NATIONAL OFFICE FOR RESEARCH ETHICS COMMITTEES

NREC-MD Meeting Minutes

19/03/2026

Attendance

Name	Role	Attendance/ Apologies
Prof Barry O'Sullivan	Chairperson	Attended
Prof Mary Sharp	Deputy Chairperson	Apologies
Prof. Declan Patton	Deputy Chairperson	Attended
Dr Alyson Bailey	Member	Attended
Dr Caitriona Cahir	Member	Attended
Dr Daniel Coakley	Member	Apologies
Dr Mireille Crampe	Member	Attended
Dr Ruth Davis	Member	Apologies
Prof Roisin Dwyer	Member	Attended
Dr Owen Doody	Member	Apologies
Dr Frank Houghton	Member	Attended
Dr James Gilroy	Member	Attended
Prof Suzanne Guerin	Member	Apologies
Ms Orla Lane	Member	Attended
Prof Cara Martin	Member	Attended
Mr Billy McCann	Member	Attended
Dr Natalie McEvoy	Member	Attended
Prof Tom Melvin	Member	Apologies
Prof Therese Murphy	Member	Attended
Dr Declan O'Callaghan	Member	Apologies
Dr Clare O'Connor	Member	Attended
Prof Paul O'Connor	Member	Attended
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
Prof Colm O'Donnell	External Expert Reviewer. Consultant Neonatologist, National Maternity Hospital (NMH); Professor, School of Medicine, University College Dublin (UCD)	Attended
Dr Louise Houston*	Project Officer, National Office for Research Ethics Committees	
Dr Sarah McLoughlin	Programme Officer, National Office for Research Ethics Committees	
Dr Lucia Prihodova	Programme Manager, National Office for Research Ethics Committees	

*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. 26-NREC-MD-007-R1	• Principal Investigator (Lead Institution): Prof Brian Walsh (CUH) • Sponsor: CergenX Ltd • Study title: Determining Grade of Neonatal Encephalopathy - Agreement between the modified Sarnat examination and automated AI assessment of Newborn Brain Function using Wave software

	• NREC-MD decision: Favourable with conditions • Associated conditions: 1. The NREC-MD requests that recruitment and consenting not occur in the delivery room as this may be distressing for parents especially if there has been an acute perinatal event. 2. The NREC-MD acknowledges that references to randomisation were added to the study materials following a query from the Committee. However, after further consideration of your response, the Committee has determined that this study is not, in fact, randomised, and that the inclusion of randomisation language may be confusing and misleading for participants. The NREC-MD therefore requests that all references to randomisation be removed from the study documentation.
6. 23-NREC-MD-022-SM3-R1	• Principal Investigator (Lead Institution): Prof. Bryan Hennessy (Beaumont Hospital) • Sponsor: Cancer Trials Ireland • Study title: Single arm phase 2 trial of neoadjuvant trastuzumab deruxtecan (T-DXd) with response-directed definitive therapy in early stage HER2-positive breast cancer: a standard chemotherapy-sparing approach to curative-intent treatment – SHAMROCK study • NREC-MD decision: Favourable with conditions • Associated conditions: 1. The NREC-MD noted that the wording on page 32 of the PIL/ICF relating to withdrawal from the study has been updated. However, the revision does not materially change the meaning of the section. The Committee reiterates its request that participants be permitted to withdraw their samples from the study at the same time they withdraw from participation where possible. The PIL/ICF should be updated accordingly to reflect this requirement.
7. 26-NREC-MD-009	• Principal Investigator (Lead Institution): Prof Gabor Szeplaki (Mater Private Hospital) • Sponsor: Abbott • Study title: • NREC-MD decision: Request for further information • Further information requested: 1. The NREC-MD noted that the application documentation states that prospective patients will be indicated for both atrial fibrillation (AF) ablation and percutaneous Left Atrial Appendage occlusion (LAAO). The NREC-MD requests clarification as to what criteria

