HRCDC
Health Research Consent Declaration Committee

Time: **10:30am – 1:30pm**
Date: **Thursday, 2nd April 2020**
Location: **Videoconference meeting**

Minutes of the Meeting

HRCDC Attendance

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

Quorum for Decisions
☒YES

Consent Declaration Amendment Request:

Applicant	Ref No.	Title
Alistair Nichol	19-004-AF2/AMD1/COV	REMAP – CAP: COVID-19 Domains and Consent Models

New Applications considered at this meeting:

Applicant	Ref No.	Title
Ger Curley	19-023-AF2	Effect of naïve and pre-activated MSCs on monocyte/macrophage function in patients with pulmonary and non-pulmonary sepsis
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
Fergus McCarthy	19-019-AF2	IMPROVED Study (Improved Pregnancy Outcomes by Early Detection)
Karn Cliffe	19-084-AF1	1 Year post-sepsis study
Ignacio Martin-Loeches	19-086-AF1	Sepsis Immunosuppression in Critically Ill Patients

Previous Applications

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

Meeting Items

1. **Opening**
   The Chair opened the meeting and welcomed the members. The Chair thanked members for their engagement and co-operation with the organisation of the meeting via videoconference and wished them well during the ongoing COVID-19 situation.

2. **Apologies**
   Claire Collins, Malcolm Kell

3. **Disclosure of Interest**
   Kathy Brickell declared her interest in application 19-004-AF2/AMD1/COV (REMAP-CAP) and was absent for this part of the meeting.

4. **Minutes of the last meeting**
   Draft minutes of the 2nd March 2020 meeting were circulated in advance and were agreed by the HRCDC.

5. **COVID-19 Rapid Review Process**
   Emily Vereker (EV) provided an overview of the proposed COVID-19 rapid review process that is under development. The process will incorporate a single application form and an integrated approach for both research ethics approval and, where relevant, requesting a consent declaration. The aim is to have a turn-around time from submission to decision within 10 working days.

   The Office of the National Research Ethics Committee (NREC) will coordinate this process. Where relevant, the NREC will forward applications for a consent declaration to the HRCDC Secretariat. Individuals will continue to liaise directly with the Secretariat on any queries relating to the HRCDC process. It was noted that COVID-19 related applications may also be submitted to the HRCDC via the standard process.

   Once a COVID-19 application is received from the NREC, it will be prioritised and triaged as soon as possible by the Secretariat. When ready, the application will be considered at a meeting of the HRCDC. The HRCDC discussed putting in place a dedicated, standing meeting time once a week to consider COVID-19 applications. Dates and times were proposed, and the Secretariat will follow up to confirm. Where no COVID-19 applications are ready then the meeting will not go ahead. Other applications will continue to be considered at standard scheduled monthly HRCDC meetings.

6. **Applications for Amendment Request**

Reference ID:	19-004-AF2
Lead Applicant:	Alistair Nichol

HRCDC
Health Research Consent Declaration Committee

Lead Data Controller	St. Vincent's University Hospital, Dublin
Title:	REMAP-CAP
Application Summary:	See HRCDC minutes of 25th July, 2019
Purpose of Amendment:	The Applicant requests an amendment to the existing consent declaration for the following reasons: • The study protocol has been amended to incorporate COVID-19 patients. • The next-of-kin assent model has been amended to include phone assent on behalf of COVID-19 patients. • In addition to those outlined in the original HRCDC application, 4 new sites are to be added (pending ethics approval).
HRCDC comments:	The Chair introduced the agenda item and requested each HRCDC member to indicate whether the request for the amendment should be made. It was the consensus of the HRCDC that the amendment to the initial HRCDC conditional declaration decision could be made: **Rationale for the amendment** • The HRCDC acknowledged the changes made to the study protocol in light of the ongoing COVID-19 health challenge • Although no public interest test is required the HRCDC noted that the amendments to the study protocol do have a high public interest case **Amended Assent Protocol** • The HRCDC noted and accepted the reasons for amending the next-of-kin assent process to include assent via a phone call. • It was commented that the phone assent process included well thought out questions which the trained researcher will ask the next-of-kin and were in line with new EU guidelines for obtaining assent. **Study Information Leaflet and Consent form** • The HRCDC discussed that the next-of-kin information leaflet and assent form provides an option for the storage of personal data for future research. • The Secretariat highlighted that a consent declaration is study specific and cannot cover the use of personal data in unknown future research studies. A separate HRCDC application maybe required for future studies that wish to use personal data from this study. **Re-affirming next-of-kin assent** • It was discussed that where a participant lacks decision-making capacity for a prolonged period, then next-of-kin assent should be re-affirmed by them at an appropriate time. • The Secretariat noted that the original consent declaration made for this study attached a condition to this effect. It was also highlighted that the conditions and recommendations attached to the original declaration remain in place should the amendment be made. **New Research Sites**

