

Minutes of the Meeting – APPROVED

Date: 12th November 2024

Location: The Health Research Board

HRCDC Attendance:

Brigid McManus
Evelyn Mahon
Alyson Bailey
Sheelah Connolly
Aideen Hartney
Dan Rea
Mary Tumelty
Patricia O'Beirne
Paul Stynes
Aisling McMahon
Brid Burke (Secretariat)
Jonny Barrett (Secretariat)
Caroline Byrne (Secretariat)

Quorum for Decisions

YES

New Applications – For consideration

Applicant: Dr Alain Cariou

Ref No.: 24-010-AF1

Title: Study about the various prognostic scores calculated upon admission to the intensive care unit for patients admitted after cardiac arrest (AfterROSC2).

Applicant: Dr Eilish Burke

Ref No.: 24-011-AF1

Title: Feasibility Assessment of the Echolight Bone Screening Device for Individuals with Intellectual disabilities.

Applicant: Dr Andrea Haren

Ref No.: 24-012-AF1

Title: Threshold for Platelets study (T4P)

Opening

The Chair opened the meeting and welcomed the members. The Chair also welcomed back Mary Tumelty to the HRCDC.

Apologies

Simon Furney, Zubair Kabir, Cornelius Cooney, Susan Smith, Barry Lyons, Kathy Brickell, John Woods.

Disclosure of Interest

Aisling McMahon (AMcM) declared an interest in the Chairperson approved amendment (23-024-AF1/AMD1) and in new application 24-012-AF1; AMcM declared she collaborates with the Principal Investigator of these studies but is not directly involved in either of these research projects. It was agreed that AMcM would not need to excuse herself from the meeting for these applications, however AMcM would be asked to speak last and would not participate in any vote on the final HRCDC decision, should this be necessary.

Minutes of the last meeting

Draft minutes of 8th October 2024 were circulated in advance of the meeting and were approved by the HRCDC.

Matters arising

- The HRCDC were informed that the Conflict of Interest Policy was circulated following the discussion at the October 2024 meeting and that, following some additional feedback, it has been updated. The latest version of the policy was circulated in advance of the November meeting and no further comments or feedback were provided.
- The Secretariat highlighted that the expression of interest (EOI) campaign for new HRCDC members has been launched and is open until 29th November 2024. The HRCDC were asked to share the EOI links available on the HRCDC website and it's LinkedIn page to their networks. It was discussed that a panel to consider the submitted expression of interests is being finalised and will convene before the end of 2024.
- Following responses from the HRCDC members, the second in-person meeting in 2025 will be held in December rather than November.

Chairperson Approvals

Applicant: Professor Jochen Prehn

Ref No.: 19-031-AF2/AMD2

Title: Bowel Disease Bio-Resource Development Identification of Potential Biomarkers for Bowel Disease

The HRCDC were informed that amendment request 19-031-AF2/AMD2 was approved via the Chairperson approval process. The amendment covers the extension of the consent declaration until 6th October 2027

Applicant: Professor Alistair Nichol

Ref No.: 23-024-AF1/AMD1

Title: Platform of Randomized Adaptive Clinical Trials in Critical Illness (PRACTICAL) Randomized Controlled Trial - Invasive Mechanical Ventilation domain”

The HRCDC were informed that amendment request 23-024-AF1/AMD1 was approved via the Chairperson approval process. The amendment covers the addition of the Mater Hospital as new site and data processor in the study.

New Applications

Reference ID:
24-010-AF1

Lead Applicant:
Pr Alain Cariou

Lead Data Controller:
Association AfterROSC

Title:
Study about the various prognostic scores calculated upon admission to the intensive care unit for patients admitted after cardiac arrest (AfterROSC2).

Research Objective:

This study is a Non-Interventional, Multicentre, Observational, Uncontrolled and Prospective Research study. The study focuses on patients admitted to the intensive care Unit (ICU) after an Out of Hospital Cardiac Arrest (OOHCA). The main complication for a patient after a cardiac arrest is the anoxo-ischemic encephalopathy that could induce a severe neurological disability or vegetative state. The main goal of the study is to determine the diagnostic performance and the clinical utility of various prognostication scores after an OOHCA in ICU to prognose the neurological outcome. The study is also designed to describe the epidemiological characteristic of the patients included in the study. The practices of the centres will not be modified; the doctors in charge of the patients will collect clinical and biological data on a daily basis. These data are already collected in all OOHCA coming into the ICU. The outcome and neurological outcome will be also collected after the ICU stay.

Reason for Declaration:

Participants enrolled onto this study will be in a coma upon enrolment due to their out-of-hospital cardiac arrest, and therefore it will not be possible to obtain their explicit consent. The consent declaration is therefore requested to process their personal data without their explicit consent (i.e., collection, transfer, analysis).

