

National Research Ethics Committee

NREC-MD Meeting Minutes

30 September 2021

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
Dr Caitriona Cahir	Member, NREC-MD
Dr Frank Houghton	Member, NREC-MD
Ms Orla Lane	Member, NREC-MD
Prof. Susan O’Connell	Member, NREC-MD
Dr Paul O’Connor	Member, NREC-MD
Dr Catherine O’Neill	Member, NREC-MD
Mr Damien Owens	Member, NREC-MD
Prof. Anne Parle-McDermott	Member, NREC-MD
Ms Riona Tumelty	Member, NREC-MD
Mr Peter Woulfe	Member, NREC-MD
Prof. Mahendra Varma	Member, NREC-MD
Dr Jennifer Ralph James	Head, National Office for Research Ethics Committees
Dr Lucia Prihodova*	Programme Manager, National Office for Research Ethics Committees

NREC Meeting Minutes

Dr Melissa Jones*

Project Officer, National Office for Research Ethics
Committees

*Drafted minutes

Apologies: Prof. Therese Murphy, Mr Billy McCann, Dr Owen Doody, Prof. Declan Patton

Quorum for decisions: Yes

Agenda

- Welcome & apologies
 - NREC Committee Business Report
 - NREC-MD Reporting relationship of ongoing MD studies
 - Minutes of previous meeting (26 August 2021) & matters arising
 - Declarations of interest
 - Application 21-NREC-MD-009-R1
 - Application 21-NREC-MD-011
 - Application 21-NREC-MD-010-R1
 - AOB
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- The acting Chairperson (Prof. Mary Sharp) welcomed the Committee and opened the meeting. Prof. Sharp chaired the meeting until agenda item 8 at which point Prof. Barry O'Sullivan joined the meeting and assumed the chairing role.
- NREC Committee Business Report: The Committee *noted* the report.
- NREC-MD Reporting relationship of ongoing MD studies: The Committee *noted* the memo.
- Minutes of previous meeting (26 August 2021) & matters arising: The minutes were *approved*.

- Declarations of interest:

Dr Melissa Jones (21-NREC-MD-009-R1). Dr Jones left the meeting for the review of 21-NREC-MD-009-R1.

Dr Lucia Prihodova (21-NREC-MD-011). Dr Prihodova left the meeting for the review of 21-NREC-MD-011.

Applications

21-NREC-MD-009-R1

- Principal Investigator: Professor David Keegan
- Study title: A prospective, multicenter post-marketing clinical investigation of the Tsert SITM System, model NG SI IMT 3X in patients with central vision impairment associated with end-stage age-related macular degeneration
- Lead institution: Mater Misericordiae University Hospital, Eccles Street, Dublin, D07 R2WY
- NREC-MD comments

- The Committee noted that this application represents the applicant’s response to a *Request for further information* from the NREC-MD.
 - The NREC-MD agreed the applicant had addressed the Committee’s request for further information satisfactorily.
 - NREC-MD decision
 - *Favourable with conditions*
 - Further information requested / Associated conditions
 - The NREC-MD requests that the insurance policy is updated to provide cover for the full duration of the study.
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21-NREC-MD-010-R1

- 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: University Hospital Galway, Newcastle Rd, Galway, H91 YR71
 - NREC-MD comments
 - The Committee noted that this application represents the applicant’s response to a *Request for further information* from the NREC-MD.
 - The NREC-MD noted that correspondence from the HPRA to the Sponsor in relation to prior studies on the MyVal device, was submitted as a part of the response to the Committee.
 - The NREC-MD agreed the applicant had not addressed the Committee’s request for further information satisfactorily, particularly in the important areas of data protection and participant-interfacing documentation.
 - The NREC-MD noted that the revised DPIA does not sufficiently clarify the locations of data processing and retention, nor does it indicate any input from the site’s DPO. To that end, the NREC-MD was not sufficiently assured that the participants’ data would be processed in line with the best practice and the Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018).
 - The NREC-MD noted that while somewhat revised, the participant information leaflet and consent form require significant revision to ensure that the consent sought from participants is truly informed and compliant with the Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018).
 - NREC-MD decision
 - *Unfavourable*
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21-NREC-MD-011

- Principal Investigator: Prof. C Geraldine McMahon
 - Study title: An observational study of ocular microtremor in mild head injury
 - Lead institution: James St, St James's Hospital, Dublin 8, D08 NHY1
 - NREC-MD comments
 - The NREC-MD noted that this study uses an optical eye movement measurement device developed at Trinity College Dublin called the itremor-RESEARCH to investigate the potential effects of mild head injury on 'ocular microtremor (OMT)'.
 - The NREC-MD commented on the challenges of securing informed consent in emergency settings. To that end the National Office agreed to assist the NRECs in their giving of further consideration to this topic.
 - NREC-MD decision
 - *Favourable with conditions*
 - Further information requested / Associated conditions
 - The NREC-MD requests that the insurance policy is updated to provide cover for the full duration of the study.
 - The NREC-MD requests an assurance that this study has been reviewed favourably by the appropriate Radiation Safety Committee.
 - The NREC-MD requests a clarification on the participant cohorts and process used to determine how 'mild' head injury during the study.
 - The NREC-MD requests a justification for the proposed indefinite storage of data.
 - The NREC-MD requests the Patient Information Leaflet is revised to reflect data processing of participants who withdrawn from the study.
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- AOB:
 - The Programme Manager updated the NREC-MD on the recent publication of NREC Guidance on data protection and data sharing, and flagged the upcoming Member clinic.
 - The Chairperson and the Programme Manager thanked the Committee who contacted them with a list of frequent issues noted from their reviews of applications.
- The Chairperson thanked the Deputy Chairperson for assistance with chairing of the meeting as well as the Committee and closed the meeting.