	will be used to determine contraindication with LAAO. Confirm what European guidelines are being used and if the inclusion criteria align with these guidance documents. 2. The NREC-MD that there is an ongoing study assessing the safety and efficacy of the Amulet 2 device and requests clarification on whether data from the current study will be compared with the outcomes of the Amulet 2 study, rather than just the historical data of the previous device. 3. The NREC-MD noted that if a participant indicates they wish to withdraw from the study early, the site should make attempts to schedule a final clinical investigation visit prior to withdrawal. This final visit includes assessments, a Modified Rankin Scale interview to determine disability and could include neuroimaging. Clarify how will it be ensured that participants wish to withdraw are respected and that they do not feel under undue pressure to undergo additional study procedures. 4. The NREC-MD requests clarification if participants will need to continue with medication required after implantation of Amulet 2 even if the implantation fails. If yes, the Committee requests that the risks due to medication without benefit of the device are included in the PIL/ICF. 5. The NREC-MD noted from the protocol that up to 20 participants may be assigned to a roll-in cohort for LAAO implanters who have not performed a prior implant attempt with the Amulet 2 device. Clarify if these patients will be considered participants in this clinical investigation even though their data will not be used in the primary analysis, and justify this approach. Clarify if data from the roll-in participants will be included in evaluation of safety / efficacy of the device. 6. The NREC-MD noted that the results from the study will only be shared with participants via a website. Given the invasive nature of this study, the NREC-MD requests that participants be given the option to be contacted directly about the results of the study. 7. The NREC-MD noted workflow data will be obtained and requests clarification as to what will be captured in the workflow data, how it will be collected and what it will be used for. The NREC-MD requests that if this will be done via questionnaires to staff, that these are provided for Committee review. 8. The NREC-MD noted that video recording of the procedure will take place and request further information on this. Clarify the following: - What is the purpose of the recording. - Will participants be asked to consent for this. If so, a specific consent line should be included in the ICF for this. - Will staff be required to consent for this e.g. voice recording etc. If so, provide details. - How and where will the recordings be stored and who and when will delete them.

	9. The NREC-MD requests that participants have minimum 24 hours to consider their participation. 10. The NREC-MD requests further information on the recruitment process e.g. time frame between identifying participants, initial contact and the information session held with the hospital. 11. The NREC-MD requests that participants will be given at least 24 hours to consider the study before consent and is clearly stated in the Participant Information Leaflet/ Informed Consent Form. 12. The NREC-MD noted from Section H2 of the Application Form that recruitment will be conducted by the patient's own clinical care team. In line with best practice the Committee request there is a separation between clinical and research activities to minimise any confusion and perceived coercion. Therefore, where possible, they should be approached about their participation by a research nurse or appropriate study team member. 13. The NREC-MD noted that while the PIL/ICF reads well, it could be further revised to improve accessibility and minimise technical language, eg the visit summary. 14. The NREC-MD noted that the PIL/ICF predominantly focuses on the 15. The NREC-MD requests that the first page of the PIL/ICF states that participation in the study is voluntary. 16. The NREC-MD requests that the risks/ adverse events of participation in the study are quantified/ categorised based on risk and likelihood of occurrence. 17. The NREC-MD noted that the neurological exam "must be completed within 14 days of your procedure". The NREC-MD requests that this is revised as it may imply that it might occur post-procedure. 18. The NREC-MD expressed concerns regarding how the trans-oesophogeal echocardiogram examination is presented in the PIL/ICF. While the procedure and its associated risks and invasive nature are described in detail, participants are subsequently informed that they may opt instead for a CT scan. The NREC-MD requests that the PIL be amended to include a balanced outline of the advantages and disadvantages of both procedures, to ensure participants receive a clear and accurate representation of their options. 19. The NREC-MD requests that the PIL/ICF outlines the reimbursement plan for travel expenses. 20. The NREC-MD requests that the alternative care options and standard-of-care options be noted in the PIL/ICF. 21. The NREC-MD noted that the Amulet 2 device contains nickel and requests that nickel hypersensitivity is included in the inclusion/exclusion criteria within the PIL/ICF.

