NATIONAL OFFICE FOR RESEARCH ETHICS COMMITTEES

# National Research Ethics Committee

## NREC-MD Meeting Minutes

**15th June 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 Mireille Crampe | Member, NREC-MD |
| Dr Ruth Davis | Member, NREC-MD |
| Dr Frank Houghton | Member, NREC-MD |
| Ms Orla Lane | Member, NREC-MD |
| Dr Sarah McLoughlin | Member, NREC-MD |
| Prof. Tom Melvin | Member, NREC-MD |
| Dr Declan O'Callaghan | Member, NREC-MD |
| Prof. Susan O'Connell | Member, NREC-MD |
| Prof. Anne Parle McDermott | 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 Owen Doody, Dr Gloria Kirwan, Mr Billy McCann, Prof. Therese Murphy, Dr Clare O'Connor, Dr Paul O'Connor, Mr Damien Owens, Ms Riona Tumelty, Prof. Mahendra Varma, Mr Peter Woulfe

**Quorum for decisions:** Yes

## Agenda

- Welcome (Chairperson)
- Report on Committee business
- Minutes of previous meeting
- Declarations of interest
- 23-NREC-MD-011
- 23-NREC-MD-013
- 23-NREC-MD-016
- 23-NREC-MD-017
- 23-NREC-MD-018
- 23-NREC-MD-019
- 23-NREC-MD-020
- 23-NREC-MD-007-SM1
- AOB

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- 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 (18 May 2023) were approved.
- Matters arising from the previous meeting: none
- Declarations of interest:
  - Prof. Tom Melvin (23-NREC-MD-016). Prof. Tom Melvin left the meeting for the review of 23-NREC-MD-016

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**Applications**

**23-NREC-MD-011**

- Principal Investigator: Prof. Gabor Szeplaki
- Study title: BoStOn SCientific Rhythm MAnagemenT REgiStry (SOCRATES)
- Lead institution: Mater Private Hospital, 72 Eccles Street, Dublin 7, D07 RD8P, Ireland
- NREC-MD decision:
  - *Favourable with conditions*

- Associated conditions:
  - The NREC-MD noted that the Sponsor commits to the creation, prior to recruitment, of age-appropriate assent forms for use with participants who are minor. The Committee requests that these forms be submitted to the NREC-MD for approval prior to use, per standard practice.
  - The NREC-MD noted that the Sponsor commits to the translation, by certified translators, of study documents requested by the site (e.g. patient information leaflet-data confidentiality agreement (PIL-DCA)). The Committee requests that certificate(s) of translation be submitted to the National Office as a non-substantial modification prior to the use of the translated documents, per standard practice.
  - The applicant is advised that, under EU and Irish law, the data subject (assuming capacity etc.) must demonstrate affirmative, explicit consent once they reach the age of consent for data processing. As per the Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018), the age of consent for data processing is 18 years, and consent for data processing which has been provided by a parent, legal guardian etc. up to that point will cease to be valid. Once minors reach the age of consent for data processing they must be reconsented, and retaining the right to withdraw will not be sufficient.
  - The applicant is advised that they must comply with applicable legislation including GDPR, MDR and local laws as they pertain to data retention periods.

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**23-NREC-MD-013**

- Principal Investigator: Prof. James Loughman
- Study title: Children Myopia control Evaluation of Novel Soft Contact Lens Designs
- Lead institution: Centre for Eye Research Ireland, Greenway Hub, TU Dublin City Campus, Grangegorman Lower, Dublin 7, Ireland
- NREC-MD decision:
  - *Favourable with conditions*
- Associated conditions:
  - The NREC-MD requests that efforts be made to disseminate the findings of the clinical investigation, in compliance with Article 77 of the Medical Device Regulation EU No 2017/745 (MDR).
  - The NREC-MD noted the use of the term ‘distance vision’ in the Child Information and Assent form and requests that an explanation or definition of this term be provided, with the target age group in mind.
  - With regard to the use of participants’ anonymised data for potential future research as per the Informed Consent Form, please ensure alignment with the HSE National Policy for Consent in Health and Social Care Research 2023.

