HRCDC
Health Research Consent Declaration Committee

Minutes of the Meeting –APPROVED

Date: 9th September 2025

Location: Zoom videoconferencing

HRCDC Attendance:

Aideen Hartney
Evelyn Mahon
Mary Tumelty
Patricia O'Beirne
Susan Smith
Paul Stynes
Aisling McMahon
Sarah Barnes Aabo
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

Antoinette O'Connor, John Woods, Jonathan Briody

Disclosure of Interest

- Aisling McMahon (AMcM) declared her interest in application 25-011-AF1 (EXTUBE). AMcM was absent during the meeting when this application was considered.
- Susan Smith (SS) informed the HRCDC that she knows the lead researcher from 25-012-AF1/CSO (RECONNECT), however SS is not involved in this research. It was determined that SS did not have conflict that would require her to be absent when this application is considered.

Minutes of the last meeting

Draft minutes of 12th August 2025 were circulated in advance of the meeting and were approved by the HRCDC.

Returning Applications

Reference ID:

25-008-AF1

Lead Applicant:

Prof. Donal Sexton

Lead Data Controller:

St. James's Hospital

Title:

GENAKI: Generative AI for Acute Kidney Injury Prediction and Management at St. James's Hospital

Research Objective:

See HRCDC Meeting minutes of 12th August 2025

HRCDC Comments:

The HRCDC were reminded of the additional information that was requested from the Applicant following the August 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.

Number of participants:

- In their replies to the HRCDC's request for clarification on the number of participants to be included the Applicant outlined that, following further discussions with statisticians, the number of participants to be included in this study would be reduced from 100,000 to a maximum of 30,000. The Applicant had noted that the REC would be informed about the reduction in study numbers.
- The HRCDC noted and discussed this reduction in the number of patients to be included. It was commented that this is large reduction and it was queried why this is occurring now and was not considered in their original application. However, it was noted that the Applicant is of the view that the study could achieve its objectives with this reduced number and it was discussed that a change in the number of participants within a study is not uncommon and that it would likely be feasible for the researchers to train AI models using this smaller participant cohort. It was also commented that this reduction in participants would also be aligned to the principle of data minimisation. It was discussed that REC approval would need to be in place with regards this change to the study methodology.

- The Applicant also provided further details on the type of data to be processed including what is meant by 'clinical note' data and why such data was required to develop and train AI models to recognise risk factors and outcomes of AKI. It was further confirmed by the Applicant that data on both acute kidney injury (AKI) and non-AKI patients would be processed within this study and that this was necessary to train the AI models to distinguish between patients who develop AKI from those who do not.
- Overall, on balance, the HRCDC noted that there is a public interest case in this study and it was satisfied with the clarifications provided by the Applicant with regards the number of participants to be included and the type and extent of data to be collected and processed.

Transparency and PPI:

- The HRCDC noted the Applicant's replies that some participants included in this study may still be attending St James's Hospital. With regards what transparency measures could be implemented for this cohort, the Applicant referenced that information will be provided on the Trinity College and St James's Hospital website, including information on their right to withdraw.
- It was of the view of the HRCDC that only providing information to participants via these websites is not sufficient; it was discussed that it would be unlikely that participants, including those who may still be attending the hospital, would visit these websites to find out more information about this project and how they can withdraw. Accordingly, the HRCDC consensus was that transparency measures would need to be enhanced, including via study specfic notices/posters within relevant areas of the hospital, that includes clear information on the participant's data rights including the right to withdraw and a clear point of contact on who to contact to exercise this right.
- It was also commented that the findings from this study should be disseminated to participants and the public, not just made available to the research community via peer-reviewed journals and conferences.
- On the matter of PPI, the HRCDC discussed that the Applicant had outlined planned activities in the original application, which was subject to successful funding. The HRCDC commented that PPI engagement for this study must be undertaken even if the funding referenced by the Applicant is not successful. It was also discussed by the HRCDC that consideration should be given to engaging with the standing PPI group in St James's hospital and to discuss the reduced participant numbers and enhanced transparency measures as part of the PPI engagement for this 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 September 2028 or until the personal data is deleted or fully anonymised, whichever occurs first.

Conditions Attached:

Condition 1. Research ethics committee approval must be in place for the reduced number of participants i.e., the reduction of 100,000 participants to no more than 30,000.

Condition 2. The HRCDC notes the detailed PPI engagement activities that are planned for this study, with the Applicant having noted that this is subject to funding. It is a condition of this declaration that appropriate PPI engagement must be undertaken prior to the study commencing.

Condition 3. It is of the view of the HRCDC that only providing information to participants via the St James's Hospital and Trinity College websites is insufficient; accordingly, it is a condition that the study's transparency measures are enhanced to include study specfic notices/posters within relevant areas of the hospital. It is also a condition of this declaration that all transparency measures implemented (i.e., websites, posters etc.) include clear information on the participant's data rights including the right to withdraw and have their data deleted, and a clear point of contact on who to contact to exercise this right. Enhanced transparency measures must be in place prior to the study commencing.

HRCDC Recommendations:

Recommendation 1. Further to Condition 2, the Applicant is requested to consider undertaking PPI activities with the standing PPI group from St James's Hospital.

