HRCDC
Health Research Consent Declaration Committee

Minutes of the Meeting – APPROVED

Date: 6th October 2026

Location: Zoom videoconferencing

HRCDC Attendance:

Aideen Hartney
Evelyn Mahon
John Woods
Paul Stynes
Aisling McMahon
Sarah Barnes Aabo
Antoinette O'Connor
Jim Blighe
Barbara Clyne
Eben Stewart
Brid Burke (Secretariat)
Jonny Barrett (Secretariat)
Caroline Byrne (Secretariat)

Quorum for Decisions

YES

Opening

The Chair opened the meeting and welcomed the members.

Apologies

Ross McMullan, Fionnuala Gough, Susan Smith, Mary Tumelty, Jonathan Briody

Disclosure of Interest

Aisling McMahon (AMcM) declared her interest in application 26-018 (VIP4). AMcM was absent during the meeting when this application was considered.

Minutes of the last meeting

Draft minutes of 8th September 2026 were circulated in advance of the meeting and were approved by the HRCDC.

Chairperson Approvals

- **Ref ID: 20-005-AF1/COV/AMD3** (The All-Ireland Infectious Diseases Cohort Project (AIID Cohort). The HRCDC were informed that amendment request 20-005-AF1/COV/AMD3 was approved via the chairperson approval process. The amendment covers the removal

of Children's Health Ireland as a data controller and for an extension of the consent declaration to 12th October 2031.

- **Ref ID: 21-010-AF1/AMD2** (A Phase 3, Multi-Arm Multi-Stage Covariate-Adjusted Response Adaptive Randomised Trial to Determine Optimal Early Mobility Training after Stroke" (AVERT DOSE). The HRCDC were informed that amendment request 21-010-AF1/AMD2 was approved via the chairperson approval process. The amendment covers an extension of the consent declaration to 30th June 2033.
- **Ref ID: 25-019-AF1/AMD1** (Understanding the risk factors contributing to outcomes of older perioperative patients in Ireland: The Irish Perioperative Outcome (IPOS) Study). The HRCDC were informed that amendment request 25-019-AF1/AMD1 was approved via the chairperson approval process. The amendment covers the addition of four new sites to the study who are also data processors.

New Applications

Reference ID:
26-018

Lead Applicant:
Aisling Mc Mahon

Lead Data Controller:
Heinrich-Heine Universität Düsseldorf, Germany (HHU)

Title:
Impact of chronic and acute cardiovascular diseases in old intensive care patients: A prospective multicenter observational study (Very old intensive care patients – VIP4)

Research Objective:
VIP4 is studying the role of heart health in how people aged 80+ fare when they get seriously ill and need intensive care, aiming to help doctors make better, more tailored care decisions for elderly patients in the future. It will also look at other age-related issues, including memory loss, frailty, chronic illnesses, and the use of multiple medications and its effects on the short and long-term outcomes of the very elderly ill patients.

Reason for Declaration:
Since this study involves patients who are admitted to the Intensive Care unit, by nature of their illness and the therapies they may be receiving, such as mechanical ventilation and sedation, a significant portion of participants for this study will have a lack of capacity in providing their explicit consent to research. Proxy assent will be obtained for those who lack decision-making capacity; if/when the patient regains capacity to give their consent, they will be approached as soon as possible.

HRCDC Comments:
The Chairperson requested the primary and secondary reviewers who were assigned to this application to outline the proposal contained in the application and any issues arising. There was then a discussion on the application by the HRCDC. Following detailed discussions, it was the consensus of the HRCDC that a consent declaration should be made, subject to

conditions attached.

Public interest case:

- The HRCDC discussed the study activities, commenting that this is a relatively under-researched population and that further research in this area is important. It was noted that data would be collected via the participant's medical record as well as survey/questionnaires; it was further highlighted that follow-up data would be collected via telephone.
- On balance, it was the view of the HRCDC that there is a strong public interest case in this research.

