HRCDC
Health Research Consent Declaration Committee

Date: 12th April 2022
Location: Videoconference by Zoom

Minutes of the Meeting

HRCDC Attendance

Name
Aideen Hartney
Alyson Bailey
Sheelah Connolly
Simon Furney
Dan Rea
Zubair Kabir
Cornelius Cooney
Mary Tumelty
John Woods
Barry Lyons
Emily Vereker (Secretariat)
Jonny Barrett (Secretariat)
Caroline Byrne (Secretariat)

Quorum for Decisions
☒YES

New Amendments - For consideration

Applicant	Ref No.	Title
Tom Rogers	21-003-AF1/AMD1	Investigating the Epidemiology of *Mycobacterium bovis* Infection in Humans

New Applications – For consideration

Applicant	Ref No.	Title
Patricia Fitzpatrick	22-001-AF1/CSO	Impact of lifestyle factors on COVID-19 outcomes

Meeting Items

1. **Opening**
   The acting Chair, Aideen Hartney (AH), opened the meeting and welcomed the members. AH was appointed acting Chair for the meeting due to apologies from the Chairperson, Brigid McManus, and the Deputy Chairperson, Evelyn Mahon.

2. **Apologies**
   Brigid McManus, Evelyn Mahon, Barry O' Sullivan, Claire Collins, Kathy Brickell.

3. **Disclosure of Interest**
   Zubair Kabir (ZK) informed the HRCDC that he professionally knows researchers named in amendment request 21-003-AF1/AMD1, and the new consent declaration application 22-001-AF1/CSO, however ZK is not involved in either study.
   The HRCDC was of the view that there was no conflict of interest that would require ZK to be excluded from the discussion of these agenda items.

4. Minutes of the last meeting

Draft minutes of 8th March 2022 were circulated in advance of the meeting and were approved by the HRCDC.

5. Matters arising

The HRCDC were informed that the HRCDC 2021 Annual Activities Report has been furnished to the Minister for Health.

6. Live consent declaration

Reference ID:	21-013-AF1
Lead Applicant:	Maeve Mullooly
Lead Data Controller:	National Screening Service and The Royal College of Surgeons in Ireland
Title:	Mammographic breast density and breast cancer outcomes in a population-based breast screening programme'
Research Objective:	See HRCDC Meeting minutes of 7th September 2021
Points to Discuss:	Condition #1/Patient and Public involvement activity report
HRCDC Comments:	• The HRCDC were provided with the Applicant's report on public and patient involvement (PPI) activity that was carried out as a condition attached to the consent declaration, made on 7th September 2021. The continuation of the consent declaration was contingent on the Applicant's report on the PPI activities undertaken in advance of processing data for the study. • The report described the extensive PPI engagement that has been undertaken to date, which includes two separate PPI panels that provided views on the importance of the study, the use of participant data, a communications strategy, and importance of the ability of participants to opt out of the study, should they wish to do so. • The HRCDC was of the view that the report was satisfactory and commended the level of PPI engagement described within. The Secretariat will forward a formal response letter to the Applicant on behalf of the HRCDC noting the report as satisfactory.

7. Amendments

Reference ID:	21-003-AF1/AMD1
Lead Applicant:	Tom Rogers
Data Controller:	St. James's Hospital Trinity College Dublin [NEW DATA CONTROLLER]
Title:	Investigating the Epidemiology of *Mycobacterium bovis* Infection in Humans
Research Objective:	See minutes of 13th April 2021 & 18th May 2021
Purpose of Amendment:	The purpose of the amendment is to add Trinity College Dublin (TCD) as a joint controller of the study with St James's Hospital (SJH).
HRCDC Comments:	The Chair introduced the amendment request and invited the Secretariat to provide further details on the amendment.

