

Research Project Details

Monash Health reference number

ERM project ID

Protocol number

Project title

Monash Health Principal Investigator

PI email address

Research coordinator

Research coordinator email

Department

- ☐ Allied Health
- ☐ Cardiothoracic Surgery
- ☐ Children's Cancer Centre
- ☐ Clinical Haematology
- ☐ Monash Lung, Sleep, Allergy Immunology (MLSAI)
- ☐ Clinical Nutrition & Metabolism
- ☐ Colorectal
- ☐ Critical Care Program - Anaesthetics
- ☐ Critical Care Program - ICU
- ☐ Dentistry
- ☐ Dermatology
- ☐ Diabetes
- ☐ Diagnostic Imaging
- ☐ Nutrition & Dietetics
- ☐ Emergency Medicine
- ☐ Endocrinology
- ☐ ENT
- ☐ External
- ☐ Gastroenterology & Hepatology
- ☐ General Medical
- ☐ General Surgery
- ☐ Infectious Diseases
- ☐ Medicine Program
- ☐ Mental Health Program
- ☐ MHRP Partners
- ☐ Monash Heart/Cardiology
- ☐ Nephrology
- ☐ Neurology
- ☐ Neurosurgery
- ☐ Newborn Services
- ☐ Nursing & Midwifery
- ☐ Obstetrics & Gynaecology
- ☐ Occupational Therapy
- ☐ Oncology
- ☐ Ophthalmology
- ☐ Orthopaedic
- ☐ Other
- ☐ Other surgical
- ☐ Paediatrics
- ☐ Palliative Care
- ☐ Pathology
- ☐ Pharmacy
- ☐ Physiotherapy
- ☐ Plastic Surgery
- ☐ Primary Care
- ☐ Psychiatry
- ☐ Psychology
- ☐ Rehabilitation & Aged Services Program
- ☐ Respiratory & Sleep Medicine
- ☐ Rheumatology
- ☐ Social Work
- ☐ Specialty Program
- ☐ Speech Pathology
- ☐ Surgery Program
- ☐ Urology
- ☐ Vascular Sciences & Medicine
- ☐ Vascular Surgery
- ☐ Women's and Children's Program

Project type

- ☐ Clinical registry
- ☐ Clinical quality registry
- ☐ Clinical drug trial
- ☐ Clinical device trial
- ☐ Clinical trial - other
- ☐ Clinical research
- ☐ Psychological
- ☐ Epidemiological
- ☐ Social science
- ☐ Social/health services
- ☐ Public health
- ☐ Other
- ☐ Investigator Initiated

Specify other project type

Clinical trial phase

- ☐ First time in patient/human
- ☐ Phase I
- ☐ Phase II
- ☐ Phase III
- ☐ Phase IV
- ☐ Not a clinical trial or N/A

Monash Health Research Progress/Final Report

Project Details

Monash Health Reference Number: [project_details_arm_1][mhref]

Title: [project_details_arm_1][projtitle]

Principal Investigator: [project_details_arm_1][mhpi]

If any of the above details are incorrect, please contact the Research Support Services team at research@monashhealth.org.

What kind of report are you submitting?

☐ Progress report

☐ Final report

The reporting period for this progress report is 1 January to 31 December last year. Please report information for this period only.

Sponsor Information

What type of sponsor does this research project have?

- ☐ Commercially sponsored
- ☐ Collaborative group
- ☐ Investigator-initiated
- ☐ Other

Specify other sponsor type

Name of commercial sponsor

Multisite Research Projects

Are you submitting this report as the lead site in a multi-site study?

☐ Yes
☐ No

Please list all sites covered by this report.

This list will be copied into your acknowledgement email so please ensure it is correct.

Site closures can be reported at any time using the site closure form. Please complete this form separately if you have any site closures to report.

Project Recruitment

Does this project involve recruitment of human participants?

- ☐ Yes
☐ No

Is Monash Health a site at which participants are being recruited for this project?

- ☐ Yes
☐ No

Monash Health Recruitment**The following questions relate to participant recruitment at Monash Health only.**

What is the total expected recruitment number?

Please provide the total number of participants expected to be recruited over the whole project at Monash Health.

Number of participants enrolled in the project as at 31 December last year?

Please include participants that have been consented and found eligible for enrolment into the project.

Number of participants withdrawn in the project as at 31 December last year?

Number of participants who have completed the project as at 31 December last year?

This refers to participants who have completed participation in the study (even if they had to cease participation due to disease progress or other reasons), and will have no further contact or activity for the project.

Was the project open to recruitment at Monash Health at any time last year?

☐ Yes
☐ No

Number of potential participants screened 1 January - 31 December last year?

Number of participants enrolled from 1 January - 31 December last year?

If all participants who consented were enrolled into the project, this number should be the same as above.

Is recruitment on target at Monash Health?

☐ Yes
☐ No

Please provide reason for why recruitment is not on target.

Overall Project Recruitment

Are participants being recruited at any other sites for this research project?

