Health Research Consent
Declaration Committee

Minutes of the Meeting – APPROVED

Date: 28th April 2026

Location: Zoom videoconferencing

HRCDC Attendance:

Aideen Hartney
John Woods
Patricia O'Beirne
Paul Stynes
Aisling McMahon
Sarah Barnes Aabo
Antoinette O'Connor
Jim Blighe
Ross McMullan
Barbara Clyne
Fionnuala Gough
Brid Burke (Secretariat)
Jonny Barrett (Secretariat)
Caroline Byrne (Secretariat)

Quorum for Decisions

YES

New Applications – For consideration

Applicant: Professor Brian Walsh
Ref No.: 26-009
Title: CergenX Wave

Applicant: Dr Mairead O'Riordan
Ref No.: 26-006
Title: (AI4Life II) Artificial Intelligence for Life II

Applicant: Dr Jonathan Briody
Ref No.: 26-008
Title: Empowering Voices, Enhancing Outcomes: Co-creating an open-source health economic model for national decisions on care in Alzheimer's Disease and Dementia in Ireland

Opening

The Chair opened the meeting and welcomed the members.

Apologies

Susan Smith, Evelyn Mahon, Jonathan Briody, Mary Tumelty were absent from the meeting.

Disclosure of Interest

Aisling McMahon (AMcM) declared a conflict of interest with regards the amendments that were approved by the Chairperson since the previous meeting, 25-001-AF1/AMD2 and 25-011-AF1/AMD4. As these amendments have already been approved AMcM's disclosure of interest was noted for record by the HRCDC.

Minutes of the last meeting

Draft minutes of 24th March 2026 were circulated in advance of the meeting and were approved by the HRCDC.

Chairperson Approvals

- **25-001-AF1/AMD2 (Acute Kidney Injury – Epidemiology in ICU Patients 2 (AKI-EPI 2):** the HRCDC were informed that amendment request 25-001-AF1/AMD2 was approved via the chairperson approval process. The amendment covers the addition of Tallaght University Hospital as a new study site.
- **25-011-AF1/AMD4 (EXTUBE):** the HRCDC were informed that amendment request 25-011-AF1/AMD4 was approved via the chairperson approval process. The amendment covers the addition of University Hospital Waterford as a new study site.

New Applications

Reference ID:

26-009

Lead Applicant:

Professor Brian Walsh

Lead Data Controller:

CergenX Limited

Title:

CergenX Wave

Research Objective:

Neonatal encephalopathy (NE) is the term used when a baby shows signs of possible abnormal brain function. A common cause is lack of oxygen, asphyxia, to the baby's brain during pregnancy or around the time of birth. A combination of NE with asphyxia is called hypoxic-ischaemic encephalopathy (HIE). A standardised neurological examination, the modified Sarnat examination, can be used to assess babies with asphyxia. This helps decide if a baby's brain function is normal or abnormal and guide their care. If their examination is moderately or severely abnormal, treatment called therapeutic hypothermia can be started. This helps to reduce the risk of brain injury but must be started within 6 hours of birth. This study will assess how a newly developed software device, compares to the standardised neurological examination, performed by the neonatology team.

Reason for Declaration:

The consent declaration is limited to the collection and storage of personal/pseudonymised data only, prior to obtaining deferred explicit consent within 30 hours or before the second assessment; deferred informed consent will be implemented because of the urgency to complete the examination and the sensitivity of the situation for the parents of the newborns immediately after birth. While the data will be collected and stored by the study, it will not be accessed or analysed by the data controller or analysed by UCC prior to obtaining deferred consent; if deferred consent is not obtained within 30 hours then all the data collected for the study will be fully deleted.

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 noted that the declaration is only required to collect the 10-minute EEG recordings which is stored but not further analysed prior to obtaining deferred consent; it was also highlighted that no other clinical data is collected by the study prior to consent and that the study findings would not influence the patient's care.
- Following extensive discussions, the HRCDC accepted why consent could not be obtained prior to study enrolment and data processing and it was also of the view that there is a strong public interest case in this research.

Consent process:

- During the HRCDC's discussions, it was highlighted that if the baby will receive an EEG for clinical purposes, that it should also be verbally discussed with the parents that EEG recordings will also be taken for the purpose of this study, with formal written consent for the study obtained at a later point; the rationale for this verbal discussion is to prevent confusion that may arise on the use of the clinical EEG versus the EEG recording for this study, particularly as this issue under study is designated as a notifiable condition.
- The HRCDC noted and welcomed this verbal discussion with parents and was of the view that such a discussion should occur with all parents of eligible participants prior to study enrolment, where practicable, regardless of whether they have a clinical EEG or not.

