HRCDC
Health Research Consent Declaration Committee

Date: April 30th, 2020
Location: Videoconference

Minutes of the Meeting

HRCDC Attendance

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

Quorum for Decisions
☒**YES**

New Applications considered at this meeting:

Applicant	Ref No.	Title
Linda Coate	20-010-AF1/COV	COVID-IYON study
Gerard Curley	20-003-AF1	Blood Brain Barrier (BBB) Disruption And Dynamic Contrast Enhanced Magnetic Resonance Imaging (DCE-MRI) Changes In Severe Traumatic Brain Injury (TBI)

Returning Applications considered at this meeting:

Applicant	Ref No.	Title
Paul Corcoran	19-021-AF3	National Self-Harm Registry Ireland
Daniel Costello	19-073-AF3	Incidences of new diagnosis of first seizures and epilepsy in Cork City and county over a one year period

Live Declarations:

Applicant	Ref No.	Title
Gerard Curley	20-006-AF1/COV	A randomized double-blind placebo-controlled trial of intravenous plasma-purified alpha-1 antitrypsin for severe COVID-19 illness
Alistair Nichol	19-004-AF2/AMD1/COV	REMAP CAP (COVID-19 Domains and Consent Models)

Gerard Curley	19-023-AF2	Effect of naïve and pre-activated MSCs on monocyte/macrophage function in patients with pulmonary and non-pulmonary sepsis
Shona Pfeiffer	19-085-AF1	Blood Biomarkers to predict recovery from Ischaemic Stroke
Michael Farrell	19-006-AF3	The contribution of Whole Genome Sequencing to Brain Tumour Biology
Emer Fallon	19-038-AF1	The Genomic Basis of Alzheimer's disease in Ireland
Paul Buitelaar	19-064-AF1	Discussion Forum use for Public Health Surveillance Study

Meeting Items

1. Opening

The Chair opened the meeting and welcomed the members.

2. Apologies

John Ferguson, Malcolm Kell

3. Disclosure of Interest

There were no disclosures of interest recorded for this meeting.

4. Minutes of the last meeting

Draft minutes of the 2nd April and 15th April meetings were circulated in advance and were agreed by the HRCDC.

5. New Applications

Reference ID:	20-010-AF1/COV
Lead Applicant:	Linda Coate
Lead Data Controller:	Limerick University Hospital
Title:	COVID-IYON study
Research Objective:	This study will collect real-time observational data regarding the impact of SARS-CoV-2 infection on patients with cancer, and on the functioning and organisation of cancer and malignant haematology services in the Republic of Ireland in response to the 2020 SARS-CoV-2 pandemic. This data is being collected in order to help coordinate national and local emergency responses to the ongoing SARS-CoV-2 pandemic within the national cancer and malignant haematology centres in the Republic of Ireland.
Reason for Declaration	The scope of the declaration being sought is for the processing of personal data of oncology & malignant haematology inpatients diagnosed with COVID-19 at relevant study sites who are unable to provide informed consent for reasons of diminished capacity.
HRCDC Comments:	The Chair introduced the research study and requested each HRCDC member to indicate whether a consent declaration should be made.

	After discussing the application, and based on the information provided by the Applicant, it was the consensus of the HRCDC that a consent declaration could be made: **National Research Ethics Approval (NREC)** • The Secretariat discussed that the application for a consent declaration was submitted as part of the new, integrated NREC-HRCDC process for COVID-19 research, and, as a result, the study had not yet received research ethics approval. • The Secretariat reiterated that the NREC and HRCDC review process for this and other applications submitted, are proceeding independently and in parallel as part of the agreed integrated rapid review process. • As part of this process the decisions of both committees will be communicated to the Applicant simultaneously. **Public Interest** • The HRCDC was of the view that given the ongoing COVID-19 pandemic and the objectives of the research, that the study had a strong public interest case. **Deferred Consent and Assent Model** • The HRCDC discussed that where it is not possible to obtain consent from the participant, that next of kin assent would be obtained from the individual's legal representative as defined in the Regulations for Clinical Trials on Medicinal Products For Human Use (S.I. 190/2004). • It was commented that although this legal representative cannot provide legal consent for data processing on behalf of the participant, the approach does provide a suitable safeguard to protect the participants data rights. • The HRCDC also noted that consent will be sought from the participant when they regain decision-making capacity. It was discussed that it would be appropriate to attach the requirement for deferred consent as an appropriate condition. • The HRCDC also discussed the approach to obtain verbal consent or next-of-kin assent due to the contagion risk posed by COVID-19. It was commented that use of witnessed verbal consent/assent appeared to be a well-considered and practical response. • The HRCDC discussed that for the purpose of clarity the term 'next-of-kin assent' should also be used alongside the term 'legal representative' in the relevant study documents. **PPI** • The HRCDC commented that this study incorporated a strong degree of patient and public involvement. **Other** • It was noted that the expected duration of the study is 12 months, which includes data collection and subsequent

