

Meeting Minutes

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

Time: 3 – 5pm

Date: 22nd July 2020

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. Andrew Green	Committee member, NREC COVID-19
Prof. Orla Sheils	Committee member, NREC COVID-19
Prof. Suzanne Norris	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. Shaun O’Keeffe	Committee member, NREC COVID-19
Ms Dympna Moran	Committee member, NREC COVID-19
Ms Caoimhe Gleeson	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

* Subset of committee convened

† Drafted minutes

Apologies: Prof. Pat Manning

Quorum for Decisions: Yes

Agenda

- Welcome & Apologies
- Minutes approval 1st July & Matters Arising
- Declarations of Interest
- Application 20-NREC-COV-078

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- Application 20-NREC-COV-081
- Application 20-NREC-COV-084
- Application 20-NREC-COV-083
- Application 20-NREC-COV-082
- Application 20-NREC-COV-085
- Application 20-NREC-COV-079
- Application 20-NREC-COV-071
- AOB

- The Chair opened the meeting and welcomed the committee
Note: Vice-Chair, Prof. Anthony Staines, assumed chairpersonship of the meeting for the last three agenda items
- It was noted that the minutes from meeting on 1st July were approved electronically
- Matters arising from the 1st July 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 were made, and the member recused himself from the discussion of the application in question:

Prof. Anthony Staines – 20-NREC-COV-084

Applications

Application Number	20-NREC-COV-078
Applicant	Dr Caitriona Cahir
Study Title	COVID-19: Exploring the psychosocial impact of the pandemic on women with breast cancer
Institution	RCSI
NREC COVID-19 Comments	<ul style="list-style-type: none"> • The committee noted that this application represents a large Irish study as a component of a European initiative on health literacy
NREC COVID-19 Decision	<i>Provisional approval</i>
Associated Conditions	1. Regarding the collaboration with sites in the UK and Quebec (Section 1.5), the committee requests clarification whether there are any agreements or permissions in place between the two Irish sites and the international sites.

	<ol style="list-style-type: none"> 2. The committee requests that you clarify why the consent form allows for a Translator's signature if English is a requirement for participation (Section 3.4). 3. The committee requests that you clarify whether letters from the two clinics will be sent out by hospital staff or the project team. 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. 5. 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 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. 6. The committee queries whether the project may be open to recruitment bias as access to advertisements and participation requires internet access. 7. The committee notes that Qualtrix is a commonly used tool, however it requires justification as to the security that it can afford the participants' data including plans to immediately de-identify the data (including URLs, cookies) when received.
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Application Number	20-NREC-COV-080
Applicant	Dr Sarah Gibney
Study Title	Health Literacy Survey in Ireland
Institution	Department of Health
NREC COVID-19 Comments	<ul style="list-style-type: none"> • The committee agreed that this application represented an extensive health care survey which presented very few issues • The committee noted that participants' use of a mobile phone during an evaluation of health literacy may inherently represent a potential bias
NREC COVID-19 Decision	<i>Provisional approval</i>
Associated Conditions	<ol style="list-style-type: none"> 1. The committee requests further information on how capacity to consent will be assessed during the phone interview (section 4.2.1). 2. The committee requests that in the Participant Information Leaflet, under the risks and benefits section, participants should be encouraged to contact their General Practitioner prior and in addition to directing them to appropriate helplines.

