Meeting Minutes

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

Time: 3 – 5pm

Date: 29th April 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
Prof. Pat Manning	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
Dr Jennifer Ralph James*	Head, Office of NRECs
Ms Aileen Sheehy	Programme Manager, Office for NRECs

***Drafted minutes**

Apologies: None

Quorum for Decisions: Yes

Agenda

- Welcome & apologies
- Minutes approval 22nd April & matters arising
- Declarations of Interest
- Application NREC-C0V-004
- Application NREC-C0V-005
- Application NREC-C0V-008
- Application NREC-C0V-009
- Application NREC-C0V-010
- Application NREC-C0V-013
- Application NREC-C0V-015
- Application NREC COV-006
- AOB

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- The minutes from meeting on 22nd April 2020 were approved.

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

  (1) The Head, Office for NRECs confirmed that responses have been received from applicants pertaining to the provisional approvals of applications 20-NREC-COV-001 and 20-NREC-COV-002 respectively. The applicant's response for 20-NREC-COV-001 was satisfactory to the Chair and final approval has been provided. Final approval is pending for 20-NREC-COV-002.

- The following declarations of interest were made, and the members recused themselves from the discussion of the applications in question:

  Dr Akke Vellinga – 20-NREC-COV-006
  Prof. Tom Fahy – 20-NREC-COV-013

Applications

Application Number	20-NREC-COV-004
Applicant	Prof. Colm Bergin
Study Title	Clinical outcomes and adverse events in hospitalised patients with covid-19 treated with hydroxychloroquine and azithromycin
Institution	St James's Hospital, Dublin 8
NREC COVID-19 Comments	• The committee agreed, in the absence of evidence of any effective drug treatment for COVID-19, any and all information on off-label therapeutic interventions on patient outcomes and potential adverse effects of off-label drugs is important • It was agreed that as a retrospective chart review, the study is associated with minimal risk. • Although there is no *pro forma* of data to be collected, it was agreed that its analysis will be limited as a small study. • The committee was unclear as to the rationale for anonymisation / pseudonymisation in this study.
NREC COVID-19 Decision	Provisional Approval
Associated Conditions	1. Recognising the objective of the study is to characterise clinical responses to off-label use of hydroxychloroquine and azithromycin in hospitalised patients with COVID-19, the committee requires information on the type of *pro forma* measures that the analysis will encompass.

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	2. The committee notes the intention to pseudonymise data, which may unnecessarily compromise patient privacy in this study; if the study as is presented involves just a single immersion in the chart records, the committee requires clarification as to the necessity of this approach. 3. The committee requests consistent usage of the drug names, hydroxychloroquine and azithromycin, throughout the documentation.

Application Number	20-NREC-COV-005
Applicant	Dr fFrench O'Carroll
Study Title	Psychological impact of Covid 19 on healthcare staff working in ICU and coping strategies used.
Institution	Children's Health Ireland at Crumlin
NREC COVID-19 Comments	• The committee agreed that as a non-interventional anonymous survey, this study will address a worthwhile question with minimal risk of harms. • It was accepted that Survey Monkey is a commonly used tool, however it was agreed that further justification is required as to the security that it can afford the participants' data. • The was noted that the survey will be voluntary and non-coercive in its intention, however the committee was unclear as to who will distribute the email. • Multiple grammar / spelling errors were observed in the survey
NREC COVID-19 Decision	Provisional Approval
Associated Conditions	1. The committee requires further justification of the use of Survey Monkey including plans to immediately de-identify the data (including URLS, cookies) when received. 2. The committee is of the view that the consent wording in the Patient Information Leaflet is insufficient in parts, such that more explicit wording around gathering and usage of participants' data should be included. Moreover, progression with the questionnaire should be marked by an agreement (eg tick box) with an explicit statement of consent. 3. The committee requires confirmation as to who is sending the email and how the email addresses will be sourced. The committee is of the firm view that the email should be distributed appropriately (eg HR Department), and not by participants' line managers, which may give rise to undue pressure.

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	4. The committee notes the plans to present the data at national meetings however, given some of the participants may not participate in these fora, are there plans to disseminate anonymised data through alternative means? 5. The committee notes that the data will be retained for 2 years and, while there is no 'rule' as such for duration of data retention, it is of the view that 2 years is insufficient. Data should be retained according to the applicant's institutional policy, and in the absence of such a policy, the data should be retained until all publications arising from the research have been published, plus a suggested 1-2 years after that, to allow for concerns be raised by peers. Mindful of GDPR principles, identifiable data cannot be retained indefinitely, and the applicant should ensure anonymisation of the data if it's to be held beyond the retention period.

