HRCDC
Health Research Consent Declaration Committee

**Date:** 17th August 2021
**Location:** Videoconference by Zoom

# Minutes of the Meeting

**HRCDC Attendance**

| Name |
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| Brigid McManus |
| Alyson Bailey |
| Kathy Brickell |
| Kevin Clarke |
| Aideen Hartney |
| Zubair Kabir |
| Barry O' Sullivan (part attendance) |
| Dan Rea |
| Cornelius Cooney |
| John Woods |
| Emily Vereker (Secretariat) |
| Jonny Barrett (Secretariat) |
| Caroline Byrne (Secretariat) |

**Observer**

| Name |
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| Sharon Kappala (Health Research Board) |

**Quorum for Decisions**
☒**YES**

**New Applications - For Consideration**

| Applicant | Ref No. | Title |
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| Edel Hennessy & Fiona Lucey | 21-010-AF1 | AVERT DOSE |
| Seamus McGuinness | 21-011-AF1/CSO | Examination of the relationship between the COVID-19 pandemic, unemployment, and social disadvantage in Ireland |



## Meeting Items

1. **Opening**
   The Chair opened the meeting and welcomed the members. The Chair also welcomed Dr Sharon Kappala from the Health Research Board, as an observer to the meeting.

2. **Apologies**
   Sheelah Connolly, Simon Furney, John Ferguson, Barry Lyons, Mary Tumelty, Evelyn Mahon, Claire Collins.

3. **Disclosure of Interest**

There were no disclosures of interest for this meeting.

**4. Minutes of the last meeting**

Draft minutes of the 20th July meeting were circulated in advance of the meeting and were approved by the HRCDC, subject to two amendments.

**5. Matters arising**

- **Application 19-044-AF2: Rare Kidney Disease bioresource and Registry.**

Following the HRCDC 20th July meeting, the Secretariat informed the HRCDC that the Applicant has confirmed that Trinity College Dublin and Firalis SAS are joint data controllers of this study. It was noted that this joint controllership has been reflected in the HRCDC decision letter and minutes of the meeting.

- **Broad Consent and the Health Research Regulations.**

Following the Secretariat's consultation with the Department of Health (DOH), in relation to the scope of a consent declaration as discussed at the HRCDC meeting of 20th July, the HRCDC noted the draft guidance document from the DOH that was provided to the HRCDC. The guidance clarified how data controllers may interpret the Amendment to Regulation 6 under S.I.18 of 2021, regarding the scope of informed consent obtained in the time of EU Data Protection Directive (1995 to May 2018). It was noted that the scope of informed consent for specific research could more broadly cover related research, but not unrelated research. Furthermore, where consent for obtained for both related and unrelated research, this did not invalid the consent, but rather the consent would be limited to the particular study and further related research, subject to ethics approval.

It was discussed that this guidance would be of particular importance and use for the data controllers of large study datasets that had previously obtained consent under the EU Data Protection Directive for future use. The Secretariat also highlighted that information from this guidance document was provided to a data controller that had applications pending HRCDC consideration, where consent was obtained prior to the Health Research Regulations. Informed by this information the data controller subsequently withdrew applications pending HRCDC consideration as a consent declaration was no longer required.

**6. New Applications**

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| Reference ID: | 21-010-AF1 |
| Lead Applicant: | Edel Hennessy & Fiona Lucey |
| Lead Data Controller: | University of Limerick Hospital Group (ULHG) |
| Title: | A Phase 3, Multi-Arm Multi-Stage Covariate-Adjusted Response-Adaptive Randomised Trial to Determine Optimal Early Mobility Training after Stroke (AVERT DOSE) |
| Research Objective: | AVERT DOSE involves participants who have had a stroke, and subsequently experience difficulty with mobility activities such as sitting, standing and walking. The main aim of the research project is to test different mobility intervention regimens in the early days after stroke to determine which provides the most benefit. Baseline assessments will be completed. Participants will be assigned to one of four different therapy groups within 48 hours of stroke onset. Each group will involve mobility training aimed at improving outcome after stroke. This training will continue until discharge from |

