HRCDC
Health Research Consent Declaration Committee

Minutes of the Meeting - APPROVED

Date: 27th January 2026

Location: Zoom videoconferencing

HRCDC Attendance:

Aideen Hartney
Evelyn Mahon
Mary Tumelty
Patricia O'Beirne
Susan Smith
Paul Stynes
Sarah Barnes Aabo
Antoinette O'Connor
Jim Blighe
Fionnuala Gough
Brid Burke (Secretariat)
Jonny Barrett (Secretariat)
Caroline Byrne (Secretariat)

Quorum for Decisions

YES

Opening

The Chair opened the meeting and welcomed the members.

Apologies

John Woods, Aisling McMahon, Ross McMullan, Barbara Clyne, Jonathan Briody

Disclosure of Interest

There were no disclosures of interest for this meeting.

Minutes of the last meeting

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

HRCDC
Health Research Consent Declaration Committee

Returning Applications

Reference ID:
25-019-AF1

Lead Applicant:
Prof John Laffey

Lead Data Controller:
Galway University Hospitals/Health Services Executive

Title:
Understanding the risk factors contributing to outcomes of older perioperative patients in Ireland: The Irish Perioperative Outcomes (IPOS) Study

Research Objective:
See HRCDC Meeting minutes of 9th December 2025

HRCDC Comments:
The HRCDC were reminded of the additional information that was requested from the Applicant following the December meeting. The replies from the Applicant to the HRCDC's request for further information were 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.

Public Interest and scientific biasness
- The HRCDC discussed the applicant's responses on how this study is different to previous research that has been undertaken and why requiring consent would introduce material selection bias.
- On balance, based on the additional information submitted, the HRCDC was of the view that it would be reasonable to make a consent declaration as there is a public interest case for this research study that seeks to process data that would already be collected for care and treatment and that the process of seeking consent would introduce bias to the study data.

Opt-out/Opt-in
- It was commented that, for some patients, the study information leaflet could be provided to them prior to their surgery, specifically those patients who will be undergoing elective surgery and that the Applicant could therefore potentially request the patient to opt-out of the study in advance of their medical procedure, where this is practicable.

Other
- The Applicant noted the other Irish hospital sites who have or will be invited to take part in this research study; it was commented that the scope of the consent declaration would be

limited to the sites named by the Applicant in their application form and only where REC approval for the sites has been obtained.
- It was also discussed that the requisite data agreements/arrangements will need to be in place and that additional information should be included in the information leaflets with regards to where the data will be transferred to and withdrawal from the study.

HRCDC Decision:
The consensus of the HRCDC was that a consent declaration should be made, subject to conditions attached.

Duration of Declaration:
The consent declaration is made until 30th June 2037 or until the personal data is deleted or fully anonymised, whichever occurs first.

Conditions Attached:
Condition 1. The necessary data agreements/arrangements must be in place between the parties for this study. Data cannot be processed, including transferred, between the parties, prior to the agreements being in place.

Condition 2. The information leaflets to be provided to the participant/proxies should clearly outline:

(i) that pseudonymised data will be transferred to and processed by Galway University Hospital for the purpose of this study.

(ii) At what point in the study is it possible to withdraw or delete data if requested.

Further to the above, it is noted that the GUH participant PIL does not reference the withdrawal form, however the proxy version does; this should also be addressed.

HRCDC Recommendations:
Recommendation 1: where practicable, for example where patients are undergoing elective surgery, the Applicant is requested to provide the patient the opt-out for the study in advance of their medical procedure.

New 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:

The SMART-FLOW study aims to improve how fluid is removed from critically ill patients in intensive care who require continuous kidney support. Decisions about fluid removal currently vary between clinicians and can affect patient safety. Using routinely collected ICU data from Galway University Hospital from 2019 to 2024, this study will develop a secure, research-grade database and apply machine learning and advanced text analysis to better understand factors linked to harmful drops in blood pressure during fluid removal. The project will also include interviews with ICU staff to explore how fluid decisions are made and recorded. All patient information will be irrevocably anonymised before analysis, and no identifiable data will be shared outside the hospital environment. The goal is to support the future development of safer, more consistent and evidence-based approaches to fluid management in critically ill patients.

