HRCDC
Health Research Consent Declaration Committee

Time: 2 - 5pm
Date: March 2nd, 2020
Location: Health Research Board, Grattan House, Lower Mount St. Dublin 2, Ireland

Minutes of Meeting[1]

HRCDC Attendance

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

Quorum for Decisions
☒ **YES**

Live Declarations

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
Michael Farrell	19-006-AF3	The contribution of Whole Genome Sequencing to Brain Tumour Biology
Jochen Prehn / Annette Byrne	19-014-AF2	COLOSSUS Study
Rose Anne Kenny	19-022-AF2	TILDA
Rose Anne Kenny	19-043-AF2	General Register Office - TILDA
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Returning Applications - Withdrawn

Applicant	Ref No.	Title
Gianpiero Cavalleri	19-011-AF3	Irish Traveller Ancestry Study
Susan Knowles / Stephen Smith	19-052-AF1	GENESIS: the genomic landscape of neonatal *Escherichia coli* sepsis

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

New Applications

Applicant	Ref No.	Title
Shona Pfeiffer	19-085-AF1	Blood Biomarkers to predict recovery from Ischaemic Stroke
Ignacio Martin Loeches	19-086-AF1	Sepsis Immunosuppression in Critically Ill Patients
Paul Corcoran	19-021-AF3	National Self-Harm Registry Ireland
Fergus McCarthy	19-019-AF2	IMPROVED Study (Improved Pregnancy Outcomes by Early Detection)
Mairead Kiely	19-018-AF2	COMBINE Study (The Cork Nutrition and Microbiome Maternal-Infant Cohort Study)

Meeting Items

1. **Opening**
   The Chair opened the meeting and welcomed the members. The Chair thanked the members for convening again at short notice.

2. **Apologies**
   Sheelah Connolly, John Ferguson, Simon Furney, Malcolm Kell, Barry O'Sullivan.

3. **Meeting of February 25th, 2020 - No Quorate:**
   Due to unforeseen circumstances, some members were unable to attend the scheduled HRCDC meeting of February 25th, 2020 and the meeting was not quorate. However, the Chair and members who could attend agreed that in accordance with the HRCDC Standard Operating Procedures (SOPs; Section 4.13), the attending members could proceed with the February 25th meeting and develop advice regarding the applications and other agenda items.

   This advice was recorded by the Secretariat and circulated to all HRCDC members in advance of the meeting of March 2nd, where a full quorum was in attendance to consider the agenda items herein. It was agreed that the advice of members from the February 25th meeting would be captured in the minutes of March 2nd, 2020.

4. **Matters arising:**
   The following items were discussed on February 25th and again at the quorate meeting on March 2nd.

   4.1 - HRCDC Membership
   The Chair discussed attendance at the meetings in 2019 and noted that most meetings have moderate to high numbers in attendance. Some dates and days of the week are not workable for some members during the year.

   There is a benefit in a wide range of views and experience at meetings and in the context of discussions with the Department of Health about a replacement member, it is proposed to suggest to the Department of Health the appointment of up to 5 extra members to facilitate meetings. Committee members were asked to input on skills/expertise that might usefully be

added. While recognising that issues can arise for members unexpectedly there was a discussion of practical steps that might help minimise risk of meetings that are not quorate.

4.2 - Operations - **HRCDC Application review**

The members discussed different models for reviewing applications to help manage the large workload of the HRCDC more efficiently. One option discussed was if a lead reviewer and co-reviewer, consisting of one 'Patient Public Involvement' (PPI) member and another HRCDC member, should be assigned to each application. All other members would be invited to comment on each application at the meeting. A similar option discussed consisted of dividing the applications equally between HRCDC members whereby each member would be assigned a proportion of the applications; again, all members would be invited to comment on each application.

The HRCDC considered if the role of the Secretariat at meetings could include introducing and summarising the applications. In particular the Secretariat could highlight what additional information was requested from the Applicant after triaging the applications. It was agreed that this process could be trialled at the next HRCDC meeting.

The members also discussed revising the format of the meeting such that all new applications will be considered first on the agenda, followed by returning applications. The HRCDC and Secretariat briefly discussed the number of pending applications for consideration and the expected amendments to the Health Research Regulations.

4.3 - Operations - Timelines for Publishing Minutes & Decisions

The members discussed and considered it reasonable that only minutes and decisions relating to applications that have completed the deliberative process should be published on the HRCDC website. The publication of the application log should also be aligned with the position of the minutes.

It was discussed that the HRCDC SOPs should be amended to reflect this new process and be consistent with the position taken when releasing requested records under the Freedom of Information Act, 2014.

4.4 - Updated HRCDC Application form

The Secretariat informed the members that a revised HRCDC application form has been drafted and circulated to members. The updated form is designed to be more user friendly for Applicants and ensure the information required for the HRCDC is complete. An informal stakeholder working group has been set up to assist with the review process which includes former Applicants, a Data Protection Officer (DPO) and members of the HRCDC.

