HRCDC
Health Research Consent Declaration Committee

Date: 28th February 2023
Location: Zoom videoconferencing

Minutes of the Meeting

HRCDC Attendance

Name
Brigid McManus
Evelyn Mahon
Alyson Bailey
Kathy Brickell
Sheelah Connolly
Aideen Hartney
Zubair Kabir
Dan Rea
Cornelius Cooney
Jonny Barrett (Secretariat)
Caroline Byrne (Secretariat)

Quorum for Decisions
☒YES
☐NO

New Amendments - For Consideration

Applicant	Ref No.	Title
Mary McCarron	19-015-AF2/AMD2	IDS-TILDA (WAVE 5)
Ignacio Martin-Loeches	20-035-AF1/AMD2	A retrospective observational chart review study to evaluate the clinical effectiveness of treatment with zanamivir 10mg/ml solution for infusion in a cohort of intensive care unit treated (ICU) patients with complicated influenza infection (IV Zanamivir Effectiveness Study)
Gianpiero Cavalleri	22-006-AF1/AMD1	A description of the evolution of phenotype in epilepsy from paediatrics through adulthood and old age (HPO Study)

New Applications – For consideration

Applicant	Ref No.	Title
Michael Kerin	19-075 AF2	University of Galway-Saolta Cancer Biobank
Janice Walshe	23-001-AF1	EUROPA T-DXd - EUropean Real-world experience Of Previously treated advanced/metastatic HER2-positive breast cancer patients Accessing trastuzumab deruxtecan through a named patient program

Meeting Items

1. **Opening**
   The Chair opened the meeting and welcomed the members.

2. Apologies
Barry Lyons, Claire Collins, John Woods, Simon Furney, Barry O' Sullivan, Mary Tumelty

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

4. Minutes of the last meeting
Draft minutes of 25th January 2023 were circulated in advance of the meeting and were approved by the HRCDC.

5. Amendments:

Reference ID:	19-015-AF2/AMD2
Lead Applicant:	Mary McCarron
Lead Data Controller:	Trinity College Dublin
Title:	IDS-TILDA (WAVE 5)
Research Objective:	Please see HRCDC meeting minutes of 17th October 2019
Purpose of Amendment:	IDS-TILDA is seeking an amendment to cover the data processing of those who lack decision-making capacity to (i) include a 5th wave of the study, (ii) extend the duration of the consent declaration previously made to 31st December 2029 and (iii) include the provision of anonymised data from IDS-TILDA in a public archive – the IDDSS. The consent declaration currently in place covers IDS-TILDA up to Wave 4 only. The purpose of Wave 5 is to continue the steady-state longitudinal data collection of IDS-TILDA, to examine the principal influences on successful ageing, to determine if they are the same or different from the influences on ageing in the general population, to compare results with previous waves of IDS-TILDA, and to inform future national policies, programmes and services.
HRCDC Comments:	The Secretariat introduced the amendment. It was noted that Wave 5 and data processing for Wave 5 had already commenced, The Chairperson requested the HRCDC to indicate whether the amendment to the 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 the amendment should be approved. **Public Interest case** • The HRCDC discussed and was of the view that there was a strong public interest case in this amendment. **Scope of the amendment** • It was discussed that Wave 5 of the study had already commenced; however, an amendment request form had not been submitted prior to data processing for Wave 5. • The HRCDC commented that the scope of the amendment and consent declaration should be made clear to the Applicant, including that future amendments would need to be submitted for consideration for any future waves or other relevant study

