

## Meeting Minutes

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

**Time:** 3 – 5pm

**Date:** 17<sup>th</sup> June 2020

**Location:** virtual meeting

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#### Attendance\*

|                          |  |
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| Prof. Mary Horgan        | Chair, NREC COVID-19                     |
| Prof. Anthony Staines    | Vice Chair, NREC COVID-19                |
| Prof. Pat Manning        | 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          |
| Prof. Suzanne Norris     | Committee member, NREC COVID-19          |
| Mr Gavin Lawler          | Committee member, NREC COVID             |
| Dr Jean Saunders         | 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 |

\* Subset of committee convened

† Drafted minutes

**Apologies:** None

**Quorum for Decisions:** Yes

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#### Agenda

- Welcome & Apologies
  - Minutes approval 10<sup>th</sup> June & Matters Arising
  - Declarations of Interest
  - Application 20-NREC-COV-062
  - Application 20-NREC-COV-064
  - AOB
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- The Chair welcomed the committee.

- The minutes from meeting on 10<sup>th</sup> June were approved.
- Matters arising from the 10<sup>th</sup> June 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

|                               |   |
|-------------------------------|---|
| <b>Application Number</b>     | 20-NREC-COV-062   |
| <b>Applicant</b>              | Dr Catherine King   |
| <b>Study Title</b>            | Home Administration of Omalizumab in patients with Chronic Spontaneous Urticaria and Angioedema during the COVID-19 Pandemic: A Patient Experience Questionnaire  |
| <b>Institution</b>            | St James's Hospital   |
| <b>NREC COVID-19 Comments</b> | <ul style="list-style-type: none"> <li>• The committee agreed that despite the small cohort size, this study may ultimately benefit patients.</li> <li>• The committee noted no potential harms to study participants.</li> </ul>   |
| <b>NREC COVID-19 Decision</b> | <i>Provisional approval</i>   |
| <b>Associated Conditions</b>  | <ol style="list-style-type: none"> <li>1. The committee recognises that Survey Monkey 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 Survey Monkey including plans to immediately de-identify the data (including URLs, cookies) when received.</li> <li>2. Noting that there are '<i>no concerns about diminished capacity or inability to consent</i>', the committee is unclear as to the purpose of the option in question 1 for an individual to complete the questionnaire on behalf of a participant, and requires clarification.</li> <li>3. The committee requires that consent is confirmed prior to actual admission to the online 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. Where patients opt for a paper-based questionnaire, the committee requires confirmation that a signed consent form will be obtained beforehand.</li> <li>4. The committee observes that the proposed participant number is relatively small; notwithstanding the familiarity the study team have with this cohort, the committee requests justification the</li> </ol> |

|                               |   |
|-------------------------------|---|
|                               | sample size and likelihood of sufficient engagement with the survey to derive meaningful results.   |
| <b>Application Number</b>     | 20-NREC-COV-064   |
| <b>Applicant</b>              | Dr Muireann Ní Chróinín   |
| <b>Study Title</b>            | Irish SARS-CoV-2 serology study of children with pneumonia during COVID -19 pandemic Short Title: SOCKs Study (Serology Of COVID in Kids)   |
| <b>Institution</b>            | Cork University Hospital  |
| <b>NREC COVID-19 Comments</b> | <ul style="list-style-type: none"> <li>• The committee agreed that this application represents a straightforward study involving reasonable numbers.</li> <li>• The committee agreed that it is exemplary to see assent forms as a component of the informed consent process.</li> </ul>  |
| <b>NREC COVID-19 Decision</b> | <i>Provisional approval</i>   |
| <b>Associated Conditions</b>  | <ol style="list-style-type: none"> <li>1. The committee notes conflicting references to participant number (150 or 200 in each of the case and control groups?) and requires confirmation in this regard.</li> <li>2. The committee is unclear whether parents will have the choice to receive the results of the antibody test. If the results are being fed back, then the committee requires that the mechanism and time scale for dealing with abnormal results, both for the family and for public health, be explained in detail; this information needs to be clear in the parents' PIL.</li> <li>3. The committee is of the view that the 'No' option in answer to questions in the consent forms is misleading; rather a clear statement with the opportunity to circle 'Yes' is more appropriate; please amend accordingly.</li> </ol> <p>Suggestion: the committee <i>suggests</i> that the study team consider covering the out-of-pocket expenses of participants not attending the hospital as part of routine clinical care.</p> |

- AOB: The committee queried whether additional funding awards have been made through national rapid-response funding calls; the Head and PM of the National Office agreed to seek clarity on this.
- The Chair closed the meeting