4.5 - Legal Representative

The Secretariat provided an overview of the current legislation on Clinical Trials of Medicinal Products for Human Use and the National Consent Policy. Both use the defined term 'legal representative' for consenting individuals who lack decision-making capacity. It was discussed that this term is broadly used in health research and can be confused with a 'legally authorised representative' such as an enduring Power of Attorney, or a committee of a ward of court.

4.6 - HRCDC, REC remit

The differentiating role of the Research Ethics Committee (REC), which approves the research study protocol, and the role of the HRCDC, to consider applications and make a declaration solely for the processing of personal data in health research, was also discussed.

5. Minutes of the last meeting

Draft minutes of the 16th December meeting were circulated in advance and were agreed by the HRCDC.

6. Disclosure of Interest

There were no disclosures of interest recorded for this meeting.

7. Live Declarations – Response to Declaration Decisions

A number of Applicants provided responses accepting the Decision made by the HRCDC or providing an update in relation to a condition attached to a Declaration made by the Appeal Panel:

Reference ID:	19-002-AF1
Lead Applicant:	Neil Crowhurst
Lead Data Controller:	Health Service Executive
Title:	A retrospective case analysis of serious untoward incidents in super catchment mental health services in the HSE South East
Application Summary:	See HRCDC Meeting minutes of 16th December 2019.
Points to Discuss:	The Applicant responded to the HRCDC decision letter of 20th 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.

Reference ID:	19-006-AF3
Lead Applicant:	Michael Farrell
Lead Data Controller:	Genomics Medicine Ireland Ltd.
Title:	The contribution of Whole Genome Sequencing to Brain Tumour Biology
Application Summary:	See HRCDC Meeting minutes of 13th June 2019; Appeal Panel minutes of 3rd September 2019 and HRCDC Meeting minutes of 17th October 2019
Points to Discuss:	The Applicant informed the HRCDC that there will be a delay in meeting the deadline for a condition attached to the declaration made by the Appeal Panel. This condition relates to the launch of a publicity campaign.
HRCDC Comments	The HRCDC acknowledged the Applicant's response and accepted the short delay to the launch of a publicity campaign. The Secretariat clarified with the Applicant that the HRCDC is not responsible for approving any publicity material but only requires a final copy for noting and confirmation that the publicity campaign has commenced.

Reference ID:	19-014-AF2
Lead Applicant:	Jochen Prehn / Annette Byrne

Lead Data Controller:	Royal College of Surgeons in Ireland
Title:	COLOSSUS Study
Application Summary:	See HRCDC Meeting minutes of 16th December 2019.
Points to Discuss:	The Applicant responded to the HRCDC decision letter of 20th 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.

Reference ID:	19-022-AF2
Lead Applicant:	Rose Anne Kenny
Lead Data Controller:	Trinity College Dublin
Title:	TILDA
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.

Reference ID:	19-043-AF3
Lead Applicant:	Rose Anne Kenny
Lead Data Controller:	Trinity College Dublin
Title:	General Register Office - TILDA
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.

Two other responses to previous Declaration Decisions were discussed by the members on February 25th and the advice recorded was considered at the quorate meeting on March 2nd;

Reference ID:	19-038-AF1
Lead Applicant:	Emer Fallon
Lead Data Controller:	Genomics Medicine Ireland Ltd
Title:	The Genomic Basis of Alzheimer's Disease in Ireland
Application Summary:	See HRCDC Meeting minutes of 17th October 2019 & 16th December 2019
Points to Discuss	The Applicant responded to the HRCDC decision letter of 23rd December 2019 confirming acceptance of the HRCDC's decision to give a conditional declaration, pending clarifications. The Applicant also provided responses in relation to the specific conditions which were highlighted by the Secretariat.
HRCDC Comments/Decision:	The HRCDC acknowledged the Applicant's response and noted that the conditions attached will be monitored as part of the annual review process.

	Based on the response provided by the Applicant to the conditions attached, the HRCDC was of the view that it would be appropriate to respond to the Applicant's acceptance letter to provide clarity on the scope of the declaration made, the role and responsibilities of the HRCDC and to re-emphasise that the HRCDC expect all conditions to reported on in significant detail.

Reference ID:	19-084-AF1
Lead Applicant:	Karn Cliffe
Lead Data Controller:	Health Service Executive
Title:	1 Year post-sepsis study
Application Summary:	See HRCDC Meeting minutes of 25th November, 2019 and 16th December 2019
Points to Discuss	The Applicant informed the HRCDC that, after further internal consultation, the HSE is the sole data controller for this study; St. James' Hospital and Tallaght University Hospital are not joint controllers. Correspondingly the Applicant has requested that the Conditional Declaration be amended to reflect this situation; specifically, Conditions 1 & 2. Members discussed that the responsibility for determining who is a data controller does not lie with the HRCDC.
HRCDC Comments/Decision:	The members discussed and confirmed that the requested amendments to the conditional declaration can be made; therefore Condition 1 and Condition 3 are no longer valid and removed from the declaration. An updated Decision Letter will be forwarded to the Applicant.

