

**PROGRESS REPORT AND RECERTIFICATION APPLICATION**

**Principal Investigator:**

**Supervisor:**

**HREC Approval Number**

**Reporting From:**

**Project title:**

**Section 1:**

|  |  |
| --- | --- |
| **Report Frequency** | **Tick Appropriate Box** |
| **Quarterly Report** |  |
| **Semi Annual Report** |  |
| **Annual Report** |  |

**Details**

|  |
| --- |
| **Kindly provide a brief description of your progress in your project over this period:** |

**Did you encounter any ethical issues/adverse events during this period?**

|  |  |
| --- | --- |
| Yes |  |
| No |  |

|  |
| --- |
| I**f yes, please give a brief description of these ethical issues and how these were managed/resolved** |

**Please state if you have finished collecting your data from human participants.**

|  |  |
| --- | --- |
| Yes |  |
| No |  |

|  |
| --- |
| I**f not, please explain why** |

**If you require an extension of ethical clearance, please complete the below section of the application.**

**Section 2: Participants**

|  |  |
| --- | --- |
| Number of participants recruited |  |
| Number of Participants enrolled |  |
| Number of participants still active in the project |  |
| Number of participants still required |  |
| Number of participants to have withdrawn from this study. If any, please explain the reasons for withdrawal |  |

**Section 3: Unanticipated Problems or Adverse events**

|  |  |
| --- | --- |
| **Have there been any unanticipated problems involving risks to participants or others or adverse events since the initial or last continuing review?** | |
| Yes |  |
| No |  |
| Not Applicable |  |

|  |  |
| --- | --- |
| **Does the research have a Data and Safety Monitoring Board (DSMB) or Committee (DSMC)?** | |
| Yes |  |
| No |  |
| Not Applicable |  |

**Section 4: Literature and New Information**

|  |  |
| --- | --- |
| **Since the last review (initial or last continuing review) has there been any new literature or new information that relates to this research, such as information about possible risks, benefits, or alternatives for participants related to this research or any significant new findings which may related to the participants’ willingness to continue participate in the research** | |
| Yes |  |
| No |  |
| Not Applicable |  |

**Section 5: Presentation/or Publications**

|  |  |
| --- | --- |
| **Have there been any presentation or publications (including abstracts) that resulted from this study?** | |
| Yes |  |
| No |  |
| Not Applicable |  |

**Section 6: Data Management**

|  |  |
| --- | --- |
| **Have you made changes to the original Data Management Plan?** | |
| Yes, if yes, please forward the updated Data Management Plan |  |
| No |  |
| Not Applicable |  |

**Section 7: Updated LS262a**

|  |  |
| --- | --- |
| **Have you attached an updated LS262a/Protocol with updated timelines and any other envisaged changes? Please Highlight these changes and attach the LS262a/Protocol on the Converis system under attachments.** | |
| Yes |  |
| No |  |
| If No, please explain why |  |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | 1. I certify that the information provided in this Continuing Review Progress Report is complete and accurate. I understand that as Principal Investigator, I have the responsibility for the protection of the rights and welfare of human participants where applicable, enrolled in the research and for the overall ethical conduct of the research. By signing this form I am indicating that I have complied with all research ethics policies and procedures relating to human participants research, as well as local laws. I confirm the following: |  | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | 1. The project was performed by qualified and trained personnel who were approved to work on the Ethics Committee approved protocol. |  | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | 1. No changes were made to the protocol or approved protocol documents without prospective Ethics Committee approval. |  | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | 1. When applicable, legally effective informed consent was obtained from all participants, unless the Ethics Committee waived consent. |  | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | 1. Any complaints or unanticipated problems that occur during the conduct of the research were reported to the Ethics Committee in a timely manner according to policy. |  | |

Date:

Signature: