HRCDC
Health Research Consent Declaration Committee

Time: **10:30am - 5:00pm**
Date: **25th November 2019**
Location: **Health Research Board**

Minutes of the Meeting

HRCDC Attendance

Name
Brigid McManus
Alyson Bailey
Kevin Clarke
Sheelah Connolly
Aideen Hartney
Barry O Sullivan
Dan Rea
Zubair Kabir
Emily Vereker (Secretariat)
Jonny Barrett (Secretariat)

Quorum for Decisions

☒**YES**

Live Declarations:

Applicant	Ref No.	Title
David Williams	19-001-AF3	Irish National Adverse Events Study (INAES-2)
Maeve Rooney	19-013-AF2	Omega 3 Study
Tom Fahey	19-017-AF2	Prescribing in primary care patients aged 70 years or older
Jochen Prehn / Deborah McNamara	19-031-AF2	Bowel Disease Bio-Resource Development
Natalie McEvoy	19-062-AF1	The relationship between Sub Epidermal Moisture (SEM) measurement and Inflammatory markers in the early identification of Pressure Ulcers
Karen Doyle	19-010-AF3	Acute Ischaemic Stroke Clot Pathology" Study

Returning Applications - Deferred until December 16th Meeting

Applicant	Ref No.	Title
Gianpiero Cavalleri	19-011-AF3	Irish Traveller Ancestry Study
Emer Fallon	19-038-AF1	The Genomic Basis of Alzheimer's disease in Ireland

New Applications considered at this meeting:

Applicant	Ref No.	Title
Paul Buitelaar	19-064-AF1	Discussion Forum use for Public Health Surveillance Study

Karn Cliffe	19-084-AF1	1 Year post-sepsis study
Leonie Young	19-012-AF2	Breast Cancer Proteomics and Molecular Heterogeneity
Rose Anne Kenny	19-022-AF2	TILDA
Rose Anne Kenny	19-043-AF3 (Directly related to 19-022-AF2)	The Irish Longitudinal Study on Ageing (TILDA) - General Register Office linkage

Meeting Items

1. Opening

The Chair opened the meeting and welcomed the members.

2. Apologies

Claire Collins, Kathy Brickell, Malcom Kell, Simon Furney, John Ferguson, Evelyn Mahon

3. Disclosure of Interest

19-022-AF2: Sheelah Connolly (SC) informed the HRCDC that she has previously accessed the TILDA database through the 'hot-desk' facility, as referenced in application 19-022-AF2. Zubair Kabir (ZK) also informed the HRCDC that his school uses TILDA data.
19-064-AF1: Barry O'Sullivan (BOS) informed the HRCDC of the connection between his institution and the Galway institution noted in the application form. BOS confirmed that he is not involved in the study described in 19-064-AF1.
The HRCDC discussed and determined that there was no conflict of interest to disclose and SC, ZK and BOS were not required to be absent for the relevant parts of the meeting.

4. Minutes of the last meeting

Draft minutes of the 17th October meeting were circulated in advance and were agreed by the HRCDC.

5. HRCDC Decisions: Conditions, Recommendations

The HRCDC discussed some of the learnings to date when making a declaration. Specifically, the HRCDC considered what should be a standard general condition attached for all declarations, as opposed to research study specific conditions, and where it might be appropriate to make recommendations and/or request information as a reporting obligation in the annual review.

It was discussed that a condition, whether general or study specific, should be set where it is of such significance that the HRCDC may decide to revoke a declaration or the declaration would become invalid if the condition is deemed not sufficiently met.

When attaching a specific condition to a declaration, consideration should also be given to the practicalities and reasonableness of implementing the condition on balance with the information that has already been provided by the Applicant in good faith; for instance, the Applicant may already be in the process of implementing a process or procedure that would fulfil a potential condition. The HRCDC discussed that some study specific conditions attached to previous declarations could be incorporated as a standard condition across all declarations.

It was noted that recommendations would normally relate to areas that are outside the specific remit of the HRCDC but would provide useful feedback that could further protect the data rights and freedom of study participants. Where further information is requested this could be done as part of the annual review that must be submitted

The HRCDC acknowledged the work the Secretariat in triaging the applications, in preparation for the HRCDC meetings. The HRCDC discussed how the Secretariat could further support the HRCDC. For example, it will be explored whether the Secretariat can clarify or identify possible technical and/or general conditions and recommendations in advance of the HRCDC meeting, to streamline meeting discussions.

In addition, the HRCDC discussed that it was important to ensure transparency in relation to the scope of a declaration, such as being clear as to what a declaration cannot cover. For example, a declaration made to a biobank cannot cover the open sharing of samples and data that is outside the scope of consent already obtained and that a declaration cannot be made to override a study participant's withdrawal of consent. Further transparency, including through the HRCDC website and decision letters, would serve a number of purposes including providing certainty for studies who have received a declaration, clarity for future Applicants and communicating elements of good practice.

In short, the HRCDC agreed that the setting of conditions, recommendations and reporting requirements as well as increased transparency will be explored further in early 2020, in the light of the experience to date. The Secretariat also noted that a review of the application forms and corresponding guidance notes will be carried out and feedback sought from stakeholders.