Study information leaflets and transparency measures:

- The HRCDC commented that the study information leaflet was quite lengthy and technical and could be simplified for the benefit of the participants; it was commented that a one-page study summary or infographic could accompany the consent documents.
- It was noted that the information leaflet and consent forms refer to the future use of data, but that limited detail was provided on this in the consent documents; it was discussed that broad consent for future research is allowed but not blanket consent.
- The HRCDC also noted the option in the maternal consent form that asks for permission for the research ethics committee and sponsor to look at relevant sections of the participant's medical notes; it was queried why the REC and sponsor would need to have such access. It was discussed that this is likely related to auditing and monitoring as well as for regulatory purposes; it was commented that this should be clarified in the consenting documents.
- It was discussed that the information leaflets and consent form could also list the options that will be available on what happens the data if the parent later decides they want to withdraw their consent. In addition, it was further discussed that it could be made clearer in the study information leaflet that this study is being conducted by a commercial entity which is a spin-off from UCC and explain what a spin-off company is.
- It was also commented that information posters about this study could be placed in the hospital so that parents attending CUMH over the course of their pregnancy may see this information.

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. Prior to obtaining written consent within 30 hours, the study must have an initial verbal discussion with the parent(s) of all the eligible study participants, informing them that their baby will be enrolled into this study and that EEG recordings will be taken, with further information to be provided and reviewed by the parents in advance of explicit consent being granted or denied.

Condition 2. The required data agreements and arrangements must be in place prior to the study commencing.

HRCDC Recommendations:

Recommendation 1. The Applicant is requested to consider the following with regards the consent documentation:

- The study information leaflet is considered quite lengthy and technical and could be simplified for the benefit of the participants; consideration could be given to the use of a one-page study summary or infographic that would accompany the consent documents
- The information leaflet and consent forms refer to the future use of data; however limited detail is provided on what such future research may involve such as the type of research or parties involved. The Applicant should review these sections and provide more detail on future research (note: under the GDPR broad consent for future research is allowed but not blanket consent)
- The maternal consent form asks for permission for the research ethics committee and sponsor to look at relevant sections of the participant's medical notes; more detail should be provided to the participant on why this is requested e.g., if it is related to auditing, monitoring or regulatory purposes.
- The information leaflet and consent form could list the options that will be available to the participant on what happens the data if they were to later withdraw their consent.
- It could be made clearer in the study information leaflet that this study is being conducted by a commercial entity which is a spin-off from UCC and outline in more detail what a spin-off company is.

Recommendation 2. Information posters about this study could be placed in the hospital so that parents attending CUMH over the course of their pregnancy may see and learn more about this study in advance of their labour.

Reference ID:
26-006

Lead Applicant:
Dr Mairead O'Riordan

Lead Data Controller:
University College Cork and Health Service Executive

Title:
(AI4Life II) Artificial Intelligence for Life II

Research Objective:
During labour, babies are usually monitored using a system called cardiotocography (CTG), which tracks the baby's heart rate and the mother's contractions. CTG is used in most labours, but it is often difficult to interpret and can give unclear or misleading results. This can lead to unnecessary interventions such as caesarean sections, while still not reliably identifying the small number of babies who may be at risk of brain injury caused by a lack of oxygen (known as hypoxic-ischaemic encephalopathy, or HIE). Since HIE is rare, large amounts of data are needed to understand which patterns on CTG truly indicate risk. Earlier research has shown that artificial intelligence (AI) may be able to interpret CTG recordings more accurately than humans alone.

The aim of this study is to develop an AI-based tool that can help clinicians identify, in real time, when a baby may be compromised so they can intervene early. This may reduce the risk of brain injury, improve outcomes for babies and families, and reduce unnecessary interventions for mothers. The project will use a large set of electronic health records and CTG data from Cork University Maternity Hospital (CUMH) to build and test this new system.

Reason for Declaration:

HIE occurs in approximately 2-3 per 1,000 births; therefore, tens of thousands of records are required to obtain a meaningful number of cases for model development. Attempting to contact every eligible mother from the study period is not feasible, and differential consent rates would introduce bias and undermine the validity and generalisability of the findings. The consent declaration is therefore requested to process the retrospective personal data of participants without their explicit consent.

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 noted and discussed the objectives of the study, including that this is a proof-of-concept development and training of an AI model to support clinical decision making, that may in the future expand into the development of a regulated medical device.
- It was noted that retrospective data from over 40,000 participants would be included and that it would not be practically possible to obtain consent from such a large cohort.
- On balance, it was the view of the HRCDC that there is a strong public interest case in this research.

Transparency measures and Public and Patient Involvement:

- It was commented that this study involves a strong level of PPI engagement.
- The HRCDC also noted the study poster that will be disseminated in the hospitals and that a public awareness campaign using social media and study website/webpage will also be rolled out.
- It was commented that the information presented on this poster could be simplified so that it is easier to read. In addition, it was discussed that the poster and the other transparency measures could/should more clearly state and focus on that if an individual gave birth in CUMH between 2019-2025 then their data will be extracted by UCC and used in this study. It was further discussed that the transparency measures, including the poster, should directly note that a participant can request for their data to be deleted from the study prior to anonymisation; not just that they can opt-out.
- It was queried whether the poster could be made more accessible for participants who do not have English as their first language.

