NATIONAL OFFICE FOR RESEARCH ETHICS COMMITTEES

National Research Ethics Committee

NREC-MD Meeting Minutes

19th October 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 Owen Doody	Member, NREC-MD
Dr Frank Houghton	Member, NREC-MD
Ms Orla Lane	Member, NREC-MD
Dr Sarah McLoughlin	Member, NREC-MD
Dr Declan O'Callaghan	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
Mr Peter Woulfe	Member, NREC-MD
Chita Murray*	Programme Manager, National Office for Research Ethics Committees
Louise Houston	Project Officer, National Office for Research Ethics Committees
Dr Emily Vereker	Head, National Office for Research Ethics Committees

*Drafted minutes

Apologies: Dr Caitriona Cahir, Dr Ruth Davis, Dr Gloria Kirwan, Mr Billy McCann, Prof. Tom Melvin, Prof. Thérèse Murphy, Prof. Susan O'Connell, Dr Clare O'Connor, Dr Paul O'Connor

Quorum for decisions: Yes

Agenda

- Welcome (Chairperson)
- Report on Committee business
- Minutes of previous meeting
- Declarations of interest
- 23-NREC-MD-029-R1
- 23-NREC-MD-030-R1
- 23-NREC-MD-031
- 23-NREC-MD-032
- 23-NREC-MD-033
- 22-NREC-MD-032-SM2
- 23-NREC-MD-008-SM1
- 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 (21st September 2023) were approved.
- Matters arising from the previous meeting: none
- Declarations of interest: None

Applications

23-NREC-MD-029-R1

- Principal Investigator: Prof. Joseph Butler
- Study title: A Single Site Post-Market Data Collection Protocol to Evaluate the Performance of Synergy Spine Solutions Synergy Disc®
- Lead institution: Mater Misericordiae University Hospital, Eccles Street, Dublin, D07 AX57
- NREC-MD decision:
  - *Favourable with conditions*

- Associated conditions:
  - The NREC-MD requests that the informed consent process be completed by an authorised designee of the Principal Investigator (as per Section 5.8.2 of ISO 14155/2020) i.e. an individual nominated from among the study team members (as per Article 63(2)(c) of the Medical Device Regulation (EU) 2017/745). Please update the Participant Information Leaflet/Informed Consent Form (PIL/ICF) accordingly to indicate that participants may approach the authorised designee with questions.
  - The NREC-MD requests that the PIL/ICF be updated to include additional information for the participant with regard to the efficacy of the device. Please also state in the PIL whether data is still being collected which will confirm the effectiveness of the device.
  - The NREC-MD requests that reasonable efforts be made to allow access to the study for participants for whom English is not their native language, or who do not speak English, taking into account that the validated questionnaires are available in 'mainstream languages' per the submitted application. In the event that the study seeks to enrol a participant who requires a translated PIL-ICF, translations must be completed by a certified translation provider, and the translation certificates submitted to the NREC-MD in advance of distribution of translated documents.

23-NREC-MD-030-R1

- Principal Investigator: Prof. Norman Delanty
- Study title: Wireless Ultra Long-Term EEG recordings in Epilepsy. A prospective long-term clinical evaluation using the UNEEG EpiSight solution
- Lead institution: Beaumont Hospital, Beaumont Road, Dublin 9, D09V2N0
- NREC-MD decision:
  - *Favourable with conditions*
- Associated conditions:
  - The NREC-MD noted that the applicant provided a justification for the collection of certain data points. The Committee requests that data not be collected for the purpose of supporting market access.

23-NREC-MD-031

- 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:
  - *Request for further information*

- Further information requested

  - The NREC-MD noted that, in the course of the proposed study, the plasma flow sequencing platform will be changed to an enhanced platform with associated software changes. The Committee requests confirmation whether the test results in this performance study, as determined by approved and upgraded assays, will be treated as a single group in the analysis. Furthermore, please confirm whether the submitted performance study seeks to demonstrate the suitability of the enhanced sequencing platform, and comment on the data to be utilised.
  - The NREC-MD noted that the submitted documents include a broad description of the genetic testing which will be undertaken on blood and tissue samples. This includes whole exome sequencing and the top-line potential areas of investigation are outlined. A third-party entity is named, and the Committee requests clarification as to the role of same.
  - The NREC-MD noted that the proposed data retention period is 25 years after the final study results have been reported, or for the length of time required by applicable laws, whichever is longer. The Committee requests confirmation of the justification for this data retention period. The justification may make reference to the requirements of the applicable EU regulation(s), national legislation, and best practice for the retention of laboratory testing data and/or biological samples which are associated to clinical trials of investigational medicinal products.

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:

- Data processing: please provide a complete response as per the requirements of this section of the application form.

