HRCDC
Health Research Consent Declaration Committee

Date: 12th December 2023
Location: Zoom videoconferencing

Minutes of the Meeting

HRCDC Attendance

Name
Evelyn Mahon
Alyson Bailey
Kathy Brickell
Sheelah Connolly
Aideen Hartney
Zubair Kabir
Dan Rea
Cornelius Cooney
Barry Lyons
Patricia O'Beirne
Susan Smith
Brid Burke (Secretariat)
Jonny Barrett (Secretariat)
Caroline Byrne (Secretariat)

Quorum for Decisions
☒YES

New Applications – For consideration

Applicant	Ref No.	Title
Prof Alistair Nichol	23-023-AF1	Sedation, Temperature and Pressure after Cardiac Arrest and Resuscitation – the STEPCARE trial
Prof Norman Delanty	23-012-AF1	Research Use of Diagnostic Genomic Testing Data for Epilepsy
Sean O'Dowd	23-013-AF1	The Prevalence of Primary Tauopathies in Ireland; a Clinically Defined Population Study in the Province of Leinster

Meeting Items

1. **Opening**
   The meeting was chaired by Aideen Hartney (Deputy Chairperson) who opened the meeting and welcomed the members.

2. **Apologies**
   Simon Furney, John Woods, Mary Tumelty (Maternity leave), Barry O' Sullivan, Brigid McManus

3. **Disclosure of Interest**
   Kathy Brickell (KB) declared her interest in (i) the matters arising agenda item i.e., 23-009-AF1 (The ABC trial) and (ii) the new application 23-023-AF1 (Sedation, Temperature and

Pressure after Cardiac Arrest and Resuscitation – the STEPCARE trial). KB was absent during the meeting when these applications were considered.

4. Minutes of the last meeting

Draft minutes of 14th November 2023 were circulated in advance of the meeting and were approved by the HRCDC.

5. Matters arising

23-009-AF1 (The ABC post-intensive care trial).

- The HRCDC were provided with the Applicant's response to the HRCDC's decision letter of 3rd October 2023. They were also provided with a note from the Chairperson in relation to this response.
- With regards Condition 4 on the requested changes to the study information leaflets, the Applicant outlined that it would take a number of weeks to address condition, with the changes requiring review and approval by the relevant parties in the trial and the Research Ethics Committee. The Applicant stated that accordingly, the commencement of this international trial in Ireland would be notably delayed.
- The Applicant proposed that the changes to the documents would be made at the next research ethics amendment request, which is expected to occur in February 2024. As an interim measure to address this condition, the Applicant proposed that the researchers in the study would go through the study documentation and provide verbal explanations to the participants and/or the person providing proxy assent, including explaining the provisions that do not apply in Ireland and other matters such as the withdrawal process and retaining data, changes that were requested in Condition 4.
- The HRCDC discussed the Applicant's response and the Chairperson note. On balance and given the impact on the study timeline and in the context of the changes requested in Condition 4 for this specific study, the HRCDC was of the view that the proposed approach was acceptable, and that the applicant would make the proposed changes at the next available opportunity with the REC.
- While the proposed approach was approved, the HRCDC commented that it is important that verbal discussions and explanations of the points requested in Condition 4 are undertaken by the research staff and an appropriate record of this should be created, where possible, including explaining the points in the documents that do not apply to participants recruited in Ireland.
- It was commented that this decision to accept the proposal is study and context specific and should not be viewed as setting a precedent.
- Lastly, it was highlighted that the use of the term 'you may have rights', as opposed to 'you do have rights', is to be examined and discussed with key stakeholders to help understand what the correct phrasing should be. It was discussed that this matter will be followed-up by the Secretariat.

6. New Applications

Reference ID:	23-023-AF1
Lead Applicant:	Prof Alistair Nichol
Data Controllers:	Helsingborg Hospital, Sweden
Title:	Sedation, Temperature and Pressure after Cardiac Arrest and Resuscitation – the STEPCARE trial
Research Objective:	Cardiac arrests (where a person's heart stops beating) outside of hospital affect around 300,000 people each year in Europe.