	22. The NREC-MD requests that the PIL/ICF is revised to clearly describe the withdrawal procedures and to specify how data already gathered will be handled if a participant withdraws 23. The NREC-MD request that the section on insurance is revised to clearly inform participants what procedures may or may not be subject to payment/ paid by their insurance. Note also clarify who will bear the cost of long-term care of patients with the Amulet 2 device once the study concludes. 24. The NREC-MD noted that “Trained Sponsor representatives may assist doctors during the study procedure and help with technical support during the follow up study visits”, however no details of their background or expertise has been included e.g. physician etc. 25. The NREC-MD requests that in line with with best practice the sponsor engages with the site DPO and includes the site DPO contact information in the PIL/ICF alongside the sponsor DPO.
8. 26-NREC-MD-010	• Principal Investigator (Lead Institution): Prof Karen Cadoo (St James's Hospital) • Sponsor: Incyte Corporation • Study title: • NREC-MD decision: Favourable / Favourable with conditions • Associated conditions: 1. The NREC-MD noted that biopsy samples can provide valuable, non-repeatable, point-in-time information that may be important for a participant’s future care. The Committee requests that, unless participants consent to future research use, any leftover samples be returned to the study sites. 2. The NREC-MD noted that the PIL/ICF was quite lengthy and overly technical in places e.g. Section “Why the study is done?”. The NREC-MD request that the PIL is further revised to improve accessibility and minimise technical/ legalistic language. 3. The NREC-MD noted that a new tumour biopsy may be required where archival sample is not available. However, the NREC-MD note that the procedure (as outlined in the PIL/ICF) reads as though it is referring to a superficial biopsy. It is not clear how ovarian/peritoneal/fallopian tube tumours could be accessed with the technique described to potential participants. Update this document accordingly to accurately reflect the procedure in question and the risks involved. 4. The NREC-MD requests that reference to the NREC clinical trials email address in the Section “Who do I contact if I have questions?” is removed from the PIL/ICF and a more appropriate sponsor email address is listed instead. 5. Further to above point, note that NREC-MD will never request access to participant data and request

	6. The NREC-MD requests that the PIL/ICF is updated to include a description of what will happen to any data or samples collection during pre-screening should a participant withdraw from the study. 7. The NREC-MD requests that in line with with best practice the sponsor engages with the site DPO and includes the site DPO contact information in the PIL/ICF alongside the sponsor DPO. 8. The NREC-MD noted that future research as it is currently described is overly broad and not in line with best practice. Note that in line with regulations/best practice future use of samples/personal data must be clearly explained to participants in the PIL/ICF 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 confined to a specified disease, related diseases or devices under study in this trial. Consent can only be obtained where future use of samples and 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. The PIL/ICF should also make it clear to participants that subsequent research ethics review will be sought for specific research once clearly defined. For further guidance, see: NREC guidance on use of biological samples and associated data - https://www.nrecoffice.ie/guidance-on-use-of-biological-samplesand-associated-data/ 9. The NREC-MD noted from the site suitability forms that three participants will be recruited at each site. However, Section G2 of the Application Form states that 22 participants will be recruited. Clarify this discrepancy. 10. The NREC-MD requests confirmation that adequate insurance as per the State Claims Agency guideline of minimum €6.5mil will be in place for the duration of the study, as currently the coverage is due to lapse in March 2030 while the study is due to end in May 2030. A copy of the insurance policy to be provided to the National Office once activated. Furthermore, a clear description of this cover to be included in the participant information leaflet / informed consent form.
9. 26-NREC-MD-011	• Principal Investigator (Lead Institution): Sinead Noonan (Cork University Hospital) • Sponsor: Ventana Medical Systems Inc. (Roche Tissue Diagnostics) • Study title:

	• NREC-MD decision: Request for further information • Further information requested: 1. The NREC-MD noted on page 37 of the Protocol that “results from the investigational device…… will not be communicated to patients” and requests that participants are informed about their individual test results. Alternatively justify why will participants not receive the results. 2. The NREC-MD noted that there is no information about reporting of incidental findings. Provide information about how incidental findings will be reported and if applicable, also include this information in the PIL/ICF. 3. The NREC-MD requests a comprehensive list of study termination criteria for the performance study. 4. The NREC-MD noted that leftover samples will be destroyed. The Committee noted that biopsy samples can be a valuable source of point-in-time information that may not be repeatable and can be important for future care of the participant and requests that leftover samples are returned to the study sites. 5. The NREC-MD requests that, in accordance with our requirements, a separate standalone PIL/ICF be provided for the performance study component of this trial. Note that retaining a single combined PIL/ICF would constitute a blocking issue for study approval. Additionally, the following comments should be included in the updated PIL/ICF. 6. The NREC-MD requests that the language used to describe false positive and negative results be simplified and made layperson friendly. 7. The NREC-MD noted that data will be transferred outside of the EU and that this has not been adequately described in the PIL/ICF. The Committee request the PIL/ICF is updated to state what data will be transferred, where it will be transferred, how data will be handled, and what legal safeguards are in place before, during and after transfer. 8. The NREC-MD requests that in line with with best practice the sponsor engages with the site DPO and includes the site DPO contact information in the PIL/ICF alongside the sponsor DPO. 9. The NREC-MD noted that data will be destroyed at the end of study (in 30 years) and requests further information about how this will be done and who will be performing this. 10. The NREC-MD noted that while the performance study is financed under the clinical trial, a study budget specific to the performance study must be provided for Committee review.
10. 26-NREC-MD-012	• Principal Investigator (Lead Institution): Ms Reha Jhunjhunwala • Sponsor: Whoop Inc. • Study title:

