

Minutes of the Meeting – APPROVED

Date: 24th February 2026

Location: Zoom videoconferencing

HRCDC Attendance:

Aideen Hartney
Mary Tumelty
Susan Smith
Paul Stynes
Aisling McMahon
Sarah Barnes Aabo
Jonathan Briody
Jim Blighe
Ross McMullan
Barbara Clyne
Brid Burke (Secretariat)
Jonny Barrett (Secretariat)
Caroline Byrne (Secretariat)

Quorum for Decisions

YES

Returning Applications - For Consideration

Applicant: Dr Bairbre McNicholas

Ref No.: 25-023-AF1

Title: A Mixed Methods Study to Develop and Validate an ML-NLP Decision-Support Framework for ICU Fluid Management-SMART FLOW

New Amendments - For Consideration

Applicant: Prof. Dr. Eric Hoste

Ref No.: 25-001-AF1/AMD1

Title: Acute Kidney Injury – Epidemiology in ICU Patients 2 (AKI-EPI 2)

New Applications – For consideration

Applicant: Anne Devlin

Ref No.: 26-003-AF1/CSO

Title: Health Inequalities in Ireland

Opening

The Chair opened the meeting and welcomed the members.

Apologies

Evelyn Mahon, John Woods, Patricia O’Beirne, Antoinette O’Connor, Fionnuala Gough

Disclosure of Interest

Aisling McMahon declared her interest in 25-001-AF1/AMD1 application (AKI-EPI 2). AMCM was absent during the meeting when this application was considered.

Minutes of the last meeting

Draft minutes of 27th January 2026 were circulated in advance of the meeting and were approved by the HRCDC.

Chairperson Approvals

- 23-010-AF1/AMD2 (ESsCAPE): the HRCDC were informed that amendment request 23-010-AF1/AMD2 was approved via the chairperson approval process. The amendment covers the use of remote Legally Appointed Representative (LAR) proxy assent where such assent cannot be obtained in person.
- 20-005-AF1/COV/AMD2 (The All-Ireland Infectious Diseases Cohort Project (AIID Cohort)): the HRCDC were informed that amendment request 20-005-AF1/COV/AMD2 was approved via the chairperson approval process. The amendment covers the data processing associated with the inclusion of ‘additional potential biobank samples, including microbiological results or isolated and excess surgical samples (tissue or fluid) if the participant is undergoing a scheduled procedure as part of their routine clinical care’.

Amendments

Reference ID:

25-001-AF1/AMD1

Lead Applicant:

Prof. Dr. Eric Hoste

Lead Data Controller:

Ghent University Hospital

Title:

Acute Kidney Injury – Epidemiology in ICU Patients 2 (AKI-EPI 2)

Research Objective:

See HRCDC Meeting minutes of 25th February 2025.

Purpose of Amendment:

To add three new sites to the study: The Mater Misericordiae University Hospital, Dublin, University Hospital Limerick and Cork University Hospital.

These sites will only be participating in the 'retrospective' component of the study; they will not be undertaking the 3- and 12-month follow-up part.

HRCDC Comments:

- The chair introduced the amendment and outlined what is requested from the Applicant. It was noted that the 3 new sites will only participate in the retrospective component of the study, not the follow-up 3- and 12- month data collection component.
- It was discussed that transparency measures should be implemented at the 3 new sites; it was noted that the Applicant had outlined in the original application that transparency measures were to be implemented at the GUH site. It was discussed that the measures should provide information about the study and the right to withdraw from the study, including how to request the removal of the patients' retrospective data.

HRCDC Decision:

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

Conditions Attached:

Condition 1. The conditions noted in the Mater Research Ethics Committee approval letter must be complied with; in addition, full REC approval must be in place for each site.

Condition 2. Transparency measures must be implemented at each of these three additional sites prior to the study commencing at these sites; measures could include study posters and leaflets that are made available in appropriate areas such as in the ICU, family waiting areas etc. These transparency measures must also outline the right to withdraw from the study and to delete/remove personal data from the study and how to exercise this right.

Returning Applications

Reference ID:

25-023-AF1

Lead Applicant:

Dr Bairbre McNicholas

Lead Data Controller:

Galway University Hospital

Title:

A Mixed Methods Study to Develop and Validate an ML-NLP Decision-Support Framework for ICU Fluid Management-SMART FLOW.

Research Objective:

See HRCDC Meeting minutes of 27th January 2026.

HRCDC Comments:

The reply from the Applicant to the HRCDC's request for further information was circulated to the HRCDC in advance of the meeting. The Chair requested the committee to indicate whether a consent declaration should be made. After discussing the application, and based

on the information provided by the Applicant, it was the consensus of the HRCDC that a consent declaration should be made, subject to conditions attached.

