HRCDC
Health Research Consent Declaration Committee

Minutes of the Meeting – APPROVED

Date: 23rd June 2026

Location: Zoom video conferencing

HRCDC Attendance:

Evelyn Mahon
Paul Stynes
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 Deputy Chairperson, Evelyn Mahon, opened the meeting and welcomed the members.

Apologies

Aideen Hartney (Chairperson), Aisling McMahon, Mary Tumelty, Susan Smith

Disclosure of Interest

There were no disclosures of interest for this meeting.

Minutes of the last meeting

Draft minutes of 26th May 2026 were circulated in advance of the meeting and were approved by the HRCDC.

Chairperson Approvals

- **21-003-AF1/AMD4 (Investigating the Epidemiology of Mycobacterium bovis infection in humans):** the HRCDC were informed that amendment request 21-003-AF1/AMD4 was approved via the chairperson approval process. The amendment covers the extension of the consent declaration to 31st May 2027.

New Applications

Reference ID:
26-007

Lead Applicant:
Prof Keelin O'Donoghue

Lead Data Controller:
University College Cork
Health Service Executive

Title:
PREDICT: Sentinel Events

Research Objective:
Although maternity care has improved, serious complications during pregnancy and birth, such as stillbirth and brain injury, continue to affect many families, causing major emotional, social, and financial impacts. Some causes of these complications can be predicted, however, a group of emergencies called perinatal sentinel events (PSEs) happen suddenly and often without warning. These include placental abruption, uterine rupture, cord prolapse and shoulder dystocia. PSEs are uncommon but remain an important cause of serious illness and death around the time of birth. In Ireland they contribute to 9.9% of stillbirths and 37.3% of newborn brain injuries requiring cooling therapy. At present, PSEs cannot be reliably predicted. This study will use maternity electronic health record data to compare pregnancies with and without a PSE. Using advanced computer analysis models (machine-learning), we aim to identify pregnancies at higher risk, supporting safer care and reducing preventable complications for mothers and babies.

Reason for Declaration:
To cover the collection, extraction and anonymisation of the HSE data by the HSE, prior to being securely sent to UCC for analysis. The study will examine the data of all pregnancies in which a PSE occurred at Cork University Maternity Hospital (CUMH) over a six-year period, from January 2019 to December 2024 inclusive, together with a matched number of controls in which a PSE did not occur; it is not considered feasible to obtain consent for these 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 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 highlighted that the scope of the consent declaration is limited to anonymisation of the personal data from CUMH, before transfer to UCC. It was also commented that the measures in place to secure the data appeared appropriate.
- 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 commented that there was an appropriate level of public and patient involvement activities in this research.
- On transparency measures, the Applicant had outlined that specific notices will be displayed online and on-site at CUMH. It was discussed that the period of retrospective data covered would mean that the children who were impacted by such sentinel events would be up to 6-years old; it was further commented that some of these participants may now be receiving ongoing treatments. It was therefore commented that there could be opportunities to inform these families about this study via providing the study poster in specific settings where this cohort may be receiving current treatment, for example in outpatient clinics, paediatric clinics or neurology clinics.

Other:

- Ensuring appropriate agreements are in place.

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

Conditions Attached:

Condition 1. Joint controller arrangements must be in place between the HSE and UCC prior to the commencement of this study.

Condition 2. Feedback on the DPIA from the HSE's data protection officer HSE must be submitted within 2 months. (Note: DPO feedback on the DPIA is required from both joint controllers of the study; only UCC DPO feedback has been submitted to date).

HRCDC Recommendations:

Recommendation 1. On transparency measures, it was noted that specific study notices/posters will be displayed online and on-site at CUMH. As the children who were impacted by such sentinel events would be up to 6-years old and may be receiving ongoing

treatment, it was the view of the HRCDC that there could opportunities to strengthen transparency measures by providing the study poster in specific settings where this cohort may be receiving current treatment, for example in outpatient clinics, paediatric clinics or neurology clinics.

