HRCDC
Health Research Consent Declaration Committee

Date: 13th June 2023
Location: Zoom videoconferencing

Minutes of the Meeting

HRCDC Attendance

Name
Brigid McManus
Evelyn Mahon
Alyson Bailey
Sheelah Connolly
Aideen Hartney
Zubair Kabir
Dan Rea
John Woods
Barry Lyons
Patricia O'Beirne
Brid Burke (Secretariat)
Jonny Barrett (Secretariat)
Caroline Byrne (Secretariat)

Quorum for Decisions
☒YES

New Amendments - For Consideration

Applicant	Ref No.	Title
Iracema Leroi	22-011-AF1/AMD1	SENSE-Cog Residential Care: A feasibility study of hearing and vision support to improve quality of life in care home residents with dementia
Tom Rogers	21-003-AF1/AMD2	Investigating the Epidemiology of *Mycobacterium bovis* infection in humans
Alistair Nichol	20-022-AF1/AMD2	Clinical evaluation of a POC assay to identify phenotypes in the Acute Respiratory Distress Syndrome - PHIND Study
Alistair Nichol	21-002-AF1/AMD1	The Mega Randomised Registry Trial Comparing Conservative vs. Liberal OXygenation Targets (Mega-ROX)

New Applications – For consideration

Applicant	Ref No.	Title
Marcia Kirwan	23-006-AF1	COST2CARE: Addressing the economic and human cost of hospital acquired and nursing-sensitive adverse events in older patients through optimal use of routine discharge data and measurement of missed nursing care.

Meeting Items

1. Opening

The Chairperson opened the meeting and welcomed the members. The Chairperson also welcomed Ms. Tricia O'Beirne to the HRCDC as a new PPI member on the Committee.

2. Apologies

Kathy Brickell, Simon Furney, Barry O' Sullivan, Mary Tumelty, Cornelius Cooney.

3. Disclosure of Interest

It was noted that Alyson Bailey (AB) had acted as a Health Research Board reviewer for this study **22-011-AF1/AMD1** (SENSE-Cog Residential Care: A feasibility study of hearing and vision support to improve quality of life in care home residents with dementia). It was agreed that, as with the original consent declaration application, AB would be absent during the meeting when this application was considered.

4. Minutes of the last meeting

Draft minutes of 9th May 2023 were circulated in advance of the meeting and were approved by the HRCDC.

5. Matters arising

The HRCDC were updated on the responses to the request for further information decisions made by the HRCDC at the 9th May 2023 meeting.

6. Amendments:

Reference ID:	22-011-AF1/AMD1
Lead Applicant:	Iracema Leroi
Lead Data Controller:	Trinity College Dublin
Title:	SENSE-Cog Residential Care: A feasibility study of hearing and vision support to improve quality of life in care home residents with dementia
Research Objective:	Please see HRCDC Meeting minutes of 13th December 2022.
Purpose of Amendment:	The amendment is requested to (i) add 3 further sites to the study and (ii) to extend the duration of the consent declaration to November 2031.
HRCDC Comments:	The Chairperson introduced the amendment, and the Secretariat outlined the scope that was requested. The Chairperson invited the HRCDC to comment on the amendment request and indicate whether it should be approved. The HRCDC queried if there were any updates or responses from the Applicant on the condition that was attached to the consent declaration requesting that PPI activities be enhanced to include residents with dementia who will be recruited to the study. The Secretariat highlighted that the Applicant had requested clarifications on what was expected of this condition; the Applicant had outlined that it is not common for a study to consult participants in a PPI capacity before commencing the intervention, as it may affect the study findings. The Applicant stated that it would be possible to consult participants, or other residents with dementia, at the end of the study to help with the feasibility of analysis, among other matters. The HRCDC noted this update and discussed that consideration should be made to consult/undertake PPI activities with representative groups such as the Alzheimer's Association.

	The Applicant had also provided a response with regards the agreements/arrangements that will be in place between the data controller and the study sites. Following correspondence from the Secretariat, it was highlighted that data agreements will be put in place. The HRCDC further noted that the 'Demonstration of Capacity' checklist contained a section that referred to the Mental Capacity Act 2005. It was discussed that this section should be updated to reflect the Assisted Decision-Making Act. After discussing the application, and based on the information provided by the Applicant, it was the consensus of the HRCDC that the amendment to the consent declaration should be approved.
HRCDC Decision:	The consensus of the HRCDC was that the amendment request should be approved
Conditions Attached:	**Condition 1.** Further to Condition 1 that was attached to the original consent declaration, the Applicant is also requested to undertake PPI engagement with relevant representative groups such as the Alzheimer's Association of Ireland.
HRCDC Recommendations:	**Recommendation 1.** It is noted that the 'Demonstration of Capacity' checklist document includes a section detailing the Mental Capacity Act 2005. The HRCDC recommends that this section is amended to align with the latest legislation in this area, namely the Assisted Decision-Making Act 2015.