8. Returning Applications - Withdrawn

Reference ID:	19-011-AF3
Lead Applicant:	Gianperio Cavalleri
Lead Data Controller:	Royal College of Surgeons in Ireland
Title:	Irish Traveller Ancestry Study
Application Summary:	See HRCDC Meeting minutes of 10th September, 2019
Points to Discuss	The Applicant had responded to the queries of the HRCDC from the September 10th meeting, but has subsequently withdrawn the application for consideration.
HRCDC Comments	The HRCDC acknowledged that the application has been withdrawn.

Reference ID:	19-052-AF1
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:	See HRCDC Meeting minutes of 16th December 2019
Points to Discuss	The Secretariat informed the members that the Applicant has withdrawn their application for consideration.
HRCDC Comments	The HRCDC acknowledged that the application has been withdrawn.

9. New Applications

Reference ID:	19-085-AF1
Lead Applicant:	Shona Pfeiffer (RCSI)
Lead Data Controller:	Royal College of Surgeons in Ireland Beaumont Hospital
Title:	Blood Biomarkers to predict recovery from Ischaemic Stroke
Research Objective	The overall aim of the research is to examine the unique molecular profile present in blood samples from patients suffering ischaemic stroke and to examine the relationship between these blood biomarkers and clinical outcome. This will identify a unique molecular signature associated with ischaemic stroke and provide invaluable information for the development of specific miRNAs as clinically relevant diagnostic and prognostic blood biomarkers. Furthermore, identification of potential therapeutic targets has significant potential for better success in the development and translation of novel neuroprotective and therapeutic agents to limit progressive neuronal damage and death in ischaemic penumbra
Reason for Declaration	The Applicant is seeking a declaration for the purpose of processing data where participants lack decision-making capacity.
HRCDC Comments:	The Chair introduced the research study and provided an overview of the advice that was developed by members on the meeting of February 25th. The Chair invited members who could not attend the February 25th meeting to provide comments and 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. The following are the discussion points raised from both the February 25th and March 2nd meetings: **Public Interest** • The HRCDC commented that although the application was challenging to read, there was a strong public interest case in this study due to the nature of the disease and its impact on people's health. **Deferred Consent** • The HRCDC queried the deferred consent process outlined by the Applicant, with specific reference made to the timeline for obtaining deferred consent and the timeline for taking of samples. • The response from the Applicant that samples will be destroyed, and no clinical data will be obtained, if deferred consent is not provided was noted as an important and appropriate safeguard by the HRCDC. The study aims to obtain deferred consent within 12 hours of hospital admission. • The HRCDC discussed whether the Applicant should be asked to report on the actual timeframe for retaining the samples and corresponding personal data if the participant does not regain

	decision-making capacity and/or if deferred consent is not provided. The HRCDC also queried whether in practice, the samples and personal data should be held for more than 12 hours without consent. • The HRCDC was of the view that other additional reporting requirements could include the proportion of participants where deferred consent is not provided and proportion of participants who do not regain capacity. **Remit of the HRCDC** • The Secretariat and the HRCDC highlighted and discussed the Applicant's misunderstanding in relation to the role and remit of the HRCDC. • The Secretariat had provided clarity to the Applicant that a consent declaration only relates to processing of personal data. It was noted that the Applicant had confirmed that they understand that that role and remit of the HRCDC relates strictly to personal data processing. • The HRCDC stated that the scope of the declaration will be emphasised in the HRCDC decision letter. **Pre-screening** • The HRCDC queried the process for identifying potential participants. It was noted that the Applicant outlines that the co-investigators, who are consultants in Beaumont undertake this activity. **Public and Patient Involvement** • It was noted that the study was lacking public and patient involvement even though this area of health is an important and common issue. **Other** • It was commented that further information and clarity could have been provided on the specific data processing activities for the study. • It was highlighted that the Patient Information Leaflets (PILs) should have clearer information in relation to the withdrawal of consent; specifically, an indicative timeline after which point personal data cannot be withdrawn from the study.
HRCDC Declaration Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made
Conditions Attached:	The following specific conditions have been attached to the Declaration as follows; **Condition 1:** As part of the Annual Review, the Applicant is requested to i) confirm the timeline for when the samples and personal data are destroyed if a participant does not regain capacity; and

	ii) provide numbers for those who regain capacity, those who lack capacity and the numbers who did not provide deferred consent as part of the Annual Review. **Condition 2**: The Applicant is requested to ensure that appropriate processes are in place regarding the timely destruction of samples and personal data. **Condition 3:** The Applicant is requested to enhance and strengthen the level of PPI in this study and provide information on PPI as part of the Annual Review.
Duration of Declaration	The Declaration is made commencing March 2nd, 2020 and shall be valid until, 31st April 2024 or upon confirmation that explicit consent has been obtained from participants once they regain capacity or that the data has been rendered anonymised or destroyed, or whichever occurs sooner.
Other Observations/ Recommendations	The following recommendation is made by the HRCDC; **Recommendation:** The Applicant is recommended to consider revising the PIL so as to provide an indicative timeline to inform participants providing deferred consent, when personal data cannot be withdrawn from the study.

