

Minutes of the Meeting – APPROVED

Date: 11th August 2026

Location: Zoom video conferencing

HRCDC Attendance:

Aideen Hartney
Evelyn Mahon
John Woods
Susan Smith
Paul Stynes
Aisling McMahon
Sarah Barnes Aabo
Jonathan Briody
Antoinette O'Connor
Jim Blighe
Barbara Clyne
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

Ross McMullan, Mary Tumelty

Disclosure of Interest

- Aisling McMahon (AMcM) declared her interest in application 26-015 (PREVENT-STROKE). AMcM was absent during the meeting when this application was considered.

Minutes of the last meeting

Draft minutes of 23rd June 2026 were circulated in advance of the meeting and were approved by the HRCDC.

Chairperson Amendment approvals

- **25-014-AF1/AMD1 (In-Touch study):** the HRCDC were informed that amendment request 25-014-AF1/AMD1 was approved via the chairperson approval process. The amendment covers the inclusion of additional nursing homes to the study; St Luke's Nursing Home and Haven Bay Care Centre.
- **24-006-AF1/AMD1 (Determining the Impact of the “Thrombocalc” VTE Risk Assessment on the Incidence of postpartum VTE in the Rotunda Hospital, and derivation of a novel postpartum VTE risk prediction model):** the HRCDC were informed that amendment request 24-006-AF1/AMD1 was approved via the chairperson approval process. The amendment covers the addition of PCRS as a data processor and PCRS data to the study.
- **20-024-AF1/COV/AMD3 (GenOMICC) – Ireland):** the HRCDC were informed that amendment request 20-024-AF1/COV/AMD3 was approved via the chairperson approval process. The amendment covers the addition of University College Cork as a data processor.
- **25-013-AF1/AMD1 (Keep My Teeth: A Pragmatic Trial of a Co-Designed, Multicomponent Oral Health Promotion Intervention in Disability Services):** the HRCDC were informed that amendment request 25-013-AF1/AMD1 was approved via the chairperson approval process. The amendment covers an extension of the declaration to November 2026.
- **24-002-AF1/AMD2 (BONANZA Trial):** the HRCDC were informed that amendment request 24-002-AF1/AMD2 was approved via the chairperson approval process. The amendment covers the addition of Cork University Hospital as a recruitment site and University College Cork as a data processor.
- **22-005-AF1/AMD4 (EPIDIVE Phase 2):** the HRCDC were informed that amendment request 22-005-AF1/AMD4 was approved via the chairperson approval process. The amendment covers an extension of the declaration to 31st July 2029.

Amendments

Reference ID:

19-045-AF2/AMD3

Lead Applicant:

Sharon O'Toole

Lead Data Controller:

Trinity College Dublin and St James's Hospital Dublin

Title:

The Gynaecological cancer bioresource (DISCOVARY Bioresource) – anonymisation of data for the purpose of the Synthetic Health Information Enhancing Early Diagnosis and Treatment of Ovarian Cancer (SHIELD-OC-2025) clinical validation study which is part of the SEARCH programme.

Research Objective:

See HRCDC Meeting minutes of 28th May 2024.

Purpose of Amendment:

This latest amendment is seeking to fully anonymise data held in the DISCOVERY biobank for the purpose of the SHIELD-OC-2025 study which focuses on synthetic data.

HRCDC Comments:

The purpose for seeking this amendment was outlined by the Secretariat. The HRCDC were asked if they approved the amendment. It was the consensus of the HRCDC that the amendment request should be approved subject to transparency measures being implemented.

HRCDC Decision:

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

Conditions Attached:

Condition 1. Transparency measures must be implemented prior to data anonymisation to inform participants about this study and how they can request to withdraw, including the withdrawal of their data.

New Applications

Reference ID:

26-014

Lead Applicant:

Dr Mike O'Callaghan

Lead Data Controller:

Irish College of GPs

Title:

GP Insights: Understanding Irish General Practice Through EMR Data

Research Objective:

GP Insights is a national research programme led by the Irish College of GPs. It aims to better understand the care delivered every day in Irish general practice by using deidentified information from GP electronic medical records. Participating practices will contribute information on the size and shape of their patient populations based on consultations they deliver, the conditions people present with, the medications prescribed, and how structured care is delivered for long-term illnesses like Type 2 Diabetes. The study does not involve identifiable patient information. Instead, it uses routine data already recorded during care to answer important questions:

- How are GPs delivering chronic disease care?
- What are the most common reasons people visit their GP?
- What prescribing trends are apparent?
- And what does the typical practice population look like?

