HRCDC
Health Research Consent Declaration Committee

Time: 10:30am - 5:00pm
Date: 17th October 2019
Location: Health Research Board

Minutes of the Meeting[1]

HRCDC Attendance

Name
Brigid McManus
Evelyn Mahon
Alyson Bailey
Kevin Clarke
Sheelah Connolly
John Ferguson
Simon Furney
Barry O Sullivan
Dan Rea
Emily Vereker (Secretariat)
Jonny Barrett (Secretariat)

Quorum for Decisions

☒**YES**

Live Declarations:

Applicant	Ref No.	Title
Alistor Nichol	19-007-AF2	TAME
Alistor Nichol	19-008-AF2	TTM2
Zena Moore & Natalie McEvoy	19-062-AF1	The relationship between Sub Epidermal Moisture (SEM) measurement and Inflammatory markers in the early identification of Pressure Ulcers.

Returning Applications considered at this meeting:

Applicant	Ref No.	Title
Gianpiero Cavelleri	19-011-AF3	Irish Traveller Ancestry Study

New Applications considered at this meeting:

Applicant	Ref No.	Title
Emer Fallon	19-038-AF1	The Genomic Basis of Alzheimer's disease in Ireland
Deborah McNamara / Jochen Prehn	19-031-AF2	Bowel Disease Bio-Resource Development (Colorectal Biobank)
Mary McCarron	19-015-AF2	Intellectual Disability Supplement to The Irish Longitudinal Study on Ageing (IDS-TILDA)

[1] An amendment has been made to the minutes originally published on the website to correct a factual error that came to attention after first publication.

Tom Fahey	19-017-AF2	Prescribing in primary care patients aged 70 years or older

New Applications postponed for consideration at the next meeting:

Applicant	Ref No.	Title
Leonie Young	19-012-AF2	Breast Cancer Proteomics and Molecular Heterogeneity

Meeting Items

1. Opening

The Chair opened the meeting and welcomed the members.

2. Apologies

Zubair Kabir, Aideen Hartney, Claire Collins, Kathy Brickell, Malcom Kell.

3. Disclosure of Interest

Evelyn Mahon (EM) informed the HRCDC of her previous professional connections with Trinity College Dublin (TCD); TCD are noted as a Data Controller in application 19-015-AF2. Simon Furney (SF) informed the HRCDC that he previously collaborated with RCSI researchers who are named in the applications. The HRCDC discussed and determined that there was no conflict of interest to disclose and EM and SF were not required to be absent for the relevant parts of the meeting.

4. Minutes of the last meeting

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

5. Matters arising

None were raised.

6. Appeals Process

The HRCDC received documents in relation to the decision of the Appeal Panel regarding application 19-006-AF3 ('Contribution of Whole Genome Sequencing to Brain Tumour Biology'). The Chair informed the HRCDC that the meeting scheduled for 5th November will be used to discuss topics of interest for the HRCDC and the appeals process. The Department of Health is reviewing the process and welcomes input from HRCDC. The meeting will provide an opportunity to discuss possible suggestions. This will allow the HRCDC time to consider the appeal decision and any implications for HRCDC work that need to be considered further. The following points were discussed in relation to the Appeal:

- It was noted that the Appeal Panel allowed the appeal and granted a declaration with conditions attached.

- The Chair noted that there was a factual error in the decision document of the Appeal Panel in relation to the HRCDC and that a clarification from the Department of Health will be included as a footnote in the final document.
- The Secretariat noted that that Appeal Panel stands dissolved once their decision has been made.
- The Appeal Panel's decision will be published on the HRCDC website in accordance with the Health Research Regulations. It is proposed that the minutes will also be published in line with the HRCDC Standard Operating Procedures.
- The Secretariat discussed the practical matter of transitioning the oversight of the conditional declaration to HRCDC. A confirmatory letter outlining the conditional declaration and request for formal acceptance, will be sent by the Secretariat to the Appellant.
- The appeal decision may i) inform the HRCDC's decision making process going forward, or ii) necessitate amendments to the Health Research Regulations for clarity. Specific areas noted were determining the practicalities of obtaining consent and weighing this against the public interest in the health research study, as well as the requirement for public patient engagement. The Chair noted that the HRCDC will liaise with the Department of Health on the matter.
- The HRCDC asked whether the appeal decision had set a precedent that the HRCDC needs to consider future applications. The Chair and Secretariat stated the decision does not create a precedent as each appeal is viewed on their own merits by a newly appointed appeal panel.
- The HRCDC had a preliminary discussion of various aspects of the appeal process that would be discussed further on 5th November. These discussion points included the type of appeal hearing and the HRCDC role in an appeal hearing and ability to comment on additional material supplied by the appellant.