	changes. It was also discussed that this amendment only comes into effect on the date of the HRCDC's meeting and it should be emphasised to the Applicant that amendments should be submitted prior to study changes commencing. **Data Security** • It was noted that paper copies of the caseload sheets that are sent to the fieldworkers are to be shredded when no longer required. It was commented that a process should be in place to validate that the paper sheets have been shredded. • The HRCDC also discussed the security of the transfer of data using postal or courier services. While the reasons for sending data and paper sheets by post was noted, it was queried if alternative and more secure means for data and paper transfer between sites could be examined and implemented. For example, it was noted that some data for the study is collected via secure iPads. **Accessibility** • It was commented that the wording of some of the medical based questions to be asked in Wave 5 could be considered difficult for some participants to understand. It was discussed that the Applicant should consider if the question can be re-worded to improve accessibility. **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, that were similar to conditions made in previous consent declarations. These observations included that the data to be made available in the IDDSS archive is anonymised, to involve those participants with an intellectual disability in the decision-making process and study activities to be best extent possible and to ensure that data is withdrawn where possible should a participant request their data to be deleted.
HRCDC Decision:	The consensus of the HRCDC was that the conditional declaration could be amended.
Conditions Attached:	**Condition 1.** It must be ensured that the data made available in the IDDSS public archive is anonymised data. **Condition 2.** For those participants with an intellectual disability who lack or may have diminished decision-making capacity, the Applicant should ensure that the participant is involved in the decision-making process and study activities to the extent that is possible, including providing the participant with the necessary support to help them engage in the study. **Condition 3.** Where a participant or their proxy wishes to withdraw from the study and have the personal data deleted (i.e., not just removing the participant's identifiers), then the data should be deleted by the data controller where this is possible to do so, taking into account any GDPR derogations that may apply.

HRCDC Recommendations:	**Recommendation 1.** The HRCDC recommends the Applicant to examine the security of the personal data, including the methods of data transfer. In particular the Applicant is requested to review and consider the security of (i) the transfer of paper/hard copy data and paper forms via post/courier and (ii) where paper caseload forms are sent to the fieldworkers, to ensure that a process is in place to verify that they have been shredded when they are no longer required. **Recommendation 2**. The Applicant is requested to review the wording of the medical questions in the questionnaire to ensure that they are accessible and easy-to-understand for participants with an intellectual disability. The HRCDC considers that the wording of some of the medical questions may be technical in nature and difficult to follow for some participants for example questions on using different forms of COVID-19 tests.

Reference ID:	20-035-AF1/AMD2
Lead Applicant:	Ignacio Martin-Loeches
Lead Data Controller:	GlaxoSmithKline Research & Development Ltd
Title:	A retrospective observational chart review study to evaluate the clinical effectiveness of treatment with zanamivir 10mg/ml solution for infusion in a cohort of intensive care unit treated (ICU) patients with complicated influenza infection (IV Zanamivir Effectiveness Study)
Research Objective:	Please see HRCDC meeting minutes of 26th January 2021 and 13th April 2021
Purpose of Amendment:	The amendment is requested to extend the study to another flu season i.e., 2022/2023 season and to reflect a change in the ratio of controls to cases from 1:1 to 2:1. An amendment to the declaration was previously granted to extend the study to include 2021/2022 flu season.
HRCDC Comments:	The Secretariat introduced the amendment. The Chairperson noted that the amendment was technical in nature and requested the HRCDC to indicate whether the amendment to the consent declaration should be made. It was noted that the amendment was similar to the previous amendment made to the declaration. The HRCDC queried why the ratio of cases to controls was changing; it was commented that this increases the statistical power of the study findings. After discussing the amendment request and based on the information provided by the Applicant, it was the consensus of the HRCDC that the amendment should be approved. It was further commented that the conditions previously attached to the consent declaration will continue to apply.
HRCDC Decision:	The consensus of the HRCDC was that the conditional declaration could be amended.