Anonymisation of the data:

- The HRCDC discussed the replies from the Applicant on the processes that will be undertaken to ensure that the data, including the unstructured free text data, is anonymised prior to the transfer and analysis by the University of Galway.
- On balance, based on the information provided, it was commented that the study will undertake a robust multi-layered process of anonymisation that includes the use of de-identification tools, human review of all the patients notes and governance oversight. It was further outlined that trained clinicians will be undertaking the human review of the patient notes.
- The HRCDC commented that the Applicant could be asked to provide an update on the anonymisation process they are implementing as part of the Annual Review, including that they remain satisfied that the process remains effective.
- It was further highlighted that the declaration will outline that only fully anonymised data will be sent to University of Galway.

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 28th February 2031.

Conditions Attached:

Condition 1. The required data agreements/arrangements must be in place between the parties prior to any data transfers.

Condition 2. It is noted that some of the transparency measures outlined in the original application or DPIA, such as a QR code on the study posters, remained outstanding and must be implemented prior to the study commencing.

Further to the above, the study poster should clearly note that the participants have the right to withdraw from this study and how to exercise this right; this information appears to be missing from the poster submitted to the HRCDC and should be addressed by the Applicant prior to the study commencing.

HRCDC Recommendations:

Recommendation 1. The Applicant is requested to provide an update on the anonymisation process they are implementing as part of the Annual Review, including that they remain satisfied that the process remains effective and whether it is accurately anonymising the data.

Recommendation 2: It is noted that the section 'How is AI involved?' in the poster could be confusing to participants; specifically, it states that 'AI will not make decision about care or

affect treatment'. While it is noted that this research would not affect the treatment of the study participants, it was noted that the purpose of the study is to develop an AI-based framework to help support clinical decision making for future patients; accordingly, this section of the poster should be amended to take this into account.

Recommendation 3: The Applicant must report in the Annual Review on which AI model/LLM is used in this study.

New Applications

Reference ID:
26-003-AF1/CSO

Lead Applicant:
Anne Devlin

Lead Data Controller:
Economic and Social Research Institute

Title:
Health Inequalities in Ireland

Research Objective:

The literature on the social determinants of health is well developed globally at this stage. Locally, recent work has found greater health impacts as a result of COVID-19 in more deprived areas and found growing health inequalities between the most deprived areas and most affluent areas between 2016 and 2022. This study is seeking to further examine health inequalities in Ireland; it will do this by examining the relationship between deprivation and health status, unmet health needs and mortality.

Reason for Declaration:

The Applicant is seeking to access, and process pseudonymised data (research microdata files) from the Health Research Data Centre, hosted by the Central Statistics Office. As the data being accessed is pseudonymised data and that it is not feasible to seek consent from individuals whose data is held by the CSO, a consent declaration is required

HRCDC Comments:

The Chair requested the committee to indicate whether a consent declaration should be made. After discussing the application, and based on the information provided by the Applicant, 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 aims and objectives of this research and noted the data security measures that are in place. It was the view of the HRCDC that there is a strong public interest case in this research, noting that the findings may influence public policy in this area.

Other:

- It was commented that the study could consider implementing enhanced transparency measures for this study, for example by disseminating information about this study and the results to targeted demographic cohorts, relevant organisations as well as the wider public.

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 2027.

Conditions Attached:

Condition 1. It is a condition that this consent declaration is not effective until final approval to access the Health Research Data Centre has been granted by the CSO.

HRCDC Recommendations:

Recommendation 1. The HRCDC commented that the study could consider implementing enhanced transparency measures for this study by disseminating information about this study and the results to targeted demographic cohorts, relevant organisations as well as the wider public.

Annual Reviews

The Secretariat has received 2 annual reviews in advance of the meeting which were deemed satisfactory:

- **Ref ID:** 24-010-AF1 (AfterROSC2)
- **Ref ID:** 23-024-AF1 Annual Review (PRACTICAL)

In addition, the HRCDC were also provided with a briefing note regarding an overdue Annual Review for 24-013-AF1. Following discussion, it was confirmed that formal correspondence will be issued to the applicant on behalf of the HRCDC notifying them that their consent declaration will be tabled for revocation at the March meeting if they do not submit the required Annual Review in advance of that date.

Activities report and events of interest

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

HRCDC Annual Report 2025

The Secretariat circulated a draft of the 2025 Annual Report to the HRCDC in advance of the meeting. The HRCDC approved the report for submission to the Department of Health, subject to final proof-reading and design.

The Chairperson thanked the Secretariat and the HRCDC for their work on this report.

Any Other Business

- A brief update was provided to the HRCDC on which members have their current term of office expiring in the next 12 months.

The Chair closed the meeting