AusME

Bridging Lived Experience and Research Excellence

A Guide for ME/CFS & long COVID Researchers

Introducing the *AusME* Registry and Biobank

The AusME Registry and Biobank is a national, patient-centred research initiative designed to support high-quality ME/CFS and long COVID research in Australia. Led by Emerge Australia as custodian, AusME ensures that the voices and experiences of people living with these conditions are central to research design, governance, and outcomes.

Through the AusME Registry and Biobank, Emerge Australia aims to support Australian researchers, accelerate meaningful research outcomes, and ultimately improve the quality of life for people affected by ME/CFS and long COVID.

Since 2020, the Mason Foundation, through Equity Trustees, has supported Emerge Australia's custodianship of the Registry and Biobank. Their renewed support has enabled the original ME/CFS Registry and Biobank to be expanded and rebranded as the Australian ME/CFS and Long COVID (AusME) Registry and Biobank.

Collaborating with Emerge Australia

Emerge Australia actively supports Australian researchers investigating the causes, mechanisms, impacts, diagnosis, and management of ME/CFS and long COVID. This includes research focused on understanding symptom burden, functional impacts, healthcare experiences, and broader social and economic consequences.

Research proposals aimed at demonstrating the effectiveness of Graded Exercise Therapy (GET) or Cognitive Behavioural Therapy (CBT) are discouraged, given the current evidence base and lived-experience concerns. However, all proposals are considered on a case-by-case basis by Emerge Australia's AusME Access Committee (AusMEAC).

The AusMEAC comprises clinicians, researchers, Emerge Australia staff, and people with lived experience, all with expertise in ME/CFS and/or long COVID. The committee meets bi-monthly throughout the year to review researcher requests.

What collaboration with Emerge Australia can offer

Depending on the needs of your study, collaboration with Emerge Australia may include:

- Support with study design and feasibility
- Letters of support for grant applications
- Participant recruitment via the AusME Registry
- Access to AusME Registry data and/or Biobank biosamples
- Study promotion and awareness through Emerge Australia's communication channels

Researchers seeking access or support are asked to complete an AusME Access Application Form, which enables the AusMEAC to assess study alignment, feasibility, and governance requirements.

Researchers may also contact the Research Manager directly for early discussions or study design advice: Michelle.Tavoletti@emerge.org.au.

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AusME Registry: Participant Involvement

The AusME Registry and Biobank includes individuals aged 12 years and over who:

- Live with ME/CFS and/or long COVID
- Are supporters or healthy volunteers (control participants)

Participants register online and, after providing informed consent, complete questionnaires covering health, medical history, demographics, and interest in biobank participation. Surveys are completed remotely, at participants' own pace, within their energy limits, and over multiple sessions if needed.

Registry participants are informed about ME/CFS and long COVID studies being conducted in Australia that they may be eligible for. All studies promoted through the Registry have been approved by the AusME Access Committee. Eligible and consenting participants may also choose to become blood donors for the AusME Biobank following appropriate screening processes.

Research Access and Governance

Access to AusME Registry data and Biobank biosamples is available to approved researchers through a formal application process reviewed by the AusME Access Committee (AusMEAC). The committee meets regularly to review and assess access and support requests.

All research involving human data or biosamples must hold approval from an NHMRC-approved Human Research Ethics Committee. The AusME Registry and Biobank are currently approved by the La Trobe University Human Research Ethics Committee (project # HEC20161 and HEC20027).

More about the *AusME Registry* for Researchers

The AusME Registry includes cohorts of healthy volunteers (controls) and individuals living with ME/CFS or long COVID, all aged 12 years and above.

Following consent, participants complete an AusME Registry onboarding process and are then invited to participate in longitudinal surveys or study visits. These may occur quarterly, half-yearly, yearly, or as one-off assessment, depending on the study design. For participants with long COVID, longitudinal follow-up typically begins three months after onboarding. Longitudinal participation for people with ME/CFS and healthy volunteers is optional, and participants may opt out at any time due to health or personal circumstances.

A core set of survey tools (refer to Tables 1-4) is used for onboarding and longitudinal follow-up, with additional study-specific questionnaires distributed, as required by approved researchers. Additional survey instruments may be implemented subject to appropriate ethical approval.