	• It was noted that the new research sites are pending research ethics approval. • The Secretariat highlighted that a consent declaration is not valid where research ethics approval is not in place and that the original declaration attached a condition to this effect. **Data Protection Impact Assessment (DPIA)** • The Secretariat stated that the data protection measures and safeguards outlined in the original application form remain applicable should be amendment be made. • The HRCDC discussed that it would be appropriate to request the Applicant to update the study DPIA and consult with their data protection officers (DPO) in light of the new participant cohort and research sites that will be included in the study.
HRCDC Amendment Decision:	The consensus of the HRCDC was that the condition declaration could be amended as requested by the Applicant.
Amendment Duration:	The Amendment is made commencing 2nd April 2020 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. (This timeline is in line with the timeline for Conditional Declaration).
HRCDC Conditions	**Condition 1.** Confirmation of Research Ethics approval from sites currently awaiting approval (Limerick University Hospital, Beacon Hospital, Mercy Hospital Cork, Cork University Hospital) must be provided to the HRCDC, once granted. No data processing can commence at these sites until such written confirmation is provided to the HRCDC.
Recommendations	In addition to the Recommendations attached to the original HRCDC decision: **Recommendation 1**. The Applicant is requested to consult with their Data Protection Officer on the Data Protection Impact Assessment for this study to ensure that any data risks continue to be identified and that the appropriate mitigating actions and safeguards are implemented. **Recommendation 2.** The HRCDC recommends a review of the assent forms and accompanying study information leaflets used by the researchers, specifically the section entitled '*STORAGE & FUTURE USE OF INFORMATION*'. A consent declaration is study specific and cannot cover the use of personal data for unknown future research studies and this section should be revised for clarity.

7. New Applications

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
Research Objective:	Sepsis is a consequence of infection where the body's immune system becomes abnormal and results in widespread damage to the body, manifest as organ failure. Sepsis is the most common condition in the

	Intensive Care Unit. Unfortunately, up to 40% of patients with sepsis in the ICU will die. Many patients with sepsis also have lung failure, a condition known as Acute Respiratory Distress Syndrome (ARDS). This project aims to understand why and how sepsis and ARDS develops, attempt to detect it earlier and develop new treatments.
Reason for Declaration	A declaration is sought to collect and process the personal data of participants who lack decision-making capacity to provide consent. Instead assent will be obtained from the participant's next-of-kin. When the participant regains capacity, they will be provided with a patient information leaflet and asked to provide explicit consent. Where participants do not regain capacity, an ongoing consent declaration will be required. The scope of the declaration being sought is for the processing of personal data i) already collected from participants since the study commenced in May 2017, and ii) from future participants who lack decision-making capacity to provide consent. Where only next-of-kin assent has been provided the scope of a declaration also includes the ongoing storage of personal data for future research but does not extend to the use of personal data in future, unknown research.
HRCDC Comments:	The Chair introduced the research study and highlighted that, as the Applicant had obtained consent compliant with the previous Data Protection legislation, under the Health Research Regulations, a public interest case is not an applicable factor in the HRCDC decision making process. In advance of the meeting the HRCDC were invited to provide written feedback on the application and this was subsequently collated and circulated to all members by the Secretariat. The Chair summarised the written feedback received. HRCDC members who could not provide written feedback were invited to indicate if 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. In making this decision the following points were raised and discussed in the written feedback and during the meeting: **Public Interest** • Although no public interest case was required as part of the application, the HRCDC were of the view that the study was in the public interest. **Scope of Declaration** • The HRCDC re-emphasised that a consent declaration relates to the processing of personal data and not the collection of samples which is not considered a data processing activity. • The HRCDC queried how many participants had not provided consent for the processing of their personal data. Based on the Applicant's responses, the Secretariat highlighted that 37 participants had been enrolled in the study to date. of which 24 had not provided explicit consent. These 24 participants, as well as prospective

