Final Report- Project Information

Welcome to the Monash Health Research Final Report form.

This form is used to notify Monash Health Human Research Ethics Committee (HREC) and/or Research Governance Office (RGO) of the closure of a research project. Project closure may occur because the project has been completed, terminated, or abandoned.

Please complete all required fields and provide accurate project information. Fields marked with a red asterisk (*) are mandatory.

Before proceeding, please ensure you have the following information available:
• Project title
• Monash Health reference number
• ERM project ID (if applicable)
• Protocol number (if applicable)
• Project and sponsorship details

Thank you for completing this final report.

Research Project Details

Please provide the project title

_____

Please provide the Monash Health reference number

_____
(Please enter this number in the format RES-##-0000-####. Examples: RES-21-0000-001A, RES-22-0000-100X)

Please provide the ERM project ID number

_____
(If unknown or not applicable, please mark 'N/A')

Please provide the project protocol number

_____
(If unknown or not applicable, please mark 'N/A')

Please indicate the 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

Specify other project type

_____

Please indicate the Clinical trial phase

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

Please indicate the sponsorship arrangement for this project	◯ Commercially sponsored ◯ Collaborative group ◯ Investigator initiated ◯ Other
Name of commercial sponsor	_____
Specify other sponsor type	_____
Investigator Completing this Report	_____
Please provide your email address	_____
Role	◯ Principal Investigator ◯ Study Coordinator ◯ Ethics Coordinator ◯ Other
If 'Other' is applicable, please specify your role	_____

Multi-Site 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.	_____ (Please provide the name of each participating site covered by this final report.)

Registry Project 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	_____

Participant Enrolment

Did this registry involve enrolment of participants?	◯ Yes ◯ No
Were any participants enrolled in this registry at Monash Health?	◯ Yes ◯ No
Total anticipated enrolment number (at Monash Health)	_____
Actual number enrolled (at Monash Health)	_____
Actual number treated (at Monash Health)	_____ (Enter NA if not applicable)
Number withdrawn (at Monash Health)	_____
Were participants enrolled at any other sites?	◯ Yes ◯ No
Total anticipated enrolment number (for all sites, including international)	_____
Actual number enrolled (for all sites, including international)	_____
Actual number treated (for all sites, including international)	_____
Number withdrawn (for all sites, including international)	_____

Participant Notification

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	_____

Record Access

Did this registry project involve access to records?	◯ Yes ◯ No
Were patient records at Monash Health accessed as part of this registry?	◯ Yes ◯ No
Target number of records (at Monash Health)	_____
Actual number of records (at Monash Health)	_____
Number of records withdrawn (at Monash Health)	_____
Were patient records accessed at any other sites?	◯ 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)	_____

Sample Use

Did this registry project involve use of samples?	◯ Yes ◯ No
Were samples used at Monash Health as part of this registry?	◯ Yes ◯ No
Target number of samples (at Monash Health)	_____
Actual number of samples (at Monash Health)	_____
Number of samples withdrawn (at Monash Health)	_____
Were samples from any other sites used?	◯ 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)	_____

Publications & Research Impact

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 listed on PBS, significant awards.)

Please provide details below

_____

(Provide any publication ID, registry number, DOI, citation, award details, guideline references, or other relevant outputs.)

Research Project Final Report

Date of project closure

_____

Was the project completed, abandoned or terminated?
- ◯ Completed
- ◯ Abandoned
- ◯ Terminated

Please explain why the project has been abandoned or terminated.

_____

Participant 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?

_____

Participant Notification

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 & Research Impact

Did this project produce any publications or research impact?

◯ Yes
◯ No

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

◯ Yes
◯ No
(For example: change to national guidelines, therapeutics listed on PBS, significant awards.)

Please provide details below

_____
(Provide any publication ID, registry number, DOI, citation, award details, guideline references, or other relevant outputs.)

Principal Investigator Declaration

Please confirm that this Final Report has been reviewed and completed accurately.

Principal Investigator Name

_____

Principal Investigator Email

_____

Principal Investigator Declaration

☐ I confirm that I have reviewed this Final Report and that the information provided is accurate to the best of my knowledge.
☐ 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.

Date

_____

Need assistance?

If there are problems you can’t fix, please contact Research Support Services via email research@monashhealth.org or call 9594 4611.

Final Report pdf