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: 13th 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
Ms Caoimhe Gleeson	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

Quorum for Decisions: Yes

Agenda

- Welcome & Apologies
- Minutes approval 29th April & Matters Arising
- Declarations of Interest
- Application 20-NREC-C0V-024
- Application 20-NREC-C0V-026
- Application 20-NREC-C0V-030-1
- Application 20-NREC-C0V-030-2
- Application 20-NREC-C0V-031

- Application 20-NREC-C0V-032
- Application 20-NREC-C0V-034
- Application 20-NREC COV-035
- Application 20-NREC COV-037
- Application 20-NREC COV-038
- Application 20-NREC COV-040
- AOB

- The Chair welcomed the committee.

- The minutes from meeting on 6th May 2020 were approved.

- Matters arising from the 6th May meeting as follows:

(1) The Head of Office for NRECs confirmed that 8 of the 9 applications receiving *provisional approval* at 6th May meeting had since received *final approval,* having satisfied the additional queries of the committee.

(2) The Head of Office for NRECs noted receipt of the committee's aligned guidance for applicants for the purposes of ethics review of research involving consent from participants who lack capacity.

(3) The Office PM confirmed response from the State Claims Agency that it is the responsibility of the applicant / Principal Investigator to inform the State Claims Agency of ethics approval by NREC COVID-19 where the Clinical Indemnity Scheme is applicable to the research study.

Applications

Application Number	20-NREC-COV-024
Applicant	Dr Liesbeth Rosseel
Study Title	Percutaneous Coronary Intervention patterns in the Republic of Ireland during the COVID-19 outbreak
Institution	Galway University Hospital
NREC COVID-19 Comments	• The committee agreed that this anonymised retrospective study would provide an objective data-set on the impact of COVID-19 on patients being treated with PCI. • The committee agreed that this study does not present notable issues from an ethics or data protection perspective.
NREC COVID-19 Decision	*Provisional Approval*
Associated Conditions	1. The committee requires confirmation that the same anonymisation approach will be taken in the other 5 centres, and requests confirmation in this regard from all centres. 2. The committee requires clarification on the sample size for this study.

Application Number	20-NREC-COV-026
Applicant	Dr Fionnuala Cox
Study Title	Emergency transition of hospital-based Immunoglobulin replacement therapy to home-based self-administration due to COVID-19; impact on disease management and patient satisfaction.
Institution	St James's Hospital
NREC COVID-19 Comments	• The committee agreed that a reasonable and straight-forward approach is proposed for this informative study. • Given there are no questions relating to COVID-19, there was a suggestion to contextualise the questionnaire with appropriate COVID-19 relevant information.
NREC COVID-19 Decision	*Provisional Approval*
Associated Conditions	1. The committee is unclear if the 38 participants in question are solely from SJH or from the collective of the three hospitals; please provide clarification. 2. Given the small number of participants with a rare disease, there is reasonable likelihood of patient identification from data variables including hospital, age and gender; the committee requires that informed consent be sought and recorded from participants. 3. Furthermore, the committee is unclear if the 64 patients already administering IV or sub-cutaneous immunoglobulin at home or in satellite clinics, will be included in the survey; if so, the committee requires that these participants are also asked for their informed consent. 4. The committee is unclear as to who is the Data Controller and Data Processor and requires confirmation in this regard. 5. The committee notes that Survey Monkey will be employed in the methodology; mindful that IP addresses can be traceable with this tool, the committee requires justification as to the security that can be afforded to participants' data.

Application Number	20-NREC-COV-030-1
Applicant	Dr Nollaig Burke
Study Title	SABS-TILDA: SARS-CoV-2 specific AntiBodieS in The Irish LongituDinal Study on Ageing (TILDA): an opportunity to assess COVID-19 rates and phenotypes in older adults in Ireland
Institution	Trinity College Dublin
NREC COVID-19 Comments	• The committee noted this application represents an amendment to TILDA, a long-running large (>6000

	participants) study, previously receiving ethics approval from TCD.
NREC COVID-19 Decision	*Provisional Approval*
Associated Conditions	1. Regarding the proposal to visit participants' homes, the committee requests clarification as to the infection control measures to be undertaken. 2. The committee notes the statement in the application that a protocol amendment is not required, however this should be done to encompass SARS-COV-2 antibody testing. 3. Further to above, the committee requires that the PIL and consent materials are updated to reflect the reasoning for and explanation of SARS-COV-2 antibody testing. 4. The committee requires that the blood draw amount be updated in the documentation to reflect the increase now required for SARS-COV-2 antibody testing.

