

## Meeting Minutes

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

**Time:** 3 – 5pm

**Date:** 1<sup>st</sup> July 2020

**Location:** virtual meeting

---

#### Attendance\*

Prof. Mary Horgan	Chair, NREC COVID-19
Prof. Anthony Staines	Vice-Chair, NREC COVID-19
Prof. Hannah McGee	Vice-Chair, NREC COVID-19
Dr Donal O’Gorman	Committee member, NREC COVID-19
Prof. Tom Fahey	Committee member, NREC COVID-19
Prof. Andrew Green	Committee member, NREC COVID-19
Prof. Pat Manning	Committee member, NREC COVID-19
Prof. Orla Sheils	Committee member, NREC COVID-19
Prof. Suzanne Norris	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
Prof. Shaun O’Keeffe	Committee member, NREC COVID-19
Ms Dymrna Moran	Committee member, NREC COVID-19
Ms Caoimhe Gleeson	Committee member, NREC COVID-19
Ms Grainne McGettrick	Committee member, NREC COVID-19
Dr Jennifer Ralph James*	Head, Office for NRECs
Ms Aileen Sheehy	Programme Manager (PM), Office for NRECs

† Drafted minutes

**Apologies:** Prof. Mary Donnelly

**Quorum for Decisions:** Yes

---

#### Agenda

- Welcome & Apologies
- Minutes approval 24<sup>th</sup> June & Matters Arising

- Declarations of Interest
  - Application 20-NREC-COV-072
  - Application 20-NREC-COV-074
  - Application 20-NREC-COV-076
  - Application 20-NREC-COV-077
  - Application 20-NREC-COV-071
  - Application 20-NREC-COV-073
  - Application 20-NREC-COV-051-amend
  - AOB
- 

- The Chair opened the meeting and welcomed the committee.
- The minutes from meeting on 24<sup>th</sup> June were approved.
- Matters arising from the 24th June meeting as follows:
  - (1) The Head of Office for NRECs provided a running count of applications considered by NREC COVID-19 to date.
  - (2) The Head of Office for NRECs confirmed the three additional meeting dates to comprise a short extension until August of the committee's tenure on approval from the Department of Health.
- Declarations of Interest: none

#### Applications

<b>Application Number</b>	20-NREC-COV-072
<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 represents a straightforward study with data to be collected in the course of routine clinical care</li> </ul>
<b>NREC COVID-19 Decision</b>	<i>Provisional approval</i>
<b>Associated Conditions</b>	1. Noting the applicant states that ' <i>indemnity is not required</i> ' (section 11.2.), the committee maintains that all studies require indemnity be in place (for example by way of institutional indemnity or the Clinical Indemnity Scheme) and requests evidence of same.

**Office for National Research Ethics Committees**

Grattan House, 67-72 Lower Mount Street, D02 H838.

	<p>2. The committee queries if this study and another proposed study by the applicant (20-NREC-COV-074) are likely to recruit the same patients, and therefore may risk double-recording of identical data?</p> <p>3. The committee requests clarity on the anticipated duration of the study (section 2.4).</p>
--	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

<b>Application Number</b>	20-NREC-COV-074
<b>Applicant</b>	Prof. Alistair Nichol
<b>Study Title</b>	European Society Of Intensive Care Medicine COVID-19 Project (UNITE- COVID)
<b>Institution</b>	St Vincent's University Hospital
<b>NREC COVID-19 Comments</b>	<ul style="list-style-type: none"> <li>• The committee agreed that this is an important and worthwhile study that will contribute to our understanding of COVID-19 in an ICU population</li> <li>• The committee noted that the study is a multicentre international point prevalence study</li> </ul>
<b>NREC COVID-19 Decision</b>	<i>Provisional approval</i>
<b>Associated Conditions</b>	<p>1. Noting the applicant states that '<i>indemnity is not required</i>' (section 11.2.), the committee maintains that all studies require indemnity be in place (for example by way of institutional indemnity or the Clinical Indemnity Scheme) and requests evidence of same.</p> <p>2. The committee queries if this study and another proposed study by the applicant (20-NREC-COV-072) are likely to recruit the same patients, and therefore may risk double-recording of identical data?</p> <p>3. Noting the data is represented in the application as anonymised, the committee requires further clarification given that pseudonymised data is referenced in the protocol.</p> <p>4. The committee notes that no sample size is proposed (section 3.1), and requests additional information in this regard.</p> <p>5. The committee queries the correctness of stating the study duration of one day (section 2.4)</p>

