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: 5th August 2020

Location: virtual meeting

Attendance*

Prof. Mary Horgan	Chair, NREC COVID-19
Prof. Hannah McGee	Vice-Chair, NREC COVID-19
Ms Grainne McGettrick	Committee member, NREC COVID-19
Dr Donal O'Gorman	Committee member, NREC COVID-19
Prof. Mary Donnelly	Committee member, NREC COVID-19
Prof. Andrew Green	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. Shaun O'Keeffe	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
Dr Therese Lynn	Project Officer, Office for NRECs

* Subset of committee convened
ǂ Drafted minutes

Apologies: Prof. Pat Manning

Quorum for Decisions: Yes

Agenda

- Welcome & Apologies
- Minutes approval 22nd July & Matters Arising

- Declarations of Interest
- Application 20-NREC-C0V-086
- Application 20-NREC-C0V-017-Amend
- Application 20-NREC-C0V-092
- Application 20-NREC-C0V-088
- Application 20-NREC-C0V-089
- Application 20-NREC-C0V-091
- Application 20-NREC-C0V-094
- Application 20-NREC-C0V-087
- Application 20-NREC-C0V-090
- Application 20-NREC-C0V-085

- AOB

- The Chair opened the meeting and welcomed the committee

- The minutes from meeting on 22nd July were approved

- Matters arising from the 22nd July meeting as follows:

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

- Declarations of Interest: none

Applications

Application Number	20-NREC-C0V-086
Applicant	Dr Padraic Dunne
Study Title	COPE-CORONA: Identifying and strengthening personal resources among international healthcare workers to cope with the Corona pandemic
Institution	RCSI
NREC COVID-19 Comments	• The committee noted this application represents a multisite anonymous survey of healthcare workers (HCWs) evaluating post-traumatic stress, anxiety, depression and burnout during the pandemic
NREC COVID-19 Decision	*Provisional approval*
Associated Conditions	1. The committee is unclear as to the study descriptor 'international' – will it involve healthcare workers (HCWs) based in different countries or international HCWs working in Ireland?

	Moreover, the committee requests confirmation of the Irish, and if relevant the international, sites involved. 2. With reference to 'strengthening' in the study title, the committee is of the view that this implies that an intervention will take place; please justify and amend accordingly. 3. The committee notes that Qualtrics will be used as the survey tool and requires assurance of the security that it can afford participants' data including plans to immediately de-identify the data (including URLS, cookies) when received. 4. 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. 5. The committee queries if supports will be made available to participants should they find the survey and interviews upsetting? 6. The committee notes that the HCWs to be included in the survey as listed in the Participant Information Leaflet does not include Social Workers and Speech & Language Therapists, and requests clarity – will all HCWs be included?

Application Number	20-NREC-COV-017-Amend
Applicant	Prof. John Laffey
Study Title	ExtraCorporeal Membrane Oxygenation for 2019 novel Coronavirus Acute Respiratory Disease (ECMOCARD)
Institution	Galway University Hospital
NREC COVID-19 Comments	• The committee noted that this application represents an amendment to a study receiving NREC COVID-19 approval on 8th May 2020
NREC COVID-19 Decision	*Provisional approval*
Associated Conditions	1. Regarding the additional two hospital sites – St Vincent's and Beaumont Hospitals, the committee requires confirmation / evidence of agreement from the respective sites. 2. The committee notes several references to Australian sites and requires clarification of their role.

