

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;
- Collect and hold the health and demographic information you provide us;
- Use this information to match you to relevant research studies; and
- Allow us to contact you about research projects that you might be interested in joining.

Who manages the register?

'Join Us' is managed by The George Institute for Global Health (The George Institute), a not-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 Dr 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?

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.

3. What do I need to do to participate?

You are eligible to join 'Join Us' if you are an adult aged 18 years or over and are currently living in Australia. If you decide to take part in the 'Join Us' register, you will be asked to:

- Read this Participant Information Statement.
- Provide personal details including your first name, last name, sex, date of birth, email address, and post code.
- Give us some information about your health and demographics that will help us match you to appropriate research studies.
- Agree to receive up to four invitations to research projects a year. Each initial invitation may be followed by one reminder if you don't get back to us. This will be a maximum of 8 messages a year.
- Complete and submit the Consent Form.

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

4. 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 all the information held (personal details and health and demographic data) will be destroyed. 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.

5. How is my information 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 self-reported health and demographic information with the researchers. The researchers will only know that you have been invited if you get back to them.

6. What will happen to my data?

How are my data stored and de-identified?

Your personal details, such as name and date of birth will be held in an industry standard, password protected, encrypted database designed to meet the privacy and security requirements of commercial, government and not-for-profit segments. The system will assign a unique reference number to your personal details.

Your health and demographic information will be transferred to 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 health and demographic information will be de-identified by tagging it only with your unique reference number and not with your personal details.

Storing your personal details separate from your health and demographic information is done to maximise the security of your data. The database linking your personal details to your unique reference number and your health and demographic information is only accessible to 'Join Us' team members with special security clearance. This arrangement ensures that no one knows which health and demographic information belongs to which person.

You will not be identifiable in published study reports and no results for individual participants will be disclosed. Additionally, your information will not be used for an unspecified purpose outside of ethically approved studies. All of your data are physically located within Australian borders.

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 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 and demographic 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 Australian privacy laws. 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 applicable privacy laws. Information on how The George Institute manages personal information can be found here. Further information about how the University of New South Wales manages personal information can be found in their Data Governance Policy and their Research Data Governance & Materials Handling Policy.

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 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 health and demographic 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 are stored separate from the health and demographic information. In addition, the health and demographic information held by 'Join Us' is de-identified and comprehensive privacy-preserve protocols are in place for procedures linking personal details to the health and demographic information in ERICA.

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 taking part in '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 participate in 'Join Us' even if you are already involved in health and medical research in another way.

10. How and when will I find out about the results of research I participate in through 'Join Us'?

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 Research 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.

Participant providing own consent

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

Complete this form to provide your consent to participate in 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 the result of research studies may be published in articles or journals.
- 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 'Join Us' register 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 my personal details and health and demographic information being collected, stored and used by the 'Join Us' register for the purposes of inviting me to participate in health research studies.

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 servicesaustralia.gov.au/privacy

Withdrawal of Participation Form

- ☐ I wish to WITHDRAW my participation in the 'Join Us' register. Destroy all information collected about me (both personal details and health and demographic information) so it can no longer be used for research 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 be 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 affect my relationship with The George Institute 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

Participant Information Statement

'Join Us' research register – data linkage option

1. What is the 'Join Us' data linkage option about?

This Participant Information Statement and Consent Form is for participants in the 'Join Us' register who also wish to participate in the data linkage option.

The 'Join Us' data linkage option will:

- Collect and hold additional personal details, namely your street address and Medicare number.
- Match your personal details and Medicare number to your electronic health records.
- Store your de-identified electronic health records.
- Allow researchers to use your de-identified electronic health records to try and answer future research questions.

Your de-identified electronic health record data may also be used to enable more precise matching of you to research studies that you may be interested in joining.

2. Do I have to participate in the 'Join Us' data linkage option?

Your participation in the 'Join Us' data linkage option is completely voluntary and there will be no cost to you. If you do not want to take part in the 'Join Us' data linkage option 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.

3. What do I need to do to participate in the data linkage option?

If you decide to participate in the 'Join Us' data linkage option, you will need to:

- Read this Participant Information Statement.
- Provide your street address and Medicare number.
- Agree to your personal details, including your Medicare number and address, being used to identify your electronic health records held by Services Australia and by the agencies or providers of the Commonwealth government, State governments or Territory governments and other health service providers.
- Allow a copy of your electronic health records to be stored in a de-identified format by the 'Join Us' register for use in approved research studies and to enable more precise matching of you to research studies that you may be interested in joining.
- Complete and submit the Consent Form.

4. Can I withdraw from the 'Join Us' data linkage option?

You are under no obligation to continue with the 'Join Us' data linkage option 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 data linkage option, 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 but it may not be possible to withdraw information already used for research or publication. Your decision to withdraw from the register will not affect your relationship with The George Institute Australia or the University of New South Wales and will not affect your healthcare or disadvantage you in any way.

