HRCDC
Health Research Consent Declaration Committee

Time: 10.30am – 5pm
Date: 10th September 2019
Location: Grand Canal Hotel

Minutes of the Meeting

HRCDC Attendance

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

Quorum for Decisions

☒**YES**

Live Declarations:

Applicant	Ref No.	Title
Alistor Nichol	19-003-AF2	TEAM
Alistor Nichol	19-003-AF2	REMAP-CAP

Returning Applications considered at this meeting:

Applicant	Ref No.	Title
Alistor Nichol	19-007-AF2	TAME
Alistor Nichol	19-008-AF2	TTM2

New Applications considered at this meeting:

Applicant	Ref No.	Title
Zena Moore & Natalie McEvoy	19-062-AF1	The relationship between Sub Epidermal Moisture (SEM) measurement and Inflammatory markers in the early identification of Pressure Ulcers.
Karen Doyle	19-010-AF2	"Acute Ischaemic Stroke Clot Pathology" Study
Gianpiero Cavelleri	19-011-AF3	Irish Traveller Ancestry Study
Maeve Rooney	19-013-AF2	Omega 3 Study

HRCDC
Health Research Consent
Declaration Committee

Meeting Items

1. Opening

The Chair opened the meeting and welcomed the members.

2. Apologies

Prof. Malcolm Kell, Prof. Bert Gordjin, Dr. Sheelah Connolly, Ms. Caroline Byrne (Secretariat).

3. Disclosure of Interest

Kathy Brickell declared her interest in four applications (19-003-AF2,19-004-AF2, 19-007-AF2, 19-008-AF2 that were returning for consideration by the HRCDC). KB was absent for this part of the meeting.

4. Minutes of the previous meeting

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

5. Matters Arising

- In relation to the appeals process, the Chair informed the HRCDC that she understood that Application 19-006-AF3 has been considered by the appeals panel. A decision had not been communicated at the time of the HRCDC meeting and no information is available on the decision. It was noted that the decision by the appeals panel, whatever the outcome, and any issues raised as part of the appeals, when available, will be considered for any issues that would usefully inform the process when making and considering applications. It is understood that the Department Of Health would be reviewing the processes and procedures for appeals in light of the experience of the first appeal. It was agreed that this would be considered again by the HRCDC at an appropriate time.

- The HRCDC discussed requirements under the Regulations. The Secretariat confirmed to members that the triage validation sheet template addresses this, ensuring a check of all requirements are in place prior to the application going to the HRCDC for consideration.

6. Live Declarations

Reference ID:	19-003-AF2
Lead Applicant:	Alistor Nichol
Lead Data Controller:	St. Vincent's University Hospital
Title:	TEAM
Application Summary:	See HRCDC Meeting minutes of 25th July 2019
Points to Discuss	The Applicant responded to the HRCDC decision letter of 9th August 2019 confirming acceptance of the HRCDC's decision to give a Conditional Declaration. The Applicant provided a response in relation to the conditions of the declaration and the recommendations made by the HRCDC.
HRCDC Comments:	• The Secretariat re-affirmed the requirement under data protection law for appropriate data processing agreements to be in place i.e. data controller-data processor contracts. This is a standard condition attached for all Declarations made.

	• It was discussed that 'next-of-kin' assent has no legal basis under Data Protection legislation. The condition attached to the Declaration made of affirming next-of-kin assent (Condition 3) is a safeguard that is required by the HRCDC to protect the privacy rights of the participants. This further strengthens the Public and Patient engagement.
HRCDC Decision:	The HRCDC was satisfied with the response provided by the Applicant.

Reference ID:	19-004-AF2
Lead Applicant:	Alistair Nichol
Lead Data Controller:	St. Vincent's University Hospital
Title:	REMAP-CAP
Application Summary:	See HRCDC Meeting minutes of 25th July 2019
Points to Discuss	The Applicant responded to the HRCDC decision letter of 9th August 2019 confirming acceptance of the HRCDC's decision to give a conditional declaration. The Applicant provided a response in relation to the conditions of the declaration and the recommendations made by the HRCDC.
HRCDC Comments:	The HRCDC confirmed that the discussion points raised in relation to Application 19-003-AF2 are wholly applicable to 19-004-AF2.
HRCDC Decision:	The HRCDC was satisfied with the response provided by the Applicant.

