HRCDC
Health Research Consent Declaration Committee

# 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)

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## 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 sever 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 HRCDC noted that ethics approval had been granted for the study where the design, methodology and ethical aspects of the study, including consent protocols are considered. Only studies that have ethical approval, or provisional ethical approval, can be considered by the HRCDC to consider if the public interest outweighs the requirement for explicit consent.

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 formal decision should be deferred pending receipt of further information.

### Public interest case:

- The HRCDC was of the view that this study is low risk as it involves the processing of personal data that is already collected/generated as part of care and treatment.
- It was the consensus of the HRCDC that there is a public interest case in this study; however, it was also the consensus of the HRCDC that while it is agreed in principle to making a consent declaration, improvements to the study consent and assent documentation are necessary and must be addressed before a final decision can be made.

### Study information leaflets and assent/consent forms:

- It was the view of the HRCDC that the study information leaflets, and assent/consent forms would, from a patient or family member perspective, be very difficult to read. The HRCDC considered that the language throughout the leaflet was unclear and the HRCDC was also of the view that the description of the study uses quite technical and medical language; therefore, the purpose of the study may not be clear to the patient or proxy.
- The HRCDC also noted that the PPI feedback submitted by the Applicant with their application referenced improvements that should be made to the study information leaflets and assent/consent forms, including explaining the technical and medical terms and including more lay-person descriptions. Based on the versions of the documents submitted by the Applicant, the HRCDC commented that this feedback does not appear to have been taken on board yet.
- It was also commented that the references made to the HRCDC in the study documents were not accurate in all case, for example referring to patients who lack capacity being included in the study with proxy assent with the ‘agreement’ of the HRCDC; such references are not an accurate description of the role of the HRCDC.
- The HRCDC also agreed with the Secretariat observations on other changes to the PILs that should be addressed.
- It was the consensus of the HRCDC that the study documentation requires further review and revision by the Applicant to take on board the PPI feedback, to describe the study to patients and their families in a clearer, less technical manner and address other points that have been raised.

### Other:

- The HRCDC queried the total number of participants who are to be included in this study from France and Ireland. It was highlighted that the Applicant states that approximately 150 participants from Ireland will be included in this study and that the survival rate is expected to be approximately 30%; therefore, up to 45 patients will need to be informed about the study and contacted during the follow-up study period.
- The HRCDC queried what will happen the data of those included in the study but who do not survive. It was highlighted that participants will not be enrolled into the study unless proxy assent is first obtained within 48 hours. The Secretariat also highlighted that the

data of deceased persons falls outside the scope of the GDPR and Health Research Regulations.

- It was noted that the proxy to provide assent will be identified mostly by the patient themselves or as the named contact for the patient. It commented that the study should ensure that the proxy understands the will and preference of the participant.
- It was commented that some further PPI engagement, including with ICUSteps, could be considered.
- It was further commented that information about this study, such as the dissemination of findings, could be provided on appropriate websites or shared with relevant organisations; it was discussed that patients are unlikely to read journal articles where the results will be published.
- The data security measures to be implemented were noted and it was discussed that they seemed appropriate.

## HRCDC Decision:

The consensus of the HRCDC was that a formal decision would be deferred pending receipt of further information.

## Request for further information:

The HRCDC reviewed the consent declaration and supporting documentation, including the study information and assent/consent forms that will be provided to the patient or their proxy. It is the view of the HRCDC that the Applicant is required to address several important matters with regards these documents and to resubmit them before the application can be considered further by the HRCDC and before a final decision can be made:

- From the perspective of the patient or their proxy, the versions of the study documentation submitted to the HRCDC would be very difficult to read/follow. In addition, the HRCDC was of the view that the description of the study uses quite technical and medical language and therefore the purpose of the study may not be clear to the patient or proxy. Linked to this, the HRCDC also commented that the feedback provided from the PPI representatives that was submitted with this application, also highlighted areas of the study documentation that need to be addressed, including the use of lay person rather than technical language; however, this PPI feedback has not been taken on board yet.
  The Applicant must take on board the PPI feedback and review and revise the study documentation to address the use of overly technical/medical language and utilise more lay-person language for the benefit of patients and their proxies.
- The study documents also refer to patients who lack capacity being included in the study with proxy assent with the ‘agreement’ of the HRCDC; such references are not an accurate description of the role of the HRCDC and should be removed.
- It should be clear in the documents that the sole data controller of the study is Association AfterROSC and, in line with the responses provided to the HRCDC, that the personal/pseudonymised data collected will be fully anonymised at the end of the study and the data archiving period of 15 years. ***Note:*** currently the documents are not clear on this matter, referring to archiving data for 15 years and then it being fully deleted in one section while also stating elsewhere it will be anonymised.

- On the further processing of *personal/pseudonymised* data in future research, the option provided in the proxy assent form should be updated to include the following bolded text: *'I give permission for the personal information of my relative to be stored for possible future research related to the current study: post cardiac arrest care in ICU and neuro-prognostication after a cardiac arrest followed by a coma without further consent being required but only if the research is approved by a Research Ethics Committee* ***and subject to approval from the Health Research Consent Declaration Committee, if applicable'*****. Note:** this additional text reflects that the scope of a consent declaration does not cover the further processing of personal/pseudonymised data in unknown future studies and that further HRCDC approval will likely be needed for future studies.

## 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 where 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**