NATIONAL OFFICE FOR RESEARCH ETHICS COMMITTEES

National Research Ethics Committee

NREC-MD Meeting Minutes

16th February 2023

Attendance

Name	Role
Prof. Declan Patton	Deputy Chair, NREC-MD
Dr Mireille Crampe	Member, NREC-MD
Dr Ruth Davis	Member, NREC-MD
Dr Owen Doody	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
Mr Damien Owens	Member, NREC-MD
Prof. Anne Parle McDermott	Member, NREC-MD
Ms Riona Tumelty	Member, NREC-MD
Prof. Mahendra Varma	Member, NREC-MD
Dr. Lorna Fanning*	Member, NREC-CT (B)
Karen McNamara*	Department of Health

Name	Role
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

*Attended in observer capacity
**Drafted minutes

Apologies:

Prof. Barry O'Sullivan (Chair)

Prof. Mary Sharp (Deputy Chair)

Dr. Catherine O'Neill

Dr. Gloria Kirwan

Dr. Paul O'Connor

Prof. Susan O'Connell

Dr. Caitriona Cahir

Dr. Frank Houghton

Mr. Peter Woulfe

Quroum for decisions: Yes

Agenda

- Welcome (Chairperson)
- Minutes of previous meeting
- Report on Committee Business
- Declarations of Interest
- 23-NREC-MD-002-R1
- 23-NREC-MD-003-R1
- 23-NREC-MD-006
- 23-NREC-MD-007
- 22-NREC-MD-002-SM1
- 22-NREC-MD-016-SM2
- 21-NREC-MD-009-SM1
- 22-NREC-MD-021-SM2

- 22-NREC-MD-032-SM1
- AOB

- The Deputy Chair welcomed the committee, acknowledged apologies sent by applicable members and opened the meeting.
- NREC Committee Business Report: The Committee noted the report.
- The minutes from the previous meeting (19 January 2023) were approved.
- Matters arising from the previous meeting as follows: none.
- The following declarations of interest were made, and the members recused themselves from the discussion of the applications in question:
  - Dr Clare O'Connor (22-NREC-MD-016-SM2) left the meeting for the review of 22-NREC-MD-016-SM2
  - Dr Tom Melvin (22-NREC-MD-021-SM2) left the meeting for the review of 22-NREC-MD-021-SM2

Applications

23-NREC-MD-002-R1

- Principal Investigator Name: Prof. Gabor Szeplaki
- Study title: SECURE - 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
- PI Institution: Mater Private Dublin
- NREC-MD Decision
  - Favourable with conditions
- Associated conditions:
  - The NREC-MD advises the Sponsor that, if applicable, copies of translation certificate(s) for the Patient Information Leaflet (PIL)/Informed Consent Form (ICF) (and/or other relevant documents) must be presented to the Committee, which will be considered verification of the translated documents, prior to their use.
  - The NREC-MD requests that the PIL informs the participants that the study safety data will be reviewed on a regular basis as part of the study protocol.
  - NREC-MD requests that the 'Costs and Compensation' section of the PIL is revised for clarity.
  - The NREC-MD noted that the ICF does not include consent for future contact to seek consent for future research. The Committee highlights the resulting limitations to the future use of study data.

23-NREC-MD-003-R1

- Principal Investigator Name: Prof. Gabor Szeplaki
- Study title: Real world Data collection in subjects treated with the FARAPULSE™ Pulsed Field Ablation system (FARADISE)
- PI Institution: Mater Private Dublin
- NREC-MD Decision
  - Favourable opinion

23-NREC-MD-006

- Principal Investigator Name: 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
- PI Institution: Beaumont Hospital
- NREC-MD Decision
  - Request for further information
- Further information requested as follows.

NREC-MD Application form:

- The NREC-MD requests justification, as not evident in the submitted documents, for the selection of the applicable documented site as the location at which the national Principal Investigator (PI) will be situated, and requests an outline of the co-ordination role which the national PI will undertake.
- The NREC-MD requests confirmation of the exact participating sites within the Mater Private Hospital network.
- The NREC-MD requests that personal email addresses be removed from the NREC-MD application form and replaced with workplace/professional email addresses, which are then used in all applicable study documentation.
- The NREC-MD seeks clarification as to the duration of the retention period of tumour blocks at the testing laboratory.
- The NREC-MD noted that the NREC-MD application form states that participants will have a minimum of 24 hours to consider taking part in the study. The Committee requests that consideration be given to extending the minimum period.
- The NREC-MD noted the NREC-MD application form states that participants can refuse to take part, or withdraw, without their medical care being affected. It additionally states that the participant's study doctor will discuss any future treatment options, which implies that medical care will be affected by withdrawal. The Committee requests that the language in this section be clarified.

- The NREC-MD requests that the NREC-MD application form be corrected to indicate that genetic testing will be conducted.
- The NREC-MD noted that the NREC-MD application form stipulates that participants may choose to practice complete abstinence if consistent with their preferred lifestyle. The Committee requests that this option is presented for both participants of childbearing potential and for participants who can father children.