6. Live Declarations

Reference ID:	19-001-AF3
Lead Applicant:	David Williams
Lead Data Controller:	Royal College of Surgeons in Ireland
Title:	Irish National Adverse Events Study (INAES-2)
Application Summary:	See HRCDC Meeting minutes of 25th July 2019, 13th June 2019 & 29th April 2019.
Points to Discuss	The Applicant responded to the declaration made by the HRCDC; they confirmed that the data has been anonymised and therefore a declaration is no longer required. Reporting requirements still stand into 2020
HRCDC Comments/Decision:	The HRCDC acknowledged the Applicant's response and noted that that Declaration is now terminated as of 31st October, 2019. The Secretariat confirmed the Applicant's response had been acknowledged by email.

Reference ID:	19-013-AF2
Lead Applicant:	Maeve Rooney
Lead Data Controller:	University College Cork
Title:	Omega 3 Study
Application Summary:	See HRCDC Meeting minutes of 10th September 2019.
Points to Discuss	The Applicant responded to the HRCDC decision letter of 24th September 2019 confirming acceptance of the HRCDC's decision to give a conditional declaration.

HRCDC Comments:	The HRCDC acknowledged and accepted the Applicants' response and noted the conditions attached will be monitored as part of the annual review process.

Reference ID:	19-017-AF2
Lead Applicant:	Tom Fahey
Lead Data Controller:	Royal College of Surgeons in Ireland
Title:	Prescribing in primary care patients aged 70 years or older
Application Summary:	See HRCDC Meeting minutes of 17th October 2019
Points to Discuss	The Applicant responded to the HRCDC decision letter of 1st November 2019 confirming acceptance of the HRCDC's decision to give a conditional declaration.
HRCDC Comments:	The HRCDC acknowledged and accepted the Applicant's response and noted the conditions attached will be monitored as part of the annual review process.

Reference ID:	19-031-AF2
Lead Applicant:	Jochen Prehn / Deborah McNamara
Lead Data Controller:	Royal College of Surgeons in Ireland Beaumont Hospital
Title:	Bowel Disease Bio-Resource Development
Application Summary:	See HRCDC Meeting minutes of 17th October 2019
Points to Discuss	The Applicant responded to the HRCDC decision letter of 1st November 2019 confirming acceptance of the HRCDC's decision to give a conditional declaration. They also stated that they will follow up in due course with evidence of implementation and responses to the conditions attached.
HRCDC Comments:	The HRCDC acknowledged and accepted the Applicant's responses and noted the conditions will be monitored as part of the annual review process.

Reference ID:	19-062-AF1
Lead Applicant:	Natalie McEvoy
Lead Data Controller:	Royal College of Surgeons in Ireland Beaumont Hospital
Title:	The relationship between Sub Epidermal Moisture (SEM) measurement and Inflammatory markers in the early identification of Pressure Ulcers
Application Summary:	See HRCDC Meeting minutes of 17th October 2019, 10th September 2019 & 25th July 2019
Points to Discuss:	The Applicant responded to the HRCDC decision letter of 24th September 2019 confirming acceptance of the HRCDC's decision to give a conditional declaration. They also provided responses to the conditions set by the HRCDC.
HRCDC Comments:	The HRCDC acknowledged and accepted the Applicant's responses. It was further acknowledged that the conditions have been met. Where conditions were specific related to data protection rights, the HRCDC noted that compliance in this area is the responsibility of the data controller and that the Applicant's response is based on the Applicant's own legal advice.

Reference ID:	19-010-AF3
Lead Applicant:	Karen Doyle
Lead Data Controller:	National University of Ireland, Galway Beaumont Hospital
Title:	Acute Ischaemic Stroke Clot Pathology" Study
Application Summary:	See HRCDC Meeting minutes of 10th September 2019
Points to Discuss	The Applicant responded to the HRCDC decision letter of 24th September 2019 confirming acceptance of the HRCDC's decision to give a conditional declaration. They also provided responses to the conditions set by the HRCDC. In their responses the Applicant raised queries and requested further clarity on the implementation of some of the conditions.
HRCDC Comments:	The HRCDC acknowledged the Applicants responses to the Conditional Declaration Decision Letter. **Condition 1:** • The Applicant outlined the proposed consenting process and asked the HRCDC if they were satisfied with this. In addition, the Applicant stated that there may be specific circumstances where obtaining consent or next-of-kin assent is not possible and were concerned that this could result in the researchers being unable to collect valuable samples and data. Examples of such circumstances include where the participant does not regain capacity and there is not a contactable next-of-kin. • The HRCDC noted that it is up to the data controller and the relevant Research Ethics Committee (REC) to confirm if a process for obtaining consent for prospective participants is appropriate and ethical. Where the Applicant implements this process but there are instances where it is not possible to obtain consent or next-of-kin consent, then the scope of a declaration will cover the processing of samples and data in such cases. • The Applicant asked the HRCDC whether they could continue to collect prospective samples and data from participants while they are in the process of obtaining REC approval to implement a practice for obtaining participant consent (and/or relative/next-of-kin assent). They estimated this would take approximately 3 months. • The HRCDC discussed that it was not the intention or expectation that the Applicant would stop collecting samples and data immediately. The declaration will therefore cover the continued collection of samples and data up until the REC approved the consent process. **Condition 2:** • The Applicant stated that they will make best efforts to obtain retrospective consent but highlighted the challenges in doing so. The Applicant asked the HRCDC to confirm that they must contact each participant whose data and sample they hold, where possible, in order to obtain consent for this project. The HRCDC re-emphasised that the condition is to ensure best efforts are undertaken and it is up to the data controller to decide on the most appropriate method for