Data retention

- It was commented that there was inconsistency in the application with regards the retention of the data; there is reference to storing data for 2 years and 10 years, including the pseudonymised paper CRFs.
- It was discussed that the applicant had stated that the personal data will be anonymised/deleted by January 2031 and that it should be highlighted to the applicant that this deadline will apply to the storage of any pseudonymised paper CRFs. An amendment request for extension of the duration of the declaration can be applied for, if needed.

Study Information Leaflets

- The HRCDC noted that the information leaflet described this study as 'urgently needed'; it was commented that this language could unintentionally place pressure on the participant or their proxy to agree to enrolment in this study.
- In addition, it was commented that the leaflets could make it clear that participants with and without cardiovascular disease are included in this research.
- It was further referenced that the PILs should outline that the participant or their proxy may be asked to provide pre-hospitalisation baseline data, how they will be asked to provide it and when.
- It was also commented that the term 'pseudonymisation' could be explained in the PILs and that the use of term 'coded data' should be amended to state 'pseudonymised data'.

Other:

- It was discussed that the consent declaration will not cover the processing of personal data in future studies beyond VIP-4.
- The HRCDC also noted that data agreements should be in place before the start of the study.

HRCDC Decision:

The consensus of the HRCDC was that a Consent Declaration is made, subject to conditions.

Duration of Declaration:

The consent declaration is made until 31st January 2031, or until the personal data is deleted or fully anonymised, whichever occurs first.

Conditions Attached:

Condition. The required data agreements and arrangements must be in place prior to the study commencing.

HRCDC Recommendations:

Recommendation. For the benefit of participants and proxies, the Applicant should consider addressing the following points with regards the study information leaflets:

- the information leaflets describe the study as 'urgently needed'; it is considered that this language could unintentionally place pressure on the participant or their proxy to agree to enrolment in this study and therefore it could be amended.
- It could be made clearer that participants with and without cardiovascular disease are included in this research.
- PILs could better outline that the participant or their proxy may be asked to provide pre-hospitalisation baseline data, how they will be asked to provide this information and when they will be approached for this data.
- the term 'pseudonymisation' could be further explained in the PILs and the use of term 'coded data' should be amended to state 'pseudonymised data'.

Reference ID:

26-020

Lead Applicant:

Dr. Conor Judge

Lead Data Controller:

HSE National Renal Office (NRO) and National Office of Clinical Audit (NOCA)

Title:

Comprehensive analysis of traditional and novel risk factors for stroke in persons with kidney failure in Ireland.

Research Objective:

People living with kidney failure, whether on dialysis or after a kidney transplant, are far more likely to experience a stroke compared to the general population. Several risk factors have been identified internationally, but little is known about the specific situation in Ireland. This project will link information from the national kidney disease system (KDCPMS) with stroke data collected by the National Office of Clinical Audit (NOCA) to explore what causes stroke among people with kidney failure. The goal is to improve prevention, care, and recovery for these patients in Ireland. The research is a national collaboration between the HSE, universities, and patient organisations and will directly inform future stroke prevention policies.

Reason for Declaration:

To link and then fully anonymise data held by the HSE and NOCA within a secure processing environment; once fully anonymised, the data will be analysed by the University of Galway as the data processor. The study will link two existing national datasets: 1. The Kidney Disease Clinical Patient Management System (KDCPMS), which contains information on all people receiving dialysis or kidney transplants in Ireland, and 2. The National Office of Clinical Audit (NOCA) Stroke Audit, which records all hospital treated strokes nationwide. It is not considered possible to obtain explicit consent from all participants because this study involves secondary use of existing health and audit data collected over many years across all renal and stroke services in Ireland. Data from 2016 to 2025 (10 years) data will be used; no data after 2026 will be used.

HRCDC Comments:

The Chairperson requested the reviewers who were assigned to this application to outline the proposal contained in the application and any issues arising. There was then a discussion on the application by the HRCDC. Following detailed discussions, it was the consensus of the HRCDC that a consent declaration should be made, subject to conditions attached.