The findings will help support future decisions about how to organise GP services, train new doctors, improve patient care, and design national healthcare policy.

Reason for Declaration:

It is not feasible to obtain explicit consent from every individual patient. The dataset includes large and dynamic practice populations over time, number of records estimated at 75-150K. Many patients would be uncontactable or would not respond, introducing systematic bias.

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; 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 the reasons for seeking a consent declaration. It was noted that the study involved an initial pilot phase, an expansive phase and the longitudinal linkage and analysis of data.
- In addition, the HRCDC noted and accepted the rationale provided by the Applicant on why consent cannot be obtained.
- On balance, it was the view of the HRCDC that there is a strong public interest case in this research.

Transparency:

- It was noted that transparency notices will be placed within the GP practices to provide detail on this study and how to withdraw, however, it was commented that the heading for this notice 'Active Research Project Notice' could be amended to provide an improved and more accessible description of the research project.
- It was also discussed that only the text of this notice has been provided and not the final designed version. It was the view of the HRCDC that the final version should ensure that the poster is noticeable by people who are attending the GP practices.
- It was further commented that the poster could provide clearer and less technical language, for example by not using or explaining the terms pseudonymisation or retrospective. It was also discussed that the notice could be clearer with regards to the description of withdrawing from the study and what will happen the data.
- In addition, reference is made by the Applicant to setting up a dedicated study page on the ICGP website, however this does not seem to be in place yet.

PPI engagement:

- On PPI engagement, the reply from the Applicant was that the ICGP PPI panel may be consulted, where appropriate, on patient facing materials and the communication of study findings; overall it was not clear whether PPI engagement had occurred to date.

Other:

- It was commented that the Applicant should confirm in their Annual Review whether the data will be deleted or fully anonymised following the end of the study retention period.
- It was further commented that the study should ensure that V1.2 or later of HTTP is used with regards the secure transfer of data.
- The required data agreements should also be in place with the GPs who provide data for this 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 August 2037, or until the personal data is deleted or fully anonymised, whichever occurs first.

Conditions Attached:

Condition 1. The dedicated study page on the ICGP website that is referenced by the Applicant in their replies must be in place prior to the study commencing.

Condition 2. When known, the Applicant should confirm in their Annual Review whether the data will be deleted or fully anonymised following the end of the study retention period.

Condition 3. Data agreements must be in place with the GPs who provide data for this study.

HRCDC Recommendations:

Recommendation 1. The Applicant is requested to review the participant notice that will be provided in the GP practices and address the following points to make it more user-friendly:

- The notice should utilise clearer and less technical language, for example by not using the terms pseudonymisation or retrospective. It could also be clearer with regards to the description of withdrawing from the study and what will happen the data.
- The design of the poster should ensure that is easily noticeable to individuals when they visit the GP practices.
- The heading for this notice 'Active Research Project Notice' should be amended to note the name of this study.

Recommendation 2. It is strongly recommended that PPI engagement is undertaken during the course of this study.

Reference ID:
26-015

Lead Applicant:
Dr. John McCabe

Lead Data Controller:

Mater Misericordiae University Hospital

Title:

Prevention of REcurrent Vascular EVENTS after STROKE (PREVENT-STROKE) Study

Research Objective:

The PREVENT-STROKE study is designed to help doctors and researchers better understand why strokes occur, how they can be prevented, and how to accurately predict who might be at risk of experiencing further health problems, such as another stroke or heart attack. Even though treatment and prevention of stroke have improved over the years, people who have had one stroke and are receiving the best available medical treatment, are still at higher risk of having another. This study hopes to find out more about why that happens and how to reduce that risk in the future. The study will include people who have had a recent stroke. The research team will collect information that is already being gathered as part of normal medical care, such as medical history of the participant, blood tests, brain scans, and heart recordings. No additional procedures new tests or scans will be done for the study, so there will be no change to the person's usual care. Researchers will use the blood samples taken during normal routine clinical care for storage with a view to doing analysis of new blood markers and genetic analysis in the future. These tests will not influence the patient's clinical care, as all of these analyses are for research purposes only.