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**23-NREC-MD-016**

- Principal Investigator: Prof. Robert A. Byrne
- Study title: Ultimaster Nagomi Sirolimus Eluting Coronary Stent System in Complex Percutaneous Coronary Interventions (PCI) Patients (Nagomi Complex study)
- Lead institution: Mater Private Hospital, Eccles St, Dublin 7, D07 WKW8, Ireland
- NREC-MD decision:
  - *Request for further information*
- Further information requested
  - Pre-screening Patient Information Leaflet (PIL):
    The NREC-MD noted that the below sections of the patient information leaflet (PIL) require additional information/amendments. The Committee requests that a revised copy of the document be submitted, with the following changes at applicable sections:
    - The Data Protection Impact Assessment (DPIA) states that data concerning race/ethnic origin will be collected. Please update the PIL to include this information.
    - With regard to pseudonymised data, the DPIA notes that this will be transferred to and stored in the US. Please update the PIL so that prospective participants are informed of this.
  - NREC-MD Application Form:
    - The NREC-MD noted the exclusion of pregnant and breastfeeding women. Please comment/provide justification for the exclusion of these potential study participants from data collection.
  - Clinical Investigation Plan:
    - Please provide details regarding the suspension or premature termination criteria for the study as referred to on page 50 of the Clinical Investigation Plan (CIP). Please clarify whether, due to the observational nature of the study, standard termination criteria are not applicable.

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**23-NREC-MD-017**

- Principal Investigator: Prof. Darren Mylotte
- Study title: TRIal to Evaluate TraNsvenous TrIcuspid Valve ReplacemenT with LuX-Valve Plus System in Patients with Severe or Greater Tricuspid Regurgitation –SafetY and Clinical Performance (TRINITY)
- Lead institution: University Hospital Galway, Newcastle Rd., Galway, H91 YR71
- NREC-MD Decision
  - *Request for further information*
- Further information requested
  - NREC-MD Application Form:

- The NREC-MD noted that patients who are eligible to take part in the study will be approached by the principal investigator (PI) or designee regarding the study. The Committee requests that, where possible, a suitably qualified authorised designee (as referred to in ISO 14155:2020), who is not involved in the clinical management of the patient, make the initial approach. This role will help to mitigate concerns regarding the potential for the prospective participant to experience pressure to participate.
- The NREC-MD requests that certificates of translation, for services which must be provided by certified translators, are submitted to the NREC prior to the distribution of translated participant-facing documents.
- The NREC-MD noted that information has not been entered with regard to the measures which will be implemented in the case of a data security breach, and requests that the specific subsection of the application form be completed.

– Pre-screening ICF Data Disclosure and Master Patient Information Leaflet/Informed Consent Form (PIL/ICF):
  - The NREC-MD noted a lack of clarity with regard to the sequence of events during which prospective participants will receive the pre-screening ICF data disclosure, followed by the Master ICF. The Committee requests that this be outlined further in the response letter to be submitted by the applicant.
  - The NREC-MD noted that prospective participants will sign a pre-screening ICF data disclosure so that ‘certain information’ in medical records can be reviewed by an eligibility committee to assess eligibility for participation. The Committee requests that the pre-screening ICF data disclosure be amended to specify the exact nature of the data which will be accessed and reviewed.
  - The NREC-MD noted that the transcatheter bioprosthetic valve consists of a trileaflet bovine-pericardial tissue valve - the only component of the investigational device which uses animal tissue. The Committee requests that both details be stated in the PIL-ICF.
  - The NREC-MD noted the below statement in the NREC-MD application form (F2) with regard to ‘roll-in’ participants. The Committee requests that this information be included in the Master PIL-ICF
    - “Up to an additional 42 roll-in subjects, up to 3 per site, may be enrolled by operators without prior experience with the LuX-Valve Plus system to gain hands-on experience. The data of roll-in subjects will not count towards the overall enrollment cap. Safety and effectiveness results of roll-in subjects will be reported separately”.
  - The NREC-MD noted that subjects will be given ‘ample time’ to read and understand the consent form. The Committee requests that participants be given a minimum of 24 hours to consider participation, and that this be stated in the Master PIL-ICF.
  - The NREC-MD requests that the target recruitment number in the Republic of Ireland of eight (8) participants be documented in the Master PIL-ICF.
  - The NREC-MD noted that the list of follow-up tests and examinations appears to include duplication i.e. Echocardiogram and TTE. The Committee requests that amendments be made, as applicable.

