NATIONAL OFFICE FOR RESEARCH ETHICS COMMITTEES

National Research Ethics Committee

NREC-MD Meeting Minutes

17th August 2023

Attendance

Name	Role
Prof. Barry O'Sullivan	Chair, NREC-MD
Prof. Mary Sharp	Deputy Chair, NREC-MD
Prof. Declan Patton	Deputy Chair, NREC-MD
Dr Ruth Davis	Member, NREC-MD
Dr Frank Houghton	Member, NREC-MD
Dr Gloria Kirwan	Member, NREC-MD
Mr Billy McCann	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
Mr Damien Owens	Member, NREC-MD
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

*Drafted minutes

Apologies: Dr Caitriona Cahir, Dr Mireille Crampe, Dr Owen Doody, Ms Orla Lane, Dr Sarah McLoughlin, Prof. Susan O'Connell, 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-024-R1
- 23-NREC-MD-025-R1
- 23-NREC-MD-026
- 21-NREC-MD-003-SM1
- 23-NREC-MD-002-SM1
- 22-NREC-MD-016-SM3
- 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 (20th July 2023) were approved.
- Matters arising from the previous meeting: none
- Declarations of interest:
- Dr Clare O'Connor (22-NREC-MD-016-SM3). Dr Clare O'Connor left the meeting for the review of 22-NREC-MD-016-SM3

Applications

23-NREC-MD-024-R1

- Principal Investigator: Prof. Gabor Szeplaki
- Study title: Luma Vision's feasibility study on the VERAFEYE system (LUMINIZE)
- Lead institution: Mater Private Hospital (Dublin), Heart & Vascular Centre, 72 Eccles Street, Dublin 7, Ireland
- NREC-MD decision:
  - *Favourable*

23-NREC-MD-025-R1

- Principal Investigator: Dr. Janusz Krawczyk
- Study title: Collection and Processing of Bone Marrow (BM) Specimens from healthy volunteers for Analytical Performance Evaluation of the BD Reagent Panels and Kits on the BD Flow Cytometer Systems
- Lead institution: University of Galway, Newcastle Road, Galway, Ireland
- NREC-MD decision:
  - *Favourable with conditions*
- Associated conditions:
  - Patient Information Leaflet (PIL):
    - The NREC-MD noted that the PIL indicates that no results from flow cytometry analysis of bone marrow samples will be communicated to the participant. There is a possibility that abnormalities could be detected in the samples. The Committee requests that this information be conveyed to the participant in an appropriate manner and in line with best practice; a description of the procedures in place if such an outcome were to be obtained is needed. This information should be clearly described to potential participants.
    - Similarly, the Committee requests a more detailed description in the PIL of how the participant will be informed of sensitive results that may arise from blood screening for viral infection, including public health reporting responsibilities, and advises that details regarding the pre-screening of the blood sample must inform the participant of the viruses that will be screened for.
    - Given the invasive nature of the procedure, the NREC-MD requests that further information be included regarding the potential after-effects experienced by the participant. The study protocol indicates that pain medication will be provided to the participant prior to leaving the sampling centre. The Committee requests that this be included in the PIL, together with greater clarity on the procedure which participants should follow in the event of adverse events following the bone marrow collection, including explicit information on who in the research facility should be contacted if the participant experiences pain or other signs/symptoms of concern.
    - The NREC-MD noted that the advertisement poster has been updated, and that the below statement has been added to the PIL. The Committee requests that the PIL explicitly states that participation in the study requires an initial screening visit during which medical information will be provided and a blood sample taken. This will be followed, if screening is satisfactory, by a second visit to donate a bone marrow sample. An indication of the likely time interval between screening and bone marrow sampling should also be given.
      - “When participating in this study you are expected to come to the Clinical Research Facility at the University of Galway for two visits.”

- The NREC-MD requests that the procedure is clearly described for informing the participant and their GP if a viral infection is detected during the blood screening.
- The NREC-MD noted that a justification was provided regarding the monetary amount of the stipend for participants. The Committee requests that this section of the PIL is updated to indicate what stipend, if any (and if none), applies to participants who may have partaken in the blood screening but do not meet the criteria for bone marrow donation.
- The NREC-MD noted the following statement in the PIL and requests that this be amended to "If you decide to donate a bone marrow sample…"
    - "If you decide to take part in this study, it will be necessary to store, analyze and otherwise process pseudonymized personal data about you"
- The NREC-MD requests that the following statement be modified by removing the word "substantially":
    - "Both your study researcher and the Sponsor will take appropriate safeguards before transferring the data to other countries to ensure the protection of your data at a level substantially equivalent to that in your country."

