HRCDC
Health Research Consent Declaration Committee

Minutes of the Meeting – Approved

Date: 25th March 2025

Location: Zoom videoconferencing

HRCDC Attendance:

Brigid McManus
Evelyn Mahon
Aideen Hartney
Barry Lyons
Patricia O'Beirne
Susan Smith
Paul Stynes
Aisling McMahon
Sarah Barnes Aabo
Jonathan Briody
Antoinette O'Connor
Jim Blighe
Ross McMullan
Barbara Clyne
Brid Burke (Secretariat)
Jonny Barrett (Secretariat)
Caroline Byrne (Secretariat)
Lucia Prihodova (Meeting Observer)

Quorum for Decisions

YES

New Amendments - For Consideration

Applicant: Prof Mary McCarron
Ref No.: 19-015-AF2/AMD3
Title: IDS-TILDA (Wave 6 amendment)

New Applications – For consideration

Applicant: Ronan O'Toole
Ref No.: 25-002-AF1/CSO
Title: An epidemiological study of COVID-19 in the Irish Traveller population

Opening

The Chair opened the meeting. The newly appointed committee members were introduced and welcomed to the HRCDC.

Apologies

Cornelius Cooney, John Woods, Mary Tumelty

Disclosure of Interest

19-015-AF2/AMD3: Antoinette O'Connor (AOC) informed the HRCDC that she works with the Principal Investigator of IDS TILDA, however AOC is not involved in this study. Evelyn Mahon (EM) also informed the HRCDC that she was a research participant in the main TILDA study but is not involved in IDS TILDA. It was determined that AOC or EM did not need to be absent when this application is considered.

Minutes of the last meeting

Draft minutes of 25th February 2025 were circulated in advance of the meeting and were approved by the HRCDC.

Amendments

Reference ID:

19-015-AF2/AMD3

Lead Applicant:

Prof Mary McCarron

Lead Data Controller:

Trinity College Dublin

Title:

IDS-TILDA (Wave 6 amendment)

Research Objective:

See HRCDC Meeting minutes of 28th February 2023.

Purpose of Amendment:

The amendment is requested to cover the processing of personal data of those who lack decision-making capacity for a sixth wave of the IDS-TILDA study. Wave 6 includes additional intellectual disability service providers who will be sites for data collection, and the inclusion of additional personal data to be collected. The amendment also requests an extension of the study until December 2032 and includes the following new data processors and data providers: National Cancer Registry Ireland, Digital Gait Labs/Azure, the participant's GP.

HRCDC Comments:

Aisling McMahon was assigned as the Primary Reviewer for this application, with Trica O'Beirne and Evelyn Mahon assigned as secondary reviewers.
The Chairperson requested the primary and secondary reviewers to outline the proposal contained in the application and any issues arising; there was then a discussion on the application by the HRCDC.
Following the discussions, it was the consensus of the HRCDC that the amendment request should be approved, subject to conditions.

Public interest case

- The HRCDC was of the view that there is a strong public interest case for a 6th wave of this longitudinal study, discussing that the study is important to inform and guide the planning, implementation of future national policies, programmes and services for this cohort of the population.

Data safeguards and DPIA

- It was noted that this additional wave of the study involves additional data providers, recruitment sites and data processors. The measures in place to safeguard the data processing were also discussed and noted, including the use of encrypted devices, password protection and legal agreements; it was commented that the application would benefit from further details on how data will be securely transferred between the participant's GP and the IDS TILDA research team.
- It was also commented that the DPIA appeared to be incomplete at this stage; specifically, it was noted that some comments from the DPO had not yet been fully addressed, for example that the researchers need to discuss certain data security matters with the data controller's ICT department and that some agreements remained pending. It was discussed that a DPIA is considered a 'living document', but that the comments raised by the DPO should be addressed.