Application Number	20-NREC-COV-008
Applicant	Prof. Ellen O'Sullivan
Study Title	CROWN CORONATION: Chloroquine RepurpOsing to healthWorkers for Novel CORONAvirus mitigaTION
Institution	St. James's Hospital, Dublin 8
NREC COVID-19 Comments	• The committee agreed that this is a large, ambitious multisite study addressing a very important question. • It was agreed that the study did not present any major concerns, rather the clarity of information to be provided to participants required addressing.
NREC COVID-19 Decision	Provisional Approval
Associated Conditions	1. The committee makes several requests as to the participant recruitment material and Information Leaflet, specifically: (a) The role of hydroxychloroquine as a treatment for COVID-19 should be explained. (b) Details should be included as to the sample size, who is funding the study, how the participants' data will be protected and what will happen with their data and the results. (c) The advertising poster is very dense with content and could be simplified and a greater emphasis on the explanation of the study. (d) As the study is recruiting healthcare workers, by definition they will come from diverse clinical and non-clinical backgrounds. The Information Leaflet should be written in less complex language to be more easily accessible to a broad audience.

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	(e) As hydroxychloroquine is to be used in Ireland, the term chloroquine could be confusing and therefore removed. (f) The Information Leaflet should include a section to remind participants to disclose medication or (over the counter) supplements they may be taking. There should also be a means to record this information in the trial documentation. 2. The committee is of the view that there is insufficient information in the Informed Consent Form and makes several requests, specifically: (a) The Informed Consent Form should be layered so participants have the opportunity to indicate understanding and agreement with all steps of the study. It should contain more detail about the protocol, data processing and confidentiality, risks and risk mitigation. (b) Please provide the FAQ section, which is mentioned but not included. (c) The response to Section 4.2.1 states "*All participants will be given the opportunity to have the trial explained, and any questions addressed, over the phone with the site PI, before enrolling.* ***If participants do not understand the verbal information provided in this conversation, they will not be permitted to enrol in the trial".*** Greater efforts should be undertaken as indicated above to ensure that the information given at this stage is simplified for a broader audience to ensure maximum participation across all staff groups. 3. The committee requires the participants' GPs are informed, as is standard practice in an IMP trial. An email to the GP would suffice instead of a letter in the circumstances. 4. The default position following non-response to two text messages at a data gathering time is that the PI will be informed. It is not made clear to potential participants why this is the case and what the PI will do/say/ask (although it's clearly a prompt to participate?). This could simply result from a participant working or not having their phone available at the required times. If the PI were to contact the participant at this stage, as a senior physician in the same hospital, they may feel pressurised. The committee request that consideration be given to an alternative approach, without the risk of coercion. 5. The applicant had a query regarding the necessity for the PI and potential participant to be in the same room when the study is being explained/consent signed. The committee's

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	view is that it would be ideal if they were together but given the current circumstances and the information provided about the procedures being implemented, we are satisfied with the proposed approach. 6. The committee notes that the study has secured funding from the Bill & Melinda Gates Foundation since the application was submitted. The committee requires confirmation that this funding will cover the cost of the drug treatment also, or is this being provided for from other resources? 7. The committee notes that it is possible that some individuals may already be taking hydroxychloroquine, therefore this information should be determined as part of the recruitment process. 8. The committee queries how will the dosing of the treatment be handled. The minimal dosage of Plaquenil, according to the information leaflet, appears to be 200 mg – therefore above the 150mg dose to be used in the study. 9. The committee requires clarification on recruitment process. While there are online resources to assist in the recruitment, the recruitment of 500 participants will involve a significant about of investigator time in explanations alone; even with self-enrolment. Is there external assistance or specialized resources to manage this process at the different sites?

Application Number	20-NREC-COV-009
Applicant	Prof. Linda Coate
Study Title	COVID-IYON Study
Institution	University Hospital Limerick
NREC COVID-19 Comments	• The committee agreed that study will address a very important question using a reasonable approach. • It was agreed that further explanation is required on the qualitative methods to be used. • There was a suggestion that open data be considered in due course to share the important data arising more widely. • There was a query on the relevance of the question on staffing levels and PPE.
NREC COVID-19 Decision	Provisional Approval
Associated Conditions	1. Noting the methodological approach of the qualitative component of the study is semi-structured interview, the

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	committee requires clarification on the rationale behind not obtaining explicit written consent from the registrars. 2. The committee is unclear if the study sub-investigators will be interviewed by the local consultants, and if so, comment should be made on the potential for the hierarchical dynamic to influence the interview. 3. The committee observes the following wording in the Patient Information Leaflet (PIL) – '*We also want to examine whether any particular chemotherapies appear to <u>increase or reduce</u> the risk of developing a severe case of coronavirus infection'.* Given the study is observational and won't be encompassing information from patients who are COVID negative, the committee requires that the text in the PIL be amended in line with the aims of the study.