Reference ID:	21-003-AF1/AMD2
Lead Applicant:	Tom Rogers
Lead Data Controller:	St. James's Hospital New Data Controller: Trinity College Dublin
Title:	Investigating the Epidemiology of *Mycobacterium bovis* Infection in Humans
Research Objective:	Please see HRCDC Meeting minutes of 18th May 2021 and 12th April 2022.
Purpose of Amendment:	The amendment is requested to (i) extend the duration of the consent declaration until May 2024 and (ii) to extend the patient cohort to include those patients diagnosed in 2021-2022.
HRCDC Comments:	The Secretariat introduced the amendment. It was noted that the original consent declaration included patients diagnosed between 2000-2020. It was also highlighted that the study protocol and the data processing activities remained unchanged i.e., data from the Irish Mycobacteria Reference Laboratory will be processed as will data from St James's Hospital patient charts if they were treated in St James's Hospital. The Chairperson requested each HRCDC member to indicate whether the amendment should be approved. After discussing the application, and based on the information provided by the Applicant, it was the consensus of the HRCDC that the amendment to the consent declaration should be approved. **Public Interest case.**

	• The HRCDC discussed that research in the area of *Mycobacterium bovis* Infection is important and that there is a public interest case to expand the study to include more recent patients diagnosed with this condition, and to also extend the duration of the data processing. **Obtaining consent** • The HRCDC acknowledged that the Applicant/data controller did not need to seek the explicit consent of participants from the original 2000-2020 study cohort. On the request to include the addition of participants diagnosed between 2021-2022, the HRCDC queried if efforts should be made to seek the consent of this new cohort specifically. • The Applicant's response for why it would not be appropriate or practicable to seek to obtain consent, including for reasons of study continuity and resource issues, was noted by the HRCDC. Notwithstanding this, the HRCDC also had consideration that the numbers of participants likely to be included in the 2021-2022 cohort would be relatively small, given that the overall study is to include approximately 100 participants since the year 2000. It was also discussed that the 2021-2022 patient cohort have been more recently diagnosed. While the HRCDC acknowledged the Applicant's previous response that patients may only be receiving follow-up care and treatment for appropriately 9 months, it was considered that obtaining the consent of the current 2021-2022 cohort, in particular the St James's patients, may be more practicable and feasible then for the previous cohort. • On balance, the HRCDC was on the view that efforts should be made by the Applicant/data controller to seek to obtain the consent of the 2021-2022 participant cohort, in particular those who were patients of St James's Hospital, including those who may still be receiving follow-up care. It was discussed that the Applicant should be requested to report on the efforts and progress made to obtain the consent of these participants within 3 months, including how many have been contacted and how many have provided consent. The consent declaration will cover the processing of participant's personal data where reasonable efforts are made to seek their consent but there is no response from the participant. **Transparency measures** • The transparency measures outlined by the Applicant were discussed. • The HRCDC commented positively on the updated clinic notice poster that was submitted and that the Applicant states are displayed at the TB clinics in St James's Hospital; however, it was commented that the separate project notice on the St James's Hospital website was not as effective or user-friendly. It was the view of the HRCDC that the project notice on the St James's Hospital website should be amended to align more closely with and look and read as user-friendly as the clinic notice poster. It was also noted that it is not clear where the project notice on the

	St James's Hospital website can be found; this project notice should therefore be made available in an easy to locate part of the website. • The HRCDC also noted the update from the Applicant that no response has been received yet from the Irish Thoracic Society. It was discussed that the Applicant should continue to follow-up with this organisation to see if information about the study can be made available on their platforms. It was also the view of the HRCDC that similar engagement should occur with other relevant organisations to enhance study transparency, for example with the Irish Lung Foundation. • The HRCDC also commented that the Applicant should explore enhancing transparency measures by social media, for example utilising the twitter and Facebook pages of St James's Hospital, Trinity College Dublin and others, linking them to the study's webpage and notices. **Data processing and scope of the declaration** • Based on the information provided by the Applicant, it was noted that data processing with regards the 2021-2022 cohort may have already occurred prior to an amendment request being approved. It was discussed that processing data of the 2021-2022 cohort was not covered by the scope of the original consent declaration made. It was further noted that the original consent declaration had recently expired on 31st May 2023. • The HRCDC noted that the decision letter should outline that this approved amendment is only in effect from the date of the HRCDC's decision i.e., 13th June 2023. It was also discussed that the DPO should be informed of the matter of processing data of the 2021-2022 participant cohort prior to an amendment being approved. **Ethics approval** • It was highlighted that the ethical approval to expand the participant cohort to 2021-2022 was in place, however approval to extend the study timeline to 2024 remained outstanding. It was discussed that confirmation of ethical approval for the extended study duration will need to be submitted by the Applicant.
HRCDC Decision:	The consensus of the HRCDC was that the amendment request should be approved.
Conditions Attached:	**Condition 1.** It is a condition that the Applicant/joint data controllers make reasonable efforts to obtain the explicit consent of the 2021-2022 participant cohort who are/were TB patients, in particular those who are/were TB patients of St James's Hospital, including those who may still be receiving follow-up care at St James's Hospital for their condition. The Applicant is requested to report within three months on the efforts made to seek explicit consent for these participants, including the numbers of those who have been contacted and who have consented. The consent declaration will cover the processing of participant's personal data where reasonable efforts are made to seek their consent but there is no response from the participant. Where a participant actively decides

