Office for National Research Ethics Committees
Grattan House, 67-72 Lower Mount Street, D02 H838.

Meeting Minutes

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

Time: 3 – 5pm

Date: 27th May 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 Greene	Committee member, NREC COVID-19
Prof. Orla Sheils	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
Prof. Pat Manning	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: Ms Sharon Foley, Prof. Hannah McGee, Prof. Mary Donnelly

Quorum for Decisions: Yes

Agenda

- Welcome & Apologies
- Minutes approval 20th May & Matters Arising
- Declarations of Interest
- Application 20-NREC-C0V-001 (amendment)

- Application 20-NREC-C0V-045
- Application 20-NREC-C0V-047
- Application 20-NREC-C0V-050
- Application 20-NREC-C0V-051
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- Application 20-NREC-C0V-056
- AOB

- The Chair welcomed the committee.

- The minutes from meeting on 20th May 2020 were approved.

- Matters arising from the 20th May meeting as follows:

  (1) The Head of Office for NRECs confirmed that 2 of the 3 applications receiving *provisional approval* at 20th May meeting had since received *final approval,* having satisfied the additional queries of the committee.

  (2) The Head of Office for NRECs provided a running count of applications considered by NREC COVID-19 to date.

  (3) The Office PM advised committee members to download the review documentation should members have trouble scrolling the files on the online Decision Time interface.

- Declarations of Interest: None

Applications

Application Number	20-NREC-C0V-001 (amendment)
Applicant	Prof. Richard Costello
Study Title	A clinical risk score for monitoring and predicting respiratory failure in COVID-19 pneumonia, the COVID Clinical Index (CCI) score
Institution	RCSI / Beaumont Hospital
NREC COVID-19 Comments	• The committee noted that this application represents an amendment to a study receiving ethics approval from NREC COVID-19 in April 2020.
NREC COVID-19 Decision	*Provisional approval*

Associated Conditions	1. Noting the intention to add an additional 11 sites, the committee requests evidence of confirmation from each site as to their agreement. 2. The committee is aware of the COVID Clinical Care Index (CCCI) as a variable collected by the ACCORD App, and request confirmation that COVID Clinical Index (CCI), the focus of this study, has not been collected by this App. If CCI was collected in the ACCORD App as the underpinning supporting data, the committee requires assurances of data protection and clarification on any commercial considerations.

Application Number	20-NREC-C0V-045
Applicant	Prof. Maccon Keane
Study Title	The ESMO-CoCARE Registry for patients with a Malignancy who are diagnosed with COVID-19
Institution	Galway University Hospital
NREC COVID-19 Comments	• The committee agreed that this study is a worthwhile component of a global initiative to rapidly accumulate knowledge to inform clinical management of a vulnerable group of patients. • The committee noted that this study is also being considered by the HRCDC.
NREC COVID-19 Decision	*Provisional approval*
Associated Conditions	1. The committee notes separate references to anonymisation and pseudonymisation in the application and requires confirmation on the approach to be taken. Furthermore, the committee is unclear as to who is entering the data to the registry and requires clarification. 2. The committee requires confirmation on who will retain the key to individuals' data and suggests the key is kept centrally in the hospital by a trusted staff member not involved in the research. 3. The committee is uncertain as to how the patient information poster will be used and requires explanation in this regard.

Application Number	20-NREC-C0V-047
Applicant	Dr Derval Igoe
Study Title	Study to investigate COVID-19 infection in people in Ireland (SCOPI)
Institution	HSE Health Protection Surveillance Centre
NREC COVID-19 Comments	• The committee noted that this study involves characterising antibody titres / serological markers over time in two areas of Ireland representing low and high COVID-19 incidence. • The committee noted the protocol for this cross-sectional prospective study is an adaptation of a WHO protocol.

NREC COVID-19 Decision	*Provisional approval*
Associated Conditions	1. The committee notes the intention for a data sharing agreement between HPSC and NVRL to be drafted for this study and requests sight of this. 2. The committee requires explanation on the approach to be taken if more participants agree to participate than is required for the study sample. 3. The committee is of the view that the Patient Information Leaflet could be made more accessible in terms of language and presentation and requires the language be improved. By way of *suggestion,* the use of images or a short video may assist in this regard. 4. The committee notes reference to 'your Mum and Dad' in the PIL and consent form and requests this be amended to 'your parent or guardian', which is more socially inclusive and appropriate for adolescents. 5. The committee requires clarification on the intended scope for participant consent for the 2-year sample storage; is the participant consenting to the sample being stored, destroyed or both? 6. Recognising that different waves of study are being carried out, the committee queries if a 2-year storage period is sufficient for each wave? Subject to the applicant's institutional data retention policy, the committee is of the view that it would be more appropriate to retain samples for the study duration to allow completion of all waves to maximise the use of participants' data for the study's purposes.