Reference ID:	19-086-AF1
Lead Applicant:	Ignacio Martin-Loeches
Lead Data Controller:	St. James' Hospital, Dublin
Title:	Sepsis Immunosuppression in Critically Ill Patients
Research Objective	Sepsis is the systemic inflammatory response to infection and is a major health problem in Europe and worldwide, occurring in approximately 2% of all hospitalised patients in developed countries and in 6—30% of all intensive care unit (ICU) patients. Despite international treatment guidelines the incidence of sepsis continues to increase. The diagnosis of sepsis relies heavily on the detection of living microorganisms by identification of the organism responsible for infection; however, the sensitivity of the available screening tests is limited, and results are not immediately available. Until the infectious organism is isolated, potent broad-spectrum antibiotics are given because delay in appropriate therapy is associated with worse outcome. The consequence is often unnecessary antibiotic prescription, which is associated with the development of antimicrobial resistance (i.e., MRSA) and further hospital infections as well as a range of avoidable adverse effects and acquisition costs of antibiotic overuse. This study is being carried out as a feasibility study to determine if a larger study is possible using the same design. The aim of this research is to develop timelier and more efficient methods (using biomarkers) in diagnosing sepsis. This will be achieved by comparing healthcare data and biomarkers across three participant groups: (a) Patients diagnosed with bacteraemia without sepsis on the general ward (b) patients diagnosed with sepsis in the ICU and (c) patients in the ICU without a diagnosis of sepsis.

Reason for Declaration	The study aims to process personal data and samples from a total of 150 patients. This application is being made because this study will involve the processing of data of participants from the ICU who may lack decision-making capacity to provide explicit consent. Relative/next-of-kin assent for participants who lack decision-making capacity to consent, will be sought as a safeguard to represent the will and preference of the participant in relation to use of their samples and data for research. If a participant regains capacity, they will be asked to consent for continued processing of their data. Samples and data will be destroyed if consent is not provided. Some participants may not regain capacity.
HRCDC Comments	The Chair introduced the research study and provided an overview of the advice that was developed by members on the meeting of February 25th. The Chair invited members who could not attend the February 25th meeting to provide comments and 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. The following are the discussion points raised from both the February 25th and March 2nd meetings: **Public Interest** • The HRCDC was of the view that there was a strong public interest in the study. **Legal Representative** • The term 'legal representative' was used interchangeably by the Applicant and this was noted as confusing, as next-of-kin cannot give lawful consent for the processing of their relative's personal data unless they are an enduring power of attorney. It was further noted that the Applicant was operating best practices as advised under the National Consent Policy. • The HRCDC also highlighted that the term 'legal representative' is used in the next-of-kin assent forms. • However, although there is no legal basis for relative assent, the HRCDC discussed that the approach provided an important safeguard for participants who lack decision-making capacity. • The HRCDC also discussed the reference made by the Applicant relating to re-affirming next-of-kin assent; specifically, that this will be undertaken at the discretion of the Principal Investigator and that re-affirming relative assent will not occur if it is deemed inappropriate or insensitive. • It was commented that causing potential distress is by itself not always a justification for not seeking to re-confirm assent and may not be relevant to every individual. However, it was also discussed that it may not be ethical to re-confirm consent in some situations, including if the participant has passed away.

	• It was discussed that an appropriate condition would include more definite timelines on re-affirming next-of-kin assent and reporting on this process as part of the Annual Review. • The HRCDC also recommended that for clarity, the Applicant should consider revising the PIL to remove the term 'legal representative' **Retention of data** • The HRCDC acknowledged that samples and data will be destroyed if next-of-kin assent is not provided or if the participant does not provide consent should they regain capacity. It was queried how soon samples and data will be destroyed in this scenario. • It was discussed that an appropriate condition would be to put in place definitive timelines for the destruction of the samples and data and to report on this in the Annual Review. **Data Controller** • Based on the information submitted by the Applicant, the HRCDC queried the roles and responsibilities of the parties involved in the study and requested clarity from the Secretariat. The Secretariat confirmed that the Applicant had clarified that St. James' Hospital was the sole data controller of the study. • In addition, the Secretariat highlighted that two agreements were provided by the Applicant. The first was an over archiving data transfer agreement to govern all research between St. James' Hospital and Trinity College Dublin. The second was a study specific agreement for 19-086-AF1. • The role of UCD in the study was also queried. The Secretariat referred to the Applicant's response that only UCD laboratory equipment will be utilised in the study to analyse blood samples; UCD personnel are not involved in the study, nor receiving any data. **Public and Patient Involvement** • The HRCDC was of the view that the study could benefit from enhanced engagement from patient representative groups such as 'ICUsteps'. • The HRCDC determined that an appropriate condition would include enhanced PPI in the study. **Information Leaflet and Assent/Consent Forms** • The HRCDC noted that the PIL states that samples will be transferred to 'Trinity College and/or St. James' Hospital. It was noted that samples will be going to both organisations, therefore the use of 'and/or' is not accurate. It was also noted that the forms describe bruising as a potential risk from the study - however it was suggested that in an ICU setting the collection of blood would likely be from an intravenous line and there may not be a risk of bruising. **Other**