☐ Yes
☐ No

Total anticipated project recruitment number (for all sites, including international)?

You are not required to report the numbers for each site individually. If other site RGOs require this information, it should be reported directly to them.

Total actual project recruitment number as at 31 December last year (for all sites, including international)?

You are not required to report the numbers for each site individually. If other site RGOs require this information, it should be reported directly to them.

Is total recruitment for the research project on target?

☐ Yes
☐ No

Please explain why recruitment for this research project is not on target.

Quality & Safety

Have there been any safety events that have not been reported to HREC?

- ☐ Yes
☐ No

Please describe the safety events

Have you encountered problems in study design, finance, facilities, equipment or staffing?

- ☐ Yes
☐ No

Please describe the issues.

Has the study been audited by an external body (e.g. TGA, FDA, study sponsor, ethics committee) at any time during the reporting period?

- ☐ Yes
☐ No

Were there any major or serious findings in the audit report?

- ☐ Yes
☐ No

Please provide details of these findings and describe corrective and preventative action(s) taken.

Does every member of the research team hold a current Good Clinical Practice (GCP) training certificate?

- ☐ Yes
☐ No
☐ N/A

As per the Monash Health Good Clinical Practice Training in Research Procedure, all internal and external personnel who are involved in conducting or supporting research at Monash Health hold current Good Clinical Practice (GCP) training to maintain safety and quality in research.

Please provide reason research team members do not have current GCP certificates.

Registry Progress

What does this registry involve?

- ☐ Enrolment of participants
- ☐ Access to records
- ☐ Use of samples

Enrolment of Participants

Are participants being enrolled in this registry at
Monash Health?

- ☐ Yes
☐ No

Monash Health Participants

Total anticipated enrolment number (Monash Health only)

Actual number enrolled (at Monash Health) as at end of reporting period

Are participants in this registry receiving treatment?

☐ Yes
☐ No

Actual number treated (at Monash Health) as at end of reporting period

Number of participants withdrawn (at Monash Health) as at end of reporting period

Number completed core project (at Monash Health) as at end of reporting period

Is enrolment of participants on target at Monash Health?

☐ Yes
☐ No

Please explain why enrolment is not on target at Monash Health

All Sites Participants

Are participants being enrolled in this registry at other sites?

☐ Yes
☐ No

Total target enrolment number (for all sites, including international)

Actual number enrolled (for all sites, including international) as at end of reporting period

Are participants in this registry receiving treatment?

☐ Yes
☐ No

Actual number treated (for all sites, including international) as at end of reporting period

Number withdrawn (for all sites, including international) as at end of reporting period

Number completed core project (for all sites, including international) as at end of reporting period

Access to Records

Are records being accessed at Monash Health as part of this registry?

- ☐ Yes
☐ No

Monash Health Records

Target number of records (at Monash Health)

Actual number of records (at Monash Health) as at end of reporting period

Number of records withdrawn (at Monash Health) as at end of reporting period

Number of records completed (at Monash Health) as at end of reporting period

Is use of records on target at Monash Health?

☐ Yes
☐ No

Please explain why use of records is not on target

All Sites Records

Are patient records from any other sites being
accessed as part of this registry?

☐ Yes
☐ No

Target number of records (for all sites, including
international)

Actual number of records (for all sites, including
international) as at end of reporting period

Number of records withdrawn (for all sites, including
international) as at end of reporting period

Number of records completed (for all sites, including
international) as at end of reporting period

Use of Samples

Are samples being used from Monash Health as part of this registry?

- ☐ Yes
☐ No

Monash Health Samples

Target number of samples (at Monash Health)

Actual number of samples (at Monash Health) as at end of reporting period

Number of samples withdrawn (at Monash Health) as at end of reporting period

Number of samples completed (at Monash Health) as at end of reporting period

Is use of samples on target at Monash Health?

☐ Yes
☐ No

Please explain why use of samples is not on target

All Sites Samples

Are samples from any other sites being used as part of this registry?

☐ Yes
☐ No

Target number of samples (for all sites, including international)

Actual number of samples (for all sites, including international) as at end of reporting period

Number of samples withdrawn (for all sites, including international) as at end of reporting period

Number of samples completed (for all sites, including international) as at end of reporting period

Final Report

Date of project closure

Was the project completed, abandoned or terminated?

- ☐ Completed
☐ Abandoned
☐ Terminated

Please explain why the project was abandoned or terminated

Recruitment

Were any participants recruited to this project?

- ☐ Yes
☐ No

Was Monash Health a site at which participants were recruited for this study?

- ☐ Yes
☐ No

How many participants were recruited at Monash Health?

How many participants were withdrawn at Monash Health?

Were participants recruited at any other sites?

- ☐ Yes
☐ No

How many participants were recruited across all sites in total for this project?

How many participants were withdrawn across all sites in total for this project?

Have you informed participants that the project has been completed, abandoned or terminated?

