

## Meeting Minutes

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

**Time:** 3 – 5pm

**Date:** 6<sup>th</sup> May 2020

**Location:** virtual meeting

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#### 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 Sheils	Committee member, NREC COVID-19
Prof. Mary Donnelly	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
Prof. Shaun O’Keeffe	Committee member, NREC COVID-19
Ms Dympna Moran	Committee member, NREC COVID-19
Ms Grainne McGettrick	Committee member, NREC COVID-19
Dr Jennifer Ralph James*	Head, Office of NRECs
Ms Aileen Sheehy	Programme Manager, Office for NRECs

\*Drafted minutes

**Apologies:** Prof. Pat Manning

**Quorum for Decisions:** Yes

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#### Agenda

- Welcome & apologies
- Minutes approval 29<sup>th</sup> April & matters arising
- Declarations of Interest
- Application 20-NREC-COV-003
- Application 20-NREC-COV-014
- Application 20-NREC-COV-016
- Application 20-NREC-COV-017
- Application 20-NREC-COV-020
- Application 20-NREC-COV-018

- Application 20-NREC-COV-022
- Application 20-NREC COV-025
- Application 20-NREC COV-019
- AOB

- The Chair welcomed the committee and introduced three new members.
- The minutes from meeting on 29<sup>th</sup> April 2020 were approved.
- Matters arising from the 29<sup>th</sup> April meeting as follows:
  - (1) The Head, Office for NRECs explained that the national office would seek to establish a regular communication with local RECs with a view to enabling a shared overview of ethically approved COVID-19 health research at a local and national level. Also confirmed was the agreement of a local REC representative to act in a liaison capacity where appropriate between the NREC and local RECs.
- The following declaration of interest was made, and the member recused himself from the discussion of the applications in question:

Prof. Andrew Green – 20-NREC-COV-019

## Applications

<b>Application Number</b>	20-NREC-COV-003
<b>Applicant</b>	Dr Michael Courtney
<b>Study Title</b>	Progression of Imaging findings in COVID19
<b>Institution</b>	St James's Hospital, Dublin 8
<b>NREC COVID-19 Comments</b>	<ul style="list-style-type: none"> <li>• The committee agreed that this retrospective chart review has a satisfactory approach overall to addressing the research question.</li> <li>• The committee agreed that evaluating diagnostic accuracy requires a robust analytical plan.</li> </ul>
<b>NREC COVID-19 Decision</b>	Provisional Approval
<b>Associated Conditions</b>	<ol style="list-style-type: none"> <li>1. Recognising the objective of the study is to characterise COVID-19 changes on imaging over time, the committee require a copy of the type of <i>pro forma</i> measures that the analysis will encompass. The information retrieved from chart review should be limited to that required to address the pre-defined research question. To appropriately compare diagnostic accuracy a robust analytical plan needs to be in place including statistical analyses bespoke for the comparators.</li> <li>2. The committee notes the intention to delete all the data when the analysis is complete and is of the view that this is unacceptable; the committee requires the applicant to confirm</li> </ol>

	<p>the data storage policy of their institution and adopt the requirements therein.</p> <p>3. The committee awaits confirmation of DPO feedback as indicated in the application.</p>
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<b>Application Number</b>	20-NREC-COV-014
<b>Applicant</b>	Dr Helen Tuite
<b>Study Title</b>	The impact of the COVID-19 pandemic on healthcare workers in the west of Ireland
<b>Institution</b>	Galway University Hospital
<b>NREC COVID-19 Comments</b>	<ul style="list-style-type: none"> <li>The committee noted that this survey proposed to involve 200 participants across all healthcare worker groups.</li> </ul>
<b>NREC COVID-19 Decision</b>	Provisional Approval
<b>Associated Conditions</b>	<ol style="list-style-type: none"> <li>Survey title and purpose <ul style="list-style-type: none"> <li>The committee requests greater clarity in the title of the survey. The research title states that it pertains to healthcare workers in the West of Ireland. However, it specifies that the survey will be undertaken in a specific hospital in Galway. This correct information should be clearly reflected in all of the survey documentation.</li> <li>The committee is unclear as to what the survey is specifically assessing. It is specified that it is looking at the impact of the pandemic on healthcare workers and separately it states that it is gathering information on the concerns and preparedness of healthcare workers during the pandemic. The committee require confirmation as to what the survey wants to achieve and to see this reflected in the questions e.g. what exactly is being assessed in this study and for what purpose?</li> <li>The committee notes in the questionnaire a statement that <i>'concerns will inform further initiatives and workforce planning'</i>. Further to the previous point, is that what the survey wishes to achieve?</li> </ul> </li> <li>Sample size: The committee requires clarification on the rationale for the sample size (n=200) given that this is an on-line survey</li> <li>Survey detail: <ul style="list-style-type: none"> <li>The committee requires confirmation of the research tool to be used as this is not stated.</li> <li>The committee request an appropriate introduction or preamble in the questionnaire including its purpose, outcome, data protection and consent.</li> <li>The field for gender should include 'other'.</li> </ul> </li> <li>Comparative research: The committee notes that references are made to two other pre-pandemic related studies (Singapore and Ireland). The committee queries if there are plans to use these</li> </ol>

