NATIONAL OFFICE FOR RESEARCH ETHICS COMMITTEES

# National Research Ethics Committee

## NREC-MD Meeting Minutes

**16th November 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 |
| Dr Gloria Kirwan | Member, NREC-MD |
| Ms Orla Lane | Member, NREC-MD |
| Mr Billy McCann | 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 |
| Prof. Mahendra Varma | Member, NREC-MD |
| Chita Murray* | Programme Manager, National Office for Research Ethics Committees |
| Louise Houston | Project Officer, National Office for Research Ethics Committees |

*Drafted minutes

**Apologies**: Prof. Tom Melvin, Prof. Susan O'Connell, Prof. Anne Parle-McDermott, Dr Sarah McLoughlin, Ms Riona Tumelty, Mr Damien Owens, Dr Caitriona Cahir, Dr Owen Doody, Mr Peter Woulfe

**Quorum for decisions:** Yes

## Agenda

- Welcome (Chairperson)
- Report on Committee business
- Minutes of previous meeting
- Declarations of interest
- 23-NREC-MD-031-R1
- 23-NREC-MD-032-R1
- 23-NREC-MD-034
- 22-NREC-MD-039-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 (19th October 2023) were approved.
- Matters arising from the previous meeting: none
- Declarations of interest:
  - 23-NREC-MD-031-R1: Dr Ruth Davis did not participate in review or discussion.

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**Applications**

**23-NREC-MD-031-R1**

- Principal Investigator: Prof. Ray McDermott
- Study title: Clinical Performance Study for the Signatera Test Used in Identification of Circulating Tumor-DNA in Muscle-Invasive Bladder Cancer Patients Enrolled Under F. Hoffmann-La Roche Clinical Study Protocol BO42843
- Lead institution: Tallaght University Hospital, Tallaght, Dublin 24, D24 NR0A
- NREC-MD decision:
  - *Favourable*

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**23-NREC-MD-032-R1**

- Principal Investigator:  Prof. Joseph Butler
- Study title: Clinical/radiological outcomes associated with the use of conduit™ anterior lumbar interbody fusion (alif) cage system in conjunction with supplemental fixation for the treatment of lumbar degenerative disc disease at one or two contiguous spinal levels from l2-s1
- Lead institution: Mater Misericordiae University Hospital, Eccles St., Dublin 7, D07 R2WY
- NREC-MD decision:
  - *Favourable*

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**23-NREC-MD-034**

- Principal Investigator: Prof. Mark Spence
- Study title: Clinical Investigation Plan (CIP) for: Safety and Performance Study for Arterial Large Hole Vascular Closure Device – ELITE study
- Lead institution: Mater Private Dublin (Heart and Vascular Centre), 73 Eccles St., Dublin 7, D07 KWR1
- NREC-MD decision:
  - *Request for further information*
- Further information requested

NREC-MD Application Form

The NREC-MD noted that the document requires additional information/amendments. The Committee requests that a revised copy be submitted, with updates at applicable sections:

- Please confirm the recruitment target for the study.
- For participants meeting inclusion/exclusion requirements;
    - What is the current standard-of-care; percutaneous closure device or surgical cut down?
    - Does current standard-of-care include iliofemoral CT imaging pre-procedure, iliofemoral angiography pre-procedure and post device deployment?
- Please comment on the use of data to ‘support other studies’ and ensure that the contents of the Informed Consent Form (ICF) are in compliance with the Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018) (HRR) in which informed participant consent is a mandatory safeguard. The Committee advises that i) consent for future use of data be unbundled (separated and made optional) 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 (as per the submitted PIL).

- Please comment on the transfer of data outside of the European Union. Transfer of pseudonymised data to countries which do not have a European Commission adequacy decision in place is likely to require control via use of the European Commission standard contractual clauses.
- The NREC-MD requests that prospective participants are offered at minimum 24 hours to consider their participation in the study, and that this be updated in the application form and documented in the Participant Information Leaflet (PIL).
- Please confirm whether every reasonable effort will be made to allow access to the study for participants for whom English is not their native language, or who do not speak English. In the event that the study seeks to enrol a participant who requires a translated PIL-ICF, please note that translations must be completed by a certified translation provider, and the translation certificates submitted to the NREC-MD as a non-substantial modification in advance of the distribution of translated documents.
- The NREC-MD application form suggests the use of pseudonymised data at the study site, followed by the entry of anonymised data only into the electronic data capture (EDC) system. Please confirm, and comment on whether transfer of data outside of the EU refers only to anonymised data.
- Please clarify the treatment of data when stating that “all personal data shall be anonymised”. The application to data of a code which has an associated identifying key etc., is typically described as pseudonymised (‘coded’).
- The Participant Information Leaflet (PIL) refers to the requirement for a CT scan. Please complete the applicable section(s) of the NREC-MD application form to align with this information.
- Please align submitted documents with regard to the reimbursement of participant expenses, including but not limited to the following; the Participant Information Leaflet, the NREC-MD application form, the Clinical Study Agreement.

Participant Information Leaflet-Informed Consent Form (PIL-ICF):

The NREC-MD noted that the document requires additional information/amendments. The Committee requests that a revised copy be submitted, with updates at applicable sections:

- With regard to the 180-day follow-up, please confirm the physical parameters, if any, to be measured at this follow-up and add clarity to the PIL with regard to the procedures to be conducted at each follow-up timepoint, whether in-person or by telephone.
- Please list the personal data points which will be collected in regard to study participants rather than stating ‘etc.’
- With regard to the stated potential for “significant personal disadvantages” as result of data transfer to the USA, please provide additional information as to the safeguards which will be in place to ensure that study data is transferred and processed appropriately. As above, transfer of pseudonymised data to countries which do not have

a European Commission adequacy decision in place is likely to require control via use of the European Commission standard contractual clauses.

- The Committee requests that the below additional consent line item be included in the ICF:
    - Consent for the participant's general practitioner (GP) and/or other treating physicians to provide data from previous examinations for the purposes of this study.

Financial Considerations:

- The NREC-MD noted that a number of the applicable insurance certificates provided as part of the application submission will require extension/renewal in order to remain valid for the duration of the study. The Committee requests confirmation that the appropriate insurance(s) will remain in place via renewal and/or extension as applicable.
- The NREC-MD noted that insufficient information has been provided in the Clinical Study Agreement with regard to budgetary arrangements for the study. Please provide additional detail including, where possible, an itemised study budget.

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**22-NREC-MD-039-SM1**

- Principal Investigator:  Prof. Gerry O'Sullivan
- Study title: Evaluation of the GORE® VIAFORT Vascular Stent for Treatment of Symptomatic Inferior Vena Cava Obstruction with or without Combined Iliofemoral Obstruction
- Lead institution: University Hospital Galway (Clinical Research Facility Galway), Newcastle Rd., Galway, H91 YR71
- NREC-MD decision:
    - *Favourable with conditions*
- Associated conditions:
    - Applicable contact details for the Principal Investigator are submitted to the National Office.

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- AOB
- The Chairperson thanked the Committee and closed the meeting.