	• It was commented that the data flow illustration provided by the Applicant was very useful and welcomed by the HRCDC. • It was noted that the case report form provided by the Applicant appears to have been obtained from ICON. The HRCDC noted that ICON were not referenced within the HRCDC application form and queried if they had a role in the study. The Secretariat would seek clarity from Applicant on ICON's role in the study, if any.
HRCDC Declaration Decision	The consensus of the HRCDC was that a Conditional Consent Declaration should be made.
Conditions Attached:	The following specific conditions have been attached to the Declaration as follows: **Condition 1:** The Applicant is requested to put in place more definite timelines as to when next-of-kin assent would be reaffirmed in situations where the participant does not regain decision making capacity and to report on this condition as part of the Annual Review. *(Please see Recommendation 1)* **Condition 2:** The Applicant is requested to establish definitive timelines for the destruction of the samples and data if consent/next-of-kin assent is not provided or if the participant directly withdraws their consent, and to report on this in the Annual Review. **Condition 3:** The HRCDC are of the view that PPI play an important role in health research studies that benefits the research and the participants. It is also recognised that a number of PPI groups have been established in this research area, such as ICU Steps. The Applicant is therefore requested to strengthen the level of PPI within this study. **Condition 4:** This Conditional Declaration is made for the processing of personal data on the basis of the REC approval that was granted to this study on 15th January 2020. Should the study obtain REC approval for the requested amendments, evidence of this approval must be provided to the HRCDC. For the avoidance of doubt the scope of this consent declaration does not extend to the amended study protocol unless REC approval has been granted. *NOTE FOR CONTEXT: It is acknowledged that the study is currently seeking an amendment from the REC which includes a request to collect other biological samples and to implement a deferred next-of-kin assent process. Information on this REC amendment request was provided to the HRCDC during its consideration process.*
Duration of Declaration	The Declaration is made commencing March 2nd 2020 and shall be valid until, 31st March 2025 or upon confirmation that explicit consent has been obtained from participants once they regain capacity or that the data has been rendered anonymised or destroyed, or whichever occurs sooner.
Other HRCDC observations/ Recommendations:	**Note:** The Secretariat will request the Applicant to provide clarity on the role, if any of ICON in this study.

	The following recommendations will be communicated to the Applicant in the decision letter: **Recommendation 1:** The Applicant is requested to consider the ethics of re-affirming next-of-kin assent, specifically in situations where the participant has passed away. **Recommendation 2:** The Applicant is requested to consider revising the PIL as follows in order to provide clarity to participants and their next-of-kin on the following points: i) That samples will be transferred to both 'Trinity College Dublin **and** St. James' Hospital' (it is currently stated in the information leaflet that samples will be transferred to Trinity College '**and/or**' St, James' Hospital). ii) Removal the term 'legal representative' as under data protection legislation a participant's next-of-kin cannot lawfully consent for the processing of their relative's personal data, except in cases where they are a legally appointed power of attorney. A more appropriate term would be 'next-of-kin assent'.

Reference ID:	19-021-AF3
Lead Applicant:	Paul Corcoran
Lead Data Controller:	National Suicide Research Foundation (NSRF)
Title:	National Self-Harm Registry Ireland
Research Objective	The National Self-Harm Registry Ireland is a national system of population monitoring for the occurrence of hospital-treated self-harm. Specifically, the Registry aims to quantify the extent to which presentations are made to acute public hospitals in Ireland as a result of self-harm; to identify the groups with the highest rates of self-harm presentations and repeat presentations; to identify the methods of self-harm that are employed; and to identify the areas in Ireland with the highest rates of self-harm. The uses of the Registry relate to patient care, public health and epidemiological research. The Registry is a valuable national service evaluation tool as well as a research resource and has contributed to increased knowledge and understanding of suicidal behaviour, thereby facilitating better treatment of the individuals involved. It identifies the groups and areas that most need to be targeted for prevention and intervention.
Reason for Declaration	The consent declaration is sought for the processing (collection, recording, pseudonymisation) of personal data on self-harm presentations (11,600 p/a) to hospital emergency departments for the National Self-Harm Registry Ireland.
HRCDC Comments:	The Chair introduced the research study and provided an overview of the advice that was developed by members on the meeting of February 25th. The Chair invited members who could not attend the February 25th meeting to provide comments and 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 raised from both the February 25th and March 2nd meetings: **Public Interest & Patient Rights** • It was queried whether it would be possible or appropriate for the study to put in place a formalised consenting process considering the nature of the Registry and the data processing activities that are undertaken – namely that this is primarily a national data collection exercise with the data analysed thereafter. • It was discussed that mental health and issues relating to self-harm shouldn't be stigmatised and that it may be appropriate to seek consent. • The HRCDC generally agreed with the Applicant's response as to why it is inappropriate or not feasible to obtain consent. It was further noted that seeking consent will likely bias the data that is collected. • Reference was also made to the Applicant's response that the process they are implementing is in line with international best practices and that the Registry has been commended by the World Health Organisation. It was queried whether there are examples of equivalent international registries that do seek the consent of participants. It was discussed that it the Applicant may have further information in this regard. **Data Minimisation and Access to Records** • Based on the information provided by the Applicant, the HRCDC noted that Data Registration Officers (DROs) appear to be accessing all medical records of all patients admitted to the Emergency Department in the hospitals. • It was queried whether the DROs who are not directly employed by the hospital and who would not normally have access to medical records, should have limited access to only relevant medical records of those who attended the emergency department for self-harm. • It was discussed that most of the hospitals would likely be recording why patients attended the emergency room in a separate data source to the patient's medical records which should help mitigate the need for DROs to review the records of all patients attending the emergency room. • The HRCDC also discussed the level of data collected by the Registry and queried if data could be minimised further by for example, not collecting the specific date of birth or the initials of the participants. **Transparency** • The HRCDC discussed the transparency measures outlined by the Applicant in relation to the Registry, specifically, the Registry Information Leaflet. It was noted that it was not transparent for participants and the public that the DROs could be accessing the medical records of all emergency department attendees.

