HRCDC
Health Research Consent Declaration Committee

Time: **10:30am - 5:00pm**
Date: **16th December 2019**
Location: **Health Research Board**

Minutes of the Meeting

HRCDC Attendance

Name
Brigid McManus
Alyson Bailey
Kevin Clarke
Sheelah Connolly
Aideen Hartney
Claire Collins
Dan Rea
Zubair Kabir
John Ferguson
Evelyn Mahon
Simon Furney
Kathy Brickell
Emily Vereker (Secretariat)
Jonny Barrett (Secretariat)

Quorum for Decisions

☒**YES**

Live Declarations:

Applicant	Ref No.	Title
Leonie Young	19-012-AF2	Breast Cancer Proteomics and Molecular Heterogeneity
Mary McCarron	19-015-AF2	Intellectual Disability Supplement to the Irish Longitudinal Study on Ageing (IDS -TILDA)
Paul Buitelaar	19-064-AF1	Discussion Forum use for Public Health Surveillance Study

Returning Applications

Applicant	Ref No.	Title
Emer Fallon	19-038-AF1	The Genomic Basis of Alzheimer's disease in Ireland
Karn Cliffe	19-084-AF1	1 Year post-sepsis study

Returning Applications - Deferred for consideration at the next meeting

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

New Applications considered at this meeting:

Applicant	Ref No.	Title

Neil Crowhurst	19-002-AF1	A retrospective case analysis of serious untoward incidents in super catchment mental health services in the HSE South East
Susan Knowles / Stephen Smith	19-052-AF1	GENESIS: the genomic landscape of neonatal *Escherichia coli* sepsis
Jochen Prehn / Annette Byrne	19-014-AF2	COLOSSUS Study

New Applications - Deferred for consideration at the next meeting

Applicant	Ref No.	Title
Fergus McCarthy	19-019-AF2	IMPROVED Study (Improved Pregnancy Outcomes by Early Detection)

Meeting Items

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

2. **Apologies**
   Malcom Kell, Barry O'Sullivan

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

4. **Minutes of the last meeting**
   Draft minutes of the 5th November meeting and 25th November meeting were circulated in advance. The HRCDC was informed that the minutes of the 5th November are with the Department of Health (DoH) and Patricia Rickard Clarke (PRC) for review in relation to their input, as they presented at the meeting. The HRCDC agreed the minutes of the 5th November meeting subject to any factual corrections from the DoH and PRC. Subject to a minor correction, the minutes of the 25th November meeting were also agreed.

5. **Response to Appeal Panel Decision (Appellant:19-006-AF3)**
   The HRCDC was provided with the HRCDC's letter to the Appellant dated November 6th, 2019 confirming the operations of the conditions attached to the decision of the Appeal Panel '(Decision Letter'), the Appellant's response and the corresponding response sent by the Secretariat on December 11th, 2019.
   The Secretariat stated that the Decision Letter was drafted in consultation with the DoH. The HRCDC was informed that the issues raised by the Appellant in their response to the Decision Letter were briefly discussed and clarified with the Appellant. The HRCDC noted the correspondence from the Appellant and the Secretariat.

6. **Live Declarations**

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:	See HRCDC Meeting minutes of 25th November 2019.
Points to Discuss	The Applicant responded to the HRCDC decision letter of 9th December 2019 confirming acceptance of the HRCDC's decision to give a conditional declaration.
HRCDC Comments/Decision:	The HRCDC acknowledged and accepted the Applicants' response and noted that the conditions attached will be monitored as part of the annual review process.

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:	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 and responding to the conditions and recommendations outlined in the decision letter.
HRCDC Comments:	The HRCDC acknowledged and accepted the Applicant's responses. It was further acknowledged that the conditions have been met.

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:	See HRCDC Meeting minutes of 25th November 2019.
Points to Discuss	The Applicant responded to the HRCDC decision letter of 9th December 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 that the conditions attached will be monitored as part of the annual review process.

