HRCDC
Health Research Consent Declaration Committee

Date: 28th July 2020
Location: Videoconference

Minutes of the Meeting

HRCDC Attendance

Name
Evelyn Mahon (Deputy Chair)
Alyson Bailey
Kathy Brickell
Kevin Clarke
Sheelah Connolly
John Ferguson
Zubair Kabir
Barry O' Sullivan
Dan Rea
Emily Vereker (Secretariat)
Jonny Barrett (Secretariat)
Genevieve Osanife (Secretariat)

Quorum for Decisions ☒YES

New Applications - For Consideration

Applicant	Ref No.	Title
Julie Regan	20-023-AF1/COV	Dysphagia and Communication Difficulties amongst Adults Hospitalised with COVID-19 across Ireland (DISCOVER): A multi-site retrospective cohort study

Meeting Items

1. Opening

The meeting was chaired by the Deputy Chair, Prof. Evelyn Mahon (EM) who opened the meeting and welcomed the members. The HRCDC were reminded of the etiquette for a videoconference meeting.

2. Apologies

Brigid McManus (Chair), Aideen Hartney, Claire Collins, Malcolm Kell, and Simon Furney

3. Disclosure of Interest

There were no disclosures of interest for this meeting.

4. Minutes of the last meeting

Draft minutes were circulated in advance of the meeting and were agreed by the HRCDC.

5. New Applications

Reference ID	20-023-AF1/COV
Lead Applicant	Dr Julie Regan

Lead Data Controller	Trinity College Dublin (TCD)
Title:	Dysphagia and Communication Difficulties amongst Adults Hospitalised with COVID-19 across Ireland (DISCOVER): A multi-site retrospective cohort study
Research Objective	This multi-site retrospective cohort study is being conducted to address the following research questions: 1. What are the clinical characteristics of swallowing and communication (voice, speech, language) difficulties amongst adults hospitalized with COVID19 across Ireland? 2. What variables are associated with swallowing and communication outcomes? 3. What are the swallowing and communication rehabilitation needs and services delivered to this clinical cohort? Patients admitted into twenty-one participating clinical sites across Ireland with confirmed COVID-19 and who are referred to speech and language therapy are eligible for inclusion in this study. Verbal consent (if patients are unwell/inaccessible, verbal proxy assent plus deferred verbal consent) will be obtained to include data in this dataset as per the ethical approval granted by the National Research Ethics Committee for COVID-19. Clinical partners responsible for data entry at each clinical site will populate the local dataset and transfer data into researchers in TCD at two timepoints. Merged data will be analysed by TCD researchers.
Reason for Declaration	For the purpose of accessing, collecting, pseudonymising, transferring and analysis of pseudonymised data of COVID-19 positive participants who lack decision-making capacity and who have been referred to Speech and Language Therapy (SLT). Processing will also include the storage of personal data for future research purposes only.
HRCDC Comments	• The Deputy Chair reminded the HRCDC that a variation of this study was considered by the HRCDC on June 10th and that no declaration was made (Ref ID: 20-016-AF1/COV). The Applicant submitted a new application form and refocused the scope of the declaration being sought with a new consent protocol. It was further noted that the Data Protection Impact Assessment had not changed since the previous application as the data flow, risks and mitigating actions remained applicable. • It was noted that provisional ethics approval and subsequently full approval for the study had been granted by the NREC COVID-19 where the design, methodology and ethical aspects of the study, including consent protocols were considered. • Only studies that have ethical approval, or provisional ethical approval, can be considered by the HRCDC to determine if the public interest outweighs the requirement for explicit consent. • The Deputy 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 a conditional declaration should be made. **Public Interest** • The HRCDC considered that there is a relatively strong level of public interest in this study. Notwithstanding this, the Committee indicated that clearer information on the study design and research questions could have been provided by the Applicant. **Consent and Assent Protocol** • The HRCDC discussed the consent and assent forms and protocol. While it was acknowledged that the Applicant had made efforts to address points raised by the HRCDC regarding the previously submitted application, the consenting protocol could be further revised to ensure greater clarity for the participant. • The HRCDC discussed the importance of identifying the most appropriate individual to provide assent on behalf of a participant who lacks decision-making capacity and to ensure they understand the will and preference of the participant. This may be an individual who has an enduring Power of Attorney or an appropriate next-of-kin, as noted in the participant's medical chart. Where a participant lives in a residential care home, the Applicant should liaise with the participants health care team to identify the most appropriate individual to provide assent. • Where verbal consent or assent is obtained, the HRCDC discussed that this should be witnessed to ensure that consent or assent is accurately recorded. It was further discussed that the signature of the participant, or those providing assent on their behalf, should be obtained once verbal consent or assent has been provided. • The HRCDC discussed that copies of the study information leaflet and consent/assent forms could be posted or emailed, with a copy retained by the individual for their own records and the signed consent/assent form then returned to the researchers. It was discussed that it should be possible to obtain a signature whilst implementing infection control measures, such as sealing the returned form for 14 days. • The HRCDC noted that the information leaflets will also be used as a script to obtain verbal consent/assent. It was discussed that these information leaflets were considerably long and may be difficult to follow for participants or individuals providing assent who are listening to the information being read out. The HRCDC considered that it may be beneficial to revise the information being verbalised such that it can be easily understood whilst being sufficiently informative about the study. • For participants who reside in residential care homes, the HRCDC discussed that a copy of the study information leaflet and assent form could be retained on the participants file by the residential care home. • The HRCDC also highlighted sections of the study information leaflets and consent/assent forms that should be revised for

