# NREC-MD Meeting Minutes

**20 November 2025**

## Attendance

| Name | Role | Attendance/ Apologies |
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| 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 | Apologies |
| Prof Roisin Dwyer | Member | Attended |
| Dr Owen Doody | Member | Apologies |
| Dr Frank Houghton | Member | Apologies |
| Dr James Gilroy | Member | Apologies |
| Prof Suzanne Guerin | Attended | 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 | Attended |
| 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 |

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| Prof. Mahendra Varma | Member | Attended |
| Mr Peter Woulfe | Member | Attended |
| Ms Simone Walsh | Member | Attended |
| Dr 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 |
| Dr Emily Vereker | Head of Office, National Office for Research Ethics Committees | Apologies |
| Ms Caroline Burke (Observing) | Project Officer, Health Research Consent Declaration Committee | Attended |
| Mr Ciaran Horan* | Administrative Assistant, National Office for Research Ethics Committees | Apologies |

**Quorum for decisions:** Yes

| **Agenda, discussion and decisions** | |
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| 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 | Prof Tom Melvin: 25-NREC-MD-025 and 25-NREC-MD-026<br>Prof Melvin stepped out of the meeting for the discussion of the application. |

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| 5. 25-NREC-MD-022-R1 | • Principal Investigator (Lead Institution): Dr Cliona Grant (St James's Hospital)<br>• Sponsor: QIAGEN Manchester Limited<br>• 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.<br>• NREC-MD decision: Request for further information<br>• Further information requested:<br>– The NREC-MD requests that participants will be given at least 24 hours to consider the study before consent. If this cannot be included in the PIL/ICF then it should be implemented in the recruitment procedures or protocols as standard practice.<br>– The NREC-MD noted from the response letter that of the potentially 6 curls collected, one curl will be used for testing, one curl will be retained for repeat extraction/repeat testing if required, and the rest will be used for future supporting studies carried out by Qiagen and/or Bicara. The NREC-MD requests a clarification on:<br>o the role of both the performance study sponsor (Qiagen) and clinical trial sponsor (Bicara) in the processing and storage of the additional four samples requested for future research.<br>o whether there is an agreement between the sponsors of the performance study and the clinical trial regarding the transfer of samples throughout the lifecycle of both studies.<br>o where the samples will be stored throughout the lifecycle of the study.<br>– The NREC-MD noted from the response letter that a separate ICF for future use of samples has been developed and approved as a part of the CTIMP review process. However, as future use of research will be carried out under samples collected as part of the performance study, this ICF, or an ICF for future use of samples from the performance study, must be submitted to and reviewed by NREC-MD.<br>Please note that in line with regulations and 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, |

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| | ○ 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,<br>○ and/or that an option is provided to enable participants to consent to be contacted in the future about other research studies.<br>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-025-R1 | – Principal Investigator (Lead Institution): Dr Roisin Colleran (Mater Private Network Dublin)<br>– Sponsor: TUM University Hospital, German Heart Center (academic), Abbott Vascular International bvba (industrial)<br>– Study title: Intracoronary stenting and restenosis – Randomized trial of drug-eluting stent implantation or drug-coated balloon angioplasty according to neointima morphology in drug-eluting stent restenosis (ISAR-DESIRE 5)<br>– NREC-MD decision: Favourable with conditions<br>– Associated conditions:<br>– Section L of the Application Form to be reviewed and signed by the medical physics expert.<br>– A copy of the GP letter to be sent to the National Office for Research Ethics Committees for our records.<br>– In line with best practice there should be separation between clinical and research activities to minimise any confusion and perceived coercion. Therefore, where prospective participants are under the care of the PI, they should be approached about their participation by a research nurse or appropriate study team member when feasible.<br>– 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. 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. |
| 7. 25-NREC-MD-026-R1 | • Principal Investigator (Lead Institution): Prof Maeve Lowery (St James's Hospital) |

