NATIONAL OFFICE FOR RESEARCH ETHICS COMMITTEES

NREC-MD Meeting Minutes

20th February 2025

Attendance

Name	Role	Attendance/ Apologies
Prof. Barry O'Sullivan	Chair	Attended
Prof. Mary Sharp	Deputy Chair	Attended
Prof. Declan Patton	Deputy Chair	Attended
Dr Caitriona Cahir	Member	Apologies
Dr Daniel Coakley	Member	Apologies
Dr Mireille Crampe	Member	Attended
Dr Ruth Davis	Member	Apologies
Dr Owen Doody	Member	Attended
Dr Frank Houghton	Member	Apologies
Dr James Gilroy	Member	Attended
Dr Gloria Kirwan	Member	Attended
Ms Orla Lane	Member	Attended
Prof. Cara Martin	Member	Apologies
Mr Billy McCann (PPI)	Member	Attended
Prof. Tom Melvin	Member	Apologies
Prof. Therese Murphy	Member	Attended
Dr Declan O'Callaghan	Member	Attended
Dr Clare O'Connor	Member	Attended
Prof Paul O'Connor	Member	Apologies
Dr Joanne O'Dwyer	Member	Attended
Mr Damien Owens	Member	Attended
Prof. Mahendra Varma	Member	Attended
Mr Peter Woulfe	Member	Apologies
Ms Simone Walsh	Member	Attended

Louise Houston	Project Officer, National Office for Research Ethics Committees	Attended
Dr Sarah McLoughlin	Programme Officer, National Office for Research Ethics Committees	Attended
Dr Lucia Prihodova	Programme Manager, National Office for Research Ethics Committees	Attended
Ciaran Horan*	Administrative Assistant, National Office for Research Ethics Committees	Attended

*Drafted minutes

Quorum for decisions: Yes

Agenda, discussion and decisions	
1. Welcome and apologies	The Chairperson welcomed the Committee, acknowledged apologies and opened the meeting.
2. Report on Committee business	Noted
3. Minutes of previous meeting	Adopted
4. Declarations of interest	• Ms Orla Lane: 25-NREC-MD-002 • Mr Damien Owens: 25-NREC-MD-001 • Ms Simone Walsh: 25-NREC-MD-003 Members listed above stepped out of the meeting for the discussion of the relevant application.
5. 25-NREC-MD-001	• Principal Investigator (Lead Institution): Dr Darren Mylotte (University Hospital Galway) • Sponsor: Medtronic Vascular Inc • Study title: A randomized controlled study of the Prevail Drug-Coated Balloon in subjects with in-stent restenosis and a single arm prospectively enrolled study of the Prevail Drug-Coated Balloon for de novo lesions in small vessel disease (Prevail Global) • NREC-MD decision: Favourable with conditions • Associated conditions:

	– For collection of any contact information about a person/ 3rd party who may be contacted during follow-up if the participant cannot be reached, the NREC-MD request that: – The contact information is only used for the reason of determining the health status of the participant in the instance where the participant cannot be contacted. – The information is processed in line with site policy and relevant principles of the GDPR. – The process of contacting such contact person/ 3rd party follows the ISO 14155-2020.
6. 25-NREC-MD-002	• Principal Investigator (Lead Institution): Prof John Crown (St. Vincent's Hospital) • Sponsor: Ventana Medical Systems, Inc. (Roche Tissue Diagnostics; "RTD") • Study title: Clinical Performance of VENTANA PD-L1 (SP263) CDx Assay as a Diagnostic Device for Detection of PD-L1 Status in a Retrospective Evaluation of Melanoma Tissue Specimens from Patients Screened for Regeneron's Phase 3 Study R3767-ONC-2011 • NREC-MD decision: Favourable with conditions • Associated conditions: – As the performance study presents a number of potential methodological limitations, eg retrospective design, differences in staining procedure, analysis of only positive samples, due consideration is given to the validity of the study outcomes in reporting of the outcomes. – Only samples from adult participants are included in this study. – In relation to participants aged 16 or 17 years, the process outlined in the NREC guidance on age of consent for regulated research in Ireland is followed. – Provide a list of countries where personal data will be transferred. – Provide a site suitability form for the laboratory where the performance study will take place.
7. 25-NREC-MD-003	– Principal Investigator (Lead Institution): Dr Patrick Nicholson (Royal College of Surgeons in Ireland) – Sponsor: CereVasc, Inc. – Study title: Pivotal Study to Evaluate the Safety and Effectiveness of the CereVasc® eShunt® System in the Treatment of Normal Pressure Hydrocephalus (STRIDE) – NREC-MD decision: Request for further information – Further information requested: – - Clarify if participants lacking/ with decreased decision-making capacity will be included in the clinical investigation as patients