Application Number	20-NREC-COV-010
Applicant	Prof. Geraldine McCarthy
Study Title	Rheumatology COVID-19 Study
Institution	Mater Misericordiae University Hospital
NREC COVID-19 Comments	• The committee agreed that study addresses a relevant question and will add significantly to the knowledge base. • The committee were unclear if all 11 sites will have access to the EULAR system. • There was a suggestion that height and weight be added to data collection as important risk factors for comorbidity. • There was a suggestion that open data be considered in due course to share the important data arising more widely.
NREC COVID-19 Decision	Provisional Approval
Associated Conditions	1. The committee notes that there will be transfers of data beyond the European Economic Area and require clarification as to how EU GDPR requirements will be met. 2. The committee observes that data collection is to extend beyond usual clinical practice. Consideration should be given to gaining participants' consent, and if not possible, a Consent Declaration should be sought from the Health Research Consent Declaration Committee (HRCDC).

Application Number	20-NREC-COV-013
Applicant	Dr Kantikiran Dasari
Study Title	Emergency department attendances during COVID-19: the impact of government pandemic measures

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Institution	Cork University Hospital
NREC COVID-19 Comments	• The committee agreed that this retrospective electronic chart review is a timely study. • It was agreed that information is lacking on aspects of the methodology.
NREC COVID-19 Decision	Provisional Approval
Associated Conditions	1. The committee notes that the research question will be addressed using data from a single hospital; in this regard, further rationale of the sample size is required including power calculations. 2. Noting the study will characterise presentations to the CUH Emergency Department, the committee requests further justification for prevailing on an already busy medical service. 3. The committee requires clarification on the approach to ensure anonymisation. Detail is also requested on who will extract the data and have access to it, and how they will ensure protection of the patient data. The application would benefit from documented advice of the CUH DPO. 4. The committee queries the appropriateness of the answer to question 3.6 as 'N/A'.

Application Number	20-NREC-COV-015
Applicant	Prof. Susan Smith
Study Title	COVID-19: Rapid evidence synthesis, identification and dissemination to support policy makers and frontline GP clinicians in the context of a global pandemic
Institution	RCSI
NREC COVID-19 Comments	• The committee agreed that study represents high value to the system. • There was agreement on clarity of the approach aside from the protocol and review methods for WP3, which weren't clear. • There is some ambiguity as to the plans for anonymisation / pseudonymisation of the data.
NREC COVID-19 Decision	Provisional Approval
Associated Conditions	1. The committee is unclear as to the anonymisation / pseudonymisation of the data to be collected; the DP questionnaire advises that qualitative data be anonymised, point 7 of the questionnaire states that the data will be pseudonymised for analysis purposes, and the PIL states that *'during analysis stage all identifying information will be*

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	removed from the data'. Clarification is requested to address this ambiguity. Given the small numbers of participants who may be indirectly identifiable from published committee membership lists, the committee requires confirmation that not only identifiers be removed, but also any content of the interview be removed which might indirectly identify the participant. 2. The committee notes that a single site is indicated (ie, RCSI), however separately, collaborators in NUIG, HIQA and ICGP are referenced; clarification is required on the intention, if any, for data sharing, and associated plans for anonymisation / pseudonymisation. 3. The committee notes that the study will be on members of committees reporting to ICGP and NPHET, and at least the NPHET list is likely to be publicly available, raising data protection issues; the committee requires clarification of the approach for mitigation in this regard. 4. The committee recognises the objective is to examine the underpinning process, and not necessarily the content, of evidence, however it would be prudent to ensure a disclaimer is associated with any printed / recorded evidence (eg Advice correct as at [date]).

Application Number	20-NREC-COV-006
Applicant	Dr Akke Vellinga
Study Title	COV SARS-CoV-2 Observational Study of community acquired acute respiratory tract infection during a time of widespread suspected COVID-19 in European primary care
Institution	NUI Galway
NREC COVID-19 Comments	• The committee agreed that the premise of the study represents an important cross-country primary care question. • Noting that an inherent component of the study is for participants to attend their GP practices, the committee agreed that it would be inappropriate during the current health emergency to direct unessential face-to-face contact in this vulnerable community setting. It was agreed that the study addresses an important question, and there would be merit in finding another way to safely conduct the study for example through coordination with existing GP Hubs and the Irish College of General Practitioners.

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	• The committee noted that while the virus is relatively uncommon in those under 16 years, a process for assent should be in place, which would benefit a future application. • The committee queried the viability of the methodological approach of self-swabbing, which risks false negative results given the technical skills required to ensure an optimal test is done, and may be onerous for a parent to conduct on a child or patients to do on themselves; a future application would require further justification of this approach.
NREC COVID-19 Decision	Approval Declined

- AOB:
  (1) There was discussion on the applicability of the Clinical Indemnity Scheme for hospital-based research under the State's Claims Agency, to research ethically approved the NREC COVID-19; the Office for NRECs will seek clarity on this matter.

- The Chair closed the meeting

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