	<p>studies for comparative purposes, and if so, requests more details.</p> <p>5. Research participant information sheet: The committee requires that explicit detail be provided in the research participant information sheet and in the survey questionnaire as to how data will be used and retained.</p> <p>6. Recruitment methodology:</p> <ul style="list-style-type: none"> <li>- The committee notes that social media platforms will be used, however these are not specified. It is not specified how participants will be recruited via email- is there a group email for the study site?</li> <li>- The committee is unclear as to how the recruitment process being managed. What efforts will be undertaken for staff who do not have an email address?</li> </ul> <p>7. Consent and data protection:</p> <ul style="list-style-type: none"> <li>- The committee asserts that consent must be clearly and explicitly sought in the questionnaire and clearly addressed in the research participant information sheet.</li> <li>- The committee recommends that the Data Protection Officer be consulted for advice on this survey.</li> </ul> <p>8. HR and Management engagement: The committee requires that the applicant inform the HR Department and the Hospital CEO of this survey in the event of further surveys emerging on similar subject matter from this site.</p>
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<b>Application Number</b>	Application 20-NREC-COV-016
<b>Applicant</b>	Prof. Martina Hennessy
<b>Study Title</b>	Survey on autonomy and supervision on ICUs during the COVID-19 crisis
<b>Institution</b>	TCD
<b>NREC COVID-19 Comments</b>	<ul style="list-style-type: none"> <li>• The committee agreed that this anonymous survey has a satisfactory approach overall to addressing the research question.</li> </ul>
<b>NREC COVID-19 Decision</b>	<i>Provisional Approval</i>
<b>Associated Conditions</b>	<ol style="list-style-type: none"> <li>1. The content and the wording of the poster should be reviewed such that it should be immediately identifiable as being targeted at healthcare workers who do not usually work in ICU.</li> <li>2. <ol style="list-style-type: none"> <li>a. The questionnaire and information leaflet have been submitted as separate documents. The committee requires confirmation that the information leaflet and survey will be presented as a single document to ensure the consent to participate is linked to the survey.</li> </ol> </li> </ol>

	<p>b. The committee requests that the information leaflet contain a title and information that makes it identifiable as the LEAP project.</p> <p>c. The committee requires the wording of the information leaflet be reviewed. The context of administering the questionnaire is based on 'the current way of scaling up the work and diluting ICU expertise'. It would be better to recognise that these non-ICU healthcare workers have come from other settings to assist ICU staff in the delivery of care to critically ill patients. The introduction may suggest that 'management' are approving and thanking staff for their input. A more straightforward introduction, clearly from the research team, for research purposes, is advised.</p> <p>d. The committee notes that the information leaflet refers to the 'results of the first questionnaire'; as there is only one questionnaire as part of this study, please provide clarification.</p> <p>e. The committee notes that potential participants are asked to circle 'Yes' if they are willing to participate but there is only a tick box on the form. Please amend appropriately.</p> <p>3. The committee requires a more detailed explanation to document the steps being undertaken to store, archive or destroy data once the research study has been completed. If the survey is being distributed, please outline what will happen to the paper copy of survey and the respective timeline for each step. Once the data is transferred to an electronic format please outline how long it is to be stored and justify whether, and when, the data is ultimately to be archived or destroyed. The committee requires the applicant to confirm the data storage policy of their institution and adopt the requirements therein. Advice from the DPO may be useful in this regard.</p> <p>4. The committee notes in Section 1.2 of the application form a statement that IC-trained personnel will be included as a reference group. This does not appear consistent with the overall purpose of the study and would require different questions in the survey as well as a means of differentiating between the two groups. The committee requires clarification on this issue.</p> <p>5. Contrary to a statement in the application, indemnity for this study does not lie with the NREC COVID-19. The Office for NREC is seeking formal confirmation from the State Claims Agency (SCA). In the interim, the understanding is that all hospital staff come under Clinical Indemnity Insurance, which should cover research as a component of their work undertaking as long as the SCA is notified.</p>
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<b>Application Number</b>	20-NREC-COV-017
<b>Applicant</b>	Prof. John Laffey
<b>Study Title</b>	ExtraCorporeal Membrane Oxygenation for 2019 novel Coronavirus Acute Respiratory Disease (ECMOCARD)
<b>Institution</b>	Galway University Hospitals
<b>NREC COVID-19 Comments</b>	<ul style="list-style-type: none"> <li>• The committee agreed that this multicentre international study represents a valuable contribution to knowledge.</li> <li>• There was discussion around where the data would be stored and under what jurisdiction.</li> </ul>
<b>NREC COVID-19 Decision</b>	Provisional Approval
<b>Associated Conditions</b>	<ol style="list-style-type: none"> <li>1. The committee notes that the data to be entered into REDCap will be fully anonymised however subsequent linkage with medical record numbers may compromise this anonymity; the committee require all identifiers be removed.</li> <li>2. The committee is unclear as to who are the '<i>designated person(s) at the site</i>' allowed access to the master file; the committee require that access be restricted to one person at each site, a specified member of the research team.</li> </ol>