	Patients who are in ICU after a cardiac arrest will have many of the normal functions of their body managed by doctors, aiming to keep their measurements within a certain range. However, it's not known exactly what these measurements should be. This trial aims to test how best to control three important measurements in ICU to decide which is best for patients. These are: 1. How deeply the participant is kept asleep (sedated) 2. How warm or cold they should be 3. What their blood pressure should be. The study will be open to unconscious ICU adult patients who have had an out-of-hospital cardiac arrest, and their heart has started pumping again. Eligible patients will be allocated at random to receive care which will test a combination of these 3 factors.
Reason for Declaration:	The consent declaration is sought to process the personal data of participants who will lack decision-making capacity to provide consent due to the nature of their illness for the purpose of the main STEPCARE study (processing includes collection, transfer, analysis, storage of data). Deferred proxy assent will be obtained in such circumstances, including deferred assent by telephone. The study also seeks to collect bio samples and associated data for future bio-marker sub-studies. In addition, to data processing for the main STEPCARE trial, the scope of the declaration will cover the subsequent storage of data, including storage of data only for future biomarker sub-studies; however, the declaration will not extend to further processing of those who lack capacity for bio-marker sub-studies; an amendment request or new application will be required.
HRCDC Comments:	The HRCDC noted that ethics approval had been granted for the study where the design, methodology and ethical aspects of the study, including consent protocols are considered. Only studies that 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 provided an overview of the study, the reason for seeking a consent declaration and the scope of data processing that will be covered by the consent declaration, if made, including the scope regarding the bio-marker sub-study. The Deputy Chairperson 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 consent declaration with attached conditions could be made. **Public interest case** • The HRCDC discussed the study activities, including the follow-up data collection and the primary and secondary outcomes. It was discussed that it would not be possible to obtain participant consent at the point of study enrolment due to the nature of the participants' conditions. • It was the view of the HRCDC that there is a strong public interest case in this research. **Sub-study**

	• The HRCDC queried and discussed the bio-marker sub-study where bio-samples would be obtained for future analysis; it was commented that the samples for this sub-study would be stored in Ireland and at a biobank in Luxembourg who were noted as a data processor. It was queried why samples would be stored in both locations. • It was highlighted that the data processor in Luxembourg will not receive clinical, demographic, or other similar data, only the sample and associated study/sample ID. It was further highlighted that biomarkers to be explored in the sub-study, and the parties that may be involved, are currently unknown. • It was discussed that the scope for the consent declaration can cover storage only of the personal data for the bio-marker sub-study and that an amendment or new application will need to be submitted to undertake further sub-study data processing. **Deferred proxy assent and consent to continue.** • The HRCDC discussed the Applicant's response on the timeline for seeking deferred proxy assent and/or participant consent to continue and what will happen the personal data. It was noted that continued efforts will be made to obtain deferred proxy assent but in the rare cases where this doesn't occur, for example a suitable proxy cannot be identified, then the study data collected will be retained at the local site and not uploaded to the study database until the participant has regained capacity and provides consent to continue. If the participant doesn't regain capacity by the point of hospital discharge, typically up to 3-4 months, then the Applicant requests that the data obtained can be uploaded to the study database for analysis. • The HRCDC discussed this request and was of the view that the personal data could be uploaded for analysis to the data controller if it occurs that deferred proxy assent or participant consent to continue cannot be obtained. It was commented that proxy assent is considered a suitable safeguard and that the consent declaration can cover data processing for such studies if proxy assent cannot be obtained following strong efforts to obtain it. **Study withdrawal** • The HRCDC noted the response from the Applicant on what will happen the personal data collected if proxy assent or consent is withdrawn; it was outlined that the personal data would be deleted but that the study would request permission from the person to keep and process the data already obtained. • It was commented that the responses provided do not clearly outline what would also happen the associated biosamples if proxy assent or participant consent is withdrawn. It was discussed that it is likely that the samples would also be deleted and that this should occur. **Study Information Leaflets**