7. Live Declarations

Reference ID:	19-007-AF2
Lead Applicant:	Alistor Nichol
Lead Data Controller:	St. Vincent's University Hospital
Title:	TAME Cardiac Arrest Study
Application Summary:	See HRCDC Meeting minutes of 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. The Applicant provided a response in relation to the conditions of the declaration and the recommendations made by the HRCDC.
HRCDC Comments:	• The HRCDC acknowledged the Applicant's responses to the Conditional Declaration Decision Letter. • The potential impact of Brexit on the legal/contractual arrangements for the transfer and processing of personal data in the UK was discussed. It was noted that a standard condition of all declarations made includes that 'necessary contractual obligations' are in place; Post-Brexit, where Data Controllers are transferring data to the UK

	for research studies, the appropriate agreements must be in place, in in compliance with data protection legislation.
HRCDC Decision:	The HRCDC was satisfied with the response provided by the Applicant

Reference ID:	19-008-AF2
Lead Applicant:	Alistor Nichol
Lead Data Controller:	St. Vincent's University Hospital
Title:	TTM2 Study (Targeted Hypothermia versus Targeted Normothermia after Out-of-hospital Cardiac Arrest: A Randomised Clinical Trial)
Application Summary:	See HRCDC Meeting minutes of 10th September, 2019 & 25th July, 2019
Points to Discuss	The Applicant responded to the HRCDC decision letter of 24th September 2019; they were pleased with the decision to make a Conditional Declaration but wished to inform the HRCDC that the TTM2 Study will no longer be implemented in Ireland.
HRCDC Comments:	The HRCDC acknowledged and accepted the Applicants responses to the Conditional Declaration Decision Letter.
HRCDC Decision:	With the study no longer being implemented the Secretariat will respond to the applicant to confirm that the Declaration has been terminated.

Reference ID:	19-062-AF1
Lead Applicant:	Zena Moore 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 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. The Applicant provided a response in relation to the conditions that request amendments to the patient information leaflet (PIL) and consent forms; specifically, the Applicant noted that any amendments will have to be approved by their Research Ethics Committee (REC) and asked the HRCDC whether they could commence data collection before these are approved by the REC.
HRCDC Comments:	It was highlighted that the Secretariat had responded to the Applicant when asked whether it is appropriate to commence collecting data from participants who are consenting using one form and then later the amended form. The HRCDC acknowledged that REC approval is required by many institutions if amendments to PILs and consent forms must be made. The HRCDC stated that they do not wish to cause undue delay for new research studies where a declaration has been made.
HRCDC Decision:	The HRCDC agreed that the Applicant could, in practice use both versions of the PIL and consent form (the original and then the amended) as is appropriate. The study can therefore commence data

	collection for this project whilst the amendments to the PIL and Consent forms, as outlined in the Conditional Declaration, are in progress.

8. Returning Applications:

Reference ID:	19-011-AF3
Lead Applicant:	Gianperio Cavalleri
Lead Data Controller:	The Royal College of Surgeons in Ireland (RCSI)
Title:	Irish Traveller History Study
Application Summary:	See HRCDC Meeting minutes of 10th September 2019
Points to Discuss	The HRCDC considered the Applicant's response to the HRCDC's request for further information in the decision letter of 24th September 2019. See HRCDC Meeting minutes of 10th September 2019.
HRCDC Comments:	The Chair introduced the agenda item and invited members to comment on the Applicant's responses to the HRCDC's request for more information. Based on the response letter received, the consensus of the HRCDC was that further information and clarification was required as the Applicant's responses did not fully address the queries raised at the HRCDC meeting of 10th September, 2019. The consensus of the HRCDC was that final decision would be deferred pending receipt of further information from the Applicant. The decision was based on the following discussion points: **Biosamples** • The HRCDC acknowledged the Applicant's response that the 39 samples which are subject of this application, underpins a peer reviewed article (Gilbert et al., Science Report 2017 Feb 9;7:42187), which provided information to substantiate the health impacts and specific benefits of the study. • HRCDC members discussed that the data already generated and analysed by the Applicant from these 39 samples has value. The HRCDC understood why researchers would not want to dispose of potentially valuable samples and associated data. • The HRCDC considered that a narrow scope declaration could be made for the continued storage and re-production of results in relation to the 2017 published paper; however, it was noted that the Applicant requests a declaration to generate new genetic data for further analysis, in addition to merging these 39 samples with larger datasets. It was discussed that the request to generate new genetic data from these 39 samples is likely due to technological advancements in the area of genetic analysis. • The HRCDC noted that there is a level of public interest in this type of genetic research as it focuses on a small and often excluded population group and that data from a distinct population is valuable for disease analysis. • It was acknowledged that the Applicant provided more information on the health impacts and specific benefits of the study and this is substantiated by the referenced 2017 research paper. • However, from the information provided, the HRCDC considered it is still difficult to determine whether the continued retention and further