Application Number	20-NREC-C0V-092
Applicant	Prof. Alistair Nichol
Study Title	Genetics of Mortality in Critical Care (GenOMICC)
Institution	St. Vincent's University Hospital
NREC COVID-19 Comments	• The committee agreed that this application represents a very important multisite international observational study
NREC COVID-19 Decision	*Provisional approval*
Associated Conditions	1. The committee is unclear on the precise genetic analyses to be conducted and requests detail in this regard. Will heritable traits be identified? If so, will relatives be informed? Will modifiable epigenetic traits be identified? 2. The committee queries if participants will be all 'COVID positive' or 'probable COVID'. 3. The committee queries where and what the control cohort will be, in addition to how many participants, including controls, will be included. 4. The committee notes the blood sample will be transported to Edinburgh for DNA extraction and requires clarity on what exactly will be done with the sample in the immediate term and future. Moreover, the committee requests assurance of the plan for the management and security of data post-Brexit. 5. The committee requests that the PIL more clearly explain the plan to link predisposition, current comorbidities and outcome. Furthermore, explanation of potential future studies should be provided eg will future studies only encompass COVID-related research, or might this cohort comprise a control set for investigation of other diseases? 6. Noting the option for a participant to withdraw and the destruction of the sample, the committee requests confirmation that the DNA and associated genomic data will also be deleted. 7. The committee requires that the key for reidentification be held by a trustworthy member of hospital staff not involved in the study. 8. The committee is of the view that the planned follow-up to determine if a participant is still alive will present more than inconvenience for some, and requests that the potential upset is acknowledged by the study team and in participant materials. 9. The committee notes that the consent / assent forms have a choice of a yes/no box 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. 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. 10. Recognising the inclusion of an assent procedure, the committee requires confirmation that the study team will observe the below: An adult not able to consent should, as far as possible, take part in the information/authorisation procedure. The objectives as well as the potential risks and benefits of the research should be explained as fully as possible using easily comprehensible language appropriate to their level of understanding. Where a prospective research participant lacks capacity but has some ability to understand the significance of the research, the researcher should ascertain the wishes of that individual with respect to his/her participation. Refusal or reluctance to participate in a research project by an individual lacking capacity should be respected. If a prospective research participant, despite all efforts possible in the circumstances, is unable to provide his or her own informed consent to participation in the study, the assent of a person - generally someone with a close ongoing personal relationship with the person- who can provide the best interpretation of the will and preferences of the person should be sought. Please note that "next of kin" has no legal authority to consent under Irish law. A person who has a close ongoing personal relationship does not have to be a member of one's family. An attorney under the Enduring Power of Attorney in Irish law does not have legal authority to consent to research. If the person subsequently recovers the ability to consent, his or her consent to use his or her data and, if appropriate, to continued participation in the study should be sought. 11. The committee notes that this study is under consideration by the HRCDC for certain elements, and in this regard asserts that no research should be undertaken until all the necessary health research approvals are in place.

Application Number	20-NREC-C0V-088
Applicant	Prof. Fiachra Cooke
Study Title	ReCaP: Rectal Cancer Management During the COVID-19 Pandemic
Institution	University Hospital Waterford
NREC COVID-19 Comments	• The committee noted that this application represents a multicentre study of rectal cancer management in Ireland and the UK conducted by surgical researchers
NREC COVID-19 Decision	*Provisional approval*
Associated Conditions	1. The committee requests sight of the finalised survey. 2. The committee requests evidence of agreement from each site to conduct the study. The committee asserts that NREC approval covers the ethics underpinning the study, however approval is required to actually conduct the study at each site. 3. Noting reference to NCCP and NCRI, the committee queries if each have agreed to collaborate and requests evidence of same. 4. Aspects of the study described in the application form and DPIA are contradictory including the approach to data transfer. Further to section 1 (iii), the committee recommends that data transfer is anonymous from each local site to the central system, and one nominated Irish site as co-ordinating centre for Ireland. 5. The committee is unclear on the study design (section 2.5); is it a case that the Irish lead centre de-identifies to invite patients to consent and then sends their information to the UK to conduct survey? 6. The committee requests assurance of the plans for data management and security in light of Brexit. The committee recommends that each local site contact their patient cohorts to invite them to participate and carry out the informed consent process pertaining to phase II; alternatively, justification is required for transfer of personal information to the UK to contact patients and that this is adequately address in the Participant Information Leaflet (PIL). 7. The committee is unclear as to how long data will be retained for and the period of data collection. 8. The committee is of the view that the PIL is poorly formatted and requires revision. (i) The opt-in / opt-out for different phases is confusing for participants as to what is actually being asked of them; please revise to ensure patients can easily understand what exactly they're agreeing to and /or requesting to be excluded from. The