HRCDC Comments:

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

Reference ID:
24-011-AF1

Lead Applicant:

Dr Eilish Burke

Lead Data Controller:

Trinity College Dublin

Title:

Feasibility Assessment of the Echolight Bone Screening Device for Individuals with Intellectual disabilities

Research Objective:

This project evaluates the feasibility of a new bone health assessment system called Echolight for people with intellectual disabilities, which uses advanced technology to measure bone density without radiation. Unlike the conventional DXA scanning, Echolight is portable, more comfortable for patients and it doesn't require them to lie in an exact position for long periods of time.

This study will involve 80 participants with varying levels of intellectual disabilities inclusive of mild, moderate, severe and profound. Inclusion of all levels of ability is critical to see how well this new method works for all individuals within the intellectual disability population and to achieve a comprehensive demographic analysis which aims to understand the correlation between intellectual disability levels and bone health issues, providing nuanced insights into the specific needs of various subgroups within the intellectual disability population. By exploring the feasibility of this technology, the study aims to improve access to early bone health assessments and promote inclusivity in healthcare. It is anticipated that approximately 20 individuals (the purpose of this application) with a severe/profound level of intellectual disability will be invited to participate in the project, whom by nature of their diagnosis may not have the capacity to consent to participate independently. To allow for such occurrences, the application of the consent declaration would be required for this specific population cohort.

Reason for Declaration:

The study involves the processing of personal data of participants with intellectual disability recruited from multiple sites in Ireland (mild, moderate, severe and profound disability). It is anticipated that approximately 20 individuals with a severe/profound level of intellectual disability will be invited to participate in the project, whom by nature of their diagnosis may not have the capacity to consent to participate independently. The consent declaration is limited to processing the personal data (collection, transfer, analysis, storage.) of approximately 20 individuals with a severe/profound level of intellectual disability who will be unable to provide explicit consent.

HRCDC Comments:

The Chair requested each HRCDC member 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 is made, subject to conditions attached.

Public interest case:

- It was the view of the HRCDC that there is a strong public interest case in this research. It was commented that the participant cohorts involved are often overlooked or understudied and that this feasibility study could help to improve their care and that the device may have other applications in the future.

Consent/assent process:

- The HRCDC discussed the consent/assent process within the study, including the use of a gatekeeper to inform participants about this study. It was also noted that in some cases a person's support or key worker may be asked to provide proxy assent if a participant has no living family member. The HRCDC was of the view that the consent/assent process was reasonable and provided appropriate safeguards for the participant but that it was important that the participant or their proxy should not feel under pressure to consent or assent to this study.
- As a further potential safeguard, the HRCDC considered that in cases where a key or support worker is providing proxy assent, that the signature from a second appropriate person might be considered by the project team.
- It was commented that the study should check if the participants with an intellectual disability have decision support agreements in place as per the Assisted Decision-Making Act.

Other:

- The HRCDC commented that the easy-to-read study information leaflets were of a high standard. It was also highlighted that proxy assent will be requested using these easy-to-read documents.
- It was noted that participant data with regards previous DXA scans may be obtained from their medical records held by the residential service. It was commented that the data agreements for this study should cover this data, if it is collected.
- The data security arrangements in place, including the use of encrypted and stored laptops, network storage of data and that the EchoLight device does not store personal data on the device was noted and discussed.
- The HRCDC also noted and agreed that confirmation of full REC approval for the Wexford site is required and that data agreements/arrangements are put in place, prior to any processing of data for those individuals lacking capacity to consent.

HRCDC Decision:

The consensus of the HRCDC was that a Consent Declaration is made, subject to conditions attached.

Duration of Declaration:

The consent declaration is made on 12th November 2024 and is valid until 28th February 2032, or until the personal data is deleted or fully anonymised, whichever occurs first.

Conditions Attached:

Condition 1. The Applicant must submit the research ethics committee approval for the Wexford site, once available. The consent declaration will not cover the Wexford site until such REC approval has been obtained.

Condition 2. The required data agreements/arrangements must be in place prior to the transfer of data between the parties.

HRCDC Recommendations:

Recommendation 1. Further to condition 2, the Applicant is recommended to ensure that the data agreements/arrangements for this study covers the collection and processing of data obtained from the participants medical records held by the residential service (i.e., previous DXA scan results).

Recommendation 2. In cases where a key or support worker is providing proxy assent, the project team is asked to consider if the signature from a second appropriate person might be sought as a further potential safeguard.