Public interest case:

- The HRCDC discussed the study activities, noting that this is a secondary data analysis study and that no hospital records will be accessed. The HRCDC also noted that it would not be feasible to obtain explicit consent from participants.
- It was the view of the HRCDC that there is a public interest case in this research.

Transparency measures:

- It was commented that transparency measures must be in place prior to the study commencing.
- On the study specific information notice, it was the view of the HRCDC that it is very detailed and technical, with the information presented in a dense format that may be difficult to read. It was commented that this document could be reviewed and amended, using more plain-language with reformatting to present the information in a more user-friendly manner.
- It was also noted that details on the participant's data rights are found at the end of this document; it was discussed that this important information could be provided more clearly and prominently in the notice. The HRCDC was also of the view that the notice should describe the use of AI tools within the study.

Other:

- It was discussed that DPO feedback from NOCA had been submitted, however feedback from the HSE DPO on the DPIA remains outstanding.
- The HRCDC commented that the PPI engagement in this study is positive.
- It was noted that the opt-out period for the study is 3 months, up until the end of 2026. It was the view of the HRCDC that the period for opting out of the study should be extended beyond December 2026 given the shortening window that is left.

- It was noted that the applicant should ensure consistency between the information presented in the DPIA and the HRCDC application form.

HRCDC Decision:

The consensus of the HRCDC was that a Consent Declaration is made, subject to conditions.

Duration of Declaration:

The consent declaration is made until 31st December 2026, or until the personal data is deleted or fully anonymised, whichever occurs first.

Conditions Attached:

Condition 1. The required data agreements and arrangements must be in place prior to the study commencing.

Condition 2. DPO review by the HSE on the DPIA must be submitted to the HRCDC prior to study commencing. Note: DPO review from NOCA has been provided, however DPO review from the HSE as the other joint controller of the study is also required.

Condition 3. Prior to the study commencing, the study specific transparency notice must be in place in the planned haemodialysis centres (and online if relevant). Further, the notice should describe the use of AI tools within the study.

HRCDC Recommendations:

Recommendation 1. Sections of the DPIA appears incomplete, namely the data risks section; this should be revisited by the Applicant.

Recommendation 2. Further to condition 3, the applicant is requested to consider following points with regards the study specific notice:

- The view of the HRCDC that the notice is very detailed and technical, with the information presented in a dense format that may be difficult to read. This document could be reviewed and amended, using more plain-language with reformatting to present the information in a more user-friendly manner.
- Details on the participant's data rights are found at the end of this notice; this important information could be provided more clearly and prominently in the notice.

Reference ID:

26-021

Lead Applicant:

Dr Rasha Shraim

Lead Data Controller:

Trinity College Dublin

HRCDC
Health Research Consent Declaration Committee

Title:
Establishing long-term systems for monitoring the impacts of climate change on health in Ireland (CHI Study).

Research Objective:
Climate change poses a major and growing public health threat in Ireland, with additional risk from extreme weather events. The Climate and Health Ireland (CHI) project will study the relationship between climate change and physical and mental health across the island of Ireland. The long-term goal of this research is to develop sustainable analyses pipelines that can be regularly updated with new data over time. The CHI projects aims to understand the association between climate factors such as temperature, precipitation, or extreme weather events and population-level health outcomes such as births, mortality, and hospitalisation. The project will further seek to understand how these effects might be different in the youth or elderly populations within Ireland.

Reason for Declaration:
The study is requesting a declaration to process national-level administrative data from HIPE data, NPRS data and NCRI data. However, this covers all acute hospitals in Ireland and 19 maternity units, therefore it is not feasible to consent all individuals' emergency hospitalised or who have given birth across the entire country. Across years 2015-2024: An average of approximately 400,000 annual emergency admissions (HIPE dataset) and approximately 66,000 annual maternity admissions (NPRS dataset). The years of the data covered are NPRS & HIPE: 2015-2024; NCRI data: 2013-2022.

HRCDC Comments:
The Chairperson requested the reviewers who were assigned to this application to outline the proposal contained in the application and any issues arising. There
was then a discussion on the application by the HRCDC. Following detailed discussions, it was the consensus of the HRCDC that a consent declaration should be made, subject to conditions attached.