	analysis. The HRCDC commented that the study duration may need to be extended should the pandemic persist. If the Applicant decides to extend the study, it was discussed that they can seek an amendment to the consent declaration. • The HRCDC highlighted that the study information leaflet state that personally identifiable information such as the participant's name, date of birth or hospital number will not be collected. However, the application form describes that data will be pseudonymised at the local hospital site; therefore, it was likely that identifiable data is collected and stored on a master list. The HRCDC noted that this section of the PIL should be amended as appropriate to ensure clarity for the participant and/or their next-of-kin. • The HRCDC discussed that the scope of the declaration would not cover the processing of personal data of the study Sub-Investigators that could be collected during the qualitative component of the study, as consent will be obtained for this activity. • The HRCDC was of the view that the application presented an extremely clear and well thought out study, as evidenced by the detailed and substantive information that reflected full consideration for the participants rights.
HRCDC Declaration Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made.
Duration of Declaration:	The Declaration is made commencing 30th April 2020 and shall be valid for the study duration of 1 year and a further 5 years after the study has concluded (April 2026).
Conditions Attached:	The following specific condition has been attached to the Declaration as follows; **Condition 1.** The HRCDC has requested that all appropriate contractual arrangements (legal agreements) must be in place between the lead Data Controller study site and individual Hospital study sites regarding the transfer of personal data for the purpose of the research study. The processing activity of transferring data between the sites cannot commence until these arrangements are in place. Confirmation that these agreements are in place must also be provided to the HRCDC.
HRCDC Recommendations:	The following recommendations are made by the HRCDC; **Recommendation 1.** The HRCDC recommends that the study information leaflets and consent forms are revised to taking into account the points herein. Please provide any updated study information leaflets to the HRCDC for information purposes. i) The HRCDC notes the reference to 'patient's legal representative' (SI.190/2004) in the application, and that the study information leaflets and consent forms require a signature from a 'Legally Acceptable Representative'. To help prevent any assumption that all relatives or next of kin are legally appointed authorised individuals to provide consent for data processing, the HRCDC recommends a clear alternative

	such as 'Representative providing assent', or 'Next of Kin/Relative/Friend Representative'. ii) The study information leaflets state '*Your Name, Date of Birth, Hospital Number, Phone Number, Address, or any other identifiable information about you will not be collected for this study'.* However, it is noted that the personal data collected is pseudonymised, and a decoding log is held at each site. To ensure clarity for participants, the HRCDC recommends revising this section of the information leaflet to reflect that identifiable information is collected, retained and pseudonymised as part of this study. iii) The relative information forms states '*We will understand if you do not want to take on this responsibility*. Further clarity should be further provided on what will happen to their relative/friend in relation to participation in the study if they do not wish to provide assent on their behalf. **Recommendation 2.** Given the current unknown duration of the current COVID19 health crisis, the HRCDC discussed that the Applicant may need to consider extending the study duration as necessary. If the study is extended, the Applicant may submitan amendment to the HRCDC seeking an extension to the declaration.