7. Returning Applications

Reference ID:	19-007-AF2
Lead Applicant:	Alistair Nichol
Lead Data Controller:	St. Vincent's University Hospital
Title:	TAME Cardiac Arrest Study
Application Summary:	See HRCDC Meeting minutes of 25th July 2019
Points to Discuss	The HRCDC considered the Applicant's response to the HRCDC's request for further information as requested in the decision letter of 9th August 2019. See HRCDC Meeting minutes of 25th July 2019.
HRCDC Comments:	The Chair introduced the agenda item and reminded the HRCDC that the study commenced prior to August 2018 and consent obtained was compliant under previous data protection legislation. The response letter was considered robust and provided the additional clarity and information requested. The Chair requested each HRCDC member indicate whether a consent declaration should be made for this research study. It was the consensus of the HRCDC that, based on the information provided by the Applicant, a consent declaration could be made: **Transfer of data outside the EEA** It was noted that samples will be retained in Ireland and Luxemburg. Monash University, Australia are further involved in the biobank sub-study element and located outside the EEA. The Applicant confirmed that agreements are in place for the transfer of the TAME trial data to this data controller. Agreements are in process in relation to the transfer of samples between the joint controllers of the biobank sub-study. The

	HRCDC re-emphasised that the transfer of any samples and associated sample data to the non-EEA data controller must be governed by appropriate legal agreements. **Consent forms** The HRCDC discussed the description of the biobank sub-study element within the overall TAME, as set out in the PIL and consent form: • Information appears to be written from the Applicant perspective rather than the patient. • The sub-study could be presented as a distinct and separate from the main study. • Consultation with PPI and Research Ethics Committee (REC) could be undertaken to determine how to communicate the information more clearly such that is fully comprehensible to patients or their next-of-kin. These approaches would provide more clarity to the participant/next-of-kin. The HRCDC agreed these points could be addressed through recommendations set out in the HRCDC Decision letter. **Conditions relevant from previous meetings** The Secretariat reminded the HRCDC that, with the specific exception of the biobank element, clear parallels between Applications 19-003-AF2, 19-004-AF2, 19-007-AF2 and 19-008-AF2 were acknowledged during discussions at the previous HRCDC meeting of July 25th. The Secretariat recalled the conditions that were made for applications 19-003-AF2 and 19-004-AF2 and wished for HRCDC to confirm the conditions applicable to 19-007-AF2, and correspondingly to 19-008-AF2.
HRCDC Declaration Decision	The consensus of the HRCDC was that a Conditional Consent Declaration should be made
Conditions Attached	**Condition 1:** The HRCDC requests all legal contractual arrangements governing the transfer of biological samples (from the Biobank sub-study) between the joint biobank data controllers is fully executed prior to samples leaving the Integrated biobank of Luxembourg. Specifically, any biological samples being transferred outside the EEA; ie to Monash University. Confirmation that these arrangements are in place must be provided to the HRCDC **Condition 2:** The HRCDC requests that all appropriate legal contractual arrangements must be in place with the relevant institutions, regarding the transfer of personal data for the purpose of the research study. This is a safeguard and confirmation of these agreements must be provided to the HRCDC. Until this confirmation is received the declaration will not cover the processing activity of transferring data. **Condition 3:** The HRCDC requests that, where a patient continues to lack capacity for a prolonged period of time and where the next-of-kin assent remains in place, the following action should be taken as an additional safeguard: The researcher should seek confirmation from the next-of-kin (or individuals) who provided assent, that they wish for the study participant's personal data to continue to be processed as

	part of this research study. Confirmation should be obtained at an appropriate stage of the study that does not cause undue distress or harm to the participants concerned.
Duration of Declaration:	The declaration is made commencing August 8th, 2018 and shall be valid until 2021 and 15 years thereafter (until August 31st, 2036) or upon confirmation that the data has been rendered anonymised, or whichever occurs sooner.
Other HRCDC observations/ recommendations	**Recommendation 1:** The HRCDC strongly recommends a review of the consent forms and patient information leaflets (PILs) used by the Applicant, to ensure there is clarity for the participants and those assenting on their behalf, regarding all strands of the research study and data processing. Specifically, the Applicants should consider an appropriate layered consent approach to ensure informed assent and consent is obtained. It is essential that consent forms and patient information leaflets are written from the perspective of the participant. When reviewing these forms, engagement with the research ethics committees and public/patient representatives should be considered ensure forms and PILs are comprehensible to participants and those providing assent. An update on this recommendation will be required in the Annual Report.