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| | the ward or for up to 14 days. Follow-up visits will occur at 3 months and 6 months after the stroke. Patients admitted to the Stroke Unit of University Hospital Limerick (UHL) with stroke of mild or moderate severity who have mobility difficulties are included in the study. Personal information such as date of birth, living arrangements and past medical history will be collected, together with details of stroke. All information will be treated as confidential and stored securely. Information leaving the hospital will not have identifying information. Results from each treatment group will be compared to determine which therapy is associated with improved unassisted walking, fewer and less severe complications, and better quality of life in the 6 months after stroke. |
| Reason for Declaration: | A consent declaration is sought for processing data for this study, where participants lack the decision-making capacity to provide consent.<br>Data processing activities include access, collection, pseudonymisation, transfer to the study Sponsor and subsequent analysis and storage of personal data, including of follow-up data collected up until 6-months. Data is also transferred to the Virtual International Stroke Trials Archive (VISTA), that holds only anonymised data. |
| HRCDC Comments: | The HRCDC noted that provisional ethics approval had been granted 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 consider if the public interest outweighs the requirement for explicit consent.<br><br>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.<br><br>**Public Interest**<br>• The HRCDC was of the view that there was a strong public interest case for the study.<br><br>**Proxy assent/Deferred consent process**<br>• The HRCDC discussed the timeline of 48hrs when consent/assent would be obtained and enrolment of the participant in the study would take place.<br>• It was noted that proxy assent on behalf of the participant will be obtained where the participant lacks decision-making capacity or where they have a language or communication impairment due to their stroke. It was commented that a language or communication impairment and a lack of decision-making capacity is not the same, such that a participant who has communication challenges may still have the decision-making capacity to provide consent. The HRCDC discussed that the study should therefore assist participants who have a language |

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| | or communication impairment throughout the consenting process and obtain their consent where they have capacity.<br>• The HRCDC was also of the view that where the participant lacks decision-making capacity for a prolonged period of time, that proxy assent on behalf of the participant should be re-affirmed as an additional data protection safeguard.<br>• The HRCDC noted the Applicant's response that deferred participant consent will be sought if the participant is deemed to have regained decision-making capacity. The HRCDC discussed and re-emphasised that deferred consent from the participant should always be obtained, where possible.<br>• It was also noted that participants will be asked questions as part of the study protocol. The HRCDC commented that participants who are able to interact and answer study questions would likely be able to provide consent for the study and therefore their consent should be obtained.<br>• It was further noted by the HRCDC that from the information provided, capacity to consent for this study is considered from a medical point-of-view. The HRCDC discussed that capacity should be considered from a functional perspective which aligns more closely with the principles of the Assisted Decision-Making Act 2015[1].<br><br>**Data Security**<br>• It was noted that a potential data protection risk identified in the Data Protection Impact Assessment related to shared user passwords.<br>• The HRCDC also queried the pseudonymisation process and who holds the link that can re-identify the participant. It was highlighted that the data collected and entered into the REDCap data system is identified by a unique study identification number and that the study Sponsor cannot identify the participant. It was noted that the pseudonymised data collected and transferred remains re-identifiable at the local hospital site.<br>• It was further noted that the participant's initials are also collected for the purpose of this study. To further protect the participant's identity the HRCDC queried if it was necessary to collect the participant's initials and transfer this data to the study sponsor, the Foley Institute of Neuroscience and Mental Health, Melbourne, Australia (Florey Institute).<br><br>**Research sites & Research Ethics Committee (REC) approval**<br>• The HRCDC discussed the Applicant's response that the study will be undertaken in other Irish hospitals, in addition to UHL. It was noted that confirmation of provisional or conditional REC approval for UHL only has been provided to the HRCDC. It was also noted that the Secretariat had sought further information on the REC approval for the other Irish sites, a response to which remained pending. |