Recommendation 2. The Applicant should explore how the findings from this study could be disseminated to participants and the public and not just made available to the research community via peer-reviewed journals and conferences. This could also be discussed as part of PPI engagement.

New Applications

Reference ID:

25-011-AF1

Lead Applicant:

Dr Matteo Parotto

Lead Data Controller:

University Health Network

Title:

EXtubation related complications - an international observational study To Understand the impact and BEst practices in the operating room and intensive care unit (EXTUBE)

Research Objective:

The EXTUBE study is an international research project investigating complications that can occur when a breathing tube is removed (extubation) after surgery or critical illness. While this is a routine medical procedure, extubation can sometimes lead to serious issues such as breathing difficulties, low oxygen levels, or the need for emergency airway support. Despite its importance, extubation has not been as thoroughly studied as intubation (placing the breathing tube). This study will collect data from hospitals worldwide to understand the frequency, risk factors, and best practices for safe extubation. The findings will help improve patient safety by identifying ways to reduce complications and develop better guidelines for healthcare providers. By studying extubation in a large, diverse group of patients, this

research aims to enhance outcomes and support safer airway management in both surgical and intensive care settings.

Reason for Declaration:

The study outlines that seeking and requiring consent would impact the scientific validity of the study and introduce selection bias. The Applicant also notes that the study protocol requires sites to have a 'consent waiver' in order to participate in this research.

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 research and the rationale for why consent could not be obtained. It was commented that extubation is an area that has not been as well researched as intubation. It was also noted why the Applicant states that seeking consent or proxy assent would not be appropriate, including that the study requires all consecutive eligible patients to be recruited and that there is a risk of scientific bias. It was also noted that this international study requires each site to have a 'consent waiver' in order to be included.
- The HRCDC further noted that while participants would not be consented, they will be provided with an information leaflet about the study and how to opt-out. It was further commented that the study involved no intervention and is considered relatively low risk.
- On balance the HRCDC accepted the Applicant's rationale for not seeking consent in the context of this specfic research and the committee was of the view that there is a strong public interest case in this research study.

Transparency and opt-out:

- Given the cohort of participants who will be included in this study, the HRCDC was of the view that if the participant lacks decision-making capacity, the information leaflet detailing the study and how to withdraw should also be provided to a suitable proxy who understands the will and preference of the participant, and that the proxy should be able to withdraw the participant from the research, if they so wish.
- The HRCDC also noted the reply from the Applicant that participants are asked to inform the researchers within 2 weeks of leaving the hospital if they wish to withdraw from the study and have their data removed. However, the Applicant further outlined that data could be removed from the database up until the point it is locked for analysis which is expected to occur within 6 months of enrolment being completed. The HRCDC commented that the information leaflet should make this fully clear to the participant and/or their proxy.
- It was further highlighted that the information leaflet does not make it clear that this is an international study with Galway University Hospital as one site and that pseudonymised

data will be transferred and processed by the Canadian data controller of the study who may also have access to medical records for auditing purposes.

Other:

- It was highlighted that the necessary data agreements and arrangements must be in place between the parties.

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 2027 and for 10 years thereafter until 30th June 2037 to include data archiving, or until the personal data is deleted or fully anonymised, whichever occurs first.

Conditions Attached:

Condition 1. Further to providing the participant with the study information leaflet, it is a condition of this declaration that, where the participant continues to lack capacity, the information leaflet detailing the study and how to withdraw should also be provided to a suitable proxy who understands the will and preference of the participant, and that the proxy should be able to withdraw the participant who lacks capacity from the research and have their data deleted.

Condition 2. The following must be addressed within the information leaflet that will be provided to the participant or the proxy:

- It should be made clear that this is an international study with Galway as one of sites involved.
- It should be clear that the study data controller is the University Health Network, Canada and that personal/pseudonymised data will be transferred to and analysed by the controller in Canada for the purpose of this study. In addition, it should clear whether the University Health Network will have access to non-coded/identifiable data, including if they will have access to the participant's medical records for the purpose of auditing or quality assurance.
- It should be outlined that participant and/or the proxy can withdraw from the study and have the data deleted up until the point the database is locked for analysis which is expected to occur within 6 months of enrolment being completed, not just requesting withdrawal within 2 weeks of leaving the hospital (As per the information provided to the HRCDC).

Condition 3. The necessary data processing arrangements must be in place between GUH and the University Health Network prior to the study commencing; this includes required agreements/arrangements for transfer of data outside the EEA, for example Standard Contractual Clauses and conducting a Transfer Impact Assessment.

HRCDC
Health Research Consent Declaration Committee

Reference ID:
25-012-AF1/CSO

Lead Applicant:
Prof. Patricia Kearney

Lead Data Controller:
University College Cork

Title:
RECONNECT: chRonic disEase: disCOvery, aNalysis aNd prEdiCTive modelling – Case study using PCRS dataset

Research Objective:
The study is a part of the RECONNECT project, which is directed at optimising use of data in the Irish healthcare system, with an initial focus on diabetes. RECONNECT aims to develop approaches to integrate healthcare data systems pertinent to chronic disease, for population health planning, health service policy and patient care, while prioritizing data privacy and governance. This case study aims to examine trends in medications prescribed for diabetes across age, sex, and social deprivation to describe current inequalities in diabetes care. The results from the study will provide insights and guide policy on developing systems for equitable care delivery for diabetes in Ireland. A consent declaration is sought for the analysis of CSO's research microdata files for this study. Explicit participant consent is not available to use the personal data for research purposes.

