HRCDC
Health Research Consent Declaration Committee

Date: 14th June 2022
Location: Zoom

Minutes of the Meeting

HRCDC Attendance

Name
Evelyn Mahon
Brigid McManus
Aideen Hartney
Alyson Bailey
Kathy Brickell
Dan Rea
John Woods
Barry Lyons
Jonny Barrett (Secretariat)
Noreen O'Brien (Secretariat)
Caroline Byrne (Secretariat)

Quorum for Decisions
☒**YES**

New Applications – For consideration

Applicant	Ref No.	Title
Michelle O'Brien	22-002-AF1	Understanding the wishes and support needs of people with intellectual disability as they grow older.
Norman Delanty	22-005-AF1	Longitudinal analysis of clinical markers of response to treatment in people with epilepsy (EPIDIVE Phase 2)
Gianpiero Cavalleri	22-006-AF1	A description of the evolution of phenotype in epilepsy from paediatrics through adulthood and old age (HPO study)
Déirdre Daly	19-026-AF2	MAMMI Study: data sharing for two sub-studies with University of Gothenburg and Murdoch Children's Research Institute

Meeting Items

1. **Opening**
   The Chair for today's meeting, Evelyn Mahon (EM), opened the meeting and welcomed the members. EM introduced and welcomed Noreen O'Brien as a temporary Project Officer to the Secretariat.

2. **Apologies**
   Claire Collins, Barry O' Sullivan, Sheelah Connolly, Simon Furney, Zubair Kabir, Mary Tumelty, Cornelius Cooney.

3. **Disclosure of Interest**
   There were no disclosures of interest for this meeting

4. Minutes of the last meeting

Draft minutes of 10th May 2022 were circulated in advance of the meeting and were approved by the HRCDC.

5. Matters arising

The HRCDC were informed of staffing updates within the Secretariat. Following an open recruitment competition, Programme Manager of the Secretariat, Emily Vereker (EV), has been appointed on a permanent basis as Head of the National Office for Research Ethics Committees. The HRCDC congratulated EV on her success and wished her the best in her new role.

6. Updates on previous applications

- Ref ID 21-013-AF1 *(Mammographic breast density and breast cancer outcomes in a population-based breast screening programme):*
  The HRCDC were informed of updates to this study that were submitted by the Applicant. Updates were provided on the study protocol with regards the anonymisation of data, and on Condition 2 relating to enhanced transparency measures. The HRCDC noted these study updates and the Secretariat's response to the Applicant.
  It was also drawn to the attention of the HRCDC that correspondence has been received from a patient advocate regarding this study. The correspondence noted the patient advocate's concerns and questions on the information being provided to participants and the granting of a consent declaration, with the individual noting that other studies have been undertaken in this area previously.
- Ref ID 22-001-AF1/CSO *(Study of the impact of lifestyle factors on COVID-19 outcomes):*
  The Secretariat noted the response from the Applicant and the subsequent Secretariat correspondence with regards Condition 1 (full REC review) that was attached to the consent declaration made for this study. The HRCDC re-emphasised that full research ethics committee review is an important safeguard and a requirement for studies that are seeking a consent declaration.

7. New Applications

Reference ID:	22-002-AF1
Lead Applicant:	Michelle O'Brien
Data Controllers:	Avista – St Anne's (Formally the Daughters of Charity)
Title:	Understanding the wishes and support needs of people with intellectual disability as they grow older.
Research Objective:	This study proposes to carry out a service-wide review of current support for residential service users at St Anne's, Roscrea and how their anticipated care needs at times of change and transition are met, including supports to ensure positive aging and ageing in place, for individuals. The study will involve collecting a range of data to develop a profile of the current needs of individual service users, supports currently received, anticipated future needs and potential gaps in services based on the current model and provision. Data sources will include administrative data from study participants care plans; an environmental audit to assess the suitability of existing residences in meeting current and anticipated future needs of individuals; and questionnaires and focus groups with a range of stakeholders including service users, family, staff,

