

National Research Ethics Committee

NREC-MD Meeting Minutes

13 April 2022

Attendance

Name	Role
Prof. Barry O'Sullivan	Chairperson, NREC-MD
Prof. Mary Sharp	Deputy Chairperson, NREC-MD
Dr Owen Doody	Member, NREC-MD
Dr Frank Houghton	Member, NREC-MD
Ms Orla Lane	Member, NREC-MD
Mr Billy McCann	Member, NREC-MD
Dr Paul O'Connor	Member, NREC-MD
Mr Peter Woulfe	Member, NREC-MD
Mr Damien Owens	Member, NREC-MD
Prof. Declan Patton	Member, NREC-MD
Prof. Mahendra Varma	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

*Drafted minutes

Apologies: Dr Caitriona Cahir, Prof. Therese Murphy, Prof. Susan O'Connell, Dr Catherine O'Neill, Prof. Anne Parle-McDermott, Ms Riona Tumelty

Quorum for decisions: Yes

Agenda

- Welcome & apologies
 - NREC Report on Committee Business
 - Minutes of previous meetings (16 March 2022) & matters arising
 - Terms of Reference
 - Declarations of interest
 - Application 22-NREC-MD-008
 - Application 22-NREC-MD-009
 - Application 22-NREC-MD-010-SA1
 - Application 22-NREC-MD-003-SA1
 - Application 22-NREC-MD-011
 - Application 22-NREC-MD-012
 - AOB
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- The Chairperson welcomed the Committee and opened the meeting.
 - The Chairperson informed the Committee that Deputy Chairperson Prof. Cathal O'Donnell stepped down from the Committee. On behalf of the Committee, he thanked the Deputy for his commitment and work on the Committee and wished him well in his future endeavours.
 - The Chairperson also noted that Dr Jennifer Ralph James was stepped down from from her role as the Head of the National Office. On behalf of the Committee, he thanked her the Head and wished him well in his future endeavours.
 - NREC Committee Business Report: The Committee *noted* the report.
 - Minutes of previous meeting (16 March 2022) & matters arising: The minutes were *approved*.
 - Terms of Reference: The Terms of Reference were *noted*.
 - Declarations of interest: none.
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Applications

22-NREC-MD-008

- Principal Investigator: Prof Karen Redmond
 - Study title: Fissure Closure with the AeriSeal System for CONVERT Ventilation Status in Patients with Severe Emphysema: A MultiCenter, Prospective Trial (CONVERT Trial).
 - Lead institution: Beacon Hospital, Sandyford Industrial Estate, Bracken Road, Dublin 18.
 - NREC-MD comments
 - The Committee noted that this application was a post-market clinical follow up study testing the utility of a device (called the AeriSeal System) to close these open air channels and stop air flow between lung compartments in participants with COPD.
 - NREC-MD decision
 - *Request for further information*
 - Further information requested:
 - Clarification on the study budget, payments to site and investigators.
 - Clarification on the process for compensation to the participants.
 - Clarification on whether there will be any cost charged to the participants or their insurance for participation in the study.
 - Revised presentation of risk associated with participation in the study in the Participant Information Leaflet.
 - More information on the data management and statistic firm.
 - A confirmation that all data processing and management is carried out in compliance with the Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018).
 - More information on the screening and recruitment process, and particularly how the Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018) will be complied with.
 - Given that COPD disproportionately affects people from lower socio-economic groups, the NREC-MD recommends that due regard be given to the study population to ensure representation.
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22-NREC-MD-009

- Principal Investigator: Dr Paul Murphy
- Study title: Real-World Outcomes Study on Subjects Treated with Radiofrequency Ablation (ROSTRA Study).

- Lead institution: Anaesthesia, Intensive Care and Pain Medicine, St. Vincent's University Hospital, Merrion Rd, Dublin 4, D04 N2E0.
 - NREC-MD comments
 - The NREC-MD noted that this application was previously reviewed by the NREC-MD and was withdrawn when the Committee issued a request for further information. The Committee noted that the issues raised by the Committee were addressed and that the submitted documentation was greatly improved.
 - NREC-MD decision
 - *Favourable with conditions*
 - Associated conditions
 - The NREC-MD requested that cover for all reasonable expenses is offered to participants.
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22-NREC-MD-010-SA1