Reason for Declaration:

The declaration is requested to process retrospective data that covers approximately 4000 ICU admissions between 1st January 2019 to 31st December 2024. The data to be processed is clinical data from Galway University and HIPE – please note that the HIPE data relates to GUH participants only. A consent declaration is requested as it is not considered practicable to seek consent from this large number of retrospective participants.

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 formal decision should be deferred pending receipt of further information.

Public interest case:

- It was discussed that the issue of fluid management within the ICU is a critical issue. It was also commented that this study is relatively low-risk and seeks to process retrospective clinical data from patients who have already been treated, with analysis of the extracted and linked data to be undertaken by the University of Galway, with the data anonymised prior to transfer. It was noted that data to be extracted includes ‘structured’ clinical data as well as ‘unstructured’ data in the form of free text clinical notes.
- The HRCDC was satisfied that it would not be practicable to obtain explicit consent given the retrospective nature of the study and expected number of 4000 participants.
- It was the view of the HRCDC that there is a strong public interest case in this research, however it also wishes to seek further information from the applicant on the anonymisation process of the data, including the ‘unstructured’ data prior to analysis by University of Galway, before determining if a declaration should be made.

Data extraction and Anonymisation process:

- The HRCDC queried who will extracting and linking the retrospective data from the multiple systems within the hospital and whether the data would then be anonymised to both Galway University Hospital and the University of Galway. It was clarified that the data

will be extracted and linked by Galway University Hospital and that the Applicant had confirmed that it will be anonymised to both parties prior to analysis.

- On the anonymisation of the data, the Applicant outlined that the data to be extracted and linked will be pseudonymised by way of a participant study identification code and that an anonymisation process will then be undertaken on both the structured and unstructured data. On the structured data, anonymisation will include the removal of direct identifiers alongside the pseudonymisation code; with regards the unstructured free-text data, the Applicant describes an iterative layered process of anonymisation involving the use of text washing tools to remove potential identifiers followed by a human-supervised anonymisation review to manually verify that no identifiable data remains.
- It was commented that it is likely that a large volume of patient notes, and therefore a large volume of sensitive free-text data, would be included in this study and would need to be anonymised; it was therefore questioned if this layered anonymisation process would anonymise such a large volume of data to a sufficient degree such that it is considered anonymised prior to transfer and analysis. On the manual human-supervised anonymisation review step, the HRCDC queried whether the study has the resources to undertake this manual review and it was not fully clear to the HRCDC if this human step is undertaken on all the unstructured data or a sample of the data. The applicant is also requested to clarify if the human supervised check is carried out by an AI tool and if so, the estimate of the accuracy of such a tool.
- It was the decision of the HRCDC that more information should be sought form the Applicant on this matter to understand the anonymisation process for this free text data.

PPI and Transparency:

- It was commented that the PPI and transparency activities outlined by the Applicant appeared robust, however some of the transparency measures, outlined in the application or DPIA, such as a QR code on the study posters, remained outstanding and should be implemented.
- On the study poster, it was discussed that it should clearly note that the participants have the right to withdraw from this study. In addition, it was commented that the section ‘How is AI involved?’ could be confusing to participants; specifically it states that ‘AI will not make decision about care or affect treatment’ however 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. It was the view of the HRCDC that this section of the poster could be amended to take this into account.

Other:

- It was noted the use of machine learning within this study will not involve the sharing of data with a third-party; it was outlined by the Applicant that an open-source machine learning system will be downloaded and used locally for this study.
- The HRCDC queried the data retention period and at what point in time the pseudonymised data would be made fully anonymised. It was clarified that the Applicant intends to extract, pseudonymise and link clinical datasets, and then fully anonymise it for

analysis, in iterative steps over 5 years. The declaration is therefore requested for 5 years. The anonymised data, that falls outside the GDPR, will then be stored for 10 years.

- It was noted that some points in the DPIA did not align with the responses to the HRCDC, including the replies to the Secretariat queries, for example it was noted that the DPIA did not align on the matter of controller and processors or data retention. It was discussed that the Applicant should review the DPIA and ensure it is accurate and aligns with the information submitted to the HRCDC.

HRCDC Decision:

The consensus of the HRCDC was that a formal decision would be deferred pending receipt of further information should be made.