	clarity by the Applicant. It was noted that the assent protocol does not outline that assent is sought because the participant lacks decision-making capacity or if deferred consent will be requested from the participant should they regain decision-making capacity. • The HRCDC discussed that the information leaflets describe that consent/assent is being sought for the Speech and Language Therapists (SLTs) to access medical records. It was discussed that SLTs would already have access to these records as part of participants care and treatment; therefore, it should be made clear that consent/assent is requested to access records for the purpose of this research study. **Participant Groups** • The HRCDC noted the study's eligibility/inclusion criteria which specifically included patients hospitalised with COVID-19 and who are referred to speech and language therapy. The HRCDC also noted that the Applicant had included patients who are intubated, under the scope of the consent declaration being requested. • The HRCDC discussed that it was unlikely that patients would be referred to speech and language therapy whilst they remain intubated and therefore would not be recruited to the study at this stage and assent from an appropriate individual for the research study would not be sought at this stage. It was acknowledged that the participant may be referred to SLT once extubated and that assent would be obtained at that point in time. • The HRCDC was of the view that the scope of the declaration should not therefore be required to cover the processing of personal data of patients that are intubated and not yet referred to SLT. • The Secretariat discussed the scope of the declaration would be clarified in its correspondence with the Applicant. **Public and Patient Involvement (PPI)** • The HRCDC noted the Applicant's intention to include a patient and public representative in the study. It was discussed that the Applicant could enhance the level of PPI that will be undertaken for this study; reference was made to organisations such as ICUSteps or engaging with patients who have experienced hospitalisation due to COVID-19. **Other** • The HRCDC discussed the protocol for determining the participant's decision-making capacity, including the use of cognitive test results from healthcare records and liaising with the multi-disciplinary clinical team.
HRCDC Declaration Decision	The consensus of the HRCDC was that a Conditional Consent Declaration should be made.
Duration of Declaration	The declaration is made commencing 28th July 2020 and valid until 31st December 2020 and for 7 years thereafter or until consent has