7. Returning Applications - Deferred for consideration at the next meeting

Reference ID:	19-011-AF3 ***[SUBSEQUENTLY WITHDRAWN, JANUARY 2020]***
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
HRCDC Comments	The HRCDC discussed Application 19-011-AF3 and the timeframe for responding to the request for more information from the HRCDC meeting of 17th October 2019. The HRCDC acknowledged that it is important to provide Applicants with a reasonable timeframe to respond to requests for further information, however in the absence of a response after a protracted period the HRCDC reserve the right to enact Regulation 8(2)(b) of the Health Research Regulations (HRRs) and may refuse an application. The HRCDC discussed that the further information requested in relation to 19-011-AF3 should be provided by the Applicant in advance of the

	next scheduled HRCDC meeting on 28th January 2020. If no response is provided, then the HRCDC may refuse the application as provided for in the HRRs. The Secretariat will communicate this to the Applicant.

8. Returning Applications - For Consideration

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 & Purpose of Application:	See HRCDC Meeting minutes of 17th October 2019
Points to Discuss:	The HRCDC considered the Applicant's response to the HRCDC's request for further information in the decision letter of 1st November 2019. See HRCDC Meeting minutes of 17th October 2019.
HRCDC Comments:	The Chair introduced the agenda item and reminded members of the further information that was requested from the Applicant. The Chair invited members to comment on the Applicant's responses. Based on the response letter received, the consensus of the HRCDC was that a consent declaration could be made. The decision was based on the following discussion points: **Public Interest Case** • The HRCDC commented that the study was ambitious as it aimed to collect 6000 samples for broad use in Alzheimer's Disease research, as opposed to addressing a specific and defined research question. • The HRCDC agreed that there is a strong public interest in the study as it has the potential to contribute to the development of new therapeutics in the area of Alzheimer's Disease (AD) through the sharing of non-identifiable data via the GMI database. In addition, when determining the public interest case, the HRCDC acknowledged that it was not possible to obtain explicit consent from many participants who live with AD. **Open Data** • The HRCDC acknowledged the Applicant's response in relation to submitting the data to a publicly available and controlled access repository after a period of time. • It was also noted that the phenotypic and genomic data of participants recruited at a specific site will in due course be made available for access and use by that institution, subject to the terms and conditions of any governing legal contract. • It was recognised that currently there is no national policy setting out guidelines as to how genomic data can be made publicly available. • It was discussed by the HRCDC that the benefit to the public would be further enhanced by making the data available in a deidentified manner in a controlled public repository for access by researchers in other institutions to enable further discoveries to be made. **Determining Capacity**

	• The HRCDC discussed the Applicant's response on how consent is sought from another individual acting as a proxy, where the study participant does not have the decision-making capacity to provide explicit consent. • It was discussed that the process outlined by the Applicant to determine a participant's capacity to consent appeared to be appropriate. However, it was queried whether representatives of GMI, specifically the GMI study monitors, are involved in determining the capacity of a study participant. • The HRCDC also noted that efforts are made to engage and communicate with study participants when determining their decision-making capacity. **Proxy Assent Process** • The HRCDC acknowledged the Applicant's response that it would not be possible to obtain the explicit consent of participants in approximately 70% of cases. • It was highlighted that current data processing legislation does not allow consent to be provided by another individual on behalf of the study participant. Therefore, the Applicant's response that the HRCDC can decide if 'proxy' assent is considered valid consent is beyond remit of the HRCDC. • The HRCDC noted that consent provided by an appropriate individual on behalf of the study participant can be considered an appropriate data protection safeguard for participants who do not have decision-making capacity. • The HRCDC discussed the Applicant's suggested process for identifying the most appropriate individual to provide proxy consent on behalf of the study participant; it was discussed that this will likely be a relative, close friend or carer of the participant. However, the HRCDC commented that no detailed criteria for identifying the most appropriate individual was provided by the Applicant. • The HRCDC also acknowledged the Applicant's response outlining how a participant who does not have capacity to provide explicit consent, will still be involved in the decision-making process. It was noted that participants will be provided the opportunity to indicate, to the best of their ability, who can provide consent on their behalf. Engagement and consultation with participants who lack decision-making capacity was considered an important safeguard by the HRCDC. • Although no official guidance exists on who maybe the most appropriate individual to provide consent for data processing on behalf of the study participant, the HRCDC stated that the Applicant must implement a clear and robust process for identifying the most appropriate individual who understands the will and preferences of the participant. As part of this process, the researchers must also first determine if the participant has a legally appointed representative and seek consent from them were applicable. **Withdrawal of consent**