Public interest case:
- The HRCDC discussed the study activities and noted the rationale for why consent could not be obtained from the participants. It was also noted that limited research has been undertaken in Ireland on this matter. It was also noted that individual data will not be linked across the datasets provided to the data controller.
- It was the view of the HRCDC that there is a strong public interest case in this research.

Transparency, Public and Patient Involvement:
- The HRCDC noted that the study is preparing future PPI engagement activities; it was discussed that PPI engagement within this research is important to undertake.
- The HRCDC is also of the view that CHI transparency measures, including the website, could be clearer on the participants' data protection rights with regards this study, including the right to withdraw, who to contact to exercise their rights and any limits or derogations to such rights.

Transparency, Public and Patient Involvement:

- The HRCDC noted and discussed the type and extent of data that will be requested from the data sources; it was commented that the study appears to be requesting a large volume and range of data and the HRCDC queried whether all of this data is necessary for the purpose of this study in line with principle of data minimisation.
- Following discussions, it was the view of the HRCDC that the applicant must ensure they are applying the principle of data minimisation when seeking the variables from the data controllers who hold the requested datasets.

Other:

- The HRCDC noted the different secure methods that will be used with regards the transfer, storage, access and analysis of data which differs depending on the source of the data. It was further noted that there may be limits to withdrawal from the study and subsequent the deletion depending on whether the data relates to HIPE, NPRS or NCRI data – for example there is no master key or directly identifiable data available for the HIPE dataset as this is not held by the HPO.
- It was commented that the necessary data agreements and arrangements must be in place.

HRCDC Decision:

The consensus of the HRCDC was that a Consent Declaration is made, subject to conditions.

Duration of Declaration:

The consent declaration is made until 31st October 2028, or until the personal data is deleted or fully anonymised, whichever occurs first.

Conditions Attached:

Condition 1. The necessary data agreements and arrangements must be in place prior to the study commencing.

Condition 2. PPI activities noted by the applicant must also be undertaken before the study commences.

Condition 3. The applicant must ensure they are applying the principle of data minimisation when seeking the variables from the data controllers who hold the requested datasets.

Condition 4. Transparency measures must be in place before the study commences.

HRCDC Recommendations:

Recommendation 1. Transparency measures could be clearer on the participants' data protection rights with regards this study, including the right to withdraw, who to contact to exercise their rights and any limits or derogations to such rights

HRCDC
Health Research Consent Declaration Committee

Reference ID:
26-022

Lead Applicant:
Dr David Keane

Lead Data Controller:
University of Galway and the HSE

Title:
HARMONY: Data-enabled, shared fluid management platform in haemodialysis

Research Objective:
People receiving haemodialysis need fluid to be removed from their bodies during each treatment. Removing too little fluid can lead to fluid overload, while removing too much can cause low blood pressure, cramps, dizziness and fatigue. HARMONY is testing whether a digital dashboard can help Participants and healthcare professionals make better shared decisions about fluid management. The dashboard presents information already collected during dialysis, such as body weight, blood pressure, target weight and the amount of fluid removed, alongside symptoms reported by the participant. This feasibility study will involve approximately 400 adults across five dialysis units. It will examine whether the dashboard can be introduced successfully into routine care, whether Participants and staff use and accept it, and whether the necessary study data can be collected. The findings will inform the design of a larger future trial evaluating whether the approach improves Participant care and outcomes.

Reason for Declaration:
The intervention is implemented at dialysis-unit level because participants and clinicians within a unit share staff, workflows and clinical practices. Requiring every eligible participant to complete an individual explicit-consent process would alter the real-world implementation being evaluated and create a substantial risk of selection bias. Participants experiencing greater illness burden, dialysis-related fatigue, lower literacy, communication difficulties, limited digital confidence or competing health concerns may be less likely or less able to complete a separate formal consent process. Their under-representation could produce misleading estimates of dashboard use, assisted use, non-use, acceptability, data completeness and implementation feasibility.
The consent declaration is sought for the HARMONY research processing for which explicit consent will not be obtained. Rather than implement an ‘opt-in’ explicit consent model, HARMONY will operate an informed opt-out model.