<b>Application Number</b>	20-NREC-COV-076
<b>Applicant</b>	Dr Afshin Nasoodi
<b>Study Title</b>	Evaluation of patients with COVID-19 undergoing CTPA
<b>Institution</b>	St. James's Hospital
<b>NREC COVID-19 Comments</b>	<ul style="list-style-type: none"> <li>• The committee is of the firm view that the research aims of the study cannot be achieved with the research design proposed;</li> </ul>

	specifically, Aim A, to assess if patients with COVID-19 have a higher risk of developing a blood clot on the lung, is not achievable without a non-COVID-19 comparator sample, and for Aims B & C, some indication of the frequency of the various outcomes (e.g how many had a pulmonary embolism, how many were admitted to ICU and how many survived) is needed before a sample size (n = 100) can be deemed adequate to answer the questions posed.
<b>NREC COVID-19 Decision</b>	<i>Approval declined</i>

<b>Application Number</b>	20-NREC-COV-077
<b>Applicant</b>	D Joan Cahill
<b>Study Title</b>	PPE Safe
<b>Institution</b>	Trinity College Dublin
<b>NREC COVID-19 Comments</b>	<ul style="list-style-type: none"> <li>The committee noted the application represents quite a complex study looking to address training, risk management, workplace stress and safety issues of healthcare workers using PPE</li> </ul>
<b>NREC COVID-19 Decision</b>	<i>Provisional approval</i>
<b>Associated Conditions</b>	<ol style="list-style-type: none"> <li>The application acknowledges that personal or sensitive information may be volunteered by participants during interviews (section 2.9); the committee requests clarification on what actions will occur or what information will be provided to participants should they become upset while disclosing their lived experience (eg, will they be advised to contact their GP / Occupational Health or provided with any contact numbers for support). The committee notes from the participant briefing form that the researcher will have contact information to hand for support groups, and requests clarity on what circumstances these might be used. The committee suggests including the option to contact their GP / Occupational Health service, in addition to the dedicated COVID-19 HSE helpline number.</li> <li>Regarding participant identification and recruitment (section 3.3), the committee is of the view that the verbal approach by CNM2 may be viewed as coercive by staff and they may not be comfortable to refuse; please provide measures to mitigate this or consider an alternative approach (eg hospital email inviting staff participation). Given the small sample size, the committee queries how the study team will ensure the sample will be diversified through the different disciplines represented and suggests a protocol to ensure sufficient diversification.</li> <li>The committee notes that groups of other hospital staff are excluded from the list eg, radiographers and radiation therapists (section 3.4 and 3.5), and queries why all HCWs are not being offered the opportunity to participate.</li> </ol>

	<ol style="list-style-type: none"><li>4. The committee is of the view that the consent process for online applications is laborious for participants and that a JPEG is not suitable for consent (Section 4.1.3 i); the committee suggests that the site lead oversees and signs consent at the site with the participant and verbal re-affirmation is done for the online process prior to proceeding.</li><li>5. The committee requests the consent documentation be clearer and separated to identify if participants wish to opt in to all 3 stages of the study or which particular stage they're consenting to participate in. The consent form mentions future research however this is not covered in any briefing documentation to describe what this might comprise. The committee questions the necessity of references to disclosure of rape / child abuse allegations etc given the topic being examined.</li><li>6. Regarding data processing and safeguards (section 9.1.1), the committee is unclear how participants will be contacted for interviews online and what data will be retained. The committee requests the consent form be amended to include participants' contact details for this study purpose.</li><li>7. The committee is of the view that the briefing document / poster not clear what the actual study process, requiring simplification for participants. It requires detail on when, where, and over what time period the interviews will take place. The information therein should be broken-down into what exactly is required at each study stage from participants, including the risk, benefits and drawbacks per stage.</li><li>8. The committee requests that the recruitment information is added to the briefing document and made into one clear, succinct participant information leaflet for participants.</li><li>9. The committee requests an option for 'other' in the Participant Profile Form as the "specific care/clinical context work in" question described may not be applicable to some participants.</li><li>10. The committee queries why medication and mindfulness are focussed on in detail with Bons Secours as identified in the PPE Safe, Research Methods and Scripts documents.</li></ol>
--	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

