

Meeting Minutes

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

Time: 3 – 5pm

Date: 3rd June 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. Mary Donnelly	Committee member, NREC COVID-19
Prof. Andrew Greene	Committee member, NREC COVID-19
Prof. Orla Sheils	Committee member, NREC COVID-19
Ms Sharon Foley	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. 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 Dymrna Moran	Committee member, NREC COVID-19
Ms Grainne McGettrick	Committee member, NREC COVID-19
Ms Caoimhe Gleeson	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. Pat Manning

Quorum for Decisions: Yes

Agenda

- Welcome & Apologies
- Minutes approval 27th May & Matters Arising

- Declarations of Interest
- Application 20-NREC-COV-053
- Application 20-NREC-COV-058
- Application 20-NREC-COV-060
- Application 20-NREC-COV-057
- Application 20-NREC-COV-059
- Application 20-NREC-COV-043
- AOB

- The Chair welcomed the committee.
- The minutes from meeting on 27th May 2020 were approved.
- Matters arising from the 27th May meeting as follows:
 - (1) The Head of Office for NRECs provided a running count of applications considered by NREC COVID-19 to date.
- The following declaration of interest was made, and the member recused herself from the discussion of the application in question:

Dr Akke Vellinga – 20-NREC-COV-053

Applications

Application Number	20-NREC-COV-053
Applicant	Dr Aoife Fleming
Study Title	A randomised controlled trial of the impact of the availability of procalcitonin testing on antimicrobial prescribing in the treatment of patients admitted to hospital with Covid-19 infection
Institution	University College Cork
NREC COVID-19 Comments	<ul style="list-style-type: none"> • The committee agreed that this study is supported by clear protocol and presents no risk to patients.
NREC COVID-19 Decision	<i>Provisional approval</i>
Associated Conditions	<ol style="list-style-type: none"> 1. The committee is of the view that this study is better described as a feasibility or pilot study rather than a clinical trial, and request that all relevant documentation, including participant materials, be amended accordingly. 2. Regarding the PIL, the committee requests that the hospital logo be included for appropriate affiliation and that the data protection information is curtailed to a few paragraphs to include

	<p>the salient information for participants. Additionally, the committee requires that the direction to participants to consult the NREC COVID-19 if required on their rights be removed.</p> <p>3. The committee requests confirmation that the study algorithm is validated.</p> <p>4. The committee requests clarification of patient number - is it 50 per group (in each of Control and PCT groups)?</p>
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Application Number	20-NREC-COV-058
Applicant	Prof. Maria Fitzgibbon
Study Title	Enhancing serology surveillance with antibody testing in SARS-CoV 2 pandemic
Institution	Mater Private Hospital
NREC COVID-19 Comments	<ul style="list-style-type: none"> • The committee agreed that this small-scale study will address an interesting question. • The committee noted that participants will be recruited from Dublin and Cork sites of the Mater Private Group.
NREC COVID-19 Decision	<i>Provisional approval</i>
Associated Conditions	<ol style="list-style-type: none"> 1. The committee is unclear if there are plans to do viral testing on staff not known to have COVID-19, and requests clarification in this regard. 2. Noting the plan to recruit participants via Occupational Health, the committee requires further detail on this approach. 3. The committee requests that there is a PIL / consent form for participants in the control group. Additionally, the committee requests the consent form be separated from the questionnaire. 4. The committee requests explanation of what information is available from the discarded blood samples, and how this integrates with other analyses. 5. The committee observes that the information provided on statistical analysis only refers to sensitivity analysis, and requests further detail on the analyses planned, including sample size calculations. 6. The committee notes the DPIA is in progress and requests evidence of its outcome. 7. The committee requests clarity on the reporting of COVID-19 test results to study participants. 8. The committee is of the firm view that test results from this research study are investigational and should not prescribe 'return to work' plans for hospital staff.