	• It was discussed that the terms 'If there is no known objection by your relative being in this study' and 'Do you have any objection to your relative taking part…' should be more positively phrased to ask the personal providing proxy assent if they are of the view that the participant would like to or be willing to be included in this research. **Data Transfer** • The HRCDC queried the process of data transfer, management and access to the study database/website and the storage and access to the master key. It was clarified that pseudonymised data from the local site in Ireland is transferred via a database/website that is managed by the data controller of the study; the login credentials for this database/website are provided by the data controller. It was also noted that the data controller will not have access to the master key that links the pseudonymised code to the participant's identity. • The statement that the data to be transferred to and analysed by the data controller is anonymised was also queried. It was highlighted that the Applicant had stated that the data is effectively anonymised to the data controller as they won't have access to the master key, however they also acknowledged that the data is pseudonymised/coded by way of the master list held at the local site who is a data processor. The HRCDC commented on the importance of data controllers' understanding when the data is pseudonymised/personal data versus when it can be considered anonymised. **Other:** • The HRCDC noted the response on the PPI engagement that has and will occur. It was commented that it would have potentially benefited the study if PPI engagement was undertaken at an earlier stage in the study. • Where telephone assent is utilised, it was noted that a copy of the study documents is posted to the proxy and includes a stamped address envelope for them to return the signed documents. It was commented that email may provide a more convenient method for some participants. • The HRCDC also noted the technical and more standard safeguards that may need to be considered by the Committee, including providing clarity on the scope of the consent declaration, reporting on PPI activities, joint responsibility for compliance with the consent declaration and obtaining permission to continue to process data where an individual wishes to withdraw.
HRCDC Decision:	The consensus of the HRCDC was that a Consent Declaration should be made, subject to conditions attached.
Duration of Declaration:	The consent declaration is made on 12th December 2023 and is valid until 31st January 2028 and for 15 years thereafter until 31st January 2043 or until the personal data is deleted or fully

	anonymised or participant consent is obtained, whichever occurs first.
Conditions Attached:	**Condition 1.** Where proxy assent/participant consent is withdrawn or is refused and the study wishes to continue to process the data already collected, then permission for this must be obtained and recorded from the proxy or participant, whichever is relevant. If such permission is obtained from the proxy on behalf of a participant who lacks decision-making capacity, then participant consent to continue must also be obtained for this continued data processing when they regain decision-making capacity. **Condition 2.** The Applicant is requested to report in the Annual Review on the PPI activities to be undertaken. It is noted that the responses provided to the HRCDC stated 'this study will be discussed with the ICC CTN PPI group at their meeting'.
HRCDC Recommendations:	**Recommendation 1.** The terms in the study documents *'If there is no known objection by your relative being in this study'* and *'Do you have any objection to your relative taking part…'* should be amended to be more positively phrased to ask the person providing proxy assent if they thought the participant would like to or be willing to be included in this research. The Applicant is requested to amend these terms in the study documentation at the earliest opportunity.

Reference ID:	23-012-AF1
Lead Applicant:	Prof Norman Delanty
Data Controllers:	Beaumont Hospital Royal College of Surgeons in Ireland
Title:	Research Use of Diagnostic Genomic Testing Data for Epilepsy
Research Objective:	As a result of research breakthroughs, it is now possible to identify a genetic cause for some people with rare, severe forms of epilepsy. Today clinicians order genetic testing in the hope that a cause for a patient's epilepsy can be found, which can sometimes guide treatment. When a genetic test is ordered in the hospital, typically the DNA sequence of all of the patient's genes is generated and analysed by the diagnostic lab. A result is returned to the doctor (positive or negative) after which the data are essentially lost to science. If these data were available to researchers, researchers can potentially discover new genetic causes, which can be translated to the hospital. This study is proposing to reuse genetic data generated in the hospital, to identify novel genetic causes of epilepsy and predictors of treatment response. The study aims and objectives are: (i) To identify monogenic genetic causes of epilepsy (ii) To identify genetic modifiers of epilepsy (iii) To identify genetic risk factors of epilepsy (iv) To identify genetic factors that influence treatment of the epilepsy (e.g. predictors of adverse reactions)