	opt-in section has details for opt-out; please ensure opt-in is rephrased and is compliant with informed consent. (ii) Noting the plan to contact participants one and three years after the pandemic, the committee notes there is no acknowledgement that patients may be metastatic or palliative. The committee requires comment on the plans to mitigate for potential distress given some participants may have passed away during this time. (iii) The content in answer to 'Why have I been chosen?' requires further explanation. (iv) The committee requests that a procedure / resources are provided should patients become upset completing the survey. (v) Please provide Irish site-specific details for patients in Ireland to contact. (vi) GDPR rights are not included in the PIL regarding data processing / transfer / access etc and retention periods of data for example; please amend accordingly. (vii) 'Page 3 of 6' is on all pages of PIL; please correct accordingly. 9. Given that University Hospital Waterford and Chichester are lead sites, and REDCAP is hosted by University of Newcastle, the committee requires confirmation both that data will be stored in compliance with GDPR and the role of Newcastle University; please clarify references to same in the PIL. 10. The committee requires evidence of sponsor's insurance. 11. The committee requires the CV of Principal Investigator. The committee is unclear as to the recruitment approach – are all consecutive cases of rectal cancer admitted to the centre being included? How will this be achieved? The committee requires explanation if all patients are discussed at MDT and if not, how will patients not discussed be included/identified? 12. The committee notes that this study is under consideration by the HRCDC for certain elements, and in this regard asserts that no research should be undertaken until all the necessary health research approvals are in place.

Application Number	20-NREC-C0V-089
Applicant	Prof. Michael Barrett
Study Title	Epidemiology, severity and outcomes of children presenting to emergency departments across Europe during the SARS-CoV-2 pandemic
Institution	Children's Health Ireland
NREC COVID-19 Comments	• The committee noted that this application represents a retrospective cross-sectional chart review of pattern of presentation to paediatric emergency departments across Europe, in which Ireland has three sites • The committee agreed that this is a high-quality and well-prepared submission, which could be an exemplar to others
NREC COVID-19 Decision	*Provisional approval*
Associated Conditions	1. The committee notes that CHI will retain data for 10 years after which it will be destroyed, and also a separate reference to an agreement that data will be made available to the Imperial College for a period of 5 years with no reference to its destruction; the committee requests confirmation of the proposed approach and alignment of the documentation accordingly.

Application Number	20-NREC-C0V-091
Applicant	Prof. Jim Walsh
Study Title	Rapid assessment of the Implications of Covid-19 for People who use Drugs & Service Providers. (Survey)
Institution	Department of Health
NREC COVID-19 Comments	• The committee agreed that this application represents a worthwhile low-risk study
NREC COVID-19 Decision	*Provisional approval*
Associated Conditions	1. The committee requests more guidance is provided on who should complete the survey (eg what level of seniority / clinical expertise) to allow for some consistency given the inherent subjectivity the survey. Moreover, what objective measurement tools are being employed? 2. The committee requires further information on the plans, including targets and means, for dissemination of the study outcomes. 3. The Participant Information Leaflet requires the Department of Health logo and Principal Investigator's details. In addition, a statement to confirm the duration for data storage should be included.

	4. The committee requires that consent is required prior to admission to the survey. An appropriate consent statement, pertaining to both participation and data collection, is required at the start of the survey to which participants can 'tick box', with preclusion to proceed if consent is not agreed. 5. Recognising the association of this study with the related study 20-NREC-COV-094, where there are shared aspects (eg data dissemination, master key holder), the committee requests consistency of approach across both studies. 6. The committee requests that the master key is held by a trustworthy member of organisational staff not involved in the research study.

