HRCDC
Health Research Consent Declaration Committee

Date: 13th October 2020
Location: Videoconference

Minutes of the Meeting

HRCDC Attendance

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

Quorum for Decisions
☒**YES**

New Applications - For Consideration

Applicant	Ref No.	Title
Ger Curley	20-027-AF1	Immune Dysfunction in Acute Brain Injury
Fintan Sheerin	20-029-AF1	Models of Care for people Ageing with an Intellectual Disability
John Laffey	19-040-AF3	The Interaction between Noradrenaline dosage, Troponin level and Mortality in Septic Shock
Austin Stack	19-060-AF3	National Kidney Disease Surveillance System and Quality Assurance Programme

Meeting Items

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

2. **Apologies**
   John Ferguson, Simon Furney and Malcolm Kell. Zubair Kabir was absent for part of the meeting.

3. **Disclosure of Interest**
   Aideen Hartney declared her interest in application 20-029-AF1 'Models of Care for people Ageing with an Intellectual Disability' and was absent for this part of the meeting.

4. Minutes of the last meeting

Draft minutes of the 23rd September 2020 meeting were circulated in advance of the meeting and were approved by the HRCDC.

5. Matters arising

The HRCDC was informed of the Applicant's intention to appeal the HRCDC decision for application 20-021-AF1/COV made at the meeting of 23rd September 2020.

6. New Applications

Reference ID:	20-027-AF1
Lead Applicant:	Ger Curley
Lead Data Controller:	Beaumont Hospital, Dublin
Title:	Immune Dysfunction in Acute Brain Injury
Research Objective:	Acute brain injuries are a common cause of death and serious disability. Patients with acute brain injury frequently require admission to the intensive care unit because of the serious nature of these conditions. This group of diseases includes: traumatic brain injury, subarachnoid haemorrhage and stroke (ischaemic stroke and intracerebral haemorrhage), as well as others. Though the causes of these conditions differ, they all share a number of similarities in the way in which they affect patients. For example, such patients often experience a "systemic inflammatory response", whereby the immune system appears clinically to be more active than normal, or alternatively appearing more vulnerable to infection than we would typically expect. White blood cells are the body's, 'immune system' cells. Whilst these cells are important for fighting infection through the generation of inflammation, when their function is abnormal or dysregulated they can be harmful to the individual. There are a large number of chemical substances made by the body that control the movement of immune cells in the body and how they behave in the blood and in the other organs. This research wishes to study the immune system of individuals with acute brain injuries. To achieve this, researchers will examine the white blood cells and the chemical substances (inflammatory mediators) that they produce in critically ill patients with and without acute brain injury, as well as healthy people (for comparison). This will be done by looking at both blood samples and samples of "washings" from the lungs (called "bronchoalveolar lavage").
Reason for Declaration:	A consent declaration is sought for participants who lack the decision-making capacity to provide consent. In such circumstances, next-of-kin assent will be sought prior to enrolment, followed by deferred consent if the participant regains capacity. The data processing activities include the collection, pseudonymisation, transfer, analysis and storage of personal data. In addition, the scope of the consent declaration includes the storage of data only for future research where next-of-kin assent has been provided. The declaration does not extend to participants recruited for the 'healthy control' cohort.
HRCDC Comments:	The HRCDC noted that ethics approval had been granted by the Research Ethics Committee for the study where the design,

	methodology and ethical aspects of the study, including consent protocols are considered. Only studies that have ethical approval, or provisional ethical approval, can be considered by the HRCDC to consider if the public interest outweighs the requirement for explicit consent. The Chair 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 conditional declaration should be made: **Public Interest:** • The HRCDC was of the view that the study has a strong degree of public interest. It was further commented that the study and research question were clearly defined and outlined by the Applicant. **Public and Patient Involvement (PPI)** • The HRCDC discussed that PPI is considered an important data protection safeguard and has been highlighted in previous decisions where consent declarations made had attached conditions or recommendations for enhanced PPI. • The HRCDC considered that the Applicant should greatly enhance the level of PPI within this study, going beyond activities relating to the dissemination of research findings, to create a more patient-centred approach with regard to the development and implementation of the study. The Acute Brain Injury group and Clinical Trials Network were referenced as potentially useful points for engagement. • The HRCDC also requested the Applicant to report on the progress made to enhance PPI within 3 months. **Transparency** • The HRCDC was of the view that broader transparency measures should be undertaken and that this could be achieved in part through enhanced PPI activities. • The HRCDC also discussed the study information leaflet and assent/consent form. It was noted that the copies provided appeared to be standard hospital templates and could be further tailored to this specific project. Specifically, some sections of the form contradicted other sections in terms of aspects of the study. • The data protection rights section of the next-of-kin information leaflet states that they have the right to access their relative's data. The HRCDC queried if this was in line with GDPR and, if not, should be amended. It was also noted that the next-of-kin information leaflet and assent form refers to the next-of-kin providing 'explicit consent' rather than 'assent'. • The HRCDC queried what happens to the participant's personal data should they or their next-of-kin wish to withdraw from the study. The Secretariat highlighted the section of the study

