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: 24th June 2020

Location: virtual meeting

Attendance*

Prof. Hannah McGee	Vice-Chair, NREC COVID-19
Prof. Mary Horgan	Chair, NREC COVID-19
Dr Donal O'Gorman	Committee member, NREC COVID-19
Prof. Mary Donnelly	Committee member, NREC COVID-19
Prof. Tom Fahey	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

* Subset of committee convened
ǂ Drafted minutes

Apologies: Sharon Foley

Quorum for Decisions: Yes

Agenda

- Welcome & Apologies
- Minutes approval 17th June & Matters Arising
- Declarations of Interest

- Application 20-NREC-C0V-065
- Application 20-NREC-C0V-067
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- Application 20-NREC-C0V-070
- AOB

- Prof. Hannah McGee (Vice-Chair) chaired the meeting and welcomed the committee.

- The minutes from meeting on 17th June were approved.

- Matters arising from the 17th June meeting as follows:

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

  (2) The Head of Office for NRECs confirmed that additional research funding awards are being made through the SFI COVID-19 rapid-response funding call, a number of which may be in scope for review by the NREC COVID-19.

- Declarations of Interest: none

Applications

Application Number	20-NREC-COV-065
Applicant	Dr Fiona Fenton
Study Title	A cross section observational study on the seroprevalence of antibodies to SARS-CoV-2 in a cohort of patients receiving Opiate Substitution Therapy: Consideration of possible protective effects of Opiate Substitution Treatment (OST) drugs on clinical manifestation of SARS-CoV-2.
Institution	HSE National Drug Treatment Centre
NREC COVID-19 Comments	• The committee agreed that this application represented a simple but worthwhile study
NREC COVID-19 Decision	*Provisional approval*
Associated Conditions	1. Noting that participants will be on Opiate Substitution Treatment (OST) and may also be taking other substances, the committee needs to be satisfied that participants will not view the study as linked to receiving their medication and therefore feel pressured to volunteer; please respond. The committee queries how potential participants with impaired judgement will be excluded. Correspondingly, the committee requests the applicant consider

	appropriate adjustments to the processes for recruitment or blood sample return in order to remove any risk of the participant feeling induced to volunteer. 2. In relation to recruitment, the committee is of the view that it would be best to recruit the 130-150 participants consecutively from clinics in order to reduce the risk of selection bias. 3. Regarding Section 2.1, the committee advises that symptomatic participants are directed to their GP for COVID-19 testing in accordance with national guidelines. *4.* The committee observes a statement in the PIL that having antibodies may confer *'some protection from future infection'* as a benefit; the committee is of the view that this generalised statement may be misleading based on what we know about COVID-19 to date, and requests it be removed. *5.* Furthermore, the committee requires the following statement in the PIL be removed: '*This could be because for example methadone can affect a patients breathing.'* 6. The committee is of the view that the data protection sections in the PIL is confusing and requires simplification. 7. The committee notes conflicting references to potential future research. For example, it is stated in the PIL that no other research will be carried out on the sample, yet in the consent form there are a range of options related to future use / destruction of material. The committee requests harmonisation of this inconsistency across the study documentation Secondly, the committee notes the range of options in the consent form is too complicated and seems unnecessary given the purpose is solely to examine seroprevalence; please clarify. Suggestion: noting the terms COVID-19 and coronavirus are used interchangeably in the PIL, the committee *suggests* that the terminology is standardised.

Application Number	20-NREC-C0V-067
Applicant	Prof. Jonathan Hourihane
Study Title	CORAL Study: Impact of Corona Virus Pandemic on Allergic and Autoimmune Dysregulation in Infants Born During Lockdown
Institution	RCSI
NREC COVID-19 Comments	• The committee agreed that this cross-sectional study on 1000 infants born between March and May 2020 has the potential to improve understanding of the early origins of lifelong diseases that constitute a major health and social burden in Ireland and other developed countries.