	participants where consent cannot be obtained, are included in the scope of the declaration. • The Secretariat noted the Applicant's response that the scope of the consent declaration also includes the storage of personal data for unknown future research purposes, which is provided as an option in the next-of-kin assent form. The Secretariat had highlighted to the Applicant that where next of kin assent has been obtained, the declaration will also cover the continued storage of personal data, does not extend to the processing of personal data for unknown, future research studies. **Obtaining Consent** • The HRCDC noted and accepted the reasons why it was not possible to obtain consent from participants at the time of admission to the intensive care unit (ICU). • It was also discussed that the next-of-kin assent process provides a suitable safeguard that helps to indicate the will and preference of the participant. • Where the participant does not regain capacity at the time of discharge from the hospital, the HRCDC discussed the reasons why the Applicant has not attempted to re-contact the participant at a later date. • It was commented that not wishing to cause distress is not a sufficient reason, on its own, for not attempting to re-contact and consent participants after they leave hospital • The HRCDC were of the view that the Applicant should develop an appropriate process to attempt to contact participants who have regained capacity and have left hospital and, where possible to do so, to obtain their consent for data processing. • In addition, where the participant lacks decision-making capacity for a prolonged period, the study should seek to re-affirm the next-of-kin assent. • The HRCDC stated such processes should be implemented for both new, prospective participants in the study and the existing 24 participants who have not provided explicit consent. The HRCDC commented that the relatively low number of participants means that this process should be feasible and should also be reported on in the Annual Review. **Appropriate Agreements** • The HRCDC discussed that one of the study's objective is the validation of a laboratory testing device known as 'SepTec'. It was queried what personal data was being transferred and processed and under what terms and conditions, to Dublin City University (DCU), proprietor of the device. • The HRCDC also discussed what personal data, if any, is transferred to the William Harvey Research Institute (WHRI), a named data processor. • The Secretariat highlighted that the validation of the SepTec device is referenced in recent versions of the study information leaflets, but not earlier versions.

	• The Secretariat also highlighted the Applicant's response that the samples sent to DCU and the WHRI are anonymised with no accompanying personal data sent with the samples. DCU receive blood culture results for comparative analysis. • The HRCDC discussed that the Applicant had not provided information on what agreements, if any, are in place with DCU and the WHRI for the transfer of data and samples under terms and conditions to protect the anonymity of participants. • Therefore, it was determined that a suitable condition to attach would be to ensure that the appropriate material and data transfer agreements are in place with DCU and the WHRI. • It was noted that data controller must ensure that the appropriate agreements are also in place with the other data processors noted in the application. **Public and Patient Involvement (PPI)** • The HRCDC discussed the level of PPI within this study. It was acknowledged that the Applicant was an experienced researcher in this field with a history of public and patient engagement on the issue of sepsis more generally. • , The HRCDC were of the view that more PPI on this specific study should be undertaken and would likely benefit the study. It was noted that a number of patient representative groups, including *ICUsteps* could be engaged. **Study Information Leaflets** • It was highlighted that the DPO recommended that the year of birth, not date of birth, be collected. However, the study information leaflet states that date of birth will be collected. The HRCDC discussed that the information leaflet could be amended to say year of birth. • It was acknowledged that the Applicant had amended the most recent study information leaflet to confirm that access to the patient's medical records would be required. However, the HRCDC highlighted that other sections of the information leaflet still contradicts this and therefore further amendments are necessary to avoid confusion. • The Applicant notes the collection of two different bio-samples; blood and bronchoalveolar lavage (BAL). It was noted by the HRCDC that the information leaflet should accurately reflect whether blood or BAL samples are collected and processed for the study or if both are collected and processed, to help ensure clarity for the participant or their next-of-kin. The information leaflets should also accurately highlight whether the samples are collected before or after next-of-kin assent has been obtained. • The HRCDC also stated that the next-of-kin should be informed via the information leaflet how consent may be sought from the participant once they leave hospital. Where the participant regains capacity, they should be informed that next-of-kin assent was previously obtained. • The HRCDC considered that the term 'next-of-kin assent' rather than 'next-of-kin consent' should be used.