Reference ID:	22-006-AF1/AMD1
Lead Applicant:	Gianpiero Cavalleri

Lead Data Controller:	*Original:* Royal College of Surgeons in Ireland *New Joint Controllers*: Beaumont Hospital and St James's Hospital
Title:	A description of the evolution of phenotype in epilepsy from paediatrics through adulthood and old age (HPO Study)
Research Objective:	Please see HRCDC meeting minutes of 14th June 2022
Purpose of Amendment:	The scope of the amendment requested is (i) to extend the duration of the consent declaration by 9 months and (ii) for a change in controllership of the study to include Beaumont Hospital and St James's Hospital as joint controllers with RCSI.
HRCDC Comments:	The Secretariat introduced the amendment. It was noted that the declaration made had recently expired, however the Applicant had confirmed that the study had not yet commenced and personal data had not been processed. The Chairperson noted that the amendment was relatively technical in nature and requested the HRCDC to indicate whether the amendment to the 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 the amendment should be approved. It was commented that the change in data controllership will not be in effect until confirmation is provided by the Applicant that the necessary research ethics committee approval is in place for this. It was also noted that the Applicant must ensure that a joint data controller arrangement is in place between RCSI, Beaumont Hospital and St James's Hospital. Further, the HRCDC discussed that the conditions previously attached to the consent declaration will continue to apply and must be progress and met, including Condition 1 on enhanced transparency measures.
HRCDC Decision:	The consensus of the HRCDC was that the conditional declaration could be amended.
Conditions Attached:	**Condition 1.** The amendment does not cover the change in the data controllership of the study until confirmation is provided that the requisite research ethics committee approval covers this. Confirmation of this approval should be provided to the HRCDC within 2 months. **Condition 2**. Appropriate joint data controller arrangements should be in place between RCSI, St James's Hospital and Beaumont Hospital with regards this study. Data processing should not commence prior to the necessary agreements/arrangements being in place.

6. New Applications

Reference ID:	19-075 AF2
Lead Applicant:	Michael Kerin
Data Controllers:	University of Galway Galway University Hospital/Saolta
Title:	University of Galway-Saolta Cancer Biobank
Research Objective:	The Cancer Biobank was established in the 1990s as a resource for breast cancer research – it began as a breast cancer genetics

	research project (a case control association study). It has since expanded to address other common cancers - colorectal, prostate, lung and thyroid. The Cancer Biobank is a store of biospecimens (including tissue, blood, paraffin embedded blocks, saliva) and specimen associated data from consenting participants. Specimens and data are stored until they are retrieved for ethically approved research studies. Participant data is pseudonymised, i.e., participants are not identifiable to researchers. Each year in Ireland over 24,000 people are diagnosed with invasive cancer and over 9,000 people die from cancer. The incidence of cancer is estimated to double by 2040. Researchers need to access and study patient data and clinical specimens, to understand how cancer develops and progresses. The Cancer Biobank aims to provide access to high quality specimens and associated data to identify new biomarkers for cancer diagnosis and treatment.
Reason for Declaration:	While consent was obtained from the participants, the Applicant has determined that a consent declaration is required for the cohort of participants who were consented/recruited using early versions of the consent documents as they are deemed not to fall under the Health Research Regulation amendment on consent under the previous Data Protection Directive. A consent declaration is requested to cover the personal data of participants who were recruited to the biobank between 1998-2008 while versions 1-2 of the study documentation were in use; specifically, this includes the breast cancer patient cohort, the smaller colorectal cancer patient cohort and the accompanying control cohort. The scope of the declaration, if made, would be limited to the storage only of the personal data in the biobank of these participant cohorts; it does not cover any other data processing activities.
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 HRCDC were reminded that the 'AF2' applications sought a declaration for studies that commenced prior to the Health Research Regulations. AF2 Applicants considered that consent obtained was compliant with the previous data protection legislation. However, further to the 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 studies as if no consent was obtained and balance the public interest case for the study. The Secretariat introduced the application and the scope of the consent declaration that would be limited to the storage of the personal data only; an amendment request form or new HRCDC application would need to be submitted for consideration if the

