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: 19th August 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
Prof. Mary Donnelly	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 Jean Saunders	Committee member, NREC COVID-19
Prof. Shaun O'Keeffe	Committee member, NREC COVID-19
Prof. Tom Fahey	Committee member, NREC COVID-19
Prof. Suzanne Norris	Committee member, NREC COVID-19
Ms Dympna Moran	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

* Subset of committee convened
ǂ Drafted minutes

Apologies: Prof. Pat Manning

Quorum for Decisions: Yes

Agenda

- Welcome & Apologies
- Minutes approval 5th August & Matters Arising
- Declarations of Interest

- Application 20-NREC-C0V-095
- Application 20-NREC-C0V-104
- Application 20-NREC-C0V-093
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- Application 20-NREC-C0V-100
- Application 20-NREC-C0V-101
- Application 20-NREC-C0V-102
- Application 20-NREC-C0V-103
- Application 20-NREC-C0V-105
- AOB

- The Chair opened the meeting and welcomed the committee

- The minutes from meeting on 5th August were approved

- Matters arising from the 5th August meeting were as follows:

  (1) The Head of the National Office provided a running count of applications considered by NREC COVID-19 to date

- Declarations of Interest: none

Applications

Application Number	20-NREC-C0V-095
Applicant	Prof. Fionnuala Ní Áinle,
Study Title	Coagulopathy of COVID-19: A Pragmatic Randomized Controlled Trial of Therapeutic Anticoagulation versus Standard Care as a Rapid Response to the COVID-19 Pandemic (RAPID COVID COAG)
Institution	Mater Misericordiae University Hospital
NREC COVID-19 Comments	• The committee notes that this study is to comprise sites in Dublin, Amsterdam, Toronto and Vancouver • The committee agreed that this application is supported by a very clear protocol with potential for significant benefit to patients
NREC COVID-19 Decision	*Provisionally Approved*
Associated Conditions	1. The committee is unclear on the number of patients to be enrolled in Ireland (the protocol states 24 yet the application form states differently) and requires clarification.

	2. The committee notes that 'ample time' will be provided to consider participation, and requests that a minimum amount of time should be specified. 3. The committee requires that for all participants, capacity to consent and participate will be assessed on a case by case basis as per the recruitment protocol. 4. The committee observes that the Participant Information Leaflet (PIL) lists 'hemorrhage' as a common (>5%) side-effect without making a distinction between the standard and experimental limbs. In this regard, the committee requests that the PIL contain the critical information that participants need to understand, along the lines of below: • Specify that most bleeding episodes are mild but serious life-threatening bleeds can occur (indicating this is more common with greater age) • Serious bleeds more likely if allocated to the experimental limb

Application Number	20-NREC-C0V-104
Applicant	Prof. John Laffey
Study Title	Charter Trial - Can Nebulised HepArin Reduce acuTE lung injury in Patients with SARS-CoV-2 Requiring Mechanical Ventilation in Ireland (CHARTER-Irl)
Institution	NUI Galway
NREC COVID-19 Comments	• The committee noted that this application represents a prospective proof of concept phase Ia/IIb study
NREC COVID-19 Decision	*Provisionally Approved*
Associated Conditions	1. Regarding the Participant Information Leaflet (PIL), the committee notes that participants will be asked for a retrospective consent if they regain consciousness and capacity; in this regard, the committee requires this component be rewritten (or an additional one provided) to reflect this. For example, '*While you were unwell, your next-of-kin agreed for you to participate in this study….'* 2. The committee notes that assent will be taken over the phone following reading out of the PIL; recognising these will be worried and stressed individuals, the committee asserts that the PIL as written could not possibly be assimilated as it is too long and complicated for this purpose. The committee suggests that a telephone script is drafted, informed by relevant information from the PIL, to support the assent process.

	3. The committee is of the view that the following PIL detail will hamper and not improve understanding, and requests it be removed: "…*samples being analysed for a marker called d-dimer (related to blood clotting), and inflammatory markers called interleukins, c-reactive protein, tumour necrosis factor, ferritin and procalcitonin*" etc. 4. The committee requests that it is made clear in the participant materials that this is a preliminary / experimental study. 5. The committee is of the view that the following sentence on risk information – *'On rare occasions bleeding in or around major organs can occur with large doses',* is too vague; the committee requests it should be made explicit that major life-threatening bleeding is a known side-effect of heparin. 6. Noting that *"The relative may be offered a copy of the blank Information leaflet / consent form by email or post if they wish to receive this*", the committee requires this is always be sent.