Bio-samples and study information leaflets

- It was noted that Wave 6 also involves the collection of blood, stool and oral swab samples from all participants who will be enrolled in this wave; the Applicant outlined that the purpose of these samples is to examine matters relating to the microbiome and also Alzheimer's Disease in individuals with an intellectual disability. The Applicant further outlined that the analysis of these samples will occur later and that it is not yet known what specific analysis will be carried out or by whom.
- It was commented that science and research is always evolving and that there is value in collecting and storing bio-samples for analysis, including in longitudinal studies such as IDS-TILDA. Notwithstanding the recognition of the scientific value in collecting and storing samples for future analysis, it was further commented that there is the potential to generate sensitive data, such as genetic data, from biosamples.
- It was highlighted that the scope of the amendment will only extend to the collection and storage of the personal data associated with the bio-samples and that further amendments will need to be submitted for consideration to use/analyse these samples and associated data.

- The HRCDC also noted that the study information leaflets provided to the participants for Wave 6 do not clearly outline that oral swab samples are collected. In addition, it was commented that the leaflets don't provide clarity on why blood, stool and oral swab bio-samples are collected for this study, as per the description outlined to the HRCDC. It was the consensus of the HRCDC that the study information leaflets should be amended to provide more detail on the purpose for collecting the bio-samples and it was commented that there should also be a process in place, through enhanced transparency measures, to inform participants/proxies in the future on what sample analysis is undertaken and that they can withdraw from the study at any point.

Research Ethics

- It was highlighted that research ethics committee approval has been obtained from Trinity College Dublin and that the Applicant must ensure that this approval is sufficient for each recruitment site, or they will need to obtain local REC approval where applicable.

HRCDC Decision:

The consensus of the HRCDC was that the amendment request should be approved.

Conditions Attached:

Condition 1. The Applicant must ensure that the requisite research ethics approval is in place for each site in Ireland; if the Trinity College Dublin REC approval is not sufficient for a site, then local REC approval for that site will need to be obtained.

Condition 2. The required data agreements and arrangements must be in place between the relevant parties prior to the transfer/sharing of data. This includes agreements with the recruitment sites, the data processors and the data providers.

Condition 3. The Applicant must ensure that the secure measures are in place with regards the transfer of data between the research team and the participant's GP. The Applicant is requested to report on this before the data is processed.

Condition 4. The Applicant must ensure that the outstanding comments/observations noted in the DPIA submitted to the HRCDC are addressed.

Condition 5. In advance of Wave 6 commencing, the study information leaflets and assent/consent forms should be amended to clearly note that oral swab samples will be obtained in Wave 6. In addition, prior to Wave 6 starting, the documents must also provide additional clarity to participants and their proxies on why the Wave 6 blood, stool and oral swab samples are collected and later processed for IDS TILDA research.
In addition, to amending the study information leaflets for Wave 6, there should also be a process in place, through enhanced transparency measures, for IDS TILDA to inform participants/proxies about the analysis of the samples undertaken in the future, including informing them of their right to withdraw.

New Applications

Reference ID:

HRCDC
Health Research Consent Declaration Committee

25-002-AF1/CSO

Lead Applicant:
Ronan O'Toole

Lead Data Controller:
Dublin City University

Title:
An epidemiological study of COVID-19 in the Irish Traveller population

Research Objective:
The Irish Traveller community suffer from higher rates of respiratory disease compared to the general population in Ireland. There is some evidence that they were particularly affected by outbreaks of COVID-19 during the pandemic. However, the full extent of the pandemic's effect on Traveller health or the underlying reasons why they may have been at greater risk from COVID-19 is not known. This limits the ability to design measures to protect Travellers in advance of future pandemics. To address this, this study proposes to research anonymised data collected in Ireland to determine the level of COVID-19 illness that occurred in the Irish Traveller community, and to understand the underlying factors that placed Travellers at risk from COVID-19. This work will be in line with the National Traveller Health Action Plan (2022-2027) from the Health Service Executive (HSE) "to minimise the impact of COVID-19 and other communicable diseases on Travellers".

Reason for Declaration:
It is recognised that it is not possible for the researchers to obtain consent as they do have access to the contact details of the individuals included in the CSO Health RDC. Also, given the large quantity of data from different individuals included in data centre, it is also not feasible to obtain consent for this large number of participants.

HRCDC Comments:
Paul Stynes was assigned as the Primary Reviewer for this application, with Patricia O'Beirne and Susan Smith assigned as secondary reviewers.
The Chairperson requested the primary and secondary reviewers to outline the proposal contained in the application and any issues arising; there was then a discussion on the application by the HRCDC.
Following the discussions, it was the consensus of the HRCDC that a Consent Declaration should be made, subject to conditions attached.

