NATIONAL OFFICE FOR RESEARCH ETHICS COMMITTEES

# National Research Ethics Committee

## NREC-MD Meeting Minutes

**21st September 2023**

### Attendance

| Name | Role |
|---|---|
| Prof. Barry O'Sullivan | Chair, NREC-MD |
| Prof. Mary Sharp | Deputy Chair, NREC-MD |
| Dr Caitriona Cahir | Member, 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 |
| Mr Billy McCann | Member, NREC-MD |
| Dr Sarah McLoughlin | Member, NREC-MD |
| Prof. Tom Melvin | Member, NREC-MD |
| Dr Declan O'Callaghan | Member, NREC-MD |
| Dr Clare O'Connor | Member, NREC-MD |
| Mr Damien Owens | Member, NREC-MD |
| Prof. Anne Parle McDermott | 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**: Prof. Declan Patton, Dr Owen Doody, Dr Gloria Kirwan, Prof. Therese Murphy, Prof. Susan O'Connell, Dr Paul O'Connor, 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-026-R1
- 23-NREC-MD-028
- 23-NREC-MD-029
- 23-NREC-MD-030
- 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 (17th August 2023) were approved.
- Matters arising from the previous meeting: none
- Declarations of interest:
  - Prof. Tom Melvin (23-NREC-MD-028). Prof. Tom Melvin left the meeting for the review of 23-NREC-MD-028.
  - Prof. Tom Melvin (23-NREC-MD-029). Prof. Tom Melvin left the meeting for the review of 23-NREC-MD-029.

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**Applications**

**23-NREC-MD-026-R1**

- Principal Investigator: Prof. Ian Flitcroft
- Study title: Stellest® Lenses Observational Multi-Centred European Study (SLOMEs)
- Lead institution: Centre for Eye Research Ireland (CERI), Environmental Sustainability and Health Institute, TU Dublin City Campus, Grangegorman Lower, Dublin 7

- NREC-MD decision:
  - *Favourable with conditions*
- Associated conditions:
  - Ensure that the titles of the various consent/assent forms are correct, aligned and consistent.
  - Include in the applicable PILs all categories of data which will be collected, as outlined in the NREC-MD application form.
  - Include a consent section in respect of data processing, in the parent consent form.
  - Correct the title contained within the PIL for 16-18 year olds, and ensure that the information provided is suitable for that age group.
  - The below documents do not sufficiently resemble the other consent forms, and do not correlate fully with the applicable PIL. Please align them more closely with the data processing information provided in the relevant PILs. In that regard, if TUD data protection policies are being relied upon, these policies along with any other relevant data processing information should be referenced in the PILs for parents and participants >18 years of age.
    - The parent consent form for data processing only for ages 16-18 years of age.
    - The participant reconsent form.

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**23-NREC-MD-028**

- Principal Investigator: Prof. Joseph Butler
- Study title: Clinical and Radiologic Outcomes Associated with the use of SYMPHONY OCT System for the Treatment of Acute and Chronic Instabilities of the Craniocervical Junction, the Cervical Spine and the Upper Thoracic Spine
- Lead institution: Mater Misericordiae University Hospital, Eccles St., Dublin 7
- NREC-MD decision:
  - *Request for further information*
- Further information requested

Patient Information Leaflet-Informed Consent Form (PIL/ICF):

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

- The NREC noted that the Participant Information Leaflet includes technical language which may not be readily understood by the participant. The Committee requests that the document be revised to improve accessibility.
- As participant information is traceable, please remove the following statement(s) from the PIL.
  - “None of the information will be held under your name or traceable to you” and “or traceable to you”.

