Australian ME/CFS and Long COVID (AusME) Registry

PARTICIPANT INFORMATION STATEMENT

You are being asked for your consent to take part in the Australian ME/CFS and Long COVID (AusME) Registry data collection. The following sections will describe the key information that we believe most people need, to decide whether to take part in the AusME Registry. After reading the Informed Consent and providing answers to two brief comprehension questions, you will be asked if you want to participate.

You can take as long as you need to read the Informed Consent. If you exit the Informed Consent, you can return by logging in with your username and password.

If you don't understand or have questions, contact the research team at information.ausme@emerge.org.au, or call our office on 1800 865 321 (toll free)

Here's some helpful information up front:

- Participating in the AusME Registry is completely voluntary
- After signing up, if you wish to withdraw your consent/participation in the AusME Registry, all you need to do is notify Emerge Australia by emailing information.ausme@emerge.org.au or phone 1800 865 321 (toll free)

1. What is the purpose of this project?

Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS) and Long COVID are still poorly understood and there are no tests to confirm a diagnosis or specific treatments that are widely accepted.

A patient registry is a place where medical information, family history and other related information from patients is collected and stored for medical research. The goal of the AusME Registry is to register individuals with ME/CFS or with Long COVID, as well as non-ME/CFS or non-Long COVID healthy control participants and compile their demographic and health information into a data bank. The Registry may also be linked to a biobank which is a place that stores tissue, blood or other samples from participants.

The AusME Registry will facilitate future research in ME/CFS and Long COVID, by making this information accessible to *approved* researchers for hypothesis generation and ethically-approved research. The AusME Registry will also help identify study participants for new research studies.

Your participation in the AusME Registry involves you giving 'unspecified' consent. This means that you allow your personal information to be used for a variety of future medical research studies, that are approved by an Institution's Human Ethics committee, but which cannot be specified at the present time.

2. Who is being asked to participate?

Individuals aged 12 and above who fall under one of these three categories:

1. ME/CFS patients - diagnosed formally or self-diagnosed
2. Long COVID patients - diagnosed formally or self-diagnosed
3. Healthy volunteers - without ME/CFS or Long COVID.

3. Do I have to take part?

No, it is completely up to you whether or not you take part.

Your participation in this study is voluntary. You may decide not to participate or leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled. Additionally, if you decide not to participate this won't affect your relationship with La Trobe University or Emerge Australia.

4. What will happen if I take part?

You will be asked to provide electronic consent that allows us to ask you for detailed information about yourself and your health.

You will be asked to complete various questionnaires about your past and current health, demographic information, and willingness to provide a biosample to the Biobank. Whilst some questionnaires capture your initial health status and background information, others are designed to track the progression of your illness over time.

We acknowledge the diverse capacities and preferences of participants. For those diagnosed with ME/CFS or participating as healthy volunteers, at the time of consent you will have the option to select from two distinct participation levels:

1) **Single Contribution:** Participate in a single, in-depth study visit once to provide a comprehensive overview of your condition.
2) **Regular Contribution:** Opt for more frequent, concise study visits every 3 months, facilitating closer observation of any health changes you experience over time.

For participants diagnosed with Long COVID, engagement in regular study visits every 3 months is necessary, as it allows Approved Researchers to quickly identify emerging patterns and trends in symptom progression or improvement. Please note that when you are informed of a study visit opening, you can choose to skip it if you don't have the time or capacity to complete it.

All data collection is facilitated using a secure website until you make the decision to withdraw from the AusME Registry. We will email to remind you to fill out surveys that you need to complete more than once.