Reference ID:
26-011

Lead Applicant:
Dr. Ann Kirby

Lead Data Controller:
University College Cork
Health Service Executive

Title:
Cost Effectiveness of Electrochemotherapy in the Treatment Skin Cancer

Research Objective:
Electrochemotherapy (ECT) is a new procedure for skin cancer, that can be used when other treatments are unsuitable or don't work. This medical procedure uses both chemotherapy drugs, that kill cancer cells, and electric pulses. ECT is typically a day procedure, offering greater effectiveness than standard chemotherapy for certain patient groups, fewer side effects, and can be repeated. Cork University Hospital (CUH) is the only hospital in Ireland delivering ECT and take referrals from across Ireland. As demand grows, objective information is required to inform investment decisions, to ensure overall population health gain is maximised, given finite healthcare budgets. Despite ECT's growing recognition as an effective treatment, evidence on its cost effectiveness is sparse and there are no Irish studies on the cost-effectiveness of ECT in Ireland. This study will address this gap by conducting a cost effectiveness analysis based on patients attending CUH for the treatment of skin cancer.

Reason for Declaration:
A consent declaration is requested to process (collect, transfer, analysis) retrospective personal/pseudonymised data from 2019 to 2025; the applicant outlines that it is not practicable to seek consent from these participants and the small sample sizes means that requiring consent could result in numbers that prevent the required 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 the reasons for seeking a consent declaration. The rationale provided by the Applicant on why consent cannot be obtained were noted and accepted.
- It was the view of the HRCDC that there is a strong public interest case in this research.

Other:

- Based on the responses provided, it was not fully clear whether participant's name and address would be recorded in the separately held master list at CUH and/or the dataset to be transferred to UCC for analysis. It was discussed that the scope of the declaration would be clearly limited to the transfer and analysis of pseudonymised data without direct participant identifiers.
- It was discussed that the UCC student who will be on the research team must also complete appropriate GDPR and research integrity training.

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

Conditions Attached:

Condition 1. It is a condition that the summer student who will be a member of the research team must also complete appropriate data protection training.

Condition 2. Transparency measures and data agreements must be in place prior to the study commencing.

Reference ID:

26-012

Lead Applicant:

Dr Bairbre McNicholas

Lead Data Controller:

Galway University Hospital

HRCDC
Health Research Consent Declaration Committee

Title:

IrelandICUdb-Optimizing outcomes from weaning from invasive mechanical ventilation in Ireland: Establishing a Federated, FAIRAligned ICU Database for Benchmarking and Policy Translation

Research Objective:

The IrelandICUdb study aims to improve how mechanical ventilation is managed and weaned from critically ill ICU patients. Decisions about ventilator weaning vary between clinicians and institutions despite existing guidelines and can significantly affect patient outcomes. Using routinely collected ICU data from Galway University Hospital (2020 –2025), this project will develop a secure, research-grade database focused on ventilator weaning. The dataset will integrate high-frequency physiological data, ventilator settings, sedation measures, and pseudonymised clinical notes, alongside linked hospital records to track outcomes such as ventilation duration and ICU stay. Advanced data analysis and machine learning will be applied to better understand patterns associated with successful weaning. All patient information will be carefully and 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 weaning management in critically ill patients.

Reason for Declaration:

Explicit consent is not feasible given the retrospective design, large cohort size, and high-risk population. Many patients were critically unwell, some deceased, and others no longer contactable. Attempting consent would introduce substantial selection bias and compromise scientific validity and generalisability.

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, aims and objectives and why consent could not be obtained. The HRCDC noted and accepted why consent could not be obtained. It was the consensus of the HRCDC that there is strong public interest case in this research.

Data processing:

- The HRCDC noted and discussed the data to be processed in this study, including the use of structured and unstructured data from the records of patients who attended the Galway ICU, and that data would be extracted, anonymised and transferred for analysis on a phased basis.
- It was commented that unstructured data could be considered high-risk with regards re-identification of the participant, however the processes involved to fully anonymise this data were noted and seemed robust, including the involvement of human review. It was further commented that the scope of the consent declaration would clearly outline that

only anonymised data will be transferred from Galway University Hospital to the University of Galway for analysis.

Transparency measures:

- The HRCDC noted that a study poster will be provided in the ICU wating room; however, it was commented that this is a retrospective cohort study and therefore participants who are included in this research would likely not see this poster. It was therefore the view of the HRCDC that other transparency measures be considered including via public and patient involvement events.
- It was also the view of the HRCDC that the poster does not make it clear that participants can withdraw their data from this study up until the point it is anonymised for transfer to and analysis by the University of Galway on a phased basis; it was noted that the poster states that participants cannot be identified from the data and that they also have the right to request to 'opt-out' of 'future research'', which could be confusing.

