

COISTE EITICE UM THAIGHDE CLINICIÚIL
Clinical Research Ethics Committee of the Cork Teaching Hospitals

Tel: +353-21-4901901

Email: crec@ucc.ie

University College Cork
Lancaster Hall
6 Little Hanover Street
Cork
Ireland

CREC Review Reference Number: ECM 4 (n) 13/12/2022

Date: 5th December 2022

Professor Suzanne Timmons
Centre for Gerontology and Rehabilitation
The Bungalow
Block 13
St Finbarr's Hospital
Douglas Road
Cork

Study Title: Irish clinical site data collection and analysis as part of the global "World Delirium Awareness Day 1-day point delirium prevalence study"

Approval is granted to carry out the above study at:

Mercy University Hospital, Cork University Hospital, St Finbarr's Hospital, University Hospital Kerry, Bantry General Hospital and Bon Secours Hospital, Cork.

The following documents have been approved:

Document	Approved	Version	Date
Cover Letter	Yes		18 th November 2022
Application Form	Yes		Signed 18 th November 2022
Proof of Insurance	Yes (UCC)		18 th November 2022
CV for Chief Investigator	Yes		November 2022
Protocol (Irish Study)	Yes	1	18 th November 2022
Protocol (Global Study)	Yes	1.2	12 th September 2022
Online Survey	Yes		14 th September 2022

We note that the co-investigator(s) involved in this project will be:

Name	Appointment Details
Dr Peter Nydahl	Nursing Research and Development
Dr Emma O'Shea	Postdoctoral Researcher
[REDACTED]	Postdoctoral Researcher
[REDACTED]	Consultant Geriatrician
[REDACTED]	Consultant Geriatrician
[REDACTED]	Consultant Geriatrician
[REDACTED]	Advanced Nurse Practitioner

The date of this letter is the date of authorization of this low-risk study.

Please keep a copy of this signed approval letter in your study master file for audit purposes. The study must be carried out in accordance with General Data Protection Regulation and Health Research Regulation 2018/2021.

You should note that ethical approval will lapse if you do not adhere to the following conditions:

1. Submission of an Annual Progress Report/Annual Renewal Survey (due annually from the date of this approval letter). **We would encourage you to keep note of this date as the CREC will not issue a reminder.**
2. Report unexpected adverse events, serious adverse events or any event that may affect ethical acceptability of the study

3. Submit any change to study documentation (minor or major) to CREC for review and approval. Amendments must be submitted on an amendment application form and revised study documents must clearly highlight the changes and contain a new version number and date. Amendments cannot be implemented without written approval from CREC.
4. Notify CREC of discontinuation of the study
5. Submit an End of Trial Declaration Form and Final Study Report/Study Synopsis when the study has been completed.

Yours sincerely



Professor David Kerins
Chairman
Clinical Research Ethics Committee
of the Cork Teaching Hospitals