	The Secretariat highlighted that TCD were designated as a data processor in the original application form, however, given the change in the roles of the researchers, TCD are now deemed to be a joint data controller for the study. It was noted that the amendment does not affect the data processing activities outlined in the original HRCDC application, including those who will have access to the personal data and medical records for the purpose of this study. The Chair requested members to indicate their approval to amend the conditional consent declaration and invited members to comment. Based on the information provided, it was the consensus of the HRCDC that the amendment to the consent declaration can be approved. The decision was based on the following discussion points: **Safeguards** • The HRCDC queried what safeguards will be implemented to protect the personal data, including safeguards regarding the access to the medical records by TCD. • It was noted that the researcher previously employed as a TCD Research Fellow, will continue to access the medical records, completing this study as TCD medical student under the supervision of the Principal Investigator in SJH. • The Secretariat highlighted that confirmation was previously provided as part of the original HRCDC application that an appropriate data agreement is in place between SJH and TCD. It was noted that a change in role from data processor to a joint data controller would necessitate updating the existing agreements/arrangements to ensure continued compliance with GDPR and the standard attached condition. • It was highlighted that the amendment request form referred to a joint controller arrangement between SJH and TCD. It was also commented that universities and hospitals commonly have overarching agreements in place with regards to collaborative research studies. • The HRCDC was of the view that both data controllers should ensure that the joint controller arrangement clearly sets out the roles and responsibilities of each party, including access to the medical records by the TCD medical student. **Ethics approval** • The HRCDC queried whether the necessary research ethics committee (REC) approval had been obtained to cover this amendment. The Secretariat confirmed that a copy of the REC approval has been provided by the Applicant. **Transparency measures** • The Applicant provided a copy of the study's privacy notice, which was unchanged to the version submitted with the original HRCDC application form.

	• It was noted that this document already refers to the involvement of TCD in this study. If not already done so, it was discussed that all transparency measures should clearly outline the role of TCD.
HRCDC Decision:	The consensus of the HRCDC was that the conditional declaration could be amended.
Amendment Duration	The approval for the amendment is made commencing 12th April 2022 and shall be valid until 31st May 2023 at which point the data will be anonymised. This is in line with the duration of the consent declaration made.
HRCDC Recommendations:	**Recommendation 1:** Notwithstanding that a joint data controller agreement is in place between the joint data-controller parties (Ref; application form), the Applicant should ensure that the data agreements/arrangements in place between St James's Hospital Dublin and Trinity College Dublin, clearly outline the roles and responsibilities of each party for this specific study. This includes clearly outlining the role and responsibilities of the study investigators, including the TCD medical student accessing the medical records. **Recommendation 2**: The privacy notice submitted as part of the amendment request form outlines that TCD are involved in this study. More broadly and linked to Condition 2 attached to the original consent declaration, the Applicant is recommended to ensure that other transparency measures to be implemented will highlight the role and responsibility of TCD in this study, if not done so already.

8. New Applications

Reference ID:	22-001-AF1/CSO
Lead Applicant:	Patricia Fitzpatrick
Data Controllers:	University College Dublin
Title:	Study of the impact of lifestyle factors on COVID-19 outcomes
Research Objective:	This is a study that will be carried out over a period of 6 months in the UCD School of Public Health, Physiotherapy and Sport Science. A pseudonymised secondary dataset will be utilised, which is available from the CSO on behalf of the HSE. The objective of the study is to assess the impact of modifiable risk factors including weight, height and BMI, smoking status, taking into account the effect of age, gender, ethnicity and co-morbidities including diabetes, hypertension, cancer and hypertension, on outcomes of COVID-19. The available pseudonymised dataset includes follow up detail by COVID-19 case on hospitalisation and ICU admission with associated data.
Reason for Declaration:	The Applicant is seeking to access and obtain pseudonymised data (research microdata files) from the COVID-19 Data Research Hub, hosted by the Central Statistics Office. As the data being accessed is pseudonymised data and that it is not feasible to seek consent from individuals whose data is held by the CSO within the COVID-19 data hub, a consent declaration is required.