Reference ID:	19-008-AF2
Lead Applicant:	Alistair Nichol
Lead Data Controller:	St. Vincent's University Hospital University College Dublin
Title:	TTM2 Study
Application Summary:	See HRCDC Meeting minutes of 25th July 2019
Points to Discuss	The HRCDC considered the Applicant's response to the HRCDC's request for further information as set out in the decision letter of 9th August 2019. See HRCDC Meeting minutes of 25th July 2019
HRCDC Comments:	Based on the information provided by the Applicant, it was the consensus of the HRCDC that a consent declaration could be made with the recognition that: • They had been favourably disposed to give a declaration at the previous meeting; • The response letter was robust and provided the additional clarity and information requested; • The discussion points and concerns raised during the discussion for Application 19-007-AF2 are also relevant and applicable for Application 19-008-AF2. The Secretariat confirmed that the original provisional REC approval letter had been provided by the Applicant confirming the project commenced before 8th August 2018.
HRCDC Declaration Decision	The consensus of the HRCDC was that a Conditional Consent Declaration should be made
Conditions Attached	**Condition 1:** The HRCDC requests that all legal contractual arrangements governing the transfer of biological samples (from the Biobank sub-study) between the joint biobank data controllers is fully executed prior to samples leaving the Integrated biobank of

	Luxembourg. Specifically, any biological samples being transferred outside the EEA; ie to Monash University. Confirmation that these arrangements are in place must be provided to the HRCDC. **Condition 2:** The HRCDC requested that all appropriate contractual legal arrangements must be in place with the relevant institutions, regarding the transfer of personal data for the purpose of the research study. This is a safeguard that the HRCDC has requested and therefore confirmation that these agreements must be provided to the HRCDC. Until this confirmation is received the Declaration will not cover the processing activity of transferring data. **Condition 3:** The HRCDC requested that, where a patient continues to lack capacity for a prolonged period of time and where the next-of-kin assent remains in place, the following action should be taken as an additional safeguard: The Applicant should seek confirmation from the next-of-kin (or individuals) who provided assent, that they wish for the study participant's personal data to continue to be processed as part of this research study. Confirmation should be obtained at an appropriate stage of the study that does not cause undue distress or harm to the individuals concerned. **Condition 4:** Confirmation of Research Ethics approval from the Beaumont Hospital and Galway University Hospital sites must be provided to the HRCDC, once granted. No data processing can commence at this site until such written confirmation is provided to the HRCDC.
Duration of Declaration:	The Declaration is made commencing August 8th, 2018 and shall be valid until July 2021 and 15 years thereafter (31st July, 2036) or upon confirmation that the data has been rendered anonymised, or whichever occurs sooner
Other HRCDC observations/ recommendations	**Recommendation 1:** The HRCDC strongly recommends a review of the consent forms and patient information leaflets (PILs) used to ensure there is clarity for the participants and those assenting on their behalf, regarding all strands of the research study and data processing. Specifically, the Applicant should consider an appropriate layered consent approach to ensure informed assent and consent is obtained. It is essential that consent forms and patient information leaflets are written from the perspective of the participant. When reviewing these forms, engagement with the REC and public/patient representatives should be considered ensure forms and PILs are comprehensible to participants and those providing assent. An update on this recommendation will be required in the Annual Report.

8. New Applications

Reference ID:	19-062-AF1
Lead Applicant:	Zena Moore Natalie McEvoy
Lead Data Controller:	Royal College of Surgeons in Ireland Beaumont Hospital
Title:	The relationship between Sub Epidermal Moisture (SEM) measurement and Inflammatory markers in the early identification of Pressure Ulcers

