NATIONAL OFFICE FOR RESEARCH ETHICS COMMITTEES

# National Research Ethics Committee

## NREC-MD Meeting Minutes

**16th March 2023**

### Attendance

| Name | Role |
|---|---|
| Prof. Barry O'Sullivan | Chairperson, NREC-MD |
| Prof. Mary Sharp | Deputy Chairperson, NREC-MD |
| Prof. Declan Patton | Deputy Chairperson, NREC-MD |
| Dr Caitríona Cahir | Member, NREC-MD |
| Dr Mireille Crampe | Member, NREC-MD |
| Dr Ruth Davis | Member, NREC-MD |
| Dr Owen Doody | Member, NREC-MD |
| Dr Frank Houghton | Member, NREC-MD |
| Ms Orla Lane | Member, NREC-MD |
| Mr Billy McCann | Member, NREC-MD |
| Dr Sarah McLoughlin | Member, NREC-MD |
| Prof. Tom Melvin | Member, NREC-MD |
| Prof. Therese Murphy | Member, NREC-MD |
| Dr Declan O'Callaghan | Member, NREC-MD |
| Dr Clare O'Connor | Member, NREC-MD |
| Dr Paul O'Connor | Member, NREC-MD |

| Name | Role |
|---|---|
| Prof. Anne Parle-McDermott | Member, NREC-MD |
| Prof. Mahendra Varma | Member, NREC-MD |
| Chita Murray* | Programme Manager, National Office for Research Ethics Committees |
| Megan O'Neill | Project Officer, National Office for Research Ethics Committees |
| Dr Emily Vereker | Head, National Office for Research Ethics Committees |

*Drafted minutes

**Apologies**: Dr Gloria Kirwan, Prof. Susan O'Connell, Mr Damien Owens, Ms Riona Tumelty, Mr Peter Woulfe

**Quorum for decisions:** Yes

## Agenda

- Welcome (Chairperson)
- Report on Committee business
- Minutes of previous meeting
- Declarations of interest
- 23-NREC-MD-001-R1
- 23-NREC-MD-006-R1
- 23-NREC-MD-007-R1
- 22-NREC-MD-032-SM1-R1
- 22-NREC-MD-021-SM2-R1
- 23-NREC-MD-010
- 22-NREC-MD-007-SM3
- 22-NREC-MD-036-SM1
- 22-NREC-MD-033-SM1
- AOB

---

- The Chairperson welcomed the Committee, acknowledged apologies sent by applicable members and opened the meeting.
- NREC Committee Business Report: The Committee noted the report.

- Minutes of the previous meeting (16 February 2023) were approved.
- Matters arising from the previous meeting: none.
- Declarations of interest:
  - Prof. Declan Patton (22-NREC-MD-007-SM3) left the meeting for the review of 22-NREC-MD-007-SM3.
  - Prof. Tom Melvin (22-NREC-MD-021-SM2-R1) left the meeting for the review of 22-NREC-MD-021-SM2-R1

---

## Applications

### 23-NREC-MD-001

- Principal Investigator: Prof. David Keane
- Study title: Adagio Medical Pulsed Field Ablation (PFA) & Pulsed Field CryoAblation (PFCA) for Persistent Atrial Fibrillation (PsAF)
- Lead institution: Blackrock Health, Blackrock Clinic, Rock Road, Blackrock, Co.

  Dublin, A94 E4X7, Ireland
- NREC-MD decision:
  - *Favourable with conditions*
- Associated conditions
  - The NREC-MD noted that the informed consent form (ICF) contains the following statement. The Committee requests that this be removed, as the information provided in the participant information leaflet (PIL) sufficiently outlines this issue.
    - *I know that if I get pregnant during the study I must immediately inform the investigator.*
  - The NREC-MD noted that the ICF has been amended to include the statement below. The Committee requests that this statement be revised to clarify whether it refers to anonymised data or pseudonymised data. The Committee additionally requests that every effort be made to facilitate data withdrawal when feasible.
    - *I know that after I stop the study, no new data will be collected. However, any data already collected for research may still be used for its intended purpose.*
  - The NREC-MD noted that the below statement has been added to the ICF.
    - *I give the researchers permission to collect and use my data for future medical research.*

    The Committee requests that:
    - the statement be revised to align with the PIL which clarifies the defined nature of the intended future research
    - the statement be presented as an optional item in the ICF, to align with the content of the PIL (i.e. “If you do you do not consent to wider use of your data, you still can participate in this study and receive the same healthcare”).
  - The NREC-MD noted that the role of gatekeeper has been included in the PIL and acknowledges this addition. The Committee requests however that this individual be

referred to as an independent researcher/investigator, stating also that this individual is the point of contact for potential participants or those eligible and interested in taking part in the study.