[1] http://www.irishstatutebook.ie/eli/2015/act/64/enacted/en/print.html

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| | • The HRCDC discussed that the consent declaration would only cover sites where confirmation of REC approval has been provided, specifically the UHL site. The Applicant will be required to provide confirmation of REC approval for the other Irish hospital sites prior to the declaration covering these sites.<br><br>**Contractual Agreements/Arrangements**<br>• The HRCDC discussed the contractual arrangements that will be in place between the parties involved in the study, including between the data controller, ULHG, and the study sponsor, the Foley Institute, who are noted as a data processor.<br>• A copy of the Clinical Trial Research Agreement (CTRA) between UHL and the Sponsor was provided to the HRCDC. It was noted that this agreement included standard contractual clauses (SCCs) for the processing of data outside the European Economic Area (EEA). The Applicant also clarified that SCCs was the legal basis for the transfer of data outside the EEA.<br>• It was further noted that a CTRA will also be in place between the Sponsor and each participating research site.<br>• The HRCDC commented that appropriate data processing agreements/arrangements must in place between the parties prior to the processing and transfer of data from each Irish site to the Sponsor, a standard condition of a consent declaration.<br><br>**Transparency and Public and Patient Involvement (PPI)**<br>• The Applicant's response regarding PPI activities, specifically a consumer consultant in Australia, was noted by the HRCDC. The HRCDC commented that it was unclear as to what a consumer consultant is, or their role in the context of PPI in research. The HRCDC was of the view that PPI activities within Ireland should be enhanced.<br>• In addition, it was commented that transparency measures could also be enhanced.<br><br>**Information leaflets and consent/assent forms**<br>• The HRCDC discussed the information leaflets and assent/consent forms submitted by the Applicant. The HRCDC was of the view that these documents should be reviewed and amended to ensure accuracy and consistency of information and that they are suitable in the Irish context, for Irish research participants, including conforming with the requirements of the General Data Protection Regulation and the Health Research Regulations.<br>• The HRCDC discussed how researchers could be supported more generally regarding the development of information leaflets and consent forms. It was commented that in general, advice from a data protection officer regarding data protection information for leaflets and consent forms could be beneficial. It was further discussed whether research active institutions could benefit from a template information leaflet and consent form, which may be particularly useful for non-Irish Data Controllers |

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| | sponsoring a research study. The Secretariat commented that it would discuss with the National Office for Research Ethics Committees, whether developing such templates was an area it could assist with. The Secretariat had commented that it was of the understanding that the Health Research Data Protection Network was carrying out work in conjunction with the Data Protection Commission to develop a template of information on research participants data protection rights for information leaflets and consent forms.<br>• The HRCDC noted that consent is used in the proxy assent documents. It was commented that the term assent, not consent, should be used when requesting agreement of the proxy to process participant personal data. In addition, the HRCDC was of the view that the term 'responsible person' is not typically used in an Irish research context when referring to proxy assent.<br>• The HRCDC discussed that the study information leaflet and assent/consent forms also continued to reference the collection and analysis of salvia samples and DNA. It was noted that this does not align with the Applicant's response confirming that such activity is no longer applicable.<br>• The HRCDC also discussed that the GDPR legal basis for processing data, and information on what happens the personal data if assent/consent is withdrawn, should be amended in the study information leaflets to align with the responses provided by the Applicant in the HRCDC application form.<br>• It was also noted that the study information leaflet recommends that the proxy individual and/or study participant informs the participant's local doctor that they have decided to take part in this study. The HRCDC queried the purpose of this approach e and discussed whether it would be more appropriate for the medical or research team to inform the participant's local doctor, or at minimum, assist the participant with communicating their involvement in the study to their local doctor.<br><br>**Other**<br>• It was queried how many participants in total will be involved in this study. The Secretariat highlighted the information provided which stated the study involves multiple sites in multiple countries and that up to 2700 participants will be recruited internationally. The Applicant had outlined that approximately 300 participants will be recruited in Ireland.<br>• The HRCDC noted and agreed with the observations of the Secretariat regarding technical and more standard safeguards that may need to be considered by the Committee. |
| HRCDC Decision: | The consensus of the HRCDC was that a Conditional Consent Declaration should be made. |
| Duration of Declaration: | The Declaration is made on 17th August 2021 and is valid until 30th June 2024 and for 7 years thereafter until 30th June 2031 or until participant explicit consent has been obtained or the personal data |

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| | has been destroyed or irrevocably anonymised, whichever occurs sooner.<br><br>*NOTE:* The consent declaration will not come into effect until Condition 1 is met. |
| Conditions Attached: | **Condition 1.** The consent declaration does not come into effect until full research ethics committee (REC) approval from the University of Limerick Hospital REC has been submitted to the HRCDC.<br><br>**Condition 2**. Further to Condition 1, no data processing including transfer of data, for which the consent declaration is required, can commence at other 5 Irish hospital sites until confirmation of full REC approval for these sites has been provided to the HRCDC.<br><br>**Condition 3.** Where a participant continues to lack decision-making capacity for a prolonged period of time and where proxy assent remains in place, the HRCDC request that the following actions should be taken as an additional safeguard:<br>(i) confirmation should be sought from the proxy who provided assent, that they wish for the participant's personal data to continue to be processed as part of this research study. Confirmation should be obtained at an appropriate stage of the study that does not cause undue distress or harm to the individuals concerned.<br>(ii) further to point (i), during the course of the study it should also be determined whether the participant has re-gained decision-making capacity (prior to or after discharge from hospital) and, where possible to do so, to obtain their deferred consent for data processing. This should be carried out prior to proxy assent being reaffirmed.<br>The Applicant must report on this as part of the Annual Review, including the number of participants where deferred consent has and has not been obtained (*See Condition 4 on capacity to consent*)<br><br>**Condition 4.** This consent declaration is made for participants who lack decision-making capacity to provide consent. Where a participant experiences a language/communication impairment as a result of their stroke, it must not be automatically assumed that they lack decision-making capacity. Where participants have decision-making capacity their consent must be obtained. Full assistance must be provided by the study to support participants who have communication impairments and ensure their inclusive engagement in the consenting process.<br><br>**Condition 5.** The data controller must ensure the following arrangements are in place prior to the transfer of personal data between the parties:<br>(i) The Clinical Trial Research Agreement (CTRA) and the appropriate legal agreements/arrangements for data processing must be fully executed prior to the transfer of data |