	obtaining consent for the use of retrospective samples and data; where it is possible and appropriate consent must be obtained from the participants and engagement with the follow-on hospitals is considered an important part of this process. Where it is not possible or where there are challenges in obtaining consent for retrospective samples and data, it must be explained in the annual review. **Condition 5** • It was highlighted to the HRCDC that the response from the Applicant which related to transparency measures, only referred to the collection of samples and data from prospective Participants. • The HRCDC discussed that transparency measures should also focus on retrospective study Participants, the follow-on hospitals. and that effective transparency measures are strongly linked to Condition 2.
HRCDC Decision:	Based on the Applicant's response it was determined that: • Condition 1 will be amended to confirm that the Applicant may continue to collect samples and data from participants until such time REC approval has been granted for the implementation of the consent process. It will also be confirmed that where it is not possible to obtain consent or next-of-kin assent then the scope of the declaration will cover the collection and use of prospective samples and data in such cases. These instances must be noted in the annual Review Furthermore, the following will be communicated to the Applicant: • The onus is on the data controller and the REC to determine the appropriate process for obtaining i) participant consent / next-of-kin assent for the collection and use of prospective studies and ii) consent from retrospective participants, • The HRCDC notes the challenges in trying to obtain retrospective consent, however Condition 2 is an important element of the HRCDC's decision and reasonable efforts to obtain consent from retrospective Participants must be made. • Where this is not possible to obtain retrospective consent, this must be justified in the annual review. • Transparency measures as outlined in Condition 5 are not limited to prospective sample and data collection and are considered important when satisfying the requirements outlined in Condition 2.

7. New Applications

Reference ID:	19-064-AF1
Lead Applicant:	Paul Buitelaar
Lead Data Controller:	National University of Ireland, Galway
Title:	Discussion Forum use for Public Health Surveillance Study
Application Summary:	Internet-based sources currently provide more than 60% of the epidemic reports. These informal health reports do not follow the same guidelines as formal reports making them more difficult to analyse using standard techniques. This research aims to develop a method ('supervised' and 'unsupervised') that can analyse and subsequently

	classify a report as having mentioned an infectious or chronic disease. The online discussion forum Reddit is used as the source of these informal reports.
Purpose of Application:	The personal data is to be obtained from relevant, selected 'sub-forums' on the Reddit website and then processed for this study without the explicit consent of the website users (participants). The personal data includes metadata relating to the website forum as well as the entire text of the post. The username of the individual who created the post is not collected. The body of the text may contain references of other users or individuals and the content relates to health and demographic data including biometric and behavioural data. The Applicant states that it is not possible to obtain explicit consent from the data subjects and have been unable to confirm from Reddit if the consent they have obtained cover such research activities. A Declaration is being sought to process any personal data that may inadvertently be obtained through the Reddit forum, for the purpose of the research study.
HRCDC Comments:	The Chair introduced the research study and requested each HRCDC member to indicate whether a consent declaration should be made. After discussing the application in detail, and based on the information provided by the Applicant, it was the consensus of the HRCDC that a consent declaration could be made: **Rationale for seeking a Declaration** • It was noted that the aim of the study is to develop a tool through hr use of 'machine learning' where the tool could identify and categorise references to diseases based on the information posted by individuals online; in this case information posted on the Reddit website. • It was acknowledged that the Applicant had requested the HRCDC to confirm whether this study would fall under the remit of the Health Research Regulations (HRRs). It was confirmed that this is a matter for the data controller to determine and not for the HRCDC. It was noted that the definition of health research within the HRRs is relatively broad. • It was also acknowledged that the data collected from Reddit to develop this tool is pseudo-anonymised – the Applicant does not collect the usernames of those who post on the website. • A declaration is sought as personally identifiable data may inadvertently be obtained and analysed by the Applicant, specifically through references to individuals within the body of the text that is posted on the website forums. The Secretariat referenced the response received from the Applicant who stated that to date they have not encountered legal names of the Reddit user within the text of the post and that the username and kinship terms (e.g. mother) are sparingly included. **Data made public** • The HRCDC discussed that Reddit is a social media platform akin to Twitter in that the information posted by individuals is made public.

	• It was noted that the privacy policy and terms and conditions of Reddit outline how user information posted on Reddit may be used and shared. As part of their terms and conditions Reddit has a ban on users from posting confidential and personal information and it was commented that Reddit is not intended to be a forum for disclosing personal information with identifiers. However, it was discussed that many users of Reddit may not read the terms and conditions when they joined the platform; it was further queried if users would reasonably expect their information to be used for other purposes that includes this type of research study. The HRCDC also recognised that the ban on posting personal or confidential information about themselves and other is challenging to enforce. • On balance, the HRCDC determined that users who post information on Reddit forums, including confidential and personal information, are knowingly making their information publicly available and therefore would likely not be surprised that the information they post will be used by others. Furthermore, it was the view of the HRCDC that personal data that has been made freely available by individuals and used for this type of study poses a low risk to the Participants and although users may post personal or confidential information about other individuals, the Reddit ban and purpose of the site helps to reduce this risk. **Public Interest Case and Obtaining Consent** • The HRCDC discussed that while there is an interest in technical aspects of this study, the overall public interest description outlined by the Applicant in relation to health benefits was relatively limited; however, it was recognised that the tool tested within this study could have the potential to contribute wider public benefits in the future, specifically in the area of epidemiology. • The public interest case in the study is considered to be relatively low. However, the HRCDC was of the opinion that on balance, the public interest outweighs the requirement to obtain explicit consent of the participants due to the nature of the study, the type of data collected and how it is handled, the low data privacy risks and that the information had been knowingly made available to the public by the users of Reddit. • In addition, the HRCDC acknowledged that obtaining consent from the participants would be impossible due to the number of Reddit forums and the geographical spread of users. **Transparency** • The HRCDC acknowledged the Applicant's proposal to establish a study website that would also provide an opportunity for participants to withdraw from the study. It was further acknowledged that the Applicant had unsuccessfully reached out to Reddit to ask if notices about the study could be placed on their forums.