Reason for Declaration:
The Applicant is seeking to access and obtained pseudonymised data (research microdata files) from the CSO Health RDC. 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 within the Health RDC, 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 scope of the consent declaration will not cover the processing of personal/pseudonymised data by other parties beyond UCC.

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 August 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.

Reference ID:
25-013-AF1

Lead Applicant:
Caoimhin Mac Giolla Phadraig

Lead Data Controller:
Trinity College Dublin

Title:
Keep My Teeth: A Pragmatic Trial of a Co-Designed, Multicomponent Oral Health Promotion Intervention in Disability Services

Research Objective:
People with intellectual disabilities and autism often experience poorer oral health due to challenges in daily mouthcare and inconsistent support. Keep My Teeth introduces a co-designed, multicomponent oral health intervention targeting staff, clients, and families in residential and day services. It compares two delivery models—Platinum and Diamond—that include policy development, training, personalised care plans, and local champions. The Diamond model adds sustained dental professional support. Delivered in partnership with St Michael's House and the National Federation of Voluntary Service Providers, the study uses a cluster randomised design and mixed methods evaluation. It aims to improve oral health outcomes, promote inclusive care, and inform a scalable national model.

Reason for Declaration:
Some participants are adults with intellectual disabilities who lack decision-making capacity to provide explicit consent for research participation, including data processing. Many do not have formal decision supporters (e.g. decision-making representatives) under the Assisted Decision-Making (Capacity) Act (ADMA). A consent declaration is therefore needed to allow inclusion of this underrepresented population; proxy assent will be obtained on their behalf.

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 research and the rationale for why consent could not be obtained. It was commented that the proxy assent process for those for lack capacity provided a suitable safeguard and that the study will assess decision-making capacity and obtain participant consent where possible.
- On balance, the HRCDC consensus was that there is a strong public interest case in this study.

Transparency and PPI:

- The HRCDC commented that there sufficient PPI in place, noting that many elements and stages are being co-designed with PPI representatives. It was recommended that there could be PPI engagement when disseminating the study findings.
- It was noted that the final versions of the study information leaflets will be refined through further co-design. The HRCDC commented that the final versions of the PILs must be approved by the relevant REC.
- It was further noted that different email addresses for the same researcher were provided in the client, staff and family documents and that this should be addressed.
- It was also discussed that the study information leaflets should make it clear that data can be removed/deleted from the study up until the point it is anonymised.
- It was recommended that the information leaflets provided to the staff and family members reference the GDPR Art.6 and Art.9 bases for processing personal data in this study.
- In addition to the study information leaflet and assent/consent forms, it was noted that a designated Keep Your Teeth study website will be created.

Other:

- It was noted that the DPIA refers to participant initials or assigned codes' for pseudonymisation; it was discussed that in the interest of data security that initials should not be used.

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

Conditions Attached:

Condition 1. The following points on the study assent/consent documentation should be addressed:

- It is noted that different email addresses for the same researcher/study email were provided in the client, staff and family documents and that this should be addressed

- The study information leaflets should make it clear that data can be removed/deleted from the study up until the point it is anonymised

Condition 2. Following the co-design activities with PPI representatives, the final versions of study information leaflets and consent/assent forms must be approved by the relevant REC and submitted to the HRCDC secretariat for noting.

Condition 3. The Study website that is referenced by the Applicant should be in place prior to the study commencing.

HRCDC Recommendations:

Recommendation 1. It is recommended that the information leaflets provided to the staff and family members reference the relevant GDPR Art.6 and Art.9 bases for processing personal data in this study.

Recommendation 2. It is noted that the DPIA submitted refers to 'participant initials or assigned codes' for pseudonymisation; in the interest of data security, use of participant initials would not be seen as good practice as a pseudonymisation measure.

Annual Reviews

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

- **Ref ID: 21-011-AF1/CSO**: Examination of the relationship between the COVID-19 pandemic, unemployment, and social disadvantage in Ireland *[Declaration no longer required]*
- **Ref ID: 19-004-AF2:** REMAP-CAP
- **Ref ID: 23-008-AF1:** ARISE FLUIDS
- **Ref ID: 24-004-AF1:** Acral Melanoma: Incidence, clinical course and survival patterns in Ireland from 1994 – 2022
- **Ref ID: 20-022-AF1:** PHIND study
- **Ref ID: 20-024-AF1:** GENOMMIC study
- **Ref ID: 24-003-AF1:** SPICE IV study

Activities report and events of interest

The Secretariat circulated a report of it's activities to the HRCDC in advance of the meeting.

Any Other Business

The HRCDC were reminded that the next meeting is scheduled for 7th October 2025.

The Chair closed the meeting