HRCDC
Health Research Consent Declaration Committee

Minutes of the Meeting – APPROVED

Date: 11th November 2025

Location: Zoom videoconferencing

HRCDC Attendance:

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

Quorum for Decisions

YES

Opening

The Chairperson opened the meeting and welcomed the members. The Chairperson informed the HRCDC that Mary Tumelty has been appointed as a Deputy Chairperson. The Chairperson also welcomed Fionnuala Gough as a new member of the HRCDC.

Apologies

Evelyn Mahon, Patricia O'Beirne, John Woods

Disclosure of Interest

- 25-015-AF1/CSO: Barbara Clyne (BC) and Susan Smith (SS) both declared an interest in application 25-015-AF1/CSO (Prevalence and Trends of Polypharmacy and Medication-Related Issues in Primary Care: A Repeated Cross-Sectional Study of GMS Pharmacy Claims Data in Ireland (2013–2024). BC and SS were absent during the meeting when this application was considered.

- 25-018-AF1: Jonathan Briody (JB) declared an interest in application 25-018-AF1 (MiPS: Metformin in Pregnancy Study) JB was absent during the meeting when this application was considered.

Minutes of the last meeting

Draft minutes of 7th October 2025 were circulated in advance of the meeting and were approved by the HRCDC.

Chairperson Approvals

- **20-005-AF1/COV/AMD1:** The HRCDC were informed that amendment request 20-005-AF1/AMD1 was approved via the Chairperson approval process. The amendment covers the addition of St James's Hospital, the National Orthopaedic Hospital Cappagh and Our Lady of Lourdes Hospital Drogheda as new joint data controllers and study sites.

New Applications

Reference ID:

25-015-AF1/CSO

Lead Applicant:

Frank Moriarty

Lead Data Controller:

Royal College of Surgeons in Ireland

Title:

Prevalence and Trends of Polypharmacy and Medication-Related Issues in Primary Care: A Repeated Cross-Sectional Study of GMS Pharmacy Claims Data in Ireland (2013–2024).

Research Objective:

This research is part of a PhD project looking at how to find the people who may benefit most from having their medicines reviewed by a pharmacist in a GP practice. To implement this service, more evidence is needed to inform the prioritisation of patient groups, such as those living with long term conditions. Several pieces of research are planned to achieve this. Some involve looking at data on medicine prescribing to understand how many people use multiple medicines (e.g. more than 5 or more than 10 medicines) or have other issues with their medicines such as drugs interacting with a person's disease or condition. This will feed into later parts of the research which will gather the views from experts (including research, health professionals, patients and the public) on how to best identify patients who may benefit most from medicines review by a pharmacist in the community setting.

Reason for Declaration:

The Applicant is seeking to access and obtain pseudonymised data (research microdata files) from the CSO Health Research Data Centre (HRDC). As the data being accessed is pseudonymised data and it is not feasible to seek consent from individuals whose data is

held by the CSO, a consent declaration is required. Primary Care Reimbursement Services (PCRS) and Irish Healthy Survey data is to be processed within the CSO HRDC.

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. It was further commented that the PPI engagement activities and transparency measures were positive.

Other:

- It was discussed that the study webpage referenced by the Applicant should be implemented.

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 November 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

Condition 2. The study webpage that was referenced by the Applicant in their replies to the HRCDC must be put in place before the study commences.

Reference ID:

25-017-AF1/CSO

Lead Applicant:

Mary Hall

Lead Data Controller:

Dublin City University

Title:

An investigation into the impact of smoking on Irish mortality 2022-2023

Research Objective:

Smoking imposes a significant health and economic burden on individuals and society. Smokers are more likely to develop chronic illnesses and die earlier than non-smokers costing the economy and themselves in terms of lower productivity and increased healthcare expenditure. Smoking is the leading cause of preventable death and preventable cancers in Ireland (and globally). The impact of smoking varies by socioeconomic class with smoking exerting a greater toll on those in lower socio-economic groups. This research project aims to investigate the impact of smoking on the Irish population. The prevalence of smoking by socio-economic group and health status will be examined. The impact of smoking on mortality (both all-cause and by major cause of death) will be modelled and the contribution of smoking to socio-economic differences in mortality will be analysed.

Reason for Declaration:

The Applicant is seeking to access and obtain pseudonymised data (research microdata files) from the CSO Health Research Data Centre (HRDC). As the data being accessed is pseudonymised data and it is not feasible to seek consent from individuals whose data is held by the CSO, a consent declaration is required. Census 2022 data will be processed in this study, alongside death registration data.