Application Number	20-NREC-C0V-093
Applicant	Prof. Eilish McAuliffe
Study Title	Expanding Care Capacity through Remote Monitoring of COVID-19 Patients
Institution	University College Dublin
NREC COVID-19 Comments	• The committee noted that this retrospective cross-sectional study involves two sites - Mater Hospital and University Hospital Limerick
NREC COVID-19 Decision	*Provisionally Approved*
Associated Conditions	1. The committee requests that you clarify how questionnaires and invitations for interview will be distributed. 2. The committee notes that Qualtrics 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 Qualtrics including plans to immediately de-identify the data (including URLS, cookies) when received. 3. The committee is of the view that some questions may be distressing to some individuals, and that this risk should be adequately captured in the Participant Information Leaflet (PIL). Furthermore, details of appropriate avenues of support should be provided in participant materials in addition to contacting a GP. 4. The committee requests confirmation of who will hold the pseudonymisation key. The committee recommends that the

	master key be retained by a trustworthy member of staff who is not part of the research study team. 5. The committee requests confirmation of who will destroy the contact data after the interviews and at what stage it will be destroyed. 6. Given the hierarchical relationship between staff members and lead investigators, the committee highlights the potential risk of coercion in the recruitment of participants and requests clarification as to how these risks will be mitigated. 7. The committee requests additional clarity around consents: a. How will participants be contacted? b. How will consent for the survey and interviews be obtained? c. How will consent for clinical material be obtained? 8. The committee notes that the lay summary text (Section 1.3) was replicated from the aims and objectives (Section 2.2). The committee requests that an appropriate lay summary is submitted.

Application Number	20-NREC-C0V-096
Applicant	Dr Elaine Smith
Study Title	An exploration of service users' and psychologists' experiences of tele-therapy during Covid-19 within HSE Psychology services
Institution	HSE Dublin South, Kildare & West Wicklow
NREC COVID-19 Comments	• The committee agreed that this application represents an important study with potential to inform future telemedicine practices
NREC COVID-19 Decision	*Provisionally Approved*
Associated Conditions	1. The committee requests further information on how the participants will be contacted, in particular for the interviews. 2. The committee notes that Survey Monkey is a commonly used tool, however it requires 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 any plans made by the investigators to immediately de-identify the data (including URLS, cookies) when received. 3. The committee requests that the consent form incorporates a checkbox after each statement for the participant to affirm their agreement, in addition to the signature for consent. 4. The committee requires a statement or set of statements of consent at the beginning of the online questionnaire with a checkbox for recipients to tick (suggested statements below).

	There should be a preclusion to proceed to the questionnaire unless this box is ticked. • I understand that you will ask me to fill in some questions • I don't have to do this, unless I want to • I am happy for you to use my answers • My answers will be kept in confidence and it will not be possible to identify me from my answers • I can stop at any point [Tick Yes to proceed] 5. The committee requests confirmation on who will hold the pseudonymisation key. The committee recommends that the master key be retained by a trustworthy member of staff who is not part of the research study team. 6. The committee requests further information on how consent will be recorded; verbal consent is mentioned – is this witnessed/recorded? 7. The committee accepts that identifying details are needed to contact the interviewees but asserts that these should be destroyed as soon as transcriptions have taken place. 8. Given the relationship between the psychologists and lead investigators, the committee highlights the potential risk of coercion in the recruitment of participants and requests explanation as to how this will be mitigated.

Application Number	20-NREC-C0V-098
Applicant	Ms. Charlotte Ryan
Study Title	A cross-sectional patient-reported study to assess the impact of the COVID-19 pandemic on the attitudes and preferences for administration of Somatostatin Analogues (SSAs) at home or in a healthcare setting for patients with a diagnosis of Neuroendocrine Tumours (NETs) or Acromegaly
Institution	University Hospital Limerick
NREC COVID-19 Comments	• The committee agreed that this application represents an important study involving University Hospital Limerick, Mercy Hospital Cork, St Vincent's University Hospital, and Beaumont Hospital
NREC COVID-19 Decision	*Provisionally Approved*
Associated Conditions	1. The committee asserts that implied consent is not valid under GDPR and requests that a question to confirm consent is added to the top of the questionnaire.

