

Meeting Minutes

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

Time: 3 – 3:30pm

Date: 31st March 2021

Location: virtual meeting

Attendance*

Prof. Orla Sheils	Acting Chair, NREC COVID-19
Ms Caoimhe Gleeson	Committee member, NREC COVID-19
Dr Donal O’Gorman	Committee member, NREC COVID-19
Prof Shaun O’Keefe	Committee member, NREC COVID-19
Ms Grainne McGettrick	Committee member, NREC COVID-19
Mr Gavin Lawler	Committee member, NREC COVID-19
Ms Dymphna Moran	Committee member, NREC COVID-19
Dr Jean Saunders	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-067-AMEND
- Application 20-NREC-COV-089-AMEND
- Application 20-NREC-COV-104-AMEND-3
- Application 20-NREC-COV-050-AMEND-2

- Application 20-NREC-COV-056-AMEND-2
- Application 20-NREC-COV-095-AMEND
- AOB

- The Acting Chair opened the meeting and welcomed the committee

Amendment applications

Application Number	20-NREC-COV-067-AMEND
Applicant	Prof Jonathon Hourihane
Study Title	CORAL Study: Impact of Corona Virus Pandemic on Allergic and Autoimmune Dysregulation in Infants Born During Lockdown.
Institution	CHI Temple Street
NREC COVID-19 Comments	<ul style="list-style-type: none"> • The Committee noted that this amendment application represents the addition of 2 questionnaires, the inclusion of new collaborator, the inclusion of a second blood sample in year 2 of the study and the use of an electronic database for data storage.
NREC COVID-19 Decision	<i>Request for further information</i> <i>[Approved – 06/04/2021]</i>
Associated Conditions / Suggestions	<ul style="list-style-type: none"> - In the 'Parental Consent to RNA Sequencing of Blood Sample', the NREC COVID-19 noted that the term pseudonymised may not be clear to participants. The NREC COVID-19 suggested that in Section 3, 'i.e.' should be added before 'identifiable only by...' - The NREC COVID-19 noted that the data will be stored in the Netherlands. The NREC COVID-19 requested further reassurance that the data will be stored in accordance to National and European legislation.

Application Number	20-NREC-COV-089-AMEND
Applicant	Prof Michael Barrett
Study Title	Epidemiology, severity and outcomes of children presenting to emergency departments across Europe during the SARS-CoV-2 pandemic
Institution	CHI Crumlin
NREC COVID-19 Comments	<ul style="list-style-type: none"> • The Committee noted that this amendment application represents an extension to the time period for data collection.

NREC COVID-19 Decision	<i>Request for further information</i> <i>[Approved – 07/04/2021]</i>
Associated Conditions / Suggestions	- The NREC COVID-19 noted that the rationale for the study extension was not clearly outlined in the application and requested a short rationale for the extension.

Application Number	20-NREC-COV-104-AMEND-3
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 changes to the inclusion criteria to allow patients in receipt of therapeutic low molecular weight heparin, and therapeutic unfractionated heparin to be recruited into the study. • The application makes reference to a publication that justifies the changes to the inclusion criteria, but the NREC COVID-19 noted that a key paper referred to in the documentation was missing from the submission.
NREC COVID-19 Decision	<i>Request for further information</i> <i>[Approved]</i>
Associated Conditions / Suggestions	- The NREC COVID-19 requested that the applicant provide additional references to academic literature in addition to the key paper mentioned in the application.

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 questions to the questionnaire. • The rationale for the additional questions was clearly explained in the application for the substantial amendment.
NREC COVID-19 Decision	<i>Approved</i>
Associated Conditions / Suggestions	N/A

Application Number	20-NREC-COV-056-AMEND-2
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 updates to details on data and sample collection, changes to language around non-participation and study withdrawal, and updates to language around data retention. • The Committee noted that the term pseudonymised was not adequately defined for participants in the participant information materials. • The Committee were unclear at what stage would the data change from being pseudonymised to fully anonymised.
NREC COVID-19 Decision	<i>Request for further information Approved – 28/04/21</i>
Associated Conditions / Suggestions	<ul style="list-style-type: none"> - The NREC COVID-19 requested that the term 'pseudonymised' is explained in the Participant Information Leaflet. - The NREC COVID-19 noted that there is no current legal basis for an Enduring Power of Attorney to make healthcare decisions and requests that this term is omitted from the documentation. - The NREC COVID-19 noted that 60 ml will be drawn from participants on up to 5 occasions every 6 months. In the Patient Information Leaflet, the NREC COVID-19 requested that the amount and the frequency is adequately described to participants. - As the data is now identifiable through pseudonymisation, the NREC COVID-19 requested confirmation whether the data will be fully anonymised at any stage. - The NREC COVID-19 noted the inclusion of Yes / No questions in the consent forms and requested clarification if No is answered for any question, whether or not the participant can proceed.

Application Number	20-NREC-COV-095-AMEND
Applicant	Dr Fionnuala Ní Áinle
Study Title	Coagulopathy of COVID-19: A Pragmatic Randomized Controlled Trial of Therapeutic Anticoagulation versus Standard Care as a Rapid Response to the COVID-19 Pandemic (RAPID COVID COAG)

Institution	UCD
NREC COVID-19 Comments	<ul style="list-style-type: none"> The Committee noted that this amendment application represents changes and updates to the study protocol in line with changes made by the global sponsor.
NREC COVID-19 Decision	<i>Request for further information [Approved – 09/04/2021]</i>
Associated Conditions / Suggestions	<ul style="list-style-type: none"> The NREC COVID-19 noted that some helpful information has been removed from the PIL such as information on deciding to participate in the study and asking questions related to the study. The NREC COVID-19 requested clarification why this information was removed.

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