Reason for Declaration:	A high proportion of epilepsy sufferers are persons who have a lack of decision-making capacity, often due to the nature of their disease or as a related co-morbid condition. They would most likely fail any functional test of capacity. Every effort will be made to support the patients, but it is more than probable that there will be individuals who will not have capacity to give explicit consent. The consent declaration is therefore requested to process the personal data of those who lack decision-making capacity to provide consent for the purpose of this study. Processing includes collection, analysing and storing data, including follow-up data. Data to be processed includes demographic and clinical data, including images, and already generated genetic data.
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 Secretariat provided an overview of the study, the reason for seeking a consent declaration and the scope of data processing that will be covered by the consent declaration, if made: - It was outlined that the genetic data to be processed in this study is what will be generated as part of standard care and treatment i.e., clinically indicated DNA testing requested by the hospital which is undertaken by an external service provider to the hospital. Accordingly, it was discussed that the study will not involve undertaking additional DNA testing beyond what is ordered by the hospital clinic for care and treatment purposes. - It was further highlighted that the study involves an initial sample size of 100 participants to determine the effectiveness of this model and that data processing is limited to Beaumont Hospital, RCSI and the external laboratory only, that is covered by the research ethics committee approval that is currently in place. It was noted that changes that may occur to this study (e.g., increase in sample size, new third parties, activities that require additional/new REC approval etc.) will not be covered and will require an amendment request form or new application to be submitted for consideration. - Lastly, it was commented that the processing of personal data (including pseudonymised data) in other research beyond this specific study is not covered. It noted that the DPO and REC have outlined that the genetic data is considered 'identifiable data'. The Applicant also confirmed that personal data on the participant's family is not processed and therefore family data is not covered. The Deputy Chairperson 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 consent declaration with conditions attached should be made.

Public interest case

- The HRCDC discussed the study activities, including the re-analysis of the genetic data, the volume of data to be processed, the numbers of participants involved and the scope of the consent declaration.
- On balance, it was the view of the HRCDC that there is a public interest case in this research.

Determining decision-making capacity

- The HRCDC queried the process of how decision-making capacity is determined. It was highlighted that a model of functional decision-making capacity will be utilised; a number of core questions that are asked of the particiapnt to determine this were provided.
- It was commented that the number of participants who lack decision-making capacity that are recruited to this study should be reported on in the Annual Review.

Incidental/secondary findings

- The HRCDC discussed what process would be undertaken if, during the course of the research, the analysis of the genetic data identifies a potentially clinically relevant finding.
- It was discussed that the study documents provided to the proxy and participant includes information and options on what will happen if there are any incidental or secondary findings. It was commented that while beyond the remit of the HRCDC, there is recognition that this is a complex area and that the approach outlined appeared to be in line with national policy on such matters.
- As part of this approach, it was noted that incidental findings that maybe relevant will be shared with the participant's doctor who will then discuss the findings with the participant if they deem it clinically important to do so. The HRCDC commented that the participants/proxy should be provided with an explicit option in the consent/assent form on if they wish to be notified of incidental findings.

PPI engagement

- Based on the information provided, it was not fully clear whether the PPI engagement to date included dialogue to capture the views of those who have reduced decision-making capacity.

