NATIONAL OFFICE FOR RESEARCH ETHICS COMMITTEES

National Research Ethics Committee

NREC-MD Meeting Minutes

16th January 2025

Attendance

Name	Role
Prof. Barry O'Sullivan	Chair, NREC-MD
Prof. Mary Sharp	Deputy Chair, NREC-MD
Dr Mireille Crampe	Member, NREC-MD
Dr Owen Doody	Member, NREC-MD
Dr Frank Houghton	Member, NREC-MD
Dr James Gilroy	Member, NREC-MD
Dr Gloria Kirwan	Member, NREC-MD
Ms Orla Lane	Member, NREC-MD
Prof. Cara Martin	Member, NREC-MD
Mr Billy McCann	Member, NREC-MD
Prof. Therese Murphy	Member, NREC-MD
Dr Declan O'Callaghan	Member, NREC-MD
Dr Clare O'Connor	Member, NREC-MD
Dr Joanne O'Dwyer	Member, NREC-MD
Prof. Mahendra Varma	Member, NREC-MD
Ms Simone Walsh	Member, NREC-MD
Sarah McLoughlin	Programme Officer, National Office for Research Ethics Committees
Lucia Prihodova	Programme Manager, National Office for Research Ethics Committees

Emily Vereker	Head of Office, National Office for Research Ethics Committees
Ciaran Horan*	Administrative Assistant, National Office for Research Ethics Committees

*Drafted minutes

Apologies: Prof. Declan Patton, Dr Caitriona Cahir, Dr Daniel Coakley, Dr Ruth Davis, Prof. Tom Melvin, Dr Paul O'Connor, Mr Damien Owens, Mr Peter Wolfe

Quorum for decisions: Yes

Agenda

- Welcome (Chairperson)
- Report on Committee business
- Minutes of previous meeting
- Declarations of interest
- 25-NREC-MD-001
- 23-NREC-MD-024-SM3
- 21-NREC-MD-015-SM3
- 23-NREC-MD-016-SM2
- 24-NREC-MD-031-R1
- 24-NREC-MD-032-R1
- 24-NREC-MD-028-R1
- AOB

- The Chairperson welcomed the Committee, acknowledged apologies sent by applicable members and opened the meeting.
- NREC Committee Business Report: The Committee noted the report.
- Minutes of the previous meeting (12th December 2024) were approved.
- Matters arising from the previous meeting: none
- Declarations of interest: none

Applications

25-NREC-MD-001

- Principal Investigator: Dr Darren Mylotte

- Study title: A randomized controlled study of the Prevail Drug-Coated Balloon in subjects with in-stent restenosis and a single arm prospectively enrolled study of the Prevail Drug-Coated Balloon for de novo lesions in small vessel disease (Prevail Global)
- Lead institution: University Hospital Galway
- Sponsor: Medtronic Vascular Inc.
- NREC-MD decision:
  - *Request for further information*
- Further information requested:
  - The NREC-MD noted that a large proportion of participants is to be recruited in Ireland and request a clarification.
  - The NREC-MD noted inconsistency about the proposed participant number and requests clarification.
  - The two CVs for the Principal investigator provide conflicting information about the duration of the PI's employment as consultant cardiologist in UHG. Clarify the start and finish dates of this position.
  - Provide information on the PI's experience in performing coronary angioplasties.
  - Provide information about the process for dealing with incidental findings and include a description of this process in the Patient Information Leaflet / Informed Consent Form (PIL/ICF)
  - Clarify who will be performing the procedures and if additional training is required for the study devices.
  - Provide information if a Sponsor representative/ technician will present for any of the procedures.
  - Page 12 of the ICF includes a section whereby participants are asked to consent to having their 'vital status collected until 5 years after the procedure', even if the participant has chosen to discontinue the complete follow-up of the trial/ has withdrawn from the study. The NREC-MD requests that this section of the consent form is removed and that following withdrawal from the study, no further participant data is collected/ retained applicable aside from information required under MDR.
  - The NREC MD noted that the PIL/ICF is too technical and uses terminology that is not accessible to the lay participant. Revise the PIL/ICF accordingly and ensure that all technical terms and acronyms are explained and include diagrams/pictures to aid description of the devices.
  - In relation to the study risks, the Committee request that likelihood/ categorisation of likelihood of risks is included.
  - In relation to the risk of rupture of the blood vessel, include a description of the process in place.
  - Include the name and location of the 'core central laboratory' that will analyse the blood samples.

- The NREC-MD noted that the biological samples from the study will be discarded following analysis, and request this is stated in the PIL.
- The NREC-MD noted that the study includes participants receiving a phone call as part of, however this is not explained in the PIL/ICF and request this is revised.
- Clearly state in the PIL how long a participant will be followed up for.
- The NREC-MD noted that the PIL refers to third parties and request these are named.
- In line with point 9 of this letter on accessibility, the section “What will I have to pay for if I am in this study?” is to be revised for accessibility.
- As the PIL states that a 3rd party may be contacted for follow-up if the participant cannot be contacted, the NREC-MD request the ICF includes a separate consent for this.
- The NREC-MD request the ICF on future use of data is revised to allow the participant to give unbundled consent for the different future uses of their personal data listed in the PIL.
- Confirm that then the insurance will be provided for the duration of the study.
- Confirm that investigators will receive no direct payments for their involvement in the study and that “payment per participant” listed in the budget is to cover the study site expenses related to the study.