Application Number	20-NREC-COV-060
Applicant	Prof. Patrick Sheahan
Study Title	ICE: Impact of COVID 19 on ENT Surgery in Ireland
Institution	South Infirmary-Victoria University Hospital, Cork
NREC COVID-19 Comments	<ol style="list-style-type: none"> 1. The committee is entirely unclear on the methodology underpinning this study, confounded by separate references to it as both an audit and observational study, and absence of duration. 2. Noting there is uncertainty as to the number of participants to be recruited, there is no information, informed by statistical advice, on the minimum number required to make the study valid. 3. The committee is unclear on how healthcare workers will be recruited, studied, or consented. 4. The committee observes that DPO approval has been secured, however no DPIA has been provided. 5. The committee is of the view that the participant materials are inadequate, for example lack of invitation or explanation of data transfer, no information on the option to withdraw and inaccessible language in the child PIL. The committee maintains that the use of a thumbprint to evidence consent is not usual practice.
NREC COVID-19 Decision	<i>Approval Declined</i>

Application Number	20-NREC-COV-057
Applicant	Dr Alin Dumitrescu
Study Title	Anxiety levels among health care workers within Irish mental health service during covid-19: A Survey
Institution	Cork University Hospital
NREC COVID-19 Comments	<ul style="list-style-type: none"> • The committee noted that this study will examine the relationship between anxiety and other factors during the Covid-19 pandemic in mental health healthcare workers in Cork using the validated instrument, GAD-7.
NREC COVID-19 Decision	<i>Provisional approval</i>
Associated Conditions	<ol style="list-style-type: none"> 1. The committee notes that Survey Monkey is a commonly used tool, however they require further justification as to the security that it can afford the participants' data. The committee requires further justification of the use of Survey Monkey including plans to immediately de-identify the data (including URLs, cookies) when received. 2. Given the focus on a number of Cork mental health services, and the applicant's membership of same, the committee is of the view

	<p>that this is potentially an identifiable community. The committee requires further explanation of how this will be mitigated.</p> <p>3. Regarding sample size for an online survey, the committee requests rationale for the n=200 and how will participants be selected.</p> <p>4. Regarding the survey, the committee requests the following:</p> <ul style="list-style-type: none"> • A more detailed introduction / preamble including its purpose and outcome, what will happen the results, data protection and consent. • The 'disagree' option be removed from Question 1; the use of agree / disagree options or yes / no boxes in consent forms should be restricted to where participants have a choice to make about individual elements of the project. • Inclusion of 'other' in the field of gender. • Further explanatory detail and editing in Questions 7-9 and 9-11 for ease of access to the research participant. <p>5. Regarding the research participant information sheet and consent:</p> <ul style="list-style-type: none"> • As consent is explicitly sought in the anonymised questionnaire, the committee requests that the detail on consent is migrated to the questionnaire. The research participant information sheet should include a short section on consent rather than having two separate documents. • Question 2.7 in the application form states <i>"In the second part of the study participants data will be divided up via their services and a series of descriptive statistics will be conducted to analyse mean anxiety levels in each hospital"</i>. Research participants should be explicitly notified in the research participant information sheet that this is how the data will be analysed given the proposed sample size and potential for individuals to be identified through their specific locations. • The committee requests that the direction to participants to contact the NREC COVID-19 concerning their rights be removed. Any questions relating to the research are the responsibility of the Principal Investigator. • Question 2.12 states that the results will be shared in peer reviewed journals; the committee requests that other additional avenues are considered to maximise participants' access to the results. <p>6. Regarding the recruitment methodology:</p> <ul style="list-style-type: none"> • The committee requests information on how the recruitment process is being managed eg who is sending the messages, emails and managing responses? How will anonymity be ensured through this recruitment process?
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	<ul style="list-style-type: none"> • Question 3.7 of the Application is blank. The committee requests that these categories are considered for inclusion given the profile of the workforce e.g. pregnant women or staff with mental health issues. <p>7. The committee observes the efforts made to contact the Data Protection Officer and requests that the applicant follow-up again with a view to sharing her feedback with the committee.</p> <p>8. Regarding engagement with HR and Management, the committee requests sight of the agreement of the HR Department and the Clinical Director/ Mental Health Head of Service for this survey.</p> <p>9. Regarding the provision of support to those completing the survey, rather than provide the contact details of two researchers, the committee requests that links to occupational health and staff support are provided in order to maintain the anonymous integrity of the study.</p> <p>10. Noting the intention to delete the excel file with survey data, the committee requires that the data is retained in accordance with the applicant's institutional policy for data storage and retention.</p>
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Application Number	20-NREC-COV-059
Applicant	Dr Colin McMahon
Study Title	European Paediatric Cardiology Multisystem Inflammatory Syndrome Survey Cardiovascular manifestations during COVID-19 Pandemia
Institution	Children's Health Ireland at Crumlin
NREC COVID-19 Comments	<ul style="list-style-type: none"> • The committee agreed that this application represents a valuable pan-European study, in line with several national alerts for individual countries for paediatric presentation post-SARS-COV-2 infection of a multisystemic inflammatory syndrome.
NREC COVID-19 Decision	<i>Provisional approval</i>
Associated Conditions	<ol style="list-style-type: none"> 1. The committee notes that consent will be obtained verbally and queries if an interpreter will be provided if needed. 2. The committee requests clarity on the chain of data transfer – will the data be transferred directly to the PI in Seville or via the PI in London? 3. The committee is unclear on the relevance of the link between pseudonymisation and lack of remuneration, and requests clarification. 4. The committee requests that the master key for the data should be held securely by a trustworthy member of hospital staff who is not directly involved in the study.

