HRCDC
Health Research Consent Declaration Committee

Date: 25th June 2020
Location: Videoconference

Minutes of the Meeting

HRCDC Attendance

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

Quorum for Decisions ☒YES

New Applications - For Consideration

Applicant	Ref No.	Title
Paul Cotter	20-020-AF1-COV	Irish Coronavirus Sequencing Consortium
Sean Kennelly	20-004-AF1-COV	Outcomes for Older People with Cognitive Impairment Attending the ED
David Galvin	19-077-AF3	Irish Prostate Cancer Outcomes Research (IPCOR)

Meeting Items

1. **Opening**
   The Chair opened the meeting and welcomed the members.

2. **Apologies**
   Simon Furney, Malcolm Kell, Kathy Brickell, Barry O' Sullivan, John Ferguson

3. **Disclosure of Interest**
   The following disclosures were made;
   - **Application 20-020/AF1/COV**: Brigid McManus disclosed her Board membership of the Children's Health Group as Crumlin Hospital was noted as a site of data collection referenced in application. There was no conflict of interest that warranted abstaining from this discussion.

- **Application 19-077-AF3**: Zubair Kabir disclosed that he has published papers for unrelated studies, with investigators that are involved in the project. ZK also uses data from the National Cancer Registry Ireland but has no involvement in IPCOR study. There was no conflict of interest that warranted abstaining from this discussion

4. Minutes of the last meeting

Draft minutes of the 10th June 2020 meeting were circulated in advance of the meeting and were agreed by the HRCDC. Minor grammatical errors were highlighted for amendment by the Secretariat.

5. Matters arising

- Application 20-017-AF1/COV: "TERAVOLT". The application was withdrawn prior to consideration. The Secretariat had undertaken to correspond with the coordinator of the study to understand if the withdrawal of the application was specifically related to the consent declaration process, or changes to the study itself. The coordinator was generally positive about the process but did state that a guidance note for International Controllers would be extremely useful. The Secretariat has undertaken to draft a note and revert once this has been finalised.
- Application 20-016-AF1/COV: "Clinical Characteristics of Dysphagia and Communication Difficulties/COVID-19". The study did not receive a consent declaration (Meeting 10th June 2020). The Secretariat updated the HRCDC that the Applicant may resubmit a new application requesting a consent declaration specifically for processing of data of individuals who lack decision-making capacity.

6. Applicant Correspondence for Noting

- Ref ID 19-073-AF3: "Cork Epilepsy Incidence Study". The Applicant responded to conditions attached to the consent declaration made by the HRCDC (Meeting 30th April 2020). The HRCDC noted the responses addressing the conditions and agreed with the feedback provided by the Secretariat to the Applicant.

7. New Applications

Reference ID:	20-020-AF1-COV
Lead Applicant:	Paul Cotter
Lead Data Controller:	Teagasc
Title:	Irish Coronavirus Sequencing Consortium
Research Objective	This study aims to discover the genetic makeup of coronavirus (SARS-CoV-2), the virus that is causing the current pandemic of COVID-19, by looking at the cDNA sequence of the virus from samples taken from COVID–positive patients throughout Ireland. Coronaviruses can mutate or change the proteins on their surface, making it more difficult to develop an effective vaccine against them. These mutations or changes have not been observed as much in the coronavirus causing COVID-19 (SARS-CoV-2). However, it is important to keep monitoring this to ensure the coronavirus doesn't change in such a way that makes it even more difficult to treat or vaccinate against. By sequencing samples from all over the country, the study will be able to help show how the virus is spreading in the community and, also, between Ireland and other countries.

Reason for Declaration	A declaration is requested to process the data of **i)** retrospective participants whose data and samples have already been obtained for COVID-19 testing in the National Viral Reference Laboratory (NVRL) and in the consortium hospital labs at the beginning of the pandemic; this includes individuals who were tested in hospital-based and community-based settings. **ii)** future/prospective patients who will be tested for COVID-19 in the community as part of standard detection testing for the virus (e.g. drive through testing centres). These samples are also sent to the NVRL or consortium hospital laboratories. The data processing activities include the collection, storage, pseudonymisation and subsequent transfer of data from the sites that hold the data, to the data controller of this study. When sequenced, the viral genome and the associated pseudonymised data will also be uploaded to publicly accessible databases for analysis by researchers.
HRCDC Comments:	The HRCDC noted that the National Research Ethics Committee (NREC) for COVID-19 had given provisional ethical approval for the study where the design, methodology and ethical aspects of the study, including consent protocols are considered. Only studies that have ethical approval, or provisional ethical approval, can be considered by the HRCDC to examine if the public interest outweighs the requirement for explicit consent. 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 a conditional declaration could be made. The following points were discussed: **Public Interest** • The HRCDC was of the view that there is a strong public interest in this study due to the impact of the coronavirus pandemic and the potential benefits the study may generate, including managing and mapping COVID-19. • It was also noted that the public interest is further strengthened by making the viral genome and associated, de-identified data available to the wider research community in a controlled manner through publicly available databases. **Study Participants** • The HRCDC queried the position of participants who have previously been enrolled and consented to the separate All Ireland Infectious Disease (AIID) study, who are also included in the Irish Coronavirus Sequencing Consortium study. From the information provided, the Secretariat clarified that previous consent obtained from participants enrolled in the AIID study, also covers the processing of their data for the Irish Coronavirus Sequencing Consortium study; a consent declaration is therefore not required to cover these participants.

