NREC-MD Meeting Minutes

11 December 2025

Attendance

Name	Role	Attendance/ Apologies
Prof. Barry O'Sullivan	Chairperson	Attended
Prof. Mary Sharp	Deputy Chairperson	Attended
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	Apologies
Dr Owen Doody	Member	Apologies
Dr Frank Houghton	Member	Attended
Dr James Gilroy	Member	Apologies
Prof Suzanne Guerin	Member	Attended
Ms Orla Lane	Member	Attended
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	Attended
Dr Clare O'Connor	Member	Apologies
Prof Paul O'Connor	Member	Attended
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
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	
Dr Emily Vereker	Head of Office, National Office for Research Ethics Committees	
Ciaran Horan*	Administrative Assistant, National Office for Research Ethics Committees	

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-022-R2	• Principal Investigator (Lead Institution): Dr Cliona Grant (St James's Hospital) • Sponsor: QIAGEN Manchester Limited

	• Study title: An interventional performance evaluation study for testing of DNA extracted from tumor tissue biopsy samples, using the therascreen® HPV Panel RGQ PCR Kit from Participants with Oropharyngeal Squamous Cell Carcinoma (OPSCC) in Bicara's Clinical Trial (Protocol No. BCA101X301) to generate data to demonstrate the performance of the Kit as a CDx. • NREC-MD decision: Favourable with conditions • Associated conditions: 1. The NREC-MD is not satisfied with the provisions for future research presented in this study, in particular in the participant information leaflet and informed consent form (PIL/ICF). As no PIL/ICF on future research under the IVDR was submitted to NREC-MD for review the Committee has come to the decision that presently the current study is not approved for any future research. If the sponsor intends to carry out future research from samples collected during the performance study, either under the performance study or the clinical trial, an updated PIL/ICF must be submitted in the form of a substantial modification for review by NREC-MD.
6. 25-NREC-MD-029	• Principal Investigator (Lead Institution): Ms Reha Jhunjhunwala (WHOOP INC.) • Sponsor: WHOOP INC. • Study title: A Post-Market Clinical Follow-up (PMCF) Study of the WHOOP Irregular Heart Rhythm Notification (IHRN) and Electrocardiogram (ECG) Feature. • NREC-MD decision: Unfavourable NREC-MD Comments: 1. As the study aims to 'help users monitor heart rhythm patterns and identify potential irregularities, such as atrial fibrillation,' the NREC-MD was significantly concerned by the absence of oversight by a clinical professional in this field (e.g., a trained cardiologist) and by the lack of engagement with participant's healthcare provider/ general practitioner. 2. The Committee also noted that while the Principal Investigator is a qualified dental practitioner with extensive experience in digital health, the documentation provided does not provide evidence of experience leading studies of comparable scale. 3. The NREC-MD noted there is no provision for support for potential participants from trained qualified individuals during the consenting process for this study, therefore potentially compromising the consent process.

	4. The NREC-MD noted that the current study has significant limitations in achieving the study aims. The study aims to quantify the likelihood of seeking clinical care earlier with a screening device compared to without a screening device in a non-interventional design. 5. Furthermore, the NREC-MD noted that participants will be assigned into 4 groups: 2 cohorts and 2 control, which do not appear to be constituted of comparable participants, therefore raising concerns about the potential interpretation and validity of results. 6. The NREC-MD expressed significant concerns regarding the requirement in the PIL/ICF for participants to agree not to share any study-related information in public forums. The PIL/ICF does include a justification nor explains how the Sponsor intends to enforce this requirement or outline the potential consequences for participants should they breach it. These details along with justification for such ask should be clarified and communicated to participants prior to consent. 7. The NREC-MD noted that the results from this study will not be published and participants will not be informed of the outcome of this study. Aside from this being contrary to obligations with MDR and best practice, it also raises transparency issues, potentially impacting public trust in research from an ethical point of view. **The NREC-MD also raised concerns about the following:** **Study procedures** 8. The NREC-MD noted that participants will be self-selecting for participation and establishing their own eligibility without any verification of age or capacity, and therefore also possibly enrolling potentially vulnerable participants with no additional support available from the study team. Furthermore, as the device functionality is dependent on appropriate fitting, the study does not involve any verification of fitting being done appropriately. 9. The NREC-MD 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. 10. The NREC-MD noted from the protocol that a sub-analysis will be carried out on participants aged over 65 years. It is not clear from the documentation how this will be done and what supports, if required, will be provided to this cohort.

11. The NREC-MD noted that the language used in the initial contact to potential participants may cause participants an unnecessary sense of urgency e.g. “LETS GO!”. The NREC-MD requests that the initial contact should be neutral in tone.
12. The NREC-MD noted in the protocol that adverse events such as death, serious deterioration in health etc. are listed but it is unclear how could these be captured accurately as they depend on the participants reporting them, therefore potentially introducing a bias to study findings.

