NATIONAL OFFICE FOR RESEARCH ETHICS COMMITTEES

NREC-MD Meeting Minutes

15th January 2026

Attendance

Name	Role	Attendance/ Apologies
Prof Barry O'Sullivan	Chairperson	Attended
Prof Mary Sharp	Deputy Chairperson	Attended
Prof Declan Patton	Deputy Chairperson	Apologies
Dr Alyson Bailey	Member	Attended
Dr Caitriona Cahir	Member	Attended
Dr Daniel Coakley	Member	Apologies
Dr Mireille Crampe	Member	Attended
Dr Ruth Davis	Member	Attended
Prof Roisin Dwyer	Member	Attended
Dr Owen Doody	Member	Attended
Dr Frank Houghton	Member	Attended
Dr James Gilroy	Member	Apologies
Prof Suzanne Guerin	Member	Attended
Ms Orla Lane	Member	Attended
Prof Cara Martin	Member	Apologies
Mr Billy McCann	Member	Attended
Dr Natalie McEvoy	Member	Apologies
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
Ms Louise Houston	Project Officer, National Office for Research Ethics Committees	Apologies
Dr Sarah McLoughlin	Programme Officer, National Office for Research Ethics Committees	Attended
Dr Lucia Prihodova	Programme Manager, National Office for Research Ethics Committees	Attended
Mr Ciaran Horan*	Administrative Assistant, National Office for Research Ethics Committees	Apologies

*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	Mr Damien Owens: 24-NREC-MD-009 Mr Damien Owens stepped out of the meeting for the discussion of the application.
5. 25-NREC-MD-027-R1	• Principal Investigator (Lead Institution): Dr. Sarah Power (Beaumont Hospital) • Sponsor: J&J MedTech, acting through Neuravi Limited • Study title: A Prospective, first in Human pivotal study to evaluate the Adaptive tip catheter used to treat acute ischemic Stroke patients during mechanical Thrombectomy (PHAST)

	• NREC-MD decision: Favourable with conditions • Associated conditions: 1. The NREC-MD requests that all references to consent, assent, and deferred consent are used consistently and appropriately across the study documentation. 2. The NREC-MD requests that the consent processes are in line with legislation and best practice, as per the HSE National Policy for Consent in Health and Social Care Research and the National Office Guidance on legally designated representatives, i.e. in the instances where a participant lacks capacity to consent for participation in the study, their legally designated representative is approached. The following individuals may be considered a legally designated representative for a research study that falls under the scope of the EU Regulations including MDR: • A family member, or someone with a personal relationship with the participant who because of their personal relationship can provide the best interpretation of the will and preferences of the individual. • If no-one in the above category is available to provide consent, a medical practitioner who is primarily responsible for the medical treatment of the participant and not involved in the conduct of the clinical trial or investigation may act as the legally designated representative. • In all cases, the person or medical practitioner acting as a legally designated representative (LDR) should be able to provide the best interpretation of the will and preferences of the participant. 3. The NREC-MD notes that in instances where the medical practitioner acts as a LDR, participant consent will be sought after the procedure. The NREC-MD requests that in the event that the participant does not regain capacity, all reasonable efforts are made to seek a deferred consent from a family member or someone with a personal relationship with the participant. 4. Note that in line with regulations/best practice, future use of samples/images/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/
6. 25-NREC-MD-030-R1	• Principal Investigator (Lead Institution): Dr Mark Hensey (SJH) • Sponsor: Aarhus University Hospital • Study title: Randomized comparison of Evolut FX versus Sapien 3 Ultra Resilia. The Compare-TAVI 2 trial • NREC-MD decision: Request for further information • Further information requested: 1. The NREC-MD noted that while the PIL/ICF was revised, it requires further revisions to ensure both accessibility and compliance with legislation. The Committee noted that there is a PIL/ICF template available at the study site (link here) which could be used to understand the general requirements of PIL/ICFs in Ireland. In particular: • Unbundled consent lines in the ICF, • Consent for anonymisation of data, • Data protection and management information. Furthermore, the NREC-MD requests that: 2. Information on how to withdraw from the study is included in the PIL/ICF. 3. The paragraph on 'Treatment of persons not participating in the trial' is revised to clarify to participants that they will receive normal follow up care. 4. The statement 'There are no additional risks associated with the study' is revised as there are potential risks related to data processing and management. 5. Finally, the NREC-MD noted that during your engagement with the site DPO will receive advice on data management and relevant PIL sections, which should be duly considered.
7. 26-NREC-MD-001	• Principal Investigator (Lead Institution): Prof Damien Kenny (CHI Crumlin) • Sponsor: Occlutech International AB