Application Number	20-NREC-COV-030-2
Applicant	Prof. Rose Anne Kenny
Study Title	Altered lives in a time of crisis: Preparing for recovery from the impact of the COVID-19 pandemic on the lives of older adults (TILDA)
Institution	Trinity College Dublin
NREC COVID-19 Comments	• The committee agreed it is unable to make a decision in the absence of the reviewing the COVID-19 questionnaire to be sent to TILDA participants.
NREC COVID-19 Decision	*Deferred*
Associated Conditions	N/A

Application Number	20-NREC-COV-031
Applicant	Dr Bairbre McNicholas
Study Title	APPROVE-CARE Awake Prone Positioning to Reduce invasive VEntilation in COVID-19 induced Acute Respiratory failure
Institution	Galway University Hospital
NREC COVID-19 Comments	1. Recognising that the study is addressing an important question on the impact of prone positioning on patients with hypoxemia due to COVID-19, the committee is unclear as to the composition of the study (one or two projects?, what is the BioImpedence substudy?), the outcomes, and the randomisation approach. Furthermore, the committee is unclear as to where the study is being done (two or seven sites) and who are the lead sub-PIs at each site.

	2. The committee notes lack of clarity on the inclusion and exclusion criteria for participants (eg RR >40 is inclusion criterion, but then listed as exclusion criterion in protocol), in addition to absence of consent forms and PILs. 3. Regarding the randomised controlled trial, the committee is of the view that the informed consent process is not robust and has concerns about the small size of the trial. 4. Regarding data protection considerations, the committee notes that the DPIA form is incomplete and DPO form is unsigned and has no outcome recorded. The committee is unclear if personal data will be entered into the central database or not due to contradictory information. 5. The committee is of the firm view that a data monitoring committee is necessary for a randomised controlled trial.
NREC COVID-19 Decision	*Approval Declined*
Associated Conditions	N/A

Application Number	20-NREC-COV-032
Applicant	Prof Eleanor Molloy
Study Title	CONTINUUM: COvid-19 NeonaTal, chIld aNd adUlt: uUnderstanding iMmune responses
Institution	Trinity College Dublin
NREC COVID-19 Comments	• The committee agreed that this study includes a clear protocol to investigate the differential immune responses of neonates, children and adults to COVID-19 infection. • The committee noted the low risk assigned by the DPO.
NREC COVID-19 Decision	*Provisional Approval*
Associated Conditions	1. The committee is unclear as to the number of participants to be enrolled; references to n=300 (DPIA document), n=200 (section 2.5, NREC application form), and n=400 (section 3.1, NREC application) are made – the committee requires confirmation. 2. The committee is unclear as to the timepoint during COVID illness that blood samples will be taken; clarification is required. 3. The committee notes that reference is made in the protocol to assessment of follow-up clinical data, and requires clarification as to what this refers, when it will occur, how often, and by whom in the research team. 4. The committee is of the view that the lay abstract is not written in plain English and requires it be rewritten accordingly. 5. The committee notes the statement that 'Data will be destroyed once the research study is completed and published', and elsewhere it is stated that data will be held for 5 years; the

	committee requires the applicant to source their institutional policy on data management and retention, and adopt the requirements therein. 6. The committee observes there is conflicting information on where the key will be stored (Trinity or Tallaght?) and requires clarification in this regard. *7.* Recognising that blood samples will be taken from both cases and controls, the committee notes separate reference to samples of urine and saliva and requires explanation of the intention of the methodological approach. 8. The committee requires clarification on how the control group will be recruited, and requests consideration be given to COVID-19 testing of the 'healthy individuals' who may have been asymptomatic for a past infection. 9. The committee is of the view that the 'No' tick boxes in answer to questions in the consent forms is misleading; rather a clear statement with the opportunity to tick the 'Yes' tick box is more appropriate 10. The committee notes several typos, including section 3.3*, 'healthy controls with inflammatory conditions'* and requires accuracy is ensured throughout.

Application Number	20-NREC-COV-034
Applicant	Dr Emma Nicholson
Study Title	CUPID COVID-19
Institution	University College Dublin
NREC COVID-19 Comments	• The committee agreed that this is a worthwhile study with a clear workplan to investigate the changes in and barriers to ED attendance by the paediatric population during the COVID-19 pandemic. • The committee agreed that potential harms were well-addressed by the applicant.
NREC COVID-19 Decision	*Provisional Approval*
Associated Conditions	1. Regarding WP2, the committee requires clarification on how long the audiotapes will be retained for and the plan for their destruction. The applicant should comment on the alignment of the study's approach with her institutional policy on data management / retention. 2. Regarding WP3, the committee is unclear as to the timeframe and means of participant consent and requires clarification in this regard.