	genetic analysis of these 39 samples are essential for achieving the research objectives versus collecting and using new samples with explicit consent. Furthermore, there is no guarantee that the 39 samples provide a large enough cohort to produce sufficient results in genetic research studies, although it may increase the chances of doing so. **Awareness of Participants** • The Applicant confirmed that no other information leaflet or consent form, specific to the collection and use of DNA, was used when the samples were collected for the documentary film. • The Applicant stated that it had been made clear to participants during the recruitment process that the documentary involved using genetic data to understand the history of the Traveller Community. The HRCDC noted that no additional information has been provided to support this assertion or indicate how participants had been informed. **Data/Biosample Transfer Pathway** • The HRCDC stated the importance of understanding the data and biosample 'pathway' from the documentary production company to RCSI, including having in place appropriate legal agreement. • It was discussed that the HRCDC should receive confirmation from the study's REC that they were aware of the origin of the data and fully informed about the transfer of the data to RCSI. **Transparency arrangements** • Improved and more explicit transparency arrangements were noted as possible measures that the Applicant could implement to increase awareness of the project among the Irish Traveller Community.
HRCDC Decision:	The consensus of the HRCDC was that a formal decision would be deferred pending receipt of further information
Further Information Requested:	1. The HRCDC noted the original use of the biosamples and data for a non-health research purpose and subsequent transfer to RCSI for health research purposes. The Applicant is requested to: i) provide a detailed overview of how the transfer of the biosamples and data from Scratch Films to Ethnoancestry to RCSI came about; and ii) provide written confirmation from the RCSI REC that it was aware of the manner in which RCSI received and become a custodian of the data and biosamples and are thus satisfied that the biosamples and data can be used in the manner outlined in the study. 2. The HRCDC requests a copy of any historical documentation, briefing notes or communication that may substantiate the assertion that individuals who consented to participate in the documentary were aware how their biosamples would be used i.e. for genetic analysis.

	3. The HRCDC requests that the Applicant detail the status of the legal agreement between RCSI and Scratch Films including the expected execution date. 4. The HRCDC requests that the Applicant consider and provide feedback on the feasibility of carrying out a publicity campaign to highlight and inform members of the Irish Traveller Community about this research study.

9. New Applications

Reference ID:	19-038-AF1
Lead Applicant:	Emer Fallon
Lead Data Controller:	Genomics Medicine Ireland (GMI)
Title:	The Genomic Basis of Alzheimer's disease in Ireland
Application Summary:	Alzheimer's Disease (AD) is one of the leading causes of dementia and represents a major cause of death globally. It is a progressive and debilitating disease with limited symptomatic treatment available. AD has a strong genetic component. This project is a longitudinal, prospective, non-interventional genomic study on this disease. It's focused on how genes, environment and lifestyle influence disease risk, disease sub-type, progression and drug response. Whole genome sequencing of blood samples will be used to conduct the analysis. The findings from the study may be used to better diagnose AD, predict progression and tailor treatment based on a person's genetic makeup. It may also lead to the identification of new drug targets for the development of novel therapeutics. The genetic and phenotypic data that is generated from the blood samples, as well as the clinical and lifestyle data collected on the participant, will be made available to authorised third-parties on a GMI controlled database. Access to this data will be under contractual arrangements and third-parties may include academic institutions and for-profit companies.
Purpose of Application:	To carry out research on AD, people with the condition are needed to participate in the research study. This presents a challenge in advancing research in this area as people with AD will have varying degrees of capacity to provide consent. The current legal position does not provide for persons that cannot provide explicit consent which can result in their exclusion from research and further hinder the pace of progress on AD research. A Declaration is being sought to process personal data for the purpose of the study.
HRCDC Comments:	The Chair introduced the 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 further information is required. Therefore, a formal decision would be deferred pending receipt of further information from the Applicant: The decision was based on the following discussion points: **Public Interest** • The HRCDC agreed that there is a high level of public interest in AD research and noted the contribution that genetic analysis can bring to this field. It was also noted that there is a level of public interest in providing other researchers access to genetic, clinical and lifestyle