	• Further information was provided by the Applicant on who can withdraw consent and what happens to the personal data and samples when consent is withdrawn. • When obtaining consent, the HRCDC was of the view that participants, and those providing consent on their behalf, should be provided with further information on the point at which personal data cannot be removed from the GMI database if consent has been withdrawn. This would provide an additional safeguard, in particular for individuals providing consent on behalf of the participant. • It was discussed that an estimated timeline from the collection of samples and personal data, to its processing and inclusion in the GMI database should be provided. **Consent Forms** • It was noted that the updated Patient Information Leaflet (PIL) and consent form provided by the Applicant contained further information on the study. • It was noted that the consent form listed only a 'Yes' tick boxes option, and not separate 'Yes' or 'No' options in certain sections of the consent form. The HRCDC discussed that the inclusion of both 'Yes' and 'No' options may reduce the risk of ambiguity for the consent was obtained for. • The HRCDC were of the view that two versions of the consent form should also be used; i) for participants with decision-making capacity to consent, even though they have a diagnosis of AD; and ii) for those who lack such capacity and where consent is provided on their behalf by a proxy individual. **Comparative database** • The HRCDC noted the Applicant's response that the data collected and analysed in this study may be used as a comparative dataset for other studies undertaken by GMI, including non-AD studies. It was acknowledged that the data collected within this study has value as a useful comparative dataset and that this use is also outlined in the PIL and consent form. • It was discussed whether the declaration made for the specific GMI AD study should extend to this processing activity. It was noted that the HRCDC application form submitted does not outline the safeguards and data protection measures that will be applied when linking the AD dataset with other disease cohort datasets and studies in GMI. • It was determined that the Applicant should submit a Declaration Amendment request to the HRCDC if they wish to undertake this form of data linkage.
HRCDC Declaration Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made.
Conditions Attached:	**Condition 1.** The Applicant is required to develop a data sharing policy which can be implemented in practice to facilitate the controlled sharing of de-identified genomic data derived from this study, with the wider research community. The Applicant is required to provide an update on

	the progress of the policy and timelines of implementation in the Annual Review. *Note for context:* The HRCDC is of the strong view that the benefit to the public and patients with Alzheimer's Disease would be further enhanced if the genetic data derived from the study is made accessible to the wider research community in a de-identified and controlled manner through publicly available repositories. It is acknowledged that currently there is no national policy setting out guidelines as to how genomic data can be made publicly available. However, there are international repositories established, such as for example, the Database of Genotypes and Phenotypes (dbGaP), the European Genome-phenome Archive (EGA) and the Global Alzheimer's Association Interactive Network (GAAIN) which can facilitate data sharing. **Condition 2.** The Applicant is required to stay abreast of and engage with stakeholders on evolving national policy and guidance in the area of open data and open science. The Applicant is required to provide updates on these discussions within the Annual Review. *Note for context:* The HRCDC acknowledges the Applicant's response that guidance from the relevant Irish authorities in the area of genomic data access remains outstanding and that input from a number of stakeholders, including the Department of Health and the Institutions involved this study, would be required. **Condition 3.** The Applicant is required to ensure there is an established and appropriate protocol implemented for determining capacity and correspondingly obtaining assent from a relative or friend, with specific attention to the points outlined below; The following points were raised by the HRCDC: - It is essential that participants who may lack decision-making capacity, at whatever level, are afforded every opportunity to engage with the consent process and are included in all discussions. - There must be assurances that the individual identified to provide assent is the most appropriate individual who can communicate on behalf of a participant and understands the participant's will and preference in this regard. Unless it's not possible, the individual providing proxy assent should be agreed by the participant in advance. Particular attention should be paid in the case where a non-relative carer is being considered. - Where it is determined that a participant does not have the capacity to provide explicit consent the protocol should first determine if the participant has a legally appointed representative, or enduring power of attorney. It should be clearly documented on the consent forms, where appropriate. The protocol and its implementation must be documented by the Applicant.