NREC COVID-19 Decision	*Provisional approval*
Associated Conditions	1. It is proposed that *'The Principal Investigator will retain the key for re-identification at CHI'*; the committee requests that the master key be retained by a trustworthy member of hospital staff who is not part of the research study team. 2. The committee notes in section 9.1.3 that personal details will be confirmed at each point of contact and is unclear if the master key is to be used to obtain these details at every data collection point in the study; please clarify. 3. The committee acknowledges that mandating a parent be fluent in written and spoken English will make the study easier to complete, however it cautions that this may negatively impact on the data collected and potentially discriminate against sectors of the community; please justify. Moreover, given the exclusion criteria, why is there a place for a translator to sign on the consent form? 4. Noting the exclusion criterion of *'Documented maternal SARS-CoV-2 infection'* (section 3.5), the committee asks what about other family members living in the same household? 5. The committee notes that *'No'* as been answered to the question on participant expenses (section 3.8), and requests justification for not covering the parents' out-of-pocket expenses. 6. The committee observes that consent will be sought for sample use in future studies '*not designed at present'* (section 6.2.5) and asserts that the study team will need to revert to the parents for additional consent. The applicant does not regard the study as comprising a biobank (section 6.2.6), however given there is a plan to retain samples for future unspecified studies, the committee suggests this is a *de facto* biobank and requests clarification in this regard. 7. The committee notes the data / sample sharing agreements are in draft and requests sight of the final signed agreements. 8. The committee maintains that genomic sequencing *may* yield *'clinically or personally relevant information'* (section 6.5.1). Future studies (unspecified) may well look at personally relevant profiles; in this regard the committee asks if metagenomic data will be linked with personal data/social demographics? 9. The committee notes that questionnaires will be checked for completeness (section 9.4.2) and queries what will happen if they are not? eg will participants' information to be deleted? 10. The committee is unclear in the GP letter as to the plan for what will happen if a clinical condition is identified and how it is to be dealt with. 11. The committee is of the view that the PIL is over-long and confusing and requests a rewrite eg explain what a biobank is. 12. Regarding the consent form: • The committee requests clarity on who will consent - one or both parent(s) / guardian(s)?

	• Both consent forms are too complicated, and the committee is unclear as to what researchers will do if certain boxes are ticked. The committee requires a simpler consent form with single tick boxes in response to each individual statement. Some questions attempt to cover more than one issue, and the committee requests that one issue is addressed by one question. • The committee requests that the following statement be removed: '*If I have further queries concerning my rights in connection with the research, I can contact the COVID19 National Research Ethics Committee, e-mail: XXXX'.* • The committee is unclear as to how parents can make the request to withdraw and to whom (PI, research nurse?). • The committee requests that the DPO's name and contact details be included. • The committee requests that the Researcher Declaration accurately reflect the nature of the consent ie, that it is parental and not patient consent. 13. The committee queries if infants who have an identified allergy will be followed up.

Application Number	20-NREC-COV-068
Applicant	Dr Fintan Sheerin
Study Title	Staff mental health while providing care to people with intellectual disability during the COVID-19 pandemic
Institution	TCD
NREC COVID-19 Comments	• The committee noted that this study proposes to examine the impact of sustained care in a pandemic on the mental health of healthcare staff working in intellectual disability care.
NREC COVID-19 Decision	*Provisional approval*
Associated Conditions	1. Noting that '*interviews will be transcribed by the data processor (AudioTrans) and the interview transcripts will then be anonymised',* the committee requests confirmation of what needs to be anonymised. Are respondents' names and place of work being used in interviews? 2. The committee observes inconsistent information on how the results will be managed; the protocol states that participants will be given the opportunity to comment on the results of the analysis of the data, and separately the PIL explains that a report will be circulated to the services involved with a general invitation for feedback. The committee requests clarification on this apparent inconsistency, noting that the PIL seems more in line with the response to the DPIA. 3. Regarding the applicant's response to the DPIA on the intention to obtain electronic signatures, the committee notes there is no