	management and key external stakeholders including HIQA and the HSE. The study aims to gather data in relation to people being supported health and wellbeing, their age profile and how this will impact on changing needs in the future; and assess where they currently live, the services they receive and how these residences and services meet their current and anticipated future needs. The resulting data will inform service planning moving forward and help St Anne's to be a service responsive to the needs of people being supported into the future.
Reason for Declaration:	A consent declaration is sought for the processing of personal data (access, collection, sharing, analysis, storage) of service user participants who lack decision making capacity for the purpose of this study. Data is collected via medical records, questionnaires and focus groups.
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 decision should be deferred pending receipt of further information: **Public Interest** • The HRCDC noted the aims and objectives of this study and queried whether these activities fall under the definition of health research as they appeared to relate to a service review. It was discussed that it is up to the data controller to determine if this is a health research study as defined in the Health Research Regulations, and if a consent declaration is required. It was further noted that the involvement of Trinity College Dublin in this project was also likely an important consideration when determining if these activities fall under the definition of health research. • The HRCDC commented that research in this specific area is important and that it is also important to involve service users who lack decision-making capacity in such research. It was discussed that the findings from the study have the potential to inform future service design and wider policy. • Overall, the HRCDC was of the view that there is potential public interest in this study but that further information and clarity is required on areas including family involvement, the data to be collected and the study information documents, to sufficiently determine if a consent declaration can be made. **Family involvement** • Where a service user participant lacks decision-making capacity, it was noted that proxy assent for data processing on

	their behalf would not be requested from a suitable individual who can understand their will and preferences, such as a family member, friend or other individual. It was noted that family members will not be involved in the study beyond their own participation in separate family member focus groups. From the Applicant's response, it was discussed that service user participants who may have diminished decision-making capacity would be engaged with, and supported by, familiar staff from the Avista service with reference made to the local service manager, speech and language therapist and multidisciplinary team. Such support will be provided when seeking to determine if the participant would like to participate in this study and during the completion of the questionnaires and focus groups. • It was discussed and acknowledged that service user participants may not have strong family relationships and therefore it could be challenging for the study to identify a suitable relative who could understand their will and preferences and therefore act and provide proxy assent on their behalf. It was also discussed that there may be challenges in identifying a suitable relative who could reasonably support the participant during the completion of study activities, including the focus groups. The HRCDC commented that staff from the service may often be best placed to assist the participant during the study. • However, notwithstanding these challenges and the role of familiar Avista staff, where a participant lacks decision making capacity the HRCDC discussed the benefits of involving family members and was of the view that the participant's family must be informed of the study and their inclusion in the study. In addition, whilst formal proxy assent won't be obtained, it was discussed that the input of the participant's family remains an important consideration and should be sought and taken on board as part of the process of understanding the participant's will and preferences. The HRCDC was therefore of the view that the Applicant should be asked for further information on these matters. The HRCDC also commented that further information should be requested on how a suitable family member who has a close relationship with the participant, if available, can support them during the study focus groups. **Data collection and security** • The HRCDC discussed the collection of data via the questionnaires and the focus groups. It was commented that the data aimed to build a profile of the service user and their needs, in particular the quantitative data collected via the questionnaire. • It was noted that the questionnaires would be completed by the Avista local service manager, with or without the service user participant being present. Given the personal nature of some of the questions, it was queried whether it would be possible for the questionnaire to be filled in by the local manager only, including in the absence of the participant. • It was discussed that Avista will likely be providing different levels and types of services depending on the participant's

	circumstances. It was commented that a close key support worker from Avista, who could be involved in providing services to the participant, may also be well placed to support the completion of the questionnaire, if available. • The HRCDC also commented that the information provided on the data to be collected for this study was inconsistent in places. The HRCDC was of the view that further clarifications should be requested on the data that will be collected, having due regard to the principle of data minimisation. • The HRCDC also queried where the audio recording of the focus groups will be securely stored and when they will be deleted. **Research Ethics Committee (REC) Approval** • It was noted that research ethics approval has been obtained from Avista, which was formally the Daughters of Charity Disability Service. It was commented that service providers have their own established research ethics committees that consider proposals for research to be conducted at their sites. • The Secretariat noted that the REC letter indicated approval from the Chair of the Avista REC. As per the requirements of the HRCDC that applies to all Applicants seeking a consent declaration, confirmation that the study has received full REC review is required. It was highlighted that such confirmation was pending from the Applicant. **Study Information Leaflet** • It was noted that two versions of the study information leaflet and consent form, an easy-read version and a standard version, will be utilised in this study, depending on the level of decision-making capacity and communication abilities of the service user participant. • It was commented that the easy-read version appears satisfactory and relatively well designed, however the HRCDC was of the view that the standard version should be reviewed and amended. Specifically, it was discussed that the standard version, when used with service users with an intellectual disability, may be complex to follow and understand. It was also discussed that the study documentation should be reviewed and amended to ensure it provides clear information on withdrawing from the study and other data protection matters. It was acknowledged that it may be difficult to delete and remove all participant data given the nature of the study should this be requested. However, it was discussed that it is important to ensure that clear information on this matter is provided to participants. **Other** • The HRCDC queried how many participants would be included in this study. It was highlighted that up to 80 participants will be recruited. It was commented that this number appeared reasonable in the context of the study's design.