APPROVED

<b>Application Number</b>	20-NREC-COV-020
<b>Applicant</b>	Dr Bairbre McNicholas
<b>Study Title</b>	A study on the role of immune dysfunction in sepsis and COVID-19
<b>Institution</b>	Galway University Hospitals
<b>NREC COVID-19 Comments</b>	<ul style="list-style-type: none"> <li>• The committee noted that this study is a proposed extension to an existing study on immune system function in sepsis to include patients with COVID-19.</li> <li>• The committee noted that this study is also seeking a consent declaration from the HRCDC.</li> </ul>
<b>NREC COVID-19 Decision</b>	Provisional Approval
<b>Associated Conditions</b>	<p>1. Noting this study will likely involve participants lacking the capacity to consent, the committee affirms that there is no legal basis for next-of-kin consent. In this regard, the committee requires the consent process and documentation be amended in line with the below position of the committee.</p> <p><i>An adult not able to consent should, as far as possible, take part in the information/authorisation procedure. The objectives as well as the potential risks and benefits of the research should be explained as fully as possible using easily comprehensible language appropriate to their level of understanding. Where a prospective research participant lacks capacity but has some ability to understand the significance of the research, the researcher should ascertain the wishes of that individual with respect to his/her participation. Refusal or reluctance to participate in a research project by an individual lacking capacity should be respected.</i></p> <p><i>If a prospective research participant, despite all efforts possible in the circumstances, is unable to provide his or her own informed consent to participation in the study, the assent of a person - generally someone with a close ongoing personal relationship with the person- who can provide the best interpretation of the will and preferences of the person should be sought. Please note that "next of kin" has no legal authority to consent under Irish law. A person who has a close ongoing personal relationship does not have to be a member of one's family. An attorney under the Enduring Power of Attorney in Irish law does not have legal authority to consent to research.</i></p> <p><i>If the person subsequently recovers the ability to consent, his or her consent to use his or her data and, if appropriate, to continued participation in the study should be sought.</i></p> <p>2. The committee requires clarification as to the control group in the study. There is a suggestion that staff doctors /</p>

	<p>postgraduate students will be recruited as controls, and the committee queries the appropriateness of this approach, particularly in light of the potential influence of a hierarchical dynamic. The committee requires a Participant Information Leaflet for participants in the control group in the study.</p> <p>3. Recognising the objective of the study is to phenotypically characterise immune cells from patients with sepsis and healthy controls, the committee is unclear as to the separate references made to collecting urine and tissue. Please clarify.</p> <p>4. The committee is of the view that the 'No' tick box in answer to questions in the consent form is misleading; rather a clear statement with the opportunity to tick the 'Yes' tick box is more appropriate. Additionally, the interchange between 'I' and 'We' in the consent forms is confusing - the committee suggests the consistent use of 'We'.</p>
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Office for National Research Ethics Committees

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

<b>Application Number</b>	Application 20-NREC-COV-018
<b>Applicant</b>	Prof. Alan Irvine
<b>Study Title</b>	Surveillance Epidemiology of Coronavirus (COVID-19) Under Research Exclusion - Atopic Dermatitis (SECURE-AD)
<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 international collaborative study has a well laid-out organisational structure, with security practices in place.</li> </ul>
<b>NREC COVID-19 Decision</b>	Provisional Approval
<b>Associated Conditions</b>	<ol style="list-style-type: none"> <li>The committee is unclear as to how outcomes from the registry will be shared with non-dermatologists including patient groups. The committee recommends the study would benefit from PPI, with information sheets circulated to patient groups and dermatology clinics to inform patients about the registry.</li> <li>The committee is of the view that registry activity could be further justified by obtaining as large a sample size as possible. No information was provided as to how all dermatology sites will be engaged with this research study. The committee requests that further consideration be given to maximising full participation from the dermatology community.</li> </ol>