Request for further information:

Query 1. The HRCDC recognises the public interest in this study, however, it also commented that it is likely that a large volume of patient notes, and therefore a large volume of complex and sensitive free-text data, would be included in this study and would undergo anonymisation.
The Applicant is requested to provide further information on how their layered anonymisation process will anonymise a large volume of unstructured free-text data to a sufficient degree such that it is considered fully anonymised prior to transfer and analysis; this includes information on the resources in place to undertake this process, whether the manual human-supervised anonymisation review step is undertaken on all the unstructured data, or a sample of the data. If undertaken on a sample of the data, the Applicant is requested to provide details on what proportion of the data will be reviewed by a human to ensure anonymisation. If the human supervised anonymisation step is carried out by an AI tool the applicant is also requested to clarify the nature of this check to the committee, including an estimation of the accuracy of such a tool.

Reference ID:

26-001-AF1

Lead Applicant:

Nigel Riordan

Lead Data Controller:

University Hospital Limerick

Title:

Functional assessment and Occupational Therapy in ICU: Predicting outcomes in mechanically ventilated patients

Research Objective:

This study looks at how people recover after spending time in intensive care (ICU) on a ventilator for three days or more. Being critically ill can lead to significant muscle weakness and difficulty moving, which affects recovery and independence. Occupational therapists (OTs) in ICU help patients start rehabilitation early, supporting movement, sitting up, and re-engaging with daily activities. This study is using a tool called the Acute Care Index of

Function (ACIF) to assess patients' physical function early in their ICU stay and on discharge. It wants to find out whether performance on the ACIF can help predict recovery and outcomes, such as mobility or discharge needs. It will also look at the relationship between early OT involvement and how patients recover. The goal is to improve understanding of how early intervention in ICU supports recovery, and how tools like the ACIF can guide care planning.

Reason for Declaration:

The consent declaration is requested to process personal data of participants from the Limerick ICU for the purpose of this prospective study. The participants will lack decision-making capacity, and the applicant outlines why consent is not possible to obtain. The personal data will be collected and pseudonymised during the course of the participants' ICU admission and will then be fully anonymised prior to analysis.

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 and commented that it is observational in nature and seeks to use data that will already be collected as part of care and treatment.
- On balance, it was the view of the HRCDC that there is a strong public interest case in this research.

Proxy assent and participant consent:

- The HRCDC discussed the Applicant's rationale for why they did not consider it practicable or appropriate to seek proxy assent where the participant lacks decision making capacity, and/or participant consent where the participant regains capacity; this includes their concerns relating to causing distress to individuals and that the research team would have limited resources and capacity.
- The HRCDC noted that the research team is made up of just two ICU-based occupational therapists, who will not be involved in the patient's clinical care once they are discharged from ICU. However, while the HRCDC acknowledge these potential challenges, it discussed that eligible participants enrolled in the study will be in ICU for at least 3 days and that it is likely that, in general, family members and friends will be attending the ICU. It was therefore commented that where the participant lacks decision-making capacity, deferred proxy assent from a suitable individual could be sought in an appropriate manner that does not cause undue distress, as occurs in other ICU based studies.
- It was also commented that while the research team is small, the target number of participants to enrol is also low, with only 40 to be recruited over a three-month recruitment period, which will be extended beyond 3 months if required to meet this target. In the context of this low number of participants, it was discussed that it would not be impracticable for the research team to make reasonable efforts to obtain proxy assent

and/or participant consent to continue during the participants' ICU admission as well as during their overall hospital journey in Limerick, such as when they are transferred to another ward. It was also noted that an exclusion criterion for the study are patients with a primary neurological diagnosis – it was therefore commented that it is likely that many of the patients could be expected to regain capacity during their hospital journey.

- On balance it was the view of the HRCDC that reasonable efforts could and should be made to obtain deferred proxy assent if the participant lacks capacity, and deferred participant consent to continue where they regain capacity, prior to the patient's discharge from hospital. It was discussed that where reasonable efforts are made to obtain proxy assent/participant consent, but this is unsuccessful, the declaration will cover data processing for those individuals.