---

**23-NREC-MD-006**

- Principal Investigator: Dr. Adrian Murphy
- Study title: Diagnostic Protocol for Use of VENTANA HER-2/neu (4B5) IUO Assay and VENTANA HER2 Dual ISH DNA Probe Cocktail in Seagen Study SGNTUC-029)
- Lead institution: Beaumont Hospital, Beaumont Road, Dublin 9, Ireland
- NREC-MD decision:
  - *Favourable with conditions*
- Associated conditions
  - The NREC-MD noted that the NREC-MD application form indicates that "the performance study does not involve genetic testing" and assessed the justification provided by the applicant. The Committee requests, as a condition of its favourable review, that the application form be amended at the below sections, and instructs the applicant to document in full the genetic testing which will be conducted.
    - *Section M(1)(a) Does this study involve genetic testing?*
    - *Section M(1)(b) If yes, please specify the nature and purpose of the genetic testing.*
  - The NREC-MD noted that the CV of one of the Principal Investigators (PI) will be provided at a later date. The Committee includes this requirement as a condition of its favourable opinion.

---

**23-NREC-MD-007**

- Principal Investigator: Dr. Matthew Sheehan
- Study title: Repeatability, Reproducibility and Demographic Reference Study in Ocular Microtremor
- Lead institution: National Optometry Centre, Central Quad, Technological University Dublin, Grangegorman Lower, Dublin, D07 ADY7
- NREC-MD decision:
  - *Favourable with conditions*
- Associated conditions
  - The NREC-MD noted and acknowledged the remote likelihood of the occurrence of the adverse event 'laser induced blind spot' (as worded in the submitted clinical investigation plan). The Committee requests, however, that the participant information leaflet (PIL) be updated as applicable to include this adverse event.

- The NREC-MD noted the submitted recruitment flyer. The Committee requests that the flyer be amended to include additional details with regard to the Principal Investigator (PI).
- The NREC-MD noted that the CV of the Co-PI has been submitted in the application. The Committee requests that it be amended to include additional information with regard to experience in regulated and/or non-regulated clinical studies and/or additional detail regarding the support which will be provided to the PIs by the Sponsor.

---

**22-NREC-MD-032-SM1**

- Principal Investigator: Mr. Barry Jones
- Study title: ProVee Urethral Expander System IDE Study/ ProVIDE Study
- Lead institution: Mater Private Dublin, Eccles St., Dublin 7, D07 WKW8
- NREC-MD Decision
  - *Favourable*

---

**22-NREC-MD-021-SM2**

- Principal Investigator: Dr. Robert Byrne
- Study title: LiquID Guide Catheter Extension Safety Study
- Lead institution: Mater Private Dublin, Eccles St., Dublin 7, D07 WKW8
- NREC-MD decision
  - *Favourable*

---

**23-NREC-MD-010**

- Principal Investigator: Dr Darren Mylotte
- Study title: Evolut™ EXPAND TAVR II Pivotal Trial
- Lead institution: University Hospital Galway, Newcastle Rd, Galway, H91 YR71
- NREC-MD decision
  - *Request for further information*
- Further information requested:

**NREC Application Form**

- The NREC-MD noted that the NREC-MD application form states that “patients who can’t understand or read English will not be allowed to participate”.
  - The Committee requests that accommodations be made, wherever possible, to allow for interpreter roles and/or translation of patient information leaflets and informed consent forms (PIL/ICF).

- Certified translators must be used when translating PIL/ICFs, and the certifications must be submitted to the NREC in advance of the PIL/ICF being distributed to participants. In addition, the Committee wish to advise the applicant of the availability of a phone translation service which may be used.
- Alternatively, if the phrase "can't understand or read English" includes participants who *can* understand English but who have compromised reading abilities, please confirm. The NREC-MD notes facilitation in the ICF of the presence of an impartial witness as per MDR [1].

