NATIONAL OFFICE FOR RESEARCH ETHICS COMMITTEES

National Research Ethics Committee

NREC-MD Meeting Minutes

24 June 2021

Attendance

Name	Role
Prof. Barry O'Sullivan	Chairperson, NREC-MD
Prof. Cathal O'Donnell	Deputy 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
Ms Orla Lane	Member, NREC-MD
Mr Billy McCann	Member, NREC-MD
Prof. Therese Murphy	Member, NREC-MD
Dr Paul O'Connor	Member, NREC-MD
Dr Catherine O'Neill	Member, NREC-MD
Prof. Declan Patton	Member, NREC-MD
Ms Riona Tumelty	Member, NREC-MD
Prof. Mahendra Varma	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

Dr Melissa Jones	Project Officer, National Office for Research Ethics Committees

*Drafted minutes

Apologies: Prof. Susan O'Connell, Mr Damien Owens, Prof. Anne Parle-McDermott

Quorum for decisions: Yes

Agenda

- Welcome & apologies
- SI 260/2021 overview
- Minutes of previous meeting (27 May 2021) & matters arising
- Declarations of interest
- Application 21-NREC-MD-003
- Application 21-NREC-MD-004
- Application 21-NREC-MD-002
- Application 21-NREC-MD-001-R1
- AOB

- The Chair welcomed the committee and opened the meeting.
- SI 260/2021 overview: The Programme Manager gave an overview of the Statutory Instrument 260 of 2021, which gives legal standing to the NREC-MD. A query was raised relating to the anticipated publication of Terms of Reference and indemnity for NREC-MD members.

Action: Head of Office will raise this with the Department of Health

- Minutes of previous meeting (27 May 2021) & matters arising: The minutes were approved.
- Declarations of interest: none

Applications

21-NREC-MD-003

- 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
- NREC-MD comments
  - The NREC-MD agreed that the Committee is not in a position to return a final ethics opinion based on the information and documentation received thus far and that the application form and participant materials, in particular, should be revised to improve readability and accessibility.

- NREC-MD decision
  - *Request for further information*
- Further information requested / Associated conditions
  - The NREC-MD requests clarification on the study scope, the investigator roles and associated sites in this study.
  - The NREC-MD requests more details on the study funding and planned payments.
  - Given the vulnerability of one of the proposed study populations (STEMI patients), the NREC-MD requests justification and safeguards for their inclusion in the study.
  - The NREC-MD requests clarification on how the study protocol meets national guidelines on consenting transiently incapacitated patients, and on the process for determining capacity of participants and for identification of their legally acceptable representative.
  - As the proposed QFR methodology utilises radiation, a section of the application form remains to be completed.

21-NREC-MD-004

- 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 NREC-MD noted that this clinical investigation of a software intervention involves the recruitment of participants who are minors.
  - The NREC-MD agreed that the Committee is not in a position to return a final ethics opinion based on the information and documentation received thus far.
- NREC-MD decision
  - *Request for further information*
- Further information requested / Associated conditions
  - The NREC-MD requests that given the scope of the study, child psychology expertise is sought.
  - The NREC-MD requests confirmation of the proposed sample size, particularly in light of anticipated participant adherence, and further details on the recruitment process.
  - The NREC-MD requests that the study documentation is revised to reflect the commitment required from potential participants, and that consideration is given to providing a support framework to support adherence.
  - The NREC-MD requests that the participant information leaflet is revised to present information in a more accessible form, and that it includes a distress protocol for

potential seizures. Additionally, the NREC-MD requests that a letter to the GP is developed.

- The NREC-MD requests that the consent process is revised to ensure both parents and child are consulted and consented appropriately, in a manner consistent with the Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018).
- The NREC-MD requests that section E (data processing and management) of the application form is reviewed in line with the Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018) to ensure transparent data collection, management and processing, and sharing.
- The NREC-MD requests more details on the study funding and planned payments.

21-NREC-MD-002-SA

- Principal Investigator: Dr Robert Byrne
- Study title: A randomised controlled trial to compare the safety and efficacy of sirolimus-eLuTIng biodegradable polymer ultra-thin stent (SUPRAFLEXTM Cruz) and everolimus-eLuting biodegradable polymer stent (SYNERGYTM) in treatment for three vessel coronary artery disease: Multivessel TALENT
- Lead institution: Mater Private Hospital, Eccles Street, Dublin 7
- NREC-MD comments
  - The NREC-MD noted that this application represents a request for ethics approval of a substantial amendment to a study originally approved by local research ethics committees.
  - The NREC-MD agreed that the Committee is not in a position to return a final ethics opinion based on the information and documentation received thus far.
- NREC-MD Decision
  - *Request for further information*
- Further information requested / Associated conditions
  - The NREC-MD requests confirmation on whether this application pertains to addition of new site only or also to encompass a change of Principal Investigator.
  - The NREC-MD requests more information on the participant recruitment, and an assurance that there is an appropriate separation of the research team and routine clinical care team.
  - The NREC-MD requests more details on the study funding and planned payments.
  - The NREC-MD requests that the participant information leaflet highlights the change from standard treatment and is reviewed with readability in mind; also, the Committee requests that it is made clear the ways to withdraw consent.
  - The NREC-MD requests the proposed exclusion criteria are specified and justified more clearly.

- The NREC-MD requests a copy of a data sharing agreement and a rationale for the plans for data sharing with the funder during the conduct of the study.

NREC-MD-001-R1a (EndoTrap) and NREC-MD-001-R1b (LeakTrap)

- Principal Investigator: Prof. Ronan Cahill
- Study title: PORSAV (Protecting OR Staff from Aerosolized Virus)
- Lead institution: Mater Misercordiae University 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
- NREC-MD decision
  - *Favourable opinion with conditions*
- Further information requested / Associated conditions
  - Section G (radiation) of the application form is completed and returned to the National Office for the Committee's records.
  - The Principal Investigator ensures that operating room staff are fully and appropriately informed on the use of lasers and safety precautions to minimise potential risks.
  - Participant information leaflet to be presented in paragraph format for reading accessibility.
  - For reporting purposes to the NREC-MD, the study is treated as two distinct studies.

- AOB: none
- The Chairperson thanked the Committee and closed the meeting.