	2. Given the relationship between patients and the lead investigators who are their treating healthcare professionals, the committee highlights the potential risk of coercion in the recruitment process and requests explanation as to how this risk will be mitigated. 3. The committee requests evidence of agreement of participation from the lead investigator at the three additional sites. 4. The committee is of the view that some questions in the questionnaire may be distressing to some individuals and that this risk should be adequately captured in the Participant Information Leaflet (PIL). Additionally, details of appropriate avenues of support should be provided in participant materials. 5. The committee notes some tracked comments and edits within the version of the questionnaire submitted for review and requests confirmation of the final version of the questionnaire.

Application Number	20-NREC-C0V-099
Applicant	Dr Conor McAloon
Study Title	Using contact tracing data to gain insights into the epidemiology of COVID-19 infection in Ireland
Institution	University College Dublin
NREC COVID-19 Comments	• The committee agreed that this application is supported by a very well put together protocol • In view of the continued operation of the national contact tracing system by the HSE, the committee suggests formal engagement with the HSE and relevant experts who developed and oversaw the national system to inform this research project, identify sources of bias in the data set (as identified in application form Section 2.6) and facilitate engagement regarding emerging results and recommendations for future practice
NREC COVID-19 Decision	*Final Approval*

Application Number	20-NREC-C0V-100
Applicant	Dr. Niamh Liddy
Study Title	What is the impact of the Covid 19 pandemic on the number and the nature of Admissions to Acute Psychiatric Units for Inpatient Care?
Institution	HSE West, Galway

NREC COVID-19 Comments	• The committee agreed that this multisite study addresses an important topic
NREC COVID-19 Decision	*Provisionally Approved*
Associated Conditions	1. The committee requests that DPO advice is sought and the feedback arising provided to the committee. 2. The committee queries whether it is possible to use patient ID numbers rather than name / date of birth to avoid the collection of personal data when identifying first-time admissions for the chart review; in this regard, the advice of the DPO will be important. 3. Given that it will be the Principal Investigator scoring data from all the charts, the committee requests justification of the risk of confirmation bias and explanation of how this risk can be mitigated to ensure that robust conclusions can be drawn. 4. In relation to the security of the dataset, the committee requests confirmation if the computer is password protected, or the file itself, or both. 5. In line with best practice, the committee recommends that the data is not destroyed until after the study is published.

Application Number	20-NREC-C0V-101
Applicant	Dr Niamh Allen
Study Title	Prevalence of COVID-19 Antibodies in Irish Healthcare Workers (PRECISE)
Institution	St. Vincent's University Hospital
NREC COVID-19 Comments	• The committee noted that this seroprevalence study will be carried out in two areas of differing levels of COVID-19 diagnosis – St James's Hospital and Galway University Hospital
NREC COVID-19 Decision	*Provisionally Approved*
Associated Conditions	1. The committee notes mention of study advertisement material (section 2.6) and requests sight of this. 2. The committee requests justification of the oversight possible by the PI if s/he is based in St. Vincent's Hospital while study being conducted in Galway and St. James's. 3. The committee is of the view that some of the language in the Participant Information Leaflet (PIL) may be perceived as coercive, for example 'requested' by NPHET and 'We hope you will agree to take part in this important study'; please amend appropriately. 4. Further to the PIL, it states that testing of blood sample at site is 'to be confirmed', which is conflicting with information in the application form; the committee requires clarification.

	5. The committee notes there are typos in St. James's Hospital website address and 'Principal Investigator' in the PIL. 6. The committee is of the view that an HSE/hospital email address in the PIL contact details is more appropriate than a Gmail address. 7. The committee observes that the PIL / consent don't state that HR/Occupational Health will not be informed of results as per application form, and requires this be made clear. 8. The committee requests that the PIL includes details of the intention to share aggregate results and by what methods eg research journals. 9. To counter potential distress, the committee requests that contact details for appropriate supports be provided to those who test positive for antibodies but never knew they may have had Covid-19. 10. The committee notes the intention to conduct 6-month follow-up and requests sight of the consent form in this regard. Moreover, the committee requires that it is made clear to participants that their data from the two tests will be linked.