	personal data was to be further processed, including the collection of follow-up data or processing data for future specific research studies. The 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 conditional declaration should be made. **Public interest case** • The HRCDC discussed the application, the scope of the consent declaration and purpose of the biobank. On balance, the HRCDC was of the view that there was a strong public interest case in making a consent declaration to enable the storage of the personal data of the 1998-2008 participant cohorts. **Re-consent** • The Applicant's response in the HRCDC application form outlined why it would not be possible to obtain re-consent of the participants recruited to the biobank between 1998-2008, including the number of participants involved. However, it was highlighted that subsequent responses from the Applicant stated that they intend to review the cohorts to establish how many participants have already been re-consented or who may be deceased, and to identify any participants who still attend Saolta and therefore who could potentially be re-consented. • The HRCDC was of the view that efforts should be made to re-consent the breast cancer participants who have been enrolled in the biobank, where this is practicable. • The HRCDC also noted and discussed the reference to a small number of living colorectal cancer patients from pre-2008 whose bio-samples and personal data are included in the biobank. It was queried what study documentation was used to recruit these participants as it was noted that versions 1-2 of the biobank information leaflets referred only to breast cancer. • Based on the information provided by the Applicant, the Secretariat highlighted that this colorectal cancer patient cohort was recruited between 1998-2008 when versions 1-2 of the consent forms were in use and that the Applicant is aiming to review and identify the documentation used to recruit these colorectal patients, however they request that the declaration also covers this small cohort. • The HRCDC was of the view that the declaration can cover the ongoing storage only of the small cohort of colorectal patients; however given the small number of these patients it was considered that it would be reasonable and practicable to obtain their re-consent. Accordingly, the HRCDC determined that the Applicant should make direct attempts to obtain the explicit consent of this small cohort of colorectal patients. **Duration of Declaration** • The HRCDC noted that the Applicant was seeking an indefinite declaration for the biobank. As policy and legalisation on the area of biobanking may evolve, the HRCDC was of the view that it

would be more appropriate to make a consent declaration of 10-years, which the Applicant could request to extend by way of an amendment request submission.

Biobank withdrawal and transparency measures

- It was commented that the documentation outlines different information regarding withdrawing from the biobank. For example, the DPIA notes that the participant's right to erasure can be exercised if data processing is being undertaken in an unlawful manner, however the response in the HRCDC application form and accompanying additional queries, notes that the participant can withdraw and are provided with the options. including an option where the donated samples and accompanying data are no longer to be used and are to be deleted.
- The HRCDC discussed that the biobank must be clear and consistent on what will happen if a participant wishes to withdraw from the biobank and have their data and bio-samples deleted, and that a clear process for withdrawal and deletion of personal data must be in place, including having a direct point of contact to whom participants can request to exercise their rights. It was commented that a consent declaration does not override the decision of a participant to withdraw from the biobank.
- It was also discussed that the biobank should enhance the level of transparency to inform participants about the biobank, the storage and processing of personal data and associated samples and their data protection rights, including the right to withdraw. It was commented that transparency measures should be enhanced via the biobank's webpage and other platforms and that the information videos referenced by the Applicant should be disseminated to relevant cancer advocacy groups and other third-party websites.

PPI engagement

- The HRCDC commented that the public and patient involvement activities referenced by the Applicant was a generic patient survey on biobanking and not necessarily specific to this biobank. The HRCDC was therefore of the view that the Applicant should undertake PPI engagement with regards this specific biobank, which should consider engagement with relevant biobank and/or cancer groups. It was also commented that PPI engagement would be important if the data held by the biobank is to be further processed.

Information leaflets

- It was commented that the biobank is storing quite extensive data on participants and therefore it should be ensured that the study information leaflets used to recruit participants clearly outline the type and amount of data that will be held by the biobank. In this regard it was discussed that references to storing and processing *'limited data'* should be removed from the study information leaflets.