	not to provide their consent then they are not covered by this consent declaration. **Condition 2**. The Applicant is requested to enhance transparency measures as follows: - It is the view of the HRCDC that the project notice on the St James's Hospital website is not as effective or user-friendly as the notice poster that is displayed in the TB clinics in St James's Hospital. The project notice on the St James's Hospital website should therefore be amended to align more closely with and look and read as user-friendly as the clinic notice poster. It was also noted that it is not clear where the project notice on the St James's Hospital website can be found; this project notice should also be made available in an easy to locate part of the website. - the Applicant should continue to follow-up with the Irish Thoracic Society to see if information about the study can be made available on their platforms. It was also the view of the HRCDC that similar engagement should occur with other relevant organisations to enhance study transparency, for example with the Irish Lung Foundation. - the Applicant should explore and implement enhanced transparency measures by other methods such as social media; for example, utilising the twitter and Facebook pages of St James's Hospital, Trinity College Dublin and others, linking them to the study's webpage and notices. **Condition 3.** Ethical approval for the extended study duration must be obtained and confirmation of this submitted to the HRCDC. The amendment is not in effect until this required ethical approval has been obtained.

Reference ID:	20-022-AF1/AMD2
Lead Applicant:	Alistair Nichol
Lead Data Controller:	St. Vincent's University Hospital, Dublin Queen's University Belfast Belfast Health and Social Care Trust
Title:	Clinical evaluation of a POC assay to identify phenotypes in the Acute Respiratory Distress Syndrome - PHIND Study
Research Objective:	Please see HRCDC Meeting minutes of 4th September 2020 and 20th July 2021
Purpose of Amendment:	The amendment is requested for the following activities: (i) The addition of two new hospital sites to the study who will also be data processors i.e., Beaumont Hospital and Galway University Hospital. RCSI are also added as a data processor given their involvement in the study at Beaumont Hospital. (ii) The inclusion of patients with Acute Hypoxemic Respiratory Failure (AHRF), which is in addition to those patients with ARDS.
HRCDC Comments:	The Chairperson requested each HRCDC member to indicate whether the amendment should be approved. After discussing the application, and based on the information provided by the

	Applicant, it was the consensus of the HRCDC that the amendment to the consent declaration should be approved. **Public interest case** • The HRCDC discussed the changes to the study that were requested as part of the scope of the amendment. It was discussed that AHRF is related to ARDs and therefore it would be suitable to consider this change via an amendment request. It was also highlighted that the inclusion of patients with AHRF in this study would apply to all the Irish hospital sites involved in this study. • The Secretariat also highlighted that the Applicant confirms that there have been no other changes made to the study, this includes changes to processing activities such as genetic data; it was noted that the only genetic processing referenced within the original declaration application was for the measurement of genetic markers. It was discussed that it will be made clear to the Applicant what the scope of the amendment covers, including that it will not cover future research studies. • On balance and based on the information provided, the HRCDC was of the view that there was a public interest case for approving the amendment. **Legal Agreements** • The HRCDC commented that the study needs to ensure that the required data agreements are in place for the new hospital sites and data processors. **Ethics approval** • It was highlighted that ethical approval for the Galway site had been made by the Chairperson of the Galway REC, which is due to be ratified by the full ethics committee. It was commented that confirmation of approval from the full Galway REC must be submitted to the HRCDC. **Future research & scope of the declaration** • The HRCDC noted that the proxy assent forms refer to requesting permission to use data and biosamples in future studies. • It was discussed that a consent declaration cannot cover the processing of personal data for the purpose of future, unknown research studies and activities; the declaration made covers the PHIND study and subsequent data storage only. • The HRCDC was of the view that requesting assent from the proxy to process personal data for the purpose of future studies could cause confusion to the proxy and future researchers, therefore references to seeking proxy permission to use data in future studies should be amended in the study documentation; the amended information should reference that the HRCDC has made a consent declaration and that proxy assent for future research is limited to the storage of the data only. • It was also noted by the Secretariat that the proxy assent forms for the Beaumont Hospital site only, includes options to destroy

