NATIONAL OFFICE FOR RESEARCH ETHICS COMMITTEES

National Research Ethics Committee

NREC-MD Meeting Minutes

16 June 2022

Attendance

Name	Role
Prof. Barry O'Sullivan	Chairperson, NREC-MD
Prof. Mary Sharp	Deputy Chairperson, NREC-MD
Prof. Declan Patton	Deputy Chairperson, NREC-MD
Dr Caitriona Cahir	Member, NREC-MD
Dr Mireille Crampe	Member, NREC-MD
Dr Ruth Davis	Member, NREC-MD
Dr Owen Doody	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
Prof. Susan O'Connell	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
Mr Peter Woulfe	Member, NREC-MD

Dr Lucia Prihodova*	Programme Manager, National Office for Research Ethics Committees
Dr Louise Houston	Project Officer, National Office for Research Ethics Committees
Dr Emily Vereker	Acting Head, National Office for Research Ethics Committees

*Drafted minutes

Apologies: Mr Frank Houghton, Dr Gloria Kirwan, Prof Therese Murphy, Dr Clare O'Connor, Prof Mahendra Varma, Ms Riona Tumelty

Quorum for decisions: Yes

Agenda

- Welcome & apologies
- NREC Report on Committee Business
- Minutes of previous meetings (19 May 2022) & matters arising
- Declarations of interest
- Application 22-NREC-MD-014-R1
- Application 22-NREC-MD-015-R1
- Application 22-NREC-MD-016-SA1
- Application 21-NREC-MD-003-SA2
- Application 22-NREC-MD-017
- Application 22-NREC-MD-018
- Overview of the S.I. No. 257/2022 – European Union (National Research Ethics Committee for Performance Studies of In Vitro Diagnostic Medical Devices) Regulations 2022
- AOB

- The Chairperson welcomed the Committee and the new members and opened the meeting.
- NREC Committee Business Report: The Committee *noted* the report.
- Minutes of previous meeting (19 May 2022) & matters arising: The minutes were *approved*.

- The NREC-MD considered a query relating to a condition of a decision letter for application 22-NREC-MD-008 setting out that the personnel involved in participant recruitment is not directly involved in direct provision of care for the potential participants.

  The Committee noted that in line with best practice, potential participants should be initially approached about participation in the study by personnel not directly involved in the direct provision of care, and also provide the potential participants with a copy of the participant information leaflet. The potential participants should be offered an opportunity to discuss any queries on the study with the PI as a follow up. Potential participants should revert to the independent research personnel for the consenting process.

  The information supplied to potential participants must be understandable and comprehensible to other individuals on the study team and potential participants without the supervision of the PI.

- Declarations of interest: none.

Applications

22-NREC-MD-014-R1

- Principal Investigator: Prof. Mark Spence
- Study title: Transcatheter Repair of Tricuspid Regurgitation with Edwards PASCAL Transcatheter Valve Repair System: A European prospective, multicenter Post-Market Clinical Follow up.
- Lead institution: Mater Private Hospital, 73 Eccles Street, Dublin 7, D07 KWR1.
- NREC-MD comments
  - The NREC-MD felt the response did not sufficiently clarify what procedures are part of standard care and what procedures are study specific.
  - The NREC-MD felt the response did not sufficiently clarify the proposed participant selection and recruitment.
  - The NREC-MD did not find the rationale for a single participant information leaflet as sufficiently justified and felt that in its present form, the participant facing documentation does not align with the principles of informed consent.
  - The NREC-MD noted that there is no study specific cover in place for the study specific procedures.
- NREC-MD decision
  - *Unfavourable*

22-NREC-MD-015-R1

- Principal Investigator: Prof. Andrew Davies
- Study title: Remote photoplethysmography for monitoring vital signs: useability and acceptance within a specialist palliative care unit.
- Lead institution: Our Lady's Hospice & Care Services, Harold's Cross, Dublin 6W.
- NREC-MD comments
  - The NREC-MD found the documentation unclear in terms of outlining the study specific procedures vs standard care.
  - The Committee noted that at present time not all members of the Data Monitoring and Ethics Committee (DMEC) have been identified. The Committee also noted that limited information on the terms of reference for the DMEC was provided.
  - The NREC-MD welcomed the clarification on the process of obtaining an informed consent provided in the response. The Committee noted that no copies of assent forms were included in the response.
  - The NREC-MD noted there it was unclear whether a consent declaration from the Health Research Consent Declaration Committee is necessary for the study to proceed.
  - The NREC-MD noted there it was unclear whether any participant data will be processed by the Lifelight application itself, and if so, where and how will the processing occur and what data protection safeguards are in place.
  - Furthermore, based on the information provided, the NREC-MD were not clear if all data processing agreements are in place.
  - Finally, the NREC-MD noted that the participant leaflet lists a broad list of external bodies with which the personal information will be shared with, without listing a specific legal basis for the sharing of the data or without it being specifically captured in the consents form.
  - The NREC-MD noted that there is no study specific cover in place for the study specific procedures.
- NREC-MD decision
  - *Unfavourable*

22-NREC-MD-016-SA1

- Principal Investigator: Prof. Carel LeRoux
- Study title: A Prospective, Randomized, Double-Blind, Sham-Controlled, Multi-Center Pivotal Study to Evaluate the Efficacy and Safety of Duodenal Mucosal Resurfacing Using the Revita® System in Subjects with Type 2 Diabetes on Insulin therapy – Substantial Amendment.