	Other • On data minimisation the HRCDC queried if it would be possible to further minimise the level of personal data that is recorded. Specifically, whether the name of the participant needs to be recorded if other personal identifiers such as gender and medical record number are also captured. • It was noted that the DPO recommends updating the data protection impact assessment over the lifetime of the study. The HRCDC commented that this would help strengthen data protection for the study. • The HRCDC noted that the Applicant wished to retain the master list which enables the identification of the participants for 15 years after the study concludes. The Secretariat highlighted that this aligns with the scope of the declaration that includes the retention of personal data for future research. • As well as not wishing to cause distress, the Applicant states that they have/will not contact participants once they leave the hospital as some may be deceased. The HRCDC noted that the processing of personal data of those who are deceased falls outside the remit of the Health Research Regulations and therefore a declaration would not be required for this cohort.
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 August 8th, 2018 and shall be valid until 31st May 2021 and 15 years thereafter (until May 31st, 2036), or upon confirmation that the data has been rendered anonymised or destroyed, or whichever occurs sooner.
Conditions Attached:	**Condition 1:** Where explicit consent has not been obtained from the participant at the point of discharge from hospital, the Applicant is requested to implement an appropriate process for re-contacting participants and where possible, to seek their explicit consent for data processing. The Applicant must make reasonable efforts to obtain consent via an appropriate process and must report on this as part of the Annual Review, including the number of participants where consent has and has not been obtained. **Condition 2:** Where a participant continues to lack decision-making capacity for a prolonged period of time and where next-of-kin assent remains in place, the HRCDC request that the following action should be taken as an additional safeguard: the Applicant should seek confirmation from the next-of-kin who provided assent, that they wish for the 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. **Condition 3:** As a data protection safeguard the HRCDC has requested that all appropriate contractual arrangements or agreements must be in place between the data controller of the study and collaborating Institutions receiving participant data and/or biosamples. Specifically;

	i) arrangements are in place with Dublin City University (DCU) and the William Harvey Research Institute (WHRI) to ensure that the data and material is transferred under appropriate terms and conditions to ensure the anonymity of the participants. ii) appropriate data processing agreements are in place with the Royal College of Surgeons in Ireland, noted as a data processors in this study. Please inform the Secretariat once this condition is met as soon as practically possible. This condition will also be a reporting requirement as part of the Annual Review. **Condition 4:** To ensure clarity for participants and their next-of-kin, the HRCDC requests the Applicant to amend the study information leaflets as follows: - Revise 'next-of-kin consent', to 'next-of-kin assent' - In line with DPO feedback, consider stating 'year of birth' will be collected not 'date of birth' - Where relevant, participants should be informed that assent was previously provided by their next-of-kin - Inform the next-of-kin how their relative's consent will be sought at a later point in time should they regain capacity - Ensure that the description of collecting of biosamples accurately reflects the practice; i) whether samples are collected before or after next-of-kin assent or participant consent is obtained and ii) whether blood or BAL samples are collected and processed or if both are collected and processed - The participant information leaflets states the study *'does not require access to medical record*s'. This should be revised/or removed entirely, as medical records will be accessed.
HRCDC Recommendations:	**Recommendation 1:** The HRCDC acknowledge the Applicant's experience in engaging with the public and patients on the issue of sepsis. The HRCDC recommend that the Applicant enhance the level of public and patient involvement in this specific study, including engagement with representative groups such as ICUsteps. **Recommendation 2:** The HRCDC recommends that the Applicant consider further data minimisation measures where possible. Specifically, **i)** considering if the name of the participant must be recorded if other personal identifiers such as the medical record number are retained, **ii)** if year of birth can be recorded instead of date of birth, **iii)** any other data minimisation measures are appropriate. The DPO should be consulted with as necessary.