HRCDC Comments:
The Chairperson requested the reviewers who were assigned to this application to outline the proposal contained in the application and any issues arising. There
was then a discussion on the application by the HRCDC. Following detailed discussions, it was the consensus of the HRCDC that a consent declaration should be made, subject to conditions attached.

Public interest case and consent:

- The HRCDC discussed the purpose of the study and the data processing activities, including the data provided from the medical records, voluntary patient reported data via a smartphone app and HARMONY platform user activity information. It was discussed that the platform is designed to be a standardised data presentation tool to help clinician decision-making, in co-operation with the patient. It was further highlighted that no data will be leaving Ireland.
- The HRCDC also discussed in detail the proposed opt-out process for participants, rather than the implementation of an explicit consent or a proxy assent process. It was highlighted that participants will be directly provided with an information leaflet detailing the purpose of the study, the processing of data and how they can withdraw if they wish. The Applicant confirmed that participants enrolled in the study will also have decision-making capacity.
- The HRCDC discussed the rationale outlined by the Applicant on why it was not appropriate to seek explicit consent; as part of its discussion the HRCDC also queried whether explicit consent could or should be sought.
- On balance, in the context of the rationale presented, the HRCDC was of the view that the public interest case for this study outweighed the requirement to obtain explicit consent.
- The HRCDC commented that, as with all consent declaration decisions, each application is reviewed by the Committee on a case-by-case basis, considering the specific context and public interest case of each study. It was noted that a decision on one study does not set a precedent for refusing or granting a consent declaration with regards other similar studies that may arise in the future.

Information leaflet:

- The HRCDC was of the view that the document to be provided to the participant was very detailed, however for ease of review it could be reduced in length with repetitive sections removed.

Other:

- On the smartphone app that participants can use to provide information, it was discussed that it should be communicated to participants that their device should be kept secure.
- It was noted that REC approval must be in place for all the participating sites.

HRCDC Decision:

The consensus of the HRCDC was that a Consent Declaration is made, subject to conditions.

Duration of Declaration:

The consent declaration is made until 31st October 2034, or until the personal data is deleted or fully anonymised, whichever occurs first.

Conditions Attached:

Condition 1. The required data agreements and arrangements must be in place prior to the study commencing.

Condition 2. REC approval must be in place for all the participating sites. The declaration does not cover the sites where REC approval is not in place.

Condition 3. It should be communicated to participants that their device which has the study application downloaded on should be kept secure.

HRCDC Recommendations:

Recommendation 1. It is the view of the HRCDC that the document to be provided to the participant could be reduced in length, with repetitive sections removed.

Draft updates to the HRCDC application form

Draft changes to the HRCDC application form to encompass potential AI related questions, were uploaded to Decision Time for the Committee. The Committee were asked to review these changes and send any comments to the Secretariat over the coming weeks.

Annual Reviews

The Secretariat has received 8 annual reviews in advance of the meeting which were deemed satisfactory:

- **Ref ID:** 19-013-AF2 (Omega-3 Study)
- **Ref ID:** 25-013-AF1 (Keep My Teeth)
- **Ref ID:** 20-024-AF1/COV (GenOMICC)
- **Ref ID:** 25-012-AF1/CSO (RECONNECT)
- **Ref ID**: 19-007-AF2 (TAME)
- **Ref ID:** 19-016-AF2 (CERVIVA HPV Primary Screening Pilot Study)
- **Ref ID:** 21-010-AF1 (AVERT DOSE)
- **Ref ID:** 19-031-AF2 (Bowel Disease Bio-Resource Development)

Any Other Business

- Proposed HRCDC meeting dates for 2027 were circulated in advance of the meeting. The Committee were asked to inform the Secretariat of the suitability of these dates before the next meeting.
- The HRCDC were reminded that the next meeting of the HRCDC is scheduled 10th November 2026.

The Chair closed the meeting