	• Although participants can withdraw their data from the Registry it was queried how patients could be made aware of this right, or aware of the Information Leaflet in general. • Furthermore, the information provided by the Applicant indicates that hospital permission is required for the Information Leaflet to be made available on their premises. The HRCDC stated that the hospitals should not prevent such transparency measures if they are supporting the remit of the Registry and that there is a responsibility to ensure participants are aware of the study. • It was commented a consistent approach to transparency should be undertaken across the country and that hospitals should be collaborative partners with regard the implementation of transparency notices. • The privacy notice on the Registry's website states that a small fee may apply if a participant wishes to exercise their right to erasure (of their personal data). The HRCDC commented that this was inconsistent with the data protection policy and perhaps misleading, therefore the privacy notice should be updated. **Data Security** • The retention and destruction protocols for the personal data was discussed. It was highlighted that the Applicant states that the shredding of documentation can't be supervised. The HRCDC felt that it should ideally be supervised due to the sensitive nature of the data. • The physical transport of the data, use of USB drives, use of laptops at home and other security processes and protocols were also discussed. • The HRCDC noted that an independent review of the Registry was conducted in 2018 and several recommendations were made. The HRCDC was of the view that it would be appropriate to request more information on the implementation of these recommendations, specifically those related to IT security measures and use of USB drives specifically. **Other** • The HRCDC noted that the Registry had previously consulted with the Data Protection Commissioner. It was discussed that a potential recommendation could include ongoing engagement with the DPCs consultation unit as necessary. • It was discussed that the Registry could include more PPI in future, such as a lay-person and that this could be a potential HRCDC recommendation. • The HRCDC highlighted that the Registry also appears to be obtaining data on deceased individuals from the Central Statistics Office, but this was not referenced within the HRCDC application form.
HRCDC Decision:	The consensus of the HRCDC was that a formal decision would be deferred pending receipt of further information from the Applicant
Further Information Requested:	**Query 1. Consent:** The HRCDC has requested feedback on the following queries with respect to the feasibility of obtaining consent;

	i) Have any international organisations (separate from those referenced in the application) undertaken to consent individuals for the purpose of collecting their personal data for an equivalent registry? ii) Has the NSRF ever tried to carry out pilot study on the feasibility and impact of seeking consent? iii) Given the current endeavours by mental health and suicide support groups to ensure openness and de-stigmatisation regarding mental health issues, has the NRSF consulted with these groups to understand in dept whether individuals do not wish to be consented? Has the NSRF discussed this matter in-depth with the newly established planning group? **Query 2: Transparency**: The HRCDC wish to understand more about the transparency arrangements in place highlighting the collection and use of individuals personals data for the Registry; i) Please clarify how individuals are made aware of the existence of the Registry Information Leaflet, as it may relate to them. Is the Information Leaflet provided to the individuals directly? Has the NSRF considered complimenting the transparency arrangements with a conspicuous poster with clear information at emergency departments? ii) The Data Protection Policy & Procedures states; *"The Registry provides an information leaflet which, subject to the agreement of hospital management, is available in all contributing hospital emergency departments"*. This statement indicates that the Information Leaflet is not available at all Hospital sites and/or Hospital approval is required. Please comment as to whether current participating Hospitals have not approved the Information Leaflet and how transparency measures will be adequately met in these locations. Please also clarify what discussions have been or will be had with the Hospitals to ensure a collaborative approach on this matter. iii) Linked with Query 3: The Information Leaflet does not specifically state that all emergency department records will be accessed to collect personal data of individuals who are suitable for inclusion in the Registry. Please comment as to whether the Information Leaflet has been considered suitably transparent for individuals reading the leaflet, whose personal data may be used. **Query 3. Records Access:** The Data Protection Policy & Procedures states that Data Registration Officers (DROs; some of whom are not Hospital employees) "*systematically searches the emergency department system that logs every attendance at the hospital's emergency department"*. i) Please confirm if DROs who are not direct employees of the hospital, are accessing all medical records of all patients who attended the emergency department, including those who were not presenting with self-harm.