	the biological samples and associated data or to destroy the samples but to still retain the data derived from the sample for future research – the forms for the other sites do not include such options. The Secretariat highlighted that if the study wishes to retain/store data for future research after the samples are destroyed, then clear information and assent for this should be provided to and requested from the proxy; if this applies to other sites outside of Beaumont it should also be included in that site's study documents. In line with the scope of the declaration that can be made, it remains that the declaration will only cover the storage of this data only and not it's use in future research studies; where such data is to be used for future studies than an amendment request form or new HRCDC application will need to be submitted for consideration. It was further noted that deferred consent should still be obtained from the participant when they regain decision-making capacity to continue to store and/or use data that is associated with destroyed bio-samples. **Study Information Leaflets** • It was noted that the latest version of the study information leaflet referenced contacting the participant's GP to assess their long-term health status. Based on the information provided it was commented that GPs may be followed-up at 60-days, however no such time-period for contacting the GPs was provided in the study information leaflets, and therefore the timeframe could be seen as open-ended. The HRCDC was of the view that the study documentation should be clear on the timeline for contacting the participant's GPs. **Other** • It was commented that the feedback/advice from the DPO regarding references to genetic data in the study information leaflets are implemented. • The HRCDC also noted and agreed with the observations made by the Secretariat regarding technical and more standard safeguards that may need to be considered by the Committee, that were similar to conditions made in previous consent declarations. These observations included changes to the study information leaflets to ensure they are fully aligned, a reminder that previous conditions attached will continue to apply, ensuring the DPIA is completed and is up to date to cover all sites, that the relevant DPOs are consulted, and ensuring participant consent for any future research is compliant and sufficient.
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 required data agreements/arrangements are in place between the data controllers of this study and the new data processors. The processing and transfer of personal data by these processors for this study cannot commence prior to the required agreements being in place.

	Condition 2. It is noted that research ethics approval for the Galway site has been made by the Chairperson of the Galway REC, which is due to be ratified by the full research ethics committee. The Chairperson approval must be ratified by the full REC as stated in the REC letter, and confirmation of such must be submitted to the HRCDC. The consent declaration does not cover Galway University Hospital unless approval has been ratified by the full REC. **Condition 3.** It is noted that the proxy assent forms for the Beaumont Hospital site includes options to destroy the biological samples and associated data or to destroy the samples but to still retain the data derived from the sample for future research. If the study wishes to retain/store data for future research in circumstances where the samples are still destroyed, then clear information should be provided to the proxy, and their assent for this continued data storage should be obtained. If these options also apply to other sites outside of Beaumont, then it should also be included in that site's study documents. Further, it remains that deferred consent should still be obtained from the participant when they regain decision-making capacity to continue to store and/or use data associated with already destroyed bio-samples for future research. **Condition 4.** To ensure clarity and consistency of information for the participants and those providing proxy assent on their behalf, the study information leaflets and consent/assent forms should be reviewed and amended as follows prior to recruiting new participants: - The information provided by the Applicant outlined that the participant's GP may be contacted/follow-up after 60-days. However, it is noted that the versions of the study information leaflets submitted with the amendment request do not provide such a timeframe; accordingly the timeframe for contacting the GP could be seen as open-ended in the study information leaflets. The study documentation should therefore be clear that GPs will be contacted at 60-days. - Yes/no options for contacting the GPs should be included in the assent and consent forms for all sites. - The original information leaflets for St Vincent's University Hospital and the new documents for Beaumont Hospital refer to measurement of genetic markers, however this is not included in the new information leaflets for Galway University Hospital. - The advice of the Beaumont DPO regarding more transparency on the future use with the consent of the participant, including genetic/genomic data and research should be addressed. - More generally, review the PILs across the study sites in Ireland to ensure the information is aligned and consistent throughout.
HRCDC Recommendations:	**Recommendation 1.** Aligned with the scope of the consent declaration made, the Applicant is strongly recommended to review the proxy information leaflets and assent forms across all Irish sites and remove references that request the proxy to provide their assent for the use of the participant's personal data in future

	research studies. As the consent declaration made is limited to the PHIND study only and the subsequent storage of this data thereafter, proxy assent for any future use should be limited to continued storage of the data only; the proxy should not be requested to provide assent or permission to use/process the participant's personal data in future research studies. Reference should also be made that a consent declaration has been made by the HRCDC. Where a participant regains decision-making capacity and provides deferred consent, the Applicant is also recommended to ensure that any consent for future research that is requested from the participants is compliant with data protection legislation. It is the responsibility of the data controller to ensure that participant consent for future research is valid and sufficient. **Recommendation 2.** A DPIA and DPO feedback from the Beaumont hospital site has been submitted with the amendment request form; it is also noted that the DPO from Queen's University had no further comment following review. The Applicant is requested to ensure that a DPIA is kept up to date and covers all the sites in Ireland, including the Galway University Hospital site, and to seek equivalent feedback from the data controller(s) DPO. The DPO feedback from the hospital sites is also recommended.