	with normal pressure hydrocephalus may experience cognitive decline. - If yes, please outline the approach to capacity assessment and update the application form accordingly. Please note that for processing of personal data of participants lacking decision-making capacity a consent declaration must be sought from the Health Research Consent Declaration Committee (HRCDC). - If not, please remove references to legally authorised representative from the application form. - Please review the HSE National Policy for Consent in Health and Social Care Research for more information. - As participants with a nickel allergy may suffer an allergic response to the implant materials, clarify why a known allergy to nickel is not included in the list of exclusion criteria for this study. - NREC-MD noted that due to resource limitations potential participants who don't speak English will not be enrolled in the study. In the interest of equitable access to research participation, the Committee request that all reasonable efforts should made to ensure the recruitment strategy as inclusive as possible. - Justify the proposed approach in which the control and intervention group are overseen by different investigators as per Section F18 of the Application form and comment on any measures put in place to minimise any potential bias stemming from this approach. - Provide a copy of all questionnaires participants will be asked to complete. - Clarify if the participation in the intervention group will have any implications for future care of participants, eg. ability to undergo MRI scans. If yes, please include these in the Participant Information Leaflet. - Clarify the role and responsibility of Prof Gerard Curley whose signature is on the Site Suitability Form. - Recruitment: - The approach to recruitment for this study is currently unclear from the presented documentation. Clarify this process in the NREC-MD Application Form. In particular the following should be addressed: - Where is the pool of patients that potential participants will be selected from? - Who will first approach potential participants? - Are there any additional recruitment documents that will be used to raise potential participants awareness of the study? - Clarify the purpose of the STRIDE Plain Summary Document.

	– Review the information in the STRIDE Plain Summary Document for accuracy e.g. length of hospital stay following procedure. – Participant information and informed consent process (PIL/ICF): – Please add missing information on site contacts to the highlighted sections of PIL/ICF. – The NREC-MD noted that in it's current format, the PIL/ICF is tailored for US sites and request the PIL/ICF is revised as some of the content, eg Costs, Research related injury, etc is not relevant for participants from Ireland and may cause unnecessary confusion and anxiety. – Consider including details of all payments should be included in the PIL/ICF. – Confirm if information on adverse events and current medications will be collected at the 6 month follow up, as it will at the 3 month and 1 year follow ups. If so, this information should be included in the PIL/ICF. – Please revise the "Study Contacts" section as the NREC-MD not in a position to discuss study details with potential participants. – In line with ISO 14155-2020 and data protection legislation, participant consent must be obtained prior to any 3rd party is contacted if the participant cannot be contacted. NREC-MD request the ICF is updated accordingly. – As data will be transferred outside of the EU to the US, the NREC-MD request the ICF is updated accordingly. – Include information on study insurance policy. – The Data protection annex is revised to provide more information on the aims of the data collection and planned data processing. – Section L12 of the Application Form should be completed. – Provide information about the process for dealing with incidental findings and include a description of this process in the PIL/ICF. – Clarify if any data or samples will be retained for future research and update the relevant documentation and PIL/ICF accordingly. – Confirm that feedback from the site DPO will be implemented prior to the study proceeding. – Provide a study specific budget. – Clarify whether the payments listed in S2 of the Application form are additional to any reimbursements for travel/ accommodation. – Confirm if the legally authorised representative will receive any payments, if applicable. – The NREC-MD noted that the insurance certificate provided cover 15 participants. However, the study documentation states that 30 participants will be recruited at the Irish site. Clarify this discrepancy.
8. AOB	• The Committee discussed their position on cost to participants and agreed that no cost should be incurred by the participants

	either directly or indirectly (via insurance) and that all study related procedures to be provided to participants free of charge. For studies using a predetermined comparator device, the investigational and comparator devices should be provided to participants free of charge. • The Chairperson thanked the Committee and closed the meeting.