**PRINCIPAL INVESTIGATOR DECLARATION**

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| I have read and will comply with the content of the Enable Ireland REQC Policy and Procedure document. **Initial:**  |
| I certify the information in this form is accurate to the best of my knowledge and belief and I understand my ethical and legal responsibilities as Principal Investigator of this study. **Initial:** |
| I confirm that all named co-investigators have signed below, have read and complied with the Enable Ireland REQC Policy and Procedure document and received the final version of the study protocol and of this application form and are in agreement with their role. **Initial:** |
| I understand the obligations to and the rights of participants particularly concerning their safety and welfare, the obligation to provide information sufficient to give explicit consent, the obligation to respect confidentiality and all the obligations as set out in the EU General Data Protection Regulation 2016. **Initial:** |
| Participants will be informed that they are in no way obliged to volunteer if there is any personal reason (which they are under no obligation to divulge) or if they simply do not want to participate in the research. **Initial:** |
| Participants will be informed that they may withdraw from the research without disadvantage to themselves and without being obliged to give any reason. **Initial:** |
| I have named the appointed gatekeeper in the REQC application form and confirm that the gatekeeper is an Enable Ireland employee. **Initial:**  |
| All relevant information about serious adverse reactions and new events likely to affect the safety of the subjects will be reported to the Enable Ireland REQC in writing.**Initial:** |
| If the study receives approval, I agree to supply interim progress report and a final report/thesis etc. to the Enable Ireland REQC. **Initial:** |
| In the event of premature termination, suspension or deferral of this project, I agree to provide a report to the Enable Ireland REQC outlining the circumstances for such termination, suspension or deferral. **Initial:** |
| Name of Principal Investigator:  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Signature of Principal Investigator:  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Name of Co-Investigators: | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Signature of Co-Investigators:  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Date:  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**PLEASE NOTE THAT IF THERE IS MORE THEN ONE APPLICANT, ALL APPLICANTS MUST SIGN THE DECALARTION**