

Meeting Minutes

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

Time: 3 – 3:30pm

Date: 15th January 2021

Location: virtual meeting

Attendance*

Prof. Mary Horgan	Chair, NREC COVID-19
Prof. Anthony Staines	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
Prof. Orla Sheils	Committee member, NREC COVID-19
Prof. Suzanne Norris	Committee member, NREC COVID-19
Prof. Andrew Green	Committee member, NREC COVID-19
Dr Akke Vellinga	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

Agenda

- Welcome
 - Declarations of Interest
 - Application 20-NREC-COV-104-AMEND-2
 - Application 20-NREC-COV-050-AMEND
 - Application 20-NREC-COV-087-AMEND
 - Application 20-NREC-COV-030/1-AMEND
 - Application 20-NREC-COV-034-AMEND
 - Application 20-NREC-COV-040-AMEND
 - Application 20-NREC-COV-056-AMEND
 - AOB
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- The Chair opened the meeting and welcomed the committee

Declarations of Interest: The Chair declared a conflict of interest with application 20-NREC-COV-056-AMEND and removed herself from the meeting during discussions related to this submission.

Amendment applications

Application Number	20-NREC-COV-104-AMEND-2
Applicant	Prof. John Laffey
Study Title	Charter Trial - Can Nebulised HepArin Reduce acuTE lung injury in Patients with SARS-CoV-2 Requiring Mechanical Ventilation in Ireland (CHARTER-Irl)
Institution	NUI Galway
NREC COVID-19 Comments	<ul style="list-style-type: none"> • The Committee noted that this amendment application represents the addition of Connolly Memorial Hospital as a new site and the expansion of the study inclusion criteria to include patients receiving other forms of advanced respiratory support other than invasive mechanical ventilation. • The Committee noted that the term 'higher level care' was not adequately defined in the exclusion criteria.
NREC COVID-19 Decision	<i>Approved</i>
Associated Conditions / Suggestions	<ol style="list-style-type: none"> 1. The Committee requires that the Site-Specific Assessment form must be signed by the site CEO and submitted to the National Office within two weeks of receipt of ethics approval for this study amendment. 2. The Committee suggests that the term 'higher level care' is defined in the documentation.

Application Number	20-NREC-COV-050-AMEND
Applicant	Prof. Mary McCarron
Study Title	Intellectual Disability Supplement to The Irish Longitudinal Study on Ageing (IDS-TILDA)
Institution	Trinity College Dublin
NREC COVID-19 Comments	<ul style="list-style-type: none"> • The Committee noted that this amendment application represents the addition of COVID-related questions to the

	<p>questionnaire and to conduct two additional waves of follow-up data collection for the IDS-TILDA COVID-19 survey.</p> <ul style="list-style-type: none"> The Committee noted that the questionnaire contains some understandably sensitive questions. The applicant is very clear that participants do not have to answer these questions.
NREC COVID-19 Decision	<i>Approved</i>
Associated Conditions / Suggestions	1. As many of the questions in the questionnaire touch off sensitive subjects, the Committee suggests Question 2D should be moved and incorporated with Question 10.

Application Number	20-NREC-COV-087-AMEND
Applicant	Prof Patrick Sheahan
Study Title	ICE: Impact of COVID 19 on ENT Surgery in Ireland
Institution	Cork University Hospital
NREC COVID-19 Comments	<ul style="list-style-type: none"> The Committee noted that this amendment application represents access to additional data from institutional Departments of Microbiology and Departments of Public Health. The Committee were unclear who will make contact with the Departments of Public Health. The Committee were also unclear as to whether the applicant was requesting access to identifiable data as well as numerical / aggregated data.
NREC COVID-19 Decision	<i>Provisionally approved</i>

Associated Conditions	<ol style="list-style-type: none"> 1. The Committee requires clarification on how the Departments of Public Health will be contacted. Will contact be made by someone from the research team and if so who? 2. The Committee requests confirmation that the data from Public Health Departments will be numeric and will not contain identifiable data.
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Application Number	20-NREC-COV-030/1-AMEND
Applicant	Dr Nollaig Burke
Study Title	Altered lives in a time of crisis: Preparing for recovery from the impact of the COVID-19 pandemic on the lives of older adults
Institution	Trinity College Dublin
NREC COVID-19 Comments	<ul style="list-style-type: none"> • The Committee noted that this amendment application represents changes to the study protocol to collect saliva samples. • The application was noted by the Committee as being clear and straight forward. • The Committee recommends some changes to the consent form and the questionnaire.
NREC COVID-19 Decision	<i>Approved</i>
Associated Conditions / Suggestions	<ul style="list-style-type: none"> • The Committee requests that Yes / No boxes within the Consent Form are restricted to items where the participant has a choice to make about individual elements of the project. • In the questionnaire, the Committee requests that Question 17 include the option for participants to select 'I don't mind / It doesn't matter to me'.

Application Number	20-NREC-COV-034-AMEND
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Applicant	Dr Emma Nicholson
Study Title	CUPID COVID-19
Institution	University College Dublin
NREC COVID-19 Comments	<ul style="list-style-type: none"> The Committee noted that this application was for the access to anonymised data.
NREC COVID-19 Decision	<i>Approved</i>
Associated Conditions / Suggestions	N/A

Application Number	20-NREC-COV-040-AMEND
Applicant	Prof Patrick Murphy
Study Title	Platform Randomised trial of INterventions against COVID-19 In older people (PRINCIPLE)
Institution	NUI Galway
NREC COVID-19 Comments	<ul style="list-style-type: none"> The Committee noted that this amendment application represents changes to the participant recruitment process and an update to the treatment arm. The Committee were of the view that the recruitment process was not clearly outlined in the documentation provided.
NREC COVID-19 Decision	<i>Provisional Approval</i>
Associated Conditions / Suggestions	<ol style="list-style-type: none"> The Committee requires further clarity around the recruitment process. They request a detailed overview of the recruitment process to clearly outline the coordination between the testing centre, access of the treatment arm, the involvement of the participant's GP

	and the trial research team, and a clear outline of the follow-up process with the participant.
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Application Number	20-NREC-COV-056-AMEND
Applicant	Prof Patrick Mallon
Study Title	The All Ireland Infectious Diseases Cohort Project (AIID Cohort Project)
Institution	University College Dublin
NREC COVID-19 Comments	<ul style="list-style-type: none"> • The Committee noted that this amendment application represents the addition of Cork University Hospital as a new site to the project. • The Committee highlighted that this project will require a substantial amount of work at each site which may have an impact on the hospital.
NREC COVID-19 Decision	<i>Approved</i>
Associated Conditions / Suggestions	N/A

- AOB:
 1. The Vice Chair and the PM of National Office thanked the committee members for taking the time to attend the meeting.
- The Vice Chair closed the meeting