HRCDC
Health Research Consent Declaration Committee

Minutes of the Meeting – APPROVED

Date: 7th October 2025

Location: Zoom videoconferencing

HRCDC Attendance:

Evelyn Mahon
Mary Tumelty
John Woods
Patricia O'Beirne
Susan Smith
Aisling McMahon
Sarah Barnes Aabo
Jonathan Briody
Antoinette O'Connor
Ross McMullan
Barbara Clyne
Brid Burke (Secretariat)
Jonny Barrett (Secretariat)
Caroline Byrne (Secretariat)

Quorum for Decisions

YES

Opening

The Chairperson (Evelyn Mahon) opened the meeting and welcomed the members.

Apologies

Jim Blighe, Paul Stynes, Aideen Hartney

Disclosure of Interest

Aisling McMahon (AMcM) declared her interest in amendment application 19-004-AF2/AMD5. AMcM was absent during the meeting when this application was considered.

Minutes of the last meeting

Draft minutes of 9th September 2025 were circulated in advance of the meeting and were approved by the HRCDC.

Chairperson Approvals

- **Ref ID: 23-002-AF1/AMD4 (EAGER Register):** The HRCDC were informed that amendment request 23-002-AF1/AMD4 was approved via the Chairperson approval process. The amendment covers the addition of the Mater Hospital to the study as a new site and therefore as another data processor. In addition, the study will now utilise the RedCap data platform.

Amendments

Reference ID:
19-004-AF2/AMD5

Lead Applicant:
Prof Alistair Nichol

Lead Data Controller:
St. Vincent's University Hospital
University Medical Centre Utrecht,
Monash University

Title:
Randomized, Embedded, Multifactorial, Adaptive Platform trial for Community-Acquired Pneumonia (REMAP-CAP).

Research Objective:
See HRCDC Meeting minutes of 25th July 2019

Purpose of Amendment:
The amendment request is for the following changes:

- To include a broader cohort of patients beyond those with CAP and COVID-19; specifically, to include all patients with acute respiratory tract infection who require organ support in the intensive care unit.
- Primary outcome measure also now includes an ordinal scale of trajectory of illness and recovery to day 28.

HRCDC Comments:
The Chairperson introduced the study, and the Secretariat highlighted the previous amendments that were made for this study and the changes that were requested for approval in this latest amendment. The HRCDC were asked if they approved the amendment. It was the consensus of the HRCDC that the amendment request should be approved.

Anonymised data

- It was noted that anonymised safety and outcome data may be shared with the manufactures of the medicines that are used in this study. It was discussed that fully anonymised data falls outside the remit of the HRCDC and that the decision letter will

clarify the scope of the consent declaration including that it does not cover the further processing of personal data. It was further commented that the REMAP-CAP study involves the use of drugs that have been approved for other conditions to understand if they are effective in this patient cohort and this may be a reason for sharing this data.

- The HRCDC noted that the latest version of the study information leaflet is not fully clear on what is meant by anonymous safety and outcome that may be shared. The HRCDC was therefore of the view that, in the interest of transparency, participants/proxies should be more fully informed about what is meant by safety and outcome data and why this is shared.

HRCDC Decision:
The consensus of the HRCDC was that the amendment request should be approved.

Recommendations Attached:
Recommendation. The latest version of the study information leaflets, provides some information to the proxy/patient that anonymous data may be shared with the manufacturers; in the interest of transparency, the HRCDC is of the view that the study information leaflets should provide more clear information on what is meant by the safety and outcome data that may be shared and why e.g., what type of data may be shared.

New Applications
Reference ID:
25-014-AF1

Lead Applicant:
Prof Suzanne Timmons

Data Controllers:
- University College Cork
- Radboud University Medical Center
- Lancaster University
- Masarykova Univerzita (MUNI)
- University of Turin (Università degli Studi di Torino)
- Universidade Católica Portuguesa
- Queen's University Belfast
- Jagiellonian University (Uniwersytet Jagielloński)

Title:
In-Touch: Implementation of a person-centred palliative care iNtervention To imprOve comfort, QUality of Life and social engagement of people with advanced dementia in Care Homes

Research Objective:
The In-Touch study is a research project aiming to improve palliative care for nursing home residents with advanced dementia. It will test a new approach combining daily sensory-based activities, with family meetings to support decision-making and care planning. The study will

assess whether In-Touch improves residents' comfort, agitation, and quality of life, while also benefiting families (satisfaction with care) and staff (job satisfaction & well-being). The trial will take place in nursing homes across Europe, including eight in Ireland, involving residents, family members, and staff. Nursing homes will be randomly assigned to either the In-Touch programme or standard care. Researchers will collect data over 12 months from health records, staff surveys, family interviews, and observations. The study will also examine costs and participant experiences. Findings will guide better dementia care in nursing homes. Results will be shared with healthcare professionals, policymakers, and families through publications, training materials, and public engagement.

Reason for Declaration:

To process the personal/pseudonymised data of participants with dementia who lack decision making capacity to provide consent – for these participants, proxy assent will be obtained on their behalf. (Note: in addition to residents with dementia, the study will also include family members, staff etc. They will provide consent and therefore they are not within the scope of the consent declaration).

HRCDC Comments:

The Chairperson requested the primary and secondary reviewers who were assigned to this application to outline the proposal contained in the application. There was then a discussion on the application by the HRCDC. It was the consensus of the HRCDC that a Consent Declaration should be made, subject to conditions attached.