	data. It was noted that the Applicant stated that no personal identifiers, such as name and date of birth, will be included in the GMI database that can be accessed by third-parties. • It was discussed that the research policy is driving the research community towards a more 'open-data' environment, as there are publicly accessible and controlled genetic databases are in operation. The HRCDC discussed whether there is a longer-term public benefit in the accessibility of this specific database to researchers, that is owned by GMI. **Research Purpose and Data Minimisation** • The HRCDC commented that although they understand that the Applicant will be conducting genetic analysis on the participant's samples, the specific research question that they wish to focus on is not clear from the application form. It would be important to understand the potential added value of this research study in order to assess the public interest. • The HRCDC noted that the Applicant references a questionnaire to be completed by the participants, however the actual questions are not detailed. Additionally, the HRCDC commented that the response provided on data minimisation was not clear. **Participant Recruitment and Capacity** The HRCDC discussed that it is not clear how participants are recruited to the study and how their level of capacity to provide consent is determined. It was discussed that a minority of participants with AD may have the capacity to provide explicit consent and, in these cases, proxy consent is not appropriate. Furthermore, where participants are unable to provide consent, the data privacy rights of the subject would be supported if they were involved in the decision-making process, and should be consulted regardless of whether they have limited capacity **Proxy consent** • The HRCDC noted from the study protocol provided that either relatives or friends could provide assent. Some members queried whether the category of a 'friend' providing assent could include the possibility of a paid carer in the home or in a care home scenario, providing assent. While recognising that a friend would be an appropriate person in some circumstances, the HRCDC discussed how in a 'non-relative' case whether a friend was in a position to assess an individual's will and preference. • The HRCDC discussed that the protocol for obtaining consent where there is a lack of capacity should be standardised and strengthened across all hospital sites in order to protect the data rights of the participant. If a declaration is made this would be an important condition and the Applicant would be required to document such a protocol. • It was also queried whether the same individual who provided proxy consent for this study is the only one who can withdraw the proxy consent.

	Consent Forms & PILs • It was commented that the current PIL and consent form could confuse participants and/or those acting as proxy consent, and that a more accurate description of the study could be provided. Specifically, this could include a more detailed study synopsis, information relating to why genetic, clinical and lifestyle data cannot be removed from the database when consent or proxy consent has been withdrawn and the process and arrangements whereby 'authorised third parties' will be given access to the data held in the GMI analytics database. • The HRCDC discussed the reference in the revised DPIA, to the participants biological samples. Where data has been generated from blood samples and included in GMI's database, that personal data cannot be removed should consent or proxy consent be withdrawn. In such circumstances their personal data will continue to be retained in the GMI database and further analysed. • It was queried why GMI would need to continue to keep the raw genetic data that has been generated from the blood samples in their database, as well as clinical and lifestyle data, when the consent obtained has been withdrawn. The HRCDC recognised that the already analysed results of such personal data can still be retained in research projects that have completed or are in progress. **Research Scope** • The HRCDC noted the Applicant's response in the DPIA, stating that the pseudonymised data may be used as a comparative dataset to study other medical conditions apart from AD, such as wellness studies, undertaken by GMI. The HRCDC noted that this does not appear to be referenced within the application form. • The HRCDC raised concerns that the data which GMI would allow third parties to access, could also be used for areas outside of AD health research. **Longitudinal Study** The HRCDC noted that the Applicant refers to this as a longitudinal study; however, the details of which were not clear as the information outlined in the application form references only one point of data collection. **Control group** It was recognised that a control group was needed in order to compare what the genetic differences are. The HRCDC asked who the 'control group' are and whether they provided explicit consent. **Auditing and Monitoring** The HRCDC noted that GMI will have access to the 'master list' located in the hospital for monitoring and auditing purposes. It was discussed that this is common in studies that have a sponsor; the HRCDC queried whether it would be appropriate to assign this role to an independent individual outside of GMI, as was discussed in relation to other applications.