Study information leaflets:

- The HRCDC noted that the submitted transparency measures of the information leaflet and poster do not make it clear that patients can only withdraw and have their data deleted before the data is anonymised prior to analysis; instead, it states that they can opt-out 'at any time'. Further, it was commented that transparency measures should make it clear that an individual can inform their clinical care team if they want to withdraw from the study, not just informing the direct research team.
- It was also noted that the PILs currently state there is no risk, however it was discussed that there may be minimal risk when carrying out research or processing data for health research.

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 November 2026 or until the personal data is deleted or fully anonymised, whichever occurs first.

Conditions Attached:

Condition 1. It is a condition of this declaration that prior to the participant's hospital discharge, a process must be implemented whereby reasonable efforts are made by the research study:

(I) where the participant lacks decision-making capacity, to obtain deferred proxy assent from a suitable individual who understands their will and preferences and

(II) where the participant has or regains decision-making capacity, to obtain their consent to continue.

Where reasonable efforts are made to obtain this deferred proxy assent and participant consent, but this is unsuccessful, the declaration will cover data processing for these individuals – it will however not cover data processing where the relevant individual refuses to provide proxy assent or consent to continue.

Condition 2. The transparency measures to be implemented in this study, including any study posters, and any leaflets that will be used to seek proxy assent and participant consent to continue (i.e., Condition 1) must ensure the following are addressed:

- It must be clear that participants can only be withdrawn and have their data deleted before the data is anonymised prior to analysis (the references in the measures submitted to the HRCDC state that they can opt-out 'at any time'.)
- It should be clear to the participant who exactly to contact should they wish to withdraw from the study (i.e., named person / contact etc.)
- The statement in the PILs that there is no risk should be reviewed and amendment; it is considered that there may be minimal risk when carrying out research or processing data for health research.

Reference ID:
26-002-AF1/CSO

Lead Applicant:
Dr Gretta Mohan

Lead Data Controller:
Economic and Social Research Institute

Title:
An Investigation of Lifestyle and Behaviour Disparities across Deprived Areas of Northern Ireland and Ireland

Research Objective:
This project will investigate health inequalities in Ireland, where life expectancy is significantly shorter, and behaviours like smoking and poor mental health are higher, in deprived areas. This application to the CSO relates to the Republic of Ireland data– though the title of the project refers to the overall project, where a separate analysis (similar to this one) will be carried out using NI data. The objective is to provide a comparable analysis of the link between area-level deprivation and major lifestyle factors, including smoking, vaping, mental health outcomes, and obesity. Only approved outputs from the analysis of the Irish Health Survey will be used in the overall project for comparison with approved outputs from the analysis carried out using NI data. The findings will produce an ESRI report. This evidence will enable the design of more effective, targeted public health policies aimed at tackling the root causes of health disparities.

Reason for Declaration:
The Applicant is seeking to access and obtained pseudonymised data (research microdata files) from the CSO Health Research Data Centre. 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.

Other:

- It was noted that the study cannot commence prior to obtaining full RDGB approval from the CSO.

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 December 2027 or until the personal data is deleted or fully anonymised, whichever occurs first.

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.

Annual Reviews

The Secretariat has received 7 annual reviews in advance of the meeting which were deemed satisfactory:

- **Ref ID: 23-012-AF1** (Research Use of Diagnostic Genomic Testing Data for Epilepsy)
- **Ref ID: 22-011-AF1** (SENSE-Cog Residential Care: A feasibility study of hearing and vision support to improve quality of life in care home residents with dementia)
- **Ref ID: 22-002-AF1** (Understanding the wishes and support needs of people with intellectual disability as they grow older) ***
- **Ref ID: 23-023-AF1** (Sedation, Temperature and Pressure after Cardiac Arrest and Resuscitation – the STEPCARE trial)
- **Ref ID: 19-045-AF2** (The Gynaecological cancer bioresource (DISCOVARY Bioresource)
- **Ref ID: 20-036-AF1** (EPO-TRAUMA)
- **Ref ID: 23-013-AF1** (The Prevalence of Primary Tauopathies in Ireland; a Clinically Defined Population Study in the Province of Leinster)

****Declaration no longer required.*

Any Other Business

- The Secretariat provided a brief update on the HRCDC annual report for 2025 which is due to be submitted to the Department of Health by end of March, as per the Regulation requirements.
- The HRCDC were informed that plans are in progress to organise an information presentation on the topic of synthetic data for research at the next meeting in February.

The Chair closed the meeting