- ☐ Yes
☐ No

Please explain why you have not informed participants that the project has been completed, abandoned or terminated?

Have you informed or will you inform participants of the project results?

- ☐ Yes
☐ No

Please explain why you will not inform participants of project results

Publications

Did this project produce any publications or research impact?

☐ Yes
☐ No

Is there any significant research output that is be available on the Monash Health research repository for publications?

☐ Yes
☐ No

Provide any publication ID/registry number if applicable.

Please provide details below.

For example: Change to National guidelines, therapeutics being listed on PBS, or a significant award.

Registry Final Report

Date of project closure

Was the registry completed, abandoned or terminated?

- ☐ Completed
☐ Abandoned
☐ Terminated

Please explain why the registry was abandoned or terminated

What did this registry involve?

- ☐ Enrolment of participants
☐ Access to records
☐ Use of samples

Enrolment of Participants

Were participants enrolled in this registry at Monash
Health?

- ☐ Yes
☐ No

Monash Health Participants

Total anticipated enrolment number (Monash Health only)

Actual number enrolled (at Monash Health)

Did participants in this registry receive treatment?

☐ Yes
☐ No

Actual number treated (at Monash Health)

Number of participants withdrawn (at Monash Health)

Number completed core project (at Monash Health)

All Sites Participants

Were participants enrolled in this registry at other sites?

☐ Yes
☐ No

Total target enrolment number (for all sites, including international)

Actual number enrolled (for all sites, including international)

Did participants in this registry receive treatment?

☐ Yes
☐ No

Actual number treated (for all sites, including international)

Number withdrawn (for all sites, including international)

Number completed core project (for all sites, including international)

Have you informed participants that the registry project has been completed, abandoned or terminated?

☐ Yes
☐ No

Please explain why participants have not been informed that the registry project has been completed, abandoned or terminated

Will participants be informed of the results of this registry project?

☐ Yes
☐ No

Please explain why participants will not be informed of the registry project results

Access to Records

Were records accessed at Monash Health as part of this registry?

- ☐ Yes
☐ No

Monash Health Records

Target number of records (at Monash Health)

Actual number of records (at Monash Health)

Number of records withdrawn (at Monash Health)

Number of records completed (at Monash Health)

All Sites Records

Were patient records from any other sites accessed as part of this registry?

☐ Yes
☐ No

Target number of records (for all sites, including international)

Actual number of records (for all sites, including international)

Number of records withdrawn (for all sites, including international)

Number of records completed (for all sites, including international)

Use of Samples

Were samples used at Monash Health as part of this registry?

- ☐ Yes
☐ No

Monash Health Samples

Target number of samples (at Monash Health)

Actual number of samples (at Monash Health)

Number of samples withdrawn (at Monash Health)

Number of samples completed (at Monash Health)

All Sites Samples

Were samples from any other sites used as part of this registry?

☐ Yes
☐ No

Target number of samples (for all sites, including international)

Actual number of samples (for all sites, including international)

Number of samples withdrawn (for all sites, including international)

Number of samples completed (for all sites, including international)

Registry Project Outputs

Did this registry project produce any publications or research impact?

☐ Yes
☐ No

Is there any significant research output that is be available on the Monash Health research repository for publications?

☐ Yes
☐ No

For example: Change to National guidelines, therapeutics being listed on PBS, or a significant award.

Please provide details including publication ID/registry number if applicable

Declaration

By completing this section, I confirm that this project is being conducted as originally approved by the Human Research Ethics Committee (and subject to any changes subsequently approved) and that all adverse events are reported to the Committee according to the guidelines for reporting of adverse events and the NHMRC National Statement.

Name of person completing this report

Please provide your email address

A copy of this report will be sent to this email address on submission.

Please indicate your role.

- ☐ Principal Investigator
☐ Study Coordinator
☐ Ethics Coordinator
☐ Other

You indicated your role as 'other'. Please indicate your role here.

Has the Principal Investigator delegated authority to you to complete and sign this report?

- ☐ Yes
☐ No

An acknowledgement email with a copy of this report will be sent to you, the principal investigator and the research coordinator (if applicable).

- ☐ Yes
☐ No

Are there any other email addresses you want to receive the acknowledgement and report?

Please enter the email address

Enter one email address only. You will be able to add more email addresses after this.

Are there any other email addresses you want to receive the acknowledgement and report?

- ☐ Yes
☐ No

Please enter the email address

Are there any other email addresses you want to receive the acknowledgement and report?

- ☐ Yes
☐ No

Please enter the email address

I declare that:

- this project is being conducted as originally approved by the Human Research Ethics Committee (and subject to any changes subsequently approved) and that all adverse events are reported to the Committee according to the guidelines for reporting of adverse events and the NHMRC National Statement.
 - I am the authorised delegate to complete progress reports for this project.
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Progress/Final Report PDF Save

2024 Report

Was a report submitted in 2024 (for the reporting period 01Jan2023 - 31Dec2023)?

- ☐ No
- ☐ Yes
- ☐ N/A