	Condition 4. In relation to the PIL and consent form, the Applicant is required to ensure the implementation of the following; i) Two versions of the PIL and consent form should be produced; one for those who have the capacity to provide consent, and one for individuals providing proxy consent (assent) on behalf of participants who lack decision making capacity; and ii) Amendment of the PIL and consent form so that a participant, or the individual assenting on their behalf, is aware of the expected timeline for when the samples and personal data will be processed and subsequently included in the GMI database, after which point it will not be possible to remove the data from the study should consent be withdrawn. iii) Reconsider amending the title 'Informed Consent Form' to state 'Assent Form', for cases where a relative or friend agreeing on behalf of participant. **Condition 5.** It is a condition of the declaration that the scope of the declaration does not extend to the processing activity of linking the Alzheimer's Disease datasets with other disease datasets within GMI. Where the Applicant intends to use the Alzheimer's Disease data as a comparator dataset within other GMI studies a Declaration Amendment request should be submitted to the HRCDC for this form of data processing. *Note for context:* It is acknowledged that the data collected within this study has value as a useful comparative dataset, to be linked with disease datasets derived from other GMI studies and that this use is outlined in the PIL and consent form. However, the information provided in the application form does not outline the safeguards and data protection measures that will be applied when linking the AD dataset to other disease cohort datasets to ensure data protection rights and freedoms. **Condition 6.** Please confirm that those involved in the recruitment of patients and determining their capacity to consent is only undertaken by the Clinical Team within the hospitals and is not in any way determined or influenced by GMI Monitors. **Condition 7.** All appropriate contractual arrangements including those that govern the collection and transfer of samples and data, must be in place and executed with the relevant hospital sites, before data can be collected at that site.
Duration of Declaration	The Declaration is made commencing December 16th, 2019 and shall be valid for 20 years after commencement of the study at the last hospital site or until December 31st, 2040, whichever is the later.

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 & Purpose of Application:	See HRCDC Meeting minutes of 25th November 2019
Points to Discuss	The HRCDC considered the Applicant's response to the HRCDC's request for further information in the decision letter of 9th December 2019. Signatures on the HRCDC application form from St. James' Hospital and Tallaght University Hospital as Joint Data Controllers remained pending. The Applicant respectfully requested the HRCDC to make a decision on their application at the meeting to prevent further delays in study recruitment.
HRCDC Comments:	• The HRCDC was informed of the Applicant's request and the Secretariat noted that the request for DPO feedback on the DPIA from each Data Controller has been provided; only Data Controller signatures on the HRCDC application remained outstanding. • With the exception of the outstanding signatories it was discussed that the applicant had provided the remaining information required by the HRCDC to make declaration decision. It was noted that the HRCDC were, in principle, in favour of making a declaration at the 25th November meeting. • The HRCDC stated that they did not wish to cause unnecessary delays for the study and therefore it would be appropriate to make a declaration on the condition that the outstanding Data Controller signatures are provided as soon as possible. • As an additional safeguard it was determined that the declaration will not cover the processing of personal data without the explicit consent of the participant's at St. James' Hospital and Tallaght University Hospital (Joint Data Controllers), until the required signatures on the HRCDC application form have been provided. This is in addition to the requirement to have Research Ethics Committee (REC) approval in place at these two sites.
HRCDC Declaration Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made
Conditions Attached:	**Condition 1.** This declaration is made on the condition that the outstanding Data Controller signatories on the HRCDC application, for St. James' Hospital and Tallaght University Hospital are submitted as soon as possible, and no later than January 17th, 2020. Processing of data from these sites cannot commence at these two sites until these signatures are provided to the HRCDC. **Condition 2.** Confirmation of Research Ethics Committee approval from Tallaght University Hospital and St. James' Hospital must be provided to the HRCDC, once granted. No data processing can commence at these sites until such written confirmation is provided to the HRCDC. **Condition 3.** It is noted from the information provided to the HRCDC, that data sharing agreements are currently being established between the HSE and the five participating hospitals. As the HSE, St. James and Tallaght University Hospital have now been confirmed as Joint-Data