Reason for Declaration:

Currently, participants enrolled in PREVENT-Stroke all provide written informed consent to participate since study commencement in October 2025. However, patients with moderate-severe acute stroke may temporarily or permanently lose capacity to consent to participate in medical research. This may be due to a variety of reasons, including aphasia, post-stroke cognitive impairment, or delirium. In accordance with the HSE National Policy for Consent in Health and Social Care Research, these patients should not be excluded from participation in medical research. A consent declaration is sought for the proportion of patients who are otherwise eligible to participate in the study, but who lack capacity to provide informed consent.

HRCDC Comments:

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

Reference ID:

26-016

Lead Applicant:

Prof. Ignacio Martin-Loeches

Lead Data Controller:

Trinity College Dublin and St James's Hospital Dublin

Title:

Chest wall movement sensor (RIBBON)

Research Objective:

This study investigates whether a small wearable sensor placed on the chest can accurately measure breathing volume. Measuring how much air moves in and out of the lungs is important for assessing respiratory health, but current methods require bulky equipment, face masks, or active cooperation from the patient — making continuous monitoring outside a clinical setting impractical. No wearable device currently exists that can measure breathing volume continuously and non-invasively. This study involves placing a small sensor patch on the chest wall of mechanically ventilated patients in the intensive care unit at St. James's Hospital, Dublin. The sensor uses commercially available, medically approved components and is attached using medical adhesive tape. It does not interfere with routine clinical care. Sensor measurements are compared against the ventilator, which provides a precise reference measurement of breathing volume. The results will inform the design of future clinical studies in broader patient populations.

Reason for Declaration:

The RIBBON study in the cohort of ventilated patients involves critically ill patients who are mechanically ventilated and fully sedated in the intensive care unit. These patients are, by definition, unable to provide explicit informed consent at the time of data collection. A process of deferred proxy assent and deferred consent will be implemented.

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. 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 the reasons for seeking a consent declaration. It was noted that the study is observational in nature, poses a low risk to the patient and that data is pseudonymised at the point of collection.
- In addition, the HRCDC noted and accepted the rationale provided by the Applicant on why consent cannot be obtained.
- On balance, it was the view of the HRCDC that there is a strong public interest case in this research.

Data Security:

- It was commented that the timeline for when and who will collect the data from the ventilator and the RIBBON device via the use of external memory drives was unclear. It was also commented that such memory drives should be encrypted together with password protection when they are used, prior to uploading their data to the researcher's cloud system.

Public and Patient Involvement:

- It was discussed that the Applicant is committed to undertaking PPI in advance of the study commencing in September 2026. The HRCDC was of the view that PPI engagement must be undertaken prior to the study commencing and an update provided

to the HRCDC on this work. It was also discussed that PPI engagement should include review and feedback of the study transparency measures, including the information leaflets and assent/consent forms.

Study Information Leaflets and Transparency:

- On the study information leaflets and proxy assent and consent forms, it was the view of the HRCDC that these should be reviewed by the Applicant and a number of issues addressed.
- It was noted that the terms 'consent' and 'assent' are used incorrectly in the documents, for example in a number of sections the proxy is asked to provide their consent, and not their assent, on behalf of the participant who lacks decision-making capacity; linked to this, it was also highlighted that documents include the incorrect use of first and third person perspectives; for example, the proxy assent forms state *'I also agree to allow non-medical researchers to access my medical records...'*
- In addition, it was noted that the updated proxy assent form submitted by the Applicant, has the heading 'verbal assent', however it was confirmed that proxy assent would only be obtained in person. It was also commented that this document does not include a space for the proxy themselves to sign the assent form; it only includes signature lines for the researcher and a witness.
- With regards the extent of data to be collected, it was also discussed that the study information leaflets should provide more details on this.
- It was commented that the study website referenced by the Applicant is not available yet.