	Other • It was noted that Applicant refers to using both paper/hard copy and digital copies of study documentation. It was queried whether both were needed by the biobank. • 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 being clear on what and who the scope of the consent declaration covers, ensuring that the required data agreements and arrangements are in place and providing missing signatures and updating the biobank's data protection impact assessment (DPIA).
HRCDC Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made.
Duration of Declaration:	The Declaration is made commencing 28th February 2023 and shall be valid for 10 years until 28th February 2033 or until the personal data has been destroyed or irrevocably anonymised, whichever occurs sooner. Prior to its expiration, the Applicant can request an extension of this declaration by way of submitting a HRCDC amendment request form for consideration.
Conditions Attached:	**Condition 1.** As outlined in the responses to the HRCDC, the Applicant should review the cohort of breast cancer patients recruited to the biobank using versions 1-2 of the study documentation, to identify any participants who may still be attending Saolta and accordingly to make efforts to obtain their reconsent should they attend the hospital, where this is practicable. The Applicant is required to report on the progress made to meet this condition in the Annual Review, including the progress on the review of this patient cohort and the number of patients who have been re-consented. **Condition 2.** The Applicant is requested to make direct attempts to obtain the re-consent of the small cohort of colorectal cancer participants who were recruited to the biobank between 1998-2008, when versions 1-2 of the consent documentation were in use. The Applicant is requested to make direct attempts to reconsent each of the living colorectal cancer patients in this cohort (n=39), regardless of whether these patients are or will be attending Saolta hospital. The Applicant is required to report on the progress made to meet this condition as part of the Annual Review, including the number of this colorectal cancer patient cohort who are reconsented. **Note:** On Condition 1 and Condition 2, should a participant actively respond that they do not wish to provide their re-consent and/or decide to withdraw from the biobank, the consent declaration does not cover the continued processing of their personal data. Where attempts are made to request a patient's reconsent, but no response is provided, then the declaration will cover the continued storage of that patient's data in the biobank.

	Condition 3. It is a condition of this declaration that the biobank's transparency measures are enhanced to better inform participants already included in the biobank, and the wider public, about the biobank, the processing of the personal data and associated bio-samples by the biobank and how participants can exercise their data protection rights, and any derogations or limits to their rights. Transparency should be enhanced by way of the biobank's own website/webpage, social media and, where possible and appropriate, by other external platforms including relevant third-party websites and cancer advocacy groups. Further, the biobank information videos referenced by the Applicant should be disseminated to relevant cancer patient advocacy groups and other third parties. **Condition 4.** Further to Condition 3, the information provided to participants on exercising their data protection rights, including withdrawing from the biobank and what will happen their personal data and associated samples in such a scenario must be clear and consistent. Further the biobank must also have in place a clear process for participant withdrawal and the deletion/destruction of personal data and the associated bio-samples if this is requested by the participant; this includes having in place a direct point of contact to whom participants can request to exercise their rights. **Condition 5**. Appropriate joint data controller agreement/arrangements must be in place between the joint data controllers of the biobank. The Applicant is requested to ensure that such agreements are in place as soon as practicable and within 2-months of receipt of this consent declaration. **Condition 6.** The signature on the HRCDC application form and DPO feedback on the DPIA on behalf of the University of Galway has been provided; however, the signature and DPO feedback of the other joint data controller remains outstanding and must be submitted as soon as practicable and within 2-months of receipt of this consent declaration. Further the DPIA must be reviewed and updated where necessary, including updated to note the University of Galway as a joint data controller and not a data processor.
HRCDC Recommendations:	**Recommendation 1.** The Applicant is recommended to undertake PPI engagement with regards this biobank specifically, including engagement with relevant biobank and or cancer patient groups. **Recommendation 2.** The Applicant is requested to ensure that the information leaflets in use by the biobank clearly outlined the type and extent of data that will be held by the biobank and used for research. Therefore, references to storing and processing *'limited data'* and other similar terms should be amended. **Recommendation 3.** Reference is made to the biobank using and holding both hard and digital copies of the study documentation. The Applicant is requested to consider whether both hard and digital copies are required, or whether only one version is necessary.