	• Study title: A multicenter, international, Prospective and Retrospective, post marketing clinical follow-up study to evaluate the efficacy and safety of the Occlutech Patent Ductus Arteriosus Occluder (The Occlutech PDA Occluder) in patients with Patent Ductus Arteriosus defects • NREC-MD decision: Unfavourable NREC-MD Comments: The NREC-MD noted that this application is a resubmission of a previous application and acknowledged the efforts made to address the issues raised by the Committee at the previous meeting (June 2025). The NREC-MD spent a considerable amount of time reviewing the documentation and noted that, in its current form, the application documentation showed a lack of understanding of the regulatory framework and consideration for prospective participants in this study as a number of key aspects are not accurately reflected in either the application documentation or, crucially, in the participant documentation. Namely: 1. This is an application for an important post market clinical follow up (PMCF) of a CE marked device routinely used at the study site and the clinical decision to use the device is done by the clinical team independently from the current study. However, the submitted study documentation does not accurately reflect the procedures, benefits and risks related to the PMCF study itself, which predominantly appears to be undertaken by collection of relevant data. 2. It is unclear to what degree there will be a separation of clinical vs research activities. In line with best practice, participants should be approached about their participation in the study by a research nurse independent from the clinical team only after they have been deemed suitable for the device by their clinical team and have consented to undergo the procedure. This is to ensure that any perception of coercion or device selection bias is minimised. 3. The documentation also speaks about prospective and retrospective participants but provides limited information on the recruitment of retrospective participants. The application should clearly list timelines for recruitment of such participants (eg no later than X number of days since the procedure). Furthermore, the participant documentation must be revised for the enrolment of retrospective participants.

	4. This study appears to also involve a usability study and an analysis of additional exploratory endpoints involving additional devices (Occlutech Occlusion Pusher (OOP) and/or Occlutech Delivery Set (ODS)). From the submitted documentation, it is not clear who will be completing the usability questionnaires and when. If the data from the usability study is collected as a part of this PMCF study, the recruitment strategy, PIL/ICF forms and data management must be also provided. 5. Likewise, if the performance of the Occlutech Occlusion Pusher (OOP) and/or Occlutech Delivery Set (ODS) is assessed in the study, this must be clearly set out in all relevant documentation, including the Participant Information Leaflet. 6. In relation to section E6 of the NREC-MD Application form, note that sponsors have a responsibility under GDPR to provide aggregated study results to study participants. The Committee noted that the findings of the study will be published at www.ClinicalTrials.gov (study code: NCT05264753). However, note as per best practice, the sponsor should provide the participant, if they wish, with aggregated study results, directly to them. 7. The Case Report Form (CRF) provided as a part of the submission includes usability questionnaires and adverse reporting. While these may be collected as a part of the study, clearly structured CRF must be provided for review. 8. The NREC-MD Application Form (section J) states that no persons of childbearing potential will be recruited in the study. As the study intends to include females from 0 to 19 (based on recruitment at 15 and in the study for four years), participants of childbearing age have the potential to be recruited or will become so during the course of the study. 9. The NREC-MD Application Form (section G8) states that the investigational site will provide an interpreter for foreign people. Note that it is the responsibility of the sponsor to provide translated patient-facing documents and interpreters for the study in the relevant language of the participant. From submitted documentation it is unclear if a participant in Ireland, who does not read, speak or understand English, will be facilitated for recruitment by the sponsor. 10. The NREC-MD Application Form (section I3(b)) states that the relationship to the minor is verified using legal documents… (which) must establish legal authority to make decisions on behalf of the child. It is unclear how will this be applied in reality, will the sponsor ask for the parents to present a birth certificate in addition to information on the hospital record or use the name recorded on the hospital record instead.

	11. The documentation should clarify if it is intended to reconsent the children when they reach the age of consenting for themselves/ adulthood. 12. The NREC-MD noted that majority (~ 90%) of prospective participants will be children of young age (0 - 10years). However, the PILs provided are for 'adults from 16 years' children 'from 7-15 years' along with a parent consent form. Clarify if there is no specific assent form for children aged 0-7 years. Also, persons of the age of 16 and 17 years old are still considered children, even though they can consent to take part in the study and to data processing of their personal data. Correct wording. 13. As stated above, all study related PIL/ICF documents must be revised as per study activities. Therefore, a consent for clinical standard of care procedures must be addressed separately by the participants clinical team. 14. While the PIL/ICFs provided with this submission are significantly improved, the NREC-MD noted that all forms require further revisions and that any images and graphics should be used for context and to aid understanding. Furthermore, in relation to the PIL for 7-15 year old participants: 15. The Committee noted that the PIL/ICF is for a broad age range with a great difference in levels of comprehension. 16. Page 2 states "You can ask questions at any time. If you feel shy or uncomfortable asking in front of your parents, you can ask to speak with your doctor alone." which the Committee noted is inappropriate. 17. There are inconsistencies in the number of visits listed across the documentation. The PIL states that there will be five visits in total, however the application states there are four follow up visits. Alternatively, if there is a first check up, and visit to place the occluder and four follow up visits, there are 6 visits in total. 18. In relation to the PIL for adults, the Committee noted the following: 19. Page 3 states: "The only study-specific activity is signing this consent form." However, the study involves access to and ongoing use of participant data. 20. The email address for the Irish Data Protection Commissioner should be included on the PIL. 21. The NREC-MD noted there appears to be lack of clarity over the role of data controller vs processor and that, in this study, the data controller for research data collected is the study sponsor and not the hospital.