	3. Noting that Qualtrics is a tool for WP3 of this study, the committee requires assurances as to the security and anonymity that this software can afford participants' data. 4. Further to WP3, the committee requires that consent is required prior to admission to the survey. An appropriate consent statement is required at the start of the survey to which participants can 'tick box', with preclusion to proceed if consent is not agreed.

Application Number	20-NREC-COV-035
Applicant	Prof. Tim Lynch
Study Title	An assessment of Neurological illness during a pandemic of severe acute respiratory syndrome – coronavirus – 2
Institution	Dublin Neurological Institute
NREC COVID-19 Comments	• The Committee agreed that this multisite observational cohort study has a satisfactory approach to address the research question. • There was a suggestion that a recruitment SOP would be useful to ensure consistency at the various sites.
NREC COVID-19 Decision	*Provisional Approval*
Associated Conditions	Potential participants are to be recruited by a variety of inpatient and outpatient interfaces (Section 3.2). Please describe in more detail the steps to be followed, for example: 1. At what point does the research team get notified of a potential participant being an inpatient? 2. Are patients being referred solely on clinical grounds or because neurology is conducting a research study? 3. When does the patient get presented with the opportunity to participate in the research study – is it at the end of their treatment and prior to discharge? How can you ensure there is sufficient differentiation between treatment and participation in the research study? 4. While minimising unnecessary interaction with patients is desirable, it would be preferable to obtain written consent, where possible, to participate in the research study. This should be feasible in most cases as participants are provided with a PIL and the project is discussed with them. The circumstances in which written consent is not possible by the participant should be identified and clear procedures documented for all sites.; the committee requires confirmation in this regard. 5. Please confirm that those with existing neurological disease will have a PIL sent to them if they are an outpatient? (Section 4.1.3 (i))

	6. The consent form should have more information about the study and not just rely on the PIL; please address. 7. The PIL should clearly outline the chart review will be repeated at 6- and 12-months (at present it is in the Data Protection section); please address. 8. The committee requires clarification if consent being sought for all chart reviews involved in the study; if so, this should be more clearly outlined and explicit consent provided - please address. 9. The committee notes that Section 4.2.1 and 4.2.2 have been left blank. What efforts will be made to support people to give consent who may need additional supports to do so?

Application Number	20-NREC-COV-037
Applicant	Prof. Catherine Darker
Study Title	Creating an evidence-based toolbox for targeted public health interventions during COVID-19: a cross-border analysis to disentangle psychological, behavioural, media and governmental responses.
Institution	Trinity College Dublin
NREC COVID-19 Comments	• The committee agreed that this collaborative all-island study poses an interesting question to improve public health responses to disease. • The committee noted the clear discussion by the applicant on the study's use of information from social media.
NREC COVID-19 Decision	*Provisional Approval*
Associated Conditions	1. Noting the intention to use social media platforms in study two, the committee requires clarification as to the particular forums intended for sourcing data. *2.* The committee is of the view that written consent by email is a more appropriate means of gaining consent for the focus group component of the study, given participants' identifiable contact details will be provided to TCD.

Application Number	20-NREC-COV-038
Applicant	Dr Katie Baird
Study Title	Compassion, social connectedness and trauma resilience during the COVID-19 pandemic: A multi-national study
Institution	Irish Centre for Compassion Focussed Therapy
NREC COVID-19 Comments	• The committee agreed that this study has a satisfactory approach overall to addressing the research question. • The committee noted that the lead institution is University of Coimbra, Portugal.
NREC COVID-19 Decision	*Provisional Approval*
Associated Conditions	1. The committee notes that a personal ID is proposed for linkage across three survey points is last 3 letters of family name and last 2 digits of phone number; a more confidential while memorable ID is advised for privacy reasons. 2. The committee requests a rationale for the sample size and suggests that this could be based on a key outcome variable. 3. The committee requires more information on the planned statistical analyses. 4. The end date to withdraw as cited in the consent form is 10-01-2021: the committee asserts that consent can't be limited in this way as final one-year follow-up data not yet collected at this time. Please address accordingly. 5. The committee requires further clarity as to the purpose of the study. The application and the PIL refers to "Compassion, Social Connectedness and trauma resilience during COVID-19" while the questionnaire refers to having "a representative picture of how COVID-19 is affecting Irish families". 6. The committee notes several language anomalies, which may have resulted from translation e.g. page 27 "I find hard picturing self getting coronavirus", what is meant by being at "high risk" – a definition is required, references to 'self-isolation' and 'social distancing.' It is possible for instance to be self-isolating in a house if a person lives alone – it is not a sick room. Physical distancing refers to keeping >2m away from anyone else. The committee's advice is to be clear what is meant by the question so the answers are interpretable across individuals, time and countries. The committee is unclear as to the purpose of the question about Irish families. Comment is required on the likelihood of participant understanding of each term refers to and the difference between them as interventions –CMT, CCT, MSC etc. The COVID-19 section needs an introduction as to the purpose of the questions - some are explicitly COVID-related while others are more general.