Staff suitability

13. The NREC-MD noted that the lead Principal Investigator for this study along with a large portion of those involved in the study, are paid employees of WHOOP and that no conflict of interest management plan or involvement of independent investigators/ oversight committee appears to be in place.

Participant information leaflet / informed consent form

14. The NREC-MD noted on page 11 that NREC-MD “may also access your study records to ensure the research is being conducted ethically and in compliance with regulations”. The NREC-MD will never request access to participant data or medical records. This should be removed.
15. The NREC-MD noted that no phone number has been provided in the PIL/ICF for participants to use if they wish to withdraw from the study.
16. The NREC-MD noted that the description of future research in the PIL/ICF as it is currently written is very open ended, blanket in nature and not in line with regulations or best practice.

    Please 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/
7. 25-NREC-MD-030	• Principal Investigator (Lead Institution): Dr Mark Hensey (St James's Hospital) • Sponsor: Aarhus University Hospital • Study title: andomized comparison of Evolut FX versus Sapien 3 Ultra Resilia. The Compare-TAVI 2 trial • NREC-MD decision: Request for further information • Further information requested: **Study procedures** 1. The NREC-MD noted that Section G5 of the Application Form states that healthy volunteers will take part in this study. Please clarify if this is correct and in what context healthy volunteers will be recruited. 2. The NREC-MD noted that ~50-100 participants will be recruited overall in Ireland. Please comment on the feasibility of reaching this number given that there will only be one site in Ireland taking part in this study. 3. The NREC-MD noted that the sponsor has addressed how valve deterioration will be handled if found. The NREC-MD requests further information on how all incidental findings will be managed in Section J17 of the Application Form. 4. The NREC-MD requests that you complete Section K17 and K21 of the Application Form. 5. The NREC-MD requests that Section L of the Application Form be completed to document the inclusion of standard-of-care radiation exposure in this study. 6. The NREC-MD noted that the PIL/ICF references potential sub-studies. Please clarify if these sub-studies will take place in Ireland and if not, please ensure these are removed from the PIL/ICF. 7. The NREC-MD noted that Ireland is not mentioned as a participating country in the clinical investigation plan nor is the PI in Ireland listed as a member of the steering committee. Please clarify this discrepancy and update the documentation accordingly.

Suitability of the investigator

8. The NREC-MD noted from the protocol that “Any procedure requires that the physician has performed at least 15 implantations with each of the THVs in use. Otherwise, the procedure is performed according to the routine of the institution”. Please confirm that all of the participating physician will have inserted at least 15 of each of the relevant devices.

Participant information leaflet / informed consent form (PIL/ICF)

9. The NREC-MD requests that the PIL is substantially revised to improve accessibility, minimise technical language and adapted for Irish setting.
10. The NREC-MD noted from Section H2 of the Application Form that patients in an outpatient clinic environment will be recruited to this study. Please clarify how much time will such patients be given to consider the information presented to them in the PIL/ICF.
11. The NREC-MD requests that “two above-mentioned valves are equivalent for the treatment of your narrowed heart valve” phrase in the side effects section of the PIL is re-phrased to “appropriate” as this study is undertaken to assess their equivalence.
12. The NREC-MD noted that patients who do not take part in the trial will have one of the two valves implanted. Please clarify if these two valves are the only current standard of care at the site or are there other valves that might be available to patients undergoing this procedure at the study site.
13. The NREC-MD noted that the PIL/ICF as it is currently written does not fully capture the extent of follow up required by this study in adequate detail. The NREC-MD requests that the PIL/ICF is updated to provide this information e.g. ECGs required by in person visits, follow up intervals, procedures undertaken at each visit etc.
14. The NREC-MD request that the phrase “drawing lots” used in the PIL/ICF is elaborated to explain the process of randomisation to potential participants. If possible, the NREC-MD suggests changing this term to describe a coin toss, which is more regularly seen in PIL/ICFs.
15. The NREC-MD noted under the heading “control and follow up examinations” that follow up will be carried out “the university department rather than at the local hospital”. Please update the PIL/ICF to make it clear exactly where the follow up will occur.

16. The NREC-MD noted that the PIL/ICF consistently refers to patient medical records as their “journal” and requests that this be updated to reflect terminology used in Ireland.
17. The NREC-MD requests that the section “disclosure of information from your journal” is revised as it currently appears to be missing content in its current format.
18. The NREC-MD requests that the section on “information on financial matters” section is revised to be participant specific e.g. reimbursement for travel etc.
19. The NREC-MD requests confirmation that the section on ‘the rights of a trial subject in a biomedical research project’ is fully applicable to participants in Ireland. The Committee noted several references to the Danish Healthcare Act and Danish Data Protection Act. Please review the documentation and replace these references with Ireland-specific legislation / information.
20. The NREC-MD requests that the PIL/ICF is reviewed for compliance with the Health Research Regulations (Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018) and is updated to include a section on data management; including but not limited to, the purpose of data collection, types of data collected, how the data will be used, stored and retained, any data sharing, data security etc. Engaging with the site DPO on this might be particularly beneficial.
21. The NREC-MD noted that images/data will be transferred to Denmark and this is described in the PIL as ‘coded’ data. The NREC-MD request that the term ‘coded’ is explained to individuals e.g. anonymised.
22. The NREC-MD requests that the consent form is revised to provide unbundled consent, ie separate boxes are included for all consent statements in the ICF.
23. The NREC-MD noted in Section H9 of the Application Form that participant data will be retained up until the point of study withdrawal. The NREC-MD request that this information is clearly outlined to participants in the PIL/ICF.
24. The NREC-MD request that the section in the PIL/ICF outlining participant withdrawal and their right to withdraw is revised and elaborated to make the process and participant rights clearer to potential participants.