	information leaflet which stated that if participants or their next-of-kin wish to withdraw that they can also request to have any of their information that has already been collected destroyed. **Reaffirming Assent** • Where the participant has not regained capacity and next-of-kin assent remains in place, the HRCDC discussed the Applicant's response, that attempts are not made at a later date to re-assess decision-making capacity and obtain consent or re-affirm next-of-kin assent. • The HRCDC was of the view that the Applicant should develop an appropriate process to follow up with participants where they have already been discharged from the hospital, to determine whether they have re-gained capacity and, where possible to do so, to obtain their deferred 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 at an appropriate time including after hospital discharge. • It was discussed that the participant's medical discharge notes should help inform whether capacity has been regained or not. **Other** • The HRCDC queried whether the data required for the study could be further minimised. For example, it was noted that date of birth, as well as exact address, medical record and contact numbers are collected. • The HRCDC noted the Applicant's response that controller-processor arrangements were not required to govern the processing of data by individuals acting under the direct supervision of the lead researcher, of the Data Controller. It was discussed that it is the responsibility of party's involved in the study to ensure that the required agreements/arrangements are in place.
HRCDC Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made.
Duration of Declaration:	The Declaration is made commencing 13th October 2020 and shall be valid until 31st March 2021 and for 10 years thereafter, until 31st March 2031 or upon confirmation that the data has been rendered anonymised or destroyed, or whichever occurs sooner.
Conditions Attached:	**Condition 1:** The inclusion of patients and the public in research is considered an important data protection safeguard to ensure the perspective of the participant is always considered. The HRCDC requests the Applicant to substantially enhance the level of public and patient involvement in this specific study. In fulfilling this condition, the Applicant is expected to undertake PPI activities beyond the dissemination of the research findings that will result in a more patient-centred approach regarding the development and implementation of the study. Consideration should be given to active engagement and consultation with the Acute Brain Injury

	group, Irish Critical Care- Clinical Trials Network and other relevant groups. The Applicant is requested to report on the progress made to enhance PPI by 31st January 2021. **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 actions 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 that does not cause undue distress or harm to the individuals concerned. -where participants have already been discharged from the hospital and prior to assent being reaffirmed, it should also be determined whether the participant has re-gained capacity and, where possible to do so, to obtain their consent for data processing. The Applicant must report on this as part of the Annual Review, including the number of participants where deferred consent has and has not been obtained
HRCDC Recommendations:	**Recommendation 1:** To ensure clarity and transparency for participants and/or their next-of-kin, the HRCDC requests that the Applicant ensures that template study information leaflets are tailored specifically for each study, removing unrelated or irrelevant content. In that regard, the HRCDC recommends amending the study information leaflet and assent/consent forms as follows: i) The information and options provided to participants and/or their next-of-kin regarding the future storage and use of data and samples is unclear and may cause confusion. For example, it is noted that samples will not be used in other research studies, however the assent/consent forms provide several options regarding the future storage and use of samples and data. The information and options provided for the future storage and use of samples and data should be consistent and clear to the participant and/or their next-of-kin so that they can clearly indicate their preferences. On the future use of data, it should also be clear to individuals that assent from the next-of-kin extends to the storage of data only. The Applicant should ensure that the consent obtained for the future use of data is compliant with data protection legislation. ii) The term 'assent' rather than 'consent/explicit consent' in the next-of-kin assent study documents should be utilised. iii) Point 8 under 'data protection' states that 'family members have the right to access the personal data of their relative'. It is recommended that this statement is discussed directly with the Data Controller's Data Protection Officer to ensure that is in line with data protection legislation.

	iv) It should be made very clear to the next-of-kin/proxy or participant, that they have the option to have their data withdrawn from the study or destroyed, and at what point in time they can no longer withdraw their data from study. **Recommendation 2:** The HRCDC recommends that the Applicant considers further data minimisation measures where possible. Specifically, consider if age, date of birth, full address and contact numbers are required if the medical record number is also collected. The DPO should be consulted with as necessary.