Proxy assent study documents

- The HRCDC discussed the submitted study documents that will be used to seek permission from a suitable proxy for the study and data processing, where the participant lacks decision-making capacity. It was noted that a single information leaflet and 'consent/assent' form are employed with the titles and content referring to '*Decision-Making Representative', Legal Representative*' and '*Decision Supporter'.*
- It was noted that a '*decision-making representative'* is a formal and legal support structure provided for in the 2015 Assisted Decision Making Act. It was further discussed that the current

	documentation and its use of terms such as 'legal representative' and 'I am the legal representative for…' do not accurately reflect the process where a relative/friend provides proxy permission on behalf of a participant who lacks capacity as a safeguard; the use of the term '*Legal Representative'* to describe the relative/friend is likely to be inaccurate in most scenarios and in the context of health research. It was further discussed that the term '*Decision Supporter'* is not appropriate. Lastly, it was noted that the wording of this study documentation was not directed at the proxy; for example, much of the content appear to be written in the first-person that refers to 'your data', 'your samples', 'your routine healthcare'. • The HRCDC was therefore of the view that the study should employ separate and specific proxy information leaflets and proxy assent forms that do not use inaccurate or inappropriate terms such as '*Decision Making Representative'*, '*Legal Representative'* and '*Decision Supporter'*, when seeking proxy assent from a suitable relative/friend who is not in a legal role, on behalf of the participant who lacks decision-making capacity. **Other** • It was commented that the principle of data minimisation is important and should be adhered to. • It was also commented that clear transparent information on how samples and data, are transferred is important, including how the bio samples are sent to the external laboratory for the purpose of the clinically indicated DNA testing. It was noted that the name of the external laboratory should also be more clearly outlined in the study documentation. • The HRCDC also noted the technical and more standard safeguards that may need to be considered by the Committee, including making the scope of the consent declaration clear to the Applicant and joint data controllers, submitting the outstanding DPO feedback and signatures, ensuring the required data agreements and arrangements are in place, and submitting the full REC approval letter.
HRCDC Decision:	The consensus of the HRCDC was that a Consent Declaration should be made, subject to conditions attached.
Duration of Declaration:	The consent declaration is made on 12th December 2023 until 31st December 2028, or until the personal data is deleted or fully anonymised or particiapnt consent is obtained, whichever occurs first.
Conditions Attached:	**Condition 1.** As part of the Annual Review, the Applicant is requested to report on the number of participants recruited to this study who lack-decision making capacity. **Condition 2.** The study should employ separate and specific proxy information leaflets and proxy assent forms aimed at the relative/friend providing proxy assent who may not be in a legal role such as a 'Decision Making Representative' or 'Legal Representative'. These separate, specific documents should use the term 'participant representative' when referring to the proxy

	individual and make it clear that the study is seeking the suitable individual's 'proxy assent' (rather than their 'consent') for data processing. In addition, the wording of this sperate proxy documentation should be clearly aimed at the proxy; accordingly, the document should not be written in the first-person that refers to 'your data', 'your samples', 'your healthcare' etc. **Condition 3.** The required data agreements and arrangements must be in place between the parties for this study prior to data being transferred. **Condition 4.** Feedback from the RCSI data protection officer on the study DPIA, and the outstanding signature from Beaumont Hospital on the HRCDC application form should be submitted as soon as practicable and within 2 months. Data processing cannot commence until these are submitted. **Condition 5.** Confirmation of full REC approval should be submitted as soon as practicable and within 2 months.
HRCDC Recommendations:	**Recommendation 1:** Based on the information provided, it was not fully clear to the HRCDC whether the PPI engagement to date included dialogue to capture the views of those who have reduced decision-making capacity. The Applicant/data controllers are requested to undertake PPI engagement to capture the views and perspectives of those with reduced capacity. **Recommendation 2:** It should be ensured that the documents provided to the proxy and/or participants, include clear transparent information on how the biosamples and data are transferred, including how the bio samples are sent to the external laboratory for the purpose of the clinically indicated DNA testing. It should also be clear that CeGaT Laboratories are the only external laboratory where samples/data are sent; therefore, the broad references to 'outside laboratories' should be amended. **Recommendation 3.** The participants/proxy should be provided with an explicit option in the consent/assent form on whether they wish to be notified of incidental findings.