	• It was discussed that appropriate agreements governing the processing of data must be in place between Avista and the data processor, Trinity College Dublin.
HRCDC Decision:	The consensus of the HRCDC was that a decision would be deferred pending receipt of further information
Further Information Requested:	**Query 1**. For service user participants who have diminished decision-making capacity, the HRCDC requests the Applicant to provide information on how their family can be informed about this study, the service user's inclusion in the study and the processing of their data. **Query 2.** Further to Query 1, the Applicant is asked to outline how the input of the service user's family can be sought and taken into account as part of the process for assessing and understanding the service user's will and preferences for participating in this study. **Query 3.** The Applicant is asked to detail whether: (i) a suitable family member who has a good relationship with the service user participant, if available, can support the participant during their focus group sessions, (ii) if other appropriate Avista staff, beyond the local service manager, who may have sufficient knowledge and understanding of the service user and their will and preferences, can be involved in and support the completion of the study questionnaire. This includes supporting the completion of the questionnaire where a participant will or will not be present. **Query 4.** It is noted that the questionnaire is extensive, encapsulating a high volume of participant data. The responses to the DPIA also states 'yes' when asked if information on physical description, biometric/genetic data and an individual's sex life is collected. Having due regard to the principal of data minimisation, please confirm or otherwise comment that (i) only the minimum amount of data is collected for this study and (ii) the data to be collected is limited to the fields included in the study questionnaire and the questions asked in the focus groups only (i.e., physical description, biometric/genetic data and data on an individual's sex life are not collected). **Query 5.** The HRCDC was of the view that the standard study information leaflet and consent form may be complex to follow and understand for service user participants who have an intellectual disability. The Applicant is therefore requested to amend the standard information leaflet and consent form so that it is more appropriately tailored to the cohort of participants with an intellectual disability who do not require the use of the easy-read versions of the study information leaflet. Further the following points should also be addressed with regards the study documentation provided to participants.

	○ Avista should be noted as the data controller of the study: the current study information leaflets note the Daughters of Charity and Trinity College Dublin (TCD) as joint data controllers ○ the role of TCD as a data processor within this study should be clearly outlined, including the data they will be receiving. ○ the legal basis for data processing (Article 6 and Article 9 of the GDPR) outlined in the information leaflet does not fully align with the legal basis noted to the HRCDC, ○ the data sources used for this study (i.e., medical records, care plans, questionnaires and focus groups and who collects the data from these sources) are not fully and clearly outlined across all versions. For example, the standard form does not reference that focus groups will be undertaken as part of this study. The duration of data storage for the study is also not outlined. ○ the easy read version does not request permission for data processing ○ as proxy assent will not be obtained, the signature section for the legal representative/guardian and references to '*your family members/person you support'* should be removed from the standard version of the study documentation. ○ information on withdrawing consent and what will happen the data collected is not clear. It must be clearly outlined in the study documentation whether and until when a participant's data can be deleted, having due consideration to any applicable derogations. Clear information and timelines should be provided on deleting and removing data before study publication and deleting data after the publication of findings. The Applicant is requested to submit the amended study documentation when responding to this query. **Query 6.** The Applicant is requested to provide information on where the audio recordings of the focus group interviews will be securely stored and if the recordings will be deleted once transcribed. **Query 7.** The Applicant is requested to provide confirmation that this study has undergone and obtained full ethical review from the Avista research ethics committee (REC).

Reference ID:	22-005-AF1
Lead Applicant:	Norman Delanty
Data Controllers:	Royal College of Surgeons in Ireland (RCSI)
Title:	Longitudinal analysis of clinical markers of response to treatment in people with epilepsy (EPIDIVE Phase 2)
Research Objective:	The aim of this project is to reveal factors associated with a positive response to seizure control sustained over time, focusing on use of anti-epileptic drug (AED) treatment, vagus nerve stimulation (VNS) and epilepsy surgery. This will be done through the analysis of current and historical clinical encounters contained