	Data Access to Researchers • It was noted that the Applicant states that the Researchers in the participating hospitals would be provided with a copy of the phenotypic and genomic data of the recruited participants if they request such from GMI. The DPIA further states that this is accessed onsite at GMI and no data can be downloaded. • The Applicant also states that the PI then becomes the Data Controller of that data; inferring that they can then determine the means and purposes of processing this data once they receive it; this contradicts a different part of the application form which stated that the hospital would be considered the Data Controller. • The HRCDC considered that PIs should automatically be provided with the copy of the phenotypic and genomic data. **REC Approval** The HRCDC noted that REC approval for one of the three hospital sites was granted directly to GMI and not the Hospital Site Researcher. The HRCDC discussed that it is standard practice to give REC approval to the Researcher and queried why a different approach was taken by Sligo University Hospital.
HRCDC Declaration Decision:	The consensus of the HRCDC was that a formal decision would be deferred pending receipt of further information.
Further Information Requested:	1. The HRCDC requests further information on the following aspects of the consent process for this study: i) how the research team in the hospital sites are systematically determining the level of capacity of participants who may or may not be able to provide explicit consent. ii) when it is determined that the participant does not have capacity to consent, the HRCDC wish to understand the process used, and how this is documented, when identifying who is the most appropriate individual to provide proxy consent on behalf of the participant. Please also set out what arrangements are in place to consult with participants during the overall decision-making process. iii) clarification on the process by which proxy consent is practically withdraw and by whom. Specifically, can proxy consent only be withdrawn by the same individual who provided proxy consent on behalf of the participant. How are such requests implemented by the Data Controller? iv) an outlined as to why the genetic data that has been generated from blood samples, as well as participants clinical and lifestyle data, cannot be removed should consent or proxy consent be withdrawn? It is recognised that results that have analysed from this data can still be obtained. *v)* an overview on the number of participants expected to have capacity to consent, versus those lacking capacity to consent. 2. Has the use of an independent auditor/monitor, external to GMI, been considered or proposed? If not, why is this not considered to be feasible?

	3. How are participants identified and recruited into the study? From the Geriatricians directly or elsewhere? 4. In relation to the research study: i) given the extent of lifestyle and clinical data to be collected and genetic analysis to be carried out, the HRCDC requests further information on the specific research question that will be addressed by the Applicant in the field of AD. ii) further details on the longitudinal aspect of the study are requested as this not clear from the information provided in the application form; this description should contain information on the data processing activities that will be undertaken, including when personal data is collected from the participants over the lifetime of the study. 5. In line with the principles of Open Access and Findable, Accessible, Interoperable, Reusable (FAIR) data, will the data be submitted to a publicly available and controlled access repository and, if so, what timescale? If not, what further public interest in the dataset can be demonstrated, if the research community cannot publicly access the dataset for the benefit of the wider AD field. 6. Has, or does the Applicant propose to have, Public and Patient representatives on the AD advisory board? 7. Will the Applicant consider providing the phenotype and genetic data to the PIs automatically as opposed to access upon request? 8. The DPIA states that 'the pseudonymised data may be used as a comparative dataset to study other medical conditions apart from AD as well as in wellness studies undertaken by GMI'. Please confirm that the declaration is only in relation to this AD study. 9. The response to the Secretariat's query letter outlined the status of the legal agreements between various parties, namely GMI and the three hospital sites and UCD. The HRCDC are seeking confirmation that all legal agreements are executed. For confirmatory purposes, the HRCDC request the Applicant to provide the executed legal agreements, or at minimum, sections thereof that relate to data protection and the signatory page. Where agreements have yet to be executed please provide expected timelines. 10. Why is the REC Approval from Sligo Hospital provided to GMI directly and not the Principal Investigator as is the case with the other REC approvals?

Reference ID:	19-031-AF2
Lead Applicant:	Deborah McNamara Jochen Prehn
Lead Data Controller:	Beaumont Hospital Royal College of Surgeons in Ireland (RCSI)
Title:	Bowel Disease Bio-Resource Development: Identification of Potential Biomarkers for Colorectal Cancer