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| | between the data controller of the study, the University of Limerick Hospital Group (ULHG), and the study sponsor and data processor, the Foley Institute of Neuroscience and Mental Health.<br>(ii) all other Irish hospital sites must also have in place the required legal agreements/arrangements, including a CTRA with the Foley Institute of Neuroscience and Mental Health as well as the appropriate data processing agreement/arrangement with ULHG as the data controller of the study. The transfer and processing of data at a hospital site cannot commence until the necessary agreements are in place for that site.<br><br>*NOTE:* it is the responsibility of each party to ensure that the required agreements/arrangements are in place.<br><br>**Condition 6.** Public and patient involvement (PPI) is considered an important activity by the HRCDC and is viewed as a key data protection safeguard in situations where the participant cannot provide consent. PPI also provides a valuable way of enhancing the level of transparency, which itself is an important data protection principle. It is a condition of this declaration that the study (i) undertakes PPI or engagement activities in Ireland for the reasons outlined above and (ii) enhances the transparency measures implemented for this study, for example via a study website or other public communication channels. Progress to meet this condition is a reporting requirement as part of the Annual Review<br><br>**Condition 7.** The HRCDC requests that the study information leaflets, and assent/consent forms are reviewed and amended to ensure clarity, transparency and consistency of information for participants and/or individuals providing assent, to ensure they are appropriate for an Irish context and conform with the requirements of GDPR. The documents should also be amended to align with the information provided by the Applicant as part of the HRCDC application process. In this context the following observations were made by the HRCDC and should be addressed as part of this condition prior to the commencement of the study:<br>(i) the term 'assent' rather than 'consent' should be used when referring to the agreement provided from a proxy individual to process the participant's personal data. 'Consent' should only be used when engaging directly with the research participant. It is important to ensure these terms are not used interchangeably. Assent is an important data protection safeguard but has no lawful basis for data processing.<br>(ii) the term '*person responsible*' is not a standard term used in Ireland and should not be used when referring to the individual who provides proxy assent of behalf of the participant who lacks decision-making capacity,<br>(iii) references to the collection and analysis of salvia and DNA should be removed as this is no longer undertaken and not covered by the scope of the declaration, |

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| | (iv) the GDPR Article 6 and Article 9 basis of explicit consent in the study information leaflet does not align with the Applicant's response to the HRCDC and should be amended,<br>(v) the information provided on what happens the personal data and the options available should consent, proxy assent or deferred consent be withdrawn does not align with the information provided to the HRCDC and therefore should be amended,<br>(vi) the study information leaflet recommends that the proxy individual and/or study participant informs the participant's local doctor that they have decided to take part in this study. The HRCDC queried the purpose of this approach and considers it more appropriate for the research or medical team to inform and communicate with the participant's local doctor about this study, or at minimum, assist the participant with communicating their involvement in the study to their local doctor. Therefore, the Applicant is requested to review the necessity of this statement and amend as appropriate to reflect a suitable approach. |
| HRCDC Recommendations: | **Recommendation.** As a further data protection measure, and in line with the principle of data minimisation, the HRCDC recommends that the Applicant considers whether the collection and transfer of the participants initials is necessary for this study. |