Other:

- It was discussed that the study should determine whether a participant has a decision support or agreement in place as per the Assisted Decision Making Act; it should not be assumed that participants would not have such support agreements in place.
- It was noted that data will be collected using paper case report forms, which will then be stored in Trinity College after the data has been digitised. It was commented that the forms need to be securely transferred and that no directly identifiable data, only the pseudonymised code, should be recorded or used on these forms.
- Where a request is made to withdraw from the study, paper records should also be destroyed.

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 30th September 2027, or until the personal data is deleted or fully anonymised, whichever occurs first.

Conditions Attached:

Condition 1. It is noted that the Applicant is committed to undertaking PPI in advance of the study commencing in September 2026. Given the importance of PPI engagement as a

safeguard, the HRCDC is of the view that PPI engagement must be undertaken and an update provided to the HRCDC on this work before commencing the research. PPI engagement should include review and feedback of the study transparency measures, including the information leaflets and assent/consent forms (Please see Condition 2 below).

Condition 2. It is the view of the HRCDC that the study information leaflets and assent and consent forms should be thoroughly reviewed by the Applicant, and the following specific points should be addressed:

- the terms 'consent' and 'assent' are used incorrectly in these documents, for example in a number of sections the proxy is asked to provide their 'consent', and not their 'assent', on behalf of the participant who lacks decision-making capacity;
- The documents include the incorrect use of first and third person perspectives; for example, the proxy assent forms state *'I also agree to allow non-medical researchers to access my medical records...'*
- The updated proxy assent form submitted by the Applicant, has the heading 'verbal assent', however it was confirmed that proxy assent would only be obtained in person.
- The proxy assent document does not include a space for the proxy themselves to sign this form; it only includes signature lines for the researcher and a witness.
- The study information leaflets for the proxy and participant should provide more details on the extent of data to be collected and processed in this study.

These changes should be made in advance of PPI engagement (Condition 1) and in advance of this study commencing.

Condition 3: the study website referenced by the Applicant should be in place prior to the start of this research.

Condition 4: It should be ensured that the memory drives used to obtain the data from the ventilator and the RIBBON device prior to uploading to the researcher's cloud system are encrypted and password protected.

Condition 5: that the study should determine whether a participant has a decision support or agreement in place as per the Assisted Decision Making Act, prior to their enrolment; it should not be assumed that participants would not have such support agreements in place.

Condition 6: The paper case report forms must be securely transferred to TCD and no directly identifiable data, only the pseudonymised code, should be recorded or used on these forms.

Condition 7: Where a request is made to withdraw from the study, the paper case report forms should also be destroyed, together with the digital data.

Reference ID:
26-017

Lead Applicant:
Professor Michael Kerin and Professor Seán Hynes

Lead Data Controller:
Galway University Hospital (GUH) / Health Service Executive and the University of Galway

Title:

External Validation of an AI-Based Digital Pathology Tool in Early-Stage and Neoadjuvant Breast Cancer Cohorts

Research Objective:

This study aims to evaluate the accuracy of a new artificial intelligence (AI) tool for predicting outcomes in breast cancer. The project will use anonymised information from patients previously treated at University Hospital Galway, including clinical details and digital images of tissue samples; this includes data from the Galway MCAN biobank as well as patient records. The AI system analyses these images to identify patterns that may help predict how patients respond to treatment and their long-term likelihood of having a recurrence. No new samples will be collected, and no identifiable information will be shared. The research will help determine whether AI-based tools can support doctors in making more personalised treatment decisions for breast cancer patients in the future, in comparison to current tools in a more efficient and potentially cost-effective way with faster turnaround times for patients. All data will be handled securely, in compliance with GDPR and national data protection regulations, and results will aim to be published in peer-reviewed scientific journals, with the goal of improving outcomes for patients with breast cancer in the future.

