HRCDC
Health Research Consent Declaration Committee

Date: 10th June 2020
Location: Videoconference

Minutes of the Meeting

HRCDC Attendance

Name
Brigid McManus
Evelyn Mahon
Alyson Bailey
Kevin Clarke
Claire Collins
Sheelah Connolly
John Ferguson
Simon Furney
Aideen Hartney
Zubair Kabir
Dan Rea
Emily Vereker (Secretariat)
Jonny Barrett (Secretariat)

Quorum for Decisions ☒YES

New Applications - For Consideration

Applicant	Ref No.	Title
Julie Egan	20-016-AF1/COV	Clinical Characteristics of Dysphagia and Communication Difficulties among Hospitalised Adults with COVID-19 in Ireland: An Observational Cohort Study.

Meeting Items

1. **Opening, Apologies**
   The Chair opened the meeting and welcomed the members.
   Apologies from: Malcolm Kell, Barry O'Sullivan, Kathy Brickell

2. **Disclosure of Interest**
   There were no disclosures of interest for this meeting.

3. **Minutes of the previous meetings**
   Draft minutes of the HRCDC meetings of 20th May 2020 and 26th May 2020 were circulated in advance of the meeting and were agreed by the HRCDC.

4. **Matters arising**
   Ref ID 20-013-AF1/COV (HRCDC meeting 20th May 2020): The Secretariat discussed correspondence received from the Applicant, where the Applicant outlined a revised consent and assent protocol and accompanying information leaflets, addressing the condition attached to the declaration. The HRCDC noted the correspondence.

5. Written Procedure: Ref ID: 19-004-AF2/AMD2/COV

Applicant: Alistair Nicholl

Study: REMAP-CAP Trial: COVID-19 Domains and Consent Models

The HRCDC noted the decision to approve the second amendment request to the existing consent declaration. The amendment related to the allows for the inclusion of two additional hospital sites: Waterford University Hospital and St. James' Hospital Dublin. The HRCDC reviewed the submitted documents by written procedure and approved the amendment. A decision letter was issued to the Applicant on 4th June 2020.

6. New Applications

Reference ID:	20-016-AF1/COV
Lead Applicant:	Julie Regan
Lead Data Controller:	Trinity College Dublin
Title:	Clinical Characteristics of Dysphagia and Communication Difficulties among Hospitalised Adults with COVID-19 in Ireland: An Observational Cohort Study
Research Objective	This multi-site observational cohort study aims to establish to clinical characteristics of people presenting with swallowing and communication (speech, voice, language) difficulties due to COVID-19 in hospital settings across Ireland and to identify factors associated with positive outcomes in this population. It also seeks to establish the swallowing and communication rehabilitation needs and services provided within this clinical population. A dataset has been developed and will be used by nominated speech and language therapists (SLTs) across healthcare settings to obtain demographic and clinical data from adults with confirmed COVID-19 who have been admitted into hospital or rehabilitation settings in Ireland and referred to speech and language therapy services.
Reason for Declaration	For the purpose of accessing, collecting, pseudonymising and analysis of personal data of patients who have been referred to a Speech and Language Therapist post COVID19.
HRCDC Comments:	The Chair requested each HRCDC member to indicate whether a consent declaration should be made. After discussing the application, and based on the information provided by the Applicant, it was the consensus of the HRCDC that no Declaration should be made. **Rationale for no consent** • The HRCDC noted the reasons outlined in the application form as to why participants may not be able to provide consent. It was discussed that best efforts should always be made by to obtain explicit consent. Furthermore, where a participant lacks decision-making capacity, assent from an appropriate individual who can indicate the participant's will and preference is considered an important data protection safeguard and should be obtained where at all possible. • The HRCDC was of the view that regardless of the data protection risks to the study deemed to be low risk, best efforts to seek assent or consent should always be made.