HRCDC Comments:	The Chair introduced the agenda item and highlighted that the study had obtained exemption from full University College Dublin (UCD) research ethics committee review. The Secretariat outlined the discussion it had with the UCD research ethics committee (REC) prior to the HRCDC meeting, to further understand the ethical review process that was undertaken for this study. The Secretariat learned that studies meeting specific criteria and deemed to be low risk, can seek an exemption from the 'full' (entire committee) REC review. If granted an exemption from full REC review, the study undergoes ethics review by the REC Chairperson. The Secretariat highlighted that this study has been ethically approved via this alternate review process for low-risk studies. 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 should be made. The decision was based on the following discussion points: **Public Interest** • On balance the HRCDC was of the view that there is a strong public interest case for undertaking this study. **REC approval** • Notwithstanding the REC review process that was undertaken and the strong data protection safeguards that are in place for the use of data within the CSO COVID-19 Data Research Hub, the HRCDC was of the view that it would be appropriate for the study to undergo full REC review. • It was commented that a full ethical review should be sought as a safeguard given the nature of the study, the extent of data being accessed and that participants are unable to consent for the use of their personal data in this research. • It was discussed that the consent declaration would not be effective until confirmation of REC approval via the full UCD review process is provided to the HRCDC. **Data minimisation** • The HRCDC discussed the extent of the data in the CSO COVID-19 Data Research Hub that will be accessed and processed for this study. From the information provided it was noted that the Applicant is requesting a large volume of data from the CSO, including information on medical diagnosis that may only apply to a smaller number of individuals. • Notwithstanding the strong safeguards that are put in place by the CSO to minimise the data protection risks, it was commented that the greater extent of data being accessed may increase the level of data protection risks.

	• Correspondingly, it was discussed that the Applicant should ensure that only the minimal amount of data is accessed and processed via the CSO COVID-19 Data Research Hub for the purpose of this study. **Data Controllership** • It was queried if the CSO was a joint data controller in this study. It was confirmed that the CSO are the data controller of the data in the COVID-19 Data Research Hub however they are not a joint controller of the study alongside UCD. **Duration of the consent declaration** • The HRCDC queried the duration of the consent declaration that was requested. • It was noted that researchers will be designated as CSO Officers of Statistics for a one-year duration, to enable access to the CSO COVID-19 Data Research Hub. While it was noted that this designation is usually for one year, the Applicant has outlined that the declaration is only required for 6 months. **Legal basis and relevant condition** • It was noted that GDPR Article 9(2)(h) 'health and social care' and Article 9(2)(i) 'public health' were stated as the relevant conditions for processing special category personal data. • While it is the responsibility of the data controller to determine the legal basis and relevant condition for processing personal data, the HRCDC discussed that Article 9(2)(j) 'Scientific Research' may be a more appropriate relevant condition to reply upon. **Transparency measures** • The HRCDC was of the view that the Applicant's response regarding transparency measures was inadequate, focusing specifically on the dissemination of the research findings. It was discussed that enhanced transparency measures should be implemented and more accessible, such that participants and the public can be made aware of this study and the use of personal data. **Public, patient and carer involvement (PPI)** • The HRCDC acknowledged the difficulties in undertaking PPI engagement in the context of this study. It was discussed that an appropriate recommendation would be for the Applicant to explore what PPI activity could be undertaken.
HRCDC Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made.
Duration of Declaration:	The Declaration is made on 12th April 2022 and is valid for 6 months until 31st October 2022.
Conditions Attached:	**Condition 1:** It is a condition of this consent declaration that the Applicant must seek and obtain full ethical review from the University College Dublin research ethics committee. For the