Reference ID:	20-003-AF1
Lead Applicant:	Gerard Curly
Lead Data Controller:	Beaumont Hospital
Title:	Blood Brain Barrier (BBB) Disruption And Dynamic Contrast Enhanced Magnetic Resonance Imaging (DCE-MRI) Changes In Severe Traumatic Brain Injury (TBI)
Research Objective	There are a variety of immediate effects on the brain following head injuries, including various types of bleeding and tearing forces that injure nerve fibres and cause inflammation, metabolic changes, and brain swelling. Secondary damage may also be caused by a breakdown in the blood-brain barrier. The blood-brain barrier preserves the separation between the brain fluid and the very small capillaries that bring the brain nutrients and oxygen through the blood. Once disrupted, blood, plasma proteins, and other foreign substances leak into the space between neurons in the brain and trigger a chain reaction that causes the brain to swell. It also causes multiple biological systems to go into overdrive, including inflammatory responses which can be harmful to the body if they continue for an extended period of time. Magnetic resonance imaging (MRI) may be used after the initial assessment and treatment as it is a more sensitive test and picks up subtle changes in the brain that the CT scan might have missed. Recently there has been increasing research into the use of Dynamic Contrast Enhanced MRI (DCE-MRI) which can demonstrate changes suggestive of blood brain barrier disruption. This study proposes to use a novel sequence of DCE-MRI to

	diagnose disruption of the BBB in cases where traditional sequences would not identify.
Reason for Declaration	Patients that will be enrolled in this study are unconscious, and do not have capacity to provide consent. The data processing activities include the collection, pseudonymisation and analysis of the participant's personal data for the purpose of this study. Pseudonymised blood samples that are associated/linked to the participant's personal data will also be analysed.
HRCDC Comments:	The Chair introduced the research study and requested each HRCDC member to indicate whether a consent declaration should be made. After discussing the application, and based on the information provided by the Applicant, it was the consensus of the HRCDC that a consent declaration could be made: **Public Interest** • On balance and considering the objectives of the research and the impact of brain injury, the HRCDC was of the view that there was a public interest in this study. **Next-of-Kin Assent & Deferred Consent** • The HRCDC discussed that the first MRI scan will be conducted within 24hrs of the patient's admission into hospital and queried at what point next-of-kin assent would be attained. • It was noted that participants will be attending follow-up clinic visits, which provides an opportunity to seek their consent for the study if they regain decision-making capacity. • Overall it was the view of the HRCDC that obtaining next-of-kin assent, and deferred participant consent when they regain decision-making capacity, provided a suitable data protection safeguard that should be attached as a condition to this declaration. • In light of the current COVID-19 health emergency, the HRCDC also discussed that the researchers should consider how assent and/or consent could be obtained by alternative means, such as verbal consent and assent. **Public and Patient Involvement (PPI)** • The HRCDC discussed that the Applicant could enhance the level of PPI for this study. • It was discussed that the findings of the study could be shared and disseminated with participants, their families and PPI groups which would help enhance transparency and public and patient involvement. **Study Information Leaflets** • The HRCDC discussed that some of the content in information leaflets and consent forms is technical and could be challenging for to follow. It was further considered that the forms and information leaflets should be carefully reviewed and tailored

	specifically for the individuals reviewing and relying on the information to provide either consent or assent, as relevant. • The HRCDC noted inconsistencies in the information outlined in the consent and assent forms and associated information leaflets provided. Specifically, the consent and assent forms did not include the same information and options for consenting/assenting to storage and future use of personal data and biological samples or, for being contacted about potential future research. It was the view of the HRCDC that participants should be able to clearly indicate their preferences regarding the storage and future use of their personal data and bio-samples, as well as being contacted in the future. • It was noted that the information leaflets refer to 'medical records' that will be accessed to obtain relevant data for this study. The HRCDC was of the view that it would be beneficial to provide clarity to the next-of-kin and/or participant that only the relevant hospital/ICU records, not broader medical records, will be accessed. • It was also highlighted that reference to 'next-of-kin' is mistakenly used in the participant consent form. In addition, the HRCDC noted that for consistency and clarity, 'assent' should be used when describing next-of-kin permission, with 'consent' used when permission is obtained directly from the participant. • The HRCDC discussed the Applicant's reference in the Data Protection Impact Assessment (DPIA) form that requests to access personal data will be discussed with the local Data Protection Officer (DPO). It was discussed that it should be clear to participants and next-of-kin how data protections right can be exercised. **Study Duration and Length of Declaration** • The HRCDC queried the duration of the study and how long personal data and samples will be stored for. It was commented that the study information leaflets note that data will be retained for 5 years while the HRCDC application says that pseudonymised data will be stored indefinitely. With regards the biosamples the HRCDC application also states that '*samples will remain anonymous but will have a unique identifier*'; the HRCDC queried if the samples would therefore be more accurately considered pseudonymised. • The Applicant's response to the Secretariat's query letter confirmed that a declaration is required until 31st December 2021, after which the personal data will be irrevocably anonymized. It was discussed that the timeline for anonymisation of the personal data should be noted in the study information leaflets. • It was also highlighted that the storage of biosamples only (i.e. samples which do not have associated personal data), in itself, falls outside the remit of the Health Research Regulations. • It was commented that the MRI scans conducted for this study are stored on and accessed from the National Integrated