Application Summary:	Colorectal cancer is the second most common malignancy in the western world. Standard treatment includes surgery with or without chemotherapy; this can lead to a general over-treatment of some patients whilst high-risk patients may not be receiving optimum therapy. The purpose of this Biobank is to develop a bio-resource of tumour and normal tissue, which is removed during the surgical procedure as standard practice, which may be used to identify common proteins and genes that may be used as effective biomarkers which could lead to improved treatment and the development of potential screening programmes for those deemed to be at high-risk of developing colorectal cancer.
Purpose of Application:	For this study consent was previously obtained from participants to collect their samples and personal data for the purposes of examining known and potential future biomarkers of bowel disease and to store the personal data and biosamples in a biobank for use in future research studies relating to bowel disease. However, the patient information leaflet (PIL) used at the time stated that samples and data would be held for 10 years and did not note RCSI as a Joint Data Controller in the study; Beaumont Hospital was referenced. A declaration is therefore sought for Beaumont Hospital and RCSI to continue to use the biosamples and personal data for biomarker analysis and to continue to store the biosamples and personal data in a biobank for future research beyond the 10 years that was stated in the PIL. The Applicant has requested an indefinite declaration duration.
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: **Public Interest** Although no 'public interest' case was required as the study had previously obtained participant consent, the HRCDC stated that there was a strong public interest case due to the nature of the disease and the value of the data and samples for research. **Duration of Declaration** The HRCDC queried whether it was reasonable and appropriate to make an indefinite declaration as was requested by the Applicant. The HRCDC noted that the policy in this area may develop and change in the future. The Chair stated that the HRCDC can grant a time limited declaration if this was considered appropriate and the Applicant could then request an extension to the declaration decision. **No Re-Consent** • The HRCDC noted that the Applicant outlined reason why re-consenting was not carried out. Some patients requested not to be re-contacted in the future. It was unknown whether patients were still alive or deceased and there were concerns that approaching patients and/or relatives may cause distress in these cases. The HRCDC

	queried whether this had been documented or is there additional evidence to support the claim that participants did not wish to be re-contacted. • The HRCDC discussed the strength of the Applicant's case for not seeking participant re-consent where the health status of participants was unknown. It was commented that efforts to try to re-consent could have be undertaken or further considered to help assess the practicalities, appropriateness and likelihood of obtaining re-consent. For example, consultation with PPI representatives or undertaking a pilot re-consent study could have been carried out. • On balance, the HRCDC accepted the rationale put forward by the Applicant for not undertaking efforts to re-consent participants. In addition, the HRCDC discussed that privacy risks may arise should the Applicant write to participants seeking re-consent. **Transparency** The HRCDC stated that it is important that public notices on this study are provided within hospitals; notices should highlight that research is being carried out using samples and data from the biobank. Patient advocacy groups could be engaged. **Data Minimisation** • The HRCDC were satisfied with the Applicant's response as to why data on the occupation of participants was collected and noted the value of this data in understanding of incidence of Colorectal cancer. • However, the HRCDC were of the view that more information could have been provided by the Applicant on data minimisation in relation to personal data that is held by the Controllers of the Biobank. **Biobank Access** • The HRCDC noted the Applicant's statement that researchers wishing access the biobank for research studies must first have REC approval. It was also noted that only anonymised data is provided to these researchers. • The Secretariat stated that third party data controllers wishing to access and process personal data and samples from the biobank in a way that is considered outside the scope of consent obtained, will themselves have to apply to the HRCDC for a Declaration. • It was noted that the Applicant accepts this situation in their response to the Secretariat Query Letter dated 6th September 2019. • The HRCDC stated that the requirement for studies to obtain REC approval, and request a separate declaration if necessary, provide further safeguards to study participants. **Collaborative Agreements** The HRCDC discussed that the 'umbrella' agreement between RCSI and Beaumont Hospital that is referenced by the Applicant should be in place as an appropriate data protection safeguard. **PIL**

	The HRCDC commented that the PIL was well written and considered from the point of the participant. However, the PIL primarily focuses on the tissue samples and that information on the other data to be retained is not as clear. **Participant Access Request** The Applicant states that requests for access to personal data by the study participants is made through the Freedom of Information (FOI) Office. The HRCDC commented that such requests to access personal data do not have to be made under the FOI Act and could be made under more appropriate mechanisms such as a Data Subject Access Request.
HRCDC Declaration Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made.
Conditions Attached:	**Condition 1:** The Applicant is requested to provide more information to support their statement that participants do not want to be re-contacted. For example, are there documented numbers of participants that actively 'opted' not to be contacted? **Condition 2:** Through engagement with PPI representatives and advocacy groups, the Applicant is requested to examine in detail the feasibility of obtaining re-consent from participants; including seeking a perspective from both healthy and ill participants. The findings of this exercise is a reporting requirement in the first Annual Review to be submitted to the HRCDC. **Condition 3:** The Applicant must develop and provide public notices to Beaumont Hospital which highlights that research is being carried out using samples and data from the biobank. **Condition 4:** The HRCDC acknowledge the Applicant's response that REC approval from RCSI was not required for this study. The Applicant is requested to provide written confirmation of this from RCSI. **Condition 5:** A material transfer and data sharing agreement or legal agreement as appropriate, must be executed between RCSI and Beaumont Hospital. Please indicate the expected timeline to have the legal agreement concluded. **Condition 6:** Once finalised and approved, the Applicant must seek explicit consent from prospective participants using the new GDPR compliant PIL and Consent forms.
Duration of Declaration:	The Declaration is made commencing August 8th, 2018 and shall be valid until October 31st, 2022; 3 years after the decision of the HRCDC to make a conditional declaration. The Applicant is invited to apply for an extension to this duration before the current declaration period expires.
Other HRCDC observations/ Recommendations:	**Note** The HRCDC will review this declaration and any extension thereof, in light of any future national policy and regulatory developments in the area of biobanking. **Recommendation**