Reference ID:

24-012-AF1

Lead Applicant:

Dr Andrea Haren

Lead Data Controller:

University of Oxford

Title:

Threshold for Platelets study (T4P)

Research Objective:

Platelet transfusions are commonly given in Intensive Care Units (ICU) as patients in ICU often have fewer platelets in their blood than healthy people. In ICUs, platelet transfusions are mainly given to try and prevent bleeding, for example during a procedure. However, platelet transfusions also have risks, such as allergic reactions. We do not know to what level the platelet count should fall (the best transfusion threshold) before the benefits of giving platelet transfusions outweigh the risks. It is intended to carry out a large clinical trial to find out the best transfusion threshold below which platelet transfusions should be given to patients who need an invasive procedure in ICU. Patients will become eligible for the study during a time critical intervention and are likely to lack capacity at the time of randomisation, therefore, a consent declaration is sought

Reason for Declaration:

Participants are likely to lack decision-making capacity to provide explicit consent at the point of enrolment. Accordingly, a consent declaration is requested to process the personal/pseudonymised data (collection, transfer, analysis, storage) of participants who lack capacity.

HRCDC Comments:

The Chair requested each HRCDC member 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, subject to conditions attached, should be made.

Public interest case:

- It was the view of the HRCDC that there is a strong public interest case in this research given the purpose of the study and that platelets are a valuable and important resource in medical treatment.

Public and patient involvement:

- It was noted that a co-investigator on this trial is a PPI representative who is actively involved in contributing to the trial design, procedures and consent process. It was further noted that this study will be discussed at the next available ICC-CTN PPI meeting.
- The HRCDC acknowledged and welcomed the PPI involvement as a co-investigator; with regards plans to discuss the study at the next available ICC-CTN meeting, it was commented that researchers should ideally aim to undertake such PPI engagement prior to the study commencing rather than potentially after the study commences; it was commented that this would help to maximise PPI input in the research. It was also discussed that where non-Irish PPI has been undertaken, that details on this should be provided, if applicable.

Other:

- It was noted that pseudonymised data from Ireland will be transferred to the parties in the UK and that the data will be encrypted for transferred via a secure platform.
- It was commented that the study information leaflets were of a high standard, providing a clear explanation of the study and the randomisation process.
- The HRCDC queried and discussed the transfer of NOCA data to the UK which will also then be used for this separate study; it was highlighted that NOCA data is already transferred to the UK for separate clinical audit purposes but that they wish to further process some of the NOCA data for this research trial.
- The HRCDC queried the reference to 'substitute decision maker' in the application; the Secretariat highlighted the responses from the Applicant that this does not refer to an independent doctor providing proxy assent but someone whom the family member or friend might refer to or engage with for the proxy assent process.
- The HRCDC also noted and agreed that clarity on the scope of the consent declaration made and that data agreements/arrangements are to be put in place should be noted in the decision letter.

HRCDC Decision:

The consensus of the HRCDC was that a Consent Declaration, subject to conditions attached, should be made.

Duration of Declaration:

The consent declaration is made until 31st December 2025 and for 10 years data archiving thereafter until 31st December 2035.

Conditions Attached:

Condition. The required data agreements/arrangements must be in place with the parties prior to the transfer/sharing of the data.

HRCDC Meeting Procedures

As agreed previously, in the event of a HRCDC decision to request further information, the Applicant could join a subsequent HRCDC meeting and address outstanding queries as needed. A proposed outline of this process was presented to the committee.

It was agreed that the Standard Operating Procedures for the HRCDC would be updated with the suggested changes. It was also agreed that the attendance at the meeting is entirely optional for the applicant. Also, the applicant may request to join a HRCDC meeting, in the event of a HRCDC decision to request further information, in relation to their application.

The applicant will be made aware that this portion of the HRCDC meeting cannot be recorded and a maximum of two people, representing the applicant will be in attendance.

Also agreed at the October meeting, the Secretariat presented a proposed procedure that involves a lead and secondary reviewer assigned to each application, in advance of any committee meeting. This was discussed and it was agreed that a pilot of this process would take place for the December HRCDC meeting.

In advance of this the Secretariat will circulate a list of headings under which the reviewers should consider the assigned application, and this can then be used by the member as a basis for discussion at the meeting itself.

Annual Reviews

The Secretariat has received 6 annual reviews in advance of the meeting which were deemed satisfactory:

- **Ref ID:** 19-026-AF2 (MAMMI Study)
- **Ref ID:** 19-003-AF2 (TEAM study)
- **Ref ID:** 19-015-AF2 (IDS-TILDA)
- **Ref ID:** 23-015-AF1 (Investigation into the use of IL-1, I-CAM1 and/or E-Selectin in identifying the effects of infection in placental tissue)
- **Ref ID:** 20-004-AF1 (Outcomes for Older People with Cognitive Impairment Attending the Emergency Department)
- **Ref ID:** 23-020-AF1 (Capture-Recapture Study to Estimate the Prevalence of Problem-Opioid Use in Ireland (2020 – 2022))

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 CSO Health Research Data Centre was launched on the 1st November last. It is envisaged the HRCDC will receive applications in the near future concerning health research studies, utilising the data made available through this data centre. The CSO Health Data Centre are invited to give a presentation to the HRCDC at the next meeting in December.

The Chairperson closed the meeting