The AusME Registry questionnaires made available to you will be of varying number and length. For some, the task of completing them may feel overwhelming, particularly when each 3-month Study Visit is only available for 14 days. To reduce the risk of participants feeling overwhelmed we do the following:

1. Provide an approximate time of completion at the beginning of a survey

2. Provide a ‘progress’ bar in each survey to visualise your progress through a survey
3. Allow for all surveys to be saved and completed in multiple sittings (within the time constraints of each study visit)
4. If you don’t feel up to completing a study visit, you can indicate this to us by clicking the ‘Skip’ checkbox on the second page of the study visit
5. You can change your participation level at any time by contacting the AusME research team

Please know that your health and wellbeing are our first priority, and any data you do contribute to the AusME Registry is greatly appreciated. If you are unwell or unable to complete a study visit, that is okay and there is no detriment to the project or your future participation.

5. What will happen to information about me?

Privacy and Data Security:

- We are committed to the security and privacy of any data you contribute to the AusME Registry
- All personal identifiers such as name, email, and date of birth are removed before sharing the data to approved researchers/research studies. This process is known as de-identification
- All data collected via the AusME Registry platform are stored indefinitely in an Australian-based data centre that adheres to the most stringent of security protocols and is HIPAA-compliant

Data Access and Usage:

- Your de-identified information could be used in approved research projects in Australia
- All research groups requiring access to AusME Registry data must have their projects approved by Emerge Australia’s Medical and Scientific Advisory Committee (MSAC) and the AusME Biobank Access Committee (committees comprising those living with ME/CFS, clinicians and researchers).
- Researchers granted access will only ever be able to access and use de-identified data

Contact Information Use:

Your contact details will be used for:

- Communicating with you about the AusME Registry regarding open study visits and available surveys
- Informing you about future research opportunities that you may be eligible for
- Inviting you to potentially provide a biological donation to the AusME Biobank
- Asking you for feedback on your AusME Registry experience

Additionally, you can choose to OPT IN to receive other communications from Emerge Australia, including (but not limited to) the newsletter, journal, and research digest.

Only Emerge Australia employees, who manage the AusME Registry will have access to your contact and health information, which will be kept strictly confidential. Should you also wish to receive communication from Emerge Australia directly, your personal contact details only will also be shared with Emerge Australia’s administration personnel. No health information that you have provided via the AusME Registry will be shared with non-AusME Registry Emerge personnel. You can choose to unsubscribe from these emails at any time by clicking the unsubscribe button at the bottom of the email.

Participation in Future Research:
While the AusME Registry aims to facilitate research participation for those affected by ME/CFS and Long COVID, not all participants may be eligible to donate blood samples or participate in future studies or trials. If a research opportunity arises, separate consent for that specific study will be required.

6. Will my taking part in the AusME Registry be kept confidential?

Yes, all information about you will be treated with confidence. Your data is de-identified and obvious personal identifiers are removed; meaning names, addresses, and other identifying information is stored separately from the health information.

A unique AusME Registry identification number is assigned to your information. A unique identification number is a combination of numbers and/or letters that do not correspond to any information you have provided to us (i.e. birth date, age, name) and which is different for each person who participates in this study.

Researchers using AusME Registry data will not have access to your personal information; all information received by researchers will have been anonymized by the research team. Before having access to your anonymized clinical information, researchers must agree to conditions that safeguard your confidentiality.

All data collected will be stored with Zoho in their Australian Datacentre, specifically:

- Sydney (Primary Server) - SOC 1 TYPE II - SOC 2 TYPE II - ISO 27001
- Melbourne (Secondary Server) - SOC 1 TYPE II - SOC 2 TYPE II - ISO 27001

and will be patched and maintained by Nova Diem.

We will keep your information indefinitely, even if the AusME Registry ceases to operate. The storage and transfer of your AusME Registry data, as well as the destruction of all identifiable information, be undertaken in accordance with the Research Data Management Policy https://policies.latrobe.edu.au/document/view.php?id=106/

The personal information you provide will be handled in accordance with applicable privacy laws and any health information collected will be handled in accordance with the Health Records Act 2001 (Vic). Subject to any exceptions in relevant laws, you have the right to access and correct your personal information by contacting Emerge Australia.