	• It was noted by the HRCDC that it is up to the data controller of the study to determine whether the consent obtained from participants is sufficient. **Obtaining consent** • The HRCDC discussed the feasibility of obtaining consent from (i) retrospective participants already tested for the virus at the beginning of the pandemic and (ii) future or prospective participants who will be tested for COVID-19 in community test centres. On the retrospective cohort, the HRCDC noted the Applicant's response on why it is not possible to get consent to use their data for the purpose of this study: i) the large number of participants, ii) the practicalities of obtaining consent for data and associated samples that have already been collected as part of standard care and treatment iii) the limited amount of data that will be processed for this study and iv) the reasons why consent for research was not obtained when individuals presented for testing during the early stages of the pandemic. • Considering the aforementioned points, and based on the information provided, the HRCDC accepted the difficulties that would be involved to obtain consent from the retrospective cohort and considered the study in the public interest, subject to significant transparency measures being undertaken. • Separately, the HRCDC considered if it was feasible and appropriate to obtain consent from the prospective participant cohort who will be tested for COVID-19 in the community setting. The HRCDC discussed the challenges and practicalities outlined by the Applicant on why it is not possible to get consent from this specific cohort. • However, notwithstanding the strong level of public interest in this study and acknowledging that there may be challenges to obtaining consent from prospective participants, the HRCDC was of the view that it would be possible and appropriate to develop and implement a consenting protocol (including verbal consent if appropriate) in order to use data and associated samples from the prospective participant cohort in this research study, • Therefore, the scope of the declaration only includes the retrospective cohort and does not cover the use of data from the prospective cohort who will be tested for COVID-19 in the community. • However, in acknowledging that the Applicant may face practical challenges in implementing a consenting process for prospective participants tested in the community, the HRCDC stated that a request for an amendment to the consent declaration could be made if, after sufficient time and effort, it is found that obtaining consent is not feasible, resulting in the study being compromised. • The HRCDC discussed that any future amendment request to broaden the scope of the declaration to include the prospective cohort, must demonstrate the Applicant's substantive efforts made to implement a consenting process and the reasons why it was not feasible in practice to obtain consent.

	• If an amendment were to be considered, concerns relating to transparency must also be sufficiently addressed for this cohort, for example by providing appropriate study information leaflets in the community test centres and outlining how individuals can withdraw from the study. **Transparency** • The HRCDC was of the view that the level of transparency should be greatly strengthened across all the participating cohorts, and, in particular, for the retrospective participants. • It was discussed that all participants should be made aware of the use of their data, the role of commercial parties as data processors in the study, their data protection rights and options for what will happen to their data if they wish to withdraw from the study. In addition, they should also be aware if there is a point in time when data cannot be withdrawn. • The HRCDC discussed that enhanced transparency could include disseminating information leaflets to participants or carrying out a wider publicity campaign. **Information leaflets and consent forms** • The HRCDC discussed information leaflets and consent forms that will be used by the study to consent prospective hospital-tested participants. It was the view that the documents should clearly outline what may happen to the data if they wish to withdraw from the study and if there is a point in time when consent cannot be withdrawn. **Data Governance** • The HRCDC noted that data sharing agreements will be put in place between Teagasc as the data controller of the study, and the sites providing the data and samples to govern the transfer and use of both the data and associated samples. In addition, it was noted that data processing agreements will also be put in place between Teagasc and the sequencing laboratories who will be data processors for the study. • The HRCDC discussed that the legal agreements in place should clearly cover the protocol for retaining and subsequently destroying the data and associated samples once the data processing activities have concluded. • The HRCDC discussed that data and associated samples cannot be transferred or processed until these agreements are in place. **Publicly Accessible Database** • The HRCDC discussed the proposed public databases that the viral genome and associated, pseudonymised data will be uploaded to. • The HRCDC queried why data will be uploaded to more than one platform and whether it would be beneficial to upload the pseudonymised data to a single platform to mitigate possible data protection risks.