5. What information is collected by the 'Join Us' data linkage option?

The 'Join Us' data linkage option will connect to a variety of databases that hold a broad range of health information. Such information is routinely collected by governments and other health care providers. 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 extend 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 be an option in the future. Before we link data from any additional source, we will always seek approval from a Human Research Ethics Committee.

Your personal details (first name, last name, email address, post code, date of birth, sex, street address and Medicare number) will be used to identify electronic records relating to your current and past health treatments, procedures, and use of health services. Your records will be extracted from the relevant databases and a copy of your records will be stored in a secure data repository within 'Join Us'. This data linkage process will be done several times every year and will require no further action from you. Your electronic health records held by 'Join Us' will be de-identified by tagging them only with your unique reference number and not with your personal details.

6. How will my de-identified electronic health records be used to try and answer research questions?

Your electronic health records may contain information that will allow researchers to better understand factors influencing your health and the health needs of the community. Researchers wanting to try and answer health research questions will discuss their study with the 'Join Us' team to see if access to the 'Join Us' register data might help address their research question. Before providing access to your data 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 the approved 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.

7. 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 Medicare Benefits Schedule, Pharmaceutical Benefits Scheme and other electronic health record information. 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 health information. A copy of your consent form will be sent securely to Services Australia and other providers who hold your health information according to their requirements. Transfer of a copy of your consent form will be done confidentially and only done to show the relevant agency that you have given us permission to access your information.

8. What will happen to my data collected for the 'Join Us' data linkage option?

How are my data stored and de-identified?

The additional personal details (street address and Medicare number) collected when you agree to participate in the 'Join Us' data linkage option will be held within our industry standard, password protected, encrypted database designed to meet the privacy and security requirements of commercial, government and not for profit segments. This is the same database in which the personal details you provided at initial entry to 'Join Us' are stored.

Your electronic health records will be stored in the University of New South Wales E-Research Institutional

Cloud Architecture (ERICA) Platform. This is the same database in which the health and demographic information you provided at initial entry to 'Join Us' are stored. ERICA is a secure cloud computing environment that has been approved by eHealth New South Wales for data security. Your electronic health records held by 'Join Us' will be de-identified by tagging them only with your unique reference number and not with your personal details.

Storing your electronic health records in a de-identified form is done to maximise the security of your data. The database linking your personal details to your unique reference number is only accessible to 'Join Us' team members with special security clearance. This arrangement ensures that no one knows which electronic health records belong to which person.

You will not be identifiable in published study reports and no results for individual participants will be disclosed. Additionally, your information will not be used for an unspecified purpose outside of ethically approved studies. All of your data are physically located within Australian borders.

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, records will be disposed 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 Australian privacy laws. 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 applicable privacy laws. Further information on how The George Institute manages personal information obtained via the register is available in the 'Join Us' privacy policy which can be found here. Further information on how the University of New South Wales manages personal information held in ERICA is available in the Data Governance Policy and the Research Data Governance & Materials Handling Policy

9. 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 and the University of New South Wales who are both world-leading research facilities with comprehensive procedures in place to manage sensitive health information.
- The 'Join Us' register will store your 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 information. In addition, the health information held by 'Join Us' is de-identified and comprehensive privacy-preserve protocols are in place for procedures linking personal identifiers to the central database of health and other information.

10. How and when will I find out about 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

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 Research Ethics Coordinator:

Complaints Contact

Position: UNSW Human Research Ethics Coordinator

T: +61 2 9385 6222

E: humanethics@unsw.edu.au

HC Reference Number

HC200256

12. 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.

13. 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.

Participant providing own consent

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

- 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 Medicare Benefits Schedule and Pharmaceutical Benefits Scheme data and/or other health-related records as outlined in the Participant Information Statement by the Commonwealth government, State governments, Territory governments and their agencies or providers and other health service 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 Medicare Benefits Schedule and Pharmaceutical Benefits Scheme data and/or 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 not 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' data linkage option 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 'Join Us' register and ask for it to be removed](#).
- I understand that I won't be paid for taking part in ['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** the use of my de-identified electronic health records held within the 'Join Us' register for approved research studies, and for inviting me to health research studies I may be interested in.

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 and other health service providers sharing my electronic health records 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 servicesaustralia.gov.au/privacy

Withdrawal of Participation Form

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 following 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 (i.e. personal details, de-identified health and demographic survey data, and de-identified electronic health records) so it can no longer be used for research and **do not contact me** about future studies.
- ☐ **Retain the de-identified health records** collected about me to date (i.e. the de-identified health and demographic survey data and the de-identified electronic health records) 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 affect my relationship with The George Institute 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