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
Research Objective	Epilepsy is a notable cause of disability and mortality and poses a substantial economic burden for health care systems, individuals and their families. Epidemiological studies are necessary to understand the

	full public health burden of epilepsy, to set public health and health care priorities within a population and to elucidate methods for early detection and treatment. Assessment of patients presenting with first seizures is critical to differentiating epileptic seizures from other conditions that resemble epileptic seizures, also known as 'seizure mimics'. This study was carried out in the defined area of Cork city and county from 1st January 2017 to 31st March 2018. The study utilised multiple data sources to capture all cases of possible first seizures, new diagnosis of epilepsy and seizure mimics whose first interaction with a medical service (community and hospital setting) for the seizure event occurred during 2017. Both prospective and retrospective methods where used to ascertain the number of cases and data processed in the study was acquired during the standard delivery of healthcare.
Reason for Declaration	A consent declaration is requested to: **(i)** continue to store and process the personal data of participants included in the 2017 incidence study, and **(ii)** to conduct a 3-year follow-up study that will involve further data collection and analysis of all participants who were included in the 2017 epilepsy incidence study (Note: the 3-year follow-up study will not include any new subjects). At the time of consideration by the HRCDC, the Applicant has not yet requested REC approval for the 3-year follow-up study. Therefore, the scope of the declaration is restricted to point **(i)** above.
HRCDC Comments:	The Chair introduced the research study. In advance of the meeting the HRCDC were invited to provide written feedback on the application and this was subsequently collated and circulated to all members by the Secretariat. The Chair summarised the written feedback received. HRCDC members who could not provide written feedback were invited to indicate if 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 that the study may not meet the requirements for a declaration and that further information is required from the Applicant. Therefore, a formal decision would be deferred pending receipt of further information from the Applicant. The decision was based on the following discussion points that were raised in the written feedback and during the meeting: **Scope of the Declaration:** • The Secretariat highlighted that queries put to the Applicant were based on the understanding that the declaration was for the continued use and retention of personal data from the 2017 study, and the collection and processing of new data in the 2020 follow-up study. • The Applicant subsequently confirmed that research ethics approval has not been granted for the 2020 follow-up study and therefore the scope of the declaration, if made, will not extend to the use of personal data for this follow on study.

	• The HRCDC considered that the 2020 follow-up study cannot be undertaken if a declaration for the continued storage of the 2017 data is not made. **Public Interest Case** • The HRCDC were of the view that there was public interest in this study, including the retention and use of the personal data to conduct the follow-up study in 2020. • However, the HRCDC were not yet confident that the public interest case sufficiently outweighed the need to get explicit consent. • Concerns were raised at the efforts that were made by the Applicant to seek consent when the study first commenced and the efforts that have been made to date. • Furthermore, the HRCDC also had concerns over the lack of information and transparency provided to participants, especially given the level of personal data that has been collected and transferred to UCC from the various data sources. **Requirement for Explicit Consent** • The HRCDC discussed the Applicant's reasons for not seeking explicit consent in 2017, namely due to its epidemiological nature, requiring consent could bias the data. It was discussed that not seeking consent for this reason was common among epidemiological studies. • In addition, the HRCDC noted the Applicant's response that some participants may not have had decision-making capacity to provide consent for data processing at the point of data collection. • The HRCDC noted that participants were identified, and their data collected, from a number of sources throughout 2017, including hospitals, General Practice, and community health services in Cork. It was highlighted that no attempts were made to seek consent from participants, or where they lack capacity, to seek next-of-kin assent, despite there being opportunities to do so during 2017 and thereafter. • The HRCDC also discussed the Applicant's response that many participants continue to be engaged with follow-up care and treatment. The HRCDC were of the view that this opportunity should have been utilised to attempt to obtain consent or next-of-kin assent for both the ongoing retention of the data and, if approved by the Research Ethics Committee, the 2020 follow-up study. • The HRCDC noted that data on children, who are a particularly vulnerable group, was collected and processed without the seeking the consent of their legal guardian. • In relation to the 2020 follow-up study the HRCDC also noted the Applicant's response that data will not just be collected from the participant's medical notes but also by a questionnaire. The HRCDC were again of the view that this provided another opportunity to obtain consent or next-of-kin assent. **Transparency** • Linked with the topic of obtaining consent, the HRCDC noted there was no evidence of transparency measures implemented to inform

