

# Minutes of the Meeting –APPROVED

**Date:**

8th October 2024

**Location:**

Zoom videoconference

**HRCDC Attendance:**

Brigid McManus  
Evelyn Mahon  
Alyson Bailey  
Kathy Brickell  
Sheelah Connolly  
Simon Furney  
Aideen Hartney  
Zubair Kabir  
Dan Rea  
John Woods  
Patricia O’Beirne  
Susan Smith  
Paul Stynes  
Aisling McMahon  
Brid Burke (Secretariat)  
Jonny Barrett (Secretariat)  
Caroline Byrne (Secretariat)

**Quorum for Decisions**

**YES**

**New Amendments - For Consideration**

**Applicant:** Prof Alistair Nichol

**Ref No.:** 21-002-AF1/AMD2

**Title:** The Mega Randomised Registry Trial Comparing Conservative vs. Liberal OXygenation Targets (Mega-ROX)

**Opening**

The Chair opened the meeting and welcomed the members.

**Apologies**

Cornelius Cooney, Mary Tumelty (Maternity leave), Barry Lyons

## Disclosure of Interest

Kathy Brickell (KB) and Aisling McMahon (AMcM) declared their interest in amendment application 21-002-AF1/AMD2 (MEGA-ROX). Both KB and AMcM were absent during the meeting when this application was considered.

## Minutes of the last meeting

Draft minutes of 13<sup>th</sup> August 2024 were circulated in advance of the meeting and were approved by the HRCDC, subject to correcting minor typos and formatting errors.

## Chairperson Approvals

- **Ref ID: 21-003-AF1/AMD3.** The HRCDC were informed that amendment request 21-003-AF1/AMD3 was approved via the Chairperson approval process. The amendment covers the extension of the consent declaration until 31<sup>st</sup> May 2026. An update from the study was also provided to the HRCDC informing them that consent will be sought for the 2021-2022 participant cohort.
- **Ref ID: 21-011-AF1-CSO/AMD3.** The HRCDC were informed that amendment request 21-011-AF1-CSO/AMD3 was approved via the Chairperson approval process. The amendment covers the extension of the consent declaration until 31<sup>st</sup> August 2025.
- **Ref ID: 24-004-AF1/AMD1.** The HRCDC were informed that amendment request 24-004-AF1/AMD1 was approved via the Chairperson approval process. The amendment covers the extension of the consent declaration to 31<sup>st</sup> March 2025.

## New Amendments

Reference ID:

21-002-AF1/AMD2

Lead Applicant:

Prof Alistair Nichol

Lead Data Controller:

Medical Research Institute of New Zealand (MRINZ)

Title:

The Mega Randomised Registry Trial Comparing Conservative vs. Liberal OXygenation Targets (Mega-ROX)

Research Objective:

See HRCDC Meeting minutes of 13<sup>th</sup> April 2021.

Purpose of Amendment:

- To add the Mater Hospital (MMUH) as a new site/data processor
- An update to the study protocol that reflects the collection of additional baseline data for both new prospective participants and participants who have already been enrolled into the study.

- To continue to process the participant's personal data if they are withdrawn from the study, where assent for such continued processing is provided by the proxy; the original consent declaration application noted that data would be deleted upon withdrawal.

#### **HRCDC Comments:**

The Chairperson introduced the amendment and highlighted what is covered by the original consent declaration that was made and what is requested in this amendment. The Chairperson requested each HRCDC member to indicate whether the amendment should be approved. After discussing the application, and based on the information provided by the Applicant, it was the consensus of the HRCDC that the amendment request should be approved.

#### **Additional data**

- The HRCDC noted the additional data that the study wishes to collect and process. It was discussed that the additional data to be collected was reasonable in the context of this study and that it did not involve collecting data points beyond the data already generated as part of standard patient care and treatment.

#### **Study Information Leaflets**

- Based on the information submitted, the applicant is commended for addressing the previous conditions attached to this consent declaration relating to amendments that were to be made to the MEGA-ROX study information leaflets and assent/consent forms.
- It was noted that in the event the assent/consent documents were to be revised by the study team in the future, that some further amendments could be made for the benefit of the participants. Consideration could be given to amending some of the technical language describing the difference between conservative and liberal oxygen so that it is provided in more lay-persons language, in so far as is possible. It was also noted that the wording of the section outlining the lawful basis for data processing could be confusing to some readers and that, if the opportunity arises, amendments to this text could be considered.
- It was further commented that the information leaflets reference that there may be limitations to the participant's data rights, for example the leaflets state: 'However, in certain circumstances, these rights may be restricted' and that rights can be exercised 'unless the request would make it impossible or very difficult to conduct the research'. The HRCDC commented that if the leaflets were to be updated in the future, it may be useful to outline some further detail or examples on what circumstances may result in data rights being restricted.