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Table 1. Survey Instruments Used in the AusME Registry

AusME REGISTRY ONBOARDING (18+ Years)		**Healthy controls**	**ME/CFS**	**Long COVID**
1	Profile Creation	X	X	X
2	Disease Status	X	X	X
3	Welcome to the AusME Registry – HC or ME/CFS or LC	X	X	X
4	Onboarding Questions | ME/CFS and long COVID		X	X
5	The AusME Symptom Assessment Survey*	X	X	Y
6	Demographics	X	X	X
7	The Aust-modified Karnofsky Performance Scale	X	X	X
8	Multidimensional Fatigue Inventory (MFI)	X	X	X
9	Covid-19 questionnaire	X	X	X
10	Hospital Anxiety and Depression Scale (HADS)	X	X	X
11	Biosample donation	X	X	X
12	Survey to define long COVID			X
13	Treatments	X	X	X
14	Conditions	X	X	X
15	Surgeries	X	X	X

**Linked to the AusME ME/CFS algorithm, identifying AusME participants who meet the Canadian Consensus Criteria for ME/CFS.*

Table 2.

AusME REGISTRY LONGITUDINAL STUDY VISITS (18+ Years)		**Healthy Controls**	**ME/CFS**	**Long COVID**
1	Welcome Back to the AusME Registry – HC, ME/CFS or LC	Q	Q	Q
2	ME/CFS or long COVID disease history		Y	Y
3	Family Health History	Y	Y	Y
4	The AusME Symptom Assessment Survey§	HY	BD	Q
5	Demographics	Y	Y	Y
6	The Aust-modified Karnofsky Performance Scale	Q	Q	HY
7	Multidimensional Fatigue Inventory (MFI)	HY	HY	HY
8	Covid-19 questionnaire	Q	Q	H
9	Hospital Anxiety and Depression Scale (HADS)	HY	HY	HY
10	Modified Beighton	O	O	O
11	SF-36	Q	Q	Q
12	DSQ-PEM		Y	Y
13	DSQ-COVID			Q
14	Treatments	Q*	Q*	Q*
15	Conditions	Q*	Q*	Q*
16	Surgeries	Q*	Q*	Q*

Q: *quarterly;* ***HY:*** *half yearly;* ***Y:*** *yearly;* ***BD:*** *prior to blood donation;* ***O:*** *once (participants choice of when),*
****:*** *participant prompted to update; §linked to AusME algorithm for ME/CFS.*

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Table 3.

SURVEYS DISTRIBUTED AS REQUIRED (18+ Years)	
COHORT	**SURVEYS**
All	• Abbreviated Symptoms Assessment Questionnaire
Healthy Volunteer	
ME/CFS & long-COVID	• DePaul Symptom Questionnaire (DSQ-2) • Epworth Sleepiness Scale • Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS) Phenotyping Questionnaire • Revised Fibromyalgia Impact Questionnaire (FIQR)
Long-COVID	• Modified COVID-19 Yorkshire Rehabilitation Scale (C19-YRSm) • Newcastle post-COVID syndrome Follow Up Screening Questionnaire • Post COVID-19 Functional Status (PCFS) Scale • Symptom Burden Questionnaire™ for Long COVID

Researcher requests for surveys not specified above will be considered upon request.

Table 4.

AusME REGISTRY PAEDIATRIC ONBOARDING & STUDY VISITS (12-17 years; all cohorts)			**LONGITUDINAL STUDY VISITS**			
		OB	Quarterly	Half -Yearly	Yearly	Once
1	Profile Creation	X				
2	Disease Status	X				
3	Paediatric Demographic and Illness questionnaire	X			X	
4	DePaul Symptom Questionnaire - Paediatric Version (DSQ-PED)[¤]	X		X		
5	Paediatric Quality of Life Paediatric Pain Questionnaire.	X		X		
6	Paediatric QoL Multidimensional Fatigue Scale	X		X		
7	Hospital Anxiety and Depression Scale (HADS)	X		X		
8	MOS SF-36 Quality of Life Survey	X		X		
9	Covid-19 questionnaire	X	X			
10	Biosample donation	X				
11	Treatments	X	X*			
12	Conditions	X	X*			
13	Surgeries	X	X*			
15	Modified Beighton	X				X

OB: *onboarding;* *******participant prompted to update; [¤]AusME algorithm for ME/CFS is currently under development.*

More about the *AusME Biobank* for Researchers

The AusME Biobank supports high-quality biomedical and translational research by providing access to well-characterised biosamples from individuals living with ME/CFS, long COVID, and healthy volunteers.

Donor Screening and Eligibility

AusME participants who express interest in becoming blood donors undergo a structured eligibility screening process conducted by the AusME Registry and Biobank Manager. This includes the opportunity to ask questions, review participant information, and provide written informed consent.