Application Summary:	Pressure ulcers, or bed sores are areas of skin damage that happen when too much pressure is put on a part of the body, for a long time. Due to critical illness and treatment interventions, patients in the Intensive Care Unit are at high risk of developing pressure ulcers. The study aims to determine if the use of a Sub Epidermal Moisture (SEM) scanner can detect early signs of pressure ulcer development and to analysis of proteins and biomarkers as indicators of ulcers and dermatitis.
Purpose of Application:	A consent declaration is being sought as it is not practicable to seek consent directly from the participants as this study intends to take place on intensive care patients who are oftentimes unresponsive because of critical illness and various treatment interventions. The relative's assent will be the method of obtaining consent for this study. When participants regain capacity, they will be provided with a patient information leaflet and will be asked to consent to continue in the study.
HRCDC Comments:	The Chair introduced the research study and highlighted that the study is considered within the 'new research' category, having commenced after 8th August 2018. The Chair requested each HRCDC member to indicate whether a consent declaration should be made for this research study. After discussing the application in detail, and based on the information provided by the Applicant, it was the consensus of the HRCDC that a consent declaration could be made: **Public Interest** There was consensus that the Applicant had outlined a strong public interest case for the study. The HRCDC discussed the following points: • This type of research being conducted in Ireland was encouraging to see, as it could benefit vulnerable and at-risk patients • The involvement of the industrial partner (Bruin Biometrics) co-funding the study and a study objective to validate the SEM Scanner they manufacture. • The validation of the SEM Scanner is just one objective of the study; others include the analysis of proteins and biomarkers as indicators of ulcers and dermatitis. • The industry-academic partnership would be considered typical as a means support PhD fellowships. **Consent** • It was unclear form the information provided what proportion of patients could provide consent Vs those that lacked capacity consent. It was discussed that a high proportion of patients in Intensive Care Units most likely would not be able to provide consent directly and that conducting research within this context is challenging due to a number of medical issues. • It was acknowledged that next-of-kin assent is no longer a legally valid form of consent, however the HRCDC considered the approach undertaken in this study to be appropriate from an ethical as well as a data safeguard and privacy perspective. **Other Points:**

	• The HRCDC discussed the study control group and the potential to be denied other treatment to prevent bed sores. It was discussed that the control group will get standard care, not substandard care • HRCDC noted that more direct public and patient engagement by the Applicant could be undertaken. • It was queried why the patient name was collected as part of this study. The Secretariat referred to the response given by the Applicant that it is collected in order to track the patient and link with the master list. It was commented whether this could also be achieved by using the Medical Record Number. It was discussed that patient name is also needed to approach relatives about the study. • The destruction of the Master list linking patient name with study ID was not clear. The Secretariat referred to the Applicant's response that the master list will be archived for five years after the study concludes. • It was confirmed that bio-samples (Sebum adhesive tape) will be transferred to RCSI in a pseudonymised format. • The HRCDC noted that further information on the data to be collected could have been provided within the application. It was acknowledged that the Applicant was asked for the data collection sheet. **The PIL and Consent Form** The HRCDC discussed certain elements of the PIL and consent form were that unclear; • The data protection rights outlined in the PIL may not be appropriate for this study and/or may conflict with data protection rights of the participants. • The PIL sets out that patient's medical records and data collected for the purpose of the study will be made available to 'monitors and auditors' acting on behalf of the Bruin Biometrics. It was discussed whether it was appropriate for the sponsor to have access to medical records with regards to the participant's privacy. The HRCDC acknowledged that monitoring and auditing are important elements of research studies to validate the data collected and processed. It was highlighted that this would normally be undertaken by an independent Clinical Research Organisation, not by an employee of Bruin Biometrics, and that the medical record would never leave the hospital site. It was noted that the text in the PIL could therefore be unintentionally misleading. The Secretariat referred to where the Applicant states that access to records will be governed by the hospital.
HRCDC Declaration Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made.
Conditions Attached:	**Condition 1**. The HRCDC requests that the Applicants provide details on the expected proportion of patients in the ICU who do not have capacity to consent Vs the proportion of patients in the ICU who do

	have capacity to consent, for this. This condition is a reporting obligation that must be fulfilled and reflected in the Annual Report. **Condition 2.** The HRCDC requests that the Applicants; (i) revise the PIL and consent forms to ensure that the benefits of the study to the patient are explicitly clear to the patient and their next-of-kin; (ii) confirm that data privacy rights Nos. 9, 10, 11 and 12 under the 'Data Protection' section of the PIL (page 7) are not contravening data protection rights under GDPR. These data protection rights also appear as general statements and not necessarily tailored to the specific study in question. Specifically, it is unclear why a participant may not be able to exercise their data protection rights if it would 'make it very difficult to conduct the research'. **Condition 3**. The HRCDC noted that page 6 of the PIL ('Records') stated '*medical records and data collected for the purpose of this study will be made available for inspection by monitors and auditors acting on behalf of the sponsor (Bruin Biometrics, BI Europe Ltd)'*. The HRCDC has requested that the Applicant; (i) clarify that medical records would only be accessed by an independent auditor/monitor designated by Bruin Biometrics, BI Europe Ltd - and not the company itself; and (ii) outline what appropriate safeguards are in place when independent auditors/monitors review patient medical records; and (iii)revise the PIL to reflect points (i) and (ii) above, to ensure participants are fully informed of this process.
Duration of Declaration:	The Declaration is made commencing 21st May 2019 and shall be valid until 31st May 2022 and 5 years thereafter (31st May 2027) or upon confirmation that the data has been rendered anonymised, or whichever occurs sooner.
Other HRCDC observations/ Recommendations:	**Recommendation 1.** The HRCDC requests that direct public and patient engagement should be carried out by the Applicant to ensure these participants and relatives are engaged with and understand the study. The Applicant should consider engaging with relevant patient advocacy groups if possible. **Recommendation 2.** Data minimisation is a key principle and safeguard of data processing. The HRCDC has requested that the Applicant consider whether it is necessary to collect the patient name from the medical record or whether a medical record number could be collected instead.