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.

PPI and transparency:

- It was commented that the study has no plans to undertake formal PPI activities. With regards transparency measures, it was noted that the results of the analysis will be promoted via social media and that the study will explore whether a study webpage is feasible, subject to resources. It was commented that researchers may not be able to commit to a designated study webpage due to controls and procedures within their organisation.
- On balance the HRCDC was of the view that the Applicant should consider strengthening the level of PPI engagement, including by engaging with relevant groups regarding transparency measures and the dissemination of findings. It was also discussed that for the benefit of increasing awareness among patients and the public, the Applicant should consider strengthening the proposed transparency measures beyond social media.

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 31st January 2029.

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 Applicant is strongly recommended to strengthen the level of PPI engagement with regards this study, including, for example, by engaging with relevant advocacy groups to increase awareness of this study and to disseminate the study findings. In addition, to further increase awareness of this study among patients and the public, the Applicant should consider strengthening the proposed transparency measures beyond social media, for example by considering press releases, inclusion in newsletters and to explore if a designated study webpage can be put in place.

Reference ID:

25-018-AF1

Lead Applicant:

Prof Fidelma Dunne and Dr Aya Mousa

Lead Data Controller:

Monash University, Australia

Title:

MiPS: Metformin in Pregnancy Study

Research Objective:

Metformin as a treatment is used in pregnant women with obesity (OB), gestational diabetes (GDM) and polycystic ovary syndrome (PCOS). A number of expensive randomized controlled trials have been conducted, each answering one clinical question. Each trial has also collected additional data which has not been used to its full potential.
The MiPS study proposes to pool data from completed randomized trials conducted worldwide and re-analyse a new combined dataset to examine unanswered clinical questions. Using data already collected to answer unanswered clinical questions is a faster and more financially acceptable proposition than setting up further new expensive randomized trials. Answering these additional clinical questions will facilitate the delivery of more patient focused care globally with metformin as a treatment option. Answering these additional clinical questions will facilitate upgrades to global policy and guidelines on the use of metformin in pregnancy.

The University of Galway was/is the sponsor of the EMERGE randomized trial of Metformin vs placebo for the treatment of GDM. The trial was completed and published in October 2023. Monash University Melbourne Australia are the sponsor of the proposed MiPS study. The PI of EMERGE, and the University of Galway as sponsor, have been invited to participate in this MiPS collaboration and a consent declaration is sought to process pseudo-anonymized data points from EMERGE for the MiPS study.

Reason for Declaration:

Consent was obtained for the original EMERGE Trial; however, the original participant consent process did not explicitly inform participants that their data could be transferred or processed outside the EU and they were not specifically informed that their data might later be transferred to international academic collaborators for secondary analyses. Therefore the researchers consider that the explicit consent obtained from the EMERGE study participants does not cover the further use of their data by Monash University for the purpose of the MiPS study.

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 aims and objectives of this study and noted the reasons why a consent declaration was requested and why reconsent could not be sought; the rationale why consent was not practicable or feasible included that only transferring the data of participants where re-consent is in place would result in a significant risk of creating scientific bias.
- It was commented that this study relates to the secondary use of previously collected clinical trial data which ensures their continued value and is an efficient and cost-effective approach. On balance the HRCDC was of the view that there is a strong public interest case in this research and that it is likely that participants would not be surprised that their EMERGE trial data would be used in such further analysis.

Transparency measures and Withdrawal from the study:

- The HRCDC noted the reply that the study will create a MiPS webpage and that posts will be made on the University's social media accounts. The Applicant further stated that where a participant from the EMERGE trial wishes to withdraw their data from the MiPS study, then this can be requested before the pseudonymised data is transferred to Monash University and also before the data is fully anonymised.
- The HRCDC discussed that transparency measures, including via social media, should be aimed at the participants from Ireland and that they should be implemented as early as possible to allow sufficient time for participants to withdraw from the MiPS study, if they wish to do so. It was commented that the transparency measures should inform participants that their EMERGE data is being transferred to Monash University for use in the MiPS study and also outline their data rights and how to exercise such rights.

Public and Patient Involvement:

- It was noted that strong PPI engagement was undertaken as part of the original EMERGE trial. With regards the MiPS study specifically, it was noted that informal engagement and communications had also occurred with two EMERGE participants who were positive about the re-use of EMERGE data for the MiPS study.
- It was commented that the findings from the MiPS study should be disseminated to the EMERGE PPI group and that consideration should be given to undertaking further PPI at an earlier stage of the study so that participants can be made aware of the research sooner.