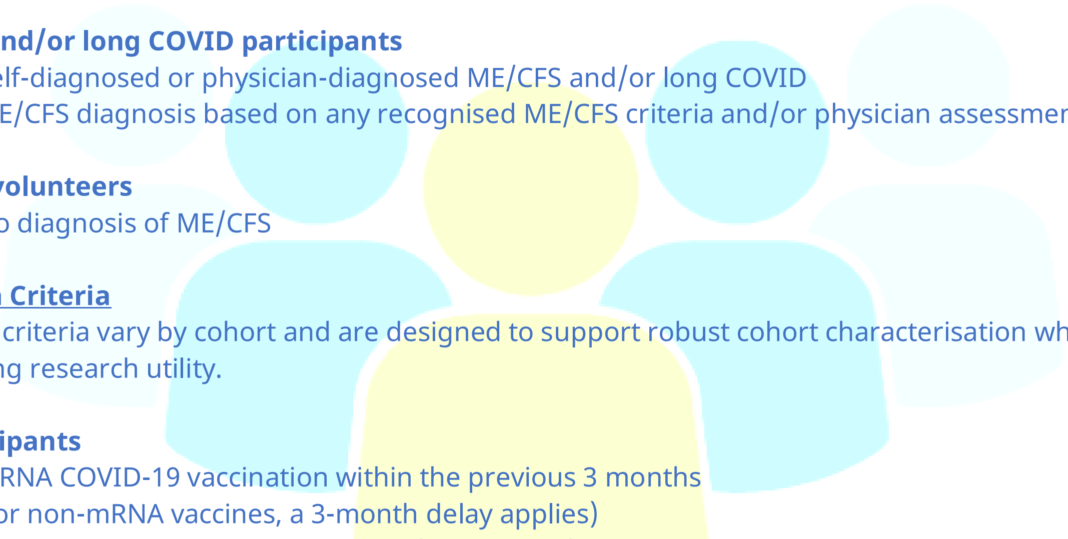
Inclusion Criteria

All participants

- Have spoken with the AusME Registry & Biobank Manager
- Have reviewed the participant information sheet and provided signed informed consent
- Are aged 12 years and over

ME/CFS and/or long COVID participants

- Self-diagnosed or physician-diagnosed ME/CFS and/or long COVID
- ME/CFS diagnosis based on any recognised ME/CFS criteria and/or physician assessment



Healthy volunteers

- No diagnosis of ME/CFS

Exclusion Criteria

Exclusion criteria vary by cohort and are designed to support robust cohort characterisation while maximising research utility.

All participants

- mRNA COVID-19 vaccination within the previous 3 months
  (for non-mRNA vaccines, a 3-month delay applies)
- Current pregnancy, lactation, or within 12 months postpartum
- Significant cognitive impairment or intellectual disability
- Severe psychiatric illness (e.g. schizophrenia or severe current mood disorder)

Healthy volunteers

- Significant comorbidities likely to impact immune or fatigue-related outcomes, including:
  - Infectious diseases
  - Cancer
  - Autoimmune conditions
  - Other illnesses likely to cause fatigue or ME/CFS-like symptoms

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Cont. Exclusion Criteria – Healthy volunteers

- Use within the previous 3 months of medications known to alter immune function, including:
    - Azathioprine
    - Cyclosporine
    - Methotrexate
    - Steroids
    - Antiviral medications

- History of acute or chronic infectious diseases such as hepatitis B or C, tuberculosis, or HIV (excluding herpes viruses or other retroviruses)
- Other severe illnesses, including cardiovascular disease, severe obesity (BMI ≥40), or uncontrolled diabetes

ME/CFS and/or long COVID participants

- Only cancer and tuberculosis are exclusionary comorbidities
- Only azathioprine and cyclosporine are exclusionary medications
- Other comorbidities, medications, and infectious disease history are disclosed to researchers to support informed cohort design rather than exclusion

Pathology Testing at Collection

The following pathology tests are performed on the day of sample collection:

- Full Blood Examination (FBE) and ESR
- Liver Function Tests (LFT)
- Electrolytes, Urea and Creatinine (EUC)
- High-sensitivity C-reactive protein (hsCRP)
- 25-OH Vitamin D
- Immunoglobulins (IgG, IgA, IgM)
- Iron studies
- Thyroid function tests (T3 and T4)

Biosample Types and Storage

Samples are processed and stored at AusME Biobank storage facilities in liquid nitrogen or at −80°C.