	<p>5. Noting reference to data being ‘transferred with no identifiers’, the committee requires explanation of what the intended reference to an ‘identifier’ is for this study.</p> <p>6. Notwithstanding pseudonymisation, given the small sample size, the committee requests comment on the possibility of identifying individuals.</p> <p>7. The committee requests that spoken confirmation of verbal consent by phone is recorded.</p> <p>8. The committee is of the view that some of the language in the PIL is inaccessible for the lay person and requests it be amended accordingly, for example minimising the use of ‘terms of art’. Additionally, the committee requests that a withdraw clause is included in the PIL. Finally, the committee requests confirmation that the PIL be sent to the family for their records.</p>
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Application Number	20-NREC-COV-043
Applicant	Dr Stephen O’Connor
Study Title	A Review of Irish Patients Presenting with Acute Coronary Syndrome During the COVID-19 Pandemic – The SARS-CoV-2 ACS Study
Institution	St. James’s Hospital
NREC COVID-19 Comments	<ul style="list-style-type: none"> • The committee agreed that this single-site study is worthwhile and presents no physical harms. • The committee noted that this application will also be considered by the HRCDC.
NREC COVID-19 Decision	<i>Provisional approval</i>
Associated Conditions	<ol style="list-style-type: none"> 1. The committee requests that the master key for the data should be held securely by a trustworthy member of hospital staff who is not directly involved in the study. 2. Noting that verbal consenting is a component of this study, the committee requires more detail on the process including the proposed documentation in patients’ notes, plan for ensuring that consent is informed (eg will the PIL be provided in advance and / or will a verbal explanation be provided by the researcher?), and how the researcher will gauge capacity to consent. 3. Where consent is obtained by telephone, to attest active consent the committee requests that spoken confirmation of verbal consent is recorded. 4. The committee observes that the consent form has a choice of a Yes / No boxes for participants to fill in, indicating they understand a specific issue. Were the participant to indicate by ticking the ‘No’ box that they did not understand the issue, the

	<p>committee maintains that would not be informed consent. Please restrict the use of Yes / No boxes in the consent form to items where the participant has a choice to make about individual elements of the project.</p> <p>5. The committee is of the view that this study is a 'controlled observational study' and not a 'case-controlled study', and requests that the relevant documentation be amended accordingly.</p>
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- AOB: None
- The Chair closed the meeting

APPROVED