	22. The list of countries in which the data will actually be processed or stored must be clearly listed in the application documentation. 23. Note that in line with regulations/best practice, future use of samples/images/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/ 24. The NREC-MD noted that the sponsor states that "Considering that the investigation does not fall under the scope of interventional clinical trials and in accordance with the applicable regulatory framework a separate study specific insurance is not deemed necessary." This approach is not aligned with 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 and must be revised. 25. Section R of the NREC-MD Application Form should state who is financing this study. 26. While the NREC-MD noted that all study follow up visits will be carried out in line with care follow up visits, participants should be offered a compensation for any reasonable expenses incurred. For example, if they have to stay in the hospital for longer due to study related procedures, then they and their carer/ parent should be offered compensation for parking or a meal.
8. 26-NREC-MD-002	• Principal Investigator (Lead Institution): Dr. Matthew Barrett (SVUH) • Sponsor: University Maastricht

	• Study title: PREDICT-CVD - PREcision meDICation in the Treatment of CardioVascular Disease • NREC-MD decision: Request for further information • Further information requested: 1. The NREC-MD noted that this is a study of non-CE marked device submitted under Article 82 of the Medical Device Regulation. Confirm that HPRA agree with the study classification and provide an outcome of your engagement with the HPRA on the study. 2. The NREC-MD requests clarification on how the data from the smart phone and application will be used in the study. 3. Additionally, clarify if the optional home monitoring by these devices is a requirement of the study or an optional sub-study. 4. The NREC-MD requests that planned subgroup/sensitivity analyses and handling of missing data are pre-specified in the statistical analysis plan. 5. The NREC-MD noted that in document 3 Site Suitability form, section A3 states that name of site is 'University College Dublin UCD, National University of Ireland, Belfield, Dublin 4' while the NREC Application Form section D2 states that the site is 'St Vincent's University Hospital, Elm Park, Dublin 4, Ireland' and elsewhere the site is listed as the 'Heart Failure Unit, St Michael's Hospital, Dun Laoghaire'. Rectify the discrepancies and update the forms with the correct site information. If the study is to take place across multiple sites, provide Site Suitability Forms for each. 6. The NREC-MD noted that as the Committee previously reviewed a study led by the PI, he has experience leading clinical trials, however it is not included in his CV. Therefore the Committee requests that the CV of the PI is updated to include information on his previous roles as PI and/or investigator in other relevant clinical trials. 7. The NREC-MD noted that eligibility criteria are well described in the application documentation. However, the Committee requests further information on and clarification of the initial selection process for potential participants, e.g. does this include a review of new patients, a review of patient charts, etc. 8. Furthermore, clarify who will approach potential participants (role/qualification) and how separation between clinical care and research invitation will be maintained to minimise undue influence, particularly for patients approached at discharge.

	9. The NREC-MD request a detailed outline of the selection and recruitment of participants. Will all eligible participants be approached about the study, etc. 10. The NREC-MD noted that the PIL states that if blood samples are no longer needed they will be destroyed, however samples may also be used for future research. Clarify this discrepancy. 11. The PIL states that blood samples will be retained for 25 years at the co-ordinator site, and also implies that if blood samples are retained for future research that they will be retained for a further 25 years. Clarify if the blood samples will be retained for 25 years only or potentially 50 years in total. 12. The NREC-MD noted that the study protocol does not clearly describe whether clinically relevant incidental results could arise from proteomics and, if so, how they would be managed/communicated. Clarify. 13. The NREC-MD noted that travel expenses of participants will be reimbursed. Give the age and health of some participants, the NREC-MD recommends that travel expenses of carers should also be reimbursed. 14. The NREC-MD noted that the Irish site should be included in section J1 of the NREC Application Form as a controller/processor of participant data. Update the Application Form with this information. 15. The NREC-MD request that you clarify retention periods for each dataset (clinical, device, app, samples) and the mechanism for deleting identifiable data upon request. 16. The NREC-MD requests that the PIL/ICF is revised for accessibility, eg any abbreviations are explained and that any typos are removed. 17. The NREC-MD requests that the PIL/ICF is revised to replace the word ‘subject’ with ‘participant’, in line with The Declaration of Helsinki. 18. The NREC-MD requests that the PIL/ICF includes the name and contact information of the PI on the first page of the PIL. 19. The NREC-MD requests the PIL/ICF is revised to clearly inform participants that this study is ‘first-in-human’. 20. The NREC-MD requests that the section ‘7. What are the pros and cons if you take part in the study?’, include information on the risks associated with an AI-program aiding clinical decision-making and risks, if any, related to AI use of participant data. 21. The NREC-MD noted that the duration of the follow up in the PIL/ICF is vague: phone calls “every six months until the last participant worldwide has completed” and could be perceived as