	in de-identified healthcare records of a population of people with epilepsy (PwE) from Beaumont Hospital and St James's Hospital.
Reason for Declaration:	The consent declaration is requested for the processing (sharing, analysis, storage etc.) of participant data that is already collected as part of care and treatment for the purpose of this specific study. Once the study is concluded, fully anonymised data will be made available in an appropriate data scientific repository. The Applicant outlines the reasons why explicit consent is not possible, including the number of participants involved and the feasibility of a consent process.
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. The Secretariat introduced the study. It was noted that RCSI has been confirmed as the data controller of this study and that the data is pseudonymised by the hospitals prior to transfer to RCSI, who will not have access to the master list to reidentify participants. It was further highlighted that the participant's record will not be directly accessed to extract data for the purpose of this study. Data is instead extracted from the separate epilepsy warehouse reporting system. The Secretariat also noted that there are a number of similarities between this application (22-005-AF1) and HRCDC application 22-006-AF1, which is also tabled for consideration at this meeting. Specifically, it was noted that both studies use the same data source and methods for extracting, pseudonymising and sharing data. 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** • The HRCDC discussed the aims and objectives of the study and noted that the study had strong data protection safeguards. It was also commented that if conducted by the hospital this study would likely not need a consent declaration. • It was the view of the HRCDC that there is a strong public interest case in this study. **Transparency** • It was noted that information on this study will be provided via the RCSI FutureNeuro website and their social media channels. • The information leaflet and notice that are made available to patients attending the epilepsy clinics at the participating hospital sites were also discussed. It was commented that both documents provided general information on the electronic

	epilepsy patient record (eEPR), including its use for clinical care and treatment, however the HRCDC noted that they provided limited information to patients that their data may be used for health research purposes. • The HRCDC commented that information on data protection rights, including the right to withdraw from research were also not outlined in the existing transparency methods. • The HRCDC discussed that other research studies using data that is captured in the eEPR, will be likely be undertaken in the future. Therefore the HRCDC was of the view that transparency measures should be enhanced more generally, rather than enhanced specifically for the EPIDIVE Phase 2 study only. • The HRCDC discussed that clear information on data protection rights and how to exercise those rights, including the right to withdraw participant data, should be provided via the FutureNeuro website as well included on the information leaflet and notices. It was further commented that transparency measures should outline that data for research is not extracted directly from the eEPR, but by an alternative process utilising the epilepsy reporting warehouse. **Data minimisation** • The HRCDC noted that the study is seeking data relating to ethnicity and noted the reasons outlined for why it is requested. Considering the principle of data minimisation, the HRCDC queried whether this data is required for this study. • The Secretariat highlighted that the research ethics committee (REC) had requested further clarification from the Applicant on the use of this data. It was commented that the Applicant should confirm that full REC approval covers the use of data on ethnicity. **Data transfer agreements** • It was noted that the appropriate agreements governing the transfer and use of data must be in place between the institutions. **Public & patient involvement (PPI)** • The HRCDC discussed the level of PPI engagement that has been undertaken previously by RCSI-FutureNeuro. It was also noted that the National Epilepsy eHealth Governance Board includes PPI representatives. It was commented that the Applicant could provide further details on the PPI representation on this board as part of the Annual Review. • On balance, the HRCDC was of the view that the Applicant should make efforts to conduct PPI engagement on a continued project specific basis, both for this EPIDIVE Phase 2 study and other future studies that maybe undertaken. **Other** • The HRCDC discussed that the Applicant must ensure that the data that will be made available to an appropriate data scientific repository at the end of this study is anonymised.

	• It was noted that reference was made in the submitted documents to the HRCDC approving the manner and duration of data archiving. It was commented that the role of the HRCDC should be clarified when responding to the Applicant. • The HRCDC noted future plans to explore if a process for obtaining participant consent for research can be integrated into the electronic epilepsy patient record. It was discussed that the Applicant should be asked to provide updates on this activity as part of the Annual Review. • 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, including the requirement to have full REC approval, outstanding signatures, and data minimisation.
HRCDC Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made.
Duration of Declaration:	The Declaration is made on 14th June 2022 and is valid until 31st January 2023 or until the personal data has been destroyed or irrevocably anonymised, whichever occurs sooner.
Conditions Attached:	**Condition 1.** The Applicant is requested to further enhance transparency measures more generally with regards the processing of personal data from the electronic epilepsy patient record (eEPR) for health research purposes. The FutureNeuro website, and the information leaflets and notices made available to patients in the hospitals, should be updated to provide clear information on the use of data from the eEPR for health research purposes. The website, leaflets and notices should further provide clear information on the participant's data protection rights and how to exercise these rights, including the right to withdraw their eEPR data from health research studies. In addition, information should be provided on how data for health research is pseudonymised and transferred from the epilepsy warehouse reporting system, rather than extracted directly from the eEPR. **Condition 2.** Confirmation that full research ethics committee approval has been obtained from Beaumont Hospital and St James's Hospital must be provided to the HRCDC. The consent declaration will not come into effect until this condition is met. **Condition 3.** The scope of this declaration is for processing personal data for the purpose of the EPIDIVE Phase 2 study, covering the Beaumont Hospital and St James's Hospital sites only. St. Vincent's University Hospital is not covered by this consent declaration. An amendment request form should be submitted for consideration by the HRCDC to cover other sites beyond Beaumont Hospital and St James's Hospital, subject to the requisite REC approval being in place. **Condition 4**. A signature on the HRCDC application from the study's Principal Investigator, Prof Delanty, must be submitted to

