

# National Research Ethics Committee

## NREC-MD Meeting Minutes

28 October 2021

### Attendance

Name	Role
Prof. Barry O'Sullivan	Chairperson, NREC-MD
Prof. Mary Sharp	Deputy Chairperson, NREC-MD
Dr Caitriona Cahir	Member, NREC-MD
Ms Orla Lane	Member, NREC-MD
Mr Billy McCann	Member, NREC-MD
Prof. Therese Murphy	Member, NREC-MD
Dr Paul O'Connor	Member, NREC-MD
Dr Catherine O'Neill	Member, NREC-MD
Mr Damien Owens	Member, NREC-MD
Prof. Anne Parle-McDermott	Member, NREC-MD
Prof. Declan Patton	Member, NREC-MD
Mr Peter Woulfe	Member, NREC-MD
Prof. Mahendra Varma	Member, NREC-MD
Dr Lucia Prihodova*	Programme Manager, National Office for Research Ethics Committees
Dr Melissa Jones	Project Officer, National Office for Research Ethics Committees

\*Drafted minutes

## NREC Meeting Minutes

**Apologies:** Prof. Cathal O'Donnell, Dr Owen Doody, Dr Frank Houghton, Prof. Susan O'Connell, Prof. Mahendra Varma, Ms Riona Tumelty,

**Quorum for decisions:** Yes

## Agenda

- Welcome & apologies
  - NREC Committee Business Report
  - Minutes of previous meeting (30 September 2021) & matters arising
  - Declarations of interest
  - Application 21-NREC-MD-008-SA-2
  - Application 21-NREC-MD-013
  - AOB
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- The Chairperson welcomed the Committee and opened the meeting.
  - NREC Committee Business Report: The Committee *noted* the report.
  - Minutes of previous meeting (30 September 2021) & matters arising: The minutes were *approved*.
  - Declarations of interest: *none*
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## Applications

### 21-NREC-MD-008-SA-2

- Principal Investigator: Professor Faisal Sharif
- Study title: The “RADIANCE II” Pivotal Study
- Lead institution: HRB Clinical Research Facility Galway (HRB-CRFG), Galway University of Ireland, 1st Floor, Galway University Hospitals, Co. Galway
- NREC-MD comments
  - The NREC-MD noted that the original study received a favourable opinion from the Clinical Research Ethics Committee at Galway University Hospitals, and that the present NREC application relates to a substantial amendment. In this regard, the NREC-MD opinion pertains only to the substantial amendment of change in recruitment strategy: use of outside service provider to run radio, newspaper and online media advertising to refer potential candidates to site study team.
  - The NREC-MD also noted that this specific substantial amendment request was already submitted to and reviewed by the Clinical Research Ethics Committee at Galway University Hospitals and received an unfavourable opinion on 11/03/2021.
  - The NREC-MD noted there was no change to the proposed substantial amendment to that reviewed by Clinical Research Ethics Committee at Galway University Hospitals, nor any consideration given to the points listed in the unfavourable decision letter.

- Additionally, the NREC-MD noted that the proposed recruitment methodology is difficult to justify given the sample size for the study.
  - Finally, the NREC noted that the proposed data processing by the external vendor lacked detail and transparency.
  - NREC-MD decision
    - *Unfavourable*
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### **21-NREC-MD-013**

- Principal Investigator: Dr Paul Murphy
- Study title: Real-World Outcomes Study on Subjects Treated with Radiofrequency Ablation
- Lead institution: Anaesthesia, Intensive Care and Pain Medicine, St. Vincent's University Hospital, Merrion Rd, Dublin 4, D04 N2E0.
- NREC-MD comments
  - The NREC-MD noted that this application pertains to a post-market clinical follow up study of a CE marked device IonicRF™ Generator, intended for lesioning of neural tissue in the nervous system as an aid in the management of pain.
- NREC-MD decision
  - *Request for further information*
- Further information requested

#### Participant recruitment and selection

- The NREC-MD requests more information on the pre-screening process.
- The NREC-MD requests clarification on the proposed exclusion criteria of potential participants and requests a list of conditions that would prevent potential participants to be included in the study.
- The NREC-MD requests assurance that there is an appropriate separation of the research team inviting participants to the study and the care team, and that the potential participants are given a minimum of 72 hours to consider their participation in the study.

#### Participant wellbeing

- The NREC-MD requests more detail on the proposed pain management protocol for study participants and clarity on how the protocol deviates from the standard of care.
- The NREC-MD requests that the potential risks of limiting pain medication are given a thorough consideration in section E2 of the application form.

#### Cost of participation

- The NREC-MD requests that participants are not charged for their participation in the study and seeks clarification on the reimbursement of participant expenses.

#### Informed Consent Form

- The NREC-MD requests that final versions of participant-facing documents tailored for Irish population are submitted to the NREC-MD.
- The NREC-MD also noted that the language in the ICF is overly technical and needs to be revised to improve accessibility.
- The NREC-MD requests that the informed consent form is revised to ensure compliance with the Data Protection Act 2018 (Section 36(2)) (Health Research Regulations 2018), eg seeks consent for data transfer to USA.

#### Data processing

- The NREC-MD requests clarification on the process of pseudo-anonymisation of the data.
  - The NREC-MD requests clarification and justification of the proposed retention period of participant data by the site, PI and sponsor.
  - The NREC-MD requests clarification of the process of withdrawal of data of participants who withdraw from the study.
  - The NREC-MD requests that a revised comprehensive DPIA compiled with an input from the DPO at study site.
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- AOB:
  - The Committee discussed the ethical aspects of commercial interests in research, and potential mechanisms for assurance that the entirety of research findings are reported in line with best practice.
- The Chairperson thanked the Committee and closed the meeting.