Application Number	20-NREC-C0V-050
Applicant	Prof. Mary McCarron
Study Title	Intellectual Disability Supplement to The Irish Longitudinal Study on Ageing (IDS-TILDA)
Institution	TCD
NREC COVID-19 Comments	• The committee remarked that IDS-TILDA, a national longitudinal study of ageing in people with intellectual disability, is in its fourth wave of data collection. • The committee noted that this application represents an amendment to reflect restrictions in the interview and consent processes, and to include additional COVID-19-related questions.
NREC COVID-19 Decision	*Approved*
Associated Conditions	None

Application Number	20-NREC-C0V-051
Applicant	Dr Julie Regan
Study Title	Clinical Characteristics of Dysphagia and Communication Difficulties among Hospitalised Adults with COVID-19 in Ireland: An Observational Cohort Study
Institution	TCD
NREC COVID-19 Comments	• The committee observed the intention of the study to gather data on a distinct cohort of adults hospitalised with COVID-19 from 22 clinical sites across Ireland who have been referred for speech and language therapy (SLT). • The committee noted that this study is also being considered by the HRCDC.
NREC COVID-19 Decision	*Provisional approval*
Associated Conditions	1. Noting the intention to include 22 sites, the committee requests the details of and evidence of confirmation from each site as to their agreement. 2. The committee is unclear as to how pseudonymisation is to take place and where/how the code will be held locally at each site and requires clarification in this regard. 3. The committee requires further information on the plan for data analyses and how the possibility of double counting of participants attending different centres at different stages of their illness, will be accounted for. 4. The committee requests comment on the transparency to be afforded by participating sites as to their processing of personal data for research. 5. The committee requests comment on the impact of the COVID-19 pandemic on the delivery of SLT services.

Application Number	20-NREC-C0V-052
Applicant	Prof. Linda Coate
Study Title	TERAVOLT: Thoracic cancERs international coVid 19 cOLlaboraTion
Institution	University Hospital Limerick
NREC COVID-19 Comments	• The committee agreed that this is an important study, driven by a worldwide consortium and represented by a clear and well-justified application. • The committee noted that this study is also being considered by the HRCDC.
NREC COVID-19 Decision	*Provisional approval*
Associated Conditions	1. The committee notes the Patient Information Leaflet is too dense, contains incomplete sentences, Americanised English and inaccessible language, and requires it be amended accordingly.

	2. Given there will be a second phase of the registry implementation, the consent materials / PIL are not explicit in this regard; the committee requests these be amended appropriately. 3. Recognising that the data will be entered into REDcap, the committee requires assurance that prevailing data protection regulations will be met, in light of the cross-jurisdiction data transfers.

Application Number	20-NREC-C0V-054
Applicant	Dr Bairbre McNicholas
Study Title	Awake Prone Positioning to Reduce invasive VEntilation in COVID-19 induced Acute Respiratory failure-APPROVE-CARE
Institution	Galway University Hospital
NREC COVID-19 Comments	• The committee noted that this application represents a resubmission for a previously declined study by the NREC COVID-19. • The committee agreed that the revised submission addresses the essential queries previously raised by the committee.
NREC COVID-19 Decision	*Provisional approval*
Associated Conditions	1. The committee notes that the sites to be included are listed in the main application form, however supporting documentation (eg CREC amendment letter and DPIA) mention just a selection of these sites; please provide clarification. 2. The committee requests the PIL be improved including consistent use of I/We, removal of signed withdrawal of consent, use of page numbering and European English, and inclusion of a question in the consent section of the PIL for use of data in other research studies. 3. Noting the reference to sample size of 194, the committee requires confirmation if this is per site or per country. 4. The committee requires further information on how risk is to be managed, specifically what signal during monitoring will be a trigger to stop the intervention. 5. The committee notes the following statement in the form / protocol: '*the use of proning outside of mechanically ventilated patients has not been studied but there is no physiological reason why it should not benefit to the same extent in self-ventilating patients requiring supplemental oxygen'.* This statement should be removed if this RCT is not withholding best practice for patients in the control group.

