NATIONAL OFFICE FOR RESEARCH ETHICS COMMITTEES

National Research Ethics Committee

NREC-MD Meeting Minutes

17 February 2022

Attendance

Name	Role
Prof. Barry O'Sullivan	Chairperson, NREC-MD
Prof. Mary Sharp	Deputy Chairperson, NREC-MD
Ms Orla Lane	Member, NREC-MD
Prof. Therese Murphy	Member, NREC-MD
Dr Catherine O'Neill	Member, NREC-MD
Dr Frank Houghton	Member, NREC-MD
Prof. Mahendra Varma	Member, NREC-MD
Mr Damien Owens	Member, NREC-MD
Mr Peter Woulfe	Member, NREC-MD
Dr Lucia Prihodova*	Programme Manager, National Office for Research Ethics Committees
Dr Jennifer Ralph James	Head, National Office for Research Ethics Committees

*Drafted minutes

Apologies: Prof. Cathal O'Donnell, Dr Owen Doody, Dr Caitriona Cahir, Mr Billy McCann, Dr Paul O'Connor, Prof. Susan O'Connell, 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 (20 January 2022) & matters arising
- Declarations of interest
- Application 22-NREC-MD-003-R1
- Application 21-NREC-MD-006-SA2
- Application 22-NREC-MD-004
- Application 22-NREC-MD-005
- AOB

- The Chairperson welcomed the Committee and opened the meeting.
- NREC Committee Business Report: The Committee *noted* the report.
- Minutes of previous meeting (20 January 2022) & matters arising: The minutes were *approved*.
- Declarations of interest: *none*

Applications

- **22-NREC-MD-003-R1 – Response to Request for Further Information**
- Principal Investigator: Dr Faisal Sharif
- Study title: Global SYMPLICITY Registry (GSR) Denervation Findings in Real World (DEFINE) is referred to as the GSR DEFINE study, Including Irish Country Addendum (IMPROVE).
- Lead institution: Department of Cardiology, Galway University Hospital, Newcastle Road, Galway, H91 YR71.
- NREC-MD comments
  - 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*
- Associated conditions
  - Participants' consent is obtained before undergoing the procedure.

- All data processing is carried out in compliance with the General Data Protection Regulations, the Data Protection Act 2018 and Health Research Regulations 2018.
- Participants' insurance is not charged for any illness or injury related to participation in the study.

21-NREC-MD-006-SA2

- Principal Investigator: Dr Darren Mylotte
- Study title: Optimise PRO (Substantial Amendment)
- Lead institution: Galway University Hospital, Newcastle Road, Galway, H91 YR71.
- NREC-MD comments
  - 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 of:

    Addition of new site (Mater Private Network, Cardiovascular Research Institute Dublin, 73 Eccles Street Dublin 7D07 KWR1, Ireland).
- NREC-MD decision
  - *Request for further information*
- Further information requested:
  - Justification for the proposed substantial amendment.
  - Updated CV for the Principal Investigator.
  - Confirmation that the provided indemnity policy will be extended for the entire duration of the study and that a copy of the updated policy will be provided to NREC-MD when available.

22-NREC-MD-004

- Principal Investigator: Mr Peter Lonergan
- Study title: The ProVIDE Clinical Study
- Lead institution: St. James's Hospital, James Street, Dublin 8, D08 NHY1.
- NREC-MD comments
  - The NREC-MD noted this is an application for a clinical research investigation of a non CE-marked medical device indicated for the treatment of obstructive lower urinary tract symptoms secondary to benign prostatic hyperplasia.
- NREC-MD decision
  - *Request for further information*
- Further information requested:

- The total number of participants anticipated to be recruited in Ireland.
- A copy of insurance and indemnity policies for all sites in Ireland is provided.
- An assurance that participation in the trial and the device itself will be free of charge.
- A clarification on whether the device implantation and sham procedure will be carried out as a part of a standard diagnostic examination for which participants might require anaesthesia or separately.
- The medication protocol for participants in the control arm.
- Section E4 of the application form (withholding of treatment) to be completed.
- Section G of the NREC-MD form to be completed.
- Section H of the NREC-MD form to be completed.
- The proposed categorisation and recoding of participants' data.
- More detail on the data management organisation.
- Revised data sharing plan.
- 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).
- A revised detailed DPIA with a consideration for the Irish Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018.
- Participation information leaflet and consent form revised in line with the Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018) and made specific to the Irish study.
- A statement related to the financial arrangement for the payment per patient to sites.

22-NREC-MD-005

- Principal Investigator: Mr S.Guan Khoo
- Study title: Treatment Evaluation of Neuromodulation for Tinnitus Stage A3
- Lead institution: Wellcome HRB Clinical Research Facility, Wellcome H&H Building, Level 2, St James's Hospital, James's Street, Dublin 8, Ireland.
- NREC-MD comments
  - The NREC-MD noted that this study aims to determine whether the addition of tongue stimulation to sound-only stimulation provides additional clinically significant improvements on the symptoms of tinnitus.
- NREC-MD decision
  - *Request for further information*
- Further information requested:

- A copy of all recruitment materials.
- Clarification on the plans for processing and retention of data gathered by the online screening questionnaire.
- Justification for the withdrawal of the device following study participation.
- Care plans offered to the participants following the trial.
- Justification for the inclusion of Mini Mental State Examination (MMSE) and State Trait Anxiety Inventory in the study, and queries the proposed approach to duty of care.
- Clarification of how the use of MMSE complies with functional approach to capacity outlined in the HSE National Consent Policy 2019.
- Copy of CN0151 TENT-A3 Case Report Form Templates_12 18.10.2021 v3.0 in English is provided.
- Copy of relevant trial agreements.
- Participant information leaflet (PIL) and informed consent form to be streamlined and revised for accessibility, and highlight the likelihood of increased tinnitus loudness and annoyance.
- Consent form to be revised in line with the Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018).

AOB

- Right of participant to receive a lay summary of study results: The NREC-MD is of the view that in line with best practice, applicants should highlight how they plan to inform participants of the study findings.
- Complaints procedure: There was discussion as to whom complaints or concerns about a study should be directed. It was agreed that there is a clear distinction between complaints regarding NREC processes and those regarding study conduct. While the first 'port of call' for a participant with any concerns about a study is the Principal Investigator, it was agreed that there should be a mechanism for participants to notify the NRECs about concerns relating to the fundamental ethical conduct of a study; the National Office agreed to research best practice in this area and delineate a corresponding procedure.
- Terms of Reference. Dr Jennifer Ralph James informed the Committee that Terms of Reference have recently been issued by the Department of Health and will be circulated in the coming days.
- Membership campaign. Dr Lucia Prihodova informed the Committee about a planned Expression of Interest campaign for additional members with specific expertise.
- Regarding substantial amendment 21-NREC-MD-014-SA1 Dr Lucia Prihodova queried the option of a 'Chairperson review' of the amendment. The Chairperson and Deputy Chairperson agreed to review the application.
- The Chairperson thanked the Committee and closed the meeting.