	the Secretariat as soon as is practicable. The consent declaration will not be in effect until this condition is met. **Condition 5.** Aligned with the principle of data minimisation, the Applicant must ensure that only the minimum volume of personal data is obtained and processed for the purpose of this study and to fully anonymise the data as soon as is practicable. With regards data on ethnicity, the Applicant is requested to consider whether this data is required for the purpose of this study. Linked to Condition 2, if data on ethnicity is to be processed then the Applicant must confirm that full research ethics committee approval covers the use of such data. **Condition 6.** The Applicant must ensure that the necessary appropriate agreements governing the transfer and processing of personal data are in place prior to data transfer. **Condition 7.** The Applicant must ensure that the data that will be made available in an appropriate scientific repository at the end of this study is anonymised. **Condition 8.** As part of the Annual Review the Applicant is requested to provide updates on the progress made to incorporate a consenting process into the electronic epilepsy patient record.
HRCDC Recommendations:	**Recommendation.** For the benefit of the EPIDIVE Phase 2 study and future studies, it is recommended that the Applicant undertakes continued public and patient involvement (PPI) activities, including on a project specific basis.
HRCDC Comments:	**Comment #1.** As part of the Annual Review the Applicant is requested to provide some additional information on the PPI representation on the National Epilepsy eHealth Governance Board. Personal details, such as names of PPI representatives are not requested, only brief, general information on the number or proportion of PPI representatives on this governance board. **Comment #2.** The HRCDC notes the comment from the St James's Hospital research ethics committee for confirmation of HRCDC approval for data archiving. Please note that the role of the HRCDC is to determine if the public interest in the health research study outweighs requirement to obtain explicit consent for the processing of personal data. The HRCDC do not provide approval with regards to the methods, security or timelines for data archiving**.**

Reference ID:	22-006-AF1
Lead Applicant:	Gianpiero Cavalleri
Data Controllers:	Royal College of Surgeons in Ireland (RCSI)
Title:	A description of the evolution of phenotype in epilepsy from paediatrics through adulthood and old age (HPO study)
Research Objective:	The aim of this project is to use analytics and visualisations to track the evolution of phenotypical characteristics associated with epilepsy in adults over time (in years) and to determine if there is

	significant variation in the frequency of occurrence of those characteristics across the historical course of epilepsy. These characteristics will be standardised and mapped to an internationally recognised clinical research language to facilitate adult/paediatric comparison with an existing standardised analysis conducted on a paediatric epilepsy dataset from a US research group.
Reason for Declaration:	The consent declaration is requested for the processing (sharing, analysis, storage etc.) of participant data that is already collected as part of care and treatment for the purpose of this specific study. Aggregated, analysed outputs will be shared with the Children's Hospital of Philadelphia Research Institute for adult/paediatric comparison. Once the study is concluded, fully anonymised data will be made available in an appropriate data scientific repository The Applicant outlines the reasons why explicit consent is not possible, including the number of participants involved and the feasibility of a consent process.
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. The Secretariat introduced the study and noted the similarities between this Application and HRCDC application 22-005-AF1. It was noted that RCSI has been confirmed as the data controller of this study and that both studies use the same data source and methods for extracting, pseudonymising and sharing data. It was further highlighted that the participant's record will not be directly accessed to extract data for the purpose of this study. Data is instead extracted from the separate epilepsy warehouse reporting system. 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. It was the view of the HRCDC that the matters and comments highlighted and discussed for application 22-005-AF1, including the conditions and recommendations relating to transparency, data minimisation and other technical safeguards also apply to 22-006-AF1. **Public Interest** • The HRCDC discussed the aims and objectives of the study and noted that the study had strong data protection safeguards. • It was the view of the HRCDC that there is a strong public interest case in this study. **Data sharing with the US**