	The Applicant is requested to review and re-consider the current process whereby personal data access requests are made via the FOI office.

Reference ID:	19-015-AF2
Lead Applicant:	Mary McCarron
Lead Data Controller:	Trinity College Dublin
Title:	Intellectual Disability Supplement to The Irish Longitudinal Study on Ageing (IDS-TILDA)
Application Summary:	IDS-TILDA is a longitudinal study researching ageing in Ireland of a representative sample of people with an intellectual disability aged 40 and over at all levels of functioning and in all living situations. IDS-TILDA aims to identify the principle influences on successful ageing in persons with an intellectual disability, and to then determine if they are the same or different influences for the general population. Data will be examined to determine similarities to and differences from the influences on the ageing lives of the general population and if there are changes in influences over time for people with an intellectual disability, and to analyse the data to inform and guide the planning, implementation and evaluation of future national policies, programmes and services.
Purpose of Application:	IDS-TILDA is seeking a consent declaration for the processing of data from individuals with an intellectual disability who are not able to give explicit consent or to designate a proxy to act on their behalf.
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: **General** • The HRCDC agreed that the Applicant had provided a sufficient level of detail on the objectives of the project and the data processing activities • Although there is no requirement to make a public interest case in this application the HRCDC stated that there is a public interest in this study and that good research practices appear to be incorporated. **Fieldworkers & Data Retention** It was noted that the timeframe for the retention of the data forms by the fieldworkers is not clear. **GDPR Training** The Applicant states that individuals involved in the study undertake one of two GDPR training options lasting either 3 days or approximately 35 minutes. The HRCDC were of the view that GDPR training for those working in this study should be standardised and queried whether the 35-minute training would be adequate in comparison to a 3-day session.

	PIL and Consent Form • It was commented that the use of the Primary Care Reimbursement Scheme (PCRS) should be incorporated into the participant and proxy consent forms. • The HRCDC also noted that only 'yes' options are available to select on the consent forms; where appropriate it was considered that a 'no' option could also be included. **Incidental Findings** The HRCDC discussed if appropriate mechanisms are in place to inform and support participants who have an intellectual disability should the analysis of the collected bio-samples identify an unexpected health issue.
HRCDC Declaration Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made
Conditions Attached:	**Condition 1:** The Applicant is requested to review and consider amendments to the PIL and consent forms with regards to the inclusion of both 'yes' and 'no' options and information on the use of the Primary Care Reimbursement Scheme numbers. **Condition 2:** The Applicant is requested to provide more information on the process that will be implemented to inform and support participants where the analysis of their bio-samples identifies any health issues. The HRCDC wish to seek assurances that participants with intellectual disabilities are appropriately supported in such circumstances where they may need to seek further medical advice.
Duration of Declaration:	The Declaration is made commencing August 8th, 2018 and shall be valid until October 31st, 2021 and 5 years thereafter (until October 31st, 2026), 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 requested to review and consider the adequacy of the GDPR training that is completed by individuals involved in the study, specifically the 35-minute session. **Recommendation 2:** The Applicant is requested to consider the timeframe and safeguards for the retention of personal data, in soft or hard copy format, held by the study fieldworkers.

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:	This research study examined whether older people with multiple morbidities (multiple chronic medical conditions) and potentially inappropriate prescriptions were more likely to have poorer health outcomes, including adverse drug reactions, emergency hospital admission and poorer health related quality of life. Between 2010 and 2012, over 900 people aged 70 years and older living in the community and 15 GP practices took part in the study over two waves. Researchers found that people with potentially inappropriate prescriptions, measured using a set of prescribing criteria, had an