BLOOD FRACTION	Additive	Aliquot Volume
Whole blood	Lithium heparin or EDTA	500 µL
Plasma	Lithium heparin or EDTA	500 µL
Serum	None	200 µL
PBMCs (lymphocytes and monocytes)	Lithium heparin or EDTA	1 mL (5×10^6 cells)

Associated Data Collection

At the time of donation, detailed participant data are collected, including:

- Demographics
- Disease status, severity, and symptom profile
- Medications and comorbidities

Donors also complete a **Day-of-Collection Survey**, documenting medications, treatments, and supplements taken in the preceding 24 hours, as well as current symptoms.

These data, alongside sample metadata (type, volume, availability), are intended to be made available to approved researchers through a searchable interface. Pathology results may also be shared subject to approval.

Researcher Access and Agreements

Researchers approved by the AusME Access Committee (AusMEAC), along with their host institutions, are required to execute:

- A **Data Sharing Agreement (DSA)**, and
- A **Material Transfer Agreement (MTA)**

These agreements govern access to de-identified biosamples and associated digital data.

Additional Useful Information about the AusME Biobank

Approved Genetic Research Uses

AusME Biobank samples are approved for genetic research, including:

- Single-gene and multi-gene analyses
- Gene–gene and gene–environment interactions
- Acquired somatic variation
- Inherited gene sequences and variants
- Gene expression studies
- Epigenetic analyses
- Bioinformatic and computational genetic research
- Clinical phenotype correlations

Activities Not Approved

The following activities are **not permitted**:

- Generation or recording of uniquely identifying biological markers (e.g. DNA fingerprinting)
- Re-contacting donors for any purpose related to their donated biosamples

Withdrawal of Consent

Participants may withdraw consent at any time. Upon withdrawal, Emerge Australia is required to:

1. Cease all contact with the participant
2. Destroy the linkage key between identifiable and de-identified data
3. Destroy any remaining biosamples held within the Biobank

Biosamples already released to approved research projects are not affected; however, no further longitudinal sampling will occur.

Research Design Considerations for ME/CFS and Long COVID

The following guidelines are intended to support researchers designing studies involving people living with ME/CFS and long COVID, both of which are energy-limiting, multisystem conditions. These considerations aim to accommodate participants' unique sensitivities and limitations and to address historical challenges in ME/CFS research, particularly the underrepresentation of severely affected individuals.

Historically, ME/CFS research has produced inconsistent and non-comparable findings due to small sample sizes, disease heterogeneity, varying diagnostic criteria, and selection bias towards less severely affected participants. Emerge Australia supports research that actively addresses these limitations.

Study Design Recommendations

Eligibility Criteria

Researchers are encouraged to use **ME/CFS diagnostic criteria that include post-exertional malaise (PEM)**, the hallmark feature of ME/CFS. Recommended criteria include:

- Canadian Consensus Criteria (CCC, 2003) – assessed using the AusME Registry algorithm
- Institute of Medicine/NAM Criteria (2015)
- Paediatric Primer Criteria (2017, based on CCC; adolescents)

Recruitment

In the absence of definitive biomarkers, participants may be classified using recognised criteria (CCC) supported by the AusME algorithm. Participants with long COVID may be followed longitudinally to determine whether they meet ME/CFS criteria over time.

Participant Cohorts

Previous ME/CFS research has disproportionately represented individuals with higher socioeconomic status and access to specialist care, while men, Indigenous people, people of colour, children/adolescents, and those severely affected remain underrepresented.

Approximately 25% of people with ME/CFS are housebound or bedbound, yet are rarely included in studies.

Researchers are strongly encouraged to recruit **diverse and representative cohorts**. Participation in the AusME Registry is open to all, reducing sampling bias. Inclusion of **sedentary control groups** is also encouraged to account for deconditioning.

Outcome Measures

ME/CFS and long COVID studies should always assess **post-exertional malaise**, as it is a core disease feature. Reliance solely on fatigue measures is discouraged.

Where possible, researchers should include **objective outcome measures** (e.g. actigraphy) and are encouraged to align with the **NIH Common Data Elements for ME/CFS**. Subjective-only outcomes, in non-blinded trials should be avoided.

Participant Retention and Accessibility

Thoughtful study design can significantly improve retention and participant experience.