Reference ID:	23-013-AF1
Lead Applicant:	Sean O'Dowd
Data Controllers:	Tallaght University Hospital Mater Misericordiae University Hospital
Title:	The Prevalence of Primary Tauopathies in Ireland; a Clinically Defined Population Study in the Province of Leinster
Research Objective:	Primary tauopathies are a group of neurodegenerative diseases primarily comprising progressive supranuclear palsy (PSP) and Corticobasal Degeneration (CBD). PSP is a rare neurological disorder within the neurodegenerative disease family. There is

	currently very limited information on the prevalence and incidence of PSP and CBS in Ireland. The aim of this study is to identify as many people as possible living within the Leinster region who have a possible diagnosis of PSP or CBS. Participants in the study will be asked to complete a number of questionnaires, alone or with the help of a carer/informant, and consent to a neurological examination. This study aims to help understand more about the number of people with PSP/CBS in Ireland, the particular challenges people with PSP/CBS face, and the natural history of these diseases. The study includes provision for blood and spinal fluid sampling to create a biobank of serum, DNA, and spinal fluid of people with PSP and CBS; however, this is not applicable to those with impaired ability to consent.
Reason for Declaration:	The majority of participants in this study will be able to provide consent. However, it is anticipated that a minority (estimate 10%) will be unable to provide consent due to lack of decisionmaking capacity. The consent declaration is therefore requested to process (i.e., access, collection, analysis, storage) the personal data of those who lack decision-making capacity for the purpose of this specific study (i.e., data from medical records, questionnaires/interviews/assessments, pre-existing clinical images, HIPE data). For those who lack capacity, proxy assent will be obtained. Note: the consent declaration will not cover (i) processing of personal data with regards the biobank element of this study, (ii) processing of personal data of family as Applicant confirms personal data is not processed on family and (iii) use of video recordings.
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 Secretariat provided an overview of the study and the scope of the consent declaration requested. It was highlighted that the consent declaration, if made, will not cover (i) the processing of personal data with regards the biobank element of this study, (ii) processing of personal data of family as the Applicant confirms personal data is not processed on family and (iii) use of video recordings. The Secretariat also highlighted that the clinical data for this study is obtained from the medical records held at the 5 named hospital sites noted in the HRCDC application and that the data would be extracted by the study's Research Fellow. It was also noted that a multifaceted approach is used to recruit participants; this approach includes referral to the research team from the 5 named hospitals, other healthcare providers such as GPs and self-referral.

	The Deputy 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 consent declaration with attached conditions should be made. **Public interest case** • The HRCDC discussed the study activities, and its aims and objectives. It was noted why participants may lack decision-making capacity and that this cohort would not be included in the biobank and video recordings. It was commented that the data processing of those who lack capacity was relatively low risk and that the study is examining an important condition. • On balance and based on the information provided, it was the view of the HRCDC that there is a strong public interest case in this research. **Consent/assent forms and Study Information Leaflets** • The HRCDC noted the use of the terms *'next-of-kin'* and '*legal representative'* in the study documents. It was commented that the term 'participant representative' should be used when referring to the proxy individual in the assent/consent documentation. • It was noted that the information leaflet for the proxy refers to seeking consent from the proxy, in some places. It was commented that this error should be highlighted to the Applicant and addressed at the next ethics amendment. In the interim it should be verbally clarified that the proxy is being requested for their assent on behalf of the participant, not their consent. • It was commented that the phrase '*Your/your family member's doctor will not be upset if you decide not to take part and it will not affect the any aspect of your medical care'* should be revised; the term 'upset' should be avoided. **Data Sources** • In addition to accessing and obtaining data from the hospital records, the HRCDC queried the data to be processed from the CSO and HIPE. • It was discussed that the CSO data is census statistics and not personal data. The HIPE data to be used is personal data and would require data agreements to be in place. It was highlighted that the HIPE data is used to determine case ascertainment; personal data from HIPE is not used in wider study analysis. **Study referral** • The HRCDC noted the process for study referral and recruitment. It was queried how GPs will be informed about the study to refer their patients and what permission will be sought from the participant/proxy before making a referral to the research team. • It was highlighted that the study has developed materials to inform GPs and healthcare providers about this study and that other methods will be used. It was also noted that the Applicant had confirmed that permission is sought from the

