

DECLARATION AND SIGNATORY PAGE

Name of Committee: **National Rehabilitation Hospital, Ethics Committee**

Title of Study:

DECLARATION OF PRINCIPAL INVESTIGATOR:

- 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.
- I confirm that all named co-investigators and collaborators have received the final version of the research protocol and of this application form and are in agreement with their role.
- If the study receives approval, I agree to supply an interim report 6 months into the study and a final report to the Ethics Committee. In addition, I will seek prior approval from the Ethics Committee of any proposed changes/amendments to this protocol.
- In the event of premature termination, suspension or deferral of this project, I agree to provide a report to the Ethics Committee outlining the circumstances for such termination, suspension or deferral.
- All relevant information about serious adverse reactions and new events likely to affect the safety of the subjects will be reported to the Ethics Committee in writing.
- I am aware of my responsibility to comply with the Data Protection Act 1988 and 2003, GDPR and Health Research Regulations.
- I confirm that the protocol and research will comply with all relevant Irish legislative requirements and will abide by the ethical principles outlined in the Declaration of Helsinki and Good Clinical Practice.

Name of Principal Investigator: _____

Signature of Principal Investigator: _____

Date: _____

The Principal Investigator who signs the Ethics Committee Application takes responsibility both for the standard and quality of this application and for the conduct of the research in accordance with the protocol and ethics committee application. Substandard application forms and substandard accompanying documentation will not be accepted for review by the committee.

DECLARATION OF CO-INVESTIGATOR (S):

- I am fully aware of the details of this project, having read the application in full and I agree for it to proceed as outlined.
- I can confirm that the application is of a high standard and of educational value and all the necessary facilities and resources are available to the researcher.
- I agree, in consultation with the Principal Investigator to supply an interim report 6 months into the study and a final report to the Ethics Committee.
- I agree, to inform the Principal Investigator of all relevant information about serious adverse reactions and new events likely to affect the safety of the subjects.

Name of Co- Investigator(s): _____

Signature of Co- Investigator(s) _____

Date: _____