#### **Other**

- The HRCDC also noted and agreed with technical and more standard safeguards that may need to be considered by the Committee, including ensuring that the required data agreements are in place, that research ethics committee approval has been obtained for the other sites to cover the additional baseline data points and amending the MMUH study information leaflets with regards the duration of the study, the period of data archiving and what will happen the personal data.

#### **HRCDC Decision:**

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

### Conditions Attached:

**Condition 1.** Data agreements/arrangements must be in place between the data controller of the study (MRINZ) and the Mater Hospital

**Condition 2.** Research ethics committee approval must be in place for each site to cover the additional baseline data to be collected.

### HRCDC Recommendations:

**Recommendation 1.** The consent declaration for MEGA-ROX was made for the duration of the study and for a further 15 years to include the archiving/storage of the pseudonymised data i.e., until 31st March 2039. However, it is noted that the study information leaflets and assent/consent documents for the Mater Hospital site provide inconsistent information on what will happen the personal/pseudonymised data after the study concludes and on data archiving:

- The Mater documents state that data will be anonymised by destroying the master list as soon as the data is cleaned
- Elsewhere, the documents note that all study documents / data will be retained or archived for either 10 or 15 years

The study documents for the Mater should be amended to clarify that pseudonymised data will be archived for 15 years after the study, as per the duration of the consent declaration and previous information provided.

### HRCDC Conflicts of Interest

The HRCDC were provided with a draft of the updated conflict of interest policy. To help inform this updated policy and how it should be interpreted by committee members in different circumstances, the HRCDC discussed different scenarios that may, in some cases, give rise to a potential or perceived conflict of interest. Areas that were discussed that might give rise to some conflict of interest, depending on the extent or significance of the potential conflict of interest, included:

- Ongoing and previous professional relationships between a HRCDC member and an applicant and the extent of such professional relationships between individuals.
- If the HRCDC member was previously involved in earlier approval processes for the study in question, such as research ethics committee approval.
- If the HRCDC member was previously involved in processes relating to the funding of the research study, such as being an independent reviewer or decision maker on funding matters
- If the HRCDC member is in a governance or managerial role within an institution noted in the application. and whether their role is significant that it possibly could constitute a material conflict of interest.

It was also recognised that research community in Ireland is small, and it would not be unexpected for HRCDC members to have a degree of professional relationship or connection with some researchers seeking a consent declaration, in particular researchers who work in specialised fields of research.

It was discussed that the conflict-of-interest policy needs to be practicable, drawing upon the skills and knowledge of members while ensuring that HRCDC consideration and decisions are independent and unbiased.

It was agreed that the Secretariat would look at the outcome of this HRCDC discussion and update the conflict-of-interest policy; this would then be circulated to the HRCDC for further consideration and the matter may be raised again at the next HRCDC meeting, if required.

## **HRCDC meeting process**

The HRCDC were informed of discussions between the Chairperson, Deputy Chairpersons and Secretariat on suggested alternative ways of working for the HRCDC; these discussions arose and were based on Secretariat observations on how the UK Confidentiality Advisory Group operate.

The conclusion was that these changes would not be implemented for all HRCDC meetings, but it was agreed that in the event of a HRCDC decision to request further information, the Applicant would join the next HRCDC meeting and address outstanding queries as needed. The Secretariat will draft a proposed procedure for approval to the next HRCDC meeting. Further, the HRCDC also discussed considering consent declarations via an alternative process that involves a lead and secondary reviewer assigned to each application. It was commented that while the HRCDC consideration process is working well there may be benefits to exploring this approach, in particular if the volume of applications increases. It was agreed that the Secretariat would draft a proposed procedure to explore this approach, and that a pilot could be considered for the December meeting.

