

1.10.1 Ethics Progress Report Form

ALFRED HOSPITAL ETHICS COMMITTEE
Progress and Final Report Form

- Alfred Ethics Committee approval for the project is ongoing but will lapse if the progress report is not received by the anniversary of the approval date or the report is deemed to be unsatisfactory by the Ethics Committee. The Ethics Office will send a reminder email when reports are due.
- All relevant sections of this report must be completed otherwise the report will be considered invalid.
- All researchers are required to complete Sections A, B, C and E.
- Upon completion of the project, Section D Final Report must also be completed.
- Please email your completed progress report and any attachments to **s 47F** [REDACTED] If the email is sent by the Principal Investigator, then the emailed report is sufficient and you are not required to send a hard copy. Receipt is acknowledged by return email. If the emailed report is not sent by the Principal Investigator, then you are also required to send a report in hard copy, signed by the Principal Investigator, to **s 47F** [REDACTED], Ethics Office, The Alfred, 55 Commercial Road, Prahran, Vic, 3181.

A. PROJECT DETAILS

1.	Alfred Ethics Committee (HREC) project number	
2.	Project title	
3.	Alfred HREC approval date	
4.	Principal researcher/s	
5.	Names of other research personnel	
6.	Research coordinator / contact person	name: email: phone: postal address:
7.	Have there been any changes to research personnel since the project was approved, that you have not yet informed us about?	Yes ☐ No ☐ If Yes, please fill out and attach <i>Changes to Research Personnel Form</i> : http://www.alfredresearch.org/ethics/amend.htm#personnel

B. PROGRESS SUMMARY

1.	Status of the project If the project has been completed, terminated or abandoned, please fill out Section D Final Report	Data collection commenced? ☐ [insert commencement date] Data collection ongoing? ☐ [estimated completion date] Data collection completed? ☐ [insert completion date] Project terminated? ☐ Abandoned? ☐ Not begun? ☐ [reason for delay? Is information in application still current?]
2.	Have you received interim results from the project?	Yes ☐ No ☐ If Yes, please provide details:
3.	Does the project involve recruitment of participants?	Yes ☐ No ☐ If No, please go to Section C. Number of participants recruited (randomised) at this site to date? [insert number recruited] Recruitment completed? Yes ☐ No ☐ Participant involvement completed? Yes ☐ No ☐ Delays in recruitment? Yes ☐ No ☐ [please provide details / will this affect study outcomes] Number of participants withdrawn from study? [insert number] [please provide numbers and reasons for withdrawal]

C. RESEARCH CONDUCT

1.	Is the project being conducted in compliance with the approved protocol?	Yes ☐ No ☐ [details of any protocol deviations / violations] Current version being used: [Version number, date and date approved by Ethics Committee]
2.	Amendments	Have there been any amendments to the project in the last 12 months? Yes ☐ No ☐ If Yes, have you forwarded them to the Ethics Office for review? Yes ☐ No ☐ If No, please do so as soon as possible: http://www.alfredresearch.org/ethics/amend.htm
3.	Participant Information and Consent Forms (PICFs) not applicable ☐ <i>Do not fill in if study does not involve recruitment of participants using a PICF</i>	Where are the signed originals of the PICFs kept? Have participants been given a copy of the signed PICF? Yes ☐ No ☐ [please provide details] Has the study been listed on the research alert sheet of the participants' medical record? Yes ☐ No ☐ If No, please do so for all medical records accessed from now on. Please list the most recent version/s used: [Version number, date and date approved by Ethics Committee]
4.	Access to Medical Records not applicable ☐ <i>Do not fill in if study does not involve access to medical records</i>	Please specify who has access to the Medical Records:
5.	Serious Adverse Events (SAEs), including SUSARs	Have there been any SAEs, including SUSARs, or significant events that impact on the study, and/or involve Alfred Health patients, in the last 12 months? Yes ☐ No ☐ If No, go to Question 7 If Yes, have you informed the Ethics Office of these events? Yes ☐ No ☐ If No, please forward a separate report form with relevant documentation: www.alfredresearch.org/ethics/adverse.htm
6.	Line listings of SAEs and SUSARs not applicable ☐ <i>For sponsored studies only</i>	Have line listings been received from the sponsor at least 6-monthly? No ☐ [If No, please provide reason] Yes ☐ If Yes, has the PI reviewed all listings and reported anything of significance to the Ethics Committee? ☐ No, listings not reviewed ☐ No, listings reviewed but significant events not reported yet <i>Please ensure this is done promptly</i> ☐ Yes, reviewed but nothing to report ☐ Yes, reviewed and reported [Insert date(s) significant event(s) reported to EC]