Reference ID:	19-010-AF2
Lead Applicant:	Karen Doyle (National University of Ireland, Galway)
Lead Data Controller:	National University of Ireland, Galway Beaumont Hospital
Title:	Acute Ischaemic Stroke Clot Pathology
Application Summary:	Mechanical thrombectomy is an effective procedure for the treatment of Acute Ischaemic Stroke (AIS) - the thrombectomy device used captures and removes the blood clot, restoring blood flow to the brain.

	The composition of the blood clot is one of the key factors that influence the performance of the procedure, but it has not been well studied. This research intends to retain up to 300 clots following the mechanical thrombectomy procedure. The clots will be analysed for cellular and protein composition by histology and immunohistochemistry and immunofluorescence. Data on the stroke case related to the sample will also be captured. The aim of the study is to establish a link between clot composition and the difficulty in removing the clots and to inform therapy solutions in AIS such as by improving medical device design or through identification of novel targets for pharmaceutical development that will ultimately impact on the mortality and quality of life of stroke patients.
Purpose of Application:	The Applicant is seeking a declaration as no consent was obtained from the patients in relation to the use of blood clot biosamples and corresponding clinical data for the purpose of health research. The Applicant outlines why obtaining informed consent from the patient is not possible at the time of the thrombectomy procedure.
HRCDC Comments:	The Chair introduced the research study and requested each HRCDC member to indicate whether a consent declaration should be made. After discussing the application in detail, and based on the information provided by the Applicant, it was the consensus of the HRCDC that a consent declaration could be made: **Public Interest** The HRCDC agreed there was strong public interest case in this study considering the impact of stroke on patient and carers, and the potential benefits of the study outcome. **Patient Perspective** The HRCDC discussed whether patients would be surprised that their biosamples (stroke clots) and clinical data was or will be obtained and used for health research. **Consent processes** The HRCDC discussed the following points regarding consent: • The Applicant outlines reasons why consent may or may not be obtained, highlighting the emergency nature of the surgery, the large proportion of patients who are transferred from Beaumont to other care facilities after surgery, and the practicalities of obtaining consent in such circumstances, and the impact this could have on the study; primarily a reduction in participant numbers. • It was noted that 15% of patients are not transferred from Beaumont after surgery. The possibility of obtaining consent from these patients and with other patients, through 'next-of-kin' assent and links with other hospitals in some point in the patient hospital journey, was discussed. • The Applicant states that consent will be obtained from patients in similar studies that will be undertaken in the future; the HRCDC discussed whether consent for the current Acute Ischaemic Stroke Clot Pathology study could therefore be undertaken going forward.

	• Other studies where the patient could not provide consent directly have utilised next-of-kin assent or obtained deferred consent from the patient at a later stage. • The blood clot samples that are removed as part of the surgical procedure, are further combined with clinical data. • As a point of information, the Secretariat referred to the application which states that a declaration is being sought to cover all 300 biosamples to be used in the study, which is both retrospective and prospective samples that have or will be used in the research study without obtaining consent. The Secretariat stated that a Declaration can be made where the data controllers have made reasonable efforts to obtain consent but there has been no response from the participant. Efforts to obtain consent would be an appropriate data protection measure within this study. • Potential approaches to obtain consent for both the retrospective and prospective samples should be considered: o increased engagement and communication with relevant staff in the patient hospital care journey o recording the patient's participation in the study in their medical notes; o request staff at the hospital where the patient is transferred after surgery to ask the patient or family to provide consent. **Transparency** It was recognised that transparency measures were in place including the 'A Tiny Spark' documentary film and other approaches to be undertaken within Beaumont Hospital; namely the publication of a booklet of research projects. The HRCDC stated that further efforts could be made to inform patients directly about this study and how their samples and personal data is used i.e. increased transparency for retrospective and prospective patients through the provision of PILs. The HRCDC noted that the study objective to improve medical device design, was not as transparent as the other study objectives, and should be made clear. The Applicant outlined the proposal to retain anonymised biosamples in a permanent biobank. The HRCDC discussed that even if the bio-banked samples are anonymised that this should also be incorporated into any transparency notices. **PPI involvement** The HRCDC acknowledged that while some PPI engagement has been undertaken for the study, this could be strengthened, in particular regarding consent and transparency measures. **Security of Sample and Data Transfer** It was discussed whether the transfer of the data collection sheets and the biosamples from Beaumont Hospital to NUIG could be further secured by transporting them separately.