Reference ID:	21-002-AF1/AMD1
Lead Applicant:	Alistair Nichol
Lead Data Controller:	Medical Research Institute of New Zealand (MRINZ)
Title:	The Mega Randomised Registry Trial Comparing Conservative vs. Liberal OXygenation Targets (Mega-ROX)
Research Objective:	Please see HRCDC Meeting minutes of 13th April 2021.
Purpose of Amendment:	The amendment is requested for the following: (i) the addition of Beaumont Hospital and Our Lady's Hospital, Drogheda to the study who are also data processors. RCSI are also added as a data processor given their involvement in the study at Beaumont Hospital. (ii) the inclusion of a sub-study known as 'LOGICAL' and the associated data processing for this sub-study for those who lack-decision making capacity, including transfer of pseudonymised data to the data controller MRINZ and the subsequent full anonymisation and transfer of anonymised data to Monash University, Australia.
HRCDC Comments:	The Chairperson requested each HRCDC member to indicate whether the amendment should be approved. After discussing the application, and based on the information provided by the Applicant, it was the consensus of the HRCDC that the amendment to the consent declaration should be approved. **Public interest and scope of amendment.** • The HRCDC discussed the changes to the study that were requested, namely the addition of 'LOGICAL'. It was queried whether LOGICAL was a sub-study of Mega-ROX or if it is a separate study. The HRCDC also discussed and queried the

participant cohort that will be included in LOGICAL; this included whether participants who are already enrolled in Mega-ROX may be enrolled in LOGICAL.

- Based on the information provided the HRCDC noted that LOGICAL is a sub-study of the overall Mega-ROX study as it continues to involve comparing oxygen therapy treatment but on a more specific patient cohort and involves collecting some additional data that is not required for the main Mega-ROX trial.
- It was also noted that the LOGICAL sub-study will only aim to recruit a sub-population of new participants enrolled onto Mega-ROX going forward, specifically those new participants recruited to Mega-ROX who have hypoxic ischaemic encephalopathy; it was noted that this is more limited population when compared to the overall Mega-ROX trial, as a person with any illness can be enrolled in Mega-ROX.
- It was further queried if those already enrolled onto Mega-ROX but where permission to process data for future research was not provided, may be included in LOGICAL. It was highlighted that recruitment to LOGICAL, and therefore the consent declaration and amendment, will only apply to newly enrolled participants going forward i.e., those already recruited to Mega-ROX will not be included as part of LOGICAL.
- It was also noted that inclusion in LOGICAL is an optional part of Mega-ROX and that a patient can request to be withdrawn from LOGICAL only but remain in Mega-ROX if they wish.
- On balance, based on the information provided it was the consensus of the HRCDC that there is a public interest case and that the amendment for the new hospital sites/data processors and the inclusion of the LOGICAL sub-study can be approved.

Research ethics approval

- It was highlighted that full ethics approval for the Drogheda site remains pending; a favourable opinion has been granted by this REC subject to receiving certain clarifications.
- The Secretariat provided an overview of the nature of the clarifications that were requested by the REC, including a recommendation on the use of telephone assent process. It was noted that a copy of the Applicant's replies to the clarifications raised by the Drogheda REC had not been provided, however much of the information requested by the Drogheda REC has previously been outlined as part of their HRCDC application.
- It was discussed that the consent declaration will not cover the Drogheda site until full REC approval for that site is in place; in addition, it needs to be confirmed that such REC approval includes the use of telephone assent. Confirmation that full REC approval is in place should also be submitted to the HRCDC.