- As the data from this study will be retained for fifteen (15) years, please remove the following statement.
  - "When this study is over, your data will be destroyed",
- The NREC-MD noted the below statement. As no samples will be taken as part of this study, please replace the word "samples" with "scans".
  - "Research performed with your coded samples and information may help us to evaluate how the SYMPHONY-OCT system is performing".
- Please include information with regard to the supports and care which will be available to participants if something goes wrong during the study.
- Please update the section "Who should I contact for information or complaints?" to include a relevant phone number and postal address.
- The NREC-MD noted that three copies of the consent form will be created and retained. Please ensure that this is made clear throughout the documentation.

Data Protection:

- The NREC-MD noted that investigators seek to access the medical records of patients who previously underwent spine stabilisation surgery using the 'Mountaineer' system, for comparison to data of patients who will undergo surgery using the 'Symphony Oct' system. Please comment on the legal basis for retrospectively accessing patient data, including reference to the Health Research Regulations 2018 (S.I. No. 314 of 2018), including the amendments as published in 2021, where applicable.

Suitability of the Principal Investigator:

- Please provide details of the potential financial or other interests of the Principal Investigator in relation to this study which could potentially lead to a conflict of interest.

Insurance and financial arrangements:

- The NREC-MD noted that a draft Clinical Trials Agreement has been provided, and that aspects of the financial arrangements are yet to be finalised. Please provide a final version which includes additional clarity and transparency on financial arrangements.

Additional ethics-related comments:

- Please comment on whether a participant implant card will be required for air travel.

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**23-NREC-MD-029**

- 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 St., Dublin 7
- NREC-MD decision:
  - *Request for further information*
- Further information requested

Study Procedures:

- The NREC-MD noted the below statement in the NREC-MD application form. Please clarify the meaning of the statement, ensuring that continuity of patient care is addressed in your response.
  - "The study may be stopped by the Sponsor at any time for any reason or the study surgeon may decide to stop collecting data for the Sponsor".
- Please comment on whether this device will continue to be considered standard of care should the sponsor stop the collection of data, or a large number of participants withdraw from the study.
- The NREC-MD noted that a thirteen (13) year follow-up will be undertaken in relation to this study. Please provide justification for this timeline. Has the applicant considered evaluating the data in blocks of 3-5 years to address emerging safety concerns/issues?
- Please comment on the requirement to select patients retrospectively rather than including only prospective participants, and address any potential for bias to occur.

Patient Information Leaflet-Informed Consent Form (PIL/ICF):

- Please update the Patient Information Leaflet to include information with regard to the efficacy of the Synergy disc.

Recruitment:

The recruitment process, as documented in the submitted application, requires the addition of some key information. Please provide the following:

- How prospective/retrospective participants will be identified, and by whom.
- Once identified, the individual who will approach the prospective participant, provide them with study information and answer any questions they might have.
- The length of time which participants will be given to decide whether to participate in the study. Please note that a period of 24 hours is typically requested by the Committee.
- In the event that a prospective participant decides to participate, please provide details of who they should follow-up with, and how.
- The individual who will complete the consenting process with the participant.
- Confirmation whether the DPIA has been signed off by all parties or, at a minimum, confirmation that the site DPO has provided their feedback on the DPIA.

Additional comments:

- The NREC-MD noted that neither the participant's General Practitioner (GP) nor hospital consultant will be notified of their participation. Please comment and provide a justification.
- Please provide a justification for the exclusion of non-native English speakers.
- The NREC-MD noted that non-operative options will only be offered to the patients for six (6) weeks. Please comment as to why the participants will not be treated with physical therapy for a longer period of time before undergoing an invasive surgical procedure.

