

**HUMAN RESEARCH ETHICS COMMITTEE**  
**TEMPLATE ANNUAL REPORT FORM**

*Only typewritten reports will be accepted.*

**HREC Approved Project No:**

**Project Title:**

**Protocol Number:**

**Principal Investigator:**

**Trial Coordinator:**

**Address:**

**All current co-investigators:**

**If any co-investigators have left the project during the year, please list their names and date of departure from the project.**

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**THIS PROJECTS HAS** (please tick appropriate box)

- |                             |                          |   |
|-----------------------------|--------------------------|---|
| <b>BEEN ABANDONED</b>       | <input type="checkbox"/> | .....<br><i>Please state reason</i>     |
| <b>NOT COMMENCED*</b>       | <input type="checkbox"/> | .....<br><i>Expected starting date</i>  |
| <b>COMMENCED</b>            | <input type="checkbox"/> | }<br>} <i>Complete page 2 of report</i> |
| <b>COMPLETED/TERMINATED</b> | <input type="checkbox"/> | }                                       |
| <b>A DRUG COMPONENT</b>     | <input type="checkbox"/> | <i>Complete Drug Trial Addendum</i>     |

\* Note if a study has not commenced within 12 months of the ethics approval date, and no approval extension has been previously arranged, the approval lapses. The study will then have to be resubmitted before it can commence.

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**WAS FUNDING SOUGHT FROM AN AGENCY OR FOUNDATION?**

**If Yes**      What Agency .....  
Was the application successful       Yes                       No

**If No**      Please state what source of funding is being used for this project

**HREC Approved Project No.**

**1. Date of ethics approval from Austin Health.** ...../...../.....

**2. Date project commenced at Austin Health.** ...../...../.....

**3. Date original ethics approval lapses/lapsed.** ...../...../.....

**4. Date when you expect to complete the project?** ...../...../.....

**5. Has an extension of ethical approval been granted?**

Yes  No  Not requested

**6.a) If yes, what is the date the extension of approval lapses?** ...../...../.....

**6. b) If no, and your expected completion date falls beyond the period of ethical approval, please write to the HREC requesting an extension of approval and providing justification for this extension.**

**7. Have any unanticipated ethical issues emerged during the course of the project?**

Yes  No  *If yes, please provide details*

**8. Is the project being conducted in compliance with the protocol?**

Yes  No  *If no, please provide details*

**9. Is the project being conducted in compliance with any conditions of approval?**

Yes  No  *If no, please provide details*

**10. Have there been, or will there be, any significant changes in procedure or direction of the project, or in the source, or manner of recruitment, number of subjects etc?**

Yes  No  *If yes, please provide details*

**11. Are the records and data collected during the conduct of the study stored and maintained in a secure location?**

Yes  No  *Please provide details*

**12. Please give a brief summary of the results of the research to date**

**13. What anticipated benefits have been involved?**

**14. Please list any published papers, or presentations relating to this study**

**15. Please state the version number, date and name of all the current Participant Information and Consent Forms used in this study**

**16. Are records being maintained according to the National Statement on Ethical Conduct in Human Research (2007)?**

**Yes**                       **No**

*If no please explain-*

**I confirm that this project is being conducted as originally approved by the Austin Health Human Research Ethics Committee, subject to any changes as indicated above and is conducted in compliance with the NHMRC/ARC/AVCC National Statement on Ethical Conduct in Human Research (2007).**

.....

*Principal Investigator*

...../...../.....

*Date*

*(An electronic signature is acceptable OR sign and send in a hard copy to the REU Office)*

## **ADDENDUM**

Use if patients are recruited

### **Total numbers of patients:**

- ..... expected on trial
- ..... screened
- ..... entered / randomised
- ..... currently on treatment
- ..... completed treatment
- ..... who dropped out without completing treatment (and reason for dropping out)
- ..... on follow-up
- ..... completed follow-up
- ..... Is the trial recruitment open? If no, when did it close .....

As Austin Health needs to know the number of patients recruited in each calendar year, please also include the following data:

- ..... entered/randomised in 2010
  - ..... entered/randomised in 2011
  - ..... entered/randomised in 2012
  - ..... entered/randomised in 2013
- 

### **Serious Adverse Events**

..... Number of internal SAE reports

Dates reported to HREC

.....  
.....

### **Protocol Violations**

List of protocol violations (include those already reported to HREC marked with an \*).

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