

SAMPLE ONLY

Monash Health Research Progress Report 2023/2024

Monash Health Research Support Services

This form is to be completed for all projects that have been approved by Monash Health HREC and/or are being conducted at Monash Health. It replaces the site and project progress reports that were previously required.



* Required

Research Project Details

1. Monash Health reference number? *

*Please ensure you enter this number in the format **RES-##-0000-####** so that submission of this report can be properly recorded. E.g RES-21-0000-001A / RES-22-0000-100X etc.*

2. ERM Project ID number?

(E.g 99100 or 100234 etc)

The value must be a number

3. Project Protocol number?

4. Project title?

5. What category does this project fall under? *

- Clinical Quality Registry
- Clinical Drug Trial
- Clinical Device Trial
- Clinical Research
- Clinical Trial - Other
- Psychological
- Epidemiological
- Social Science
- Social/Health Services
- Public Health
- Other

6. Please indicate the sponsorship arrangement for this study: *

- Commercially sponsored
- Collaborative group
- Investigator initiated
- Investigator initiated with industry support
- Competitive research grant

7. Name of Sponsor *

8. What time frame is this report being submitted for? *

- 01 Jan **2022** - 31 Dec **2023**
- 01 Jan **2023** - 31 Dec **2023**
- Other

9. What type of report are you submitting? *

- Progress Report (i.e. the project is ongoing)
- Final Report (i.e. the project has been completed or abandoned)
- Site Closure Report

Final Report

10. Date of project completion *

11. Was the project completed, abandoned or terminated? *

- Completed
- Abandoned
- Terminated

12. Please explain reason(s) the project has been abandoned or terminated? *

13. Were any participants recruited to this project? *

- No
- Yes

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

- No
- Yes

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

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

- No
- Yes

17. Please explain why you will not inform participants of project results *

18. Did this project produce any publications or research impact? *

Yes

No

19. Is there a significant research output that would not be available on the MH research repository for publications, that you would like to inform at this time?

(e.g. change to National guidelines, therapeutics being listed on PBS, or a significant award).
Provide any publication ID/registry number if applicable.

Site Closures

20. Are you completing this report as the lead site in a multi-site study?

Yes

No

21. Were any sites closed during 2022/2023?

No

Yes

22. Name of the site closed (please provide details of first site and then there will be an option to add more sites if required) *

23. Principal Investigator at site closed *

24. Date of site closure *

25. Has the project been completed, abandoned or terminated at the site? *

Completed

Abandoned

Terminated

26. Please explain reason(s) the project has been abandoned or terminated at the site? *

27. Were any participants recruited to the project at this site? *

- No
- Yes

28. Have you informed participants at the site that the project has been abandoned or terminated? *

- No
- Yes

29. Please explain why you have not informed participants at the site that the project has been abandoned or terminated? *

30. Were any other sites closed during 2022/2023? *

- No
- Yes

31. Name of the site closed *

32. Principal Investigator at site closed *

33. Date of site closure *



34. Has the project been completed at the site or abandoned or terminated? *

- Completed
- Abandoned
- Terminated

35. Please explain reason(s) the project has been abandoned or terminated at the site? *

36. Were any participants recruited to the project at this site? *

- No
- Yes

37. Have you informed participants at the site that the project has been abandoned or terminated? *

- No
- Yes

38. Please explain why you have not informed participants at the site that the project has been abandoned or terminated? *

39. Were any other sites closed during 2022/2023? *

- No
- Yes

40. Please provide details of additional sites closed:

- Name of the site closed;
- PI of the site closed;
- Whether the project was completed, abandoned or terminated at the site.

If the project was abandoned or terminated, please also include:

- The reason(s) the project was abandoned or terminated;
- Whether participants were recruited at the site;
- If participants were advised that the project was abandoned and if not, why. *

Project Recruitment

41. Does this project involve recruitment of human participants? *

No

Yes

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

No

Yes

43. Is this a multi-site or single-site project? *

Multi-site

Single-site

44. Total anticipated project recruitment number for the reporting period (for all sites, including international)? *

45. Total actual project recruitment number for the reporting period (for all sites, including international)? *

Monash Health Recruitment

The following questions relate to participant recruitment at Monash Health only

46. Total expected recruitment number *

The value must be a number

47. Total actual recruitment as at 31 December 2023? *

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

The value must be a number

48. Was the project open to recruitment at Monash Health at any time in 2023? *

No

Yes

49. Number of potential participants screened 1 January 2023 - 31 December 2023 *

The value must be a number

50. Number of participants enrolled from 1 January 2023 - 31 December 2023 *

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

The value must be a number

51. Total number of participants withdrawn to date? *

This refers to participants that have left the project prematurely due to patient choice or reasons such as non-compliance

52. Number of participants who have completed the project to date? *

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

The value must be a number

53. Is recruitment on target? *

No

Yes

54. Please provide reason recruitment is not on target

Quality & Safety

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

- No
- Yes

56. Please describe the safety events

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

- No
- Yes

58. Please describe the issues

59. Has the study been audited by an external body (e.g. TGA, FDA, study sponsor, ethics committee) at any time in 2023? *

- No
- Yes

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

- No
- Yes

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

Site Closure Report

62. Are you completing this report as the lead site in a multi-site study?

Yes

No

63. Name of the site closed? *

64. Date of site closure *

65. Principal Investigator at site closed *

66. Reason for site closure? *

Completed

Abandoned

Terminated

67. Please explain reason(s) the project has been abandoned or terminated at the site? *

68. What was the targeted participant enrollment number at this site? *

The value must be a number

69. Were any participants recruited into the project at this site? *

- No
- Yes

70. Reason for why no participants were recruited at this site? *

(e.g. project is a registry)

71. How many participants were recruited in total at this site? *

The value must be a number

72. Did any participants withdraw from project at this site? *

- No
- Yes

73. Number of participants withdrawn from project at this site? *

The value must be a number

74. Have you informed participants at the site that the project has been completed, abandoned or terminated? *

- No
- Yes

75. Please explain why you have not informed participants at the site that the project has been completed, abandoned or terminated? *

Demographic Information

NOTE: This section will ask for personal information, which is OPTIONAL for you to answer. Please note that your answers to the questions in this section DO NOT impact the submission and progression of this report.
We only request this information to monitor workforce trends and metrics across the organisation.

76. Name of person completing this report *

77. Role *

If 'other' is applicable, please specify your role.

- Principal Investigator
- Study Coordinator
- Ethics Coordinator
- Other

78. What gender do you identify as?

- Male
- Female
- Non-binary
- Transgender
- Prefer not to say
- Other

79. What professional background do you hold?

- Medical Doctor
- Registered Nurse
- Registered Pharmacist
- Allied Health Professional (with AHPRA Registration)
- Scientist
- Other

80. Does every member of the research team hold a current ICH-GCP training certificate?

Yes

No

Declaration

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.

81. Name of person completing this report *

82. Your email address? *

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

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

Yes

84. What is the Principal Investigator's name? *

85. Principal Investigator email address?

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

86. Please enter any other email addresses to which you would like to send copies of this report?

For multiple email addresses, separate email addresses with a semicolon (;).

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