Participant Information Leaflet:

- The NREC-MD noted that the device-specific Participant Information Leaflet (PIL) does not sufficiently outline the potential risks and consequences to the participant, and requests that it be updated to outline the likelihood of diagnostic material remaining following completion of testing.
- The NREC-MD noted that the device-specific PIL does not refer explicitly to the standard contractual clauses (SCCs) which are required under GDPR in the event of transfer of data outside of the EU. The Committee requests that the device PIL be updated to include an assurance that SCCs will be in place.
- The NREC-MD noted that, in order to obtain the required sample size, screening will be conducted on a large number of individuals. The Committee requests that greater clarity be added to the device PIL with regard to all the potential outcomes, for participants, of this screening process.
- The NREC-MD noted that the device PIL does not sufficiently outline the risks to the participant of receiving a false positive test result. The Committee requests that the device PIL be updated to outline the associated risks and potential outcomes in this instance of being assigned to treatment under the associated Clinical Trial of an Investigational Medicinal Product (CTIMP) protocol.

Insurance:

- The NREC-MD noted that the applicable submitted insurance policy does not appear to accept liability for cyber incidents, and seeks clarification. The Committee further notes that, under GDPR, certain damages will accrue and seeks confirmation as to how such damages will be dealt with.

Principal Investigators:

- The NREC-MD noted that one of the named site Principal Investigators (PI) may not previously have acted as PI as part of a national study. The Committee requests that the applicant confirms, via submitted documentation, the suitability of this individual to act as a site PI on this occasion.

23-NREC-MD-007

- Principal Investigator Name: Dr. Matthew Sheehan
- Study title: Repeatability, Reproducibility and Demographic Reference Study in Ocular

- Microtremor
- PI Institution: National Optometry Centre
- NREC-XX Decision
  - Request for further information
- Further information requested:
  - The NREC-MD requests that the following details be clarified, and that they be documented consistently in applicable study documents and application form:
    - Funding arrangements,
    - Participant involvement,
    - Data retention period.
  - The NREC-MD requests that an up-to-date insurance policy be submitted.
  - The NREC-MD noted the use of a flyer as part of recruitment and requests that this be included in the application form.
  - The NREC-MD requests further documented evidence of the Principal Investigator's (PIs) experience pertaining to clinical investigations, including up-to-date GCP training.
  - The NREC-MD requests further detail in the site suitability form regarding the roles, qualifications and expertise of the staff members involved in the study.
  - The NREC-MD requests further clarity in the Patient Information Leaflet (PIL) with regard to the legal bases under which participant's data will be processed.
  - The NREC-MD requests that information be added to the PIL to make it clear to participants that their data can be withdrawn only up to the point of anonymisation.
  - The NREC-MD noted that the PIL states that there are no risks associated with the ocular microtremor (OMT) procedure, however the OMT clinical investigation plan (CIP) refers to monitoring for adverse events (AEs), and makes reference to specific AEs. The Committee requests that participants be informed of these risks in the PIL.

22-NREC-MD-002-SM1

- Principal Investigator Name: Anita Sayers
- Study title: Tinnitus Patient Registry at Ótologie Tinnitus Care(Ótologie)
- PI Institution: Hermitage Clinic
- NREC-MD Decision
  - Favourable opinion

22-NREC-MD-016-SM2

- Principal Investigator Name: Prof. Carel le Roux
- Study title: A Prospective, Randomized, Double-Blind, Sham-Controlled, Multi-Center Pivotal Study to Evaluate the Efficacy and Safety of Duodenal Mucosal Resurfacing Using the Revita® System in Subjects with Type 2 Diabetes on Insulin therapy.
- PI Institution: Diabetes Complications Research Centre
- NREC-XX Decision
  - Favourable with conditions
- Associated conditions:
  - The NREC-MD requests that the blood glucose values (both randomised and non-randomised) in the Participant Information Leaflet (PIL) be expressed to one decimal point.
  - The NREC-MD noted that the applicant has indicated that submission of this substantial modification to the HPRA was not required. Under Article 75 of EU Regulation 2017/745 (MDR), sponsors are required to submit substantial modifications to the HPRA prior to their implementation. The Committee requests that the applicant liaises with the HPRA and informs them of this substantial modification.

21-NREC-MD-009-SM1

- Principal Investigator Name: Prof. David Keegan
- Study title: A prospective, multicenter post-marketing clinical investigation of the SING IMT System, model NG SI IMT 3X in patients with central vision impairment associated with end-stage age-related macular degeneration
- PI Institution: Mater Misericordiae University Hospital
- NREC-MD Decision
  - Favourable opinion

22-NREC-MD-021-SM2

- Principal Investigator Name: Dr. Robert Byrne
- Study title: LiquID Guide Catheter Extension Safety Study
- PI Institution: Mater Private Hospital
- NREC-MD Decision
  - Request for further information
- Further information requested:

- The NREC-MD requests that further detail be provided in the site suitability form (SSF) including clarification of the following:
    - Number of PCIs performed per year in the unit and the number of staff involved with PCIs in the unit/site,
    - Number of study team members and their relevant qualifications,
    - Number of studies conducted/completed at the site.
- The NREC-MD requests confirmation of the exact participating sites within the Mater Private Hospital network.

22-NREC-MD-032-SM1

- Principal Investigator Name: Mr. Barry Jones
- Study title: ProVee Urethral Expander System IDE Study/ ProVIDE Study
- PI Institution: St. James's Hospital
- NREC-MD Decision
    - Request for further information
- Further information requested:
    - The NREC-MD noted that the new national Principal Investigator (PI) will also act as site PI at a named site. The Committee requests confirmation, as not evident in the submitted documents, that the new national PI is employed by the named site and/or has the appropriate authorisation(s) to act as PI at that site.

- AOB
- The Deputy Chair closed the meeting.