	participant/proxy before their clinician refers them to the research team, who will then make contact and undertake the assent/consent process. The HRCDC commented that clinicians making referrals should record permission from the proxy/particiapnt before referring them to the research team and sharing their data for this purpose. • The HRCDC also noted differences in who would be referred to this study. Some information outlines that potentially eligible patients will be those with a diagnosis of these conditions, while other information, including the correspondence to GPs, refer to potential or suspected cases. **Data minimisation** • The HRCDC commented that data minimisation is an important principle that should be adhered to. The HRCDC queried if the data could be further minimised, for example whether date of birth and age are both needed. **Other:** • It was noted that the DPIA referred to digitised pseudonymised data being retained indefinitely, which is not in line with the duration outlined to the HRCDC and accordingly the duration of the consent declaration. • The HRCDC queried the extent to which the feedback provided from the DPOs have been considered and implemented. In this context, it was noted that comments were made by the DPO to ensure that information is presented to the proxy/participant in an accessible form. It was commented that the Applicant could be signposted to useful resources on this. • The HRCDC also requests that the number of participants recruited who lack decision-making capacity should be reported on in the Annual review and that the study should ensure the participants are not covered by a decision-support structure/agreement as provided for in the Assisted Decision-Making Act. • The HRCDC also noted the technical and more standard safeguards that need to be considered, including seeking permission to continue to process data after an individual withdraws, being clear on the scope of the declaration, ensuring the required data agreements/arrangements are in place, further clarity in the information leaflet on where data is obtained from, seeking consent to obtain data form medical records only and the role of the research team in this study.
HRCDC Decision:	The consensus of the HRCDC was that a Consent Declaration should be made, subject to conditions attached.
Duration of Declaration:	The consent declaration is made on 12th December 2023 and is valid until 31st January 2031, or until the personal data is deleted or fully anonymised, whichever occurs first.
Conditions Attached:	**Condition 1:** The required data agreements and arrangements must be in place prior to the transfer of personal data. This includes

	agreements with and between the 5 hospital sites, joint controller arrangements, as well as agreements with HIPE. **Condition 2:** before referring potential participants to the study, clinicians who are making referrals should record permission from the proxy/participant to refer them to the research team and to share their data for this referral. **Condition 3:** The following statement was provided to the HRCDC '*If participants do not wish to complete an interview, but wish to participate in the study, they can consent to a review of their clinical notes'.* Where this occurs then clear assent/consent for the review of clinical notes only, should be obtained. **Condition 4.** As part of the Annual Review, the Applicant is requested to report on the number of participants recruited to this study who lack-decision making capacity. **Condition 5.** Where proxy assent/participant consent is withdrawn or is refused and the study wishes to continue to process the data already collected, then permission for this must be obtained and recorded from the proxy or participant, whichever is relevant.
HRCDC Recommendations:	**Recommendation 1:** With regards the study information leaflets and assent/consent forms, the Applicant is requested to consider the following: ○ the terms 'next-of-kin' and 'legal representative' should not be used in the documentation used to obtain proxy assent on behalf of a participant who lacks decision-making capacity. Instead, 'participant representative' should be used as it is considered more appropriate. ○ It should be clearly outlined where the clinical data is obtained from i.e., the medical records of the 5 named hospital sites. In addition, the references to obtaining scans and data from records '*held by other healthcare providers who have been involved in the participant's care'* that are not the 5 named sites should be amended as this won't occur. ○ It was noted that the information leaflet for the proxy refers to seeking 'consent' from the proxy, in some places. The term 'proxy assent', not 'consent', should be used when referring to seeking permission for data processing from a relative. ○ It was commented that the phrase '*Your/your family member's doctor will not be upset if you decide not to take part and it will not affect the any aspect of your medical care'* should be revised; the word 'upset' should be avoided. The points above should be addressed as soon as practicable or by the next ethics amendment. **Recommendation 2:** Data minimisation is an important principle that should be adhered to. In this context the study should ensure that only the minimum data is collected and processed for this study; for example, are date of birth and age both needed. **Recommendation 3:** It was noted that the DPIA refers to digitised pseudonymised data being retained indefinitely, which is not in line