	reference to an electronic signature in the PIL / consent form; please confirm the means of securing signatures – written, electronic or both. 4. The committee requests sight of the data transfer agreement between AudioTrans and the School of Nursing & Midwifery. 5. Recognising that *'individual interviews will be conducted online/by telephone'*, the committee requests explanation of how they will be conducted online. 6. Acknowledging that '*The research team will also connect participants to relevant sources of mental health support,* instead of the Samaritans, the committee requests that there a standard line in the script for anyone who might be distressed, reminding them to consider contacting their GP or occupational health service. Regarding the PIL statement*, 'Let us know if you would like to access support from staff health support services',* the committee is of the view that it is not appropriate that researchers have a role in this type of service access. 7. The committee is unclear as to how the service providers will let suitable staff know and requires clarification. 8. The committee is unclear as to how potential participants will contact the research team and requires clarification. The applicant could consider providing copies of the forms to the service providers. 9. Regarding section 3.7, the committee maintains that the criterion 'Adults in emergency situations' does not apply to adults working during the health emergency. 10. Regarding the consent form, the committee requests the reasoning both for including Centre ID (given there are only 3 sites) and Witness Name and suggests both could be removed unless there is good reason. The committee requests removal of reference to 'patient' in the PIL / consent materials. Finally, the committee requests a thorough spell-check of the PIL. Suggestion: the committee is of the view that monthly updates to the HSE and Department of Health are unnecessary and could be omitted. The committee further suggests that translations of the findings into French, Spanish, Portuguese, and Chinese are unlikely needed.

Application Number	20-NREC-COV-069
Applicant	Prof. Paul Cotter
Study Title	Irish Coronavirus Sequencing Consortium
Institution	Teagasc Food Research Centre, Moorepark
NREC COVID-19 Comments	• The committee agreed that the rationale for this multicentre Irish study is well-outlined. • The committee noted that this study proposes to use samples from the All Ireland Infectious Diseases (AIID) Cohort, for which the NREC COVID-19 provided ethics approval in May.
NREC COVID-19 Decision	*Provisional approval*
Associated Conditions	1. Notwithstanding that recruitment will be largely via the AIID cohort, the committee requests that the PIL and consent forms are revised for participants not already recruited through the AIID. 2. The committee notes the data protection notice from the APC Microbiome that participants are expected to sign, as well as a separate PIL and consent form that participants are to sign in addition. The committee requests that a single PIL and consent form is drafted, clarifying the name of the organisation running the study. 3. Further to the PIL, the committee requests clarity therein that patient identifiable data is not being sent to Teagasc, but coded in either the hospital or the NVRL, prior to being sent on. Additionally, the committee requests an introduction to the PIL indicating why the participant is being approached, and who is making the approach (e.g. a clinician in the treating hospital). 4. The committee notes the statement that '*Most patients included in the study will have provided consent for the use of samples for research purposes through prior enrolment in the All Ireland Infectious Disease Cohort Study (AIID)*'; the committee requires clarity on this statement, which reads ambiguously. 5. The committee requires assurance that the study meets data protection obligations; in this regard, data processing agreements need to be in place with all sequencing labs (as data processors), and data sharing agreements need to be in place between participating hospitals and Teagasc. 6. The committee requires clarity on the inclusion of deceased patients, and that only samples from deceased participants already recruited by the AIID cohort will be analysed. Suggestion: the committee observes that *'research participants who might not adequately understand verbal or written information will not be included in the study*; the committee *suggests* the applicant considers appropriate ways of supporting such individuals' capacity to consent, rather than excluding them from the study.

Application Number	20-NREC-COV-070
Applicant	Dr Dmitri Wall
Study Title	Surveillance Epidemiology of Coronavirus (COVID-19) Under Research Exclusion – Alopecia (SECURE-Alopecia)
Institution	UCD
NREC COVID-19 Comments	• The committee agreed that this application is well-written with appropriate governance and DPIA. • The committee strongly recommended the registry is promoted effectively to maximise full participation from the dermatology community and suggests that the study would benefit from appropriate patient public involvement (PPI), with information sheets circulated to patient groups and dermatology clinics to inform patients about the registry.
NREC COVID-19 Decision	*Approved*

- AOB: None

- The Vice-Chair closed the meeting