	Data Security Measures • It was noted that the data will be encrypted and may be transferred from the hospital sites to Teagasc using a USB device. The HRCDC discussed that data transfers must be done using secure methods to minimise data protection risks. **Public and Patient Involvement** • It was notable that no public and patient involvement (PPI) for this study had been undertaken. The HRCDC was of the strong opinion that the PPI engagement should be enhanced. It was also considered that the development of a consenting protocol for prospective participants should involve consultations with public and patient representatives. **Other** • For the prospective participant cohort, the HRCDC noted the exclusion of participants with learning disabilities and those that lack decision-making capacity and queried the impact on the study by not including these individuals. • The HRCDC noted that the information provided in the NREC application suggested that consent was the basis for participant enrolment, however, for 50%, and possibly more of the participants, obtaining consent is considered not to be feasible.
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 June 25th, 2020 and shall be valid for six months, and 15 years thereafter (until 31st December 2035) or upon confirmation that the data has been irrevocably rendered anonymised or destroyed, or whichever occurs sooner. Condition 1 must be met prior to data processing commencing.
Conditions Attached:	The following conditions are attached to the consent declaration made only for the processing of retrospective collected personal data associated with clinical and community-tested biosamples, which are already obtained and tested (in the early stages of the pandemic). **Condition 1:** The Applicant must ensure that all appropriate legal agreements or arrangements, as required, governing the transfer and use of data and associated samples are concluded between the Data Controller and Data Processors, and other parties as required. The agreements/arrangements should also clearly cover the protocol for retaining and subsequently destroying the data and associated samples once the data processing activities have concluded. This condition must be met prior to the commencement of data processing. **Condition 2:** The Applicant is requested to enhance the level of transparency for this study such that the retrospective participant cohort, can be made aware of the existence of the study. For both retrospective and prospective participants, the Applicant is

	requested to clearly outline in transparency notices and study information leaflets, the participant's data protection rights and specify the options available if the participant wishes to withdraw from the study, including if there is a point in time when data cannot be withdrawn. **Condition 3:** The HRCDC considers public and patient involvement (PPI) in health research an important safeguarding element, in particular, where no explicit consent is being sought, to ensure a public/patient perspective is reflected in the overall study. The Applicant is requested to enhance the level of PPI in the study. If there are constraints using normal means to engage with PPI representatives and advocacy groups in light of the ongoing coronavirus situation, the Applicant is advised to engage by alternative means such as email and videoconference as appropriate. 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 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 Recommendations:	**Recommendation 1:** The HRCDC recommend that the Data Controller of the study, limit uploading of pseudonymised/de-identified data associated with the viral genome data, to the EMBL's European Bioinformatics Institute COVID-19 Portal, as it is aligned with European Open Science Cloud (EOSC) principles. The EOSC enables FAIR data use (Findable, Accessible, Interoperable, Reusable) in a trusted and safe manner and facilities research productivity and improved reproducibility in science, which would be in the public interest for this particular study. If other non-EU open access databases are used, it is recommended to ensure use of robust security measures of GDPR standard, and data sharing principles similarly aligned to, and no less stringent, than European Open Science Cloud (EOSC) principles. It is recommended to consult with the Data Controller's Data Protection Officer to ensure that all public databases meet appropriate data protection standards. **Recommendation 2:** The Applicant must ensure that data is transferred securely between all the parties in the study. Specifically, where data is to be transferred using USB device the Applicant is requested to examine other secure methods of transfer to mitigate data protection risks.
HRCDC Comments:	• The HRCDC acknowledged that the Applicant may face practical challenges in implementing a consenting process for prospective participants to be tested for COVID-19 in a community setting. It was discussed that a request for an amendment to the consent declaration could be made in the future, if it is found that obtaining consent from the prospective cohort is not feasible or practicable, despite best endeavours.

	• Any future amendment request for this prospective cohort would be subject to the expectation that substantive efforts to develop and implement a consenting process had been made. The Applicant would also be expected to substantiate the reasons why it is not feasible in practice to obtain consent. • Other outstanding safeguard measures relating to transparency, data protection rights and enhanced PPI (as outlined in Conditions 2 & 3) must similarly be addressed for the prospective participant cohort if an amendment is requested.