	• NREC-MD decision: Request for further information • Further information requested: 1. The NREC-MD again expressed concerns about the lack of care and protection for enrolled participants and the concern and distress the device alerts may cause without any supports provided through the study. The Committee also noted that while the risk of harm may be low, the Committee must be assured that there are appropriate protections and supports given to participants. Comment on how this will be achieved. 2. Further to point 4, outline the qualifications of individuals monitoring the telephone/ email listed on the PIL/ICF, especially in terms of supporting individuals in distress. 3. The NREC-MD requests a copy of the statistical analysis plan, and in particular how will the primary and secondary endpoints for this study be assessed. Clarify: - How the likelihood of participants seeking clinical care earlier and receiving an earlier diagnosis will be calculated and what methods or variables will be used to assess this endpoint are. - Provide more detail on the planned exploratory analyses, longitudinal modelling, and subgroup analyses. 4. The NREC-MD noted that the CIP proposes a benchmarking analysis comparing WHOOP to SOTA. Clarify how will this be achieved. 5. The NREC-MD noted that the study appears as an investigation of the device beyond it's intended purpose and requests confirmation on whether the sponsor engaged with the Health Products Regulatory Authority (HPRA) to determine the Article of the Medical Device Regulations. 6. The NREC-MD noted from the protocol that the Fitzpatrick Skin Classification Scale will be used in this study. Clarify how it will be used and what its purpose is in relation to this specific study. 7. The NREC-MD noted that participants are required to self-declare age and health status (only including healthy volunteers) while noting the justification in the cover letter. The Committee is not satisfied with the justification of this being a decentralised study and requests that you explore alternative ways to verify age of participants. 8. The NREC-MD noted that this study is being conducted as a post market surveillance survey and that users of the device will be contacted and invited to take part in this. Clarify if users will have already consented to being contacted for such a purpose. 9. The NREC-MD noted in Section 2.13 of the PIL/ICF that a "summary of the overall study results may be made available upon reasonable request after the study has been completed and analysed". The NREC-MD requests that the results are always

	made available upon request by a participant and a specific consent line for this is included in the ICF. 10. The NREC-MD noted that data will be transferred outside of the EU to the USA. However, it is unclear to the Committee why data must be transferred outside of the EU and for what purpose this is being done and requests clarification.
11. 25-NREC-MD-028-SM1	• Principal Investigator (Lead Institution): Prof Gabor Szeplaki (Mater Private Hospital) • Sponsor: Abbott • Study title: BLAST OFF Study • NREC-MD decision: Favourable / Favourable with conditions • Associated conditions: 1. The NREC-MD noted under Section 6.3 of the CIP, that the questionnaire will be administered any time prior to hospital discharge. The NREC-MD requests that this is updated to provide an exact timeframe for participants. 2. The NREC-MD requests revision of the PIL/ICF to clarify to participants the number of questionnaires and timing of when each is administered. The current text inconsistently refers to one or two questionnaires, creating confusion given that three questionnaires will be to be used throughout the study (AFEQT-Q, EQ-5D-5L, and QoR-40). The Committee requests the PIL/ICF is updated for simplicity and suggests considering a brief table or list summarising the questionnaire schedule to improve clarity for participants.
12. 21-NREC-MD-007-SM5	• Principal Investigator (Lead Institution): Prof Faisal Sharif (UHG) • Sponsor: Endotronix Ireland Limited • Study title: A Prospective, Multi-Center, Open-Label, Single-Arm Clinical Trial Evaluating the Safety and Efficacy of the Cordella™ Pulmonary Artery Sensor System in New York Heart Association (NYHA) Class III Heart Failure Patients (SIRONA 2 Trial) • NREC-MD decision: Favourable
13. 22-NREC-MD-036-SM5	• Principal Investigator (Lead Institution): Prof Faisal Sharif (UHG) • Sponsor: Endotronix Ireland Limited • Study title: A Prospective, Multi-Center, Open Label, Single Arm Clinical Trial Evaluating the Safety and Efficacy of the Cordella™ Pulmonary Artery Sensor System in New York Heart Association (NYHA) Class III Heart Failure Patients (PROACTIVE- HF Trial) • NREC-MD decision: Favourable

14. AOB	• NO to undertake a review of documentation required for submission with the view to streamline the documentation.