

National Research Ethics Committee

NREC-MD Meeting Minutes

16 December 2021

Attendance

Name	Role
Prof. Barry O'Sullivan	Chairperson, NREC-MD
Ms Orla Lane	Member, NREC-MD
Mr Billy McCann	Member, NREC-MD
Dr Paul O'Connor	Member, NREC-MD
Dr Catherine O'Neill	Member, NREC-MD
Ms Riona Tumelty	Member, NREC-MD
Mr Damien Owens	Member, NREC-MD
Mr Peter Woulfe	Member, NREC-MD
Dr Lucia Prihodova*	Programme Manager, National Office for Research Ethics Committees

*Drafted minutes

Quorum for decisions: Yes

Agenda

- Welcome & apologies
 - Declarations of interest
 - Application 21-NREC-MD-014-R1
 - Application 21-NREC-MD-015-R1
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- The Chairperson welcomed the Committee and opened the meeting.
 - Declarations of interest: *none*
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Applications

21-NREC-MD-014-R1

- Principal Investigator: Dr Martin Buckley,
- Study title: Randomised, single dose, crossover, open label, placebo controlled, single site confirmatory clinical investigation in patients with gastro-oesophageal reflux, to characterise the acid neutralisation activity of a calcite chewing gum, using oesophageal ambulatory pH monitoring.
- Lead institution: Gastroenterology/ GI Physiology Laboratory, Mercy University Hospital, Grenville Place, Centre, Cork, T12 WE28.
- NREC-MD comments
 - The Committee noted that this application represents the applicant's response to a Request for further information from the NREC-MD.
- NREC-MD decision
 - *Favourable opinion with conditions*
- Further information requested / Associated conditions
 - Potential participants are identified during routine clinic appointments and pre-screening via the investigational site carried out in line with the Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018).
 - Participants/ participant health insurance are not charged for their participation in the study.
 - The remote access to participant medical record is configured to highest level of cybersecurity.
 - Data is retained by the sponsor beyond the period specified by MDR is fully anonymised.
 - Participant consent is sought for the proposed data retention process.

- All data collection and retention for the purpose of the clinical investigation is carried out in line with Data Protection Act 2018 (Section 36(2)) (Health Research Regulations 2018).
 - Incentive policy aligned with site policy on research participant compensation/ incentives.
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21-NREC-MD-015-R1

- Principal Investigator: Professor Robert A Byrne
 - Study title: Fractional Flow Reserve or 3D-Quantitative-Coronary-Angiography Based Vessel-FFR guided revascularization
 - Lead institution: Cardiology Department, Mater Private Hospital, 73 Eccles Street, Dublin 7, D07 KWR1.
 - NREC-MD comments
 - The Committee noted that this application represents the applicant's response to a Request for further information from the NREC-MD.
 - NREC-MD decision
 - *Favourable opinion*
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- The Chairperson thanked the Committee and closed the meeting.