	Controllers, an appropriate Joint Data Controller arrangement also should be in place between these parties. It is advisable to discuss this with each Institution's legal office and Data Protection Office, as necessary.
Duration of Declaration:	The Declaration is made commencing 16th December and shall be valid for three years after the commencement of the study at the last hospital site or until December 31st, 2022, whichever is the later.

New Applications

Reference ID:	19-002-AF1
Lead Applicant:	Neil Crowhurst
Lead Data Controller:	Health Service Executive Waterford Institute of Technology
Title:	A retrospective case analysis of serious untoward incidents in super catchment mental health services in the HSE South East.
Application Summary:	Mental health services in the counties of Waterford and Wexford were amalgamated in 2011. Concern has been expressed about the level of serious incidents involving users of mental health services. This study proposes to look at the collective contextual issues which may contribute to serious incidents occurring which may include psychiatric morbidity, use of alcohol and drugs, the physical environment and external issues such as homelessness.
Purpose of Application:	The project will involve the principal investigator reviewing personal data in the form of incident reports and from the patient's notes without explicit consent. A pilot exercise to review 10 charts will also be undertaken within this study for reliability and research quality purposes.
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:** • The HRCDC was of the view that the research objectives outlined by the Applicant appear ambitious for a single study that focuses on a review of existing reports and medical charts. Nonetheless the HRCDC commented that the findings of this study have the potential to contribute to an important and unmet area of research that aims to benefit both patients and the wider health service. • It was discussed that the study provides an opportunity for reflective practice on serious untoward incidences in mental health services, which also has a strong public interest case. **Obtaining Consent** • The HRCDC discussed the Applicant's case for not seeking the explicit consent of the study participants. • It was noted that the study will review the medical charts of approximately 100 patients who have been involved in a serious

	untoward incidence; it was commented that obtaining consent from this number of participants could be considered practicable. • However, the HRCDC referenced the information provided by the Applicant which outlined why it is not appropriate to seek the consent of participants. It was noted that obtaining consent was considered early in the study design, however the REC raised concerns that doing so could cause potential distress to the participants. **Transparency** • The HRCDC acknowledged the development of an information leaflet to inform individuals about the study. However, as consent will not be obtained the HRCDC stated that further efforts should be made to inform participants and staff about this study before the commencement of data collection, for example through public notices within each of the institutions/sites where data is collected. • It was also determined that the enhanced transparency arrangements should incorporate information on how participants can withdraw from the study. **Joint Controllership** • The HRCDC discussed the applicant's responses in relation to the data controllership of the study. It was highlighted that where there are joint data controllers a joint data controller arrangement should also be in place. **Other** • The HRCDC noted that the Applicant will be undertaking a pilot study involving approximately 10 medical charts and that the scope of a declaration, if made, would include this activity • The adequacy of the security measures in place to protect the data were queried, specifically the email system used to transfer the personal data and the researcher's laptop. • The Secretariat referenced the information provided in the application form and the data sharing agreement outlining the security measures used.
HRCDC Declaration Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made
Conditions Attached:	**Condition 1.** In addition to the staff and patient information leaflets developed, to further enhance the data protection principle of 'transparency', the Applicant is requested to ensure more robust transparency arrangements are in place to inform staff and patients about this study and the data being used for the study. Transparency can be enhanced by way of providing public notices at the relevant mental health services sites involved in this study. These notices should include relevant contact information and practical steps for individuals who may wish to withdraw from the study, if they believe their personal data may be included. The notices should be clearly visible at each site and in place prior to data collection commencing at that location. Other means of making the information about the study publicly available, should be considered, as appropriate.

