NATIONAL OFFICE FOR RESEARCH ETHICS COMMITTEES

National Research Ethics Committee

NREC-MD Meeting Minutes

18th May 2023

Attendance

Name	Role
Prof. Barry O'Sullivan	Chairperson, NREC-MD
Prof. Declan Patton	Deputy Chairperson, NREC-MD
Prof. Mary Sharp	Deputy Chairperson, NREC-MD
Dr Mireille Crampe	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 Declan O'Callaghan	Member, NREC-MD
Dr Susan O'Connell	Member, NREC-MD
Dr Clare O'Connor	Member, NREC-MD
Dr Paul O'Connor	Member, NREC-MD
Mr Damien Owens	Member, NREC-MD
Prof. Mahendra Varma	Member, NREC-MD
Mr Peter Woulfe	Member, NREC-MD

Name	Role
Dr Emily Vereker	Head of Office, National Office for Research Ethics Committees
Chita Murray*	Programme Manager, National Office for Research Ethics Committees
Megan O'Neill	Project Officer, National Office for Research Ethics Committees
Bríd Burke**	Programme Manager, Health Research Consent Declaration Committee

*Drafted minutes

** Attended as observer

Apologies: Dr Caitriona Cahir, Dr Ruth Davis, Dr Gloria Kirwan, Dr Sarah McLoughlin, Prof. Tom Melvin, Prof. Therese Murphy, Prof. Anne Parle McDermott, Ms Riona Tumelty

Quorum for decisions: Yes

Agenda

- Welcome (Chairperson)
- Report on Committee business
- Minutes of previous meeting
- Declarations of interest
- 22-NREC-MD-036-SM2-R1
- 23-NREC-MD-014
- 23-NREC-MD-015
- 21-NREC-MD-007-SM2
- 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 (20 April 2023) were approved.
- Matters arising from the previous meeting: none
- Declarations of interest: none

Applications

22-NREC-MD-036-SM2

- 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: HRB Clinical Research Facility Galway, Galway University Hospital Galway, H91 YR71
- NREC-MD decision:
  - *Favourable*

23-NREC-MD-014

- Principal Investigator: Dr Colm Hanratty
- 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 Dublin, Eccles St., Dublin 7, D07 WKW8
- NREC-MD comments:
  - The NREC-MD noted that the Principal Investigator declared a financial interest in the study. Given the central role of a Principal Investigator in a clinical investigation, the Committee were not assured that this did not present a substantial conflict of interest, and that it would not compromise the integrity of the clinical investigation.
- NREC-MD decision:
  - *Unfavourable*

23-NREC-MD-015

- Principal Investigator: Prof. Jarushka Naidoo
- Study title: Diagnostic Protocol for VENTANA PD-L1 (SP263) CDx Assay in Arcus Biosciences Study ARC-10
- Lead institution: Beaumont Hospital, Beaumont Road, Dublin 9, D09V2N0
- NREC-MD decision:
  - *Request for further information*
- Further information requested
  - NREC-MD Application Form:
    - The NREC-MD noted that the companion diagnostic will determine eligibility for participation in a named clinical trial. The Committee requests clarification

as to whether this clinical trial may proceed without the use of the companion diagnostic.

- The NREC-MD notes that one site in the Republic of Ireland will be included in the study. The Committee requests clarification as to why additional sites will not be participating.
- The NREC-MD noted the inclusion/exclusion criteria for screening of samples under the companion diagnostic (CDx) protocol. The Committee requests clarification whether the inclusion/exclusion criteria for participants into the clinical trial, as listed in the applicable protocol, is exhaustive. Please comment on the evaluation of other treatments/options available that might exclude participation of an individual in the clinical trial and therefore participation in the pre-screening study. Please outline which test(s) will be used to determine front line treatment eligibility, such as anaplastic lymphoma kinase (ALK), epidermal growth factor receptor (EGFR) and other genetic markers.
- The NREC-MD noted that an additional biopsy may be required in certain circumstances. The Committee requests clarification of the number of biopsies which the participant will undergo, and the justification for each.
- The NREC-MD noted the below statement with regard to reporting of false positive/negative test results which are generated during sample testing under the CDx protocol. The Committee requests to know whether the participant will be informed in the event that such false test results are identified.
    - *If during the conduct of this Dx protocol, there is evidence to confirm a false result was reported, this event will be reported to the pharmaceutical study sponsor and handled and reported according to regulations.*
- The NREC-MD noted that additional detail on the non-small cell lung cancer (NSCLC) patient standard diagnosis journey would be beneficial and would enhance application review. The Committee requested further information in order to evaluate the benefits and risks of participation in the pre-screening in the overall context of the study.
- The NREC-MD noted the below statement in the NREC-MD application form. The Committee requests confirmation that an interpreter will be made available to participants when applicable in order to facilitate fully informed consent.
    - *If there are provisions at the research sites for an interpreter and if the investigator believes this will not affect patient safety, patient compliance and true informed consent, this will be used.*
- The NREC-MD notes that participants of child-bearing potential will not be included in the associated clinical trial. The Committee requests justification why this cohort will not be eligible for inclusion.
- NREC-MD noted that the application form includes the below statement. The Committee requests clarification with regard to the protection of participant data.
- NREC-MD requests clarification with regard to the protection of participant data during monitoring and auditing processes.

        - The NREC-MD noted reference to retention periods for samples and/or data. The Committee requests confirmation of alignment with the retention periods set down in the applicable Irish legislation and EU regulations including but not limited to Regulation (EU) No 536/2014 (CTR) and Regulation (EU) 2017/746 (IVDR).
    - Pre-screening Patient Information Leaflet (PIL):
        - The NREC-MD noted an apparent lack of differentiation between the role of the pre-screening procedure for evaluation of eligibility for the clinical trial, and the patient diagnosis path, to determine which treatment is more appropriate for each patient's condition. The Committee requests clarification as to where this study fits within the patient diagnosis and treatment journey, especially as the potential treatment appears to be proposed as front line.
        - The NREC-MD requests clarification with regard to management of the samples of participants who do not wish to participate in future optional research.
    - Data Protection Impact Assessment (DPIA)
        - The NREC-MD noted some difficulty in ascertaining from the DPIA the risk profile and the mitigations associated with the pre-screening aspects of the study. The Committee requests confirmation that processing of data will be in compliance with applicable regulations and legislation including Regulation (EU) 2016/679 (GDPR), the Data Protection Act 2018, and the Health Research Regulations 2018.

21-NREC-MD-007-SM2

- 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 (SIRONA 2 Trial)
- Lead institution: Galway University Hospital, Galway, H91 YR71, Ireland
- NREC-MD Decision
    - *Favourable*

- AOB:
    - The National Research Ethics Committees Annual Report 2022 is now pending publication.
    - The National Office will seek to add new members to both NREC-CT(s) and to NREC-MD in the coming months.
    - Development of the Statement of Compliance with regard to data protection is reaching completion, with the involvement of the Chairs and Deputy Chairs.
- The Chairperson thanked the Committee and closed the meeting.