NATIONAL OFFICE FOR RESEARCH ETHICS COMMITTEES

NREC-MD Meeting Minutes

21st August 2025

Attendance

Name	Role	Attendance/ Apologies
Prof. Barry O'Sullivan	Chair	Attended
Prof. Mary Sharp	Deputy Chair	Attended
Prof. Declan Patton	Deputy Chair	Apologies
Dr Alyson Bailey	Member	Attended
Dr Caitriona Cahir	Member	Apologies
Dr Daniel Coakley	Member	Apologies
Dr Mireille Crampe	Member	Attended
Dr Ruth Davis	Member	Apologies
Prof Roisin Dwyer	Member	Apologies
Dr Owen Doody	Member	Apologies
Dr Frank Houghton	Member	Attended
Dr James Gilroy	Member	Attended
Prof Suzanne Guerin	Member	Attended
Ms Orla Lane	Member	Apologies
Prof. Cara Martin	Member	Attended
Mr Billy McCann (PPI)	Member	Attended
Dr Natalie McEvoy	Member	Apologies
Prof Tom Melvin	Member	Apologies
Prof Therese Murphy	Member	Apologies
Dr Declan O'Callaghan	Member	Apologies
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	Apologies
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	None
5. 25-NREC-MD-017-R1	• Principal Investigator (Lead Institution): Dr Andrew Simpkin (UHG) • Sponsor: UHG • Study title: A stagewise assessment of the ability of healthy volunteers to utilise pressure monitoring technology for improving the targeted application, monitoring, and maintenance of compression therapy

	• NREC-MD decision: Favourable
6. 25-NREC-MD-019-R1	• Principal Investigator (Lead Institution): Prof Gabor Szeplaki (Mater Private Hospital) • Sponsor: Boston Scientific International S.A • Study title: A Registry on the FARAVIEW Technology of the OPAL HDx Mapping System When Used With the FARAWAVE NAV Ablation Catheter in the Treatment of Atrial Fibrillation (OPALISE) • NREC-MD decision: Favourable with conditions • Associated conditions: 1. The NREC-MD noted that the sponsor intends to forward the documentation to the site for review of data protection. The Committee requests that the study is reviewed by the site DPO and that their feedback is addressed before the study start. 2. The NREC-MD request that the PIL/ICF is updated in line with the above-mentioned site DPO consultation (when it is completed) so that any references to data collection, use, storage, processing or transfer are compliant with GDPR and HRR. 3. The NREC-MD noted that the updated PIL contains a sentence under the heading Medical Records Recovery that may lead to confusion regarding future research: 'This information will be used for research purposes and will be kept confidential'. The NREC-MD request that this sentence is revised to remove ambiguity and ensure reference is to the current study only. 4. The NREC-MD noted that the future use of data is not described in line with regulations or best practice on pg. 6 of the PIL and pg. 2 of the ICF. The NREC-MD request that future use of data is sufficiently explained to participants in the PIL/ICF documents so as to constitute broad informed consent, as required under the Health Research Regulations (Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018). Furthermore, it should be made optional and it should be confined to a specified disease, related diseases or device under investigation in this study. Consent can only be obtained where future use of data is defined such that participants are fully informed, and/or that an option is provided to enable participants to consent to be contacted in the future about other research studies. Optional future research should be made into a separate and explicit consent item in the ICF, with separate participant

	information section and signatures section, so it is distinct from the main consent to participate in the study. The PIL/ICF should also make it clear to participants that subsequent research ethics review will be sought for specific research once clearly defined.
7. 25-NREC-MD-020-R1	• Principal Investigator (Lead Institution): Prof Sherif AH Sultan (University of Galway Ireland) • Sponsor: FeelTect Ltd • Study title: Randomised control study of using a pressure monitoring technology for improving the targeted application, monitoring, and maintenance of compression therapy in patients with Venous Leg Ulcers • NREC-MD decision: Favourable with conditions • Associated conditions: 1. The NREC-MD noted that participants "may withdraw at any time without giving a reason, by letting your clinician know in your next clinical visit". The NREC-MD request that participants are allowed to withdraw from the study at any time and that the PIL/ICF is updated accordingly. Therefore, a contact number or email address should be included to facilitate this. 2. Regarding the DPO contact details, the Committee noted that the Participant Information Leaflet/Informed Consent Form (PIL/ICF) includes contact information for the Feeltect duty manager. The NREC-MD requests that consideration be given to whether the DPO contact details for University of Galway/ Galway Clinic should also be included in the PIL/ICF. 3. The risks of participation in the PIL/ICF are quantified and categorised based on likelihood of occurrence. 4. The benefits of participation in the study are currently misleading and should be revised to reflect that the participant may or may not benefit from participation in this study. 5. The PIL/ICF should be updated to make it clear that data from the sham group will not be transmitted to a research nurse and therefore no potential corrective action will be taken on individuals in this study group. 6. As data will be transferred outside of the EU to be processed by Galen Data in US, a specific consent line for this should be included in the ICF. 7. As pregnant participants, those with intellectual disability and with dementia may be included in this study, Section J1 and Section F11 of the Application Form should updated to reflect this.

	8. The NREC-MD noted that "The study design allows for the involvement of carers who can facilitate participation and can provide informed consent on a participant's behalf if they are unable to do so". Reference to the use of a legally designated representative should be removed from the documentation as the process for identifying a legally designated representative or any assent forms have not been included in this application. If required, these must be submitted as a future substantial modification. 9. Study insurance as per the State Indemnity Guidance (SIG) 10-03: Indemnity and Insurance Arrangements for Clinical Trials Health Research Between Delegated State Authority Healthcare Enterprises and Academic Institutions is in place for the duration of the study.
8. 24-NREC-MD-007-SM2	• Principal Investigator (Lead Institution): Professor Ray McDermott (TUH) • Sponsor: Pfizer • Study title: An Open-label, Randomized, Controlled Phase 3 Study of Disitamab Vedotin in Combination with Pembrolizumab Versus Chemotherapy in Subjects with Previously Untreated Locally Advanced or Metastatic Urothelial Carcinoma that Expresses HER2 (IHC 1+ and Greater) • NREC-MD decision: Favourable
9. 24-NREC-MD-031-SM1	• Principal Investigator (Lead Institution): Prof. Robert Byrne (Mater Private Network) • Sponsor: Teleflex Medical GmbH • Study title: BIOTRONIK – Safety and Clinical Performance of the Drug Eluting Resorbable Coronary MAGnesium Scaffold System (Freesolve®) in the Treatment of Subjects with de Novo Lesions in Native Coronary Arteries: BIOMAG-II: A randomized controlled trial • NREC-MD decision: Favourable
10. 23-NREC-MD-002-SM5	• Principal Investigator (Lead Institution): Prof Gabor Szeplaki (Mater Private) • Sponsor: J&J • Study title: An observational post-marketing study for evaluation of ongoing safety and effectiveness of catheter mapping and ablation using commercially approved BWI medical devices for the treatment of patients with cardiac arrhythmias • NREC-MD decision: Favourable with conditions

	• Associated conditions: 1. The participant information leaflet / informed consent form to be updated to include information on the devices added to the study and any additional clinical data that will be collected from participants treated with the Dual Energy SmartTouch SurroundFlow (DE STSF) ablation catheter.
11. AOB	• None