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| **PROGRESS REPORT** |
| The ‘National Statement on Ethical Conduct in Human Research’ paragraph 5.4.8 requires researchers to provide progress reports to the relevant ethical review body/ies and institution/s.Progress reports are to be submitted to Departments of Defence and Veterans’ Affairs Human Research Ethics Committee at least annually. For clinical trials, progress reports are to be submitted six monthly. Due dates for submission of the reports will be stated on the outcome letter advising that ethical approval has been granted.Reports are to be signed by the 1st listed Principal Investigator. Failure to submit a progress report may result in withdrawal of ethical approval. Failure to complete all relevant fields will result in the report being returned and the additional information being requested. Completed reports are to be emailed to ddva.hrec@defence.gov.au |
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| **SECTION 1: PROJECT DETAILS** |
| **Project Number:** |  |
| **Project Title:** |  |
| **Anticipated completion date:** |  |
| **Is this student research?** | [ ]  Yes | [ ]  No |
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| **SECTION 2: INVESTIGATOR DETAILS** |
| **Principal Investigator** |
| **Name:** |  |
| **Organisation (command/division):** |  |
| **Phone:** |  |
| **Email:**  |  |
| **Student (where applicable)** |
| **Name:** |  |
| **Organisation (command/division):** |  |
| **Phone:** |  |
| **Email:**  |  |
| **Changes to Investigators** |
| Advise of any changes to the research team since ethics approval was granted (for new research projects) or since the date of the previous Progress Report. If an amendment form was not submitted a request for amendment form must be submitted and include an explanation as to why it was not submitted previously. *Insert additional rows as required.* |
| **Name** | **Institution** | **Amendment Form submitted** |
|  |  | [ ] Yes | [ ]  No |
|  |  | [ ] Yes | [ ]  No |
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| **SECTION 3: SUMMARY OF PROGRESS** |
| **Current status of research project** |
| **Has the study started?**  | [ ] Yes | [ ]  No |
| **If no, do you plan to start this project?** Note: Submission of a Final Report form is also required if there is no intention to start the project. | [ ]  Yes | [ ]  No |
| **If you intend to commence the study at a future date, what is the anticipated start date?** |  |
| **If you don’t intend to start the study, please provide an explanation:****Note:** If a research project does not commence within 12 months of receiving ethical approval, the ethical approval will lapse unless there is a valid reason. |
| **If the study has started, what was the actual start date?** |  |
| **If the study has started, indicate what phase the project is in** *(Choose one)* | [ ]  Currently recruiting |
| [ ]  Active follow-up continues  |
| [ ]  Long-term follow-up continues  |
| [ ]  Ongoing analysis only  |
| Does the study rely on Defence’s United States Federal Wide Assurance?  | [ ]  Yes  | [ ]  No |
| Was ethical approval required from another ethical review body for this study? | [ ]  Yes  | [ ]  No |
| If additional ethical approval was required, has evidence of their approval been provided to the Secretariat for inclusion on your file? If no, please provide a copy of the outcome letter in support of this report. | [ ]  Yes  | [ ]  No |
| Is an extension to the period of ethical approval required? | [ ]  Yes  | [ ]  No |
| If yes, please indicate when the extension is being requested until and include reasons for the request for extension. **Note:** An extension in excess of three years will not be granted. Any studies that require extensions longer than that period will need to submit an additional request for extension closer to the period of expiration of the revised period of ethical approval. [Please ensure that the extension date aligns with the anticipated completion date]  |
| Are records being maintained in accordance with the approved application? | [ ] Yes | [ ]  No |
| If no, please provide details: |
| Is the research project being conducted according to the application? | [ ]  Yes | [ ]  No |
| If no, please provide details: |
| Are all conditions of ethical approval being met?  | [ ] Yes  | [ ]  No |
| If no, please provide details: |
| **Provide a brief summary of the essential aspects of progress or results to date:** |

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| **SECTION 4: PARTICIPANTS** |
| Does the study involve recruitment of participants as part of the research design? [Participants were asked to engage in activities (such as surveys, interviews, focus groups)] If no, go to section 5. | [ ] Yes [ ]  No |
| Participant recruitment target:  |  |
| Recruitment to date: |  |
| Is recruitment on target:  | [ ]  Yes  | [ ]  No |
| If recruitment is not on target, provide an explanation: |
| Withdrawn to date:  |  |
| Provide reason(s) for withdrawal: |
| Advise participant numbers if multiple reasons apply: |
| Do you plan to increase the planned recruitment of participants into the study? Note: Any increase in planned recruitment should be notified to the Committee as a substantial amendment for ethical review. | [ ] Yes | [ ]  No |

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| **SECTION 5: USE OF EXISTING DATA** |
| Does the study involve use of existing data? If no, go to section 6. | [ ] Yes [ ]  No |
| Describe the data transfer process: |
| Description of data:  |
| Number of records: |
| Has the data custodian released the data? |  |

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| **SECTION 6: SITE INFORMATION** |
| Do you plan to increase the total number of sites proposed for the study? Note: A request for amendment will be required.  | [ ] Yes | [ ]  No |
| Has research been discontinued from any site? | [ ] Yes | [ ]  No |
| If yes, please provide details:  |

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| **SECTION 7: ADVERSE EVENTS** |
| Have there been Adverse Events or Serious Adverse Events occur since the last report? | [ ]  Yes | [ ]  No |
| If yes, please summarise: |
| If yes, has formal notification been submitted to the Departments of Defence and Veterans’ Affairs HREC? If no, you will need to submit and Adverse Event/Serious Adverse Event Form. | [ ]  Yes | [ ]  No |

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| **SECTION 8: COMPLAINTS** |
| Have any participants, researchers or others expressed any complaint about the project? | [ ] Yes  | [ ]  No |
| If yes, please summarise: |
| Have any participants claimed to have suffered harm or injury?  | [ ] Yes | [ ]  No |
| If yes, please summarise: |

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| **SECTION 9: CLINICAL TRIALS** |
| Is the study a clinical trial? If no, go to Section 10 | [ ] Yes  | [ ]  No |
| Is the study registered on a publicly accessible register? | [ ] Yes | [ ]  No |
| If yes, provide the name of the register and the registration number. |
| If no: |
| a. | What is the reason for non-registration? |
| b. | What are you intentions for registration? |

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| **SECTION 10: OTHER ISSUES** |
| Are there any other developments in the project that you wish to report to the Committee? | [ ] Yes | [ ]  No |
| If yes, please provide details: |
| Are there any ethical issues on which further advice is required? | [ ] Yes  | [ ]  No |
| If yes, please provide details: |

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| **SECTION 11: PRINCIPAL INVESTIGATOR DECLARATION** |
| I confirm that this project is being conducted in keeping with the conditions of ethical approval, and accurately reflects the status of the above research project. I confirm that the project is being conducted in compliance with the *National Statement on Ethical Conduct in Human Research*.I confirm that I have not received any information in any form from anyone involved in the project to suggest this report does not accurately reflect the progress of the project to date. |
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| **Name** | **Signature** |
| **Date:** |  |