	participants, or their next-of-kin, that their personal data was collected and transferred to UCC for this study. • It was highlighted that at one point the study had engaged with Epilepsy Ireland to try and seek consent but this process was not commenced. • The HRCDC commented that the Applicant initially sought to consent participants who were identified by Epilepsy Ireland. Although this was not undertaken the HRCDC stated that the study could have continued to engage with this and other public and patient representative groups. • The HRCDC were of the strong view that much robust attempts should have been made by the study to inform participants and/or their next of kin about this study and the use of their data.
HRCDC Declaration Decision:	The consensus of the HRCDC was that a formal decision would be deferred pending receipt of further information
Further Information Requested:	**Query 1.** The Applicant is requested to provide the HRCDC further information on: **(i)** what protocol can be implemented to seek explicit consent from participants, or to seek next-of-kin assent where the participant lacks decision making capacity, for the use of data already collected; and **(ii)** what transparency measures will be put in place to ensure that participants and their next-of-kin are aware of the study, the processing of their personal data and how to withdraw from the study. **(iii)** please outline the feasibility and willingness to implement a consent/assent protocol and the transparency measures. *Note for context*: The HRCDC note the reasons highlighted for not obtaining consent for the collection of personal data in 2017, including the decision-making capacity of participants being a factor and concerns relating to data bias. Based on the information provided, the HRCDC have the following concerns: - A wide range of data points have been collected from the broad source of medical records. - The participants and their next-of-kin have not been made aware of the study or that their personal data has been and maybe further processed for health research. - No attempts have been made to follow-up with participants to seek their consent, or, where they may still lack decision-making capacity, to obtain next-of-kin assent. - Opportunities existed and may continue to exist, to obtain consent or next of kin assent, particularly where the participants are continuing to receive follow-up care and treatment. - It is stated that where medical records are incomplete, patients or next-of-kin will be contacted, which suggests a means of obtaining consent or assent at that point in time. It is understood from the application that the 2020 follow-up study would involve contacting the same participants whose personal data has already been collected, participate in a phone interviews and

	questionnaires. This indicates there it is feasible to contact participants to seek explicit consent, or next-of-kin assent, for the retention of data already collected and the processing of new data. **Query 2.** The HRCDC has requested detail as to how engagement with public and patient representative groups will be considered regarding: **(i)** the collection and use (processing) of the data and for its use for future studies, and **(ii)** including the topic of obtaining explicit consent or next-of-kin assent. *Note for context:* Although there was initial contact with Epilepsy Ireland, there does not appear to be any contact with Epilepsy Ireland or other advocacy groups to seek consultation from a patient perspective on the design of the study, and future studies. Although consent was not obtained via Epilepsy Ireland, the HRCDC were of the view that engagement with Epilepsy Ireland should be continued and with other public and patient representative groups as appropriate. **Query 3.** Personal data has been collected and transferred from a number of data sources to UCC. Please detail what arrangements or agreements, or equivalent appropriate safeguards, are or will be in place between UCC and the organisations or individual practitioners that provided this data.

8. Live Declarations

Reference ID:	19-019-AF2
Lead Applicant:	Fergus McCarthy
Lead Data Controller:	University College Cork
Title:	IMPROVED Study (Improved Pregnancy Outcomes by Early Detection)
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 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:	19-084-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, 16th December 2019 and 2nd March 2020
Points to Discuss:	The Applicant responded to the HRCDC decision letter of 13th March 2020 confirming acceptance of the amended 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:	19-086-AF1
Lead Applicant:	Ignacio Martin-Loeches
Lead Data Controller:	St. James' Hospital, Dublin
Title:	Sepsis Immunosuppression in Critically Ill Patients
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 HRCDC's decision to give a conditional declaration. The Secretariat provided clarity in relation to one of the attached Recommendations.
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.

9. Previous Applications

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 and 2nd March 2020
Points to Discuss:	The Applicant confirmed to the HRCDC that having withdrawn the HRCDC application, the samples and associated data have since been destroyed.

10. Annual Report

The HRCDC's 2019 Annual Activities Report was circulated to members in advance of the meeting. Members suggested some minor amendments to the report and were invited to provide further comments by email to the Secretariat.

11. Any other Business

a. The Secretariat informed the HRCDC that the Applicant of application 19-006-AF3 had commenced the publicity campaign, as a required by the Appeal Panel under the Condition Declaration made. A copy of the publicity notice was provided to the HRCDC for its records.

b. The Secretariat provided a copy of newly published EU 'Guidance on the Management of Clinical Trials during the COVID-19 (Coronavirus) Pandemic' and the Department of Health 'Ethical Framework for Decision-Making in a Pandemic'. The Secretariat highlighted the references to the importance of obtaining informed consent, and using alternative, but equally valid means to obtain consent from patients.