	ii) Please comment as to whether DROs who are not directly employed by the hospital can be restricted to only accessing medical records limited to those presenting with self-harm. **Query 4. Data minimisation**: Has the Registry considered collecting less personal data, and if not, what would the impact be on the Registry if less identifiers were collected. *e.g could date of birth be replaced with age? are initials required if the MRN is being recorded?* **Query 5. Independent Review, 2018** (*Professor David Gunnell & Jon Hallet)***:*** i) The HRCDC wish to understand how the NSRF have acted on the recommendations since the report was published. Specific detail regarding the recommendations for the IT security procedures are of interest to the HRCDC and should be elaborated on. *eg What improved security procedures are in place regarding the transfer of physical copies of the data and retention period of the data by DROs.* ii) Please elaborate why USB drives are used and if they are encrypted. Has the study considered using other, more secure means of transferring data? **Query 6. CSO Linkage:** The supporting documentation provided by the Applicant references that data on deceased individuals is also obtained from the Central Statistics Office (CSO), however this activity is not described within the HRCDC application form. Please provide a brief description of this data processing activity, specifically how data collected on self-harm by the Registry is linked with data from the CSO. **Query 7. NSRF Website:** The website privacy policy currently states that individuals have the right to i) access their data and ii) change or erase their data. The website further states "*A small fee may apply and proof of identification will be required*". The Data Protection policy submitted with the application separately states "*They will be advised that a copy of all information recorded about them by the Registry will be provided to them, that this will be done free of charge, that any inaccurate information will be rectified or erased and if they wish all information in the Registry related to them will be erased".* i) Will the website be amended such that, in line with the current legislation, individuals are aware that no fees will apply unless a request is voluminous, in which case a fee may apply at the discretion of the NRSF. Please consult with your organisations Freedom Of Information officer and DPO to ensure consistency of information across all NSRF documents and sites.

Reference ID:	19-019-AF2
Lead Applicant:	Fergus McCarthy
Lead Data Controller:	University College Cork

Title:	IMPROVED Study (Improved Pregnancy Outcomes by Early Detection)
Research Objective	Prompted by the current absence of a clinically useful screening test for pre-eclampsia, the IMPROVED consortium study aimed to develop a robust predictive blood test suitable for use in a clinical environment. In total 4,063 women were recruited to the IMPROVED study across 5 centres in 4 countries throughout Europe. In Ireland the participants were pregnant women attending Cork University Maternity Hospital. In addition, the study aimed to establish a biobank of residual tissue and samples collected during the IMPROVED study that could be accessed by the scientific community for high quality research in the future. This biobank is held in University College Cork (UCC).
Reason for Declaration	The Applicant has stated that a consent declaration is sought for the continued storage of the samples and the accompanying clinical data held in the IMPROVED biobank in UCC for use in future research studies. The Applicant states that the PILs and consent forms used are not considered compliant under the Health Research Regulations for a number of reasons, including that; UCC were not noted as the data controller; that the retention periods for the samples and clinical data within the biobank were not noted; and data subject rights were not outlined.
HRCDC Comments:	The Chair introduced the research study and provided an overview of the advice that was developed by members on the meeting of February 25th. The Chair invited members who could not attend the February 25th meeting to provide comments and 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. The following are the discussion points raised from both the February 25th and March 2nd meetings **Scope of a Declaration** • The Secretariat provided a summary of the application; the reasons for seeking a declaration and the scope of the requested declaration. • Based on the responses provided by the Applicant, it was confirmed that a declaration is required for the continued storage and retention of personal data and associated samples for use in future research. • The scope of the declaration is not required to extend to the analysis that is ongoing as part of the main IMPROVED study which includes the analysis of samples and data by Metabolomics Diagnostics. It was noted that the PILs refer to samples and data being analysed by an Irish and Belgium company as part of this study and thus participants would have provided informed consent in this regard. **Previous Consent and re-consenting**

	• It was noted that the study had obtained consent from participants and the reason for seeking a declaration is because this consent is not considered to be fully GDPR compliant for the reasons outlined by the Applicant. • The HRCDC discussed the Applicant's response as to why re-consenting was not feasible, as it involves over 4,000 participants from across Europe. • It was noted that a declaration is for the data and associated samples relating to the Irish cohort, for which UCC is the data controller. The Applicant confirmed that of the more than 4,000 participants in the study over 1,500 were recruited at the Irish site. • It was noted that participants in the IMPROVED study are also recruited for other studies that are undertaken by the INFANT centre at UCC. • The HRCDC queried whether it is feasible to seek re-consent for the IMPROVED study from the Irish participants who are currently involved in other studies, and where there is contact with these participants. The response provided by the Applicant confirmed that none of the participants that consented to the IMPROVED study remain engaged in other INFANT studies and all study visits have concluded. • It was also discussed whether re-consenting for the continued storage of samples and data for future research was disproportionate given that participants provided consent previously and may ask why they are being asked to re-consent to something they have already agreed to. • Based on the information provided by the Applicant the HRCDC accepted the rationale for not seeking to re-consent participants. **Industry Collaborators** • The analysis of samples and anonymised data by Metabolomic Diagnostics (MD) forms part of the main IMPROVED study that is governed by the overall Consortium Agreement; it is therefore not within the scope of a requested declaration to continue to store personal data for future studies. • However, the HRCDC noted that the destruction of the samples by MD once they have been analysed is not incorporated into the IMPROVED Consortium agreement or Material Transfer Agreement. • The HRCDC queried if this should be addressed by the Applicant and could form a HRCDC recommendation to enhance safeguards. The Secretariat highlighted the Applicant's response which outlined several safeguards that are included within the existing agreements and the view of the Applicant that the existing agreements are sufficient. • The HRCDC noted this response and further noted that it is the responsibility of the data controller to be satisfied that the agreements in place are sufficient data protection safeguards. **Master List**

