

Meeting Minutes

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

Time: 3 – 5pm

Date: 20th May 2020

Location: virtual meeting

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
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 for NRECs
Ms Aileen Sheehy	Programme Manager (PM), Office for NRECs

*Drafted minutes

Apologies: Prof. Pat Manning, Ms Caoimhe Gleeson

Quorum for Decisions: Yes

Agenda

- Welcome & Apologies
- Minutes approval 13th May & Matters Arising
- Declarations of Interest

- Application 20-NREC-COV-041
- Application 20-NREC-COV-044
- Application 20-NREC-COV-042
- AOB

- The Chair welcomed the committee.
- The minutes from meeting on 13th May 2020 were approved.
- Matters arising from the 13th May meeting as follows:
 - (1) The Head of Office for NRECs confirmed that 6 of the 11 applications receiving *provisional approval* at 13th May meeting had since received *final approval*, having satisfied the additional queries of the committee.
 - (2) The Office PM confirmed that the processes and procedures for NREC COVID-19 have been captured in a Standard Operating Procedure (SOP) document now accessible on the committee webpage.
- 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-042

Applications

Application Number	20-NREC-COV-041
Applicant	Prof. Alistair Nichol
Study Title	Short PeRIod IncideNce sTudy of Severe Acute Respiratory Infection (SPRINT-SARI)
Institution	St Vincent’s University Hospital
NREC COVID-19 Comments	<ul style="list-style-type: none"> • The committee noted that this application represents an amendment to a study, originally approved by St. Vincent’s Hospital REC, to include two additional sites (Wexford and Kilkenny/Carlow).

	<ul style="list-style-type: none"> The committee agreed that sufficient information is provided for the additional sites and PIs and there are no ethical concerns with this amendment.
NREC COVID-19 Decision	<i>Provisional Approval</i>
Associated Conditions	<ol style="list-style-type: none"> Noting the intention for personnel from the UCD Clinical Research Centre to gather data from the additional sites, the committee is unclear as to the arrangement, contractual or otherwise, between UCD CRC and these hospital sites. The committee suggests that authorisation would usually be given to local personnel to do this by the local PI at each site. As this seems not to be the case, the committee requests clarification.

Application Number	20-NREC-COV-044
Applicant	Dr Eoghan de Barra
Study Title	COVID19 in healthcare workers, utility of serology and exhaled breath condensate in informing staffing
Institution	RCSI
NREC COVID-19 Comments	<ul style="list-style-type: none"> The committee agreed that this study is investigating an important question on SARS-CoV-2 antibodies in symptomatic and asymptomatic healthcare workers The committee agreed that the consent and data protection issues are outlined and clear.
NREC COVID-19 Decision	<i>Provisional Approval</i>
Associated Conditions	<ol style="list-style-type: none"> The committee requests clarification on the involvement of volunteer asymptomatic healthcare workers, particularly the plans for recruitment, consenting and follow-up, mindful of potential power relationships. The committee notes the comprehensive detail contained in the PIL pertaining to data protection considerations, however the committee is of the view that there is insufficient information to inform consent for the procedures involved in participation and requests an amendment accordingly. The committee notes that the consent form has a choice of Yes / No boxes for the 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, that would not be informed consent. The committee requests restriction of 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.

	4. The committee is unclear as to when pseudonymisation will be / not be used locally for carrying out testing. Noting that diagnostic testing needs to be carried out on identifiable samples, the committee requires clarification in this regard.
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Application Number	20-NREC-COV-042
Applicant	Dr Akke Vellinga
Study Title	SARS-CoV-2 Observational Study of community acquired acute respiratory tract infection during a time of widespread suspected COVID-19 in European primary care
Institution	NUI Galway
NREC COVID-19 Comments	<ul style="list-style-type: none"> • The committee noted this application represents a resubmission of a previously declined application. • Compared with the previous application, the committee noted that children are no longer included in the study cohort.
NREC COVID-19 Decision	<i>Provisional Approval</i>
Associated Conditions	<ol style="list-style-type: none"> 1. The committee is of the view that there is potential for confusion for participants on the purpose of self-swabbing ie, for research or clinically indicated swabbing. The committee requests that the materials for patients (eg PIL) and communications to GPs contains clear emphasis that the self-swabbing is for research purposes only, that it will not provide results within a timeframe that can assist with diagnosis or management, and that arrangements will have to be made separately for any 'official' HSE national test swab. 2. As the committee highlighted in the previous submission, there are concerns with storing samples in COPAN Swab and Universal Transport Media (UTM) in participants' freezers. Reviewing the product information for UTM, there is no evidence (nor the contrary) supporting viability of samples in storage at home freezer temperatures (-15°C to -20°C). The committee requires comment on the likelihood of ensuring viability of samples with a view to ensuring integrity of results. 3. The committee requires clarification on conflicting information on the sample size in Ireland. In one section of the application form the sample size is indicated as '50 in current pandemic, 50 in next flu season (2020-2021)' however, separately another section says 'We do not intend to plan this study with a limit on sample size'. 4. The committee notes that 'No' is answered for question 3.7; this suggests that pregnant women / women of child-bearing age,

	<p>adults suffering from dementia and adults with learning disabilities are excluded, or it might imply that those with dementia or learning difficulties can't by definition consent. The committee requires clarification as to the potential inclusion of these groups.</p> <ol style="list-style-type: none">5. The committee requests that the following statement regarding consent for the Irish component of the study be omitted: <i>'No medical records will be accessed. Information will only come from patient themselves'</i>.6. The committee notes unclear direction as to how participants should return the samples, and requests uniformity throughout the documentation.7. The committee notes that the outcome from the DPO at NUI Galway is pending and awaits confirmation in this regard.
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- AOB: The committee requested that the national office provide a running count of applications considered at the weekly meetings.
- The Chair closed the meeting

APPROVED