Scope of the declaration:

- It was clarified by the Applicant that only Monash University will be accessing and processing the pseudonymised data from the EMERGE trial for the purpose of the MiPS study; no other third parties will be receiving, accessing or processing this data.
- It was also confirmed by the Applicant that the consent declaration is limited to the processing of this pseudonymised data for the purpose of the MiPS study and that the declaration will not cover processing the pseudonymised data in other sub-studies or future research; it was confirmed by the Applicant that any future sub-studies will only be on fully anonymised data conducted and will be undertaken within the controlled research environment, and that an amendment or new declaration application will be needed if personal or pseudonymised data is further processed.

Other:

- It was noted that the Monash research ethics approval had expired and that this should be drawn to the attention of the Applicant.
- It was discussed that the requisite data agreements and arrangements, including for transfer outside of the EEA, need to be in place prior to the transfer of data from Ireland.
- It was commented that only the minimal amount of data should be transferred from Ireland to Monash University.

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 31st May 2028 or until the personal data is deleted or fully anonymised, whichever occurs first.

Conditions Attached:

Condition 1. The necessary data agreements and arrangements, including for transfer of data outside of the EEA, need to be in place prior to the transfer of data from Ireland.

Condition 2. It is noted that the research ethics approval letter from Monash University submitted to the HRCDC, expired on 23rd June 2025. The Applicant/data controller must address this issue as soon as possible and ensure that REC approval from Monash remains in place and is valid for the MiPS study.

HRCDC Recommendations:

Recommendation 1. For the benefit of participants and the study, it is recommended that the findings from the MiPS study are disseminated to the EMERGE participants/PPI group. In addition, further to the informal engagement that has occurred to date with two EMERGE study participants on the MiPS study, consideration should be given to undertaking further PPI engagement, including at an earlier stage of the study so that participants can be made aware of the research sooner.

Recommendation 2. The transparency measures referenced by the Applicant, including via social media, should be aimed at the participants from Ireland and be implemented as early as possible to allow sufficient time for participants to withdraw from the MiPS study, if they wish to do so. The transparency measures should inform participants that their EMERGE data is being transferred to Monash University for use in the MiPS study and outline their data protection rights and how to exercise such rights, including how to request the withdrawal of their data.

Annual Reviews

The Secretariat has received 10 annual reviews in advance of the meeting which were deemed satisfactory:

- **Ref ID: 24-008-AF1** (Development and Validation of a Risk Prediction Model of Adverse Drug Events in Older Adults Presenting to an Acute Tertiary Hospital)
- **Ref ID: 19-007-AF2** (Targeted Therapeutic Mild Hypercapnia After Resuscitated Cardiac Arrest: A Phase III Multi-Centre Randomised Controlled Trial (TAME Cardiac Arrest Study))
- **Ref ID: 21-010-AF1** (A Phase 3, Multi-Arm Multi-Stage Covariate-Adjusted Response Adaptive Randomised Trial to Determine Optimal Early Mobility Training after Stroke (AVERT DOSE))
- **Ref ID: 19-026-AF2** (MAMMI Study: data sharing with University of Gothenburg and Murdoch Children's Research Institute)
- **Ref ID: 23-016-AF1** (Personalized Mechanical Ventilation Guided by UltraSound in Patients with Acute Respiratory Distress Syndrome (PEGASUS))
- **Ref ID: 23-014-AF1** (Adolescent and Young Adult (AYA) Cancer Epidemiology in Ireland – a retrospective review of National Cancer Registry Ireland (NCRI) data from 2002 to 2018)
- **Ref ID: 19-015-AF2** (Intellectual Disability Supplement to The Irish Longitudinal Study on Ageing (IDS-TILDA)
- **Ref ID: 19-031-AF2** (Bowel Disease Bio-Resource Development)
- **Ref ID: 23-020-AF1** (Capture-Recapture Study to Estimate the Prevalence of Problem-Opioid Use in Ireland (2020 – 2022)
- **Ref ID: 19-060-AF3** (National Kidney Disease Surveillance System and Quality Assurance Programme)

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 invites for the 2026 Meeting Dates have been circulated.
- The HRCDC were reminded that the next meeting on 9th December is in-person.

The Chair closed the meeting