Application Number	20-NREC-C0V-102
Applicant	Dr Irina Tal
Study Title	Irish Attitudes to Privacy in Times of COVID19
Institution	Dublin City University
NREC COVID-19 Comments	• The committee agreed that the study underpinning this application is not high risk
NREC COVID-19 Decision	*Provisionally Approved*
Associated Conditions	1. The committee queries if the survey has been piloted as it is quite lengthy; in this regard, it requests justification of its feasibility. 2. The committee notes the sampling frame is limited in restricting approach of participants via social media, DCU mailing list, LERO and ADAPT research centres; the committee requests justification of this approach to obtain a representative sample from the general population.

Application Number	20-NREC-C0V-103
Applicant	Prof. Colin Doherty
Study Title	Analysing blood-brain barrier integrity to inform on protection from CoVID-19 associated encephalopathy.
Institution	St James's Hospital
NREC COVID-19 Comments	• The committee noted that this study comprises three related work-packages examining the impact of COVID on the blood brain barrier
NREC COVID-19 Decision	*Provisionally Approved*
Associated Conditions	1. The committee requires further clarity on the proposed access to brain tissues post-mortem – how is the relevant tissue being provided? 2. The committee requires additional information on the consent process for the post-mortem component. The committee asserts that consent for research is distinct from consent to retain samples. Therefore, a separate consent to research on the retained samples must be obtained. 3. Regarding the consent for MRI procedure, the committee observes that consent will be obtained 'just before the MRI' but that the Participant Information Leaflet will be provided 2 weeks before. The committee requires that sufficient opportunity is afforded to participants to ask questions before they attend for the procedure. *4.* The committee requests more information in the answer in the Participant Information Leaflet to '*Will I be told the outcome of the study?'* to reflect other relevant issues beyond maintaining the privacy of the participants' data. Participants may have other reasons why they would wish to be told the outcome of the study and these should be addressed.

Application Number	20-NREC-C0V-105
Applicant	Ms. Norma Caples
Study Title	A study to determine the perceived value, impact, use and the effect of the Fluid Heart Tracker App on patients with heart failure and on service providers.
Institution	University Hospital Waterford
NREC COVID-19 Comments	• The committee noted that this multisite study will involve heart failure nurse specialists at 16 research sites • The committee agreed that this study is represented by a well put together application
NREC COVID-19 Decision	*Provisionally Approved*

Associated Conditions	1. The committee requires a number of methodological issues be clarified: • What is the primary outcome measure for the study? • How does the primary outcome relate to the proposed sample size calculation? • How will the process of care be altered by the App (eg intensification of treatment)? • How will patients' symptoms in relation to the monitoring of weight be dealt with? 2. Regarding the Participant Information Leaflet, the committee requests: • The aims of the study are restated in more accessible language • Clarity on how long the study will last, in addition to the option to withdraw • Typos are corrected including duplication of heading 'ARE THERE ANY RISKS TO TAKING PART IN THE STUDY?, and several in data protection section • The detail on contacting the GP is separated into an independent paragraph • The numbering of sections is reworked (use of a, b, c or i, ii, iii etc may assist) 3. Due to an unclear box tick in section 10, the committee seeks to confirm that a consent declaration from the HRCDC is not required nor sought.

- AOB:

(1) It was agreed that for the small number of applications with pending responses to provisional approvals, who have yet to respond despite reminders, that the committee's decision can be withdrawn in consultation with the Chair.

(2) The Head the National Office explained the process for the standing sub-committee, which will be in place to meet oversight and related responsibilities for the research approved by the NREC COVID-19.

(3) The Head the National Office reminded the committee of the webinar on 3rd Sept to explain the work of the NREC COVID-19.

(4) The Chair and the Head of the National Office thanked the committee for their hard work and commitment over the five-month tenure of NREC COVID-19

- The Chair closed the meeting