Reference ID:	23-001-AF1
Lead Applicant:	Janice Walshe
Data Controllers:	Daiichi Sankyo Inc (US Sponsor) Daiichi Sankyo Europe GmbH (Sponsor's EU affiliate)
Title:	EUROPA T-DXd - EUropean Real-world experience Of Previously treated advanced/metastatic HER2-positive breast cancer patients Accessing trastuzumab deruxtecan through a named patient program
Research Objective:	EUROPA is an observational real-world data collection (RWDC) project related with trastuzumab deruxtecan (T-DXd) for advanced metastatic breast cancer. Patients were treated with T-DXd within a Named Patient Programme (NPP), which will be the basis for the RWDC project. The RWDC project is to be carried out in Ireland, as well as Spain and Italy, to evaluate T-DXd's treatment outcomes from evidence sourced in an observational, real-world clinical setting. Such early insights, along with other relevant evidence, may assist the Sponsor in informing appropriate treatment protocols for the benefit of future patients.
Reason for Declaration:	This study involves both retrospective patients and those who are currently being treated with T-DWd as part of the Named Patient Programme (NPP), which is the basis for this real-world data collection study. The study will seek the explicit consent of eligible patients for EUROPA; however, a consent declaration is required for patients whom the study is unable to contact and who are therefore considered to be lost to follow-up. The data processing activities includes collection, transfer, analysis, storage of personal data taken from patient's medical records held at site that were completed within the NPP. Anonymised data will also be shared with a third party, AstraZeneca who is a collaborator on the development of T-DXd.
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 introduced the study; it was noted who were the joint data controllers and that the Applicant had clarified that the study does not involve processing the personal data of participants who lack-decision making capacity to provide explicit consent. The 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 conditional declaration should be made. **Public interest case** • The HRCDC discussed the purpose of the study and was of the view that there is a public interest case as the research seeks to

	analyse real-world data from patients' whom it is known have been treated with T-DXd. It was commented that real-world data collection studies have increased in importance in recent years. **Consenting participants.** • It was discussed that the declaration is only requested for those who are considered lost to follow-up i.e., those whom the study is unable to contact. The HRCDC noted that the Applicant will seek to contact each participant to obtain their consent at least 3 times over a period of 8 weeks, after which, if there is no response, the participant would be considered lost to follow-up. • The HRCDC welcomed this process, however it commented that may be beneficial to extend this process beyond 8 weeks to provide participants with a greater opportunity to respond. It was also discussed that where a participant responds after the contact timeframe has concluded, it remains that the study must still consider and respect their wishes, including if they reply to confirm that they do not consent to be included in this study. Similarly, if the participant who is lost to follow-up is later back in contact with the hospital site for other reasons, then their consent for the study should be sought. • The HRCDC also noted that the process for contacting potential participants would be left to each individual site. The HRCDC was of the view that it is important that each site in Ireland follows the same standard, consistent process for contacting potential participants and that they employ the same communication materials for this process, such as study letters. In addition, it was discussed that the study information leaflet and consent form should be sent to the potential participants as part of this contact process. **Data Controllership and declaration compliance** • It was noted that the sponsor and one of the joint data controllers was based in the United States. It was discussed that a consent declaration can be made to a non-Irish data controller. It was further highlighted that one of the joint controllers of the study is based in the European Union and that it has been confirmed that the Irish hospital sites will, alongside the data controllers, be responsible for implementation of and compliance with the consent declaration. It was discussed that this safeguard has been attached to previous consent declarations. • It was also discussed that anonymised data only will be shared with another third-party, AstraZeneca, as part of the study. It was highlighted that the Applicant confirmed that AstraZeneca is not a data controller or data processor in this study and that the data to be shared with them will be anonymised. **Transparency and PPI engagement** • The HRCDC discussed that transparency measures should be enhanced including by providing study information on the hospital's websites and other relevant platforms. • It was commented that the study information leaflets were considered relatively long and could be shortened and simplified.