	been obtained from the participants or the personal data has been irrevocably anonymised or destroyed.
Conditions Attached	The following conditions are attached to the declaration made for the purpose of processing personal data of participants are follows; **Condition 1:** The Applicant is requested to carefully review and revise the consent and assent protocol and documentation to ensure clarity and consistency of information provided, and that informed consent and assent is appropriately recorded. Specifically, the Applicant is requested to amend the protocol and documentation as follows: - Revise the study information leaflet being used as a script to obtain verbal consent/assent, to ensure information is provided in an appropriate format. - Verbal consent/assent being obtained by the researcher, should where possible, be witnessed and recorded, for example by a witness countersignature. - Where verbal consent/assent is obtained, a copy of the study information leaflet and consent/assent forms should also be forwarded to the participant and/or those providing assent on their behalf. Where the participant resides in a residential care home, a copy should be kept on file in the participant's records. - Correspondingly, the signature of the participant, or those providing assent on their behalf, should be obtained on the consent/assent form and returned to the research team once verbal consent or assent has been provided. Infection control procedures, such as sealing the returned document for 14 days, should be undertaken. - A 'consent to continue' information leaflet and deferred consent form should be developed and used to obtain consent from those who regain decision-making capacity. - Where assent is provided by an appropriate individual who understands the will and preference of the participant, references to 'your explicit consent' should be removed from the study information leaflets and assent forms. The Applicant should also outline the reasons why assent is being sought and that deferred consent will be obtained when the participant regains decision-making capacity. - It should be clarified in the documentation that consent/assent is requested to access records for the purpose of the research study, separate to care and treatment. The Applicant is requested to report on the implementation of the above points as part of the Annual Review. **Condition 2:** It is a condition of the declaration that public and patient involvement (PPI) in the development of this study is enhanced to ensure knowledge in context and experience can be gained through direct engagement with the public and patients. Engagement with representative groups such as ICUSteps should be considered. The Applicant should also be aware of the recent statement made by the Irish Platform for Patient Organisations, Science and Industry (IPPOSI), setting out the importance of

	understanding the patient perspective during the COVID-19 pandemic. The Applicant is requested to report on efforts to enhance PPI as part of the Annual Review.
HRCDC observations/ Recommendations	**Recommendation 1:** The Applicant is recommended to review, and where necessary, update the DPIA form in consultation with the relevant data protection officer(s) to ensure that the data protection risks and mitigating actions remain applicable with regards to the updated study protocol. **Recommendation 2:** With regards to the implementation of the assent protocol, which is considered an important safeguard, the Applicant should be satisfied that; - decision-making capacity is established by the appropriate health care team, which may include health care teams within a residential care home. - the most appropriate individual who understands the will and preference of the participant and is providing assent on behalf of a participant who lacks decision-making capacity, is identified. - if assent is being obtained outside a hospital setting, such as in a residential care home, it is done so in accordance with the residential care home's policies and procedures.

6. Annual Reviews

The Secretariat informed the HRCDC that the obligation of Applicants completing an Annual Review has commenced. The Secretariat is requesting Applicants to complete an Annual Review prior to the anniversary date that the declaration was made. The Secretariat have received 2 Annual Reviews to date. After review, the Applicants' Annual Review are deemed to be complete.

7. Activities

The HRCDC were informed of the following events and documents of interest:

- HRB-TMRN Webinar Series: 'Implementing a National Approach to Research Ethics Review during a Pandemic – the Irish Experience of NREC COVID-19'

https://www.hrb-tmrn.ie/training-education/upcoming-events/

- Report on the Science Europe workshop 'The GDPR in International Research Collaborations' (Brussels, 27-28 January 2020).

8. Any other Business

The HRCDC noted the recent decision by The European Court of Justice (ECJ) on the 'Privacy Shield' agreement between the EU and United States (US). It was discussed that, as a result of this decision, other suitable legal agreements should be relied upon to transfer personal data to the US. It was also discussed that it is up to the relevant data controllers to ensure that the required legal agreements or arrangements are in place which is in line with the standard conditions attached to all consent declarations made by the HRCDC.