	• It was noted that data from this study in Ireland will also be shared with the Children's Hospital of Philadelphia Research Institute. It was discussed that the purpose of this sharing is to enable a comparison of data between the adult patients in Ireland with paediatric data that has already been collected from the USA. It was clarified that data on children in Ireland is not obtained and processed as part of this RCSI study. • It was noted that the Applicant has confirmed that individual patient level pseudonymised data is not shared with the Children's Hospital of Philadelphia Research Institute, only anonymised, aggregated data will be shared. While personal data will not be shared, the HRCDC discussed that it would be considered good practice to put in place an appropriate data sharing agreement between RCSI and the Children's Hospital of Philadelphia Research Institute. **Other** • 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, including the requirement to have full REC approval, outstanding signatures, and data minimisation.
HRCDC Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made.
Duration of Declaration:	The Declaration is made on 14th June 2022 and is valid until 31st January 2023 or until the personal data has been destroyed or irrevocably anonymised, whichever occurs sooner.
Conditions Attached:	**Condition 1.** The Applicant is requested to further enhance transparency measures more generally with regards the processing of personal data from the electronic epilepsy patient record (eEPR) for health research purposes. The FutureNeuro website, and the information leaflets and notices made available to patients in the hospitals, should be updated to provide clear information on the use of data from the eEPR for health research purposes. The website, leaflets and notices should further provide clear information on the participant's data protection rights and how to exercise these rights, including the right to withdraw their eEPR data from health research studies. In addition, information should be provided on how data for health research is pseudonymised and transferred from the epilepsy warehouse reporting system, rather than extracted directly from the eEPR. **Condition 2.** Confirmation that full research ethics committee approval has been obtained from Beaumont Hospital and St James's Hospital must be provided to the HRCDC. The consent declaration will not be in effect until this condition is met. **Condition 3.** The scope of this declaration is for processing data for the purpose of the HPO study, covering the Beaumont Hospital and St James's Hospital sites only. St. Vincent's University Hospital is not covered by this consent declaration. An

	amendment request form should be submitted for consideration by the HRCDC to cover other sites beyond Beaumont Hospital and St James's Hospital, subject to the requisite REC approval being in place. **Condition 4**. A signature on the HRCDC application from the study's Principal Investigator, Prof Cavalleri, must be submitted to the Secretariat as soon as is practicable. The consent declaration will not come into effect until this condition is met. **Condition 5.** Aligned with the principle of data minimisation, the Applicant must ensure that only the minimum volume of personal data is obtained and processed for the purpose of this study and to fully anonymise the data as soon as is practicable. With regards data on ethnicity, the Applicant is requested to consider whether this data is required for the purpose of this study. Linked to Condition 2, if data on ethnicity is to be processed then the Applicant must confirm that full research ethics committee approval covers the use of such data. **Condition 6.** The Applicant must ensure that the necessary appropriate agreements governing the transfer and processing of personal data are in place prior to data transfer. **Condition 7.** The Applicant must ensure that the data that will be made available in an appropriate scientific repository at the end of this study is anonymised. **Condition 8.** As part of the Annual Review the Applicant is requested to provide updates on the progress made to incorporate a consenting process into the electronic epilepsy patient record.
HRCDC Recommendations:	**Recommendation 1.** For the benefit of the HPO study and future studies, it is recommended that the Applicant undertakes continued public and patient involvement (PPI) activities, including on a project specific basis. **Recommendation 2.** The Applicant is recommended to put in place a data sharing agreement between RCSI and the Children's Hospital of Philadelphia Research Institute governing the processing of the data and to ensure that the anonymity of participants from Ireland is protected.
HRCDC Comments:	**Comment #1.** As part of the Annual Review the Applicant is requested to provide some additional information on the PPI representation on the National Epilepsy eHealth Governance Board. Personal details, such as names of PPI representatives are not requested, only brief, general information on the number or proportion of PPI representatives on this governance board. **Comment #2.** The HRCDC notes the comment from the St James's Hospital research ethics committee for confirmation of HRCDC approval for data archiving. Please note that the role of the HRCDC is to determine if the public interest in the health research study outweighs requirement to obtain explicit consent for the processing of personal data. The HRCDC do not provide

	approval with regards to the methods, security or timelines for data archiving**.**