7.	Issues of ethical significance	Have findings of ethical significance arisen at this site or elsewhere? No ☐ please go to Question 8 Yes ☐ [please provide details] Have Alfred Health participants been informed of these events? Yes ☐ No ☐ [please provide details of why not]
8.	Data Safety and Monitoring Board (DSMB) no DSMB ☐	Has the DSMB been constituted? Yes ☐ No ☐ Is the DSMB independent of the sponsor? Yes ☐ No ☐ How many times has the DSMB met? Please describe the key outcomes of the meeting/s and/or attach report:
9.	Privacy and Confidentiality of Data	Please describe how security and confidentiality of data is maintained: Please list people, by role, who have access to data storage area: Please list people, by role, who have access to data:
10.	Quality Control not applicable ☐	Please provide details of the quality control checks undertaken, relating to equipment/lab services that are being used in the project, and their frequency:
11.	Registration not applicable ☐	Has the trial been registered with a WHO-accredited clinical trials registry? Yes ☐ [name of registry and registration number] No ☐ [please explain why not]
12.	Audit	Has the project been audited by someone other than the Alfred Ethics Unit? Yes ☐ please attach report No ☐ Please complete the Alfred Hospital Ethics Committee's <i>Self Audit for Research Personnel</i> and submit with this report: www.alfredresearch.org/ethics/monitor.htm ☐ attached ☐ copy added to study file
13.	Insurance not applicable ☐	Is the insurance certificate current? Yes ☐ please attach copy No ☐ please obtain a current copy from the sponsor and forward to us as soon as possible
14.	Compensation	Have any compensation payments (damages) been awarded to any participants as a result of their participation in this study? Yes ☐ [please provide details] No ☐

D. FINAL REPORTNot applicable ☐

Please complete this section, as well as all other sections, if your project meets at least one of the following criteria:

- the results have been published or presented
- the study documents are ready for archiving
- data analysis is complete and a Lay Summary of Findings is included in this report.

1.	Date the project was completed	
2.	Lay summary of findings <i>Briefly summarise the findings in Plain English (no more than one page)</i>	
3.	Total number of participants recruited at Alfred Health <i>(by group if applicable)</i>	
4.	Details of any publications accepted or in press	
5.	Details of any presentations given	
6.	Have study participants been informed of the results? How?	
7.	If the project has been completed with no plans for publication, please explain why	
8.	Do you think there should be any changes in practices at this hospital as a result of this project?	
9.	Is there is any reason why you think the documentation associated with this project should <i>not</i> be kept indefinitely?	
10.	Archiving	If this project is being archived, please fill in and submit the form at: http://www.alfredresearch.org/ethics/archiving.htm If the study documents have already been archived, please indicate where they are stored:

Project no: *[insert Alfred HREC project no]*

E. SIGN-OFF

I confirm that this project has been conducted as originally approved by the Alfred Hospital Ethics Committee (and subject to any changes subsequently approved as amendments).

I confirm that this project continues to be conducted in compliance with the NHMRC National Statement on Ethical Conduct in Human Research (NHMRC, 2007).

I confirm that this report accurately reflects the progress of the project at:

[insert date here]

Date

[print name here]

Name of Principal Researcher

[insert signature here]

Signature of Principal Researcher

[Office use only: Alfred Ethics Office Acknowledgement]

**Original to be sent to the Ethics Office
Duplicate to be kept by researchers**