<b>Application Number</b>	20-NREC-COV-071
<b>Applicant</b>	Dr Conor Loftus
<b>Study Title</b>	Covid-19: " A Frontline Worker's Perspective"
<b>Institution</b>	University Hospital Limerick (HSE Limerick/Midwest HSE)
<b>NREC COVID-19 Comments</b>	<ul style="list-style-type: none"> <li>The committee noted that this application represents a relatively straightforward study</li> </ul>
<b>NREC COVID-19 Decision</b>	<i>Provisional approval</i>
<b>Associated Conditions</b>	<ol style="list-style-type: none"> <li>The committee requires confirmation that the applicant has initial consent from those on the database / portal to contact them about research opportunities in the first instance.</li> <li>Noting that the methodology proposes that the initial contact with participants is made by phone, the committee is of the view that this may be inferred as coercive; please justify and consider email as a more appropriate means of initial contact.</li> <li>The committee is unclear as to the rationale for the questions on contact tracing.</li> <li>As the information is to be recorded manually second hand, the committee suggests this might introduce an element of bias, and suggests one way to reduce this is to have the OH worker read back the answers to the HCW participant to ensure accuracy.</li> <li>The committee requests more information on plans for publication and public dissemination of the results.</li> <li>The committee observes that the PI and research team may have had contact with the HCWs as patients during the review period and suggests it may be difficult for participants to provide negative feedback; the committee requests comment on this.</li> <li>The committee requests that the 'No' option removed from question 1 and that consent is affirmed by selecting a 'Yes' option or by initialling agreement. The committee notes typos in questions 7 and 8 in the questionnaire – should be 'If no skip to Q8 and Q9' respectively</li> <li>For process, the committee notes the application form needs signing and dating.</li> </ol>

<b>Application Number</b>	20-NREC-COV-073
<b>Applicant</b>	Dr Richard Conway
<b>Study Title</b>	Global Rheumatology Alliance survey on impact of COVID-19 on rheumatology trainees
<b>Institution</b>	St. James's Hospital
<b>NREC COVID-19 Comments</b>	<ul style="list-style-type: none"> <li>The committee agreed that this is a useful study without major ethics issues</li> </ul>
<b>NREC COVID-19 Decision</b>	<i>Provisional approval</i>
<b>Associated Conditions</b>	<ol style="list-style-type: none"> <li>The committee requests that consent is explicitly sought prior to admission to the survey. An appropriate consent statement is required at the start of the survey to which participants can 'tick box', with preclusion to proceed if consent is not agreed.</li> <li>The committee is unclear as to how trainees will be invited to participate – directly by the study PI or will it be done through RCPI?</li> <li>The committee queries how the trainees' contact emails will be obtained.</li> </ol>

<b>Application Number</b>	20-NREC-COV-051-amend
<b>Applicant</b>	Dr Julie Regan
<b>Study Title</b>	Clinical Characteristics of Dysphagia and Communication Difficulties among Hospitalised Adults with COVID-19 in Ireland: An Observational Cohort Study
<b>Institution</b>	Trinity College Dublin
<b>NREC COVID-19 Comments</b>	<ul style="list-style-type: none"> <li>The committee noted that this application represents an amendment to a study previously approved by the NREC COVID-19 (considered at meeting 27<sup>th</sup> May 2020)</li> <li>The committee observed that the applicant has amended the study and PIL in line with previous NREC and HRCDC recommendations</li> </ul>
<b>NREC COVID-19 Decision</b>	<i>Approved</i>

- AOB: The committee suggested that, in addition to sharing the meeting minutes online, a separate excel file listing the decisions made by the committee would be useful.
- The Chair closed the meeting