	7. The committee requires that the questionnaire include a more detailed introduction, restating purpose, consent, and data protection considerations. 8. Regarding the PIL, and the answer to 'Why invited' as 'because you are an adult' – please provide more explanation. It states participants will sign, however it's electronic distribution. 9. The committee requires clarification on the surety that participants are from Ireland if advertising is on social media. The committee suggests that this may need to be a question in the form – i.e confirm age 18+ and living in Ireland. 10. The committee notes that the PIL does not describe what is being asked of participants. There is no mention of the different measures/concepts being used; please address. 11. Advert/introduction letter doesn't state participation is voluntary and they can withdraw at any time; please address. 12. The committee requires a copy of professional indemnity, noting that the PI has personal indemnity. 13. Regarding recruitment, the committee requires clarification on what social media platforms are being used and information on efforts to ensure representation across age and socio-economic groups. 14. The committee notes that participants are directed to lodge complaints arising from the use of their information to an email address for the DPO in Portugal. The committee requests confirmation that complaints will be dealt with by someone who is proficient in the English language.

Application Number	20-NREC-COV-040
Applicant	Prof Andrew Murphy
Study Title	Platform Randomised trial of INterventions against COVID-19 In older people (PRINCIPLE)
Institution	National University of Ireland, Galway
NREC COVID-19 Comments	• The committee agreed that this platform randomised control trial clearly represents a valuable contribution to research. • The committee noted this application pertains to the Irish arm of an international study based at Oxford.
NREC COVID-19 Decision	*Provisional Approval*
Associated Conditions	1. Recognising this study is a proposed extension to a clinical trial ongoing in the UK, the committee is unclear as to who the Principal Investigator is in Ireland. If it is Prof. Andrew Murphy, a CV should be provided to the committee, and clarification provided on the PI role in Ireland. 2. Further to above, localisation for Ireland (eg logos) is also lacking on documentation, in addition to referral of participants to an Irish source of information on rights with respect to personal data (eg www.dataprotection.ie); the committee requires that the documentation throughout is tailored appropriately. 3. The committee is unclear on the recruitment strategy for the 20 as yet unidentified practices in Ireland and require explanation in this regard. 4. The committee requires further information on where and how the COVID-19 testing will be done in Ireland, mindful of not contributing to unnecessary person-to-person contact during the health emergency. If using normal routes to testing via GPs the committee requires assurance that the system will not be overwhelmed but testing should be at normal rates. 5. The committee requires clarification on how questions can be feasibly posed and addressed for participants who complete consent forms online. The committee is of the view that a form of 'active' consent needs to be put in place e.g. a set of consent statements similar to a normal consent form plus a box to tick if the respondent agrees/consents. 6. The committee requires clarification on how many arms are being proposed in the Irish study as the full protocol and PILs etc given in the documents submitted mention 3 arms – an extra 'usual' treatment arm. If just 2 arms in Ireland the information sheets etc need to be adjusted accordingly. 7. The committee requires confirmation on source and funding of the medications under investigation. Furthermore, noting the pharmaceutical presentation of the medication in a 15-tablet

	pack, the committee requests comment on the suggestion to dispose the 15th tablet, in light of this medication being a potentially scarce resource. Is there a way to reduce this wastage? 8. The committee requests confirmation that the other medications taken by patients, including those with comorbidities, will be recorded with a view to managing potential drug interactions. If reliant on GPs' assessment on the eligibility CRF will there be checks made to prevent anyone being given an inappropriate treatment on randomisation?

- AOB: None
- The Chair closed the meeting