Application Number	20-NREC-C0V-055
Applicant	Dr Niamh Reidy
Study Title	Burden of COVID-19 Infection in a Roma Population in an Urban Irish Setting: A Retrospective Review
Institution	RCSI /Beaumont Hospital
NREC COVID-19 Comments	• The committee agreed that this study is necessarily small and represented in a well-written application. • The committee concurred that the applicant may need to reconsider their associated application to the HRCDC.
NREC COVID-19 Decision	*Provisional approval*
Associated Conditions	1. The committee requires comment on how the applicant proposes to address the possibility of potential double-counting of participants, for example if a participant attends twice or at both hospitals. 2. Noting the intention to derive the social deprivation index from a small area address code, the committee requires justification as to how this potentially identifiable code can afford participants the privacy expected. Moreover, comment is requested on how the social implications of potentially linking COVID-19 to clusters in this community will be mitigated for. 3. The committee requests explanation of the potential benefits of the study outcomes to this community. Has the applicant consulted with a community representative organisation (eg Pavee Point)? 4. The committee is of the firm view that consent is achievable for this study, and requests the protocol be amended accordingly.

Application Number	20-NREC-C0V-056
Applicant	Prof. Patrick Mallon
Study Title	The All Ireland Infectious Diseases Cohort Project (AIID Cohort Project)
Institution	UCD
NREC COVID-19 Comments	• The committee agreed that this application represents an important study of a rich data set. • The committee observed that the study already has ethics approval for three local sites and the applicant is now seeking approval for an additional seven sites. • The committee noted that the applicant is in correspondence with the HRCDC secretariat with a view to an application.
NREC COVID-19 Decision	*Provisional approval*
Associated Conditions	The committee requires each of the points below be addressed:

	1. The inclusion criteria need clarification: …"*All patients attending clinical services in the applicant hospitals with a suspected Infectious Disease including COVID-19 will be eligible*." ○ Are they recruiting patients with concurrent HIV and Covid-19 and Hep-C and Covid -19 or all three diseases separately? Is there evidence that Covid-19 establishes chronic infection? Are they recruiting patients with other acute infections? 2. Please provide clarity regarding processing and collection of additional urine, faeces, sputum samples and what they will be tested for; Sections 2.6 to 6.2.2 states they will only be collecting blood. 3. Are there Material Transfer Agreements in place for each site that will be transferring samples/materials? 4. Noting there will be no blood sampling if concerns regarding anaemia, is this strong enough to ensure protection from (possible) harm? - please justify. 5. Please provide clarification regarding section 6.5.3 of how, in the event that any subsequent proposed project highlights results of genetic data that would be clinically relevant to the patient concerned, this will be fed back to the local Principal Investigator who will be able to access the patient identifiable details and inform the patients primary clinician? Moreover, how will it be decided what should be fed back and what will happen to incidental findings? This should be included in the PIL. 6. The committee is unclear as to the plans for consenting adults lacking capacity. ○ In Q 3.4 it states that the only exclusion criterion is persons under the age of 18. ○ In Q 3.5, there is a reference to a participant who does not regain competency. ○ However, in Q4.2.2. the form states that we are not seeking consent to recruit participants with reduced capacity. ○ The scope of the study from a consent perspective needs to be made clear, recognising different obligations will arise if the study is to apply to persons lacking capacity. 7. Noting that the HRCDC decision is pending, will this cover the original 2 hospitals/UCD sites or the whole study including the other sites? 8. The committee requires clarification on the identity of the responsible person for pseudonymised data entry at each site.

	9. How are samples for biobanking to be transported to central site? Please provide clarification on plans for storage, mindful of the institutional policies on data retention and sample storage. 10. The committee is of the view that inclusion criteria (section 3.6) should be expanded given that some patients may be unconscious or have cognitive impairment as per the study's plan. 11. The committee requests the PIL be revised to be more user-friendly; for example, the use of words 'database' and 'create' instead of 'dataset' and 'establish' respectively. Also, the purpose of the study in the second paragraph will be difficult for patients to understand. The committee questions the necessity of using DOB and suggests year of birth could be used instead. Noting that patients are referred to 'Quality Department', should this not be Patient Representative? The permission for future use consents also need more explanation. In summary, the committee requires a review of the PIL; the Mater Hospital PIL included in the appendix of Cohort Protocol V 1.6 is a good example.

- AOB: None
- The Chair closed the meeting