Data Protection

- The NREC-MD noted that a data protection impact assessment (DPIA) has been carried out with regard to activities associated with clinical trial protocol. Since the pre-screening phase will involve genomic data, the Committee requests confirmation of the steps which are being taken to address and mitigate applicable privacy risk(s).

Insurance

- The NREC-MD noted that the insurance information submitted covers activities associated with the clinical trial of the investigational medicinal product. The Committee requests assurance that applicable insurance policies are in place with regard to the pre-screening and surveillance study.

23-NREC-MD-032

- 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 Street, Dublin, D07 AX57
- 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 update the list of exclusion criteria to include pregnancy as the Participant Information Leaflet (PIL) indicates that the device is not suitable for use in pregnancy.
- Please comment on the management plan in the event that the surgical intervention does not succeed, or complications arise during surgery, or there is a need for further surgery.
- Please make reasonable efforts 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 Participant Information Leaflet/Informed Consent Form (PIL/ICF), translations must be completed by a certified translation provider, and the translation certificates submitted to the NREC-MD in advance of distribution of translated documents.
- Please comment on whether the aggregated data will be transferred to the United States.
- Since this study will involve radiation which is considered to be additional to standard of care (SOC), please complete the applicable section of the application form. Please comment on the x-rays which will be taken during the five (5) follow-up visits, noting which are additional to SOC.
- The NREC-MD noted that participants will undergo five (5) follow-up visits. The Committee requests confirmation, as above, whether these visits are part of SOC and, if not, requests that participants be reimbursed for reasonable receipted expenses. Note that the Committee does not specify a value for reimbursement/expenses. Please update the PIL, as applicable, to inform the participant that reimbursement of expenses will be available.

Budget:

- The NREC-MD requests confirmation of applicable payment(s) to the Principal Investigator (PI).

23-NREC-MD-033

- Principal Investigator: Prof. Brian Walsh
- Study title: An observational study of the NeuroBell EEG Monitor (a portable and wireless EEG monitor)
- Lead institution: Cork University Maternity Hospital, INFANT Research Centre, Paediatric Academic Unit, Cork University
- Hospital, Wilton, Cork,
- NREC-MD decision:
  - *Request for further information*
- Further information requested

  Clinical Investigation Plan:

  - It is noted that qualitative feedback on the device will be sought from users, and reference has been made to the use of useability questionnaires for this purpose. Please provide copies to the NREC-MD of any questionnaires which are intended for use in this clinical investigation.

  Recruitment:

  - Please confirm whether non-native English speakers will be considered for inclusion in this study. Please make reasonable efforts 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 Participant Information Leaflet/Informed Consent Form (PIL/ICF), translations must be completed by a certified translation provider, and the translation certificates submitted to the NREC in advance of distribution of translated documents.
  - Please confirm whether the Principal Investigator (PI) is also involved in care of the participants. Has the Sponsor given consideration to assigning recruitment activities to an authorised designee (as per ISO 14155) who is a member of the investigating team (as per the Medical Device Regulation (EU) 2017/745)?

  Principal Investigator:

  - The NREC-MD noted that the submitted documents appear to name two (2) lead Principal Investigators (PIs) for this clinical investigation, and requests applicable revisions to ensure consistency throughout.

  Budget:

  - The NREC-MD noted that funding will be provided by the Enterprise Ireland Commercialisation Fund. Please clarify whether the documented amount of funding is specific to this clinical investigation or if it has been allocated to a wider project.

22-NREC-MD-032-SM2

- Principal Investigator: Mr. Barry Jones
- Study title: ProVee Urethral Expander System IDE Study (ProVIDE)
- Lead institution: St. James's Hospital, James Street, Dublin 8, D08NHY1
- NREC-MD decision:
  - *Favourable*

23-NREC-MD-008-SM1

- Principal Investigator: Prof. Faisal Sharif
- Study title: SPYRAL HTN-ON MED Global Clinical Study of Renal Denervation with the Symplicity Spyral™ multi-electrode renal denervation system in Patients with Uncontrolled Hypertension on Standard Medical Therapy
- Lead institution: University Hospital Galway, Newcastle Road, Galway, H91 YR71
- NREC-MD decision:
  - *Favourable*

- AOB:
  - The Programme Manager and colleagues from the National Office and the HPRA are participating in an EU-wide project with representatives from competent authorities and ethics committees from other Member States (MS). The project seeks to understand the landscape of national legislation, and the impact of EU regulations on the assessment of applications under CTR/MDR/IVDR.
  - Following a successful Expression of Interest campaign, five new members have been appointed to the NREC-MD and will be onboarded in the coming months.
  - NREC Lunch & Learn speaker session for October will feature a guest speaker from the GCP Compliance unit of the HPRA.
  - The HRB Ethics Conference speaker programme is now available online.
- The Chairperson thanked the Committee and closed the meeting.