	Material and Transfer Agreement The Secretariat referred to the Material Transfer Agreement submitted by the Applicant. It was noted that it only refers to the samples and not the clinical data. The HRCDC agreed that this should be amended appropriately to include clinical data.
HRCDC Declaration Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made.
Conditions Attached:	**Condition 1:** The HRCDC noted that informed consent will be obtained from participants in future studies, unrelated to this study. Given that informed consent is therefore practicably possible, the HRCDC requests the Applicant to establish and implement a practice of obtaining participant consent and/or relative/next-of-kin assent for all prospective data and biological material collection for this study. Patients must have the opportunity to assent to their participation the study at some point in their hospital journey. This declaration will cover processing activities of prospective data and biological material collected for this study only if a consent/assent process is implemented and confirmed to the HRCDC. This condition is a reporting obligation that must be fulfilled and reflected in the Annual Report. **Condition 2:** The HRCDC requests that the Applicant make best reasonable efforts to obtain retrospective consent from individuals whose data and biological material has been collected to date. This condition is a reporting obligation that must be fulfilled and reflected in the Annual Report. **Condition 3.** To ensure robust security safeguards are in place, the HRCDC requests that the physical transport of the pseudonymised data and biological samples from Beaumont Hospital to NUIG are transported separately, and not together. **Condition 4.** The HRCDC requests that patient and public engagement is strengthened and more direct feedback and involvement from patients and public is sought regarding the consent process and the study itself. Additionally, outline what specific feedback was received from stoke survivors at the screening of 'A Tiny Spark' in December 2018. **Condition 5.** In line with the advice of the Data Controller's Data Protection Officer, the HRCDC has requests that data protection transparency measures implemented within the Hospital setting to ensure patients and their relatives, or those accompanying patients, are aware of the study and the use of clinical data and biological samples, and role of both Data Controllers. For example, transparency measures should ensure patients are made aware of how to exercise their data privacy rights. **Condition 6:** The Joint Data Controller relationship (Beaumont Hospital and NUIG) is currently governed by a Material Transfer Agreement (MTA), which only provides for the transfer of the biological material. To ensure the appropriate safeguarding of the pseudonymised clinical data, the HRCDC requests that the MTA is amended appropriately with suitable data transfer contractual clauses.

Duration of Declaration:	The Declaration is made commencing August 8th, 2018 and shall be valid until March 2021 and 5 years thereafter (until March 31st, 2026), or upon confirmation that the data has been rendered anonymised, or whichever occurs sooner.

Reference ID:	19-011-AF3
Lead Applicant:	Gianperio Cavalleri
Lead Data Controller:	The Royal College of Surgeons in Ireland
Title:	Irish Traveller History Study
Application Summary:	The history of the Irish Traveller population's population is not well understood, due in large part to a lack of written records. The analysis of genetic variants from individuals representing a population such as the DNA and associated de-identified data will be analysed to further describe population structure and history. This study falls under the definition of health research as one of the long-term goals is to improve the health of the Irish population as a whole including the Traveller subpopulation, through a better understanding population structure and history. The data that is the subject matter of this application was initially collected via participant consent for a study that was part of a documentary series; included within this initial study was DNA analysis. The study and the associated data was later brought into the academic arena under the auspices of the RSCI. Further work with additional samples, and more dense datasets may aid the identification of new genetic groups within the Irish Travellers and provide more statistical power in investigating the origins of this population.
Purpose of Application:	A consent declaration is sought in relation to 39 DNA samples and associated data where it has not been possible to obtain explicit consent. These 39 samples in question are historical samples for which GDPR compliant consent was not recoded at the time of collection; they were initially recruited as part of the "Blood of the Travellers" RTE documentary series in 2011. This initial study also took place outside of the academic arena; it was later sought to bring the study and associated data under RCSI. Some participants have been contacted to provide explicit consent however the Applicant has been unable to do so for these 39 participants. The Applicant wishes to 1) continue to hold the 39 DNA samples and associated data, 2) generate new genetic data from these samples, and 3) analyse the resulting dataset. The Irish Traveller History study will also merge these samples and data with larger datasets to help achieve the study objectives.
HRCDC Comments:	The Chair introduced the research study and requested each HRCDC member to indicate whether a consent declaration should be made. After discussing the application in detail and based on the information provided by the Applicant, it was the consensus of the HRCDC that further information is required from the application. 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:**