Reference ID:	20-029-AF1
Lead Applicant:	Fintan Sheerin
Lead Data Controllers:	Trinity College Dublin The National Disability Authority
Title:	Models of Care for people Ageing with an Intellectual Disability
Research Objective:	People ageing with an intellectual disability are more likely to have complex health issues. Given that complexity, this study looks at the different ways in which services (specialist intellectual disability services and nursing homes) provide for their care and support. It will explore how effective those different care models are in terms of health and quality of life and what the cost implications are now and into the future. It will do this through reviewing the existing evidence, interviewing the management teams in intellectual disability services and nursing homes, interviewing older individuals living in those services and their family members. It will also survey all intellectual disability services to find out what types of services and supports are offered, to give an overall national picture of what is available.
Reason for Declaration:	A consent declaration is sought for participants who lack decision-making capacity to provide consent for data processing.
HRCDC Comments:	The HRCDC noted that ethics approval had been granted by the Research Ethics Committee for the study where the design, methodology and ethical aspects of the study, including consent protocols are considered. Only studies that have ethical approval, or provisional ethical approval, can be considered by the HRCDC to consider if the public interest outweighs the requirement for explicit consent. The Chair 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 decision should be deferred pending receipt of further information: **Public Interest and Research Objective** • The HRCDC noted that the question on public interest was not directly addressed by the Applicant. Notwithstanding this, the HRCDC acknowledged that there is potential public interest, but was of the view that further information on the study's objectives

	and design are required in order to sufficiently determine the significance of the public interest in the study in the context of the overall study. • Specifically, it was discussed that further information should be provided to understand what is meant by exploring and comparing models of care, and what extent of data will be collected from the interviewees in order to answer the research question. **Assent/Consent Process** • It was the view of the HRCDC that information regarding the assent/consent process was inconsistent and therefore further clarity should be provided by the Applicant. For example, the Applicant states that participants and their families will be provided with information on the study and after one week the site co-ordinator will follow up to obtain consent to participate. However, elsewhere the Applicant noted that the participant will be asked to sign and return a separate 'expression of interest form' if they wish to take part. • It was also not clear which study documents are provided to participants and their families or at what point in time. The accessible study information leaflet indicated that up to three different documents may be sent to the participant at once. The HRCDC was of the view that doing so could cause confusion. • Where a participant lacks decision-making capacity, the HRCDC noted that a family member who has been involved in the care arrangements for the participant may act as a proxy interview respondent. • However, it was not clear if formal next-of-kin or relative assent, on behalf of the participant, is obtained to process the participant's personal data. The HRCDC was of the view that formal assent should also be obtained as an appropriate data protection safeguard. • Furthermore, while it was acknowledged that a specific family member may be best placed to act as a proxy respondent at the interview stage, the HRCDC queried if they will also always be the most appropriate individual to provide assent for data processing on behalf of the participant. **Participant/Family Interviews** • It was queried how the study, specifically the interviews, will be conducted in the context of the ongoing COVID-19 situation. • Furthermore, it was not clear how or if the participant who lacks decision-making capacity will be involved in the interview process, for example, whether the participant can attend the interview or contribute any feedback to the interview questions. **Public and Patient Involvement (PPI)** • The HRCDC noted the Applicant's response that the advice gained from the Intellectual Disability Study - The Irish