Application Number	20-NREC-C0V-094
Applicant	Prof. Jim Walsh
Study Title	Case studies for the Rapid assessment of the Implications of Covid-19 for People who use Drugs & Service Providers
Institution	Department of Health
NREC COVID-19 Comments	• The committee agreed that this application represents a worthwhile study with potential to inform ongoing policy
NREC COVID-19 Decision	*Provisional approval*
Associated Conditions	1. Regarding the proposed approach of semi-structured interview, the committee queries if this format may lead to identifiable personal data being obtained regarding participants or service users. 2. Further explanation of the nature of the case studies, including the likelihood of sharing of identifiable personal data, will in turn necessitate a revision of the Participant Information Leaflet. 3. The committee requests that the data protection elements of the consent form is revised to include specific mention of 'I consent to the use of my personal data in the following ways….etc' (those ways depending on the extent of the risk of identifiable personal data being revealed in the case studies). 4. The committee requests comment on how the methodology contained in application 094 will address the research questions as set out in section 2.2. 5. Recognising the association of this study with the related study 20-NREC-COV-091, where there are shared aspects (eg data dissemination, master key holder), the committee requests consistency of approach across both studies.

	6. The committee requests that the master key is held by a trustworthy member of organisational staff not involved in the research study.

Application Number	20-NREC-C0V-087
Applicant	Prof. Patrick Sheahan
Study Title	ICE: Impact of COVID 19 on ENT Surgery in Ireland
Institution	South Infirmary-Victoria University Hospital Cork
NREC COVID-19 Comments	• The committee noted that this application represents a re-submission of an application that was declined by the NREC COVID-19 on 3rd June 2020 • The committee agreed that the resubmission is much improved and addresses many of the previous queries of the NREC COVID-19
NREC COVID-19 Decision	*Provisional approval*
Associated Conditions	1. Noting reference to the collection of 'some extra data' in the Participant Information Leaflet, the committee requires that a brief appropriate explanation is provided therein. 2. Regarding the recruitment of children as participants, the committee requests that a script is provided for the conversation with parents, in addition to a parental consent form. 3. The committee notes the statement that surgeons' data will be 'fully anonymised' at a national level but is unclear if the surgeons' data will be linked to the patients they operate on. 4. The committee asserts that the data of professional participants deserves no less protection than that of their patients, and requests that data protection assurances are provided (in line with Section 9) for both groups. 5. The committee notes references to retrospective and prospective components to the study; as this is not described in the protocol, it requests clarity in this regard. 6. There is a consent process inconsistency whereby HSW consent is formally recorded but that of patients is not. The committee is unclear as to how patient consent will be actually be recorded; please clarify (eg patient consent form template). Furthermore, the committee asserts that thumbprint is inappropriate means of recording consent. 7. The application does not refer to the risk of transmission from HCW to patient and the committee requests that this risk is acknowledged in the patient materials; moreover, the committee cautions against an assumption that transmission only goes one way.

	8. Given the possibility of a cluster effect (eg medical teams, wards), the committee requires that this is factored into any analysis.

Application Number	20-NREC-C0V-090
Applicant	Prof. Patricia Fitzpatrick
Study Title	Analysis of the impact of COVID-19 pandemic on people with cystic fibrosis and parents of children with cystic fibrosis.
Institution	University College Dublin
NREC COVID-19 Comments	• The committee agreed that the application representing this online anonymous survey of Irish adults with cystic fibrosis (CF) and parents / guardians of children with CF, is well presented overall
NREC COVID-19 Decision	*Provisional approval*
Associated Conditions	1. The committee queries the statement in the Participant Information Leaflet (PIL) on the option to withdraw at any stage, however given the data is anonymised on submission, this will not be possible; please amend accordingly. 2. The committee notes mention of Survey Monkey (p. 37), however throughout the application SmartSurvey UK is referenced as the tool to be used; the committee requires confirmation in this regard. 3. The committee requests an estimation of predicted sample size. 4. The committee asserts that more information is to be gathered than is necessary for the research question under investigation by the UCD team; the details of and rationale for additional data (for example for analyses by Cystic Fibrosis Ireland) should be explained in the PIL.

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	• The committee noted that this study received provisional approval from the NREC COVID-19 on 22nd July 2020 • The committee discussed the applicant's response to its queries • Regarding the applicant's response to point 5, the committee was satisfied with the proposed approach of user-generated codes and this element of the study does not now need to be modified
NREC COVID-19 Decision	*Approved*

- AOB: none

- The Chair closed the meeting