Reference ID:	19-026-AF2
Lead Applicant:	Dr Déirdre Daly
Data Controllers:	A. Trinity College Dublin B. The following collaborators are joint controllers with TCD for the respective academic sub-studies utilising MAMMI data: (i) University of Gothenburg, Sweden (ii) Murdoch Children's Research Institute, Australia
Title:	MAMMI Study: data processing for sub-studies with University of Gothenburg and Murdoch Children's Research Institute.
Research Objective:	The Maternal Health and Maternal Morbidity In Ireland (MAMMI) study is a longitudinal study exploring the health and health problems experienced by women during their first pregnancy up to 12 months after the baby's birth. A total of 3047 women were recruited from three maternity hospitals in Ireland between January 2011 and March 2017. Follow up studies are currently being conducted with consenting women after their 2nd baby's birth and 5 years after their first baby's birth. This consent declaration relates specifically to two sub-studies/collaborations involving the use of MAMMI data, that are to be conducted with collaborators from Sweden and Australia.
Reason for Declaration:	The scope of the consent declaration requested is limited to processing specifically for the purpose of the two sub-studies with Australia and Sweden and where participant consent is in line with previous EU Data Protection Directive and the Data Protection Acts 1988 & 2003 only. The personal data to be processed for the sub-studies and covered by the declaration, is also limited to the data collected as part of the initial MAMMI study between 2011-2018 only (i.e., first pregnancy), not the follow-up studies. The Applicant states that the consent previously obtained from participants for the MAMMI study, initially did not specify that research might be conducted by, and data shared with third parties and notes that there are different interpretations on what is meant by anonymised data.
HRCDC Comments:	This was an 'AF2' application for Applicant's seeking a declaration for studies that commenced prior to the Health Research Regulations (HRR). AF2 Applicants considered that the consent obtained was compliant with the previous data protection legislation. However, further to the HRR amendments being made, some Applicants have now reviewed the consent obtained, and considered it not in line with the previous data protection legislation and still require a consent declaration. Therefore, the HRCDC must consider these applications and balance the public interest case for the study. The HRCDC noted that ethics approval had been granted for the studies 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 Secretariat introduced the application and noted the relevant joint data controllers and the limited scope of the consent declaration requested. It was highlighted that the data transferred to Australia and Sweden is considered anonymised to those collaborators. It was further noted that when transferred to Australia and Sweden that the data will not contain the participant's study number. 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** • The HRCDC discussed the purposes of the two sub-studies/collaborations and the reasons why a consent declaration was required. It was commented that participants who previously provided consent would be unlikely to be surprised that their data, collected as part of the MAMMI study, would be shared for the purposes of these two sub-studies. • On balance with the data security arrangements in place, it was the view of the HRCDC that there is a public interest case in sharing and processing data for the sub-studies with Australia and Sweden. **Reconsent and the scope of the declaration** • The reconsent process that has been undertaken by the MAMMI study was noted and discussed. It was queried how many participants will be included in these two sub-studies with Australia and Sweden, specifically the cohort of participants who could not be reconsented and who therefore fall within the scope of the consent declaration. • It was clarified that data from all 3047 participants who were recruited to the MAMMI study between 2011-2017 will be shared for the purpose of the sub-study with Australia, while fewer participants will be included in the sub-study with Sweden. • The Applicant outlined that since 2019 they had contacted 1830 of these participants to seek their reconsent and of these over 700 had responded and provided reconsent. The Applicant outlined that participants where not contacted to reconsent if they were lost to follow-up and/or opted-out or withdrew from further participation in the MAMMI study. The Applicant stated that no participant has withdrawn their consent for the processing of their data or requested their data to be deleted. • It was discussed that a consent declaration cannot be made to override a participant's decision to withdraw their consent for data processing and that it is the responsibility of the data