	• It was queried how the study website would or could be effectively publicised to a very wide audience; the HRCDC recognised that it was highly unlikely that Reddit would promote or provide a link to the study website on their forums. **Other** • Although each application is considered on its own merit, the HRCDC was mindful not to dismiss potentially valuable studies that utilise data mining methods on publicly open platforms. There is a risk that if you cannot obtain and use personal data without consent for research from this type of platform then arguably you cannot use data from other traditional platforms such as newspapers. • It was noted that the Applicant confirmed that data is collected from the Reddit website, whose servers are in the USA, via the 'Application Program Interface (API)' tool. The collection and use of this data via the API tool are set out within the tool's terms of use. • The HRCDC acknowledged that the Applicant has taken measures to minimise the likelihood of capturing data that relate to children or other vulnerable groups although some limited concerns remain as it cannot be guaranteed that such data won't be unintentionally obtained.
HRCDC Declaration Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made.
Conditions Attached:	**Condition 1:** The HRCDC recognised the efforts already made and those proposed by the Applicant in relation to transparency and informing participants about the study. The Applicant is requested to establish the study website that was outlined in their application submission, including incorporating a participant opt-out feature, within three months of receipt of declaration decision. In addition, the Applicant is requested to explore other transparency measures such as public engagements. **Condition 2:** The Applicant shall include in the annual review to the HRCDC, any issues or matters that may arise in terms of data that may be inadvertently obtained from children or other vulnerable groups. If such a scenario were to arise the study team shall outline how they dealt with such issues.
Duration of Declaration	The Declaration is made commencing November 25th 2019 and shall be valid until, 31st December 2019 and 5 years thereafter (until December 31st, 2024), or upon confirmation that the data has been rendered anonymised or destroyed, or whichever occurs sooner.

Reference ID:	19-084-AF1
Lead Applicant:	Karn Cliffe
Lead Data Controller:	Health Service Executive (HSE) St. James' Hospital Tallaght University Hospital
Title:	1 Year post-sepsis study
Application Summary:	The primary aim of this study is to identify the long-term impacts of sepsis on patients within an Irish regional context. Secondary aims of

	the study include identifying patient experiences of sepsis and sepsis survivorship; identifying the factors which contribute to early recognition, intervention or treatment; identifying possible delays in early recognition, intervention or treatment and identifying any service gaps to inform service provision needs for sepsis survivors.
Purpose of Application:	A consent declaration is sought for the processing of personal data for potential participants who lack decision-making capacity and who do not have an identified legally appointed proxy to provide consent on their behalf for stage 1 consisting of pre-screening and collecting data from the participant's healthcare records as well as follow-up questionnaires and interviews; a declaration is not required for stage 2 of the study, which will involve implementing a tailored and augmented discharge process for sepsis survivors.
HRCDC Comments:	The Chair introduced the research study and requested each HRCDC member to indicate whether a consent declaration should be made. Based on the information provided by the Applicant, the HRCDC was, in principal, in favour of making a declaration, however in light of new information provided by the Applicant the consensus of the HRCDC was that further information is required: **Public Interest** • It was the consensus of the HRCDC that the Applicant had put forward a strong public interest case in their submission **Capacity & Proxy Consent** • Based on the information set out in the application form, the Secretariat clarified that a 'proxy' consent protocol was to be implemented in this study. It was noted that no alternative proxy consent, such as next-of-kin, will be sought where a legally appointed proxy is not available. Next-of-kin will only be sought to participate in the follow-up interviews if the legally appointed proxy is of the opinion they are unable to provide accurate information on behalf of the participant. • The HRCDC commended the researchers on the methods they will take to i) determine a participant's level of capacity, ii) seek consent from a legal proxy when necessary and iii) consult and support participants whose decision-making capacity is lacking or limited. • The HRCDC was of the opinion that the nature of the study and the consent and participant consultation approaches to be implemented by the researchers provided appropriate safeguards for the study participants. **Updated Responses** The Secretariat informed members that the Applicant had submitted updated responses to two previous queries on the morning of the meeting which were uploaded to the meeting agenda. The responses clarified the relationship between the parties involved in the study, stating that: • The legal entity that a declaration is being made to are the Joint Controllers: the HSE (which the Dublin Midlands Hospital Group

	(DMHG) statutory hospitals come under) and the two DMHG voluntary hospitals, Tallaght University Hospital and St. James' Hospital. • The individual hospitals involved in the study are data controllers for the patient records they store. • No data processors are employed for this study and data sharing agreements are currently being established between the HSE and all participating hospitals. In light of this recently provided information it was discussed that DPO feedback on the DPIA from all Joint-Controllers would be required before the HRCDC can finalise a decision. **Other** • The HRCDC queried what proportion of participants would have capacity to consent compared to those who may lack such capacity. It was noted that this information could be requested as part of the Annual Report to the HRCDC should a declaration be made.
HRCDC Declaration Decision:	The HRCDC noted the new information received by the Secretariat on the Data Controllers and the consensus of the HRCDC was that a formal decision cannot be made until receipt of the information as set out below; **1.** As it has been determined that the HSE, St. James' Hospital and Tallaght University Hospital are Joint-Data Controllers, the Applicant is required to submit DPO feedback on the DPIA from each Data Controller before the HRCDC can make a formal decision. It was noted that one DPIA is sufficient. **2.** A signature from each Data Controller is also required on the HRCDC application form and an appropriate joint data controller arrangement should also be in place.