	NOTE: Further information on providing transparent information can be found on the Data Protection Commission's website; https://www.dataprotection.ie/en/organisations/know-your-obligations/transparency. It is advisable to consult with the Institution's Data Protection Officer as needed. **Condition 2.** As the Health Service Executive & Waterford Institute of Technology have now been confirmed as Joint-Data Controllers, an appropriate Joint Data Controller arrangement also should be in place between these parties. It is advisable to discuss this with the Institution's legal office and Data Protection Officer, as appropriate.
Duration of Declaration:	The Declaration is made commencing December 16th, 2019 and shall be valid until 31st March 2023 or upon confirmation that the data has been rendered anonymised or destroyed, or whichever occurs sooner.

Reference ID:	19-052-AF1 ***[SUBSEQUENTLY WITHDRAWN, JANUARY 2020]***
Lead Applicant:	Susan Knowles (NMH) Stephen Smith (TCD)
Lead Data Controller:	National Maternity Hospital (NMH) Trinity College Dublin (TCD)
Title:	GENESIS: the genomic landscape of neonatal Escherichia coli sepsis
Application Summary:	This study aims to determine if there is a statistically significant relationship between *E. coli* isolates and the risk factors associated with the development of neonatal sepsis. Escherichia coli is associated with maternal and neonatal sepsis. Recent evidence has suggested that *E. coli* has become the most important pathogen associated with early-onset sepsis in preterm very low birthweight (VLBW) neonates, with a marked increase in the incidence of early-onset and late-onset sepsis arising from antibiotic-resistant *E. coli*. Little is known about the contemporary genetic determinants and antimicrobial susceptibility patterns of *E. coli* associated neonatal sepsis in Ireland (Corcoran *et al.* 2016). Therefore, through the use of next generation sequencing, the study aims to analyse the virulence factor genes, serotypes and antibiotic resistance genes of *E. coli* isolates from neonatal and maternal cases of early onset/late onset sepsis. This research study intends to analyse the data generated from next generation sequencing to determine the genetic relationship between *E. coli* isolates. Additionally, this project intends to investigate the relationship between the pathogen (*E. coli*) and the clinical outcomes.
Purpose of Application:	The data to be used for this study would have already been collected during the care of the patients (Mother and Neonates) in the NMH. No extra information is being solicited from the patients. The data will be pseudonymised by clinical collaborators, the identity of the patient and hospital identifier number will be unknown to TCD/Dr. Smith or other collaborators. Consent was not obtained from the patients. The study is drawing down from clinical data and *E.Coli* isolate samples derived from blood, urine, vaginal and placental swabs and cerebrospinal fluid.
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 case** • The HRCDC discussed and agreed that the research aimed to answer an important research question and there was a strong public interest case in this study. **Obtaining consent** • The HRCDC discussed whether it was possible and/or appropriate for the Applicant to seek the consent of participants who have previously been admitted to the NMH (retrospective participants) and those who will be admitted during the remaining lifetime of the study (prospective participants). • It was stated that more information could have been provided on why attempts to seek the consent of retrospective participants or to provide them with further information on the study were not made. In addition, it was queried why participants could not be consented at any follow-up visits. • The projected number of study participants from the NHM was noted to be relatively small and this was an important factor when determining if consent can be practically obtained. • The HRCDC was of the view that it would not be unreasonable or impracticable for the Applicant to seek the consent of prospective participants, therefore the Applicant should be requested to outline what consent process could be established and implemented for the processing of personal data for prospective study participants. **Previous consent** • The HRCDC discussed that the NMH, among other hospitals, may have previously implemented an internal consenting process whereby women admitted to the hospital were asked to provide general consent for the use of their samples and personal data in future research. Therefore, determining whether participants in the retrospective cohort refused to provide consent previously is important to consider as a declaration cannot override the participant's wishes. • The HRCDC stated that if such a process was undertaken by the NMH, then the Applicant should ensure that study participants included in the retrospective cohort, and for which a declaration is sought, exclude women who explicitly did not agree to provide consent for the use of their samples and data in future research.. **Transparency** • Ensuring participants are aware of the study is important when processing personal data for health research without the explicit