Study Information Leaflets and Consent Forms

- The HRCDC noted that the Applicant should be informed about the incorrect current use of 'assent' and 'consent' in the study information leaflets; it was highlighted that 'consent' continued to be used incorrectly in the proxy assent documentation and

	therefore should be addressed. It was further commented that the statement in the information leaflet '*If there is no known objection by your relative to being included'* should be phrased more positively. • It was also the view of the HRCDC that the study information leaflets should outline that the proxy who provides assent on behalf of the participant who lacks decision-making capacity, will be asked to complete the 6-month follow-up, if the participant lacks capacity to complete the assessment. • The HRCDC also commented and noted the observations from the Drogheda REC on the PILs including that the study information leaflets should be made more user-friendly and other minor amendments. It was further highlighted by the Secretariat that any conditions and/or recommendations made by the HRCDC in respect of the study information leaflet will apply to the study documentation for all the sites in Ireland and in general that the applicant will need to ensure that the information in the study documentation is aligned and consistent. **Parties involved and data transfers** • The Applicant outlined the role of Monash University, Australia, in the context of this requested amendment. It was outlined that the data controller of the study, including the LOGICAL sub-study, remains the Medical Research Institute of New Zealand (MRINZ). MRINZ will receive pseudonymised data from the Irish sites. Once the LOGICAL sub-study has concluded and data cleaning and preparing is completed by MRINZ, fully anonymised data will be transferred from MRINZ to Monash University for analysis. The Applicant confirmed that Monash University is not a joint data controller or a data processor in the Mega-ROX or LOGICAL studies. • The HRCDC noted this response form the Applicant and was of the view that the data controller must ensure that the data transferred to Monash University is fully anonymised. **Legal Agreements** • It was commented that the required data agreements/arrangements are in place, including with regards the new study sites/data processors. **Data minimisation** • It was noted that additional data will be collected and processed for the purpose of the LOGICAL sub-study; this includes new data such as both education status and employment. The HRCDC queried if all the additional data for LOGICAL is required and whether it could be further minimised. **Number of Irish participants** • The number of participants to be recruited in Ireland was unclear. It was commented that it would be useful to have more

	information on the numbers to be recruited to the main Mega-ROX trial and the LOGICAL sub-study. **Other** • It was noted that the DPIA stated that the study will gain explicit informed consent from individuals. It was commented that this should be amended to reflect that this study involves a deferred assent process, followed by consent to continue when the participant regains capacity. • The HRCDC also noted and agreed with the observations made by the Secretariat regarding technical and more standard safeguards that may need to be considered by the Committee, that were similar to conditions made in previous consent declarations. These observations included ensuring that the DPIA completed reflects and covers all sites, to seek feedback from the relevant DPOs and remove references to UCD in the study documentation, where relevant.
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 required data agreements/arrangements are in place between the data controllers of this study and the new hospital sites and data processors. The processing and transfer of personal data by these processors for this study cannot commence prior to the required agreements being in place. **Condition 2.** It is noted that final, full research ethics approval for the Drogheda site remains pending. The consent declaration does not cover Our Lady's Hospital Drogheda until full REC approval for this site is in place. Confirmation of this approval should also be provided to the HRCDC when obtained. With regards the use of a telephone assent process, this will not be covered for the Drogheda site unless the REC approval for Drogheda covers the use of telephone assent. **Condition 3.** The Applicant/data controller is requested to revisit the matter of data minimisation for the LOGICAL sub-study to ensure only the minimal amount and type of data is collected and processed. For example, to review and consider if data on both educational attainment and employment required for the purpose for the LOGICIAL study. The data controller should ensure compliance with the principle of data minimisation throughout the course of the study timeframe. **Condition 4**. The data controller must ensure that the data from the LOGICAL study that is to be transferred to Monash University is fully anonymised. **Condition 5**. To ensure clarity and consistency of information for the participants and those providing proxy assent on their behalf, the study information leaflets and consent/assent forms for each of the sites in Ireland should be reviewed and amended as follows prior to recruiting new participants:

	- it is noted that the terms 'consent' and 'assent' are not used correctly throughout the study documentation, for example page 2 of the Beaumont Hospital consent to continue information leaflet refers to a 'person responsible' having previously 'consented'. The term 'consent' should be used when referring to seeking the permission of the study participant, not their next-of-kin or proxy; the term 'assent' should be used when referring to seeking permission form a proxy individual on behalf of a participant who lacks decision-making capacity. The Applicant is requested to review the study documents for each site and ensure the correct term is used. - references to UCD in the study documentation should be removed as it has been confirmed that UCD are not involved in this study. - the study information leaflets should clearly outline that if a participant is unable to complete the 6-month follow-up assessment due to lack of capacity, that the person who provided proxy assent may be asked to complete the assessment. - the phrase '*If there is no known objection by your relative to being included'* should be rephrased more positively to ask the proxy if they believed the individual would wish to be included in this study. Lastly, it should be ensured that the feedback provided by the Drogheda REC on the study information leaflets and assent/consent forms are addressed and, more generally, ensure that the information within the documents used for each of the sites in Ireland are aligned and consistent. *(Please also see Recommendation 1)* **Condition 6.** As part of the Annual Review, the Applicant is requested to provide information on the number of participants that have been recruited at the Irish sites with regards (i) the main Mega-ROX study and (ii) the LOGICAL sub-study.
HRCDC Recommendations:	**Recommendation 1.** The Applicant is requested to consider and take on board the points outlined in Recommendation 3 that was attached to the original consent declaration with regards the updated study information and assent/consent forms for all the hospital sites in Ireland. **Recommendation 2.** The Applicant is requested to ensure that the DPIA for this study remains up to date and applicable for all the hospital sites in Ireland, including Our Lady's Hospital Drogheda, and correspondingly to consult with the relevant DPOs, including the DPO of the data controller of the study. **Recommendation 3.** The DPIA states that the study will gain 'explicit informed consent' from individuals. The DPIA should be amended to reflect that this study involves a deferred assent process, followed by consent to continue when the participant regains capacity.