	Imaging System overseen by the HSE. The HRCDC considered that the study information leaflets should also clarify what will happen the scans after the study concludes. **Other** • The HRCDC emphasised that, although options to assent to the future use of personal data are provided to the participant's next-of-kin, the scope of this declaration will not extend to the use of personalised data in unknown, unspecified future research studies.
HRCDC Declaration Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made.
Duration of Declaration:	The Declaration is made commencing 30th April 2020 and shall be valid until 6 months after the recruitment of participants for the study has been completed, by 31st December 2021.
Conditions Attached:	The following specific conditions have been attached to the Declaration as follows: **Condition 1:** The HRCDC has requested that, where the participant lacks decision-making capacity, a protocol is implemented whereby next-of-kin assent for data processing is obtained as soon as practicably possible and that deferred consent is subsequently obtained, as soon as possible, when the participant regains capacity. Consideration should be given to seek deferred consent at the participant's follow-up clinic visits as part of this process. Details of the implementation of this assent/consent protocol, including the number of participants who have provided deferred consent is a reporting requirement as part of the Annual Review. **Condition 2:** It is a condition of the declaration that the level of public and patient involvement (PPI) in the development of this study is enhanced to ensure knowledge in context and experience can be gained through direct engagement with the public and patients. Engagement with representative groups such as *ICUsteps* should be considered as should the dissemination of study findings with participants, their families and PPI groups. The Applicant is requested to report on efforts to enhance PPI as part of the Annual Review. **Condition 3:** As data protection safeguard measure, the Applicant is requested to ensure that agreements or arrangements, as appropriate, are in place with the co-investigator's institution, Trinity College Dublin. This is to ensure that the data transferred to the co-investigator is transferred under appropriate terms and conditions to ensure the anonymity of the study participants. Specifically, to ensure that no attempts will be made to re-identify study participants by the co-investigator.
HRCDC Recommendations:	**Recommendation 1**. The Applicant is recommended to review the DPIA to ensure the information provided for data protection risk analysis, reflects the activity being out in the study. For

	example, it is noted in the DPIA that 'no patient shall be recruited into the study without informed consent', yet next-of-kin assent will be obtained. **Recommendation 2:** The HRCDC strongly recommends that the study information leaflets and accompanying assent and consent forms, should be carefully reviewed and amended as necessary to ensure there is clarity and consistency of information provided to the participants or their next-of-kin. This will ensure there is an appropriate level of transparency and allow informed consent and the safeguard of assent to be obtained for the study. More specifically the following information points should be reconsidered; i) The study information leaflets were considered overly technical in nature, including the section '*Why is this study being done'*. More accessible and less technical language within the information leaflets should be considered. ii) Reference is made to 'medical records' that will be accessed to obtain relevant data for this study. It would be beneficial to provide clarity to the next-of-kin and/or participant that only the relevant hospital/ICU records, not broader medical records, will be accessed. iii) The Applicant is recommended to ensure there are no inconsistencies with the information outlined in the consent and assent forms and associated information leaflets provided. Specifically, the consent and assent forms did not include the same information and options for consenting/assenting to storage and future use of personal data and biological samples or, for being contacted about potential future research, or access by commercial entities. It was the view of the HRCDC that participants should be able to clearly indicate their preferences regarding the storage and future use of their personal data and bio-samples, as well as being contacted in the future. However, all multiple 'yes'/'no' options should be clear and minimised to avoid any confusion. iv) The Applicant is recommended to ensure that there is consistency and clarity, and use in the right context, regarding terms such 'assent' and 'consent' as they relate to participants and next-of-kin. v) The participant's data protection rights outlined in the consent and assent forms, such as right to access and withdrawal of personal data and any relevant derogations for data protection rights, should be clear and understandable and in compliance with the General Data Protection Regulations (GDPR).