Reference ID:	20-004-AF1-COV
Lead Applicant:	Sean Kennelly
Lead Data Controller:	Tallaght University Hospital
Title:	Outcomes for Older People with Cognitive Impairment Attending the Emergency Department (ED)
Research Objective:	It is estimated that there will be more than 140,000 people living with dementia in Ireland by 2041. People living with dementia have complex care needs and are known to be at higher risk of adverse outcomes across healthcare settings. Dementia is present in almost 40% of older patients attending the ED but is under-recognised in this setting. The ED environment is often unsuitable for those living with dementia and may contribute to poorer outcomes seen in those with dementia following an ED attendance. Few patients have access to gerontological review at ED presentation. People living with dementia are a diverse group but are under-represented in research. This research study aims to recruit participants aged over 75 years to investigate the prevalence of cognitive impairment and dementia following an ED attendance, factors that may contribute to these outcomes and barriers to care for those with dementia in the ED. It is hoped that the results will allow improvements in care for all people living with dementia in the future.
Reason for Declaration:	A minority of participants with dementia may be unable to give fully informed consent due to significant cognitive impairment; a declaration is therefore sought for these participants. The data processing activities include: collection, pseudonymisation, analysis and storage of personal data that is already collected as part of usual patient care (i.e. medical records) as well as data collected for the purpose of this study. This includes the collection of follow-up data at six months and one year (via medical records and phone call)
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 a consent declaration could be made. The following points were discussed: **Public Interest and Consent** • The HRCDC was of the view that there is a strong public interest in this study and discussed the reasons why it is not feasible to obtain explicit consent. On balance it was considered that the public interest significantly outweighed the requirement to obtain

	explicit consent, as the study aimed to improve future care for individuals living with dementia. **Consent/Assent Protocols** • The HRCDC discussed that the assent/consent protocol appeared to provide an appropriate and suitable safeguard to protect the participant's data protection rights. • The HRCDC noted however, that the consent and assent forms were different and do not contain the same consenting options. • It was also discussed that, where applicable, the participant's legally appointed representative (ie enduring Power of Attorney) should be the individual providing assent on their behalf. • It was further discussed whether the assent protocol could be strengthened to include interaction with the participant's General Practitioner (GP) to help ensure that assent is obtained from the most appropriate individual who understands the participant's will and preference. • It was highlighted that deferred consent to continue in the study will be sought where the participant regains decision-making capacity. The HRCDC commented that it is important not to assume that the participant continues to lack decision-making capacity over a prolonged period of time. In this regard, the HRCDC considered that deferred consent should be obtained from the participant, if appropriate and possible, at the 6-month and 1-year follow-up phone calls before contacting the relative or carer who provided assent on their behalf. **Public and Patient Involvement (PPI)** • The HRCDC commented that a strong level of PPI was undertaken for this study. **Other** • The HRCDC queried whether the results of the additional tests carried out for the purpose of the study are also included in the participant's medical records. • The practicalities of carrying out the Mini Mental State Examination (MMSE) in an ED setting was queried, as this is typically carried out in a clinical setting. • The HRCDC also queried the number of participants who will be included in the study. It was highlighted that up to 300 participants will be recruited, consisting of those with and without the capacity to provide consent.
HRCDC Declaration Decision:	The consensus of the HRCDC was that a Declaration should be made.
Duration of Declaration:	The Declaration is made commencing 25th June 2020 and shall be valid until 30th June 2023 or upon confirmation that the data has been rendered anonymised or destroyed, or whichever occurs sooner.
HRCDC Recommendations:	**Recommendation 1:** As an additional safeguard, the HRCDC recommends that the Applicant considers interaction or correspondence with the participant's GP if practically possible and

	as applicable, to make them aware of the study and inform them of the individual that has provided assent. **Recommendation 2:** The HRCDC recommends that the Applicant review the assent and consent forms and study information leaflets, to ensure there is consistency in information and consenting/assenting options for the individuals providing assent or consent. **Recommendation 3:** So as not to assume that the participant continues to lack decision-making capacity over a prolonged period of time, the HRCDC recommends considering whether it is appropriate and possible to obtain deferred consent, at the 6-month and 1-year follow-up phone calls, before contacting the relative or carer who provided assent on their behalf previously. **Recommendation 4.** Where applicable, the Applicant should first determine if the participant who lacks decision-making capacity to provide consent, has a legally appointed representative (e.g. an enduring Power of Attorney).