<b>Application Number</b>	Application 20-NREC-COV-022
<b>Applicant</b>	Dr Barry Hutchinson
<b>Study Title</b>	Assessment of accuracy of portable chest x-ray in the diagnosis of COVID-19
<b>Institution</b>	Mater Misericordiae University Hospital
<b>NREC COVID-19 Comments</b>	<ul style="list-style-type: none"> <li>The committee agreed that this is a low-risk retrospective single-site study, with the potential to yield useful results.</li> <li>The committee agreed that evaluating diagnostic accuracy requires a robust analytical plan.</li> </ul>
<b>NREC COVID-19 Decision</b>	Provisional Approval
<b>Associated Conditions</b>	<ol style="list-style-type: none"> <li>Recognising the objective of the study is to compare the diagnostic accuracy of COVID-19 diagnosis by CXR and RT-PCR, the committee requires a copy of the <i>pro forma</i> measures that the analysis will encompass. To appropriately compare diagnostic accuracy a robust analytical plan needs to be in place including statistical analyses bespoke for the comparators.</li> <li>The committee notes that just two radiologists will be involved in reviewing CXR, and queries if this is sufficient for data validation, particularly given inter-rater reliability.</li> <li>The committee notes the intention to retain data for 5 years; the committee requires the applicant to confirm the data retention / storage policy of their institution and adopt the</li> </ol>

	<p>requirements therein. Feedback from the DPO may assist in this regard.</p> <p>4. The committee requires that the investigators complete GDPR training as indicated in the application prior to commencing the study.</p> <p>5. The committee queries the appropriateness of leaving question 3.6 (i) unanswered.</p>
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<b>Application Number</b>	Application 20-NREC COV-025
<b>Applicant</b>	Dr Siobhan Masterson
<b>Study Title</b>	Rapid response and learning for later: establishing high quality information networks and evaluation frameworks for the National Ambulance Service response to COVID-19
<b>Institution</b>	St. Conal's Hospital, Donegal
<b>NREC COVID-19 Comments</b>	<ul style="list-style-type: none"> <li>The committee agreed that this cross-European framework study is well-planned and potentially useful.</li> <li>The committee agreed that the data protection risks are low and well-managed.</li> </ul>
<b>NREC COVID-19 Decision</b>	Provisional Approval
<b>Associated Conditions</b>	<p>1. Noting an objective of the second work-package is to establish an international network, it is unclear if such networks already exist, and surprising if they were not looking at a similar COVID-19-related activity. The committee requests an explanation in this regard. Additionally, the committee requests clarity on the numbers to be involved in and origins of the membership (eg EU).</p> <p>2. Given that National Ambulance Service staff recruitment is proposed to occur through their managers, the committee queries the appropriateness of this approach, particularly in light of the potential influence of a hierarchical dynamic. Furthermore, the committee suggests an alternative independent method of recruitment such as the HR department.</p>

<b>Application Number</b>	Application 20-NREC COV-019
<b>Applicant</b>	Dr Mary Keogan
<b>Study Title</b>	Development of a validation panel to compare the sensitivity and specificity of SARS-CoV-2 antibody assays.
<b>Institution</b>	Beaumont Hospital
<b>NREC COVID-19 Comments</b>	<ul style="list-style-type: none"> <li>The committee agreed that this study to validate diagnostic panels to allow diagnostic laboratories evaluate and compare tests for antibodies to SARS-Cov-2, represents very important work, with no major risks.</li> <li>The committee noted that a consent declaration was sought but not required upon consultation with the secretariat of the HRDCD.</li> </ul>
<b>NREC COVID-19 Decision</b>	Provisional Approval
<b>Associated Conditions</b>	<ol style="list-style-type: none"> <li>The committee is unclear if patients with a COVID-19 diagnosis are to be approached prior to discharge or through the OPD and requires clarification in this regard.</li> <li>The committee notes conflicting timeframes for sample retention referenced in the application (Sections 2.4 and 6.25) and requires clarification in this regard.</li> <li>The committee requires confirmation as to who will be responsible for consenting participants, specifically for patients discharged to OPD follow up, including ensuring they are provided the appropriate participant information.</li> </ol>

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- AOB:
    - (1) It was agreed that the new committee members would be divided among the existing review teams for the preparatory ethics review work in advance of the committee meeting. The Chair reminded the NREC COVID-19 that it is the committee as a whole that makes the final decision on each application after full discussion at the meeting.
    - (2) It was observed that the notion of next-of-kin consent is a common misconception in that there is no legal basis for next-of-kin consent in Ireland. For the purposes of ethics review of research involving participants who lack capacity, it was agreed that the NREC COVID-19 will derive guidance for applicants, informed by the HSE National Consent Policy (Part 3, Research).
  - The Chair closed the meeting