Reason for Declaration:

The consent declaration is requested to extract, link and then fully anonymise personal data of breast cancer patients previously treated at University Hospital Galway, including clinical details and digital images of tissue samples. This data will be sourced from the separate MCAN Galway biobank and the Galway hospital records. When fully anonymised, the data will be transferred to Ataraxis in the US to evaluate the prognostic accuracy of their Ataraxis AI platform. The Applicant states that consent cannot be obtained from these participants due to the retrospective nature of this study; the study cohort comprises patients diagnosed and treated for breast cancer at Galway University Hospital between since 2005 and approximately 550 patients will be included in the study - the final year of diagnosis when patients may be included in this retrospective study will be 2021. With regards the MCAN biobank, some eligible participants may have previously provided their consent for the Galway MCAN biobank, however the Applicant has confirmed that such previous consent does not cover this specific AI focused 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. 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 the reasons for seeking a consent declaration. It was discussed that the scope of the consent declaration is limited i.e., collection, linkage and anonymisation of data; only anonymised data will be sent to the data processor in the USA. It was commented that the use of AI as predictive tools are important emerging areas for research and medicine.

- In addition, the HRCDC noted and accepted the rationale provided by the Applicant on why consent cannot be obtained.
- On balance, it was the view of the HRCDC that there is a strong public interest case in this research.

PPI and Transparency:

- It was discussed that it was not clear whether the Applicant had undertaken PPI engagement to date; it was the view of the HRCDC that PPI engagement should be undertaken prior to the study commencing.
- The HRCDC also commented that the planned transparency measures of a plain language summary to be sent via PPI networks, information on the HSE website and notices displayed in outpatient and hospital areas should be implemented prior to the study commencing. It was further commented that these measures must also outline the participants' right to withdraw, to have their data deleted from the study and how to exercise this right.

Other:

- It was discussed that the study team should receive written notification from the data processor when they have deleted the anonymised data.

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 1st July 2028, or until the personal data is deleted or fully anonymised, whichever occurs first.

Conditions Attached:

Condition 1. PPI engagement must be undertaken prior to the study commencing, and an update on this submitted to the HRCDC. In addition, the planned transparency measures of a plain language summary to be sent via PPI networks, information on the HSE website and notices displayed in outpatient and hospital areas should also be implemented prior to the study commencing. It was further commented that these measures must outline the participants right to withdraw, to have their data deleted from the study and how to exercise this right.

Condition 2. DPO feedback on the DPIA is to be submitted from GUH. DPO feedback has been provided from University of Galway, but feedback is required from both joint controllers. This condition should be met within 2 months.

HRCDC Recommendations:

Recommendation 1. The study team should receive written notification from the data processor when they have deleted the anonymised data

Annual Reviews

The Secretariat has received 13 annual reviews in advance of the meeting which were deemed satisfactory:

- **Ref ID:** 24-006 (Thrombocalc)
- **Ref ID:** 22-006 (HPO Study)
- **Ref ID:** 25-003-AF1 (Cirrhosis-Acute Kidney Injury Cohort Study)
- **Ref ID:** 24-013-AF1 (Learning from Incidents – a mixed-method study of incident reviews)
- **Ref ID:** 19-026-AF2 (MAMMI Study: data sharing with University of Gothenburg and Murdoch Children's Research Institute)
- **Ref ID:** 22-005-AF1 (Longitudinal analysis of clinical markers of response to treatment in people with epilepsy (EPIDIVE Phase 2))
- **Ref ID:** 19-077-AF3 (Irish Prostate Cancer Outcomes Research (IPCOR) Study)
- **Ref ID:** 19-025-AF2 (Irish National AATD Registry' (The Alpha-1 Registry)
- **Ref ID:** 21-002-AF1 (Mega-ROX)
- **Ref ID:** 22-009-AF1 (Linking and harnessing health and population data to improve outcomes in Out-of-Hospital Cardiac Arrest)
- **Ref ID:** 22-008-AF1 (Evaluation of policies and practices to support safe and appropriate controlled drug prescribing)
- **Ref ID:** 23-005-AF1 (The journey from wardship to supported decision-making: An examination of the process and the experiences of people leaving wardship)
- **Ref ID:** 19-041-AF3/COV (The role of T-Regulatory and Mononuclear Phagocyte Cells causing Immune Dysfunction in Sepsis (A study on the role of immune dysfunction in sepsis and COVID-19))

Any Other Business

The HRCDC were informed that the next meeting is scheduled for Tuesday 8th September.

The Chair closed the meeting