## **Expression of Interest campaign for new HRCDC members**

It was highlighted that the term of office for six committee members will expire in March 2025. The Chairperson and Secretariat discussed a proposal to undertake a public expression of interest campaign as part of the process to identify suitable individuals who could be considered by for appointment to the HRCDC by the Minister for Health.

It was discussed that this campaign would seek to help fill the knowledge, experiences and skills of the outgoing members and to add additional areas of suitable expertise, where appropriate. It was noted that the Secretariat are aiming to commence this campaign by the end of October 2024 with a view that potentially suitable individuals would be identified by January 2025. It was also agreed there will be a panel for review of potential members in place, including an external person.

The HRCDC were asked to inform the Chairperson or Secretariat if they had thoughts and suggestions on any potential skill gaps that should be considered when seeking new committee members.

## **2025 Meeting Dates**

The HRCDC agreed on meeting dates for 2025.

## **Annual Reviews**

The Secretariat has received 23 annual reviews in advance of the meeting which were deemed completed:

- **Ref ID:** 21-007-AF1/COV (INPBS-COVID 19)
- **Ref ID:** 23-006-AF1\*\* (COST2CARE)

- **Ref ID:** 23-003-AF1 (The CADY Sub-study 1: Biomarker and Major Adverse Cardiovascular Events (MACE) data Analysis)
- **Ref ID:** 22-008-AF1 (Evaluation of policies and practices to support safe and appropriate controlled drug prescribing)
- **Ref ID:** 19-004-AF1 (REMAP-CAP)
- **Ref ID:** 21-011-AF1/CSO (Examination of the relationship between the COVID-19 pandemic, unemployment, and social disadvantage in Ireland).
- **Ref ID:** 22-003-AF1\*\* (A Phase 3, multicenter, randomized, double-blind, placebo-controlled study to assess the efficacy, safety, and tolerability of AVP-786 for the treatment of agitation in patients with dementia of the Alzheimer's type)
- **Ref ID:** 23-014-AF1 (Adolescent and Young Adult (AYA) Cancer Epidemiology in Ireland - a retrospective review of National Cancer Registry Ireland (NCRI) data from 2002 to 2018)
- **Ref ID:** 22-002-AF1 (Understanding the wishes and support needs of people with intellectual disability as they grow older)
- **Ref ID:** 22-007-AF1 (OPTIMATE)
- **Ref ID:** 21-003-AF1 (M-Bovis study)
- **Ref ID:** 19-062-AF1\*\* (The relationship between Sub Epidermal Moisture (SEM) measurement and Inflammatory markers in the early identification of Pressure Ulcers)
- **Ref ID:** 23-005-AF1 (The journey from wardship to supported decision-making: An examination of the process and the experiences of people leaving wardship)
- **Ref ID:** 19-013-AF2 (Irish Omega-3 study)
- **Ref ID:** 23-008-AF1 (ARISE FLUIDS)
- **Ref ID:** 21-002-AF1 (MegaROX)
- **Ref ID:** 19-006-AF1 (BTIS)
- **Ref ID:** 19-031-AF1 (Bowel Disease Bioresource)
- **Ref ID:** 21-013-AF1 (Mammographic breast density and breast cancer outcomes in a population-based breast screening programme)
- **Ref ID:** 19-007-AF2 (TAME Cardiac Arrest Study)
- **Ref ID:** 23-016-AF1 (Personalized Mechanical Ventilation Guided by UltraSound in Patients with Acute Respiratory Distress Syndrome (PEGASUS))
- **Ref ID:** 23-017-AF1 (PREVENTION Study)
- **Ref ID:** 23-010-AF1 (ESsCAPE)

## Activities report and events of interest

The Secretariat circulated a report of its activities to the HRCDC in advance of the meeting. The following upcoming event of interest and other relevant updates were also noted:

- **Irish Health Research Forum: Public trust in health research: are we doing enough?** 9:30 - 13:00, Thursday, 14th November 2024; The Ashling Hotel, Parkgate St, Stoneybatter, Dublin 8, D08P38N: <https://www.eventbrite.ie/e/public-trust-in-health-research-are-we-doing-enough-registration-1007498835137?aff=oddtcreator>

## Any Other Business

- The HRCDC were informed that the updated HRCDC website has been launched: [www.hrcdc.ie](http://www.hrcdc.ie).
- The HRCDC were reminded that next HRCDC meeting on 12th November is in-person.

**The Chair closed the meeting**