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**23-NREC-MD-030**

- 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 Rd, Beaumont, Dublin
- NREC-MD decision:
  - *Request for further information*
- Further information requested

Participant Information & Informed Consent Form (PIICF):

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

- With regard to the 'additional procedures' referred to in the below statement, please include further information which outlines the management involved in using the device, and the potential impacts on daily life.
  - "Please note that there are other factors to consider before agreeing to participate such as additional procedures, use of your personal information, and other possible risks not discussed here".
- With regard to the data points listed in Section 10 ("What will be done with your data?"), please provide a justification for the collection of these data points, including but not limited to those which follow below. Please confirm the relevance of each, in the context of the study as described in the submission.
  - cohabitation, employment status, education level.
- With regard to the retention period of study data, please amend the following sentence to clarify that the storage period includes documents from the study and data collected during the study:
  - "For how long do we store your data? The hospital is obliged to store the documents from this study for five years after the study report has been signed. The sponsor is obliged store the documents from this study for at least 15 years after the study report has been signed, however the documents at sponsor will be coded to protect your privacy"

Consent

- Please take steps to more closely align the appearance of the below two documents, including placement of the signature entries toward the end of document #32, such that participants have the opportunity to review the information before entering their signature.
    - Participant Information & Informed Consent Form (PIICF) (#8)
    - Consent for future use of data (#32)
- 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).

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:

- The Committee requests that the applicant clarifies the proposed recruitment process, and considers the appointment of an authorised designee of the Principal Investigator (as per Section 5.8.2 of ISO 14155/2020) nominated from among the study team members (as per Article 63(2)(c) of the Medical Device Regulation (EU) 2017/745).
- The investigator or their representative will contact potential participants via telephone, email, letter or in person. Please provide NREC-MD with a draft of the sample telephone script/email/letter for review purposes.
- With regard to the below statement, please outline further the nature of the discussion between the participant and the treating physician. Please comment on the potential for dependency on the device which may have developed during the study; the suitability of either the CE marked device and/or the investigational device (assuming it has obtained its CE mark) for individual participants; and the clinical need(s) which may indicate that continuing use of the device may/may not necessarily be advised by the treating physician.
    - “On the decision of the Principal Investigator and the participant, the participant may have the implant longer than the clinical investigation period. In such case the participants will have to utilise the CE marked EEG recorder, 24/7 EEG™ SubQ, or in case the UNEEG EpiSight has obtained its CE mark the participant can utilise this. In this case the participant will follow standard of care”.
- Please include additional detail with regard to the protocol/ management plan for facilitating continued access to the applicable device.
- The NREC-MD application form states that the participant’s GP/Hospital Consultant will not be informed of their participation. The informed consent form (Appendix D to the PIICF) states the below. Please align and a) if the participant’s GP will *not* be informed, please clarify the reason, in view of the potential role of the GP in suture removal, b) if the participant’s GP *will* be informed, please provide NREC-MD with a copy of the letter for the GP for review purposes.

  - "I give the investigator consent to inform my general practitioner that I am taking part 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 PIL-ICF, translations must be completed by a certified translation provider, and the translation certificates submitted to the NREC-MD in advance of the distribution of translated documents.

Curriculum Vitae of the Principal Investigator

- The NREC-MD requests additional information with regard to the experience of the PI, specifically his participation in the conduct of clinical investigations and/or other applicable clinical studies.

Site Suitability Form (SSF)

- Please provide additional detail in each site suitability form with regard to the suitability of the site(s), and the suitability of the facilities and equipment at the site(s).

Financial Considerations

- With regard to the reimbursement of participant expenses, please align the information provided in the submitted documents, including but not limited to those listed below. Please note that the NREC-MD typically requests that reasonable, receipted participant expenses be reimbursed, without the application of a maximum amount (such as €35).
  - NREC-MD Application Form
  - Itemised Study Budget
  - Clinical Investigation Agreement
- The NREC-MD application form indicates that the Principal Investigator (PI) and other investigators do not have any direct/indirect involvement in the outcome of the study that could in any way be regarded as a possible conflict of interest. Please provide a statement from each investigator which confirms this information.

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- AOB:
  - Chair and committee members discussed the possibility of the National Office creating guidance documents for publication on the National Office website in order to assist applicants, which would include brief summaries on the common pitfalls which applicants make when submitting applications.
  - Request for confirmation of member tenure periods.
- The Chairperson thanked the Committee and closed the meeting.