Reference ID:	19-012-AF2
Lead Applicant:	Leonie Young (RCSI) Arnold Hill (Beaumont Hospital) Bryan Hennessy (Beaumont Hospital)
Lead Data Controller:	Royal College of Surgeons in Ireland Beaumont Hospital Heath Service Executive South
Title:	Breast Cancer Proteomics and Molecular Heterogeneity
Application Summary:	Breast cancer is the most commonly occurring cancer in women and the second most common cancer overall. Metastatic disease arising from breast cancer occurs in approximately 30% of patients. There are limited therapeutic options, reflected in the poor prognosis of this patient's group. Numerous genes and proteins have been identified in breast cancer cells whose presence associates with tumour outcome. Identification of these may open up new possibilities to monitor disease progression and develop new therapeutic strategies. This research study aims to define these proteins and genes in breast cancer and determine their clinical relevance to improve outcomes for patients with

	advanced disease. The study involves recruiting patients with a confirmed diagnosis of breast cancer from whom tissue, and blood samples are collected during their treatment. These samples are subsequently analysed, and the results correlated with other health data including treatment history and lifestyle data. New biomarker and therapeutic targets identified in these studies are developed.
Purpose of Application:	The study aims to recruit up to 5,000 patients; to date all patients in the study (n=2,871) have signed a consent form and have been provided with a patient information leaflet. However, several versions of Patient Information Leaflets (PILs) have been utilised throughout the course of this study: • Earlier versions are considered non-GDPR compliant for different reasons, for example, it is not made clear to the data subject that they can withdraw their consent. • Different data processing activities are noted in the different versions of PILs and consent forms. A consent declaration is sought in relation to the processing of data obtained from patients who consented using these early PIL and consent forms which are not compliant under the HRRs. These forms contain different information on data processing activities, where it is not possible to obtain reconsent.
HRCDC Comments:	The Chair introduced the research study and 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 could be made: **Obtaining re-consent** • The HRCDC acknowledged the efforts made by the Applicant to try and re-consent participants where it is possible to do so i.e. those who are on active follow-up within the clinics • It was noted that updated consent forms and PILs that are compliant under the HRRs will also be used for recruiting new participants • The Applicants rationale outlining why re-consenting patients who are lost to follow-up is not practicable or appropriate was generally accepted by the HRCDC. **Linkage with NCRI** • It was discussed that data linkage with the National Cancer Registry of Ireland (NCRI) was a processing activity that was not clearly referenced in the application form and was not described within many of the earlier versions the PILs and consent forms submitted by the Applicant. • The Secretariat referenced the response provided by the Applicant which stated that data linkage with the NCRI would only apply to data collected from participants who were consented to do so when recruited at later stages. Therefore, it will be clarified to the Applicant that a declaration, if made, is not required to cover this element of the study and does not enable them to link personal data with the NCRI for those recruited using earlier versions of the PIL and consent forms.

	• It was further stated by the HRCDC that an appropriate data sharing agreement is required between the relevant parties in this study and the NCRI; this would fall under the standard condition of a declaration that the Applicant must have any necessary contractual obligations in place. **Biobank** • The HRCDC discussed the biobanking element of the study and acknowledged that the Applicant is putting in place a governance framework in relation to the biobank. • HRCDC members also wished to ensure that the Applicant understood that a declaration, if made, does not permit the data controller to openly share samples and personal data with any parties for research studies without consent. • The HRCDC noted that there may be a national regulatory framework implemented in the short to medium future, which may have an impact on the governance of biobanking. • The Secretariat stated that the study has utilised several different PILs and consent forms throughout its timeframe; in relation to the biobanking of samples and personal data, a declaration, if made, will allow the Applicant to continue to process this data as outlined in the PIL and consent form used to recruit the participant. • Where participant samples and data are held in a biobank without consent, then a declaration can only apply to their continued storage and management in the biobank; it will not enable their use in future unknown studies. • The Secretariat also noted that if a researcher wishes to process samples and personal data from a biobank beyond the scope of activity consented for (or where no consent has been obtained), then they will be required to seek a declaration; a declaration cannot be given to the biobank itself to enable this activity. • In addition, the Secretariat highlighted that blanket consent is not compliant under current or previous data protection legislation; as in the case of GDPR compliant consent, it is not the remit or role of the HRCDC to determine if consent already obtained would be constitute blanket consent. **Duration of a Declaration** • The HRCDC discussed that the Applicant requests a declaration for a duration of 7 years after the publication of the study. • The Secretariat noted that the Applicant was requested to clarify the duration of a consent declaration in line with the most recent PIL and consent form which stated that samples and coded data will be retained indefinitely. The Secretariat referred to the Applicant's response in which they confirmed that a declaration is required for 7 years to cover the processing of personal data for Participants who cannot be re-consented. **Withdrawal of consent** • In reviewing the latest version of the PIL and consent form, the HRCDC was of the opinion that more information could be provided to