	controller to ensure that they are complaint with data protection legislation with regards data processing. • The HRCDC commented that the Applicant must be satisfied that consent for data processing has not been withdrawn and remains in place, having due regard to any information and options provided to participants regarding the processing of their data if they withdraw or opted-out from further study participation or future contact. **Data agreements** • The HRCDC discussed that the required agreements and arrangements must be in place between the parties, including an appropriate data sharing agreement and joint controller arrangements. In addition, it was noted that transfers to Australia must meet the requirements of Chapter V of the GDPR, including the use of standard contractual clauses. **Public & patient involvement (PPI)** • The HRCDC commended the level of PPI activities that have been undertaken to date. **Other** • 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, including the provision of an outstanding ethics approval letter, data minimisation and the feasibility of removing shared data if consent for data processing is later withdrawn. • It was also commented that the relevant section of the MAMMI website should be updated to provide clear information to participants on whether data could be withdrawn from the Australian and Swedish sub-studies.
HRCDC Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made.
Duration of Declaration:	The Declaration is made on 14th June 2022 and is valid until 31st December 2027 or until the personal data has been destroyed or irrevocably anonymised, whichever occurs sooner.
Conditions Attached:	**Condition 1.** It is a condition that the scope of this consent declaration does not cover the sharing of participant data for the Australian and Swedish sub-studies if participant consent for data processing has been withdrawn. Where participants have withdrawn/opted-out from future study participation and contact, the Applicant must be satisfied that consent for data processing has not been withdrawn and remains in place. In this context the Applicant must have due regard to any information and options that were provided to participants regarding the processing of their personal data if they withdraw or opted-out from further study participation or future contact. **Condition 2.** The Applicant must ensure that the required appropriate data agreements and arrangements are in place between Trinity College Dublin and the University of Gothenburg,

	Sweden and Murdoch Children's Research Institute, Australia. This includes appropriate data sharing agreements, joint data controller arrangements and the standard contractual clauses for the transfer of data outside the EEA. Data sharing cannot occur until this Condition has been met. **Condition 3.** The Applicant must submit the outstanding requisite research ethics approval letter that covers the Australian sub-study. The consent declaration will not be in effect for this sub-study until this condition is met. **Condition 4.** Aligned with the principle of data minimisation, the Applicant is requested to ensure that only the minimum amount of data is shared and processed for the purpose of the Australian and Swedish sub-studies. The Applicant is further requested to consider if data can be deleted prior to 31st December 2027, if possible. **Condition 5.** Having due regard to the practicalities and any GDPR derogations that may apply, the Applicant is requested to explore if it is feasible to remove participant data from the sub-studies after it has been shared with Australia and Sweden, should a participant wish to withdraw their consent for data processing and have their data deleted. The Applicant is also requested to update the relevant section of the MAMMI website to provide clear information on if, and until when, participant data can be removed from the Australian and Swedish sub-studies if requested by a participant.

8. Annual Reviews

The Secretariat has received 8 annual reviews in advance of the meeting which were deemed satisfactory:

- Ref ID 19-003-AF2: Alistair Nichol, Treatment of Invasively ventilated adults with Early Activity and Mobilisation (TEAM) Trial.
- Ref ID 19-023-AF2: Ger Curley, Effect of naïve and pre-activated MSCs on monocyte/macrophage function in patients with pulmonary and non-pulmonary sepsis.
- Ref ID 19-027-AF3: Sharon Glynn, Identification of predictive and prognostic biomarkers in triple negative breast cancer
- Ref ID 19-085-AF1: Shona Pfeiffer, Blood Biomarkers to Predict Recovery from Ischaemic Stroke
- Ref ID 19-086-AF1: Ignacio Martin-Loeches, Sepsis Immunosuppression in Critically Ill Patients
- Ref ID 20-022-AF1: Alistair Nichol, PHIND Study
- Ref ID 20-035-AF1: Dr Ignacio Martin-Loeches, IV Zanamivir Effectiveness Study
- Ref ID 20-039-AF1: Bairbre McNicholas, A pilot multicentre trial comparing patients with shock

9. Activities report and events of interest

The following upcoming events of interest and other relevant updates where noted:

- **European Health Data Space:** The Secretariat highlighted the launch of the European Health Data Space (EHDS) by the European Commission. It was noted that EHDS aims to provide individuals with better control of their data and to create a framework and infrastructure for the use of health data for research purposes. It was discussed that the EHDS is at an early stage and that further information and guidance on the EDHS, and how it may impact the work of the HRCDC, remains pending. (https://ec.europa.eu/commission/presscorner/detail/en/ip_22_2711 & https://ec.europa.eu/health/ehealth-digital-health-and-care/european-health-data-space_en)
- **Webinar on Data Sharing and Governance Act, 23rd May 2022:** The Secretariat attended a webinar on the Data Sharing and Governance Act presented by the Data Governance Unit in the Department of Public Expenditure and Reform. The Act provides a framework setting out how and what data can be shared between public sector bodies. The sharing of health data is excluded from this Act.

10. Any Other Business

- **Update on iPads:** the Secretariat discussed the use of HRCDC iPads for accessing the reading room software Decision Time. It was discussed that the HRCDC iPads only must be used for accessing Decision Time. Members who have not yet received an iPad will be sent one shortly.

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