Public interest case:

- It was the view of the HRCDC that there is a very strong public interest case in this research; it was discussed that the prevalence of dementia is increasing and that it is associated with decreasing quality of life for individuals affected by the disease.

Data transfer and flow:

- The HRCDC noted and discussed the transfer and flow of data within this study, including that pseudonymised data from Ireland will be stored by one of the joint data controllers, Radboud University Medical Center.
- It was also noted that data obtained from the patient's wearable device will be stored by the service provider of the device on a cloud server in the US, this data is then downloaded by UCC to their servers. It was highlighted that this data remains pseudonymised, although the service provider will not have access to the Master Key to reidentify the patient; it was commented that the required agreements/arrangements will therefore need to be in place with regards the storage of data outside the EEA and that this data held on the cloud servers of the service provider in the US should be deleted as soon as possible.
- It was noted that data may be collected on paper prior to upload to the eCRF and the security and retention of these physical papers was discussed by the HRCDC. It was highlighted that the Applicant had outlined that paper records would be securely stored in locked cabinets and that they would be destroyed once the data has been uploaded to eCRF. It was discussed that some paper records such as consent documents, would likely be stored for longer as per policy or regulatory requirements.

- The HRCDC discussed the point at which personal data would be fully anonymised; it was highlighted that the study is expected to conclude data collection by December 2027 and that a consent declaration is requested until June 2028 when the data is expected to be fully anonymised. It was commented that the study information leaflets could also make it clearer when the data would be fully anonymised and therefore when the participant proxy can request to have the data withdrawn from the study.

Study Information leaflets:

- It was commented that, for the benefit of participants and their proxies, that the study information leaflets could provide additional lay-person information to provide clarity to individuals that the nursing homes, and not just the participants, had been selected and randomised to be either an intervention site or a control site. It was also discussed that participants from the nursing homes who are taking part in the control group should be clearly informed early in the information leaflet that they are part of the control site and would not receive the intervention, to avoid potential confusion.
- It was noted that as well as noting the Article 6 basis, the information leaflets should also detail the Article 9 specfic condition for processing special category data that applies to this study.

Other:

- It was noted that the Applicant had named 14 Irish nursing home sites who are agreeable to take part in this study and that 8 would be selected. It was discussed that the Applicant should report in the Annual Review on which of these nursing homes are selected to participate in this study.

HRCDC Decision:

The consensus of the HRCDC was that a Consent Declaration, subject to conditions attached, should be made

Duration of Declaration:

The consent declaration is made until 30th June 2028, or until the personal data is deleted or fully anonymised, whichever occurs first.

Conditions Attached:

Condition 1. The data held on the US cloud server should be deleted from their server as soon as possible, once the data has been downloaded by UCC. The US service provider is storing data only and will not be processing the data any further.

Condition 2. The required data agreements and arrangements must be in place prior to the data processing or sharing commencing. This includes required data agreements with the selected Irish nursing homes, the joint data controller and data transfer agreements between the In-Touch consortium members (i.e., the joint data controllers) and data agreements with US service provider. In addition, the required arrangements/legal basis for transfer of data outside the EEA must also be in place, including for example, standard contractual clauses with regards data to be stored in the US.

Condition 3. The applicant is requested to address the following points with regards both the control and intervention resident proxy assent documents and the resident consent documents:

- The study information leaflets for the residents should provide an estimated timeline for when the data is expected to be fully anonymised and therefore the point up to which it can be requested to have the participant's data removed from this study. Further, as data will be fully anonymised by June 2028, incorrect references that 'The personal data collected in the study will be kept for a period of 15 years as per the research partners' Code of Research Conduct after the end of the study' should be corrected.
- The leaflets and assent/consent forms should make it clear that pseudonymised data is being stored in the US – not fully anonymised data.

Condition 4. The Applicant is required to report in the Annual Review which of the nursing homes noted in the HRCDC application have been selected to participate in this study.

HRCDC Recommendations:

Recommendation 1. For the benefit of participants and those providing proxy assent on their behalf, the proxy and resident study information leaflets could provide additional lay-person information that clarifies that the nursing home, and not the individual residents, have been selected and randomised to be either an intervention site or a control site in this study. In addition, to avoid potential confusion, the individual should be informed early in the information leaflet that they are part of either the control site or the intervention site and therefore whether they will be receiving the In-Touch intervention or not.

Annual Reviews

The Secretariat has received 6 annual reviews in advance of the meeting which were deemed satisfactory:

- **Ref ID:** 23-004-AF1 (REACT Shock RCT)
- **Ref ID:** 24-006-AF1 (Thrombocalc)
- **Ref ID:** 19-016-AF2 (CERVIVA HPV Primary Screening Pilot Study)
- **Ref ID:** 19-006-AF3 (Contribution of Whole Genome Sequencing to Brain Tumour Biology)
- **Ref ID**: 23-010-AF1 (ESsCAPE)
- **Ref ID:** 19-013-AF2 (OMEGA-3 study)

Activities report and events of interest

The Secretariat circulated a report of its activities to the HRCDC in advance of the meeting.

Any Other Business

- The HRCDC were provided with proposed meeting dates for 2026. The members were requested to reply to the Secretariat with regards these dates within the next 2 weeks.
- The HRCDC were reminded that the next HRCDC meeting is scheduled for 11th November. They were also reminded that 9th December meeting will be held in-person.

The Chair closed the meeting