- The NREC-MD requests that the following sections of the NREC-MD application form be completed in full. (Sections K4(b), K5, K6, K7, K8, K10 and K19)

**Participant Information Leaflet/Informed Consent Form**

- The NREC-MD requests that individual tick boxes be added to the informed consent form (ICF) for each of the itemised consents to aid the understanding of the participant.
- The NREC-MD noted that the following statement appears in the ICF. The Committee requests that reference to the ethics committee be removed, as not applicable:
    - *I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from 'Medtronic', from regulatory authorities or from the Ethics Committee, where it is relevant to my taking part in this research. I give permission for these individuals to have direct access to my medical files.*
- The NREC-MD requests that an additional individual line item be added to the ICF which includes consent for the transfer of data outside the European Union.
- The NREC-MD noted that the PIL/ICF includes the below statement which appears to seek blanket consent for future use of data for undefined research. This type of consent is not in compliance with the Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018), where informed participant consent is a mandatory safeguard. The Committee requests that i) consent for future use of data be unbundled from the other consent items, ii) consent can only be obtained where future use of data is defined such that participants are fully informed, and/or iii) that an option is provided to enable participants to consent to be contacted in future where the future research is currently undefined.
    - *I agree to take part in future research using my data saved from this study*

**Study Protocol**

- The NREC-MD noted that the projected duration of the study is approximately thirteen (13) years. The Committee requests, given the longevity of the study, that the applicant comments on the provisions or safeguards which will be implemented to allow the participant to identify a proxy individual who understands their will and preference in the event of loss of, or fluctuating, decision-making capacity.

[1] Medical Devices Regulation (EU) 2017/745

- The NREC-MD noted that aortic stenosis is a progressive condition, with the applicable implications for the control group who are likely to proceed to require intervention during the projected duration of the study. The Committee requests that the applicant comments on the planned interventions and/or treatment management for this group, in this eventuality.

**Site Suitability Form**

- The NREC-MD requests additional detail in each section of the site suitability form (SSF) to assist with assessment of this application on the merits of the submitted documentation.
- The NREC-MD additionally requests confirmation of the number of transcatheter aortic valve replacement (TAVR) procedures which are completed annually at the site.

**Clinical Trial Agreement**

- The NREC-MD noted that the clinical trial agreement (CTA) requires correction in the investigator details in the signature section.

**Study Budget**

- The NREC-MD noted that the clinical trial agreement (CTA) contains a breakdown of the compensation scheme and procedure costs. The Committee requests that an overall study budget be provided for the Republic of Ireland.

**Principal Investigator(s)**

- The NREC-MD requests additional documented detail with regard to the previous clinical study experience of the applicable Co-Principal Investigator.

**Additional Comments**

- The NREC-MD noted that “the study doctor will collect the name of a person who may be contacted” if the participant cannot be reached. The Committee advises that the nominated contact must provide explicit (documented) consent for this role and for their contact details to be held on file, and that the explicit consent must be retained for the applicable period.

---

**22-NREC-MD-007-SM3**

- Principal Investigator: Prof. Caroline McIntosh
- Study title: A Pilot Study to Investigate the Use of Remote Thermovisual Monitoring in Patients with a Previous Diabetic Foot Ulcer, during the COVID-19 pandemic

- Lead institution: Discipline of Podiatric Medicine, Aras Moyola, NUI Galway, Newcastle Road, Galway
- NREC-MD decision
  - *Favourable*

---

**22-NREC-MD-036-SM1**

- Principal Investigator: Prof. Faisal Sharif
- 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)
- Lead institution: University Hospital Galway, Newcastle Rd, Galway, H91 YR71
- NREC-MD decision
  - *Favourable*

---

**22-NREC-MD-033-SM1**

- Principal Investigator: Dr Darren Mylotte
- Study title: Randomized Comparison of Abluminus DES+ Sirolimus-Eluting Stents versus Everolimus-Eluting Stents in Coronary Artery Disease Patients with Diabetes Mellitus Global (ABILITY Diabetes Global)
- Lead institution: Galway University Hospital, Newcastle Road, H91 YR71, Galway
- NREC-MD decision
  - *Favourable*

---

- AOB:
- The Head of Office introduced the following topics for brief discussion:
  - The requirement for gatekeepers is being assessed within the National Office for discussion with the Committee in due course.
  - The requirement for data protection impact assessment (DPIA) forms is being assessed within the National Office for discussion with the Committee in due course.
  - Remuneration of NREC members.
  - Expanding the NREC membership.
- The Chairperson thanked the Committee and closed the meeting.