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| Reference ID: | 21-011-AF1/CSO |
| Lead Applicant: | Seamus McGuinness |
| Lead Data Controller: | Economic and Social Research Institute (ESRI) |
| Title: | Examination of the relationship between the COVID-19 pandemic, unemployment, and social disadvantage in Ireland |
| Research Objective: | It has been well documented internationally that the impacts of the COVID-19 pandemic have been disproportionately felt by low-income households, both from health and economic perspectives. Many low paid workers are in essential occupations, such as retail and medical auxiliary services, and have a higher exposure to the virus. Low-income households are also more likely to be of higher density, which makes social distancing problematic leading to a greater spread of the virus. Sectors such as accommodation and food, which contains a high proportion of minimum wage employees, were forced to furlough or close, which again disproportionately impacts low-income households. This study proposes to explore the relationship between the COVID-19 pandemic and spatial variations in social deprivation. This will be done by examining infection rates and hospitalisations. |
| Reason for Declaration: | The Applicant is seeking to access and obtained 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 HRCDC noted that ethics approval had been granted for the study where the design, methodology and ethical aspects of the study, including consent protocols are considered. Only studies that |

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| | have ethical approval, or provisional ethical approval, can be considered by the HRCDC to consider if the public interest outweighs the requirement for explicit consent.<br><br>The HRCDC was reminded that the HRCDC application had been adapted specifically for researchers accessing the COVID19 Data Research Hub. Specifically, sections of the application form relating to data protection security measures, have been pre-populated based on the security measures that are in place by the CSO for accessing the COVID-19 Data Research Hub. These sections were populated in consultation with the CSO to ensure accuracy of information.<br><br>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.<br><br>**Public Interest**<br>• The HRCDC was of the view that there was a significant public interest case made for the study and that the Applicant had submitted a comprehensive application.<br><br>**Data protection measures**<br>• The HRCDC discussed that the measures in place to protect the personal data were robust.<br>• It was noted that data is accessed and analysed within the confines of the CSO COVID-19 Data Research Hub and only anonymised data is extracted from the hub.<br><br>**Transparency measures**<br>• The HRCDC discussed the transparency measures that will be undertaken by the Applicant, including a designated webpage on the ESRI website. It was commented that the measures to be implemented were robust. It was also discussed that the Sponsor's website, Pobal, may also provide a channel for communicating about the study.<br><br>**Legal Basis**<br>• The HRCDC discussed the GDPR Article 6 and Article 9 legal basis for processing data for this study. It was noted that it is up to the data controller to determine the most appropriate legal basis.<br><br>**Other**<br>• It was discussed that the consent declaration will not be effective until final approval to access the COVID-19 Data Research Hub has been granted by the CSO.<br>• The HRCDC also noted the RDGB recommendation with regards disseminating publications via Open Access Forms. |

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| | • It was discussed that the data sources within the CSO COVID-19 Research Data Hub are linked via a Protected Identifier Key (PIK). |
| HRCDC Decision: | The consensus of the HRCDC was that a Conditional Consent Declaration should be made. |
| Duration of Declaration: | The Declaration is made on 17th August 2021 and is valid for one year, until 17th August 2022, in line with the duration of the Officer of Statistics appointment made to the Applicant by the Central Statistics Office (CSO).<br>*NOTE 1:* The consent declaration will not come into effect until Condition 1 is met.<br>*NOTE 2:* The Applicant may submit an amendment request to the consent declaration if an extension to the duration of the consent declaration is required, subject to the Applicant's reappointment as an Officer of Statistics and approval by the CSO. |
| Conditions Attached: | **Condition 1**. It is a condition that 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. |

**7. Annual Review of Declarations**

The Secretariat has received 1 Annual Review in advance of the meeting which was deemed to be satisfactory:

- Ref ID: 20-020-AF1 (Paul Cotter - Irish Coronavirus Sequencing Consortium)

**8. Activities Report & Upcoming Events**

Upcoming events and an article of interest were noted to the HRCDC:

- Improving Inclusion in Health & Care Research, Event 1: The Project Level: https://www.eventbrite.co.uk/e/improving-inclusion-in-health-care-research-event-1-the-project-level-tickets-154678406277?mc_cid=ba1d4b98e1&mc_eid=c0d6dee216
- Future Health Summit: https://futurehealthsummit.com
- ESRI Report: Developments in Healthcare and Information Systems in Ireland and Internationally (https://www.esri.ie/system/files/publications/SUSTAT105_0.pdf)

**9. Any Other Business**

The Secretariat provided an update on the 'AF2' applications (where consent was obtained prior to the Health Research Regulations) pending HRCDC consideration. It was noted several pending applications have been withdrawn as the data controllers have confirmed a consent declaration if not longer required, after further consideration of the S.I. 18 of 2021 amendments. The Secretariat highlighted that 2 of the pending AF2 applications have confirmed that they still require a consent declaration while the remaining applications are pending confirmation from the data controller as to whether they need to proceed. The HRCDC discussed that it will endeavour to process the AF2s that still require a consent declaration as soon as possible.