23-NREC-MD-024-SM3

- Principal Investigator: Prof Gabor Szeplaki
- Study title: LUMA Vision's feasibility study on the VERAFEYE System
- Lead institution: Mater Private Network
- Sponsor: LUMA Vision Ltd.
- NREC-MD decision:
  - *Favourable*

21-NREC-MD-015-SM3

- Principal Investigator: Prof Robert Byrne
- Study title: Fractional Flow Reserve or 3D-Quantitative-Coronary-Angiography Based Vessel-FFR guided revascularization
- Lead institution: Mater Private Network
- Sponsor: European Cardiovascular Research Institute (ECRI)
- NREC-MD decision:
  - *Favourable*

23-NREC-MD-016-SM2

- Principal Investigator: Prof Robert Byrne
- Study title: A Post-Market Clinical Follow-up Study with Ultimaster NagomiTM Sirolimus Eluting Coronary Stent System in Complex PCI Subjects
- Lead institution: Mater Private Network
- Sponsor: Terumo Europe N.V.
- NREC-MD decision:
  - *Favourable*

24-NREC-MD-031-R1

- Principal Investigator: Prof Robert Byrne
- Study title: BIOTRONIK – Safety and Clinical Performance of the Drug Eluting Resorbable Coronary MAGnesium Scaffold System (Freesolve®) in the Treatment of Subjects with de Novo Lesions in Native Coronary Arteries: BIOMAG-II: A randomized controlled trial
- Lead institution: Mater Private Network, Beacon Hospital
- Sponsor: BIOTRONIK AG
- NREC-MD decision:
  - *Favourable with conditions*
- Associated conditions:
  - The NREC-MD request that both the investigational and comparator devices as well as all study related procedures be provided to participants free of charge. No cost should be incurred by the participants either directly or indirectly (via insurance).
  - More detailed information on OpenAI is included in the PIL/ICT, including:
    - highlighting that the information fed into the system will be retained indefinitely,
    - that the narratives generated by it may not be accurate, and
    - a specific consent item is included in the ICF for participant data to be processed by OpenAI.
  - The NREC-MD requests that reasonable efforts are made to allow access to the study for participants for whom English is not their native language, or who do not speak English. If the study seeks to enrol a participant who requires a translated PIL/ICF, translations must be completed by a certified translation provider, and the translation certificates submitted to the NREC-MD as a non-substantial modification in advance of the distribution of translated documents.

24-NREC-MD-032-R1

- Principal Investigator: Prof Niamh Nowlan
- Study title: Fetal Movement Device Clinical Investigation: Evaluation of a novel wearable fetal movement monitor over the third trimester.
- Lead institution: National Maternity Hospital
- Sponsor: UCD
- NREC-MD decision:
  - *Favourable with conditions*
- Associated conditions:
  - As a way of dealing with incidental findings if/when they arise, an initial screening of scores in the World Health Organisation-Five Well-Being Index (WHO-5) is to be carried out by the research nurse upon receipt of a completed questionnaire. Any concerning scores are to be escalated to the clinical team, perinatal mental health unit or other specialist service in line with current clinical practice in the site. Note there is no expectation that any detailed data analysis on the WHO-5 scores is carried out at that point
  - The NREC-MD noted that the findings from FeMo1, along with literature provided in the CIP, do not support a concern that increased tracking of foetal movement by the mother leads to increased anxiety. Further, the Committee noted that the response to this query indicates that assessment and management of maternal anxiety is part of established care in the unit, via perinatal mental health services. Therefore, this procedure would be considered an additional safeguard should the participant mental health deteriorate unexpectedly.
  - To ensure transparency, participants should be made aware of this in the Participant Information Leaflet.

24-NREC-MD-028-R1

- Principal Investigator: Prof Jarushka Naidoo
- Study title: Clinical Performance Study Protocol for Use of VENTANA PD-L1 (SP263) CDx Assay for Determining PD-L1 Status in Genmab Phase 3 Trial GCT1046-06
- Lead institution: Beaumont Hospital, University Hospital Waterford, University Hospital Limerick, St James's Hospital, St Vincent's University Hospital, Cork University Hospital
- Sponsor: Ventana Medical Systems, Inc (Roche Tissue Diagnostic, RTD)
- NREC-MD decision:
  - *Favourable with conditions*
- Associated conditions:
  - All references to future exploratory and mutational analyses are revised in line with sponsors response confirming that future research will be limited to the device being

studied and no additional exploratory analyses will be carried out, eg page 3 of Prescreening Participant Information Leaflet/ Informed Consent Form (PIL/ICF).

- The section “How will my coded data be used” is revised as per original comment 6 and the response from sponsor, ie limited to PD-L1. Furthermore, a separate consent item on future uses of samples is to be added to the ICF.
- Participants are provided with both prescreening PIL/ICF and main PIL/ICF at the time of consent to the performance study. This is necessary to facilitate informed consent process as the prescreening PIL/ICF still refers to the main PIL/ICF.

- AOB: None