6. Returning Applications: For Consideration

Reference ID:	19-021-AF3

Lead Applicant:	Paul Corcoran
Lead Data Controller:	National Suicide Research Foundation (NSRF)
Title:	National Self-Harm Registry Ireland
Application Summary:	See HRCDC Meeting minutes of 2nd March 2020
Points to Discuss	The HRCDC considered the Applicant's response to the HRCDC's request for further information in the decision letter of 13th March 2020. See HRCDC Meeting minutes of 2nd March 2020.
HRCDC Comments:	The Chair introduced the agenda item and reminded members of the further information that was requested from the Applicant. The Chair invited members to comment on the Applicant's responses. Based on the responses received, the consensus of the HRCDC was that a consent declaration could be made. The decision was based on the following discussion points: **Public Interest & Consent** • The HRCDC noted the Applicant's response to the HRCDC's query, that similar registries internationally have not obtained consent form participants. • The HRCDC was of the view that, overall, the Applicant had reasonably addressed their queries relating to consent and that the public interest in the study significantly outweighed the requirement to obtain explicit consent. **Public and Patient Involvement (PPI) & Transparency** • The HRCDC were of the view that PPI within this study should be enhanced, including engagement with mental health support groups where appropriate. In addition, the HRCDC considered that public and patient advocates could also sit on the NSRF's new Research Advisory Group. • It was discussed that the topic of patient consent for this study should be examined through enhanced PPI. • On transparency arrangements, the HRCDC noted the Applicant's response in relation to the provision of information posters/leaflets within the hospital and that these notices do not outline that medical records will be accessed. It was discussed that clear arrangements should be in place with the hospitals regarding the provision of transparency notices on their premises and that notices could also be provided in other targeted areas of the hospital. In addition, it was discussed that the information posters/leaflets should be amended to outline that medical records will be accessed for the purpose of this Registry. • The HRCDC also considered that further transparency measures could be implemented, for example, upon discharge individuals could be provided with information on support groups and about the existence of the Registry. It was also discussed that details of the Registry could be provided on the website of self-harm support groups and that publications and reports produced by the registry could be disseminated to public and patient representatives.

	Data Registration Officers (DROs) • The HRCDC noted the Applicant's response that the DROs are not accessing all records of all patients who attended the emergency room; only the records of those who attended for suspected self-harm are accessed. • The HRCDC considered that as a safeguard DROs should only access the minimum required records of patients who only attended the emergency room for suspected self-harm. **Length of Declaration** • The HRCDC discussed that it would be suitable and appropriate to make a conditional declaration for 2 years. This would provide the Applicant time to enhance the level of PPI, including discussing the topic of patient consent, and to enhance transparency measures. • After 2 years the Applicant can request an extension to the declaration at which point the HRCDC will consider the progress that has been made regarding conditions attached. **Other** • The HRCDC considered that it would be appropriate to ask the Applicant to report on how many participants wanted to withdraw from the study as part of the Annual Review.
HRCDC Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made.
Duration of Declaration:	The Declaration is made commencing 30th April 2020 and shall be valid for 2 years, until 30th April 2022. The Applicant may request an extension to the duration of the declaration. Upon request for an extension to the declaration, the HRCDC will consider the progress made to met the conditions attached.
Conditions Attached:	The following specific conditions have been attached to the Declaration as follows: **Condition 1:** The HRCDC requests that the level of public and patient involvement is enhanced. This includes engagement with mental health support groups such as Pieta House and the Samaritans, as well as with patients and their families. As part of this engagement, the feasibility and appropriateness of obtaining patient consent or next-of-kin assent, where the patient lacks decision making capacity, for the inclusion of their data in the registry, should be discussed with public and patient representatives. **Condition 2**: The Applicant is requested to enhance the level of transparency so that participants and their families are aware of the following; i) the existence of the Registry and the potential inclusion of their personal data in the Registry, ii) that medical records are accessed, and personal data collected, as part of the Registry, and

	iii) how they can request to withdraw their personal data from the Registry and what will happen their personal data in such circumstances. The Applicant is requested to ensure that clear and robust arrangements are in place with the hospitals regarding the provision of transparency notices. In addition, the Applicant is asked to consider other transparency measures such as ensuring that notices are provided in targeted areas of the hospital and whether an information sheet with details of support groups and the Registry itself could be provided to patients upon discharge from hospital. The Applicant should also consider providing information on the Registry on the websites of support groups such as Pieta House and the Samaritans, and to widely disseminate Registry publications including to public and patient representative groups. **Condition 3:** The Data Registration Officers (DROs) should only access the medical records of those who attended the hospital for suspected self-harm. In addition, the DROs should only access the required medical records of these patients and do so as minimally as possible.