Other:

- There was referenced made by the Applicant to this being a federated database, which would indicate that the data would be shared with other researchers. It was highlighted that the scope of the declaration will not cover the processing of personal/pseudonymised data in other studies or by unknown third parties.

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 June 2036, or until the personal data is deleted or fully anonymised, whichever occurs first.

Conditions Attached:

Condition 1. The study poster does not make it clear that participants can withdraw their data from this study up until the point it is anonymised for transfer to and analysis by the University of Galway (UoG). The Applicant must ensure that the poster is clear on how and when participants can withdraw from this study i.e., up to the point of anonymisation and transfer to UoG.

Recommendations:

Recommendation 1. The HRCDC noted the study poster that would be made available in the ICU waiting room. However, as this is a retrospective cohort study and therefore participants who are included in this research would likely not see this poster, other transparency measures aimed at those included in this study must be implemented; for example placing the poster in other appropriate settings, the use of websites and social media and transparency measures via appropriate public and patient involvement events. In addition, transparency measures must be in place prior to the study commencing.

Amendments

Reference ID:
19-016-AF2/AMD2

Lead Applicant:
Cara Martin

Lead Data Controller:
Trinity College Dublin

CervicalCheck

The National Screening Services

Title:
CERVIVA HPV Primary Screening Pilot Study (use of anonymised data for the SHIELD CC-2025 study)

Research Objective:
See HRCDC Meeting minutes of 4th September 2020.

Purpose of Amendment:
The CERVIVA study focused on examining different ways to screen for cervical cancer using HPV tests and using additional tests to look for specific markers that we know are linked to HPV infection.
This amendment request seeks to utilise anonymised data from CERVIVA in the SHIELD study which aims to create, test and validate the use of synthetic data from a cervical screening population; TCD who is a joint controller of CERVIVIA is the sole controller of the SHIELD study and no third parties are involved.

HRCDC Comments:
The purpose for seeking this amendment was outlined by the Secretariat; it was noted that while the original CERVIVA study had obtained pre-GDPR compliant consent, this consent did not reference the anonymisation of data for future studies. The HRCDC were asked if they approved the amendment. It was the consensus of the HRCDC that the amendment request should be approved.

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

Reference ID:
24-013-AF1/AMD1

Lead Applicant:
Prof Samuel Cromie

Lead Data Controller:
HSE
Trinity College Dublin

Title:
Learning from Incidents – a mixed-method study of incident reviews.

Research Objective:
See HRCDC Meeting minutes of 10th December 2024

Purpose of Amendment:
A request to remove Condition 1, relating to transparency measures, that was attached to the consent declaration. Due to the challenges they have experienced, it has not been possible to obtain the contact details of participants to meet condition 1.

HRCDC Comments:
The purpose for seeking this amendment was outlined by the Secretariat; specifically, it was outlined that the amendment is requested to remove condition 1 relating to transparency. The Secretariat also provided an overview of the history of this study and what they have a consent declaration for i.e., for Stage C of the study that focuses on the review of NIMS reports and that a declaration is not required for the study survey or interviews.
The HRCDC noted and discussed the applicant's replies, including with regards to the Applicant's view that it would not be appropriate or feasible to implement other alternative transparency measures. However, the HRCDC was of the view that alternative transparency measures to inform participants about the study, the use of their data and how to withdraw must be implemented.

HRCDC Decision:
The consensus of the HRCDC was that the amendment request should be approved to amend Condition 1 that was attached to the original consent declaration.

Conditions Attached:
Condition 1. While the study is no longer required to inform the participants about the use of their NIMS review reports via the originally planned survey invites, other alternative and appropriate transparency measures must be implemented to inform participants about this study, the use of their NIMS report data and how they can withdraw from the study. Options to consider may include information about this study on relevant HSE and TCD webpages, the HSE's National Incident Management website, or communication via the recently established HSE patient councils. Such measures must in place before the study commences the NIMS review.

Annual Reviews
The Secretariat has received 2 annual reviews in advance of the meeting which were deemed satisfactory:
- **Ref ID:** 21-007-AF1/COV (INPBS-COIVD 19)
- **Ref ID:** 24-002-AF1 (BONANZA)

Any Other Business
The HRCDC were reminded that there is no July meeting; the next meeting of the HRCDC is scheduled for 11th August.

The Chair closed the meeting