinus.org.au

12. What if I have a complaint or any concerns about 'Join Us'?

If you have a complaint regarding any aspect of the 'Join Us' register or the way it is being conducted, please contact the University of New South Wales (UNSW) Human Ethics Coordinator:

Complaints Contact

Position

UNSW Human Research Ethics Coordinator

T: +61 2 9385 6222

E: humanethics@unsw.edu.au

HC Reference Number

HC200256

13. Will I receive compensation if I suffer any injuries or have complications?

If you suffer any injuries or complications as a result of a research study that the 'Join Us' register has matched you to, you should contact the study team leading that research study as soon as possible to arrange appropriate medical treatment. If you are eligible for Medicare, you can receive required medical treatment free of charge, as a public patient in any Australian public hospital.

14. What should I do if I have further questions about my involvement in the register?

You can contact the 'Join Us' team by phone or email:

T: (02) 8052 4798

E: info@joinus.org.au

If you need to contact researchers who are conducting a research study you have agreed to participate in, you can find their contact details in the Participant Information Statement you received from that study.

Important Information: This form is only to be used by people aged 18 years or over

- Complete this form to provide your consent to join the 'Join Us' register;
- Complete this form to request the release of your personal Medicare Benefits Schedule and Pharmaceutical Benefits Scheme data by Services Australia to the 'Join Us' register; and
- Complete this form to request the release of your other health-related information as outlined in the Participant Information Statement by the Commonwealth government, State governments, Territory governments and their agencies or providers, to the 'Join Us' register.

Declaration by the participant

- I understand that I am being asked to provide consent to participate in the 'Join Us' register.
- I have read the Participant Information Statement and understood it, or someone has read it to me in a language that I understand.
- I understand that my Medicare Benefits Schedule and Pharmaceutical Benefits Scheme information may be disclosed by Services Australia for the purposes of the 'Join Us' register.

- I understand that other health-related information as outlined in the Participant Information Statement may be disclosed by the Commonwealth government, State governments, Territory governments and their agencies or providers for the purposes of the 'Join Us' register.
- I understand that the result of research studies may be published in articles or journals.
- I understand that my name will never be disclosed by Services Australia, the Commonwealth government, State governments, Territory governments, their agencies or providers or the 'Join Us' register.
- I understand that my participation in the 'Join Us' register is completely voluntary.
- I understand that I can withdraw my participation in the 'Join Us' register at any time and I do not have to provide a reason for my withdrawal.
- I understand that my information could be held indefinitely unless I withdraw from the study and ask for it to be removed.
- I understand that I won't be paid for joining 'Join Us'.
- I have been given the opportunity to ask questions and any questions I have asked have been answered to my satisfaction.
- I declare that the information on this form is true and correct.

Consent by the participant

I consent to (tick all that apply – you will need to tick at least one of these two options to participate):

- My personal information being provided to the Australian Institute of Health and Welfare and other Australian and State and Territory Government agencies to enable release of information from Australian Government records for the purposes of inviting me to participate in health research studies.

AND/OR

- The use of my de-identified health data held within the 'Join Us' register for approved research studies.

I consent to (tick all that apply – you will need to tick at least one of these three options to participate):

- The Commonwealth government, State governments, Territory governments and their agencies or providers sharing my health information with the 'Join Us' register.

AND/OR

- Services Australia providing my Medicare Benefits Schedule information to the 'Join Us' register.

AND/OR

- Services Australia providing my Pharmaceutical Benefits Scheme information to the 'Join Us' register.

Signed: _____ (participant's signature)

Dated: ____/____/____
DD/MM/YYYY

Privacy and your personal information

The privacy and security of your personal information is important to us and is protected by law. We need to collect this information so we can process and manage your applications and provide services to you. We only share your information with other parties where you have agreed, or where the law allows or requires it. For more information, go to servicessaustralia.gov.au/privacy

I wish to **WITHDRAW** my participation in the 'Join Us' register.

I request that the 'Join Us' register handles the information they have collected about me in the follow way:

Choose one option (Where both boxes are ticked, or neither box is ticked, we will destroy all information that has been collected about you):

- Destroy all information collected about me (both personal details and de-identified health data) so it can no longer be used for research and do not contact me about future studies.
- Retain the de-identified health data collected about me to date but delete my personal details from the database, do not collect any further information about me and do not contact me about future studies.

I understand that:

- No further information about me will be collected for the 'Join Us' register from the withdrawal date;
- Information about me that has already been analysed and/or included in a publication may not be able to destroyed;
- Choosing to withdraw from the 'Join Us' register will not affect my access to health services or government benefits;
- Choosing to withdraw from the study will not my relationship with the George Institute Australia or the University of New South Wales.

Signed: _____ (participant's signature)

Dated: ____/____/____
DD/MM/YYYY

The form can be either emailed to info@joinus.org.au

or posted to

Join Us Research Register
Level 5
1 King Street
Newtown
NSW 2042