Insurance and financial arrangements

25. The NREC-MD noted that the insurance appears to be in the name of the PI for the study, rather than the sponsor or site.

	Please clarify if there is a procedure in place should the PI change for any reason. Please confirm that the clinical trial policy is in line with the State Claims Agency guidance. 26. The NREC-MD requests clarification as to whether reimbursement for transportation will include the use of a participants own car e.g. petrol and parking costs. Moreover, as this study involves an ageing population, the NREC-MD requests due consideration is given to the option of covering transportation costs for a participant's carer / guardian travel. **Data protection** 27. The NREC-MD noted that Section H3 of the application form states that "The Sponsor will not have access to any directly identifiable personal data at any stage of the study". Please clarify whether sponsor monitors listed in the CIP will have access to patient charts or personal data. 28. The NREC-MD noted that Sections J2 and J6 of the Application Form provide conflicting information stating that the data collected from participants will be pseudonymised and anonymised respectively. Please clarify this discrepancy and update the documentation accordingly. Please note that if any data is to be anonymised, participant consent for anonymisation must be obtained. 29. The NREC-MD noted that the PIL/ICF does not contain any references to future research. However, Section J15 of the Application Form states that "…we state in the patient consent form that data can be used for further collaborative research". Please clarify this discrepancy and update the relevant documentation accordingly.
8. 25-NREC-MD-031	• Principal Investigator (Lead Institution): Dr Sinead Cuffe (St James's Hospital) • Sponsor: Ventana Medical Systems, Inc • Study title: Diagnostic Protocol for Evaluating the Clinical Performance of the VENTANA TROP2 (EPR20043) RxDx Assay in Determining TROP2 Biomarker Status in Non-Small Cell Lung Carcinoma tissue specimens for Merck Sharp & Dohme LLC's Phase 3 Study MK2870-023 • NREC-MD decision: Request for further information • Further information requested: **Biological samples** 1. The NREC-MD noted that 20 slides will be collected for the purpose of the study and that future research will be carried

	out on leftover samples. The Committee noted that 20 slides may be excessive for analyses carried out under current performance study. Unless justified, the NREC-MD requests that only the required size of samples is sent from the study site to the sponsor any unused samples are returned to the site in order to be available for the participants care in the future. Hence, clarify if any remaining samples will be returned to the participant's hospital and provide justification if not. 2. The NREC-MD request that you provide information about the location and use of any leftover or excess samples after the conclusion of the study, including any positive or unenrolled samples. **Data protection and future use of samples** 3. The Committee is not satisfied that the current study falls within the consent received from the clinical trial participant information leaflet / informed consent form (PIL/ICF) for the following reasons: • The future use of samples is not adequately or explicitly explained in the PIL/ICF provided. • The consent as it is currently presented in the provided PIL/ICF is bundled which is not in line with best practice. • Moreover, the participants did not have the option to request to be notified when this future use of data would occur. If future research is to be carried out, then this should be outlined clearly in the documentation and a specific consent line for this should be included in the ICF. Please 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/ The NREC-MD request that participants whose samples are used as part of this study are consented separately and a detailed overview of how this will occur including any associated documentation required to do so (e.g. PIL/ICF) is provided. 4. The NREC-MD noted from Section J6 of the Application Form that personal data will be retained for up to 25 years. However, the PIL/ICF provided states that data will be retained for up to 15 years. Please clarify this discrepancy and update the documentation accordingly. If the data will be stored for longer than 15 years, please note that all participants will need to re-consent for this.
9. 24-NREC-MD-030-SM1	• Principal Investigator (Lead Institution): Prof Stewart Walsh (University Hospital Galway) • Sponsor: RCSI • Study title: Randomised Controlled Trial comparing partial calcanectomy plus local application antibiotic impregnated bone graft substitute for calcaneal osteomyelitis vs partial calcanectomy alone (The ACHILLS Trial) • NREC-MD decision: Favourable
10. 25-NREC-MD-001	• Principal Investigator (Lead Institution): Dr Darren Mylotte (Galway University Hospital) • Sponsor: Medtronic • 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
11. AOB	• The Chairperson thanked the Committee for their work, wished all happy holidays and closed the meeting.