

# National Research Ethics Committee

## NREC-MD Meeting Minutes

**21<sup>st</sup> December 2023**

### Attendance

Name	Role
Prof. Barry O'Sullivan	Chair, NREC-MD
Prof. Declan Patton	Deputy Chair, NREC-MD
Dr Owen Doody	Member, NREC-MD
Dr Frank Houghton	Member, NREC-MD
Dr Gloria Kirwan	Member, NREC-MD
Ms Orla Lane	Member, NREC-MD
Mr Billy McCann	Member, NREC-MD
Dr Sarah McLoughlin	Member, NREC-MD
Dr Declan O'Callaghan	Member, NREC-MD
Prof. Susan O'Connell	Member, NREC-MD
Dr Clare O'Connor	Member, NREC-MD
Prof. Anne Parle McDermott	Member, NREC-MD
Prof. Mahendra Varma	Member, NREC-MD
Dr Daniel Coakley	Member, NREC-MD
Prof. Cara Martin	Member, NREC-MD
Ms Simone Walsh	Member, NREC-MD
Chita Murray*	Programme Manager, National Office for Research Ethics Committees
Louise Houston	Project Officer, National Office for Research Ethics Committees

\*Drafted minutes

**Apologies:** Prof. Mary Sharp (Deputy Chair), Dr Caitriona Cahir, Dr Mireille Crampe, Dr Ruth Davis, Prof. Tom Melvin, Prof. Therese Murphy, Dr Paul O'Connor, Mr Damien Owens, Ms Riona Tumelty, Mr Peter Woulfe, Dr James Gilroy, Prof. James O'Neill

**Quorum for decisions:** Yes

### **AgendaAm738YPR#Nt**

- Welcome (Chairperson)
- Declarations of interest: None
- 23-NREC-MD-033-R1
- 23-NREC-MD-034-R1
- AOB

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- The Chairperson welcomed the Committee, acknowledged apologies sent by applicable members and opened the meeting.
  - NREC Committee Business Report: N/A
  - Minutes of the previous meeting: N/A
  - Matters arising from the previous meeting: N/A
  - Declarations of interest: None

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### **Applications**

#### **23-NREC-MD-033-R1**

- Principal Investigator: Prof. Brian Walsh
- Study title: An observational study of the NeuroBell EEG Monitor (a portable and wireless EEG monitor)
- Lead institution: Cork University Maternity Hospital, Wilton, Cork, Ireland
- NREC-MD decision:
  - *Favourable*
- Associated conditions

### **23-NREC-MD-034-R1**

- Principal Investigator: Prof. Mark Spence
  - Study title: Clinical Investigation Plan (CIP) for: Safety and Performance Study for Arterial Large Hole Vascular Closure Device – ELITE study
  - Lead institution: Mater Private Dublin, 73 Eccles Street, Dublin 7, D07 KWR1, Ireland
  - NREC-MD decision:
    - *Favourable with conditions*
  - Associated conditions
    - The NREC-MD seeks confirmation that any participant data that may be used in the future (to support other studies performed on the same device or family of devices) will be anonymised data only or, if not anonymised, will be subject to the explicit consent of the data subject (as per the optional item in the Informed Consent Form which will record consent for future contact in order to obtain explicit consent).
    - The NREC-MD advises that participants should be reimbursed for reasonable expenses which may be incurred in the event that visits to the study site are required which are additional to the standard-of-care visits which have been outlined in the application. The Committee requests that the availability of such reimbursement be included in the Participant Information Leaflet.
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- AOB: None
- The Chairperson thanked the Committee members present and closed the meeting.