Reference ID:	19-073-AF3
Lead Applicant:	Daniel Costello
Lead Data Controller:	University College Cork
Title:	Incidences of new diagnosis of first seizures and epilepsy in Cork City and county over a one year period.
Application Summary:	See HRCDC Meeting minutes of 2nd April 2020
Points to Discuss	The HRCDC considered the Applicant's response to the HRCDC's request for further information in the decision letter of 17th April 2020. See HRCDC Meeting minutes of 2nd April 2020.
HRCDC Comments:	The Chair introduced the agenda item and reminded members of the further information that was requested from the Applicant and that the scope of the declaration is limited to the retention of the personal data collected from the 2017 study; Research Ethical Approval has not yet been granted for the planned 2020 study. The Chair invited members to comment on the Applicant's responses. Based on the response letter received, the consensus of the HRCDC was that a consent declaration could be made. The decision was based on the following discussion points: **Public Interest** • On balance, the HRCDC discussed and considered that there is a public interest case for the retention of the 2017 data. However, they were also of the view that it was still feasible and appropriate to obtain, or at minimum, seek to obtain the consent of participants or next-of-kin assent for those who lack decision-making capacity. **Obtaining Consent/Assent**

	• It was considered that the Applicant's response to the HRCDC queries highlighted an intention and willingness to write to all participants, or their next-of-kin, to inform them of the overall study and to seek their permission to contact them for a structured interview in 2020. The HRCDC discussed the planned proposal to issue a 'consent to contact' letter that gives the participant or their next-of-kin, the choice to (i) allow the researchers to contact them, (ii) decline the option for contact or (iii) to decline the option for contact and to not use the personal data that has been collected to date for research. • The HRCDC emphasised that although a consent declaration can be made where reasonable efforts have been made to obtain consent and where there is no response, participants must be given sufficient opportunity to provide clear, informed consent for the processing of their personal data using suitable and appropriate study information leaflets and consent forms. It was commented that the outlined protocol and letter provided by the Applicant in their response appeared to be more of an opt-out option than a request for consent to retain participants personal data. • Overall, the HRCDC was of the view that the Applicant could have provided more information on their proposed consent protocol. From the Applicant's response it was not clear to the HRCDC that all participants in the study will be asked to give informed consent for the retention of the personal data that was collected in the 2017 study, once contact was made, or if more detailed study information leaflets and consent/assent forms will be used. • The Applicant's 'consent to contact' letter also did not provide information on whether personal data will be destroyed or retained if the participant or their next-of-kin requests not to be contacted and/or request that their data is not used for research. In addition it was not clear what will happen to personal data if no response is provided from the participant or their next-of-kin. • From the information provided, the HRCDC considered that it would be suitable and appropriate to make a limited, 6-month declaration for the retention of the personal data collected from the 2017 study in order to seek consent or next-of-kin assent, where possible. Within those 6-months, an appropriate protocol to obtain participant consent, or next-of-kin assent should be developed, and a plan for how they will handle the personal data if no response is provided. • It was highlighted that the protocol, including the study information leaflets and assent/consent forms, should also be discussed with the research ethics committee, the institution's DPO and PPI groups such as Epilepsy Ireland. • Furthermore, it was highlighted that where the personal data collected in 2017 related to participants under the age of consent for data processing, consent should be sought from that individual if they are now aged 18 years or over.