	increased risk of having an adverse drug reaction and also reported poorer health related quality of life. Further work in this research study (Wave 3) is currently ongoing to assess whether high-risk prescriptions are being monitored with the relevant blood tests by general practitioners (GPs) and to assess the performance of tools that predict which patients will experience an adverse event related to their medications. Results from this study may help develop systems to assist prescribing decisions and to support the reduction of unnecessary medication. A 4th Wave of this study is also planned and will involve eligible participants from Wave 3.
Purpose of Application:	The Applicant will be inviting eligible participants from Wave 3 to continue to participate in a 4th wave of the study - the support of a declaration is therefore not required for Wave 4 where the participant provides re-consent. The Applicant requests the support of a consent declaration for: i) The retention of patient identifiers, or 'Patient Key', collected from Wave 1, to undertake the re-consenting process for Wave 4; ii) The continued retention and use of personal data that was collected from Waves 1-2 of the study as a timeframe was not outlined in the original PIL and consent form; iii) The processing of personal data for Wave 3 which received a 'consent waiver' from the Research Ethics Committee; this includes data linkage with the HSE- Primary Care Reimbursement Scheme. Personal data from Wave 3 data will then be retained for further use in this study. iv) Collecting and processing new follow-up data from the GP medical record for Wave 3 participants who are not eligible to take part in Wave 4. Once completed the patient identifiers will be destroyed for this cohort rendering the dataset anonymous. v) Processing personal data and retaining the patient identifiers of participants who are eligible for Wave 4 but who provide no response to requests for re-consent; this includes the collection and processing of new follow-up data from the GP medical record The support of a declaration is requested until 7 years after the publication of the final report from Wave 4 of the 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, 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 public interest in this type of study. • The HRCDC further considered it commendable that GPs are collaborating with Consultants on this study.

	Participant Non-response The Secretariat noted that, generally, where reasonable efforts have been made to contact participants to re-consent for a study, but where there is no response from the participant, then the HRCDC may make a declaration in such circumstances. **Patient/Consultant Involvement** The HRCDC commented that the study appeared to involve minimal patient involvement. **The Primary Care Reimbursement Scheme (PCRS)** The HRCDC queried whether the Applicant required data to be linked with the PCRS and could information on prescriptions be provided directly by the GPs as an alternative. The HRCDC discussed that the PCRS would likely offer a more accurate view of the medicines dispensed to the study participants. **GP Consenting and Feedback** • The HRCDC acknowledged that the Applicant had also requested the consent of GP practices to participate in the study. It was discussed if participating GPs, in addition to the study participants, should also be asked to provide consent. • It was noted that as part of the original REC approval, the study was expected to provide feedback to each GP practice on the outcomes; however, this was not incorporated into in the later REC letters. **Withdrawal of consent** • The HRCDC noted that personal data cannot be anonymised and subsequently retained when consent has been withdrawn; instead it must be deleted. • Therefore, where eligible participants from Wave 3 are invited to provide re-consent for Wave 4 of the study but state they do not wish to continue to participate then the Applicant cannot anonymise the personal data obtained to date by deleting the patient key.
HRCDC Declaration Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made
Conditions Attached:	**Condition 1:** The HRCDC considered that a declaration cannot be made to overwrite a participant's withdrawal of consent. Where eligible participants actively respond and state, they do not wish to continue to participate in Wave 4 of the study - then this must be regarded as a withdrawal of consent. Therefore, where consent is withdrawn, it is a condition of this declaration that the Applicant cannot subsequently anonymise (continue to process) the personal data and must instead delete the personal data of the participant that was originally collected. The analysed results of this personal data can be retained. Please see Recommendation 1. **Condition 2:** Where it is feasible to do so, the Applicant must also provide participants who are ineligible to participate in Wave 4 of the study, the opportunity to be re-consented for the continued retention of their personal data and the collection of new follow-up data from the GP

	record. Where there is a non-response the support of a Declaration will extend to this processing activity until the data has been anonymised. **Condition 3:** The Applicant must provide the HRCDC with updates on the number of participants who do not respond to the request for re-consent as part of their Annual Report to the HRCDC. **Condition 4:** As was undertaken during the initial Wave of the study, participating GPs should be re-consented for Wave 4 of the study.
Duration of Declaration:	The Declaration is made commencing August 8th, 2018 and shall be valid 7 years after the publication of the final report on Wave 4 of the study, 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 the following; where seeking participants re-consent for inclusion in Wave 4, the Applicant should provide for the participants to consent to the anonymisation of their personal data for future Wave 4 if they do not wish to participant in Wave 4. **Recommendation 2:** In line with earlier REC Approvals and recommendations, the HRCDC recommend that participating GPs receive feedback on the outcomes of the study.

10. Any other Business

There was no other business discussed and the Chair closed the meeting.