	avoidance of doubt the consent declaration will not become effective until full ethical review and approval is obtained for this study and confirmation of this is provided to the HRCDC. **Note:** Any material changes to the study and data processing activities that may result from the full ethical review must be highlighted to the HRCDC. The HRCDC reserve the right to review the consent declaration made based on the decision and feedback of the UCD REC. **Condition 2:** Further to Condition 1, this consent declaration is not effective until final approval to access the COVID-19 Data Research Hub has been granted by the CSO. Confirmation of final CSO approval must be provided to the HRCDC as soon as possible. **Condition 3**: In consultation with the Central Statistics Office, the Applicant must review the extent of data that will be accessed and processed from the COVID-19 Data Research Hub for the purpose of this study, and thoroughly examine whether the necessary data to be processed can be further minimised. **Condition 4.** The Applicant is required to implement enhanced transparency measures that go beyond the dissemination of the study findings. To meet this condition substantively, such measures should: (i) inform participants and the public about the existence of this study and the use of personal data in this study, (ii) ensure there is clarity of information on the purpose of this study, how and where the data is accessed for this study, and (iii) the extent of the data that will be accessed and processed from the CSO. Transparency measures could include an easy-to-locate study website/webpage, social media channels and other communication platforms. Such measures should be implemented prior to the commencement of the study and in place during the 6-month study timeframe. This is a reporting requirement of the Annual review.
HRCDC Recommendations:	**Recommendation 1.** In discussion with the data controller's data protection officer, the Applicant is recommended to review and consider the appropriateness of the selected Article 9 relevant conditions for the processing of special category personal data. Specifically, the Applicant is requested to consider if Article 9(2)(j) 'Scientific Research' may be more appropriate in the context of this research study. **Recommendation 2**. Public and patient involvement (PPI) is considered an important data protection safeguard in situations where it is not possible to seek participant consent. The Applicant is requested to explore and consider what PPI activities could be

	undertaken with regards this specific study, for example engagement with relevant representative groups or other individuals. PPI activities can inform and benefit the development of this study and other matters such as transparency measures.

9. Annual Reviews

The Secretariat has received 3 annual reviews in advance of the meeting which were deemed satisfactory:

- Ref ID: 19-022-AF2; Rose Anne Kenny, TILDA Study
- Ref ID: 19-019-AF2; Fergus McCarthy, IMPROVED Study
- Ref ID: 19-024-AF2; Geraldine Boylan, INFANT-Seizures

10. Activities report and events of interest

- The Secretariat provided a report on its activities to the HRCDC in advance of the meeting.
- The following upcoming events of interest of where noted:
  - The National Office of Clinical Audit - *Annual Conference 'Data Driving Quality'*: Wednesday 20th April, 10am-1pm (https://www.noca.ie/events/noca-annual-conference-2022)
  - University of Hong Kong – 'Personal Data Protection Regimes and the Sharing of Human Genetic Data for Research': Friday 22nd April, 8pm HKT (https://www.cmel.hku.hk/events-detail.php?id=90)
- The following documents/publications of interest where noted:
  - US-EU data transfers: The US Privacy shield is being replaced by a Trans-Atlantic data privacy framework (https://ec.europa.eu/commission/presscorner/detail/en/FS_22_2100). The HRCDC discussed that it is the responsibility of data controllers to maintain compliance when transferring personal data to the US.
  - HSE National Consent Policy has been published; Part 3 'Research' has not been updated as the this section is still under revision. (https://www.hse.ie/eng/about/who/qid/other-quality-improvement-programmes/consent/hse-national-consent-policy.pdf)
  - HRCDC Ref ID: 20-024-AF1 '*The GenOMICC study - Genetics of Mortality in Critical Care'* - has been published in Nature (https://www.nature.com/articles/s41586-022-04576-6) and in the Irish Times (https://www.irishtimes.com/news/science/new-study-can-help-improve-outcomes-in-critically-ill-covid-patients-irish-researcher-1.4821637?mode=sample&auth-failed=1&pw-origin=https%3A%2F%2Fwww.irishtimes.com%2Fnews%2Fscience%2Fnew-study-can-help-improve-outcomes-in-critically-ill-covid-patients-irish-researcher-1.4821637)

11. Any Other Business

- The Chair reminded members that the next meeting of the HRCDC on 10th May, will be held in person at the offices of the Health Research Board. It was further noted that a speaker is confirmed to discuss the topic of public interest at this meeting.

Members were invited to forward any specific queries they have regarding public interest to the Secretariat in advance of 10th May meeting.

- It was noted that letters of re-appointment from the Minister for Health have been forwarded to the relevant committee members regarding their 2nd term on the HRCDC.
- The Secretariat informed the HRCDC that work is ongoing with the Department of Health to appoint 2 additional members to the HRCDC.
- An update was provided regarding on the status of the small number of remaining AF2 applications on record. It was discussed that a letter from the Chair may be issued in the coming weeks to those Applicants who have yet to respond to the most recent Secretariat correspondence.

****The Chair closed the meeting****