NATIONAL OFFICE FOR RESEARCH ETHICS COMMITTEES

National Research Ethics Committee

NREC-MD Meeting Minutes

19 May 2022

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
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 Paul O'Connor	Member, NREC-MD
Mr Peter Woulfe	Member, NREC-MD
Mr Damien Owens	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
Dr Emily Vereker	Acting Head, National Office for Research Ethics Committees

*Drafted minutes

Apologies: Dr Catherine O'Neill, Prof. Anne Parle-McDermott, Prof. Declan Patton, Ms Riona Tumelty

Quorum for decisions: Yes

Agenda

- Welcome & apologies
- NREC Report on Committee Business
- Minutes of previous meetings (13 April 2022) & matters arising
- Declarations of interest
- Application 22-NREC-MD-008-R1
- Application 22-NREC-MD-011-R1
- Application 22-NREC-MD-012-R1
- Application 21-NREC-MD-004-SA2
- Application 22-NREC-MD-014
- Application 22-NREC-MD-015
- AOB

- The Chairperson welcomed the Committee and opened the meeting.
- The Chairperson noted that this was the last NREC-MD meeting before the IVDR comes to force.
- NREC Committee Business Report: The Committee *noted* the report.
- Minutes of previous meeting (13 April 2022) & matters arising: The minutes were *approved*.
- Declarations of interest: none.

Applications

22-NREC-MD-008-R1

- 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 NREC-MD noted this was a response to request for further information issued at the 13 April 2022 NREC-MD meeting.
- NREC-MD decision
  - *Favourable with conditions*
- Associated conditions
  - Data sharing agreements between the site, sponsor and any third parties involved in statistical analyses are put in place.
  - The personnel involved in participant recruitment is not directly involved in direct provision of care for the potential participants.

22-NREC-MD-011-R1

- 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 NREC-MD noted this was a response to request for further information issued at the 13 April 2022 NREC-MD meeting.
- NREC-MD decision
  - *Favourable with conditions*
- Associated conditions
  - Participants are reimbursed for all reasonable expenses related to their participation in the study.

22-NREC-MD-012-R1

- Principal Investigator: Dr Cían Hughes
- Study title: DermAssist Ireland Study.
- Lead institution: Google Docks, Barrow Street, Dublin 4, D04 V4X7.

- NREC-MD comments
  - The NREC-MD noted this was a response to request for further information issued at the 13 April 2022 NREC-MD meeting.
  - The NREC-MD felt the response did not sufficiently clarify the intended use of the device as defined by the Medical Devices Regulation (EU) 2017/745.
  - The NREC-MD welcomed the updated list of collaborators and noted that the response letter referred to updated PI CV, which was omitted from the response dossier.
  - The NREC-MD felt that the issue of age verification was not sufficiently addressed.
  - The NREC-MD noted that whilst the age of digital consent in Ireland is 16 years, the age of consent for health research and for data processing in Ireland is 18 years.
  - The NREC-MD considered the updated approach to duty of care and was not sufficiently assured about the proposed process to fully protect and safeguard participants safety and wellbeing.
  - The NREC-MD was not assured that the proposed process aligns with the principles of informed consent and the respect for the rights of the individual persons.
- NREC-MD decision
  - *Unfavourable*

- **21-NREC-MD-004-SA2**
- 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 the original study received a favourable opinion from the NREC-MD on 30/07/2021, and that the present application relates to a substantial amendment. In this regard, the NREC-MD opinion pertains only to the substantial amendment of:
    1. Modifications in the investigational device and the app content and related IFU and user manual
    2. Adherence booster materials
    3. MyopiaX video script
- NREC-MD decision
  - *Favourable with conditions*
- Associated conditions

- Existing participants are made aware of any changes to the modifications in functionality and change in data processing.