	• It was noted that the public interest from the study would be primarily for the Traveller Community, a group that experience a number of challenges within society. The Chair commented that the public interest does not have be measured at the level of the general population. • The HRCDC discussed that the direct health benefit of the study for this community or generally was not clear from information provided. The HRCDC queried the public interest from the study weighed against the data privacy rights from the 39 participants. **Obtaining consent** The HRCDC acknowledged that; • Out of the 49 participants in the documentary, the Applicant had successfully obtained consent from 10 participants. • The Applicant stated in their responses that they are open to suggestions from the HRCDC on how they can try to obtain consent from the remaining 39 participants • The Applicant provided a supporting letter from the documentary production company indicating that efforts have been made to try and obtain consent from these 39 participants. • There are challenges in obtaining consent from the 39 participants, especially in retracing their location. **Scope of Use** The HRCDC discussed the following points; • 39 samples and associated data were originally collected for a non-academic purpose, under a film release form. • It was not clear from the information provided whether a specific consent form or information leaflet that outlines the use of DNA and genealogical data was used at any point during the television documentary. • Whether participants be surprised that blood samples and data they provided for the documentary were now being used by an academic institution for further research purpose; it was the opinion of members that participants could be surprised and that this may not be considered a fair use of data. • The arrangements in relation to the transfer of the data to RCSI after the documentary, including agreements and other safeguards, is not clear. **Sample Size** The Secretariat provided clarity on the number of samples that are the subject of the Declaration application; 60 members of the Traveller Community are included in the larger 'Atlas' dataset referenced by the Applicant that in total includes 300 individuals. Out of the 60 participants, 49 were involved in the documentary programme. The Applicant obtained consent from 10 of these 49, thus 39 samples are the subject of this application. The Secretariat also confirmed that a Declaration, if made, will not cover the use of these 39 samples for future research studies.

	The HRCDC discussed if samples and data from other members of the Traveller Community could be collected and processed with their explicit consent to replace the 39 that are the subject of the HRCDC application. **Transparency and PPI involvement** The HRCDC noted the efforts to inform the Traveller Community about the study and provision of letter of support from a leading figure in the Traveller movement. **Data Anonymisation** The HRCDC discussed the Applicant's intention to anonymise and store DNA and data, as biobank for future use. for the and reference to a biobank. Anonymisation will be achieved by destroying the master list linking the DNA and associated data to the participant identifiers. As genetic data is unique to each individual, it may not be considered technically possible to irreversibly anonymise such information The HRCDC reiterated that the Data Controller is responsible and accountable for determining whether data is considered fully anonymised and whether they require the support of a Declaration to undertake anonymisation; therefore it is the Data Controller for the Traveller History Study who will determine whether the data has been anonymised or if another application to the HRCDC needs to be made.
HRCDC Declaration Decision:	The consensus of the HRCDC was that a formal decision would be deferred pending receipt of further information
Further Information Requested	**1.** The HRCDC requests why the 39 samples are essential to the overall study and why, for example, new participant recruitment could not be considered as an alternative. **2.** The HRCDC has noted that the only consent form signed by the participants historically is the 'Release Form' provided by Scratch Films for the Francis Barrett Documentary. The Release form does not reference the collection and use of DNA. The HRCDC wish to understand whether any other consent form was signed, consenting for the collection and use of DNA samples **3.** The HRCDC requests confirmation as to what arrangements, if any, where in place between RCSI and RTE/Scratchfilms, governing the transfer of data and DNA samples **4.** To further understand the public interest case, the HRCDC wish to understand what specific health impacts and benefits this study will have. This is briefly referenced in Applicant Response letter to the Secretariat, but not specific.

Reference ID:	19-013-AF2
Lead Applicant:	Maeve Rooney
Lead Data Controller:	University College Cork
Title:	Irish Omega 3 Study
Application Summary:	To investigate whether Omega 3 fatty acid food supplements can reduce the risk of transition to psychosis in high risk individuals.