	Identifying Deceased Individuals • It was noted that the Applicant intends to review the participant's medical record to determine if they are deceased. The HRCDC discussed that medical records may not provide up to data information on whether an individual has died and RIP.ie maybe a more accurate source.
HRCDC Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made.
Duration of Declaration:	The Declaration is made commencing 30th April 2020 and shall be valid for 6 months, until 31st October 2020. The Applicant can request an extension to the duration of the declaration. A request for an extension will consider the efforts and progress made by the Applicant to obtain participant consent or next-of-kin assent.
Conditions Attached:	**Condition 1**: The HRCDC requests that the Applicant develop and implement a suitable protocol to obtain participant consent or next-of-kin assent for the retention of the personal data that was collected as part of the 2017 study. This protocol should include the use of appropriate and clear study information leaflets and consent/assent forms that also outlines what will happen the personal data if the participant does not want to provide consent or assent. Where the data from the 2017 study related to participants under the age of consent for data processing, the Applicant should seek consent if the individual is now aged 18 years or older. The Applicant is requested to consult with their research ethics committee, data protection officer and PPI groups such as Epilepsy Ireland on the protocol, study information leaflets and consent/assent forms. These forms must be provided to the HRCDC before implementing the protocol. (**Note for context:** the HRCDC acknowledged and welcomed the Applicant's response that they will seek to contact all participants in the study. However, based on the information provided it was not clear to the HRCDC that informed consent or next-of-kin assent for the retention of personal data collected as part of the 2017 study data, will be obtained. The HRCDC were of the view that the 'consent to contact' letter may constitute a study opt-out and not a valid consenting process) **Condition 2:** The contact letter to be sent to participants should provide clear information and options to the participant regarding what they wish to happen to their personal data, should they opt not to be contacted. **Condition 3:** Linked to the Condition 2, the Applicant is requested to provide a data management plan regarding the retention or destruction of personal data if no response is provided to the request for consent or next-of-kin assent. **Condition 3:** Where the Applicant wishes to retain the personal data of participants who did not respond to the request for consent/assent beyond the 6-months declaration duration, a

	request for an extension to this declaration can be submitted to the HRCDC. As part of the submission process, the Applicant is requested to provide information on the efforts that have been made to seek consent or next-of-kin assent including the numbers of participants where consent or next-of-kin assent was not provided or where no response was received.
HRCDC Recommendations:	**Recommendation 1:** To more accurately identify if a participant is deceased, the Applicant is recommended to search RIP.ie before referring to the medical records, as medical records may not be updated.

7. Live Declarations

Reference ID:	20-006-AF1/COV
Lead Applicant:	Ger Curley
Lead Data Controller:	The Royal College of Surgeons in Ireland
Title:	A randomized double-blind placebo-controlled trial of intravenous plasma-purified alpha-1 antitrypsin for severe COVID-19 illness
Application Summary:	See HRCDC Meeting minutes of 15th April 2020
Points to Discuss	• The Applicant responded to the HRCDC decision letter of 17th April 2020 confirming acceptance of the HRCDC's decision to give a conditional declaration. • The Applicant also confirmed that the condition attached to the declaration, of implementing a process whereby next-of-kin assent is obtained for each participant as soon as possible, has been fulfilled. • The recommendations set out by the HRCDC have also considered and will be reported on as part of the annual review process.
HRCDC Comments	The HRCDC acknowledged and accepted the Applicants' response and noted the recommendations will be monitored as part of the annual review process.

Reference ID:	19-004-AF2/AMD1/COV
Lead Applicant:	Alistair Nichol
Lead Data Controller:	St. Vincent's University Hospital
Title:	REMAP CAP (COVID-19 Domains and Consent Models)
Application Summary:	See HRCDC Meeting minutes of 2nd April 2020
Points to Discuss	The Applicant responded to the HRCDC decision letter of 10th April 2020 confirming acceptance of the approval of the Declaration Amendment request. It was noted that a copy of the Ethics Approval will be forwarded to the HRCDC. The Applicant also provided an updated Data Protection Impact Assessment (DPIA) form, as recommended by the HRCDC.
HRCDC Comments:	The HRCDC acknowledged and accepted the Applicants' response and noted the recommendation of updating the DPIA for the study, has been fulfilled.

Reference ID:	19-023-AF2

Lead Applicant:	Gerard Curley
Lead Data Controller:	Beaumont Hospital
Title:	Effect of naïve and pre-activated MSCs on monocyte/macrophage function in patients with pulmonary and non-pulmonary sepsis
Application Summary:	See HRCDC Meeting minutes of 2nd April 2020
Points to Discuss	The Applicant responded to the HRCDC decision letter of 17th April 2020 confirming acceptance of the HRCDC's decision to give a conditional declaration.
HRCDC Comments:	The HRCDC acknowledged and accepted the Applicants' response and noted the conditions attached will be monitored as part of the annual review process.