	• The HRCDC discussed the Applicant's response in relation to the retention and destruction of the master list which can enable the identification of participants who were recruited at the Irish site. • The HRCDC was of the view that the Applicant should provide updates on the retention and destruction of the master list as a reporting requirement of the Annual Review.
HRCDC Decision:	The consensus of the HRCDC was that a Consent Declaration should be made.
Duration of Declaration:	The Declaration is made commencing March 2nd, 2020 and shall be valid for 25 years, until 31st March 2045 or upon confirmation that the data has been rendered anonymised or destroyed, or whichever occurs sooner.
Other HRCDC observations/ Recommendations:	**Note:** As a reporting requirement of the Annual Review, the Applicant is requested to provide an update on the retention and/or destruction of the study master list.

Reference ID:	19-018-AF2
Lead Applicant:	Mairead Kiely
Lead Data Controller:	University College Cork
Title:	COMBINE Study (The Cork Nutrition and Microbiome Maternal-Infant Cohort Study)
Research Objective	Nutrition during pregnancy and infancy has a lasting impact on a child's physical and neurological development, with diet during the first 2 years of life a critical component for lifelong health. The COMBINE cohort study is an observational study on babies that were recruited from the IMPROVED pregnancy study. All participants are followed over the first two years of life to investigate how their diet and environment affects their growth, their neurological development and the development of their gut bacteria.
Reason for Declaration	The Applicant states that the original consent form was not GDPR compliant as it did not outline who the data controller was, the retention period of samples and clinical data or the rights of data subjects A GDPR compliant addendum to the original PIL and consent form has been developed, and once approved by the REC, it will be sent to all participants to obtain re-consent. It is anticipated that not all parents will return the signed addendum, therefore a declaration is requested to continue to process data for these participants. The data processing activities for which a declaration will cover is the continued analysis of the samples and personal data within the objectives of the COMBINE study; it is anticipated that the planned analysis for this study will be completed by 2025.
HRCDC Comments	The Chair introduced the research study and provided an overview of the advice that was developed by members on the meeting of February 25th. The Chair invited members who could not attend the February 25th meeting to provide comments and 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. The following are the discussion points raised from both the February 25th and March 2nd meetings **Re-consenting and Withdraw of consent** • The HRCDC acknowledged that the study had obtained consent from participants and that a GDPR addendum has been drafted to request re-consent. • It was also acknowledged that where participants wish to withdraw from the study that they are asked if their personal data and samples can still be used in the study. Where participants agree to this their data and samples are anonymised. • The Applicant also confirmed that if participants want to have their data and samples destroyed (i.e. not just anonymised) that this is fulfilled in line with the Right to Erasure. **Teagasc - Moorepark** • The HRCDC noted that some biosamples are stored in a repository at the Teagasc Moorepark facility and queried what agreements or arrangements are in place with UCC. It was noted that selected anonymised data is also sent to Moorepark once analysis begins. • In their response the Applicant confirmed that a Co-Investigator of the study has a joint Teagasc-UCC academic appointment. • The Secretariat highlighted that biosamples in isolation may not be considered personal data and would not fall under the Health Research Regulations or within the remit of the HRCDC. • Personal data connected to biosamples or personal data generated from any analysis of the biosamples could fall within the Health Research Regulations. • The HRCDC was of the view that appropriate agreements or arrangements should be in place between UCC and Teagasc to ensure that the data and biosamples are transferred under appropriate terms and conditions to ensure is anonymity of the participants is maintained.
HRCDC Declaration Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made.
Condition Attached:	The following condition has been attached to the Declaration as follows: **Condition 1:** As data protection safeguard measure, the Applicant is requested to ensure that agreements or arrangements, as appropriate are in place between UCC and Teagasc, to ensure that the data transferred to Teagasc-Moorepark is transferred under appropriate terms and conditions to ensure the anonymity of the participants. Specifically, that no attempts will be made to re-identify study participants by the researchers in Teagasc-Moorepark.
Duration of Declaration	The Declaration is made commencing August 8th, 2018 and shall be valid until 31st December 2020 or upon confirmation that the data has

	been rendered anonymised or destroyed, or whichever occurs sooner.

10. Any other Business

The Chair discussed that under the Health Research Regulations, an Annual Activities Report on the HRCDC activities for 2019 was due to the Minister for Health, on March 31st. The Secretariat was progressing the development of the report as a matter of priority and a draft for review will be circulated in the coming weeks.

The Chair closed the meeting.

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