	consent of the data subject. The HRCDC noted that the principle of transparency should and could be enhanced for this study. **Other** • It was discussed that further clarity could have been provided by the Applicant on the study methodology and data flow. • The HRCDC discussed that researchers and patients could benefit in the future if hospitals were to implement a standard process for obtaining broad consent, compliant under data protection legislation, for the use of patient samples and data in future research. • The HRCDC queried if the *E.Coli* isolates used in the study are considered human biological material. The Secretariat referenced the Applicant's response that no human biological material is used in this study, only bacterium, although these samples are still derived from a patient. • The HRCDC noted that one of the deliverables of the study is the establishment of a microbial repository at the National Children's Research Centre for the storage of the *E.Coli* samples and *E.Coli* genomic DNA samples. The HRCDC discussed that the repository appeared to be related to the storage of *E.Coli* samples for the lifetime of the study and is not designed to act as a repository for future research. In addition, it was noted that the scope of a declaration, if made, would be solely for the GENSIS study until 2022, at which point the data will be anonymised. • The HRCDC discussed the extent of participant clinical data that is collected and processed for the study. The Applicant referenced that much of the data collected from the study has been made public; it was clarified that incidents of infection are publicly reported by hospitals in an aggregated and de-identified format. • The HRCDC commented that there appeared to be limited public patient involvement and/or consultation in the study. • The Secretariat highlighted the correspondence with the REC; the Secretariat wished to clarify to the REC that the required REC approval (or provisional approval) must be in place before an application for a consent declaration can be considered by the HRCDC.
HRCDC Declaration Decision:	The consensus of the HRCDC was that a formal decision would be deferred pending receipt of further information
Further Information Requested:	**Query 1.** It is unclear from the information provided to the HRCDC whether the National Maternity Hospital had previously implemented a consenting process, whereby women admitted to the hospital were consented for the retention of their bio-samples and personal data for use in future research. If bio-samples and data were collected under consent, it is also unclear what arrangements are in place to ensure that data and bio-samples from individuals who did not consent, are not included the study. Clarity on the following points is requested; **i)** did the NMH previously implement a process for obtaining consent for the use of bio-samples and data for general future research use; and

	ii) if a consent process was in place during the period 2008-2017, which relates to the retrospective cases that are the subject of this application, please provide the consent and patient information leaflets used at the time; and **iii)** if consent was sought, what arrangements are in place to ensure that participants who did not agree to provide consent, are not included in the retrospective cohort for this study. **Query 2.** In relation to the use of the retrospective samples and personal data for inclusion in this specific study; **i)** please elaborate as to why no attempt was made to seek explicit consent for the 150 cases identified; and **ii)** please outline what transparency arrangements will be place in place to ensure individuals identified for the study will be informed of the use of their data and samples for the study. For example, has the Applicant considered the provision of information leaflets or developing publicity notices? **Query 3.** The HRCDC is of the view that it should be possible to obtain explicit consent from participants for prospective sample and data collection. The Applicant is requested to indicate their willingness to put in place a consent process for prospective sample collection and provide information on the type of process that would be put in place and the timeline for commencement.

Reference ID:	19-014-AF2
Lead Applicant:	Jochen Prehn Annette Byrne
Lead Data Controller:	Royal College of Surgeons in Ireland (RCSI)
Title:	COLOSSUS Study
Application Summary:	Colorectal cancer is one of the most common cancers in Europe. This type of cancer can involve a number of different mutations (known as 'MSS RAS mt mCRC'), however there are limited treatment options for patients when they develop resistance to standard therapies. COLOSSUS is an international, multi-site consortium study that aims to study patient samples and apply advanced computational modelling approaches to identify new and specific 'subtypes' of this form of cancer. Subtyping is a way of looking more closely at the differences and similarities between different tumours and grouping similar tumours together with the aim of treating them differently. This strategy aims to help predict patient outcomes and to enable the design of more targeted and personalised care. In Ireland clinical data and tumour samples are obtained from the Bowel Disease biobank in Beaumont Hospital.
Purpose of Application:	A consent declaration is sought for the use of retrospectively collected samples and clinical data (approximately 50 samples) that has been obtained by the Beaumont Hospital Bowel Disease Biobank, for the COLOSSUS Study. The Applicant states that patients who provided consent for the biobank also for the future use of their tissue and data in studies approved by a REC. Although the Applicant states that the