	participants regarding what will happen their data and samples should they withdraw their consent or object to their data being processed. • It was also stated that as a declaration cannot be made to cover the processing of personal data where a Participant has withdrawn their consent, that the Applicant should consider referencing the relevant derogations outlined in the GDPR that they may wish to rely on, for example Article 17 ('Right to Erasure'). • However, it is noted that data controllers are responsible for ensuring they are compliant with such derogations whenever participant consent has been withdrawn. **Other** • It was noted that providing study PILs and consent forms on the day of surgery may not be appropriate and could cause undue distress to participants. • In acknowledging that data is being transferred outside of the EEA as part of this study, the HRCDC stated that contractual agreements covering the transfer of data are important safeguards to implement.
HRCDC Declaration Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made
Conditions Attached:	**Condition 1:** The HRCDC acknowledges that the Applicant will establish a governance framework for researchers who wish to access personal data and samples stored in the biobank, for research studies. A governance framework is recognised as an appropriate safeguard to protect the data protection rights and freedom of the participants. Therefore, Applicant is required to provide information on the development and implementation of the governance framework as part of the annual review.
Duration of Declaration:	The Declaration is made commencing August 8th, 2018 and shall be valid until 31st July 2025 and for 7 years after the final study publication or report, or upon confirmation that the data has been rendered anonymised or destroyed, or whichever occurs sooner.
Other HRCDC observations/ Recommendations:	**Recommendation 1:** The Applicant is advised to consider providing further information to participants as to what will happen to their personal data and samples should they withdraw their consent or request their information to be deleted. Furthermore, the Applicant should also consider including information on the relevant GDPR derogations that they may wish to rely on in such circumstances, including Article 17. **General Points for Noting:** • In relation to the biobank element of this study, the scope of this declaration is limited to the data processing activities as outlined in the PILs and consent forms used to communicate to and obtain consent from the participants. • Where participant samples and data are held in a biobank without consent, then this declaration only applies to the continued storage and maintenance of the samples and data in the biobank; it does not cover the use for future undefined studies. • If a researcher wishes to access and process samples and personal data from the biobank outside the scope of consent obtained (or where

	no consent has been obtained) a declaration maybe required for that separate study. • Based on the information submitted to the HRCDC by the Applicant, the declaration is not required to cover the data linkage with NCRI, as this activity will only be carried out where consent has been obtained.

Reference ID:	19-022-AF2
Lead Applicant:	Rose Anne Kenny
Lead Data Controller:	Trinity College Dublin
Title:	The Irish Longitudinal Study on Ageing (TILDA) Public Archives & Researcher Access
Application Summary:	The Irish Longitudinal Study on Ageing (TILDA) was established in 2006 with funding from the Department of Health, The Atlantic Philanthropies and Irish Life. The core vision of TILDA is "Towards making Ireland the best place in the world to grow old". Prior to TILDA, only minimal national information was available on health, economic and social data for the ageing population, therefore impeding proper policy development and future planning that should be based on evidence. TILDA addresses this gap by providing evidence-based data on the ageing population in Ireland to inform policy; track policy changes (e.g. prescription charges) and natural experiments (e.g. effects of recession); healthcare utilisation; health and social systems; end of life experiences; comparisons with other countries; and opportunities to make new discoveries regarding physical, mental and cognitive ageing and the biology of ageing.
Purpose of Application:	TILDA participants are aged 50+, with a proportion over 75. When recruiting for Waves 1 to 5 of TILDA, a broad approach was taken when developing the PILs and consents forms to ensure that the information was provided in an easy to understand format and to minimise participant burden. These forms highlighted that the data would be analysed and used for research purposes by the TILDA team and collaborators and that data confidentiality is a priority although specific details of the collaborations were not provided. Anonymised datasets are also provided to the public archives and therefore fall outside of GDPR. This was not referenced in the PILs but information about data access through the public archives has been available on the TILDA website and in all TILDA publications and presentations since the archiving began. Additionally, at baseline, all adults had to be cognitively capable of providing informed consent to take part in the study. As the study progresses, some participants may become vulnerable as they experience declines in physical or cognitive function and may require a proxy interview where a close family member or friend completes the interview on their behalf. All participants requiring a proxy interview will continue to be followed up at each wave. This consent declaration is being sought to enable TILDA to: • Continue to make anonymised datasets available nationally and internationally through the public archives in Dublin (UCD) and US (ICPSR) and to collaborate with researchers from other institutions, • Sharing of anonymised data with LifePath consortium, • Sharing of anonymised data with EU and/or International consortia,