Recommended strategies include:

- Providing study materials in multiple formats (digital and printable)
- Using accessible fonts, left-justified formatting, and clear summaries
- Conducting studies remotely where possible
- Offering flexible scheduling and avoiding early morning appointments
- Minimising visit duration and frequency
- Providing home visits or mobile phlebotomy for housebound participants
- Supporting travel with transport assistance or priority parking
- Providing appropriate compensation
- Supplying a clear study resource pack (directions, study summary, contacts, instructions)

Study Visit Considerations

Before the Visit

- Confirm participants have received study materials
- Ensure understanding of study requirements
- Identify accessibility needs (e.g. escort, wheelchair, parking)

During the Visit

- Provide a quiet, dark resting space
- Accommodate carers where needed
- Offer both digital and printed materials
- Adjust lighting and sensory stimuli as required

Blood collection:

People with ME/CFS often have low blood volume. Fluid intake should be encouraged before, during, and after collection. Volumes <80 mL are recommended where possible. A skilled phlebotomist is essential, and preparation for orthostatic intolerance or presyncope is advised.

After the Visit

- Thank participants and acknowledge their contribution
- Check for symptom exacerbation or PEM
- Confirm compensation has been received
- Provide reminders for follow-up visits or tasks
- Reiterate study contact details

Special Considerations

Many people with ME/CFS and long COVID have lived with their illness for years and may appear outwardly well despite severe symptoms. Past experiences of dismissal or misdiagnosis mean some participants may be cautious or distrustful. Clear communication, patience, and respect are essential.

Cognitive dysfunction and sensory sensitivities are common. Speaking slowly, using clear language, and avoiding unnecessary repetition can improve communication. Reading responses back for confirmation may also be helpful.

Post-Exertional Malaise (PEM)

PEM may occur before, during, or after study participation and may be delayed by hours or days. Study designs should minimise exertion, allow recovery time between visits, and avoid disrupting participants' treatment regimens unless clinically advised. Flexibility is essential, as symptom fluctuations may necessitate last-minute cancellations.

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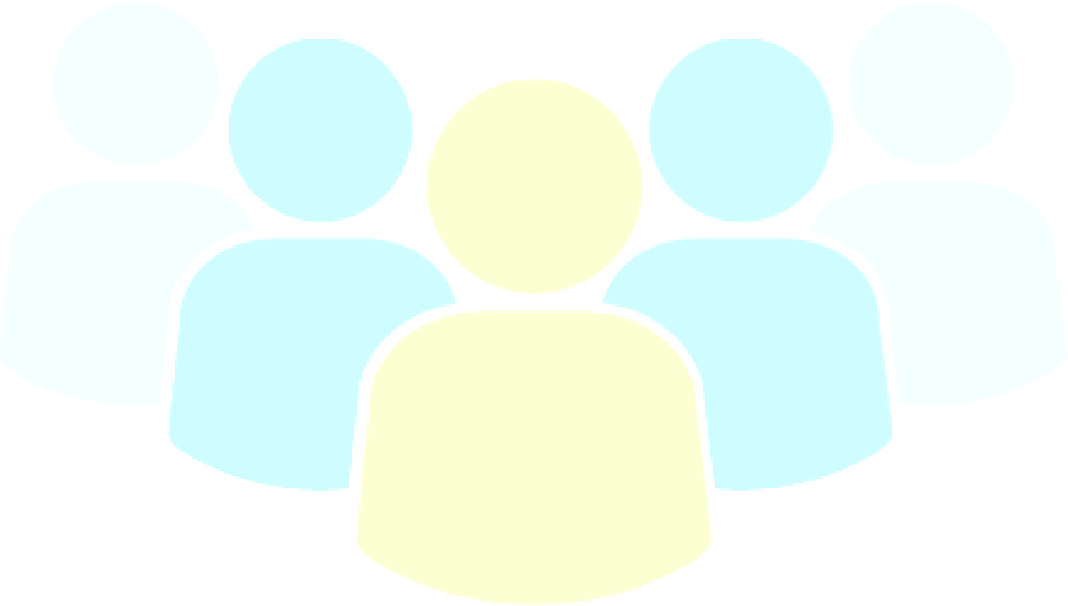
Final Note

Emerge Australia advocates for people living with ME/CFS and long COVID and supports high-quality research that advances understanding, diagnosis, and treatment. We thank researchers for their interest and commitment to advancing this field and are available to support study design and implementation.

For further assistance, please contact the Research Manager:
Michelle.Tavoletti@emerge.org.au or 1800 865 324.



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