	The HRCDC noted that the study information leaflet is based on a standard template designed by these Irish sites and discussed the challenges faced by researchers to provide participants with sufficient but balanced and understandable information on the study, data processing and their data protection rights when obtaining explicit consent. It was the view of the HRCDC that it should be recommended to the Applicant to review the study documentation and to simplify it where possible. • It was also commented that the level of public and patient engagement within this study was poor; however, given that the study is effectively a retrospective chart review, it was acknowledged that the opportunities for PPI activities may be limited. Nonetheless, the HRCDC discussed that PPI would be important and therefore the Applicant should undertake PPI engagement for the benefit of the study, including for example engaging with PPI representatives, such as cancer patient group to discuss their views of the study and examine the readability of the study information leaflets. **Other** • It was commented that the information on what would happen the personal data if a participant withdrew was not fully clear in the study information leaflets. The Applicant's reply to the HRCDC noted that if a participant withdraws then no new data would be collected and that they have the right to request the deletion of their data, if the data is no longer required. It was discussed that a consent declaration does not override the wish of a participant to withdraw from the study and have their data deleted and that a participants wish to exercise their data protection should fully align with Irish legislation; where a participant requests that their data is deleted then this should occur, taking into consideration any derogations that may apply. • The HRCDC discussed that the required data agreements and arrangements must be in place for this study, including joint controller arrangements and agreements covering the transfer of data outside of the EEA. • It was commented that access to identifiable data for the purpose of study audits should be done on site only and not remotely. • The HRCDC noted that an amendment request form would be required if additional sites in Ireland are to be added to this study. • The information outlined in the data protection impact assessment (DPIA) noted why a DPIA was being undertaken. It was commented that a DPIA is required when conducting health research in Ireland. • 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 emphasising the scope of the declaration, ensuring there is a point of contact in Ireland for participants, providing clear information to participants on what will happen their personal data if they do not reply to the

	contact process, the completion of data protection training, changes and amendments to the study information leaflets and submitting missing signatures.
HRCDC Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made.
Duration of Declaration:	The Declaration is made commencing 28th February 2023 and shall be valid for 10 years until 30th April 2033 or until the personal data has been destroyed or irrevocably anonymised, whichever occurs sooner.
Conditions Attached:	**Condition 1.** The Applicant is requested to extend the proposed 8-week timeframe of the contact process to provide potential participants with more time to respond. In addition, the following should also be undertaken: **(i)** A standard and consistent process across the Irish sites must be designed and implemented with regards contacting potential participants; accordingly standard materials must also be employed as part of this process and used by the Irish sites (e.g., a standard contact letter or other correspondence should be used). As part of this contact process, the Irish sites must also inform the potential participant about what will happen if they do not reply i.e., the individual must be informed that they will be considered lost to follow up and will be included in the study and have their personal data processed. The potential participants must also be informed about their data protection rights, any limitations to those rights, how to exercise their rights and be provided with a clear point of contact for the study in Ireland. Participants should also be informed if there is a point in the study where their data cannot be deleted**.** (ii) When contacting participants, the study information leaflet and consent form must also be sent. **Condition 2.** Further to Condition 1, should a participant respond to the contact process after the extended timeframe has concluded (i.e., they have already been deemed lost to follow-up), it remains that the study must still consider and respect the participant's wishes, including if they reply that they do not consent to be included in this study and to have their personal data processed. If a scenario arises where the participant who was deemed lost to follow-up is later in contact with the hospital site for other reasons, then the Applicant should seek to obtain their consent for this study if the opportunity arises. **Condition 3.** The Irish hospital sites must, alongside the joint data controllers, be responsible for implementation of and compliance with the consent declaration and data protection requirements; there should also be a point of contact in Ireland if the participant has queries or otherwise wishes to exercise their rights. **Condition 4.** The Applicant must ensure that the required data agreements and arrangements are in place for this study, including data transfer agreements, joint controller arrangements and