7. New Applications

Reference ID:	23-006-AF1
Lead Applicant:	Marcia Kirwan
Data Controllers:	Dublin City University
Title:	COST2CARE: Addressing the economic and human cost of hospital acquired and nursing sensitive adverse events in older patients through optimal use of routine discharge data and measurement of missed nursing care.
Research Objective:	Older patients make up the largest proportion of acute hospital inpatient populations. Pneumonia, delirium, urinary tract infections and pressure injuries are four common adverse events that occur in older patients, known collectively as 'Failure to Maintain (F2M)' events. These are nursing-sensitive patient outcomes, predominantly affected by the quality of nursing care provided, that contribute to higher healthcare costs, lower quality care, and less satisfactory patient experiences. In this study, the researchers aim to determine how these nurse sensitive outcomes are currently represented in routinely available national discharge data in Ireland. These data are collected as Hospital In-Patient Enquiry data and known as HIPE data. A structured chart review will be conducted in one hospital to validate the rates of nursing-sensitive events available in the HIPE data. The cost of these events to the Irish health service will be calculated using ICD10 data, length of stay, and other variables associated with Cost of Illness calculations. Through nurse and patient-reported surveys, the human costs of missed care will be further examined.
Reason for Declaration:	The activities for which a consent declaration is requested are as follows: (i) Receiving and processing personal data from the HPO to identify the sample of charts from the Mater Hospital. (ii) Accessing the patients charts and extracting data variables onto a spreadsheet i.e., retrospective chart review activity. (Note: once this is completed, the unencrypted MRN and admission and discharge date data will be deleted from the spreadsheet to anonymise the data in the spreadsheet). (iii) Following the chart review and the removal of the unencrypted MRN by DCU, the Healthcare Pricing Office will disclose further pseudonymised clinical data to DCU; this will be linked via a separate encrypted MRN; the Applicant states that this data is considered anonymised when received by DCU as they cannot and will not reverse the encrypted MRN. A consent declaration is not requested for other study activities i.e., surveys or data analysis. For the points outlined above, informed consent will not be obtained from the patients whose charts will be reviewed. The Applicant outlines the reasons for this including the large sample size of patient charts needed to conduct the chart review.
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 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.
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.

Public Interest case.

- The HRCDC discussed the public interest case. It was queried whether the study design and methodology, including that data is being collected from one hospital site, would generate sufficient findings to help achieve the research aims. It was commented that the study was aspirational in its aims. The HRCDC also commented that more information could have been provided by the Applicant on how the methodology to be employed will address the research question.
- However, the HRCDC also discussed that the data protection risks where relatively low with the personal data to be processed, including access to medical records, limited to a small number of personnel in DCU. It was also noted that once the chart review has been completed, the data that is collected will be anonymised by the removal of the unencrypted MRN and other variables, after which the data that is stored and the other data that will be received is considered fully anonymised to DCU. The HRCDC also noted and accepted the reasons outlined by the Applicant on why consent cannot be practicably obtained.
- On balance, the HRCDC was of the view that there is a public interest case in this study to make a consent declaration.

Transparency measures

- The HRCDC discussed the Applicant's responses to the Secretariat's pre-preview queries, detailing the transparency measures that the study plans to implement. Measures referenced by the Applicant focused on placing notices in public areas in the Mater Hospital to inform participants of this study, the processing of data and data protection rights, including how to withdraw from the study. PPI representatives will be consulted on about these notices. Reference was also made to a project website.
- The HRCDC commented positively on the planned transparency measures to be implemented. It was the view of the HRCDC that a condition on transparency measures should be attached and that the Applicant should report on the implementation of transparency measures within 3 months. It was discussed that transparency measures should be in place prior to the study commencing.

