

National Research Ethics Committee

NREC-MD Meeting Minutes

16 March 2022

Attendance

Name	Role
Prof. Barry O'Sullivan	Chairperson, NREC-MD
Prof. Mary Sharp	Deputy Chairperson, NREC-MD
Prof. Cathal O'Donnell	Deputy Chairperson, NREC-MD
Ms Orla Lane	Member, NREC-MD
Dr Paul O'Connor	Member, NREC-MD
Dr Catherine O'Neill	Member, NREC-MD
Dr Frank Houghton	Member, NREC-MD
Mr Damien Owens	Member, NREC-MD
Prof. Anne Parle-McDermott	Member, NREC-MD
Prof. Declan Patton	Member, NREC-MD
Ms Riona Tumelty	Member, NREC-MD
Dr Lucia Prihodova*	Programme Manager, National Office for Research Ethics Committees
Dr Louise Houston	Project Officer, National Office for Research Ethics Committees
Mrs Patricia Kenny	Project Officer, National Office for Research Ethics Committees

*Drafted minutes

Apologies: Dr Owen Doody, Dr Caitriona Cahir, Mr Billy McCann, Prof. Therese Murphy, Prof. Susan O'Connell, Mr Peter Woulfe, Prof. Mahendra Varma

Quorum for decisions: Yes

Agenda

- Welcome & apologies
 - NREC Report on Committee Business
 - Minutes of previous meetings (17 February 2022) & matters arising
 - Declarations of interest
 - Terms of Reference
 - Application 22-NREC-MD-006
 - Application 22-NREC-MD-007-SA1
 - Application 22-NREC-MD-004-R1
 - Application 22-NREC-MD-005-R1
 - AOB
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- The Chairperson welcomed the Committee and opened the meeting.
 - The Chairperson welcomed Mrs Patricia Kenny and Dr Louise Houston, Project Officers who recently joined the National Office.
 - NREC Committee Business Report: The Committee *noted* the report.
 - Minutes of previous meeting (17 February 2022) & matters arising: The minutes were *approved*.
 - Declarations of interest:
Prof. Declan Patton (22-NREC-MD-007-SA1). Prof. Patton left the meeting for the review of 22-NREC-MD-007-SA1.
 - Terms of Reference: NREC-MD noted that the final Terms of Reference are pending.
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Applications

- **22-NREC-MD-006**
- Principal Investigator: Dr Darren Mylotte

- Study title: LANDMARK Trial: A prospective, multinational, multicentre, open-label, randomized, noninferiority trial to compare safety and effectiveness of Meril's Myval Transcatheter Heart Valve (THV) series vs. Contemporary Valves (Edwards' Sapien THV series and Medtronic's Evolut THV series) in patients with severe symptomatic native aortic valve stenosis.
 - Lead institution: Galway University Hospital, Newcastle Road, Galway, H91 YR71.
 - NREC-MD comments
 - The Committee noted that this application was previously reviewed by the NREC-MD and received an unfavourable opinion. The Committee noted that the issues raised by the Committee were addressed and that the submitted documentation was greatly improved.
 - NREC-MD decision
 - *Favourable opinion with conditions*
 - Associated conditions
 - Sections G and H of the NREC-MD form are completed and returned to the National Office.
 - Participation information leaflet and consent form are revised in line with the Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018).
 - Confirmation that the lead site DPO was consulted on all aspects of proposed data processing is provided.
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22-NREC-MD-007-SA1

- Principal Investigator: Prof. Caroline McIntosh
- Study title: A Pilot Study to Investigate the Use of Remote Thermovisual Monitoring in Patients with a Previous Diabetic Foot Ulcer, during the COVID-19 pandemic.
- Lead institution: Discipline of Podiatric Medicine, Aras Moyola, NUI Galway, Newcastle Road, Galway.
- NREC-MD comments
 - The NREC-MD notes that the original study received a favourable opinion from the Galway University Hospitals Regional Ethics Committee. In this regard, the NREC-MD opinion pertains only to the substantial amendment of the device, clinical investigation protocol and participant information leaflet.
- NREC-MD decision
 - *Favourable with conditions*
- Associated conditions

- The proposed change to data processing and participant's access to their own data is carried out in compliance with the Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018) and the General Data Protection Regulation (GDPR).
 - The insurance policy is extended for the duration of the study.
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22-NREC-MD-004

- Principal Investigator: Mr Peter Lonergan
 - Study title: The ProVIDE Clinical Study
 - Lead institution: St. James's Hospital, James Street, Dublin 8, D08 NHY1.
 - NREC-MD comments
 - The NREC-MD noted this was a response to request for further information issued at NREC-MD meeting held on 17 February 2022.
 - The NREC-MD deemed the risk-benefit ratio of the proposed study unfavourable.
 - The NREC-MD noted that some of the information and documentation requested was not provided, such as a copy of insurance and indemnity policies for all sites in Ireland, updated DPIA with a DPO input or a statement related to the financial arrangement.
 - The NREC-MD also found that the response did not clarify retention period for electronic files.
 - While the NREC-MD welcomed the updates to the participation information leaflet and consent form, the documents were not revised throughout and in the present form were not compliant with the Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018) or made specific to the Irish study.
 - NREC-MD decision
 - *Unfavourable*
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22-NREC-MD-005

- Principal Investigator: Mr S.Guan Khoo
- Study title: Treatment Evaluation of Neuromodulation for Tinnitus Stage A3
- Lead institution: Wellcome HRB Clinical Research Facility, Wellcome H&H Building, Level 2, St James's Hospital, James's Street, Dublin 8, Ireland.
- NREC-MD comments
 - The NREC-MD noted this was a response to request for further information issued at the 17 February 2022 NREC-MD meeting.
- NREC-MD decision

- *Favourable with conditions*
 - Associated conditions
 - All data processing is carried out in compliance with the Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018) and the General Data Protection Regulation (GDPR).
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AOB

- Membership campaign. Dr Lucia Prihodova reminded the Committee about the ongoing Expression of Interest campaign for additional members with specific expertise.
- The Chairperson thanked the Committee and closed the meeting.