	necessary agreements covering the transfer and processing of data outside the EEA. **Condition 5**. It is a condition of this declaration that the data to be transferred to AstraZeneca is anonymised data only. **Condition 6.** The Applicant is requested to enhance the transparency measures to be implemented in this study, beyond the provision of study information leaflets. The Applicant is requested to enhance transparency via the websites of the Irish hospital sites and other appropriate platforms that may be available. The information provided on the websites should outline the purpose of the study, the processing of personal data and the data protection rights of participants, including any limitations to those rights and how to exercise those rights. Consideration should also be given to enhancing transparency methods by way of dissemination of study findings. **Condition 7.** Only on-site access to identifiable data for the purpose of study audits must be undertaken; remote audits and access to identifiable data should not occur. **Condition 8.** Data protection training must be completed by all personnel involved in this study. **Condition 9.** The study information leaflets, and consent forms should be reviewed and amended as follows to ensure clarity and consistency of information for potential participants: (i) The joint controllership of this research study must be clearly noted i.e., the US Sponsor and it's European Affiliate must be named as joint data controllers of the study, (ii) It must be outlined that anonymised data will be transferred/shared with AstraZeneca as part of this study, (iii) The time period of the data covered by this study must be clear, (iv) It must be outlined what will happen the personal data if a participant wishes to withdraw from the study (i.e., no further data will be collected) and to clearly note their rights with regards the erasure/deletion of data if the participant wishes to exercise their rights. Any derogations to the participant's right to withdraw and to have their data deleted should also be outlined, as should any point in the study where it may not be possible to delete their personal data if requested. (v) The signature of section for the legal representative should be removed as participants who lack decision-making capacity are not included in this study. **Condition 10.** Please submit a signature on the HRCDC application form from the Irish Principal Investigator, Prof Janice Walshe, as soon as practicable and within 2 months for receipt of this consent declaration.
HRCDC Recommendations:	**Recommendation 1.** The Applicant is recommended to review the study information leaflets and where possible make simpler and shorten the document for the benefit of participants.

	Recommendation 2. The Applicant is recommended to undertake engagement with public and patient (PPI) representatives about this study, for example engagement with cancer patient groups. Matters of discussion with PPI representatives should include informing representatives about the study, seeking their views on the study as well as engaging with representatives on the language, length and readability of the study information leaflets. PPI engagement should also examine how to enhance other transparency measures such as via the hospitals or other websites and platforms.

7. HRCDC Annual Activities Report 2022

In advance of the meeting the HRCDC were provided with a copy of the draft HRCDC Annual Activities Report for 2022. The HRCDC discussed and provided some feedback on the draft report and the Chairperson requested members to forward any additional comments or feedback to the Secretariat. The Secretariat informed the HRCDC that the report will be proofread and designed prior to submission to the Minister for Health. The final proposed draft and version of the report will be tabled at the next HRCDC meeting. The Chairperson thanked the Secretariat for the work in producing this report.

8. Annual Reviews

The Secretariat has received 5 annual reviews in advance of the meeting which were deemed satisfactory:

- **Ref ID: 19-002-AF1;** Neil Crowhurst - A retrospective case analysis of serious untoward incidents in super catchment mental health services in the HSE South East.
- **Ref ID: 19-015-AF2;** Mary McCarron - IDS-TILDA
- **Ref ID: 19-084-AF1**; Karn Cliffe - 1 Year post-sepsis study
- **Ref ID: 20-003-AF1;** Ger Curley - Blood Brain Barrier (BBB) Disruption And Dynamic Contrast Enhanced Magnetic Resonance Imaging (DCE-MRI) Changes In Severe Traumatic Brain Injury (TBI)
- **Ref ID: 21-005-AF1**; Akke Vellinga - CARA Study

The Secretariat highlighted that a consent declaration was no longer required for applications 19-002-AF1, 19-084-AF1 and 20-003-AF1. Updates were also provided on the status and progress made to meet some of the conditions attached to 20-003-AF1.

9. Activities report and events of interest.

The HRCDC were informed that a recording of the HSE's launch of the National Consent Policy for Health and Social Care Research would be circulated after the meeting.

10. Any Other Business

- The Secretariat provided an update to the HRCDC on 20-001-AF1/AMD1 ('A retrospective analysis of the Irish national Acute Coronary Syndrome (ACS) programme database'), whose amendment request was not approved by the Secretariat. The Applicant informed the Secretariat that they are no longer processing personal data.

- The HRCDC were reminded that the next HRCDC is scheduled for Wednesday 29th March 2023.

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