	Participants are randomised to take a fruit juice drink containing either placebo or Omega-3 fatty acids daily for 6 months.
Purpose of Application:	The Applicant is seeking a declaration as the current consent and study information leaflets are not compliant under the current GDPR legislation
HRCDC Comments:	The Chair introduced the study and reminded members that there is no public interest test to consider for this application since the research began before August 2018 and had obtained consent that was compliant with previous legislation. 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: **Reason for seeking a Declaration** The HRCDC discussed the rationale for seeking a Declaration; the consent forms and information leaflets appeared reasonably aligned with the ongoing data processing activities. Re-contacting participants could provide an alternative and appropriate measure to provide the participants with any updated information. The HRCDC noted that every effort will be made to contact patients who have already provided consent and participants will be asked to return a signed Data Protection Notice which has been approved by the Research Ethics Committee. **Challenges in contacting research participants** The HRCDC acknowledged the challenges the of re-consenting participants. A number were students at the time of their enrolment in the project and have since moved away and uncontactable. A proportion of the participants would have transitioned to psychosis having been considered 'high-risk' before taking part in the research. It was discussed that the study also involves participants attending scheduled clinic visits for a year which could provide an effective contact opportunity for the Applicant; however, it was recognised that this approach was not useful for participants recruited several years ago and no longer attending the clinics. **Public Interest** While acknowledging that no public interest case needs to be met, there was a consensus that there was a level of public interest from the study. **Safeguards** The Applicant describes that an IT service provider and an external Irish laboratory will be contracted to undertake some data processing activities involving pseudo-anonymised data. **Other analysis** The HRCDC discussed that a Declaration does not extend to other analysis and data processing that are outside the scope of the Omega-3 study.

HRCDC Declaration Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made.
Conditions Attached:	**Condition 1.** The HRCDC has requests that the Applicant make continued efforts to follow up with participants to reconsent and provided updated information regarding the study. **Condition 2.** The HRCDC noted the that the scope of work may include 'analysis of similar substances found in the blood which are also involved in the inflammatory process may be considered'. For the avoidance of doubt, this Conditional Declaration is made specific to the Omeg-3 study and for no additional processing activities outside the scope of the study. **Condition 3**. The HRCDC has requested that the appropriate data controller - data processor contractual arrangements (legal agreement) must be in place Clinical Trials EndPoint Ltd and UCC, regarding the transfer of data for the purpose of the research study. This is an essential data protection safeguard that the HRCDC has requested and confirmation that these agreements are in place must be provided to the HRCDC as soon as possible. **Condition 4.** The HRCDC requests a copy of the new data protection notice once approved by the Research Ethics Committee, and notice of approval from the REC.
Duration of Declaration:	The Declaration is made commencing August 8th, 2018 and shall be valid until 10 years after the completion of the study (Completion date: December 31st, 2019) - until December 31st, 2029

9. Activities report

EV gave an overview of the Activities Report which was provided to the HRCDC. Developments in relation to the Assisted Decision Making Act (2015) will be important to the work of the HRCDC in the future. EV provided more information on the Secretariat's input into the revised HSE National Consent Policy that is currently underway.

10. Information and Training sessions

The Chair referenced that the Secretariat aims to organise information and training sessions on topics that are relevant to the HRCDC at the monthly meetings. The Secretariat is arranging an information session on biobanks and members have been asked to propose other topics that are of interest. Capacity for consent and the National Consent Policy were raised as possible options to consider.

EV noted that information documents on biobanks can be accessed through the library section on 'Decision Time'.

It was discussed that Regulations on Artificial Intelligence will be published to the European Commission in early 2020 which may be of interest to the work of the HRCDC.

11. Future meetings

The Secretariat provided an update on the number of applications submitted to the HRCDC for consideration. The HRCDC discussed holding additional meetings in 2019 if necessary, to alleviate the back log of applications pending. Applications related to 'new' research studies should be allocated enough time in the meeting agendas to prevent delays in research studies commencing. If required, an entire meeting could be designated for 'new'

research applications. The Secretariat stated that they are in the process of contacting the 'new' research applicants to ascertain their study timelines.
Meeting dates for 2020 were also discussed. The Secretariat will ask members to indicate their availability for the first half of 2020 through a doodle poll.

12. AOB

The Chair informed the HRCDC that fellow member Bert Gordijn (BG) will be stepping down from the HRCDC due to other commitments. The HRCDC acknowledged his role over the previous meetings and the professional insight he brought to the discussions.

An update was provided on the FOI requests received by the Secretariat. The Secretariat will update the website to ensure Applicants are aware that applications are deemed 'records' and are subject to the FOI ACT, 2014.