	3. The committee notes that the gender options are currently only 'male and female' in the questionnaire and requests these options be broadened as per best practice for inclusion.
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Application Number	20-NREC-COV-081
Applicant	Prof Martina Hennessy
Study Title	Professional Identity Formation of Junior Doctors during the COVID Crisis, the Role of Agency and preparing for Follow- up.
Institution	TCD
NREC COVID-19 Comments	<ul style="list-style-type: none"> The committee noted that this application represents a multisite survey of junior medical doctors interning in 2019 and 2020
NREC COVID-19 Decision	<i>Provisional approval</i>
Associated Conditions	<ol style="list-style-type: none"> The committee notes that the start date on the application form is May 2020 (section 2.3) and requests clarity on whether study has already commenced or not. The committee notes mention of 'validated inventories', which address stress and resilience (section 2.5); however, no further detail is provided on these. The committee requests that further information is provided on the 'validated inventories' used in the questionnaire. The committee requests clarity on what the survey wants to achieve and justification of how this is reflected in the questions, and what is being measured in each of the sections. The committee requests more information on the purpose of the 6-month follow-up and whether the same methodology will be used. The committee requests confirmation of the survey tool to be used. The committee requests inclusion of an introduction / preamble to the survey with information on the purpose, outcome, data protection and consent. The committee requests more information on the recruitment of participants: <ol style="list-style-type: none"> Who in the organisation will send out emails and requests? How are the participants for the qualitative element to be selected and how will confidentiality be maintained with the small sample size? What methodology will be used to gain access to the 2019-2020 cohort of interns who have now finished?

	<p>8. The committee requests that consent is clearly and explicitly sought in the questionnaire and clearly addressed in the Participant Information Sheet.</p> <p>9. The committee requests that information on how data will be collected and retained is clearly set out in the research Participant Information Sheet.</p> <p>10. The committee notes that the applicant has stated that GDPR is not applicable to this study (section 9.1.1). The committee requests more information on how the survey will be administered, who will have access to the participants' email addresses, how qualitative data will be anonymised and stored, and who will have access to this data.</p> <p>11. The committee requests that the applicant consult their institutional DPO for data protection advice before the study commences.</p>
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Application Number	20-NREC-COV-084
Applicant	Dr Niamh O'Flaherty
Study Title	Anti-SARS-CoV-2 IgG Seroprevalence in Irish Blood Donors
Institution	Irish Blood Transfusion Service
NREC COVID-19 Comments	<ul style="list-style-type: none"> The committee agreed that this application proposes a very straightforward approach to a study poised to contribute national seroprevalence data
NREC COVID-19 Decision	<i>Approved</i>

Application Number	20-NREC-COV-083
Applicant	Dr Ann Payne
Study Title	Burnout on the Frontline, The impact of COVID-19 on Emergency Department staff wellbeing
Institution	St Stephen's Hospital, Cork
NREC COVID-19 Comments	<ul style="list-style-type: none"> The committee agreed that this study constitutes an important piece of work with a straightforward approach of an anonymous cross-sectional survey
NREC COVID-19 Decision	<i>Provisional approval</i>
Associated Conditions	<ol style="list-style-type: none"> The committee requests that ED staff are notified of the study activity generally in advance, for example by displayed poster or internal communication system. The committee notes there is no power calculation provided and suggests the study will be unlikely to recruit the number

	<p>required to derive information on burnout rates in different staff groups; the committee requests justification of same.</p> <ol style="list-style-type: none"> 3. Regarding the participant information leaflet (PIL) ('invite'), the committee requests the logos of the two organisations involved are included, in addition to the name and contact details of the Principal Investigator. 4. The committee requires confirmation that the Principal Investigator will endeavour to provide the PIL to all potential participants in advance of verbal approach in the ED. 5. The committee is of the view that the cartoon is inappropriate on the 'invite' given the topic, and requests its removal. 6. The committee suggests the timeframe is tight for data collection by one individual in a very busy environment across two geographically separate sites, and requests comment on this challenge. 7. The committee asserts for the record that the data controller for the study is the Principal Investigator and not the medical student gathering the data.
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Application Number	20-NREC-COV-082
Applicant	Prof. Maria Brenner
Study Title	Perspectives of parents / guardians and nurses of respite services for children with complex care needs in CHO1
Institution	TCD
NREC COVID-19 Comments	<ul style="list-style-type: none"> The committee noted that this application represents an amendment to a study receiving prior approval from three local ethics committees, namely HSE NE, Sligo and Letterkenny.
NREC COVID-19 Decision	<i>Approved</i>

