|  |
| --- |
| **Email the completed form and relevant documents to** **humanethics@unisa.edu.au** **1 month prior to the end of each year of approval. Answer questions in relation to the previous 12 months. All Students are required to complete this form in discussion with their supervisors – and the supervisor MUST sign the form at Section 10. If attachments are necessary, the file name should include the Question number.** |

|  |
| --- |
| **SECTION 1: PROJECT DETAILS** |
| Chief Investigator |  |
| Project Title |  |
| Project Number |  | Original Approval Date |  |
| **APPROVAL FROM NON-UNISA HREC** |
| Does this project have non-UniSA HREC ethics approval? |
| [ ]  Yes – *please attach a copy of the approval from the Primary HREC for the annual report or approved extension request* | [ ]  No |

|  |
| --- |
| **SECTION 2: PROJECT STATUS – Please select your reason for completing this form**  |
| **Status** | **Select** | **Indicate Date** | **Instruction** |
| In Progress |[ ]  Anticipated Date of completion:  | Go to Section 5 |
| Extension Required |[ ]  Anticipated Date of completion (*maximum 1 additional year)*: | Go to Section 5 |
| Discontinued / Not commenced |[ ]  Date work was stopped: | Go to Section 3 |
| Completed |[ ]  Date of completion: | Go to Section 4 |

|  |
| --- |
| **SECTION 3: DISCONTINUED/ NOT COMPLETED PROJECTS**  |
| **Section 3.1** Did the project commence? | [ ]  Yes | [ ]  No |
| **Section 3.2** Detail why the project was discontinued or did not commence, including whether this created any ethical issues and if so, how they were resolved. If data were collected, detail what has been done with them to destroy or secure them (please provide details below) |
|  |
| **Go to Section 7** |

|  |
| --- |
| **SECTION 4: COMPLETED PROJECTS –**  |
| **Section 4.1** List original aims of the project (from the original approved application): |
|  |
| **Section 4.2** Were the aims of the project achieved? Provide a brief summary of the findings to date below: | [ ]  Yes | [ ]  No |
|  |
| **Section 4.3** Have study participants been informed of the results? Provide details. | [ ]  Yes | [ ]  No | [ ]  N/A |
| **Go to Section 7** |

|  |
| --- |
| **SECTION 5: PROJECTS IN PROGRESS** |
| **Section 5.1** Please provide a brief outline of how data collection is progressing, including if any participants have already been involved in the project: |
|  |
| **Section 5.2** Indicate current stage and progress of the project *(tick one)*: |
|  |
| [ ]  Project Establishment/Planning | [ ]  Recruitment | [ ]  Data Collection |
| [ ]  Data Analysis | [ ]  Write Up | [ ]  Other |
| **Section 5.3** List the version numbers and approval dates of the Participant Information Sheet and Consent Form used (where applicable): |
| **Documents** | **Version number and date** | **Date Approved** |
| Participant Information Sheet |  |  |
| Consent Form |  |  |
| **Go to Section 6 if an Extension is Required; otherwise go to Section 7** |

|  |
| --- |
| **SECTION 6: EXTENSION REQUIRED** |
| **Section 6.1** Explain why an extension of ethics approval is requested: |
|  |
| **Go to Section 7** |

|  |
| --- |
| **SECTION 7: CLINICAL TRIALS**  |
| **Complete this section if this study is a clinical trial only, otherwise go to Section 8.** Please note that section 5.5.9 of the National Statement states that it may be unethical for a researcher to continue a clinical trial if:1. there are or have been substantial deviations from the trial protocol;
2. adverse effects of unexpected type, severity, or frequency are encountered; or
3. as the trial progresses, the continuation of the trial would disadvantage some of the participants as determined by the researchers or others monitoring the trial.
 |
| **Section 7.1** Tick one of the following for this study: [ ]  Clinical trial with full industry sponsorship [ ]  Clinical trial with sponsorship from a collaborative or non-profit group[ ]  Clinical trial initiated by the Chief Investigator |
| **Section 7.2** Is this study being conducted under either: |
| Clinical Trial Exemption (CTX) Scheme | [ ]  Yes | [ ]  No |
| Clinical Trial Notification (CTN) Scheme | [ ]  Yes | [ ]  No |
| **Section 7.3** Does the study have a Data Safety Monitoring Committee (or similar) which has reviewed the study in the past 12 months? If yes, attach a copy of the Committee’s report and describe the potential impact on ethical acceptability and the need for action. |
|  |
| **Section 7.4** If a safety report is not available, is action planned on the basis of any safety information received in the last 12 months?If yes, describe the potential impact on ethical acceptability and the need for action. | [ ]  Yes | [ ]  No |
|  |
| **Section 7.5** Has the trial been registered on a publicly accessible register complying with international standards? If yes please provide the names of register(s) and **registration number(s).** | [ ]  Yes | [ ]  No |