– NREC-MD Application Form:

- Section S of the application form on the re-imbursement of participants should indicate what stipend, if any (and if none), will be paid to participants who, following screening, do not meet the criteria for bone marrow donation.

23-NREC-MD-026

- Principal Investigator: Prof. Ian Flitcroft
- Study title: Stellest® Lenses Observational Multi-Centred European Study (SLOMEs)
- Lead institution: Centre for Eye Research Ireland (CERI), Technological University Dublin City Campus, Grangegorman Lower, Dublin 7
- NREC-MD decision:
    – *Request for further information*
- Further information requested

Parent & Participant Information Leaflets (PILs):

The NREC-MD noted that the document(s) require additional information/amendments. The Committee requests that a revised copy of the document(s) be submitted, with the following changes at applicable sections.

– Under "what are the possible disadvantages of taking part?" or applicable section of each PIL, please outline that the participant will experience an initial adjustment period when using the trial lenses, and may experience persistent reduced clarity of peripheral vision. Please clarify the extent to which peripheral vision is compromised, the anticipated duration of the blurred peripheral vision, and any implications for the

safety of the participant (e.g. navigating their environment). Please include any other applicable information as to how the wearer might experience the Stellest® glasses.

- Both participant PILs (age 6-10, age 11-16) state that the glasses “might slow your myopathy”. The parent PIL further notes “but we cannot be sure”. Please include this additional statement in the participant PILs.
- Please consider including drawings and/or photographs (or links to videos) of the trial lenses if they will look significantly different to the typically prescribed lenses which the minors are accustomed to, to explain the obligations of the wearer during the study, and/or to explain the mechanism of action of the lenses.

Participant Information Leaflet Age 6-10 years:

- Please include a statement outlining that the participant will be asked to wear the trial glasses for as long as possible every day.
- Please explain the word ‘pupil’ in this context.

Participant Information Leaflet Age 11-16 years:

- Please amend “your eyes will be normal again soon” to “your eyes will feel normal again after a day or so” or as applicable - the NREC-MD application form indicates a period of 24 hours.
- Under “what will the study involve?” please include the number of hours per day (7 to 12 hours per day) that the spectacles should be worn, and the total duration of participation in the study (24 months).

Parent Information Leaflet:

- Under “invitation to take part” please state that the prospective participant will be given a minimum of 24 hours to decide whether to participate (as noted in the NREC-MD application form).
- Please briefly explain the following terms: “retinal detachment, myopic maculopathy, glaucoma, and cataract”, “choroidal thickness” and “cycloplegic autorefraction”.
- Please clarify the duration of the screening visit and follow-up visits. Please align as necessary throughout the documents, including PILs. Consider including the table of scheduled activities in the parent PIL.
- Please amend “urge your child to wear the glasses” to “remind your child to wear the glasses”.
- The protocol lists some remediation options for the “expected symptoms associated with cycloplegic eye drops” including “wearing sunglasses or a peaked cap to protect the eyes from glare”. Please include these in the parent PIL.
- Under “who has reviewed the study?” please include the full title of the National Research Ethics Committee for Medical Devices (NREC-MD). (Note: This committee is mandated in the Rep. of Ireland to give a single national ethics opinion for studies

conducted under the Medical Device Regulation (EU 2017-745) as per the associated statutory instrument (current reference S.I. No. 260/2021)).

- Aligned with the section entitled “How will study data be used and stored?” please add further information including:
    - the type of data which will be collected,
    - the process of pseudonymisation,
    - that data will be kept in Ireland (and therefore not subject to transfer outside of EEA),
    - an explicit statement with regard to further use of personal data,
    - the Rights of the Data Subject (as per GDPR).

