

National Research Ethics Committee

NREC-MD Meeting Minutes

27 July 2021

Attendance

Name	Role
Prof. Barry O'Sullivan	Chairperson, NREC-MD
Prof. Mary Sharp	Deputy Chairperson, NREC-MD
Dr Caitriona Cahir	Member, NREC-MD
Dr Owen Doody	Member, NREC-MD
Dr Frank Houghton	Member, NREC-MD
Mr Billy McCann	Member, NREC-MD
Prof. Therese Murphy	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
Prof. Declan Patton	Member, NREC-MD
Mr Peter Woulfe	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. Cathal O'Donnell, Ms Orla Lane, Ms Riona Tumelty, Prof. Mahendra Varma

Quorum for decisions: Yes

Agenda

- Welcome & apologies
 - Substantial amendments: NREC review approach
 - NREC Conflict of Interest Policy
 - NREC Committee Business Report
 - Minutes of previous meeting (24 June 2021) & matters arising
 - Declarations of interest
 - Application 21-NREC-MD-005
 - Application 21-NREC-MD-006-SA
 - Application 21-NREC-MD-008-SA
 - Application 21-NREC-MD-002-SA-R1
 - Application 21-NREC-MD-003-R1
 - Application 21-NREC-MD-004-R1
 - AOB
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- The Chair welcomed the Committee and opened the meeting.
 - Substantial amendments: NREC review approach: The Programme Manager presented an overview of the NREC approach to review of substantial amendments including particular considerations for the remit of NREC-MD under SI 252/1994 and SI 260/2021
 - Update from the National Office - Conflict of Interest Policy: The Head of the National Office presented an overview of NREC Conflict of Interest policy.
 - NREC Committee Business Report: The Committee *noted* the report.
 - Minutes of previous meeting (24 June 2021) & matters arising: The minutes were *approved*; there were no matters arising
 - Declarations of interest: none
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Applications

21-NREC-MD-005

- Principal Investigator: Dr Jonathan Lyne
- Study title: Conduction System Pacing Optimized Therapy (CSPOT)
- Lead institution: Beacon Hospital, Beacon Court, Bracken Road, Sandyford Business Park, Sandyford, Dublin 18
- NREC-MD comments

- The NREC-MD noted that the application is in effect a feasibility study to test a new form of cardiac resynchronisation therapy, the CSPOT technique, and as such represents a device that is yet to receive CE marking.
 - NREC-MD decision
 - *Favourable with conditions*
 - Further information requested / Associated conditions
 - Participant information leaflet and consent forms are revised for ease of participant accessibility and clarity.
 - The consent form is revised to fully comply with the 2018 Health Research Regulations.
 - Citations are provided for studies referenced in the application.
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21-NREC-MD-006-SA

- Principal Investigator: Dr Darren Mylotte
 - Study title: Optimize PRO
 - Lead institution: University Hospital Galway, Newcastle Rd, Galway
 - NREC-MD comments
 - The NREC-MD noted that this application represents a request for ethics review of a substantial amendment to an ongoing aortic stenosis study, including expansion of the study and refinement of specific study end-points.
 - The NREC-MD noted that the original study received a favourable opinion from the Clinical Research Ethics Committee at Galway University Hospitals. In this regard, this NREC-MD opinion pertains only to the substantial amendment outlined in the application submitted to the National Office.
 - NREC-MD Decision
 - *Favourable*
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21-NREC-MD-008-SA

- Principal Investigator: Prof. Faisal Sharif
- Study title: The "RADIANCE II" Pivotal Study
- Lead institution: HRB Clinical Research Facility Galway (HRB-CRFG), University of Ireland, 1st Floor, Galway University Hospitals, Co. Galway
- NREC-MD comments
 - The NREC-MD noted that this application represents a request for ethics review of a substantial amendment to an ongoing hypertension study, namely to proceed with changes to the patient information sheet and consent form, revisions to the patient brochure, and the inclusion of a new home blood pressure diary.

- The NREC-MD noted that the original study received a favourable opinion from the Clinical Research Ethics Committee at Galway University Hospitals. In this regard, the NREC-MD opinion pertains only to the substantial amendment outlined in the application submitted to the National Office.
 - NREC-MD Decision
 - *Favourable with conditions*
 - Further information requested / Associated conditions
 - Participant information leaflet and consent forms are revised for ease of participant clarity.
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21-NREC-MD-002-SA-R1

- Principal Investigator: Prof. Patrick Serruys
 - Study title: A randomised controlled trial to compare the safety and efficacy of sirolimus-eluting biodegradable polymer ultra-thin stent (SUPRAFLEX™ Cruz) and everolimus-eluting biodegradable polymer stent (SYNERGY™) in treatment for three vessel coronary artery disease: Multivessel TALENT
 - Lead institution: Mater Private Hospital, Eccles Street, Dublin 7
 - NREC-MD comment
 - The Committee noted that this application represents the applicant's response to a *Request for further information* from the NREC-MD following its review of a substantial amendment application
 - The NREC-MD agreed the applicant had addressed the Committee's request for further information satisfactorily.
 - The NREC-MD noted that the original study received a favourable opinion from the Clinical Research Ethics Committee at Galway University Hospitals, the SJH/TUH Research Ethics Committee, the Beaumont Hospital Ethics (Medical Research) Committee and the Research Ethics Committee at UL Hospital Group. In this regard, the NREC-MD opinion pertains only to the substantial amendment of the addition of the Mater Private Hospital.
 - NREC-MD decision
 - *Favourable*
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21-NREC-MD-003-R1

- Principal Investigator: Prof. Patrick Serruys
- Study title: Non-inferiority of angiography-derived physiology guidance versus usual care in an all-comers population treated with unrestricted use of healing-targeted supreme stent (HT Supreme) and P2Y12 inhibitor monotherapy after 1-month of dual-antiplatelet therapy: the PIONEER IV trial

- Lead institution: National University of Ireland, Galway, Newcastle Road, Galway, Ireland
 - 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*
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21-NREC-MD-004-R1

- Principal Investigator: Prof. James Loughman
 - Study title: MyopiaX Treatment for the Reduction of Myopia Progression in Children and Adolescents: Safety and Efficacy Investigation
 - Lead institution: Center for Eye Research Ireland (CERI), Technological University Dublin, Dublin 7
 - 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
 - Participant information leaflet and consent forms are revised for ease of participant clarity.
 - The consent form is revised to fully comply with the 2018 Health Research Regulations.
 - The participants are provided with a separate 'quick reference' document outlining key contacts in case of any emergencies or questions on the device or trial itself.
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- AOB:
 - The Committee discussed the importance of rigorous informed consent procedures in relation to data processing and data sharing in health research studies. The Head of the National Office informed the Committee that the Office is developing a guidance document on data protection for research purposes. While this guidance will not comprise prescriptive information nor replace legal advice, the intention is to support applicants in their consideration of data protection matters for their research.

NREC Meeting Minutes

Action: The Head of the National Office to circulate finalised NREC guidance on data protection for research purposes for applicants to the members

- The Committee acknowledged the National Office for responsiveness in dealing with questions arising at the NREC-MD meetings in a timely and professional manner.
- The Chairperson thanked the Committee and closed the meeting.