	• It was discussed that there is precedence to implement suitable verbal or written consent and assent protocols coupled with deferred consent, for emergency/intensive care unit research and for COVID19 research which has additional challenges. • The HRCDC considered that there should be opportunities to obtain assent and/or deferred consent at some point in the study timeline. The Applicant states '*where possible, clinicians will do their utmost to verbally inform patients and/or family members on-site'*, however it was unclear to the HRCDC why assent or explicit consent could not be obtained at this point through the provision of information leaflets and forms and/or recording informed consent or assent. In addition, it was unclear why deferred consent cannot be obtained later in the hospital stay or when participants attend follow-up speech and language therapy appointments. **Public and Patient Involvement (PPI)** • It was discussed that no public and patient representatives have been involved in the study to date. • The HRCDC considers PPI in health research an important safeguarding element, where no explicit consent is being sought, to ensure a PPI perspective is reflected in the overall study. The HRCDC notes the recent statement made by the Irish Platform for Patient Organisations, Science and Industry (IPPOSI), setting out the importance of understanding the participant perspective during the COVID-19 pandemic. **Data Transfer Agreement** • It was discussed that data transfer agreements will be provided to all clinical sites and signed by 'clinical partners'. However, it was not clear whether the authorised signatory was responsible for data compliance. **Transparency and Data Protection Rights:** • The HRCDC was of the view that insufficient transparency measures were to be implemented and, participants would not be informed about this study, their data protection rights, including the right to withdraw, or how their personal data is to be processed. The Privacy notice provided to the HRCDC was considered too generic and would not adequately inform participants of these necessary details allowing them to exercise their data protection rights. **Public Interest:** • The HRCDC was of the view that there was a degree of public interest in this study. However as a significant quantity of personal data is being collected, the HRCDC considered that clearer and more defined research questions and study information would have been useful. • When weighing up the aforementioned points of discussion, the HRCDC was not of the opinion that public benefit and interest in

	research study *significantly outweighed* the data protection rights of participants and mitigated the requirement to obtain explicit consent. This view was coupled with the view that there was insufficient evidence of strong data protection safeguards as required under the Health Research Regulations.
HRCDC Decision:	The consensus of the HRCDC was No Declaration should be made.
HRCDC Comments:	The HRCDC discussed that although no declaration was made, this does not preclude the Applicant Data Controller from submitting a new application, seeking a consent declaration for the processing of personal data for participants who may lack decision-making capacity; this would be in line with Section 7 of the HRCDC Standard Operating Procedures. The HRCDC discussed that should the Applicant wish to submit a new application in the future for this study, the application submitted must set out how the points outlined above have been fully considered, including details of an implementable assent/consent protocol, patient and public involvement, and robust data protection safeguards. In such a case, any HRCDC decision would be made on the basis of the new application.

- The Secretariat highlighted that the application entitled 'TERAVOLT' (Ref ID 20-017-AF1/COV) had been withdrawn from HRCDC consideration. The Applicant had informed the Secretariat that patients who lacked decision-making capacity will now not be included in the study and therefore a consent declaration was no longer required.
- The Secretariat discussed the advice received from the Department Of Health regarding international data controllers, such as registries, of a research study wishing to obtain de-identified personal data from an Irish data controller, as was the case for the aforementioned TERAVOLT study. It was discussed that an international data controller could apply for a consent declaration, however it would be important for the HRCDC to give additional consideration to i) ensuring robust safeguards for data subject rights and ii) the ability to enforce terms of any conditions attached to the consent declaration and ii) Chapter 5 provisions in GDPR (Transfers of personal data to third countries or international organisations).
- It was further discussed that a data controller who is being asked to disclose the personal data they hold, is not the one who seeks the consent declaration. It is the data controller of the study that is seeking to obtain personal or pseudonymised data that applies for a consent declaration. Disclosure is a processing operation. Therefore, a disclosure by a data controller of personal data that has been pseudonymised to a third party (including, an international data controller) must comply with GDPR and the Health Research Regulations, even if in the hands of the recipient data controller, that data is anonymous.

7. Activities Report

- The Secretariat highlighted that presentations from the recent 'Public and Patient Involvement in Research' conference were now available online.
- The Secretariat attended the 'Future of Healthcare' event on line, discussing the use of AI technology in Healthcare.
- The Secretariat highlighted the recent report from the Irish Health Research Forum Meeting Health held in November 2019.

8. Any other Business

- The HRCDC discussed whether less detailed conditions attached to declarations relating to patient information leaflets and consent forms, would be informative enough for researchers to understand what the issues are. The HRCDC noted that requesting researchers to consult with relevant Patient & Public Involvement groups on the consent forms would be beneficial for researchers to get patient and public perspective.
- The Secretariat discussed the template data privacy notice for COVID19 research that had been developed by the Health Research Data Protection Network (HRDPN). The template refers to the HRCDC. It was agreed that the Secretariat would engage with the HRDPN on the details in the template.
- The Secretariat highlighted the following documents that may be of interest;
  - 'Recommendations and Guidelines - COVID19', developed by the Research Data Alliance COVID-19 Working Group. The table of contents shows scope of the document covering all aspect of data sharing for COVID19 research, including ethical and legal considerations (https://www.rd-alliance.org/).
  - COVID19: Public and patient involvement, now more than ever. The article authors, researchers and PPI contributors, discuss that PPI is important, now more than ever.