Consenting Process:

- Please be aware of the following consenting age requirements (with reference to the Health Research Regulations 2018 and the HSE National Policy for Consent in Health and Social Care Research), incorporate the management of dynamic consenting into the consenting process, and adjust the study document suite accordingly.
    - Minors who reach the age of 16 (if not being withdrawn from the study) must provide explicit consent for the clinical investigation in their own right. However, their legal representative must provide consent for data processing elements, up to the age of 18. Thus, for 16 year olds, two consent forms will be required; a) by the 16 year old to participate in the study and b) by the parent/guardian for the associated data processing.
    - Please also note that, if a participant reaches the age of 18 during the retention period of the data (proposed as five years from the completion of the study), the participant will need to be reconsented for this purpose.
- The submitted PILs do not refer to nor allow for optional consent for future specified research, nor to the anonymisation of data. Consequently, these are not permitted under the consent process.

Protocol:

- With regard to the below statement please include reference to the Health Research Regulations 2021 (and as amended), for completeness.
    - “Electronic data files are encrypted, and all data is stored in keeping with the Data Protection Act 1988, amended Data Protection Act 2003, EU GDPR 2016/679 and Data Protection Act 2018 and local privacy laws”.

Application Form:

- Please clarify:
    - whether the trial lenses will be incorporated into/onto the participant’s existing/typically prescribed lenses, or worn alone.

  - whether the aims/objective of the study include establishing superiority or non-inferiority of the trial lenses (e.g. when compared to existing datasets, or as applicable).
  - the difference between participation and non-participation in the study e.g. will non-participants be offered an alternative treatment, or will they continue to wear their typically prescribed lenses?

- Please provide additional information with regard to any observation of blurred peripheral vision in the studies with the Chinese population.
- Please comment on the potential for damage to the eye, associated with both participating and not participating in the study. Additionally, please comment on the potential risk to participants if not receiving current standard-of-care, in the event that the trial lenses provide less than equivalent management of myopia than the participant's typically prescribed lenses.
- Please confirm whether individuals with myopia are expected to:
  - wear Stellest® lenses indefinitely (i.e. instead of ordinary prescription lenses) or,
  - wear Stellest® glasses for a defined period of time, at which point they may have no need for glasses, or may revert to wearing ordinary lenses, or may revert to wearing lower-strength lenses.
- The NREC-MD application form states that the informed consent process will be conducted with study participants before the study commences. Please also refer to the parent/legal guardian or 'data subject' as relevant (i.e. not solely data subjects).
- Please include additional information with regard to the scope of the data collection e.g. the specific data points which will be collected.
- The participant/parent facing materials and the NREC-MD application form state that data will be stored for five (5) years, although the protocol states that clinical data will be stored for fifteen (15) years. Please clarify and align as applicable.
- The NREC-MD application form states that "explicit assent has been obtained from each data subject". As "explicit assent" does not have legal standing, this section should refer to "explicit consent and assent, as appropriate" and should refer to the "parent/legal guardian or data subject as relevant" rather than solely to data subjects.

Financial Arrangements:

- The NREC-MD noted that travel and other costs will not be reimbursed. The Committee requests that parents/participants (as applicable) be reimbursed for reasonable, receipted out-of-pocket expenses. Please amend the NREC-MD application form and the parent PIL to include this information.

Insurance:

- The NREC-MD noted that the insurance policies submitted with the application will expire in 2024. The Committee requests assurance that the policies will be renewed as applicable for the duration of the study.

21-NREC-MD-003-SM1

- Principal Investigator: Prof. Patrick W. Serruys
- Study title: Non-inferiority of angiography-derived physiology guidance versus usual care in an All-comers population treated with unrestricted use of Healing-Targeted Supreme stent (HT Supreme) and P2Y12 inhibitor monotherapy after 1-month of dual-antiplatelet therapy: the PIONEER IV trial
- Lead institution: University of Galway, Newcastle Road, Galway, Ireland
- NREC-MD decision:
  - *Favourable*

23-NREC-MD-002-SM1

- Principal Investigator: Prof. Gabor Szeplaki
- 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
- Lead institution: Mater Private Hospital (Dublin), 72 Eccles Street, Dublin 7, Ireland
- NREC-MD decision:
  - *Favourable*

22-NREC-MD-016-SM3

- Principal Investigator: Prof. Carol 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
- Lead institution: Conway Institute/Diabetes Complications Research Centre, University College Dublin, Belfield Downs, Dublin, Ireland
- NREC-MD decision:
  - *Favourable with conditions*
- Associated conditions:
  - Please provide documented justification why submission of the substantial modification(s) to the HPRA is not applicable.

- AOB: None
- The Chairperson thanked the Committee and closed the meeting.