Application Number	20-NREC-COV-085
Applicant	Dr Damien Lowry
Study Title	Evaluating Factors Associated with Mental Health Outcomes among Dublin Hospital Healthcare Workers Exposed to the COVID-19 Pandemic
Institution	Mater Misericordiae University Hospital
NREC COVID-19 Comments	<ul style="list-style-type: none"> The committee noted that this application represents an online pseudonymised study of mental health in over 500 healthcare workers in 5 Dublin Adult hospitals.
NREC COVID-19 Decision	<i>Provisional approval</i>
Associated Conditions	<ol style="list-style-type: none"> The committee notes that Qualtrix is a commonly used tool, however it requires justification as to the security that it can afford the participants' data including plans to immediately de-identify the data (including URLs, cookies) when received. The committee is of the view that the indicated timeframe of 10 minutes to complete the online form is unrealistic and that 30 minutes is a more appropriate estimate; please amend accordingly. The committee asserts that the survey methodology as proposed will inherently have a healthy work bias, and requests comment on how the Principal Investigator proposes to manage this. The committee observes that the study will be run at three time-points, however it is unclear if the intention is for the same group from time-point 1 to be surveyed again at the second and third time-points, or if three separate recruitments take place. Furthermore, the committee is unclear if the population being asked to participate are those who will be employed by the same hospital for all three time periods, which may exclude junior doctors on rotation. Further to above, the committee is unclear if the intention of the study is to generate longitudinal data. Depending on confirmation of same by the Principal Investigator, the committee requires that one of two alternative approaches be pursued. If the intention is to conduct a longitudinal study, the committee requests that true appropriate identifiers are collected (and not use the proposed code) to enable accurate data and meaningful observations to be derived. Alternatively, if the intention is to gather data at three time-points over three independent exercises, then there is no requirement to attempt to link the data and therefore the proposed code should not be used

Application Number	20-NREC-COV-079
Applicant	Dr Eoghan de Barra
Study Title	The Relationship of Social Deprivation to Outcomes in COVID-19 in an Urban Irish Setting
Institution	RCSI
NREC COVID-19 Comments	<ul style="list-style-type: none"> The committee agreed that this application represents a useful study to inform future planning to protect those most vulnerable during infectious disease pandemics.
NREC COVID-19 Decision	<i>Provisional approval</i>
Associated Conditions	<ol style="list-style-type: none"> The committee notes there is agreement between the clinical leads at the sites, however it queries whether formal agreements are in place between the respective hospitals. Recognising that the participant list will be generated from the microbiology laboratory records, the committee requests clarification on the agreement from the laboratories to do this; for example, are the clinical leads from these laboratories? The committee advises that the use of postal addresses to generate a person's socioeconomic/deprivation status is not necessarily accurate and therefore this should be recognised in any analyses. It also requests some explanation as to how this link will be made on entering the data without the address going into the database first so that this link can be made afterwards. It seems unlikely that the researchers will be able to do this immediately while gathering this data – as intimated in the application. If it is to be done later assurance needs to be given that the data will be kept securely until this is done and that the link will be made ASAP and addresses deleted. The committee requests amendment to the inclusion criteria to include those who are in fact 18 years of age (ie, ≥18 years)

Application Number	20-NREC-COV-071
Applicant	Dr Conor Loftus
Study Title	Covid-19: " A Frontline Worker's Perspective"
Institution	University Hospital Limerick (HSE Limerick/Midwest HSE)
NREC COVID-19 Comments	<ul style="list-style-type: none"> The committee noted that this study received final approval from the NREC COVID-19 on 9th July, having been considered at the meeting convened on 1st July The committee noted the applicant's request to amend the survey with the addition of one question The committee agreed that this question requests more identifying data, which increases the risk of re-identification;

	however, the committee was satisfied that this risk is not precluded from the Patient Information Leaflet
NREC COVID-19 Decision	<i>Approved</i>

- AOB: None
- The Vice-Chair closed the meeting

APPROVED