	• Sharing of blood samples (500) with collaborators, • Linkage with death registration records held by the Genera Register Office** (this processing activity will be considered separately in 19-043-AF3) • Continued use and storage of biobanked samples from previously consented participants where reconsent is not possible, • Sharing of anonymised datasets through public archives with third party researchers.
HRCDC Comments:	The Secretariat highlighted that there were two TILDA applications on the meeting agenda, 19-022-AF2 & 19-043-AF3. Both applications are closely linked; application 19-043-AF3 could be considered an additional processing activity that falls under the main TILDA study outlined in 19-022-AF2. The Secretariat stated that they discussed the connection and similarities between these two applications with the Applicant and the rationale for submitting them separately was outlined to the HRCDC. It was determined that applications 19-022-AF2 and 19-043-AF3 could be considered side by side in the interest of time and for ease of review for the HRCDC. The Chair introduced the research study and 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 could be made: **Public Interest** • Although no public interest case is required for the HRCDC to make a declaration decision, it was noted that there is a strong public interest in this type of study as it is a major longitudinal study on an important cohort of the population. • In addition, the HRCDC recognised the value that data obtained as part of the TILDA study has in relation to the wider research environment. **Sharing data with collaborators** • The HRCDC discussed and acknowledged that pseudonymised data is shared with other researchers, collaborators and international consortium and that this is considered anonymised in the hands of the recipient. The Applicant has determined that a consent declaration is required for this activity as it was not explicit in the PILs and consent forms. • It was noted that a data sharing agreement between Trinity College and the Interuniversity Consortium for Political and Social Research (ICPSR) is currently being reviewed. **Processing Activities** • The HRCDC recognised that a number of processing activities are being undertaken as part of this study, under the various Waves. This made the application challenging to consider in terms aligning the scope of the study with the scope of the declaration.

	• The HRCDC also noted that the extent of data collected in this study is considerable, but it was understood why it was required given the nature of the study. Furthermore, the HRCDC recognised that not all the data collected by research team is shared with collaborators. **Withdrawal of consent** • The HRCDC discussed the reference in the application to participants who have withdrawn; it was not clear from the information submitted whether they have withdrawn from the entire study and requested for their data to be deleted or if they just decided not to participate in one of the study waves. • The Secretariat referred to the Privacy Notice provided by the Applicant that outlines what will happen to a participant's data if they withdraw from the study. • The HRCDC acknowledged the Privacy Statement and the difficulties that would be created for the study if the data controller were to delete the data of participants who have withdrawn. • However, it was re-emphasised that a consent declaration cannot be made to override a participant's withdrawal of consent and that it is up to the data controller to determine if they can continue to process personal data in compliance with GDPR in such circumstances. It its correspondence with the Applicant, the Secretariat had referred the Applicant to Article 17 of GDPR ('Right to Erasure') and advised they consult with their DPO on the matter. **Length of Declaration** The HRCDC discussed the request to seek an indefinite declaration for this study. Considering the longitudinal nature of the study, where further waves may be undertaken in the future, the HRCDC determined that it was reasonable to make an indefinite declaration, and the HRCDC reserves the right to review this duration at regular intervals in light of any changes that may arise during the course of the study.
HRCDC Declaration Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made
Conditions Attached:	**Condition 1:** A declaration cannot be made to override the withdrawal of consent. It is a condition of this declaration that the Applicant has robust procedures and processes in place to ensure that data processing activities do not include data from participants that have withdrawn from the study as the scope of this declaration does not cover the use of personal data of participants who have withdrawn from the study. Please see Recommendation 1 below. **Condition 2:** An appropriate data sharing agreement must be in place between Trinity College Dublin and the Interuniversity Consortium for Political and Social Research (ICPSR).
Duration of Declaration:	The Declaration is made commencing August 8th, 2018 and shall be valid indefinitely. The declaration shall be subject to the annual review. The HRCDC reserve the right to review the declaration duration at regular intervals to consider any relevant changes that may have arisen during the course of the study.

Other HRCDC observations/ Recommendations:	**Recommendation 1:** It is acknowledged that the TILDA privacy notice outlines what shall happen to the participant's personal data if consent is withdrawn, and why continued use is necessary. To add further clarity for participants, the Applicant is advised to consider providing clear information, in plain language, as to what specific GDPR derogations they are relying upon in such circumstances. **NOTE**: Data controllers who wish to continue to process personal data of participants who have withdrawn from the study are responsible for ensuring they are compliant with data protection legislation, including the derogations outlined within the GDPR, for example Article 17 and informing participants of what shall happen to their data should they withdraw from a study. The Data Protection Officer should be consulted where necessary. **Recommendation 2**. The Applicant is advised to consider, for their own clarity, whether participant withdrawal from the study relates to withdrawal from the entire study or a single Wave, or whether they should not be contacted as requested. This matter should be discussed with the Applicant's Data Protection Officer.

Reference ID:	19-043-AF3
Lead Applicant:	Rose Anne Kenny
Lead Data Controller:	Trinity College Dublin
Title:	The Irish Longitudinal Study on Ageing (TILDA) - General Register Office linkage
Application Summary:	The Irish Longitudinal Study on Ageing (TILDA) was established in 2006 with funding from the Department of Health, The Atlantic Philanthropies and Irish Life. The core vision of TILDA is "Towards making Ireland the best place in the world to grow old". Prior to TILDA, only minimal national information was available on health, economic and social data for the ageing population, therefore impeding proper policy development and future planning that should be based on evidence. TILDA addresses this gap by providing evidence-based data on the ageing population in Ireland to inform policy; track policy changes (e.g. prescription charges) and natural experiments (e.g. effects of recession); healthcare utilisation; health and social systems; end of life experiences; comparisons with other countries; and opportunities to make new discoveries regarding physical, mental and cognitive ageing and the biology of ageing.
Purpose of Application:	The consent declaration is being sought to allow TILDA to link existing data with the death registration records held by the General Register Office (GRO), specifically for a subset of the participants who have withdrawn from the study or who have been lost to follow-up (i.e. letters returned, unable to contact, moved outside of Ireland). Some of the withdrawn and lost to follow-up participants will have passed away in which case the data falls outside of GDPR legislation, however some will still be alive. TILDA will carry out checks on www.rip.ie to identify any deaths in this cohort, however, it may not be possible to find all participants or alternatively, a participant with a similar name and

