

## Meeting Minutes

### National Research Ethics Committee for COVID-19-related Research (NREC COVID-19) – Study amendment review

**Time:** 3 – 3:30pm

**Date:** 09 December 2020

**Location:** virtual meeting

#### Attendance\*

Prof. Mary Horgan	Chair, NREC COVID-19
Prof. Hannah McGee	Vice-Chair, NREC COVID-19
Dr Donal O’Gorman	Committee member, NREC COVID-19
Prof. Mary Donnelly	Committee member, NREC COVID-19
Ms Grainne McGettrick	Committee member, NREC COVID-19
Ms Dympna Moran	Committee member, NREC COVID-19
Ms Caoimhe Gleeson	Committee member, NREC COVID-19
Ms Aileen Sheehy †	Programme Manager (PM), National Office for RECs
Dr Melissa Jones	Project Officer (PO), National Office for RECs

\* Subset of committee convened

† Drafted minutes

**Quorum for Decisions:** Yes

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## Agenda

- Welcome
- Declarations of Interest
- Application 20-NREC-COV-104-AMEND
- Application 20-NREC-COV-072-AMEND
- Application 20-NREC-COV-008-AMEND
- Application 20-NREC-COV-041-AMEND
- AOB

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- The Chair opened the meeting and welcomed the committee
  - Declarations of Interest: none

## Amendment applications

<b>Application Number</b>	20-NREC-COV-104-AMEND
<b>Applicant</b>	Prof. John Laffey
<b>Study Title</b>	Charter Trial - Can Nebulised HepArin Reduce acuTE lung injury in Patients with SARS-CoV-2 Requiring Mechanical Ventilation in Ireland (CHARTER-Irl)
<b>Institution</b>	NUI Galway

<b>NREC COVID-19 Comments</b>	<ul style="list-style-type: none"> <li>The committee noted that this application for amendment represents changes to the study protocol and patient information leaflets based on recommendations from the HPRA and the HRCDC.</li> </ul>
<b>NREC COVID-19 Decision</b>	<i>Approved</i>
<b>Associated Conditions</b>	<ol style="list-style-type: none"> <li>The committee requests that check boxes are added to the consent forms.</li> <li>The committee requests that the next of kin documentation includes space for the next of kin to sign the assent form.</li> </ol>

<b>Application Number</b>	20-NREC-COV-072-AMEND
<b>Applicant</b>	Prof. Alistair Nichol
<b>Study Title</b>	Post-Intensive Care Nutrition Status in Patients with COVID-19
<b>Institution</b>	St. Vincent's University Hospital
<b>NREC COVID-19 Comments</b>	<ul style="list-style-type: none"> <li>The committee noted that this application for amendment was for the addition of Cork University Hospital as a new site in the study.</li> </ul>
<b>NREC COVID-19 Decision</b>	<i>Approved</i>
<b>Associated Conditions</b>	<ol style="list-style-type: none"> <li>The committee flagged that the date on the letter from the CUH Principal Investigator confirming participation was incorrect. The committee requests that this date is amended, and the letter resubmitted to the National Office as a condition of approval.</li> </ol>

<b>Application Number</b>	20-NREC-COV-008
<b>Applicant</b>	Prof. Ellen O'Sullivan
<b>Study Title</b>	CROWN CORONATION: An international, Bayesian platform adaptive, randomized, placebo-controlled trial assessing the effectiveness of candidate interventions in preventing COVID-19 disease in healthcare workers
<b>Institution</b>	St James's Hospital
<b>NREC COVID-19 Comments</b>	<ul style="list-style-type: none"> <li>• The committee noted that this application for amendment relates to replacing the investigational medical product in the initial clinical trial protocol with a live attenuated MMR vaccine arm vs placebo arm.</li> <li>• The committee commented on the significant change in the sample size from the original application with an increase from 2,500 participants to 30,000 as part of the amendment.</li> <li>• The committee noted that the applicant states that the MMR vaccine is not controversial but does not provide robust information to support this position.</li> <li>• The committee specified that the study would benefit from the involvement of an immunologist or infectious diseases expert.</li> <li>• The committee highlighted that the information on the patient information leaflet is out of date and does not include reference to the recent developments in the imminent availability of a COVID vaccine.</li> <li>• The committee commented on how the imminent availability of a COVID vaccine shifts the ethical dimension of the study. The study proposes to evaluate a vaccine for other conditions in this context at a time when a number of vaccines for COVID have become available.</li> </ul>

	<ul style="list-style-type: none"> <li>The committee was of the view that it could not endorse this study as it considered it unethical to recruit healthcare and frontline workers to this trial, and potentially ask that they defer offers of a COVID vaccine while participating in the study, which is otherwise prioritised for them in their frontline roles in order to protect both themselves and patients.</li> </ul>
<b>NREC COVID-19 Decision</b>	<i>Declined</i>
<b>Associated Conditions</b>	N/A

<b>Application Number</b>	20-NREC-C0V-041-AMEND
<b>Applicant</b>	Prof Alistair Nichol
<b>Study Title</b>	Short PeRiod IncideNce sTudy of Severe Acute Respiratory Infection (SPRINT-SARI)
<b>Institution</b>	St. Vincent's University Hospital
<b>NREC COVID-19 Comments</b>	<ul style="list-style-type: none"> <li>The committee noted that this application for amendment was for the addition of Our Lady of Lourdes Hospital Drogheda as a new site in the study.</li> </ul>
<b>NREC COVID-19 Decision</b>	<i>Approved</i>
<b>Associated Conditions</b>	N/A

- AOB:

1. The committee suggested that the National Office contact applicants to review their study protocols in light of developments in the global understanding of COVID-19 and recent successes of new treatments and vaccines.
  2. The Chair and the PM of National Office thanked the committee members for taking the time to attend the meeting.
- The Chair closed the meeting

APPROVED