	consent obtained does not necessarily limit the nature of collaborations and use of samples and data from the biobank by either country or sector (i.e. academic/ non-academic), the work being undertaken by the COLOSSUS study may not align with the scope of consent obtained for the biobank for the following reasons; The PIL and Consent form: i) Did not inform participants that such studies may include industrial/commercial collaborations and that there might be the potential for commercialisation ii) Did not specifically note that the nature of future studies may involve collaborations or studies that take place outside of Ireland iii) Originally stated that data will be held for 10 years; pseudonymised data has been retained beyond this. Based on points (i) & (ii) above, the Applicant states that this consent may be considered too broad for COLOSSUS.
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: **Previous Consent** • The HRCDC queried why a declaration was necessary for this study as the Applicant is using samples from a biobank that had obtained consent. • The Secretariat referenced the Applicant's response that a declaration is sought because the consent obtained for the biobank does not directly inform the participant that future studies may include commercial and international collaborators, however the Applicant also stated that the consent does not exclude such activities. • The HRCDC queried whether participants who provided consent at the time for the biobank would be surprised that their samples and data were to be used for this type of study. The HRCDC was of the view that this was unlikely considering the consent already provided however the Applicant's reasons for seeking a declaration was acknowledged. • The Secretariat informed the HRCDC that a declaration has been made for the biobank (HRCDC Ref ID 19-031-AF2), which the COLOSSUS study is accessing. The declaration made for the biobank was for the continued maintenance of the biobank and additional retention period for processing of samples and personal data within the scope of the consent already obtained. • It was also highlighted to the HRCDC that RCSI is a data controller for the COLOSSUS study and a joint data controller for the biobank. In addition, it was noted that the RCSI Principal Investigator (PI) on COLOSSUS and is also a PI on the biobank. • In view of the role of RCSI and the PI it was noted that the personal data and samples from the biobank is unlikely to be considered anonymised within the COLOSSUS study.

	Re-consent • It was noted that the declaration only relates to approximately 50 samples from the biobank. In the context that the biobank and COLOSSUS have the same data controller and PI, the HRCDC discussed whether it was practicable and reasonable to obtain re-consent from this small cohort of participants. • Reference was made to the response in the application form which reflected the rationale previously outlined in 19-031-AF2, for not seeking re-consent in this separate application to the HRCDC. It was agreed that obtaining re-consent for the COLOSSUS study would therefore not be appropriate. **Scope of Declaration** • The HRCDC confirmed that a declaration will only cover the processing of personal data within the COLOSSUS study and does not extend to other research studies.
HRCDC Declaration Decision:	The consensus of the HRCDC was that a Consent Declaration should be made
Duration of Declaration:	The Declaration is made commencing August 8th, 2018 and shall be valid until 31st December 2027 or upon confirmation that the data has been rendered anonymised or destroyed, or whichever occurs sooner.

9. Activities
Emily Vereker (EV) provided an overview of the Activities Report which was provided to the HRCDC in advance of the meeting. The HRCDC was also informed of upcoming events that may be of interest to members.

10. Overview of 2019
Jonny Barrett (JB) provided a brief statistical overview of the HRCDC activities in 2019. EV noted that an Annual Report is due to be submitted in March 2020. The HRCDC also discussed the number of applications that are pending consideration.

11. Future Meetings
The HRCDC was informed that an electronic poll for meeting dates in the latter half of 2020 will be circulated.

12. Expenses
The HRCDC was reminded to submit any expense claims

13. AOB
The Chair thanked HRCDC members and the Secretariat for their work during 2019. The HRCDC thanked the Chair for her facilitation of the meetings.

The Chair closed the meeting.

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