	address may be identified in error. The consent declaration is only required for those individuals who have withdrawn from the study or who have been lost to follow-up and are still alive at the time of linkage with the GRO database.
HRCDC Comments:	The Chair introduced the research study and highlighted the similarities and connection with application 19-022-AF2, including the identical information presented. The Secretariat highlighted that the data linkage activity described by the Applicant in this application form could have been considered an additional processing activity within 19-022-AF2 and therefore could have been incorporated within a single application. The HRCDC was informed and understood why two separate applications were submitted. 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 consent declaration could be made: **Public Interest** • The HRCDC discussed and recognised that there was a public interest and benefit in linking the TILDA data to the GRO. **Processing Activities** • The HRCDC discussed what data processing of living individuals is being undertaken if the data linkage is focused on deceased Participants who fall outside the remit of data protection legislation • It was clarified that the data controller needs to share personal data (i.e. a list of participant names) with the GRO to identify who is deceased. **Withdrawal of Consent** • As with all applications, including 19-022-AF2, a consent declaration cannot be made to process the personal data of participants, where they have withdrawn from the study; this includes data linkages. • It was stated that it is not clear from the information submitted whether participants have withdrawn from the entire study and requested for their data to be deleted or if they just decided not to participate in one of the study waves. • The HRCDC also noted that where a participant confirms that they do not wish to be contacted again that this is different to consent having been withdrawn. • The HRCDC acknowledged that there were would be challenges for the study if the data controller had to delete the data of withdrawn Participants, including creating potential study bias. • However, it was re-emphasised that it is up to the data controller to determine if they can continue to process personal data in compliance with data protection legislation if consent has been withdrawn. **Length of Declaration**

	• The HRCDC discussed the request to seek an indefinite declaration for this study. • Considering the longitudinal nature of the study, in that further waves may be undertaken in the future, the HRCDC determined that it was reasonable to make an indefinite declaration, but where the HRCDC reserves the right to review this duration at regular intervals in light of any changes. A signature from each Data Controller is also required on the HRCDC application form and an appropriate joint data controller arrangement should also be in place.
HRCDC Declaration Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made
Conditions Attached:	**Condition 1:** A declaration cannot be made to override the withdrawal of consent. It is a condition of this declaration that the Applicant has robust procedures and processes in place to ensure that data processing activities do not include data from participants that have withdrawn from the study as the scope of this declaration does not cover the use of personal data of participants who have withdrawn from the study. Please see Recommendation 1 below. For the avoidance of doubt, the scope of this declaration is specifically for the processing of personal data of participants who have been lost to follow up.
Duration of Declaration:	The Declaration is made commencing August 8th, 2018 and shall be valid indefinitely. The declaration shall be subject to the annual review and the HRCDC reserve the right to review the declaration duration at regular intervals to consider any relevant changes that may have arisen during the course of the study.
Other HRCDC observations/ Recommendations:	**Recommendation 1:** It is acknowledged that the TILDA privacy notice outlines clearly what shall happen to the participant's personal data if consent is withdrawn, and why continued use is necessary. To add further clarity for participants, the Applicant is advised to consider providing clear information, in plain language, as to what specific GDPR derogations they are relying upon in such circumstances. **NOTE**: Data controllers who wish to continue to process personal data of participants who have withdrawn from the study are responsible for ensuring they are compliant with data protection legislation, including the derogations outlined within the GDPR, for example Article 17 and informing participants of what shall happen to their data should they withdraw from a study. The Data Protection Officer should be consulted where necessary. **Recommendation 2**. The Applicant is advised to consider, for their own clarity, whether participant withdrawal from the study relates to withdrawal from the entire study or a single Wave, or whether they should not be contacted as requested. This matter should be discussed with the Applicant's Data Protection Officer.

8. Activities

Emily Vereker (EV) provided an overview of the Activities Report which was provided to the HRCDC.

9. Future Meetings

The HRCDC was informed of the proposed dates for meetings in 2020. The Chair discussed that best efforts were made to accommodate members who can't attend on certain days, while recognising that these dates facilitated significantly more attendance than other dates. It was discussed that members who cannot attend in person, could attend via video or conference call, subject to the availability of teleconferencing facilities.

The HRCDC was reminded that the next meeting is scheduled for Monday 16th December 2019. Applications will be considered, and a biobank information session will be delivered by an expert in the field. The HRCDC was invited to submit any biobank queries to the Secretariat in advance of the meeting. Minutes of the 5th November HRCDC information meeting will also be provided for approval on the 16th December.

10. Expenses

The HRCDC was reminded to submit any expense claims as soon as possible in light of the upcoming holiday break.

11. AOB

- The HRCDC noted technical questions in relation to the Decision Time software. Jonny Barrett (JB) stated he will follow up this query with the software provider.
- EV informed the HRCDC that there were no further updates to report in relation to the discussion points of the HRCDC meeting on 5th November 2019.
- The Chair thanked members for attending and closed the meeting.

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