HRCDC
Health Research Consent Declaration Committee

Minutes of the Meeting - APPROVED

Date: 9th December 2025

Location: The Health Research board

HRCDC Attendance:

Aideen Hartney
Evelyn Mahon
Mary Tumelty
John Woods
Patricia O'Beirne
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

Opening

The Chair opened the meeting and welcomed the members.

Apologies

Fionnuala Gough, Antoinette O'Connor, Jonathan Briody

Disclosure of Interest

- 25-011-AF1/AMD1 and AMD2: Aisling McMahon (AMcM) declared an interest in both the Chairperson approvals for 25-011-AF1 which were noted by the HRCDC at the meeting.
- 25-007-AF1/AMD1: AMcM declared an interest in this Chairperson approval for 25-007-AF1 which was noted by the HRCDC at the meeting.
- 25-019-AF1: AMcM informed the HRCDC that she works with the PI of this study but is not involved in this particular study. It was determined that AMcM did not need to be absent when this application was considered.

- 25-022-AF1/CSO: Barbara Clyne (BC) and Susan Smith (SS) both informed the HRCDC that they collaborate with the PI of this study but neither are involved in this study. It was determined that BC and SS did not need to be absent when this application was considered.

Minutes of the last meeting

Draft minutes of 11th November 2025 were circulated in advance of the meeting and were approved by the HRCDC.

Chairperson Approvals

- **25-011-AF1/AMD1 (EXTUBE):** The HRCDC were informed that amendment request 25-011-AF1/AMD1 was approved via the chairperson approval process. The amendment covers the addition of Tallaght University Hospital and Mayo University Hospital as study sites and data processors.
- **25-011-AF1/AMD2 (EXTUBE):** The HRCDC were informed that amendment request 25-011-AF1/AMD2 was approved via the chairperson approval process. The amendment covers the addition of the Mater University Hospital and Cork University Hospital as study sites and data processors.
- **24-005-AF1/AMD1 (Lung Health Check Pilot):** The HRCDC were informed that amendment request 24-005-AF1/AMD1 was approved via the chairperson approval process. The amendment covers the extension of the duration of the declaration until 31st December 2026.
- **25-007-AF1/AMD1 (SepTec Feasibility study)** The HRCDC were informed that amendment request 25-007-AF1/AMD1 was approved via the chairperson approval process. The amendment covers the addition of the Mater University Hospital as a study site and data processor.

New 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:

The IPOS study is a nationwide research project in Ireland examining how older patients with multiple health conditions fare after major urgent or planned surgeries. As advances allow more complex operations in older, sicker patients, they still face a higher risk of

complications. Ireland currently lacks detailed data on surgery risks, complications, and healthcare resources used for these patients. This study will observe patients across multiple centres to measure their health risks, identify common complications and find factors that can be changed to improve outcomes. It will also look at Ireland's ability to provide timely and high-quality surgical and critical care. The results will help guide healthcare planning and policies to improve safety and fairness in surgical care for high-risk patients nationwide.

Reason for Declaration:

To fully understand the true complexity and risk profile of older patients presenting for major elective surgery across Ireland, the applicant states that it is important that the study sample is free from selection bias. The study requires the sequential enrolment of all patients undergoing emergency or major elective surgery over a defined time period, until the entire sample is collected. For this study to enrol a truly representative patient sample across Ireland, essential for its scientific credibility and ability to produce valid and actionable data, a consent declaration is requested.

HRCDC Comments:

The minutes of the discussion for this application will be updated and published once the HRCDC have completed their deliberations.

Reference ID:

25-021-AF1

Lead Applicant:

Antoinette O'Connor

Lead Data Controller:

Tallaght University Hospital, Trinity College Dublin

Title:

Biomarkers in the identification of Alzheimer's Disease in people with Down Syndrome (Bio-MinDS).

Research Objective:

Nearly every person with Down syndrome develops Alzheimer's disease (AD) during their lifetime. Despite urgent clinical need, people with Down syndrome have historically been excluded from AD clinical trials. The Bio-MinDS study aims to identify reliable biomarkers to improve early detection, diagnosis, and monitoring of AD in this population. Adults with, and without Down syndrome will attend annual visits at Tallaght University Hospital, where they will complete health checks, memory and thinking tests, and provide blood samples. Samples and data will also be shared with trusted academic collaborators in Sweden and the United Kingdom. The findings will guide future clinical trials and contribute to better treatments, as well as deepen understanding of healthy brain ageing. This study seeks to improve care for people with Down syndrome and reduce health inequalities.

Reason for Declaration:

Many potential participants will lack the capacity to provide explicit consent for data processing.

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, subject to conditions attached, should be made.

Public interest case:

- The HRCDC discussed the study activities, aims and objectives. It was noted that the study involves participants attending a clinic for annual visits for ten years, where their personal data will be collected from the assessments and the TUH medical records.
- It was the view of the HRCDC that there is a very strong public interest case in this research study and that it has the potential to benefit not just individuals with Down Syndrome but also the wider population.

Scope of the declaration:

- The HRCDC noted the references made by the Applicant to the use of data in future studies. It was discussed that the scope of the consent declaration would be limited only to the Bio-MINDs study and the processors specifically outlined to the HRCDC; other studies and/or collaboration would not be covered and would require an amendment or new HRCDC application to be submitted for consideration.