- The NREC-MD noted the list of potential risks to the participant. The Committee requests that the death of the participant be listed as a potential risk, in the applicable subsection.
- The NREC-MD noted the below statement in the Master ICF (page 11). The Committee requests that the item be included as a separate, optional item in the consent form such that the participant may decline contact with regard to future research, but may still participate in the study.
    - "In the event an external researcher wants to use the data in a project not yet described in this document, this project will have to be approved by an Ethics Committee and by you again".
- The NREC-MD noted that participants will be reimbursed for extra travel expenses. The Committee requests that 'extra' be defined or removed such that participants will be reimbursed for travel expenses which they incur as a result participation in the study.
- The NREC-MD noted the below statement in the ICF. The Committee advises the applicant that the explicit consent of this individual, for storage of their personal data (under the General Data Protection Regulation (GDPR) (EU) 2016/679) must be documented and retained.
    - "I herewith provide the name of someone that can be contacted by the research doctor in case I cannot be reached for a follow-up visit"
- The NREC-MD noted that contact will be made with participants' general practitioner. The Committee requests that a copy of the letter for the GP be submitted to the committee for review, per standard practice.
- The NREC-MD noted the below statement in the Master ICF. The Committee requests that the word "required" be removed and that the statement be made an optional consent item.
    - "In the event of an examination likely to detect anomalies, I agree to be required informed of information relating to my state of health and any anomalies that could be detected during the research"
- The NREC-MD noted the below statement in the Master ICF. The Committee requests that the statement be amended as a legally designated representative cannot give consent for data processing under the Data Protection Act 2018 (Section 36(2)) (Health Research) (Amendment) Regulations 2021. If a legally designated representative will give consent for the participant to be included in the study, the applicant must contact the Health Research Consent Declaration Committee (HRCDC) with regard to obtaining consent for data processing.
    - "I confirm that I or my legally designated representative agree [to] the use of my relevant personal data for the purpose of clinical investigation"

– Insurance:
    - The NREC-MD noted that the current insurance policy for the study expires in September 2028. The Committee advises the applicant that insurance will need to be extended at the appropriate time to cover the six year duration of the study period.

**23-NREC-MD-018**

- Principal Investigator: Prof. Ken McDonald
- Study title: First In Human Clinical Investigation of the FIRE1™ System in Heart Failure Patients
- Lead institution: St. Vincent's University Hospital, Elm Park, Dublin 4
- NREC-MD Decision
  - *Request for further information*
- Further information requested

The NREC-MD requests that the following queries be addressed as a matter of priority.

- Is it planned to record and assess device fractures that are not 'clinically significant'? If yes, how?
- How has the applicant assessed the risk of 'not clinically significant' fractures becoming significant later due to structural deterioration over time?
- The NREC-MD noted design/developmental phases which resulted in new iterations ('generation') of the sensors. The Committee posed specific technical questions for the applicant to respond to, and requested that explanations be added to the investigator's brochure. The Committee further requested confirmation of the generation of sensors which will be used in the study in Ireland.
- The NREC-MD requested that wording in the informational video(s) and patient brochure be aligned with statements made in the documentation submitted to the Committee, with regard to benefits to participants i.e. that there will be no direct benefit for study participants.
- Insufficient information has been provided with regard to the below-listed items. Please amend the participant information leaflet to include:
  - the risks and implications for the participant associated with permanent implantation of the device,
  - the risks and implications for the participant associated with undertaking lifelong antiplatelet therapy,
  - the anticipated risk of device fracture, not limited to the two year period during which monitoring will be performed.
  - the implications of device fracture, not limited to the two year period during which monitoring will be performed
- Insufficient information has been provided with regard to the need for further interventions, for example in the case of device fracturing requiring reintervention.
  - Can this device be explanted?
  - Is safety information available regarding other interventions such as ballooning?
- Please provide the following additional information with regard to the Gen2 implant:
  - Has Gen2 been tested in animal models?
  - What device was used in the animal testing referenced in the investigator's brochure?

