

Meeting Minutes

National Research Ethics Committee for COVID-19-related Research (NREC COVID-19)

Time: 3 – 5pm

Date: 22nd April 2020

Location: virtual meeting

Attendance

Prof. Mary Horgan	Chair, NREC COVID-19
Prof. Hannah McGee	Vice Chair, NREC COVID-19
Prof. Anthony Staines	Vice Chair, NREC COVID-19
Dr Donal O’Gorman	Committee member, NREC COVID-19
Ms Sharon Foley	Committee member, NREC COVID-19
Prof. Andrew Greene	Committee member, NREC COVID-19
Prof. Orla Shiels	Committee member, NREC COVID-19
Prof. Mary Donnelly	Committee member, NREC COVID-19
Prof. Pat Manning	Committee member, NREC COVID-19
Mr John Woods	Committee member, NREC COVID-19
Mr Gavin Lawler	Committee member, NREC COVID-19
Dr Akke Vellinga	Committee member, NREC COVID-19
Dr Jean Saunders	Committee member, NREC COVID-19
Ms Caoimhe Gleeson	Committee member, NREC COVID-19
Prof. Suzanne Norris	Committee member, NREC COVID-19
Prof. Tom Fahey	Committee member, NREC COVID-19
Dr Jennifer Ralph James*	Head, Office of NRECs
Ms Aileen Sheehy	Programme Manager, Office for NRECs

*Drafted minutes

Apologies: None

Quorum for Decisions: Yes

Agenda

- Decision Time Training
 - Minutes approval 15th April & matters arising
 - Declarations of Interest
 - NREC COVID-19 Decision-making model
 - Review Calibration
 - Application NREC-COV-001
 - Application NREC COV-002
 - AOB
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- The committee received an orientation by the UK company Decision Time on the software. The trainer left the meeting after this item.

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- The minutes from meeting on 15th April 2020 were approved.
- Matters arising from the 15th April meeting were clarified by discussion with Department of Health as per below:
 - (1) The Chair clarified the nature of studies for prioritised review by NREC COVID-19 and what might be appropriate for local research ethics committees (RECs) to review; a communication detailing this refinement of the process will very shortly be communicated to the local RECs and other key stakeholders.
 - (2) The DoH confirmed that it is the intention that a repository of ethically approved COVID-19-related health research be established to enable a shared overview on the research ongoing at a national level. The Office for NRECs will seek to maintain a regular communication with local RECs to provide summary information on studies receiving ethics approval from NREC COVID-19, and to collate summary information on COVID-19 studies approved by local RECs.
 - (3) The application form was amended in line with committee feedback and is now accessible on the webpage.
- There were no declarations of interest made.
- It was agreed that the NREC COVID-19 will rely on the consensus-based model of decision-making, as is recognised best practice.
- Recognising the challenges that virtual ways of working can present and in an effort to calibrate approach to review, members agreed to work in teams in the first instance to focus on an in-depth review of a select number of applications in advance of the committee meeting; it was underscored that it is the NREC COVID-19 as a collective that will arrive at the final decision on every application after full discussion at the meeting. The Chair emphasised the ethical principles of fairness, reciprocity and privacy, as particularly applicable to review of research during a pandemic.

Applications

Number: 20-NREC-COV-001

Applicant: Prof. Richard Costello

Study title: A clinical risk score for monitoring and predicting respiratory failure in COVID-19 pneumonia, the COVID Clinical Index (CCI) score.

Institution: RCSI

It was agreed that this small retrospective study was straightforward, with the potential to inform but not impinge on medical practice. It was noted that COVID-19 does not behave like most other viral infections; some of the parameters captured by the National Early Warning Score (NEWS) are not the predominant features of patient presentation with COVID-19 infection, therefore there is a rationale for exploring the utility of CCI score in infected patients with a view to gaining a novel understanding

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of this virus. Ethically, the committee had no difficulty with this study, however several aspects were identified as requiring consideration or clarification by the applicant. The potential bias for including 'presumed positive' or 'suspect COVID' patient data in the study was discussed. Recognising the objective of the study is to compare the NEWS with CCI score, the committee were unclear on the specific analyses / measures to be carried out on patient data, in addition to the final outcome (ie, how will the applicant determine if CCI score is better than NEWS). Although the committee were aligned on the potential for useful information to be derived from the study, it was noted this is a preliminary study with relatively small participant numbers, for which the applicant should provide further justification as to the judgement that can feasibly be made.

The NREC COVID-19 agreed to *provisionally approve* application 20-NREC-COV-001; full approval pending clarification / further justification from the applicant on (1) participant number, (2) specific analyses to be carried out, and (3) the defined outcome for comparing CCI score and NEWS.

Number: 20-NREC-COV-002

Applicant: Mr Mel Corbett

Study title: Anxiety and Resilience in Ear Nose and Throat departments during COVID-19

Institution: RCSI

It was agreed that the study poses a good question, given the understandable anxiety in 'aerosolised-focused' healthcare professionals during the COVID-19 health emergency. The committee noted that Survey Monkey is a commonly used tool, however they require further justification as to the security that it can afford the participants' data. Acknowledging the relevance of the Ear, Nose & Throat (ENT) community selected, the committee were of the view that this is a potentially identifiable community. Consideration must be given to the necessity for all questions about locations and grades, which could identify individuals. The committee were unclear as to the inclusion criterion – 'Healthcare workers currently working in ENT departments in Ireland', and separately, there is a more granular reference to ENT consultants and NCHDs. The committee were of the firm view that a patient information leaflet should be provided to enable recipients to make an informed judgement on their participation or not. The committee queried the relevance of including 'resilience' in the study title as there is no standardised measure for this.

The NREC COVID-19 agreed to *provisionally approve* application 20-NREC-COV-002; full approval pending clarification / further justification on (1) use of Survey Monkey including plans to immediately de-identify the data (including URLs, cookies) when received; (2) plans to mitigate for potential identification of individuals from ENT specialty; (3) the target participants and justification of sample size. Furthermore, the committee require a participant information leaflet to accompany the emailed survey and evidence of support of this study and its methodological approach to contacting members from the Irish Otolaryngology Society.

- AOB: None
- The Chair closed the meeting