	open-ended. Revise and include an estimated maximum duration/range. 22. The NREC-MD requests that information about data collection, processing, data protection and the legislative bases for each is included in the Patient Information Leaflet and Informed Consent Form (PIL/ICF). 23. The NREC-MD requests that information about what data from the Huawei D2 SmartWatch and the CardioSignal Research Application will or may be stored in the cloud and where it will be located is included in the PIL/ICF. 24. The NREC-MD request that the ICF is revised for clarity, to ensure all consent lines are consistent. Include tick boxes for each consent line. 25. The NREC-MD request that the ICF is revised to include a consent line for participants to be contacted again in future regarding future use of data/samples in research as per best practice. 26. Additionally, as the National Clinical Trials Office (NCTO) was closed in 2025, remove all references to it in the PIL/ICF. Similarly, remove references to the Medical Ethics Review Committee of St Vincent's Healthcare Group. 27. The NREC-MD requests further information to clarify whether the proteomics research is part of the current study or if it will be part of further future research. 28. Note that in line with regulations/best practice, future use of samples/images/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. 24-NREC-MD-009-SM1	• Principal Investigator (Lead Institution): Prof Jonathan Lyne (Beacon Hospital) • Sponsor: Medtronic • Study title: Affera Global Registry • NREC-MD decision: Favourable
10. 23-NREC-MD-002-SM6	• Principal Investigator (Lead Institution): Prof Gabor Szeplaki (Mater Private Hospital) • Sponsor: Johnson & Johnson MedTech • 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: Request for further information • Further information requested: • The hospital target recruitment number increased from 300 to 400. The Committee noted that this is in line with design and purpose of this MDR study. Clarify if the total number of participants in the study is increasing across all study sites. Furthermore, comment on how will this increase impact the data analyses and interpretation of results of the study. • The NREC-MD noted that a justification has not been provided for all study endpoints that were removed. Provide a rationale for all endpoints that are removed. • Furthermore, clarify if any 'old' endpoint data have been collected and whether this data will be retained or deleted. If the data are retained, clarify how will the data be used. • The NREC-MD noted that safety reporting changed from immediately to 2 weeks and one month in some cases. Provide justification for this approach and comment on how this change aligns with the Medical Device Regulation (EU 2017/745) and the ISO 14155/2020.
11. 21-NREC-MD-007-SM4	• 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

12. 24-NREC-MD-020-SM3	• Principal Investigator (Lead Institution): Prof Ronan Cahill (UCD) • Sponsor: UCD • Study title: CLASSICA: Validating AI in Classifying Cancer in Real-Time Surgery • NREC-MD decision: Request for further information • Further information requested: 1. The NREC-MD requests further information to fully understand the plans to pseudonymise the personal data and how this pseudonymised data will be used for future research. 2. The NREC-MD notes the request to align the wording for pseudonymisation of data for future use in the PIL and ICF. 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. • sharing of samples/personal data for future use should be limited to specific partners or organisations and this should be clearly specified and described in the PIL/ICF. 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/
13. 25-NREC-MD-011-SM3	• Principal Investigator (Lead Institution): Prof Christina Fleming (UHL) • Sponsor: Qufora A/S • Study title: A randomized clinical investigation to assess efficacy of low volume Transanal Irrigation by Qufora® Irrisedo Minigo versus conservative treatment for Low Anterior Resection Patients • NREC-MD decision: Favourable with conditions • Associated conditions:

	1. For the ICF amendment that adds the GDPR legal basis for processing sensitive data, a reference to the GDPR should be added as currently the sentence makes reference only to specific articles and fails to name where they can be found. 2. The following sentence is removed from the PIL as it is inaccurate: 'The review by the ethics committee [ie, NREC-MD] ensures the protection of study participants and compliance with their rights.'
14. 25-NREC-MD-023-SM1	• Principal Investigator (Lead Institution): Prof Robert Byrne (Mater Private Hospital) • Sponsor: Boston Scientific International S.A • Study title: AGENT Drug-Coated Balloon for STent AvoidANCE in PCI for De Novo Coronary Artery Disease • NREC-MD decision: Favourable
15. AOB	• None