Withdrawal from the study

	• If a participant wishes to withdraw, the HRCDC noted the Applicant's response on the ability and process for removing a participant's data from this study and the point in thew study where this is possible. • It was discussed that the withdrawal process will likely need to involve the co-operation of the Healthcare Pricing Office (HPO) and the Mater Hospital, given that the data controller, DCU, would in practice be unable to identify the individual participants from the it has data collected once the chart review activities have been completed. • It was commented that the participant's right to withdraw from the study remains essential during the course of the study and therefore it is important that a clear process for removing data from this study is in place, and that the HPO and Mater are involved in the process of exercising a participant's rights. **Data security** • Reference was made by the Applicant to a '*preferably encrypted laptop'*. The HRCDC commented that laptops and devices used in this study must be encrypted. **Other** • It was discussed and clarified that the retrospective chart review stage of the study will involve the processing of data of approximately 1000 individuals. • It was noted that a health economist and other third parties, including universities inside and outside of Ireland, will be involved in this study. The Applicant confirmed in their responses that the data received by the health economist will be aggregated data and anonymised and therefore not personal data. The role of the other third parties referenced by the Applicant are to provide advice to the researchers; they will not be processing any data. It was confirmed by the Applicant that there are no data processors employed in this study. • The HRCDC commented that once the data has been anonymised by DCU following the chart review activities, that it is ensured that the variables to be deleted to anonymise the data have been deleted and that other identifiable data is not being retained. • The HRCDC also noted and agreed with the observations made by the Secretariat regarding technical and more standard safeguards that may need to be considered by the Committee, that were similar to conditions made in previous consent declarations. These observations included receiving confirmation of full ethical approval from the Mater Hospital REC, ensuring that the data sent to the health economist and the other parties referenced is fully anonymised and that safeguards are in place and having the required data agreements and arrangements.
HRCDC Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made.
Duration of Declaration:	The consent declaration is made on 13th June 2023 and is valid until 31st July 2024.

Conditions Attached:	**Condition 1.** The Applicant is requested to ensure that strong transparency measures are implemented for this study; specifically, and as detailed in the responses provided by the Applicant, transparency measures should include the placing of clear and informative notices in the public areas of the Mater Hospital and on the project website. Transparency measures should inform participants about this study, the processing of their personal data and their data protection rights, including the right to withdraw and how to exercise their rights. Measures should also outline at what point in the study that data cannot be removed. The Applicant is requested to provide an update on the implementation of these transparency measures as soon as practical and within 3 months of the date of this consent declaration; accordingly, a copy of the notice to be provided in the hospital and a link to the project's website should be provided. The study should not commence prior to these transparency measures being in place. **Condition 2.** Linked to condition 1, a clear process for withdrawing from the study and deleting personal data from the study must be in place, should a participant wish to exercise their rights. Based on the information provided by the Applicant, the Healthcare Pricing Office and the Mater Hospital should therefore be involved in this process. **Condition 3**. Full ethics approval from the research ethics committee of the Mater Hospital must be in place, and confirmation of this approval must be submitted to the HRCDC. The consent declaration will not be effect until full REC approval has been obtained. **Condition 4**. It is a condition of the consent declaration that the required data agreements/arrangements (e.g., data sharing agreements) are in place between the DCU and the providers of personal data, including agreements with the HPO and the Mater Hospital. Data should not be transferred or processed without the required agreements being put in place. **Condition 5.** To protect the data, the laptops and devices used by the researchers in this study should be appropriately encrypted. **Condition 6.** With regards the anonymisation of the data by DCU (i.e., the removal of the unencrypted MRN and other variables), the data controller should ensure that the required variables to anonymise the data have been removed/deleted and such data is not being retained. It is the responsibility of the data controller, DCU, to determine and ensure that the data has been anonymised. **Condition 7.** The data controller must ensure that any data shared with the health economist for the purpose of this study is fully anonymised and that measures are in place to protect the participant's anonymity.

8. Annual Reviews

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

- **Ref ID:** 21-018-AF1/CSO; Alberto Alvarez-Iglesias, *Quantifying the Effects of Public Health Interventions in Ireland* ***[Declaration no longer required]***
- **Ref ID:** 20-010-AF1/COV; Linda Coate, *COVID-IYON study*

9. Activities report and events of interest.

- The HRCDC were provided with an activities report outlining the events attended by the Secretariat since May 2023.
- The following upcoming events of interest and other relevant updates where noted:
  - RARE DISEASE FORUM: Patient and Public Involvement in Rare Disease Research (An online meeting led by Health Research Charities Ireland on behalf of the Rare Disease Forum (RDF); Wednesday 14th June @ 6.30pm; https://www.eventbrite.ie/e/rare-disease-forum-patient-and-public-involvement-in-rare-disease-research-tickets-642173657697?keep_tld=1

10. Any Other Business

- The HRCDC was asked to inform the Secretariat about their availability for the July and August HRCDC meetings, to determine if a quorum will be reached. It was discussed that the HRCDC will be updated on the status of the meetings in due course.

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