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| | • Sponsor: Luminate Medical Inc<br>• Study title: IMPACT: A Clinical Investigation on IMproving Peripheral Neuropathy Induced by Chemotherapy with Advanced Compression Technology – A Safety and Efficacy Study<br>• NREC-MD decision: Favourable |
| 8. 25-NREC-MD-027 | - Principal Investigator (Lead Institution): Dr Sarah Power (Beaumont Hospital)<br>- Sponsor: J&J MedTech, acting through Neuravi Limited<br>- 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)<br>- NREC-MD decision: Request for further information<br>- Further information requested:<br>- The NREC-MD requests clarification of the time to inclusion in the study, from when a potential participant first presents at the site.<br>- While the NREC-MD noted that exposure to radiation in this study is comparable to standard of care, the NREC-MD requests that a Medical Physicist Expert reviews and signs of on Section L of the Application Form.<br>- The NREC-MD requests further information on the publication plan and requests that when this data is published that data from all 74 participants (10 participants for preliminary data and 64 subsequent participants) is included.<br>- The NREC-MD request clarification of the role of the Principal Investigator (PI), Dr Power, and their relationship with J&J, as the NREC-MD noted that Dr Power receives payments from the Sponsor for a consultancy services. The Committee noted that the PI has unique expertise in this area and research however given the complexity of this study, request that you provide a conflict-of-interest management plan for the PI.<br>- Further to the above, as the PI will be responsible for evaluating the study outcomes, please outline what measures will be in place to prevent bias in the interpretation of results. This can be included in the above conflict of interest management plan if appropriate.<br>- The NREC-MD noted discrepancies throughout the application documentation in terminology pertaining to consent vs assent and the role of legally designated representative as outlined in Irish legislation and policies. The Committee requests the applicant reviews and aligns the application form and their recruitment process as per the HSE National Policy for Consent |

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| | in Health and Social Care Research and the National Office Guidance on legally designated representatives.<br>- Regarding deferred consent for participants lacking decision-making capacity, the NREC-MD noted that Section H12 of the Application Form states: 'excluding such participants would mean it is not possible to assess the device's safety, effectiveness, and potential benefit for treating acute ischemic stroke.' However, as this is a first-in-patient study for the device, the NREC-MD considers that relying solely on deferred consent to achieve the study objectives is not sufficiently justified. The Committee also noted that the study plans to enrol 10 participants in Ireland over an 18-month period. Please provide details on the potential participant pool presenting to Beaumont Hospital during this timeframe, and indicate the expected incidence of cases where neither the patient nor their legally designated representative is able to provide consent.<br>- The NREC-MD seeks clarification on timelines for applying deferred consent: when a participant arrives without a legally designated representative, is there a defined timeframe for contacting the LDR and obtaining assent before the PI initiates deferred consent?<br>- Given that this study involves deferred consent, please clarify if the Sponsor has liaised with the Health Research Consent Declaration Committee (HRCDC), and provide details of this discussion. If not, please note that in line with Data Protection Act 2018 (Section 36(2) (Health. Research) Regulations 2018, an application to Health Research Consent Declaration Committee (HRCDC) may be necessary and the NREC-MD recommends that you engage with them to determine if an application for consent declaration for this study is required.<br>- The NREC-MD noted that the PIL/IC states that 'the adaptive tip catheter is not currently approved by the European authorities' and request that the statement clarifies if it is approved in other jurisdictions.<br>- The NREC-MD requests that in line with the Data Protection Act 2018 (Section 36(2) (Health. Research) Regulations 2018 consent form is revised to provide unbundled consent, i.e. separate boxes are included for all consent statements in the ICF.<br>- The NREC-MD noted that the application dossier did not include PIL/ICF templates used for obtaining assent by legally designated representative nor a template for affirming consent from the participant in situations where deferred consent/ LDR assent was obtained prior to the study procedure. |

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| 9. 25-NREC-MD-028 | – Principal Investigator (Lead Institution): Prof Gabor Szeplaki (Mater Private Hospital Dublin)<br>– Sponsor: Abbott<br>– Study title: BaLloon-based PFA Ablation poST approval Outcomes for PAF and PersAF<br>– NREC-MD decision: Favourable with conditions<br>– Associated conditions:<br>– The NREC-MD noted the following from the PIL/ICF "There may be a representative from Abbott present at your ablation procedure to help collect this study information". Please update the PIL/ICF to confirm that this individual will be a suitability qualified individual.<br>– The PIL/ICF as it is currently written implies that additional testing and future research may be carried out on participant data. 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.<br>Please note that in line with regulations and 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,<br>– 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,<br>– and/or that an option is provided to enable participants to consent to be contacted in the future about other research studies.<br>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/<br>– The NREC-MD requests that the welfare and dignity of participants, in particular in relation to identifying factors, are at the forefront of procedures involving recording and live streaming of procedures. |
| 10. 23-NREC-MD-006-SM3 | • Principal Investigator (Lead Institution): Dr Adrian Murphy (Beaumont Hospital)<br>• Sponsor: Seagen Inc. |

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| | • Study title: An Open-label Randomized Phase 3 Study of Tucatinib in Combination with Trastuzumab and mFOLFOX6 versus mFOLFOX6 given with or without either Cetuximab or Bevacizumab as First-line Treatment for Subjects with HER2+ Metastatic Colorectal Cancer<br>• NREC-MD decision: Favourable |
| 11. AOB | • None |