- Lead institution: University College Dublin, Belfield Downs, Conway Institute / Diabetes Complications Research Centre, Dublin, D14 YH57.
- NREC-MD comments
  - The Committee noted that this application was an application for a substantial amendment of a study initially approved by the St Vincents Ethics and Medical Research Committee.
- NREC-MD decision
  - *Request for further information*
- Further information requested:
  - The NREC-MD requests clear justification for the proposed substantial amendment, which was not set out in the application form.
  - The NREC-MD requests clarification on whether the social media recruitment campaign poses a substantial amendment in method of study participant recruitment.
  - The NREC-MD noted that the participant information leaflet contains overly technical language and requests that the participant information leaflet is revised for accessibility and is tailored specifically for participants in Ireland.
  - The NREC-MD requests the language throughout the promotional materials is revised to provide more balanced tone.
  - The NREC-MD requests that the Informed Consent Form is revised in line with the Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018).
  - The NREC-MD requests a confirmation that the insurance will be extended to cover the entire period of the study.

- **21-NREC-MD-017**
- Principal Investigator: Prof. Rustom Manecksha
- Study title: Real world evidence observational study to evaluate performance and safety of intravesical sodium hyaluronate (Cystistat®) in the treatment of patients with interstitial cystitis (IC)/bladder pain syndrome (BPS).
- Lead institution: Department of Urology, Tallaght University Hospital, Tallaght, Dublin D24 NR0A, Ireland.
- NREC-MD decision
  - *Request for further information*
- Further information requested:
- Study justification
  - The NREC-MD requests more information on the study justification and on potential contribution to existing evidence on the use of the device.

- The NREC-MD requests more information on whether the health care staff providing medical care to the participants will be involved in any aspects of the study and if so, what measures have been put in place to minimise any perception of coercion.
- The NREC-MD requests clarification on whether only female participants are eligible to enrol in the study (Section D1.3 Application Form). If yes, the Committee requests a justification.
- Given the commitment required of participants, the NREC-MD requests more information on what measures are in place or can be implemented to support participants throughout the course of the study.
- The NREC-MD requests clarification on whether any aspects of the study will require the participants to undertake additional hospital visits. If yes, the NREC-MD requests that participants are offered a refund for all reasonable expenses.
- The NREC-MD requests clarification on whether participants, who notify the research team of their intention to withdraw from the study, will be asked to continue to provide any further information or complete any forms. If so, the NREC-MD requests a justification for this approach.
- The NREC-MD requests a justification for the proposed statistical approach and on the source of statistical advice in the design of the study.
- The NREC-MD requests a justification for the proposed sample size calculation assuming 10% drop out rate.
- The NREC-MD requests more information on the proposed approach to missing data, and what is the minimum number of data points per participant required in order for the participant data to be included in the analyses.
- The NREC-MD noted that the Participant information leaflet contains overly technical language and requests that it is extensively revised for accessibility.
- The NREC-MD requests that participants are informed in writing of any changes to the study contacts over the course of the study.
- The NREC-MD noted that no study specific insurance policy has been included in the submission and requests a justification.
- The NREC-MD requests details on the external service providers involved in processing of the data.
- The NREC-MD requests a clarification as to whether data of participants who withdraw from the study, will be deleted, or otherwise clarify what specifically is the withdrawal process.
- The NREC-MD requests an assurance that all data processing and management will be carried out in compliance with the Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018).
- The NREC-MD requests a clarification on the study cost per participant.
- The NREC-MD also requests more information on the payment arrangement between the study site and sponsor.

22-NREC-MD-018

- Principal Investigator: Prof. Seamus Linnane
- Study title: A wearable in-phase chest wall vibration device for relief of dyspnoea in COPD: a first-in-human exploratory study.
- Lead institution: Beacon Hospital, Beacon Court, Bracken Rd, Sandyford Business Park, Sandyford, Dublin 18, D18 AK68.
- NREC-MD comments
- The Committee noted that this application was for an exploratory first-inhuman study of a prototype wearable therapeutic device for the management of chronic obstructive pulmonary disease symptoms.
- NREC-MD decision
  - *Request for further information*
- Further information requested:
  - Based on the information provided in the application dossier, the NREC-MD noted that only limited information on the Principal Investigator experience in clinical investigations/ trials was provided and requests a full CV. Additionally, the NREC-MD requests a confirmation that the Principal Investigator has undertaken Good clinical practice / ISO 14155 training.
  - The prevent any perception of coercion, the NREC-MD requests that personnel involved in participant recruitment is not directly involved in direct provision of care for the participants.
  - The NREC-MD noted that the funding for the study is not in place yet. The Committee requests a clarification on what will happen if the anticipated funding sum is not secured.
  - The NREC-MD noted that the participant information leaflet should be revised for clarity by outlining that the focus of the study is to test the device when embedded in a wearable garment.
  - Given that the proposed study does not include a data monitoring committee, the NREC-MD requests more information on i) how will the safety of participants be monitored over the course of the study and ii) the process for terminating/ restarting of the study.

AOB

- Dr Lucia Prihodova, Programme Manager at the National Office for Research Ethics Committees presented on the Statutory Instrument 257 of 2022.
- The Chairperson thanked the Committee and closed the meeting.