NATIONAL OFFICE FOR RESEARCH ETHICS COMMITTEES

National Research Ethics Committee

NREC-MD Meeting Minutes

20 January 2022

Attendance

Name	Role
Prof. Barry O'Sullivan	Chairperson, NREC-MD
Prof. Mary Sharp	Deputy Chairperson, NREC-MD
Prof. Cathal O'Donnell	Deputy Chairperson, NREC-MD
Dr Caitriona Cahir	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
Dr Owen Doody	Member, NREC-MD
Dr Frank Houghton	Member, NREC-MD
Prof. Susan O'Connell	Member, NREC-MD
Prof. Mahendra Varma	Member, NREC-MD
Ms Riona Tumelty	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 Marta Pisarska	HRB Postdoctoral Intern
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: None

Quorum for decisions: Yes

Agenda

- Welcome & apologies
- NREC Report on Committee Business
- Minutes of previous meetings (28 November 2021 & 16 December 2021) & matters arising
- Declarations of interest
- Application 22-NREC-MD-001-SA
- Application 21-NREC-MD-008-SA3
- Application 22-NREC-MD-002
- Application 22-NREC-MD-003
- Meeting Ireland's regulatory requirements under EU In-vitro Device Regulation (IVDR; 2017/746)
- AOB

- The Chairperson welcomed the Committee and opened the meeting.
- NREC Committee Business Report: The Committee *noted* the report.
- Minutes of previous meeting (28 November 2021 & 16 December 2021) & matters arising: The minutes were *approved*.
- Declarations of interest: *none*

Applications

- **22-NREC-MD-001-SA**
- Principal Investigator: Dr Jasna Pavičić-Astaloš.
- Study title: Multicentric Post-Market Clinical Follow-up (PMCF) Investigation to Determine Safety and Efficacy of a Hydrophobic EDOF Intraocular Lens (IOL) in Comparison to a Monofocal IOL (Substantial Amendment).
- Lead institution: Institute of Eye Surgery, UPMC Kildare Hospital, Prosperous Road, Clane, Co. Kildare, W91 W535.
- NREC-MD comments
    - The NREC-MD noted that the original study received a favourable opinion from the Clinical Research Ethics Committee of the Cork Teaching Hospitals, University College Cork. In this regard, the NREC-MD opinion pertains only to the substantial amendment of the addition of the study site in the Institute of Eye Surgery, Clane, Co. Kildare.

- NREC-MD decision
  - *Favourable opinion with conditions*
- Associated conditions
  - Information that this is a bilateral surgery is highlighted in the PIL.
  - Adequate insurance cover is provided for the full duration of the study.
  - Inclusion criteria on the minimum age of participants and data retention policy is in line with original REC approval.
  - Due to the location of the study site, the NREC-MD recommends that cover for all reasonable expenses is offered to participants.

21-NREC-MD-008-SA3

- Principal Investigator: Dr Faisal Sharif
- Study title: The RADIANCE II Pivotal Study (Substantial Amendment).
- Lead institution: Department of Cardiology, 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:

    COVID-19 related amendments and other updates to the clinical investigation protocol.

    Changes to patient facing documents.

    Revised instructions for use documents.

    Updated CE Certificate.
- NREC-MD decision
  - *Favourable*

22-NREC-MD-002

- Principal Investigator: Ms Anita Sayers
- Study title: Tinnitus Patient Registry at Ótologie Tinnitus Care (Ótologie)
- Lead institution: Center for Eye Research Ireland (CERI), Technological University Dublin, Dublin 7.
- NREC-MD comments
  - The NREC-MD noted this is an application for a clinical research investigation of a CE-marked medical device intended to alleviate the symptoms of tinnitus. This is a

single site, single-arm prospective registry of patients being treated at Ótologie Tinnitus Care (formerly Neuromod Medical).

- NREC-MD decision
  - *Favourable with conditions*
- Associated conditions
  - Data retention policy is aligned with the MDR.
  - Potential participants are presented with PIL before asked to consent to participation. The process of consenting to the study should be clearly separated from other communications to participants in relation to their treatment.
  - Study termination criteria and participant withdrawal from the study are clearly described in the PIL.
  - Consent form is revised in line with the Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018).
- The Committee also wished to comment on a query about involving participants that are not residing in the Republic of Ireland. The Committee noted that in order to involve such participants in the study, the following conditions need to be met:
  - Adequate insurance to cover non-residents to ensure duty of care is in place.
  - Ethics approval from the resident's country is secured.

22-NREC-MD-003

- 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 NREC-MD noted that this study aims to document the long-term safety and effectiveness of the SymplicityTM renal denervation system in a real-world patient population with hypertension.
- NREC-MD decision
  - *Request for further information*
- Further information requested
  - The NREC-MD requests clarification on the study objectives and end-points.

- The NREC-MD requests clarification on how the participants will be selected and recruited for the study and any inclusion / exclusion criteria.
- The NREC-MD requests confirmation on how and by whom and where will the participants' medical information be accessed and extracted for the purpose of the study.
- The NREC-MD requests more information on the location, data sharing agreement and access to participant angiograms for CoLab – how will this be facilitated.
- The NREC-MD requests clarification on the proposed consenting process.
- The NREC-MD requests that the PIL and ICF are revised in in line with the Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018).
- The NREC-MD requests clarification of how many of the proposed hospital visits are study specific and additional to the standard care.
- The NREC-MD requests confirmation that participants and / or participants' insurance are not charged for their participation in the study.
- As the procedure involves angiograms, the NREC-MD requires section H of the application form to be completed.
- The NREC-MD wishes to comment on the provision of a DPIA as a part of the application process to the NRECs. The DPIA is a study-specific document and the completion of a DPIA is a mandatory requirement under GDPR and the Health Research Regulations 2018 for studies that are deemed 'high risk' for the processing of personal data as per the Data Protection Commissioner's website. While it is not the responsibility of the NREC to verify compliance with data protection law, during the process of research ethics review it needs to be *assured* that the legally compliant data protection measures are in place for a research study, to safeguard the interests of research participants; to this end, the NREC-MD requires a study-specific DPIA to provide that assurance. Where the Data Controller is situated outside of Ireland, the National Office strongly advises that the DPO of the lead Irish-based institution should be given the opportunity to review and provide comment on the DPIA to further ensure the data protections rights of Irish research participants are safeguarded.
- In relation to this specific study, the NREC-MD requests that a DPO of the lead Irish-based institution is given the opportunity to review and provide comments on the submitted DPIA to further ensure the data protection rights of Irish research participants are safeguarded.

Meeting Ireland's regulatory requirements under EU In-vitro Diagnostics Medical Devices Regulation (IVDR; 2017/746)

- The Programme Manager (PM) presented an overview of Ireland's regulatory requirements under the EU In-vitro Diagnostics Medical Devices Regulation (IVDR; 2017/746).
- Informed by consultation with the Department of Health, the PM presented the proposal that the NREC-MD enable the regulatory requirement of a national mechanism for research ethics review under the IVDR. The Committee supported the proposal for the

NREC-MD to review applications under the IVDR on a pilot basis. The Committee agreed that its involvement would be dependent on an increase in the membership of the Committee to both add expertise related to this niche area and supplement review capacity, while maintaining the balance of lay and expert members. To that end, the Committee was clear that the NREC-MD should remain a single fully integrated decision-making entity with an expanded remit under the IVDR.

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