22-NREC-MD-014

- Principal Investigator: Prof. Mark Spence
- Study title: Transcatheter Repair of Tricuspid Regurgitation with Edwards PASCAL Transcatheter Valve Repair System: A European prospective, multicenter Post Market Clinical Follow up.
- Lead institution: Mater Private Hospital, 73 Eccles Street, Dublin 7, D07 KWR1.
- NREC-MD comments
- The Committee noted that this application was a post-market non-randomized study concerning the commercially available/CE-marked medical device Edwards PASCAL Transcatheter Valve Repair System, which is currently considered as the standard treatment for mitral regurgitation and tricuspid regurgitation.
- NREC-MD decision
  - *Request for further information*
- Further information requested:
  - The NREC-MD requests clarity on what are study-specific procedures vs standard care procedures.
  - The NREC-MD noted that there are a number of economic measures e.g. length of hospital stay included in the study protocol that are not included in the ethics application. The NREC-MD requests clarification if this information is going to be collected in Ireland.
  - The NREC-MD requests more detail on how participants will be recruited and selected, and what steps will be undertaken to minimise any potential selection bias.
  - The NREC-MD requests that the Participant Information Leaflet is revised to improve accessibility and clarity.
  - The NREC-MD requests more information on the external providers involved in processing of the data, including their role, location, qualification and arrangement with the applicants in terms data sharing agreements.
  - The NREC-MD requests an 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).
  - The NREC-MD requests that copies of product and study specific insurance/ indemnity policies are provided.
  - The NREC-MD requests that section H of the application form is completed.

22-NREC-MD-015

- Principal Investigator: Prof. Andrew Davies
- Study title: Remote photoplethysmography for monitoring vital signs: useability and acceptance within a specialist palliative care unit.
- Lead institution: Education and Research Centre, Our Lady's Hospice & Care Services, Harold's Cross, Dublin 6W.
- NREC-MD comments
- The Committee noted that this application was a for a study evaluating the useability, acceptability and performance of the Lifelight® application to measure vital signs in a palliative care patient population.
- NREC-MD decision
  - *Request for further information*
- Further information requested:
  - The NREC-MD requests clarification on the roles of the various team members.
  - The NREC-MD requests clarity on how possible conflicts of interest will be managed.
  - Given the vulnerability of the study participants, the NREC-MD requests more detail on the study governance and oversight to ensure transparency and reduce the potential for bias.
  - The NREC-MD more information on the consent process, in terms of allowing potential participants time to consider their participation in the study.
  - The NREC-MD requests more information on how will their decision-making capacity to consent be ascertained and what formal provisions will be made for these participants to assist them if necessary, with the consent process.
  - The NREC-MD requests more detail on the proposed approach to consent for participants who may have diminished decision-making capacity to consent over the course of the study.
  - The NREC-MD requests more clarity on the role of the participants' family/carer, or proxy individual who understand the will and preference of the participant, in the consent/ assent process.
  - The NREC-MD requests more clarity on withdrawal from the study and the role of family/carer, or proxy individual in the process.
  - The NREC-MD requests that the Consent Form is updated in line with the Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018).
  - The NREC-MD requests clarification if the staff should be in fact considered as participants in the study and what measures will be put in place to reduce any perception of coercion and bias in their participation and reporting.
  - The NREC-MD requests more information on what form of technical support will be offered to staff.

- The NREC-MD requests justification for acceptability testing at month one out of six, rather than at later stage of the study.
- The NREC-MD noted that the Participant Information Leaflet is exceedingly long and requests that the PIL is revised to improve accessibility.
- The NREC-MD requests more information on the external providers involved in processing of the data, including their role, location, qualification and arrangement with the applicants in terms data sharing agreements.
- The NREC-MD requests an 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).
- The NREC-MD requests clarification on the insurance/ indemnity policies for the study and requests that copies of product and study specific policies are provided.
- The NREC-MD requests itemised breakdown of the study budget.

AOB

- Anniversary of the NREC-MD and the Medical Devices Regulation. The Chairperson noted that this meeting constitutes 1 year anniversary of the NREC-MD and the Medical Devices Regulation, and that the National Office will invite HPRA Devices Department to present an update on the first year of MDR at the next meeting.
- Expression of interest campaign and IVDR implementation. The Chairperson noted that ahead of IVDR implementation, the recommendations following the expressions of interest have been made to the Department and that new members will be joining the Committee in June 2022.
- The Chairperson thanked the Committee and closed the meeting.