NATIONAL OFFICE FOR RESEARCH ETHICS COMMITTEES

National Research Ethics Committee

NREC-MD Meeting Minutes

26 August 2021

Attendance

Name	Role
Prof. Barry O'Sullivan	Chairperson, NREC-MD
Prof. Mary Sharp	Deputy Chairperson, NREC-MD
Dr Frank Houghton	Member, NREC-MD
Ms Orla Lane	Member, NREC-MD
Mr Billy McCann	Member, NREC-MD
Prof. Therese Murphy	Member, NREC-MD
Prof. Susan O'Connell	Member, NREC-MD
Dr Catherine O'Neill	Member, NREC-MD
Mr Damien Owens	Member, NREC-MD
Prof. Declan Patton	Member, NREC-MD
Ms Riona Tumelty	Member, NREC-MD
Prof. Mahendra Varma	Member, NREC-MD
Dr Lucia Prihodova*	Programme Manager, National Office for Research Ethics Committees
Dr Melissa Jones	Project Officer, National Office for Research Ethics Committees

*Drafted minutes

Apologies: Dr Caitriona Cahir, Dr Owen Doody, Prof. Anne Parle-McDermott, Dr Paul O'Connor, Prof. Cathal O'Donnell, Mr Peter Woulfe

Quorum for decisions: Yes

Agenda

- Welcome & apologies
- NREC Committee Business Report
- Minutes of previous meeting (29 July 2021) & matters arising
- Declarations of interest
- Application 21-NREC-MD-009
- Application 21-NREC-MD-010
- AOB

- The Chair welcomed the Committee and opened the meeting.
- NREC Committee Business Report: The Committee *noted* the report.
- Minutes of previous meeting (29 July 2021) & matters arising: The minutes were *approved*. The Programme Manager updated the Committee on REC reporting relationship for clinical investigations of medical devices approved prior to implementation of EU MDR.
- Declarations of interest: Dr Melissa Jones (21-NREC-MD-009). Dr Jones left the meeting for the review of 21-NREC-MD-009.

Applications

21-NREC-MD-009

- 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 NREC-MD noted that this is an application for a study of CE-marked visual prosthetic implantable device and aims to utilise participant recruitment via social media only.
- NREC-MD decision
  - *Request for further information*
- Further information requested

- The NREC-MD requests more information on the potential benefits, risks and ethical aspects of the proposed recruitment strategy.
- The NREC-MD requests a clarification on the insurance policy for the study.
- The NREC-MD requests more information on the rationale, use and data processing of the proposed video recordings.
- The NREC-MD requests a rationale for the duration of the study.
- The NREC-MD requests clarity on the proposed length of data retention (5 vs 10 years).
- The NREC-MD requests more information on the study monitor and to what extend will they be able to access personal data.
- The NREC-MD requests a clarification on personal data collected as a part of the investigation and who will have access to participant's personal data.
- The NREC-MD requests more information on the process of seeking participant health records.
- The NREC-MD requests that the participation information leaflet and consent form need to be revised in line with the Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018).
- The NREC-MD requests that the PIL includes more detail on possible adverse events and on the alternative device to be implanted if participant is deemed ineligible during the surgery.
- The NREC-MD requests more information and that more consideration is given to the consent process, such as giving the participants minimum of 72 hours to consider their participation in the trial.
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21-NREC-MD-010

- 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 NREC-MD noted that the LANDMARK trial is a prospective, multinational, multicentre, open-label, and randomized controlled trial designed to prove the noninferiority of Myval transcatheter heart valve against contemporary transcatheter heart valves (Sapien THV Series and Evolut THV Series) over 10 years.
- NREC-MD decision

- *Request for further information*

- Further information requested
  - The NREC-MD requests that the PIL is revised to clarity and accessibility in lay terminology. Additionally, the participation information leaflet and consent form need to be revised in line with the Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018).
  - The NREC-MD requests that the participants are given minimum of 72 hours to consider their participation in the trial.
  - The NREC-MD requests that participants are made aware of the fact that the valve is of animal origin. While the NREC-MD recognises that this is applicable to all such devices, the participants should be informed of this as there could be conscience based or religious based preferences.
  - The NREC-MD requests clarity on the proposed data processing and retention as a part of the study to ensure compliance with the Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018). To that end, the NREC-MD also requests a revised comprehensive DPIA is resubmitted.

- AOB:
  - The NREC-MD commented on the volume of documentation required to be reviewed for each application. The Chairperson encouraged the Committee members to reflect on frequent issues noted from their reviews of applications that could inform the content of FAQs for applicants and to send these on to him and the Programme Manager.
- The Chairperson thanked the Committee and closed the meeting.