- Principal Investigator: Dr Darren Mylotte
 - Study title: A prospective, single arm clinical investigation evaluating safety and effectiveness/performance of the Microport CardioFlow VitaFlow Liberty™ - Transcatheter Aortic Valve System for the treatment of symptomatic severe aortic stenosis via transcatheter access in increased surgical risk patients. VITALE Study: Substantial Amendment.
 - Lead institution: St. James's Hospital, James Street, Dublin 8, D08 NHY1.
 - NREC-MD comments
 - The NREC-MD noted 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:
 - Amendment to the Clinical Investigation / Trial Protocol (CIP),
 - Change of Sponsor's Legal Representative,
 - Amendment to Patient Information Leaflet and to Consent Form,
 - Modification of the Sample Patient Card,
 - Modification of the GP letter,
 - Modification of the Instructions for Use (IFU),
 - Modification of the Investigator Brochure (IB),
 - Notification of a temporary suspension in clinical investigation,
 - Notification to request restart of clinical investigation.
 - NREC-MD decision
 - *Favourable*
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22-NREC-MD-003-SA1

- Principal Investigator: Dr Faisal Sharif
 - Study title: Global SYMPPLICITY Registry (GSR) Denervation Findings in Real World (DEFINE) is referred to as the GSR DEFINE study, Including Irish Country Addendum (IMPROVE): Substantial Amendment.
 - Lead institution: Department of Cardiology, Galway University Hospital, Newcastle Road, Galway, H91 YR71.
 - NREC-MD comments
 - The NREC-MD noted that this is a substantial amendment application and, in this regard, the NREC-MD opinion pertains only to the substantial amendment of addition of two new sites to the study:
 - The Mater Misericordiae University Hospital, Site PI: Prof. Ivan Casserly,
 - St Vincent's University Hospital, Site PI: Dr Charles McCreery.
 - NREC-MD decision
 - *Favourable*
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22-NREC-MD-011

- Principal Investigator: Prof. Mark Spence
- Study title: Feasibility study of the HighLife 28mm trans-septal transcatheter mitral valve in patients with moderate-severe or severe mitral regurgitation and at high surgical risk (HighLife Study).
- Lead institution: Mater Private Hospital, 73 Eccles Street, Dublin 7, D07 KWR1.
- NREC-MD comments
 - The Committee noted that this application was a for a study evaluating the feasibility, safety and performance of the HighLife 28mm Transcatheter Mitral Valve and its delivery systems in patients with moderate-severe or severe mitral regurgitation.
- NREC-MD decision
 - *Request for further information*
- Further information requested:
 - Clarification on the proposed number of participants screened and enrolled in the intervention.
 - Clarification on the timeframe given to participants to consider their participation.
 - Clarification on the proposed medication plan for participants.
 - Estimated radiation dose per CT scan is provided.
 - Revised PIL to improve accessibility.
 - Further information about the repair of puncture of the interatrial septum.

- Further information on the system used to livestream the procedure and the security measures put in place for the live stream.
 - More information on the organisations involved in processing of the data and arrangement with the applicants in terms data sharing agreement.
 - Assurance that all data processing and management will be carried out in compliance with the Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018).
 - Confirmation that the Data monitoring committee is fully independent from the investigation, and that declarations of conflict of interest from the committee members will be sought.
 - Clarification on the study budget, payments to site and investigators.
 - Clarification on the process for compensation to the participants.
 - Clarification on whether there will be any cost charged to the participants or their insurance for participation in the study.
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22-NREC-MD-012

- Principal Investigator: Dr Cían Hughes
- Study title: DermAssist Ireland Study.
- Lead institution: Google Docks, Barrow Street, Dublin 4, D04 V4X7.
- NREC-MD comments
- The Committee noted that this application was a post-market clinical follow up study aimed to better understand “real-world” users of the DermAssist application in Ireland.
- NREC-MD decision
 - *Request for further information*
- Further information requested:
 - Clarification on the DermAssist device as a Medical Device in the context of the Medical Devices Regulation (EU) 2017/745 and the proposed study.
 - Clarification whether the device is currently available on other EU markets.
 - Confirmation that HPRA advice on the study classification has been sought.
 - Justification for the proposed study team, clarification of expertise in delivering studies on a similar scale and a copy of a PI certificate of attendance of Good Clinical Practice training course.
 - Clarification on how the age of participants will be verified.
 - Justification for the proposed participant recruitment plan.
 - Justification of the proposed approach in which all cost of care for the participants is born by themselves or the public health system.

- More information on the data sharing arrangements with Qualtrics.
 - Assurance that all data processing and management is carried out in line with the Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018).
 - Clarification on whether the app data will be stored in data centres in the EU.
 - Revised participation information leaflet and consent form to comply with the Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018).
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AOB

- Deputy Chairperson and Expression of Interest campaign. The Chairperson informed the Committee that the review of expressions of interest is ongoing, and that he will discuss the proposed plan for appointing a new Deputy Chairperson with the National Office.
- Clinical indemnity: Dr Owen Doody informed the Committee on the recently issued guidelines on the Clinical Indemnity Scheme.
- The Chairperson thanked the Committee and closed the meeting.