Reference ID:	19-085-AF1
Lead Applicant:	Shona Pfeiffer (RCSI)
Lead Data Controller:	Royal College of Surgeons in Ireland and Beaumont Hospital
Title:	Blood Biomarkers to predict recovery from Ischaemic Stroke
Application Summary:	See HRCDC Meeting minutes of 2nd March 2020
Points to Discuss	The Applicant responded to the HRCDC decision letter of 13th March 2020 confirming acceptance of the approval of the Declaration Amendment request.
HRCDC Comments:	The HRCDC acknowledged and accepted the Applicants' response and noted the conditions attached will be monitored as part of the annual review process.

Reference ID:	19-006-AF1
Lead Applicant:	Hannah Moran & Michael Farrell
Lead Data Controller:	Genomics Medicine Ireland (GMI) & Beaumont Hospital
Title:	Contribution of Whole Genome Sequencing to Brain Tumour Biology
Application Summary:	See HRCDC Meeting minutes of 3rd September 2019
Points to Discuss	GMI updated the HRCDC on its publicity campaign, a condition of the declaration made by the Appeal Panel and provided the HRCDC with a copy of the publicity notice. GMI confirmed that the campaign was carried out in accordance with the timelines and requirements set out by the Appeal Panel.
HRCDC Comments:	The HRCDC acknowledged receipt of the correspondence and the publicity notice provided.

Reference ID:	19-038-AF1
Lead Applicant:	Emer Fallon
Lead Data Controller:	Genomics Medicine Ireland
Title:	The Genomic Basis of Alzheimer's disease in Ireland
Application Summary:	See HRCDC Meeting minutes of 16th December 2019
Points to Discuss	The Applicant acknowledged the clarifications provided by the Secretariat regarding the conditions attached to the declaration made by the HRCDC.

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

Reference ID:	19-064-AF1
Lead Applicant:	Paul Buitelaar
Lead Data Controller:	National University of Ireland, Galway
Title:	Discussion Forum use for Public Health Surveillance Study
Application Summary:	See HRCDC Meeting minutes of 25th November 2020
Points to Discuss	The Applicant notified the HRCDC of the progress on Condition 1 attached to the declaration. The condition of the declaration was to establish the study website which incorporated a participant opt-out feature, within three months of receipt of declaration decision. The Applicant provided a link to the study website highlighting the study.
HRCDC Comments & Recommendations:	The HRCDC made the following points regarding the study website; • The webpage does not feature any specific instruction as to how an individual may 'opt out' from the study, as was outlined in the condition attached. • It is not clear from the webpage how individuals would be aware of the study initially, and how data protection rights can be exercised. Specifically, the HRCDC queried if the study has been publicised on other social media and communication platforms, such as Reddit, Twitter etc
HRCDC Recommendations:	The HRCDC made the following points that should be considered with respect to meeting this condition substantively which will be sent to the Applicant; • The Applicant is advised to consult with the Data Controller's DPO to ensure the webpage providing an overview of the project, meets all data protection requirements, including transparency measures for data subjects whose data may be used for the study. • An opt-out feature, or contact details for participants to opt out, should be visible on the website. • Efforts should be made to publicise the study and website on available platforms in order for study participants to be aware of the website, study details and opportunity to exercise their right to opt-out of the study.

8. Any other Business

- For information purposes the Secretariat provided the HRCDC with a statement from European Network of Research Integrity Offices (ENRIO) on *'Research integrity during a Pandemic'*. The HRCDC were also provided a link to the article '*The Ethics of conducting clinical trials in the search for treatments and vaccines against COVID-19'* from the Faculty of Pharmaceutical Medicine blog, 21 April 2020

- The HRCDC were provided with a template of the updated Integrated NREC-HRCDC Application form for COVID-19 research.
- The Secretariat informed the HRCDC an event that may be of interest; the HRB Primary Care Clinical Trials Network Ireland's fifth national Public and Patient Involvement (PPI) in Research conference