7. What will happen to the results of studies using my data?

Any results of research published using your de-identified data, will be made available to a wide variety of interested parties, including funders/sponsors, people responsible for health services, healthcare professionals, groups who oversee research (in Australia, the Australian Research Council and National Health and Medical Research Council), and people with ME/CFS and/or Long COVID and their representatives. The results may also be published in peer-reviewed journals and presented to diverse audiences, including scientific and clinical conferences. Significant results may also be made available on research team websites in a format that can be understandable by non-professionals. The identity of AusME Registry participants WILL NOT BE revealed, in any report.

8. What are the possible risks of taking part?

Please consult with your health professional to discuss any concerns you may have prior to your consenting to being a AusME Registry or research study participant. Concerns regarding AusME Registry participation can be voiced to Emerge Australia via email (information.biobank@emerge.org.au). Research study concerns can be communicated with the Research Study coordinator, noted on the Participant information statement prepared for every research study.

Noteworthy, there is minimal risk in taking part in the AusME Registry. We have listed the risks that we are aware of below. This will help you decide if you want to participate in the AusME Registry.

1. The AusME Registry includes questions that may be sensitive, and you may feel uncomfortable answering. You do not have to share any information, that you do not want to.
2. There is the risk of participants feeling overwhelmed by the number, length, and frequency of the questionnaires. All surveys can be completed at your own pace, in multiple sittings. Estimated completion times and progress bars are available in every survey to assist you in deciding if, when, or at all, you can complete the survey.
3. There is an unlikely risk that there could be a breach of the security system resulting in the access of information about your family or medical history. Safeguards are in place to minimize this risk and Emerge Australia's Zoho instance/platform is HIPAA compliant. If, in an unlikely event there is a privacy breach affecting the AusME Registry, all participants and the relevant authorities will be notified. Please feel free to contact us if you would like any further information regarding the security of your data.

9. What are the possible benefits of taking part?

There are potentially no direct advantages to you if you participate in using the AusME Registry online platform. However, the information and data you provide may add to a greater understanding of ME/CFS and/or Long COVID, what causes it, and what treatments could be developed, and thus may help you and others in the future.

10. What will happen if I do not want to continue or if I lose my capacity to consent?

Withdrawing your consent means we won't seek more information from you, and you won't be able to add new data to the AusME Registry. Existing data will remain available to researchers indefinitely, as it will not be possible to recall your specific data. Withdrawing your consent also means we will sever the link between your de-identified data and your personal information. If you can't consent, your legal representative or medical decision-maker can withdraw on your behalf. Your participation can be halted by the sponsor or research oversight groups at any time.

You are free to withdraw your consent at any time. You do not have to give a reason for changing your mind and your decision to withdraw will not affect your relationship with La Trobe University or Emerge Australia. You can withdraw your consent by emailing the AusME Registry and Biobank Manager at information.ausme@emerge.org.au, or by phone on 1800 865 321.

11. Who is organising and funding this project?

The initial phase of this project has been funded by the Mason Foundation and will be carried out by Emerge Australia in partnership with Latrobe University. The AusME Registry and Biobank are governed by Emerge Australia's Medical and Scientific Advisory Committee (MSAC) and the Biobank Access Committee. These committees comprise Australian researchers and clinicians with expertise in the field,

as well as those living with ME/CFS and /or Long COVID. Project continuity will be dependent upon future funding opportunities and the AusME Registry and Biobank will also be funded by those approved to utilise biosamples and/or registry data, in a cost-recovery manner only.

12. Who can I contact for questions or if I require further information?

If you would like further information about the AusME Registry and Biobank, your rights under this project and/or have questions/concerns about the AusME Registry and/or Biobank, you can:
contact Emerge Australia's AusME Registry and Biobank Manager by email (information.ausme@emerge.org.au), or call our office on 1800 865 321.

We will aim to respond to you within 3 business days of your request.

13. Who can I contact if I have a complaint?

If you have a complaint about any part of this project, please contact:
La Trobe University, Senior Research Ethics Officer
+61 3 9479 1443
humanethics@latrobe.edu.au
Quote ethics reference number: HEC2016