

National Research Ethics Committee

NREC-MD Meeting Minutes

27 May 2021

Attendance

Name	Role
Prof. Barry O'Sullivan	Chairperson, NREC-MD
Prof. Cathal O'Donnell	Deputy Chairperson, NREC-MD
Prof Mary Sharp	Deputy Chairperson, NREC-MD
Dr Caitriona Cahir	Member, NREC-MD
Dr Owen Doody	Member, NREC-MD
Dr Frank Houghton	Member, NREC-MD
Ms Orla Lane	Member, NREC-MD
Mr Billy McCann	Member, NREC-MD
Prof. Therese Murphy	Member, NREC-MD
Prof. Susan O'Connell	Member, NREC-MD
Dr Paul O'Connor	Member, NREC-MD
Mr Damien Owens	Member, NREC-MD
Dr Catherine O'Neill	Member, NREC-MD
Prof. Anne Parle-McDermott	Member, NREC-MD
Prof. Declan Patton	Member, NREC-MD
Ms Riona Tumelty	Member, NREC-MD
Prof. Mahendra Varma	Member, NREC-MD
Dr Tom Melvin*	HPRA

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Dr Gearoid McGauran*	HPRA
Dr Ria Mahon*	HPRA
Dr Michele Meagher*	HPRA
Dr Jennifer Ralph James	Head, National Office for Research Ethics Committees
Dr Lucia Prihodova*	Programme Manager, National Office for Research Ethics Committees
Dr Melissa Jones	Project Officer, National Office for Research Ethics Committees

*Drafted minutes

* Attended HPRA presentation only

Apologies: Mr Peter Woulfe

Quorum for decisions: Yes

Agenda

- Welcome & Apologies
 - HPRA Introductions
 - National Office Team Update
 - Declarations of Interest
 - Application 21-NREC-MD-001
 - AOB
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- The Chair welcomed the committee.
- HPRA Introductions: MD team from HPRA presented on Medical Device Clinical Investigations
- National Office Team Update: The Head of the NREC office is in frequent conversations with the Department of Health on the progress of the Statutory Instrument on medical devices and issue of Terms of Reference for the NREC-MD.
- The following declarations of interest were made, and the members recused themselves from the discussion of the applications in question:
 - Damian Owens and NREC-MD-001

NREC-MD requested that the NREC Office drafts a COI guidance document for Committee members.

Applications

21-NREC-MD-001

- Principal Investigator: Prof. Ronan Cahill
- Study title: PORSAV (Protecting OR Staff from Aerosolized Virus)
- Lead institution: Mater Misericordiae University Hospital, Eccles Street, Dublin 7
- NREC-MD comments
 - The NREC-MD noted that this project addressed an important issue even before the COVID-19 Pandemic.
 - The NREC-MD agreed that the Committee is not in a position to return a final ethics opinion based on the information and documentation received thus far.
- NREC-MD Decision
 - Request for further information

- Further information requested / Associated conditions
 - The NREC-MD requests clarity on the governance structure of the PORSAV project, in addition to roles and responsibilities of all entities participating, i.e. the PI, Sponsor, UCD, EU project, Mater Public and Mater Private, the research team, and the clinical care team. The NREC-MD notes that the contract between the project team and Mater Private Hospital is outstanding.
 - To ensure transparency and mitigate perception of any financial conflict of interest, the NREC-MD requests clarification on the proposed use of the study funding.
 - The NREC-MD requests explicit rationale for examining two different medical devices in one research project. Given the proposed sample size and methodology, the NREC-MD requests confirmation on whether the proposed study is in fact a feasibility or proof of concept study.
 - As the PORSAV study proposes to use laser imaging, the NREC-MD requires section G (ionising radiation) of the application form to be completed.
 - Participant selection and recruitment: In line with the Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018), the NREC-MD requires more information on the participant recruitment and selection process, specifically:
 - Information on who will be reviewing patient records to identify potential participants and how will they be approached.
 - Process for selecting participants if a greater number than planned express interest to participate.
 - How will be participants allocated to the different arms of the study?
 - Additionally, the proposed exclusion criteria need to be more specific and justified, and elements reconsidered in their phrasing e.g. the inference of pregnancy being an illness
 - The NREC-MD requires additional information on the role of the OR team in the project and whether they should be also considered as actual participants in the PORSAV project. In this regard, what are the processes to ensure they are informed about the project and its potential impact on their work? If the OR team are envisaged to assist the project, what training will be made available for them?
 - The application indicates that “information will be provided to the patient at the time of consent prior to surgery.” The NREC-MD requires more information on the consent process – who, when, where and how will participants be consented and what processes are in place to prevent risk of coercion.
 - Participant information leaflet: The NREC-MD makes a number of observations on and requests for the PIL:
 - The option to not participate or withdraw from the study should be specified on the first page.
 - Separate PIL should be prepared for each device.
 - PIL should undergo review to ensure accessibility to participants with various levels of literacy.

- Contact details of the research team should include email addresses.
 - Data collection, processing and retention processes to be described in greater detail in the PIL.
 - Review of the section on harms to reflect the use of ionising radiation.
 - The NREC-MD noted that section E of the application form should be reviewed in line with the Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018) to ensure transparent data collection, management and processing, such as providing a list of data being collected, named data controllers and processors. The NREC-MD requires clarity on the data sharing processes between the partners involved, and the justification to retain participant identification for the proposed period.
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- AOB:
- The NREC-MD Committee agreed to include a short break to the future meetings.
- The NREC-MD requested to be notified when the assessment reports are uploaded to the system. The NREC-MD also suggested a special meeting to be held in the future to review of the assessment form.
- The Chair thanked the Committee and closed the meeting.