|  |
| --- |
| **SECTION 8: ETHICAL ISSUES** |
| Tick YES or NO to the following questions.  |
| **Section 8.1** Have you departed at all from the approved project? If ‘YES’ provide details below and confirm if a [Project Variation form](https://i.unisa.edu.au/siteassets/staff/ris/docs/project-variation-form-191004.docx) has been submitted for approval of these changes. If you have departed from the approved project and a [Project Variation form](https://i.unisa.edu.au/siteassets/staff/ris/docs/project-variation-form-191004.docx) has NOT been submitted, complete and submit the [Project Variation form](https://i.unisa.edu.au/siteassets/staff/ris/docs/project-variation-form-191004.docx) for approval. | [ ]  Yes | [ ]  No |
|  |
| **Section 8.2** Did any participants withdraw from the project during this year? If ‘YES’, provide details below: | [ ]  Yes | [ ]  No | [ ]  N/A |
|  |
| **Section 8.3** Did any [ethical implications](https://i.unisa.edu.au/staff/research/research-ethics/human-research-ethics/ethical-implications) arise during the research? If ‘YES’ provide details below, including whether or not they were foreseen, and how they were resolved | [ ]  Yes | [ ]  No |
|  |
| **Section 8.4** Have any participants suffered harm or [adverse effects](https://i.unisa.edu.au/staff/research/research-ethics/human-research-ethics/ethics-management-for-approved-projects/)?If YES, provide the date reported to UniSA HREC?If not provide details as to why not and submit the reports. | [ ]  Yes | [ ]  No | [ ]  N/A |
|  |
| **Section 8.5** Have any complaints been received regarding the project? If ‘YES’ provide the date, source and nature of the complaint, actions taken, and the current status (resolved/in process/other). Include the date UniSA HREC or detail why no notification occurred. | [ ]  Yes | [ ]  No |
|  |
| **Section 8.6** Has the project been audited by the sponsor, the Human Research Ethics Office or any other body since the last progress report was submitted? If YES, provide details. | [ ]  Yes | [ ]  No |
|  |
| **COMPLETE THE FOLLOWING 2 QUESTIONS ONLY IF YOU HAVE CONDUCTED RESEARCH IN A COUNTRY OTHER THAN AUSTRALIA-**  |
| **Section 8.7** Did you identify any legal, ethical, governmental or other local requirements that you needed to meet? If YES, provide details. | [ ]  Yes | [ ]  No |
|  |
| **Section 8.8** Did you meet all such requirements and has written evidence been provided to the ethics office? If YES, provide details.If not, provide details as to why written evidence has not yet been submitted and provide a copy of the relevant document(s).  | [ ]  Yes | [ ]  No | [ ]  N/A |
|  |

|  |
| --- |
| **SECTION 9: DATA STORAGE *Please note: Data must be stored as specified in the approved project. All data must eventually be destroyed, unless explicit consent is obtained from the participants to archive their data.*** |
| **Section 9.1** State how and where your data is being stored. Have all records (including data) been maintained in a manner consistent with the arrangements and security measures that were proposed in the approved application? If NO, provide details and submit the [Project Variation form](https://i.unisa.edu.au/siteassets/staff/ris/docs/project-variation-form-191004.docx) for approval |
|  |
| **Section 9.2** How long will the data be kept after the end of the project? |
|  |
| **Section 9.3** Has there been any breach of confidentiality or data security issues, which includes identifying information? If ‘YES’ provide details of actions to remedy the breach, including date reported to UniSA HREC or reasons why it was not reported | [ ]  Yes | [ ]  No |
|  |

|  |
| --- |
| **SECTION 10: DECLARATION** |
| [ ]  I confirm that the research has been undertaken as per the approved project. |
| *Chief Investigator Signature* | *Printed Name* | *Date* |
| *Supervisor’s Signature (students only)* | *Printed Name* | *Date* |