Consent/assent and PPI:

- The HRCDC commented that the consent and proxy assent process to be implemented in this study was robust and it commended the study information leaflets and assent/consent forms. It was highlighted that the study information leaflets should be clear and consistent that participant data can be fully deleted, not just their contact details and up to what point can their personal/pseudonymised data be deleted form this study. It was also commented that the PILs could outline that there may be risks to sharing data with ‘third countries’.
- The HRCDC was also of the view that there is a satisfactory level of PPI in this research with a proposed plan for the dissemination of findings.

Other:

- IT was noted that the PILs refer to a lumbar puncture, however the applicant confirmed that CSF samples are not included in this study.

HRCDC Decision:

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

Duration of Declaration:

The consent declaration is made until 31st January 2051 or until the personal data is deleted or fully anonymised, whichever occurs first.

Conditions Attached:

Condition 1. Data Controller to data processor agreements, as per the GDPR, must be in place between TCD/TUH and the processors UCL and University of Gothenburg, prior to the sharing of data and associated samples.

Condition 2. The outstanding data protection officer feedback from Tallaght University Hospital on the DPIA must be submitted before the study starts.

Condition 3. The Applicant is requested to address the following within the study information leaflet:

- It should be clear and consistent that participant data can be fully deleted if requested, not just their contact details, and it should be clear up to what point their data can be fully deleted from this study (note: pg 14 of the study information leaflet only notes that contact details can be deleted, however the replies provided to the HRCDC said data can be fully deleted).
- Reference to the inclusion of a Lumbar puncture should be removed from the information leaflets as the Applicant has confirmed that CSF samples will not be used in this study.

HRCDC Recommendations:

Recommendation 1. The Applicant should consider informing participants within the study information leaflet that there may be risks to sharing data with 'third countries' i.e., those outside the EEA and who do not have an adequacy decision in place. It is recognised that this must be done in an appropriate manner for the overall style of the information leaflet.

Reference ID:

25-022-AF1/CSO

Lead Applicant:

Prof Emma Wallace

Lead Data Controller:

University College Cork

Title:

Trends in Respiratory Medication Prescriptions in Ireland Before and After the Introduction of a Chronic Disease Management programme in General Practice: An Interrupted Time Series.

Research Objective:

This study aims to examine the patterns and quality of respiratory medication prescribing in Ireland before and after the implementation of the GP-led structured Chronic Disease Management (CDM) programme in Ireland. Respiratory conditions include asthma and Chronic Obstructive Pulmonary Disease (COPD). This study will provide an overview of real-world prescribing practices that can inform strategies to optimise prescribing quality and improve patient care. This study will use data on prescriptions for adults who are eligible for free GP care (have a medical card) over a 10-year period in Ireland.

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 commented that the Applicant could consider exploring PPI engagement with relevant asthma groups or representatives, in addition to the COPD groups who have been contacted to date.
- It was noted that the study cannot commence prior to full research ethics approval being obtained as well as RDGB approval.

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 1st September 2028.

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 and until full REC approval is in place.

HRCDC Recommendations:
Recommendation 1. Applicant could consider exploring PPI engagement with relevant asthma groups or representatives, in addition to the COPD groups who have been contacted to date.

Discussion Topics
The Secretariat, as part of ongoing HRDC process evaluation, conducted a review of conditions for all declarations made in the period August 2024 to September 2025. The purpose of this evaluation was to ensure conditions made, on a case-by-case basis, continue

to ensure a reasonably consistent application of GDPR, the Health Research Regulations (HRR) and other relevant Irish Guidelines / Legislation.
These were presented to the Committee and it was agreed that the outcome will facilitate a framework for discussions on future conditions. Each of the conditions presented were as a result of the judgement of the HRCDC on a case-by-case basis, ensuring the specific situations of each study were taken into account. All agreed this was an exercise that would be completed on an annual basis to ensure a reasonable level of consistency in the decision making process as far as possible.
On a separate matter, it was also agreed by the Committee that the Annual review form could be signed by the PI of the study in Ireland, recognising the difficulty, in some cases, of obtaining the signatures of the data controller of the study, especially in the case where the data controller may be based outside Ireland.

Annual Reviews

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

- **Ref ID:** 23-017-AF1 (PREVENTION study)
- **Ref ID:** 22-012-AF1 (TRAUMA study)
- **Ref ID:** 19-012-AF2 (Breast Cancer Proteomics and Molecular Heterogeneity)
- **Ref ID:** 19-005-AF2 (St James's Hospital Biobank)
- **Ref ID:** 24-011-AF1 (EchoLight Bone study)**
- **Ref ID:** 20-027-AF1 (Immune Dysfunction in Acute Brain Injury)
- **Ref ID:** 19-022-AF1 (TILDA)
- **Ref ID:** 23-019-AF1 (Tranexamic acid for hyperacute spontaneous IntraCerebral Haemorrhage (TICH-3)

***Declaration no longer required.*

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 informed that an updated standard confidentiality agreement would be circulated in the coming days and that each member is requested to sign.
- The HRCDC were reminded that the next HRCDC meeting is scheduled for Tuesday 27th January 2026.
- The Chairperson thanked the HRCDC and the Secretariat for their work in 2025 and looks forward to 2026.

The Chair closed the meeting