Public interest case:
- The HRCDC discussed the aims of the study and noted that it was aligned with the National Traveller Health Action Plan which recommended research into the effects of the COVID-19 Pandemic on the Traveller Community. It was noted that due to the limited data to be accessed in the CSO Health RDC, it may be difficult to address all the questions and objectives of this study, however the HRCDC was still of the view there that there is a public interest case in this study.

Data Security:

- The HRCDC discussed the strong security arrangements in place when researchers are accessing and processing data from the CSO Health RDC. It was noted that researchers must be assigned as CSO Officers of Statistics in order to access the data, that the data is pseudonymised with no direct identifiers, that data can only be processed within the Health RDC secure processing environment and cannot be downloaded. It was commented that the data risks are considered low.

Transparency and PPI:

- It was noted that the study had previously engaged with the representative traveller organisation, Pavee Point, who have supported this work, and that the results of this study will be communicated to this organisation and made available to the public. This engagement was welcomed by the HRCDC, however it was commented that efforts could be made to explore engagement and communications with other Traveller Community networks.
- The HRCDC also noted and welcomed the planned use of plain English summaries of this study. It was also discussed that transparency measures could be further enhanced to inform the traveller community about this study, such as through the use of video or other appropriate measures; it was commented that further PPI engagement could also be undertaken with traveller representatives to help determine and design appropriate transparency measures for this community. It was also discussed that other measures could be considered to inform the wider public more generally about this study, given that data from the non-Traveller community will also be processed.

Other:

- It was commented that agreements must be in place between the data controller and Trinity College Dublin as the data processor.
- It was also discussed that the consent declaration is not in effect until final approval to access the Health RDC has been granted by the CSO.

HRCDC Decision:

The consensus of the HRCDC was that a Consent Declaration, subject to conditions attached, should be made.

Duration of Declaration:

The consent declaration is made until 31st March 2028 or until the researchers are no longer assigned as CSO Officers of Statistics for this study, whichever occurs first.

Conditions Attached:

Condition 1. It is a condition of this consent declaration that transparency measures should be further enhanced to better inform the traveller community about this study and the processing of data. Transparency measures should therefore be enhanced beyond the dissemination of findings and Pavee Point, to include wider Traveller networks and other

suitable transparency measures for this cohort, with measures enhanced at the commencement of the study and duration the life of the research.
In addition, given that data of the non-traveller community will be processed, consideration should be given to reaching out to this cohort more generally via enhanced transparency measures.

Condition 2. Data agreements/arrangements must be in place between the data controller, DCU, and Trinity College Dublin as the data processor.

Condition 3. It is a condition that this consent declaration is not effective until final approval to access the Health Research Data Centre has been granted by the CSO.

HRCDC Recommendations:

Recommendation 1. Linked to condition 1, further PPI engagement with traveller representatives should be considered to help determine and design further appropriate transparency measures for this community.

Annual Reviews

The Secretariat has received 2 annual reviews in advance of the meeting which were deemed satisfactory:

- **Ref ID:** 20-006-AF1/COV (A randomized double-blind placebo-controlled trial of intravenous plasma-purified alpha-1 antitrypsin for severe COVID-19 illness)
- **Ref ID:** 19-027-AF3 (Identification of predictive and prognostic biomarkers in triple negative breast cancer)

Activities report and events of interest

The Secretariat circulated a report of its activities to the HRCDC in advance of the meeting. The following webinars, other upcoming events of interest and other relevant updates where also noted:

