**ADVERSE EVENT/PROGRESS/FINAL REPORT AFTER ETHICAL APPROVAL**

Version date: 17 July 2018

*CRICOS Provider 01037A*

|  |  |
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| OFFICE USE ONLY | |
| Application Number |  |
| Date of ethical approval |  |

Has your research project been approved by the University of Divinity Research Committee?

Yes  No  (tick one)

|  |  |
| --- | --- |
| Date of Approval |  |

Adverse event reports must be made as soon as practicable after an adverse event takes place. Progress reports are due every 12 months from the commencement of the ethics approval period. A final report, using this same form, is also required at the completion of the project.

***Failure to submit a progress report may mean that ethics approval may lapse.***

|  |  |
| --- | --- |
| **Personal details** | |
| Name |  |
| Researcher Status (HDR student, academic staff, honorary researcher) |  |
| College |  |
| Project Title |  |
| Email |  |
| Name of Supervisor  (if applicable) |  |

Answers must be expressed succinctly, keeping to the word limits indicated, and using plain, jargon-free language. Do not use technical or discipline-specific language.

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| --- | --- | --- | --- | --- |
| **1.** | NATURE OF REPORT (insert tick in whichever is applicable) | | | |
|  | Adverse Event Report |
|  | Progress Report |
|  | Final Report |
| **2.** | STATUS OF PROJECT | | | |
|  | Data collection continuing | | Anticipated date of completion |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Data collection completed | Date completed |  | | |
|  | Project discontinued | Date project discontinued |  | | |
| If project discontinued, please provide the following information. Otherwise go to Question 3 | | | | | | |
| a) | The reason for discontinuance: | | | |
|  |  | | | | |
| b) | Has data already been collected (please tick one)? YES  NO | | | | |
| c) | Have participants been informed of the project’s discontinuance? YES  NO | | |
|  | If NO, please provide the reason or provide a date as to when they will be informed: | | | | |
|  |  | | | | |

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| --- | --- | --- |
| **3.** | | PROJECT REPORT |
| Please indicate if your research proceeded as described in your initial application and modification requests (if any), as approved by the HREC. | | | |
|  | | Project proceeding / proceeded as approved |
|  | | Project procedures have varied from those approved |
|  | Please indicate how your procedures varied from those approved and whether they have ethical implications. | |
|  | |  |

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| --- | --- | --- |
| **4.** | DATA SECURITY | |
| a) | Are data secure as advised in your initial application and any approved modification?  YES  NO | | |
|  | If NO, please explain: |
|  |  | |

N.B. Data and source documents must continue to be stored in accordance with the University’s relevant policies after completion/discontinuation of the project.

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| --- | --- | --- | --- |
| 5. | | PARTICIPANT WITHDRAWAL | |
|  | Please indicate whether any participant withdrawals occurred during the project, the numbers involved and the reasons for withdrawal. | |
|  | |  |

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| --- | --- | --- |
| **6.** | | ADVERSE EVENTS OR INCIDENTS |
|  | Have any adverse events or ethically significant incidents arisen during your research, or any complaints received from participants? YES  NO  If No, proceed to section 7. If Yes, complete following;   1. Please indicate what the adverse events or ethically significant incidents or complaints received from participants. | | |
|  | |  |
|  | | b) What steps have been taken to investigate the cause/s of the adverse event? |
|  | |  |
|  | | c) What steps have been taken to limit the effect/s of the adverse event on participants and any other affected persons? E.g. provide counselling or other support, redesign procedures, etc. |
|  | |  |
| **7.** | | PLEASE PROVIDE 250 WORDS of ABSTRACT FOR YOUR PROGRESS/FINAL REPORT | | |
| **8.**  a)  b)  c)  d)  **9.** | | |  | | --- | |  |   ***IF THIS IS YOUR FINAL REPORT, please answer the following question;***  Has the data been provided to the University in electronic format? YES  NO  If NO, please provide reason and provide a date as to when they will be provided   |  | | --- | |  | | Where are the data and the source documents? Please be specific including room number as appropriate | |  | | Has consent for re-use of data for future research been obtained?YES  NO |   ***SIGNATURES*** | | |

### SIGNATURE OF RESEARCHER

|  |  |  |  |
| --- | --- | --- | --- |
| **Researcher** | | | |
| Signature |  | Date |  |
| Name  *Write SURNAME in capitals* |  | | |
| **Principal Supervisor** (if applicable) | | | |
| Signature |  | Date |  |
| Name  *Write SURNAME in capitals* |  | | |