Reference ID:	19-077-AF3
Lead Applicant:	David Galvin
Lead Data Controller:	Clinical Research Development Ireland
Title:	Irish Prostate Cancer Outcomes Research (IPCOR)
Research Objective:	Irish Prostate Cancer Outcomes Research (IPCOR) has established a national prostate cancer disease registry, which captures high-quality clinical and quality of life information from newly diagnosed prostate cancer patients from 15 hospitals across Ireland. IPCOR generates high quality data on a range of important clinical outcomes in men with prostate cancer, assesses quality of care and provides recommendations to clinicians, hospitals, decision-makers and the National Cancer Control Programme, to promote equal access to healthcare services and improvements in care nationally. By bringing together data on prostate cancer patients, collected over time, the IPCOR study will ultimately lead to the improvement of patient experiences and maximise quality of life for men diagnosed with prostate cancer in Ireland.
Reason for Declaration:	The Data Controller of the IPCOR study wish to obtain pseudonymised clinical data from the National Cancer Registry of Ireland for the purpose of storing, analysing and further pseudonymising that data and sharing with co-investigators of the study. The nature of the clinical data being obtained is; diagnostic pathways, cancer treatment and longitudinal outcomes. [NOTE: Additional quality of life data or patient reported outcomes data (PROMs) obtained through questionnaires with explicit consent, is linked to the clinical data and provided to the IPCOR Study. This 'PROMs' data does not require a consent declaration].
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 a consent declaration could be made. **Public Interest** • The HRCDC was of the view that there is a strong public interest in this study and discussed the reasons why it is not feasible to obtain consent. On balance it was considered that the public interest significantly outweighed the requirement to obtain explicit consent. **Transparency:** • The HRCDC noted the transparency measures that were in place. The HRCDC was of the view that transparency measures could be further strengthened such that all participants may be sufficiently informed of the study, how their personal data collected by NCRI will be used in the IPCOR study, and how they can exercise their data protection rights. It was discussed that weblinks to the IPCOR study could be provided on the National Cancer Registry Ireland website. **Study Information Leaflets and Consent Forms** • Where consent had been obtained to collect patient quality of life or reported outcomes data, the HRCDC noted that the consent forms do not contain 'yes/no' options and queried the benefit of having both options for clarity. **Transfer of data** • It was discussed that there are UK co-investigators collaborating on the study and appropriate agreements/arrangements governing the transfer and use of data must be in place whenever data is shared or transferred. • The Secretariat highlighted the Applicant's response that data has not yet been shared but that appropriate agreements will be put in place when this occurs. The Applicant was also conscious that the UK will be a third party once the Brexit transition period is over. **Public and Patient Involvement (PPI)** • The HRCDC discussed and noted that there is a public and patient representative on the study's steering group. On balance the HRCDC discussed that the level of PPI could always be further strengthened for the benefit of the study and the participants.
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 8th August 2018 and shall be valid until 31st July 2020 and for five years thereafter (until 31st July 2025) or upon confirmation that the data has been rendered anonymised or destroyed, or whichever occurs sooner.

Conditions Attached:	The following condition has been attached to the Declaration as follows: **Condition 1.** The Applicant must ensure that appropriate agreements or arrangements governing the transfer and use of data, are in place prior to any transfer to organisations. Special consideration should be given to arrangements required for the transfer of data to recipient organisations in the UK, which will become a third country (non-EU) once the Brexit transition period is over.
HRCDC Recommendations:	**Recommendation 1.** The Applicant is recommended to examine how the level of PPI for this specific study could be further enhanced. **Recommendation 2.** The Applicant is recommended to consider strengthening transparency measures for the study to ensure that all participants can exercise their data protection rights, including the right to withdraw and understand what will happen to their data in such circumstances. It should be made clear how their personal data collected by NCRI, will be used in the IPCOR study. It is further recommended that links to the IPCOR study on the National Cancer Registry Ireland website are visible and accessible to participants.

8. Any other Business

- Recent references to the HRCDC within the media were highlighted, specifically in relation to HRCDC application 19-006-AF3 and the subsequent appeal. It was discussed that it may not be clear to the general public as to the role and remit of the HRCDC in the context of the wider health research environment, in particular in the context of approvals and authorisations required to carry out health research. This could be clearly outlined on the HRCDC website.
- The Secretariat provided an update on the tenure of the COVID-19 National Research Ethics Committee (NREC) which is due to end in the coming months. An update was also provided with regards to the outstanding COVID-19 HRCDC applications that the Secretariat are awaiting feedback from Applicants prior to consideration by the HRCDC.
- The Chair noted that there might be a potential quorum issue for part of the meeting as some members couldn't attend and others indicated they needed to leave the meeting early. While recognising that issues could arise at short notice, she asked members to let the Secretariat know as early as possible if they could not attend for all or part of the meeting. She noted that while special "COVID-19" are scheduled for two hours, the "standard" meeting would be a full half day for the foreseeable future given the backlog of applications to consider.

The Chair closed the meeting.

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