        - What is the expected time to endothelialisation for Gen2?
- The NREC-MD reviewed the informed consent form, and the Committee noted the following:
    - Per the Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018), explicit consent for specified future research is a mandatory safeguard. Since future research has not been referred to in the submitted patient information sheet/informed consent form, nor consent to be contacted with regard to future research, the consent given by the participant must be understood to relate exclusively to the study at hand and not to future research.
    - The following items should be 'unbundled' (made optional) such that the participant may decline consent for optional items, yet still be enrolled in the study:
        - "I agree to allow my coded personal data to be processed by the Sponsor for training purposes and for use in its marketing materials"
        - "If I participate in audio or video recording of interviews or feedback sessions, I consent to the disclosure of those recordings to the Sponsor and third parties contracted by it for the purposes of the study"
    - Permission to anonymise data should be added as a standalone consent item, since images will be anonymised prior to publication in scientific journals etc.

In addition, the NREC-MD raised the following queries and the Committee requests that additional information be provided, as outlined.

- The NREC-MD noted that the NREC-MD application form (S1) confirms that participants will be reimbursed for expenses (such as travel and related reasonable out-of-pocket expenses), however the draft budget does not include this cost. Please confirm.
- The NREC-MD noted that evidence of data protection officer (DPO) engagement has been provided with regard to the development of data protection impact assessments (DPIAs). The Committee requests confirmation that the comments of applicable DPOs have been incorporated into the relevant DPIAs.
- The NREC-MD noted that data will be 'exported to the cloud' (e.g. NREC-MD application form, D4). The Committee requests confirmation as to the location of the cloud, and assurance of compliance with applicable EU and local, regulatory and legislative data protection requirements.
- The NREC-MD noted in the NREC-MD application form (G3) that participants 'will be invited to consent to new versions of the clinical investigation that result in changes in the PICF'. The Committee requests confirmation that substantial modifications which result in such changes to the patient information sheet/informed consent form will be submitted to the NREC-MD for review.

**23-NREC-MD-019**

- Principal Investigator: Prof. Mark Kennedy
- Study title: A Non-Randomized Clinical Study Evaluating Use of the CapBuster System Medical Device for the Crossing of Chronic Total Occlusions in Coronary Arteries
- Lead institution: Mater Private Hospital, Eccles St, Dublin 7, D07 WKW8, Ireland
- NREC-MD Decision
  - *Favourable*

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**23-NREC-MD-020**

- Principal Investigator: Dr. Janusz Krawczyk
- Study title: Collection and Processing of Peripheral Blood (PB) Specimens from healthy volunteers for Analytical Performance Evaluation of the BD Reagent Panels and Kits on the BD Flow Cytometer Systems
- Lead institution: National University of Ireland Galway, Oak House, Lime Tree Avenue, Millennium Park, Naas, Co. Kildare, Ireland
- NREC-MD Decision
  - *Favourable with conditions*
- Further information requested
  - NREC-MD Application Form:
    - The NREC-MD notes that the advertisement states that expenses will be reimbursed for participants, however the applicable of the NREC-MD application form does not align. The Committee requests confirmation that participants will be reimbursed for expenses.
    - Please confirm the location of the BD testing facility for sites and ensure that this aligns with the answer provided in section L16(g).
    - Please confirm the location of the investigation site and that it matches the location of the national Principal Investigator.
  - Patient Information Leaflet (PIL):
    - The Committee requests that the PIL be updated to state that participants will be given a minimum of 24 hours to consider whether to participate.
    - The NREC-MD requests that consideration be given to the possibility of identifying an abnormal blood profile upon testing of healthy volunteers. If applicable, the PIL should be updated to inform participants of how this information may be handled should it occur.
  - Advertisement Poster:
    - The NREC-MD requests that changes be made to the advertisement poster to improve clarity, including amendments to text and an outline of collaborators.

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**23-NREC-MD-007-SM1**

- Principal Investigator: Dr. Matthew Sheehan
- Study title: Repeatability, Reproducibility and Demographic Reference Study in Ocular Microtremor
- Lead institution: National Optometry Centre, Central Quad, TU Dublin, Grangegorman Lower, Dublin, D07 ADY7, Ireland
- NREC-MD Decision
  - *Favourable*

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