- The European Health Data Space (EHDS) Regulation has been published in the Official Journal of the European Union: https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space-regulation-ehds_en
- The following webinars and FAQs on the EHDS are available:
  - EUHPP webinar on European Health Data Space (1/3): Primary Use of health data and Electronic Health Record Systems: https://vimeo.com/1058600495
  - EUHPP webinar on European Health Data Space (2/3): Secondary Use of health data: https://vimeo.com/1061194721
  - EUHPP webinar on European Health Data Space (3/3): Implementation and governance – who does what?: https://vimeo.com/1063212738
  - EHDS FAQ document form the European Commission: https://health.ec.europa.eu/latest-updates/frequently-asked-questions-european-health-data-space-2025-03-05_en
- EDPB Proposed Guidance on Pseudonymisation: https://www.edpb.europa.eu/our-work-tools/documents/public-consultations/2025/guidelines-012025-pseudonymisation_en
- Event of interest: 'Enabling access to the use, re-use, and sharing of health data for research in Ireland'. Friday 28th March, 9am - 4pm @ RCSI, 123 St. Stephen's Green. Register at:

https://forms.office.com/pages/responsepage.aspx?id=50FwYBKocEa9MDD52yEPBgzaTBgveOFKlhX7PYT5hv5UMUZIVkxKQjFWTU1KOTE5TlNNQVA2NlkyNi4u&route=shorturl.

Feedback on Primary and Secondary Review pilot process

The Chair proposed deferring this item to the April HRCDC meeting; this would also allow for the newly appointed members to provide their thoughts on this pilot process. Prior to the next meeting, it was highlighted that HRCDC members can also discuss their views and feedback on this pilot process with the Secretariat or the Chairperson.

HRCDC Topics for Discussion

Following on from 28th January 2025 meeting, the HRCDC were provided with the remaining proposed topics for discussion on matters that have arisen following discussions with applicants and other stakeholders. The following topics were discussed:

Data Protection Impact Assessment (DPIA):

- The HRCDC discussed whether Applicants should continue to be required to submit the entire DPIA that has been completed for the study, or whether a copy of the results only of the DPIA would be sufficient for the HRCDC.
- On balance, given that a DPIA must be completed by the Applicant if they are seeking a consent declaration and given the useful information they provide on a study, it was the view of the HRCDC that researchers would continue to submit the full DPIA with their application form.

Independent Doctor assent:

- It was noted that the Clinical Trial Regulations 2022 allows for a medical practitioner, who is not involved in the clinical trial, to enrol a patient in a clinical trial if the patient's family is not available to provide such permission. It was highlighted that while such an independent doctor can enrol a participant into the study under such circumstances, it remains that they or a family member cannot provide valid legal consent for the processing of the patient's personal data in the research study.
- It was highlighted that the use of suitable family member or friend proxy assent to process personal data is considered a data protection safeguard by the HRCDC, however the HRCDC has previously raised concerns about an independent doctor being asked to provide proxy assent for data processing if a family member or close friend of the participant is not available. It was noted that this issue has arisen in previous applications to the HRCDC.
- The HRCDC were asked to consider whether a participant lacks decision-making capacity, the default position would be that efforts would be made to seek proxy assent from their family member or close friend in the first instance; where a relative or friend is not available and efforts to seek such proxy assent are recorded, then the consent declaration will cover the processing of personal data for the study in the absence of relative/friend proxy assent. This would not preclude the study from obtaining permission from an independent doctor to enrol the participant in the trial as is allowed for under the clinical trial regulations.

- The HRCDC discussed the proposal and agreed on this position, noting that the clinical trial regulations allow for recruitment to a study on the basis of the independent doctor permission in certain circumstances.

Other Issues:

- The HRCDC were also presented with other issues raised by researchers in relation to previous conditions attached by the HRCDC, namely certain changes to study information leaflets. It was highlighted that it was the view of some researchers that certain changes were ethical issues and therefore more appropriate for research ethics committees.
- It was discussed that although study information leaflets and assent/consent forms are reviewed and approved by RECs prior to submitting them as part of a consent declaration application, the HRCDC reserves the right to highlight issues and request changes to such study documents where they are pertinent to public interest issues and / or data protection matters.
- With regards international clinical trials, the HRCDC also discussed that there is a public interest in having such trials conducted in Ireland and that it is important that the consent declaration process, more generally, is not considered a deterrent for research.

Any Other Business

- The HRCDC were informed that the 2024 Annual Report is in the final design phase and will be forwarded to the Department of Health before the end of March. A copy of the final report will also be circulated to the HRCDC.
- Members were reminded that the next HRCDC meeting will be held in-person on 29th April.

The Chair closed the meeting