	with the duration noted to the HRCDC and accordingly the duration of the consent declaration that has been made. The Applicant is requested to revisit the DPIA and amend this.

7. Proposal Chairperson approval for technical amendments

- The HRCDC were provided with a proposal document to consider. This document outlined a process whereby the Chairperson of the HRCDC could review and make decisions on low-risk, technical amendment requests and advise the Committee of approvals issued in this regard at the next meeting.
- It was noted that this process would be undertaken for low-risk, technical amendments only and that more material amendments would continue to be considered by the full Committee at their standard meetings. It was also highlighted that if the Chairperson is of the view that the nature of the amendment is such that it should not be approved by them alone, then it will be tabled at the next available HRCDC meetings. It was discussed that any amendments approved by the Chairperson will be noted at the next HRCDC meeting.
- Following a discussion, the HRCDC approved the proposal. It was commented that the process should also provide for approval of low-risk, technical amendments by a Deputy Chairperson if the Chairperson is not available.

8. Overview of 2023

The Secretariat gave a brief overview of the HRCDC's and Secretariat's work in 2023. It was discussed that this and additional information will form part of the HRCDC's Annual Report to the Minister.

9. Annual Reviews

The Secretariat has received 7 annual reviews in advance of the meeting which were deemed completed:

- **Ref ID:** 19-006-AF3; Michael Farrell, '*Contribution of Whole Genome Sequencing to Brain Tumour Biology'*
- **Ref ID:** 19-012-AF2; Prof Leonie Young, '*Breast Cancer Proteomics and Molecular Heterogeneity'*
- **Ref ID:** 20-005-AF1/COV; Prof Patrick Mallon, '*The All-Ireland Infectious Diseases Cohort Project (AIID Cohort)'*
- **Ref ID:** 19-015-AF2; Prof Mary McCarron, *'Intellectual Disability Supplement to The Irish Longitudinal Study on Ageing (IDS-TILDA)'*
- **Ref ID:** 21-007-AF1/COV; Prof Alistair Nichol, '*Irish National Pandemic Biological Sampling in critically ill – COVID-19 (INPBS-COVID 19)'.*
- **Ref ID:** 19-033-AF3; Prof Gerard Bury, '*The Medical Emergencies Responder - Integration and Training (MERIT) programme study (Cardiac Arrest and Pre-Hospital Thrombolysis in Irish General Practice)'*
- **Ref ID:** 22-012-AF1; Prof Frank Doyle, '*Targeted Review and Amalgamation of Unmapped Major Trauma and Ambulance Data in Ireland: TRAUMA Study'*

10. Activities report and events of interest.

The Secretariat circulated a report of its activities to the HRCDC in advance of the meeting. The Secretariat also provided an overview of some of the changes to the UK data protection legislation that is expected to occur in mid-2024.

11. Any Other Business.

The Deputy Chairperson thanked the HRCDC and Secretariat for their time and work in 2023 and looks forward to working with them in 2024.

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