Other:

- It was noted that the AI tool to be developed is an ‘in-house’ UCC tool with no involvement of, or sharing of data with, third parties as part of its development.

- It was queried by the HRCDC why this extent and type of data is required; it was discussed that the training and development of the AI tool requires a significant amount of data to help ensure its accuracy. This was noted by the HRCDC and it was discussed that decision letter should remind the Applicant to have due regard to the GDPR principle of data minimisation.
- The HRCDC noted that the data security measures in place for this study appeared satisfactory.

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 2029, or until the personal data is deleted or fully anonymised, whichever occurs first.

Conditions Attached:

Condition 1. The transparency measures must be in place prior to the commencement of the study; this includes the study poster and the information campaign that is to be rolled out via social media and the website, as per the Applicant’s responses to the HRCDC.

Condition 2. The required data agreements and arrangements must be in place prior to the study commencing; this includes joint controller arrangements and data transfer agreements.

HRCDC Recommendations:

Recommendation 1.

- It is recommended that consideration should be given to simplifying the study poster so that it is easier to read; specifically the poster could more clearly state and focus on the key point that if an individual gave birth in CUMH between 2019-2025 then their data will be extracted by UCC and used in this study and more directly state that a participant can request for their data to be deleted from the study prior to anonymisation, not just that they can opt-out; the other study transparency measures should also provide this detail.
- As many participants to be included in this study may not have English as a first language, the Applicant is also recommended to explore if the study poster could be made more accessible to such cohorts; for example, the use of a QR code link to translated information.

Reference ID:

26-008

Lead Applicant:

Dr. Jonathan Briody

Lead Data Controller:

Royal College of Surgeons in Ireland

Title:

Empowering Voices, Enhancing Outcomes: Co-creating an open-source health economic model for national decisions on care in Alzheimer's Disease and Dementia in Ireland

Research Objective:

Alzheimer's disease and dementia have a major impact on people living with the condition, their families, and the health system in Ireland. Decisions about services and treatments are often informed by economic models; however, these models do not always reflect the real-life experiences, costs, and priorities of those affected. This study aims to work directly with people living with Alzheimer's disease or dementia (PwAD) and with family supporters to better understand what matters most to them. Through a series of three workshops, participants will share their experiences related to costs, quality of life, and preferences for interventions. The information gathered will be used to develop a publicly available tool to help decision-makers better understand the true impact of dementia care in Ireland. By incorporating lived experience, this research seeks to support fairer and more informed decisions about dementia services and supports.

Reason for Declaration:

To process the personal data of participants who lack decision-making capacity.

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 commented that this is a low-risk study that involves voluntary workshops with participants and their families. On balance, it was the view of the HRCDC that there is a strong public interest case in this research. It was also commented that involving people with dementia in the research activities, including those who lack or have reduced capacity, is very important and was welcomed.

Consent process:

- It was noted that the study will be implementing a process consent procedure whereby the capacity of the participant with dementia and their ability to provide consent will be assessed throughout the study.

Other:

- It was commented that the level of public and patient involvement in this research is strong, noting that there is a PPI advisory panel and that findings will be disseminated at public engagement events.
- It was noted that the study questionnaires will be gathered via SurveyMonkey; it was commented that the Applicant should ensure that this platform provides a GDPR compliant and secure method for collecting he questionnaire data and that, if necessary, data agreements should be in place with this provider.

- It was commented that the audio recordings of interviews/workshops should be deleted as soon as possible.
- The HRCDC highlighted that the declaration will not include the sharing/uploading of personal/pseudonymised data to an open archive; it must therefore be ensured that only fully anonymised data is provided to such an archive.

HRCDC Decision:

The consensus of the HRCDC was that a Consent Declaration should be made.

Duration of Declaration:

The consent declaration is made until 30th September 2029, or until the personal data is deleted or fully anonymised, whichever occurs first.

HRCDC Recommendations:

Recommendation 1. It must be ensured that the SurveyMonkey platform used in this study provides a GDPR compliant and secure method for collecting the questionnaire data.

Annual Reviews

The Secretariat has received 4 annual reviews in advance of the meeting which were deemed satisfactory:

- **Ref ID:** 19-027-AF3 (Identification of predictive and prognostic biomarkers in triple negative breast cancer)
- **Ref ID:** 19-086-AF1 (Sepsis Immunosuppression in Critically Ill Patients)
- **Ref ID:** 23-002-AF1 (EAGER)
- **Ref ID:** 24-009-AF1 (INCLUDE)

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 the 2025 HRCDC Annual Report was submitted to the Department of Health.
- The Chairperson reminded the HRCDC that the next HRCDC meeting on 25th May will be held in-person.
- The Chairperson informed the HRCDC that today was the final meeting for PPI committee member Patricia O’Beirne, who is stepping down from the HRCDC following the end of her first term in early May. The Chairperson thanked Patrica for all her work and commitment whilst on the HRCDC and wished her the best for the future.
- The HRCDC were asked to circulate the expression of interest notification to their networks that the Committee is seeking a new PPI member.

The Chair closed the meeting