	Longitudinal Study on Ageing (IDS-TILDA), through its consultation process, is being applied in this study. • However, the HRCDC was of the view that specific PPI should be undertaken for this study in addition to seeking the expertise of those overseeing the IDS-TIDA study. **Audio files and Transcripts** • With regard to the participant's data protection rights as outlined in study information leaflet, it was queried how participants could request a copy of the interview recording or transcript once they have been anonymised or destroyed. • It was also not clear when the audio file, sent to the data processor for transcribing, is subsequently destroyed by the data processor. **Other** • In addition to the disability service providers, the HRCDC noted that two participants with an intellectual disability may be recruited from an advocacy organisation. The HRCDC queried whether the scope of the declaration will include these participants. The Secretariat noted that the scope of the declaration is for participants who lack decision-making capacity to provide consent.
HRCDC Decision:	The consensus of the HRCDC was that a decision would be deferred pending receipt of further information.
Further Information Requested:	**Query 1- Public Interest:** The Applicant is requested to provide the HRCDC with further information on specific elements of the study so that it can sufficiently determine the level of public interest. Specifically, the Applicant is requested to directly describe the public interest in undertaking this study and, correspondingly, to further clarify the research question that it aims to address, including providing information on what is meant by exploring and comparing 'models of care'. In addition, the HRCDC requests further information on the types of, and importance of the data that will be collected from the interviewees in order to answer this research question. *Note for context:* The HRCDC acknowledges that the study has potential public interest. However, based on the information provided the HRCDC is unable to determine if the level of public interest is of a sufficient degree to make a consent declaration. Therefore, the Applicant must directly address the points outlined in Query 1 so that the HRCDC can consider if a consent declaration should be made. **Query 2 - Consent/Assent:** The HRCDC requests the Applicant to **i)** clearly outline the assent/consent process including confirming whether formal assent on behalf of the participant who lacks decision-making capacity will be obtained for data processing from an appropriate individual.

	Where assent will be obtained, the Applicant is also requested to **ii)** clarify who assent will be obtained from - if it will be obtained from the participant's next-of-kin or the family member who is acting as the proxy interviewer, or from a separate individual. The Applicant is also requested to **iii)** clarify the extent to which, and how, participants who lack decision-making capacity will be involved in the interview process. When responding to this query, the Applicant is requested to **iv)** consider how the ongoing COVID19 restrictions will impact the implementation of the assent / consent process. *Note for context:* The HRCDC considers assent for data processing from an appropriate individual to be an important data protection safeguard in scenarios where the participant lacks decision making capacity to provide consent. With regard to the assent and consent process, the information provided by the Applicant is inconsistent and unclear. For example: - The Applicant states that participants and their families will be provided with information on the study and after one week the site co-ordinator will follow up to obtain consent to participate. However, elsewhere the Applicant states that the participant will be asked to sign and return a separate 'expression of interest form' if they wish to take part. - It is not clear which documents such as study information leaflets and consent forms are provided to participants and their families or at what point in time. The accessible study information leaflet indicated that up to three different documents may be sent to the participant at once. - The Applicant states that a family member who has been involved in the care arrangements may act as a proxy respondent at the interview stage and a consent form for this family member's participation in the interview has been provided. However, it is not clear if formal assent for data processing on behalf of the study participant who lacks decision making capacity is obtained from an appropriate individual such as the next-of-kin or another family member, or from the proxy respondent. **Query 4 – Patient & Public Involvement:** The HRCDC has requested further detail as to how specific public and patient involvement could be further undertaken and implemented for this study. *Note for context:* The HRCDC notes the Applicant's response regarding the advice gained from researchers overseeing the IDS-TILDA study. However, the HRCDC is of the view that PPI should be undertaken on a per study basis, wherever possible. **Query 5:** The HRCDC requests confirmation that all copies of the audio file sent to the data processor (Audiotrans) for transcribing, is subsequently deleted when the transcribing has been completed.

	Please provide a timeline as to when the data processor will delete the audio files.

Reference ID:	19-040-AF3 ***(Application subsequently withdrawn)***
Lead Applicant:	John Laffey
Lead Data Controller:	Galway University Hospital
Title:	The Interaction between Noradrenaline dosage, Troponin level and Mortality in Septic Shock
Research Objective:	Septic shock is a condition where severe infection causes the blood pressure to fall to below normal. This low blood pressure can be fatal. The most common medication used in intensive care units to treat this low blood pressure is called noradrenaline and is usually effective in increasing the blood pressure back to normal levels. Sometimes high doses of this drug are required to achieve a normal blood pressure. The likelihood of dying from septic shock is increased considerably if very high doses of noradrenaline are required. The reasons for this may be that higher doses of noradrenaline are needed if the patient has a more severe infection, but it might also mean that very high doses cause damage to the heart. A blood test called "Troponin" is used to detect damage to the heart muscle in many conditions and is done frequently in ICU patients. This study wants to see if patients who require high doses of noradrenaline have more of a chance of dying if their troponin is also elevated compared to patients who are on equally the same amount of noradrenaline without an elevation of troponin. It also wants to see what influence the need for higher doses of noradrenaline in patients with septic shock and if these are related to a worse outcome.
Reason for Declaration:	Patients admitted to the ICU at University Hospital Galway since 2005 are recorded in a clinical information system. Over 20,000 patients have been treated in the ICU and have data stored in this system. This study seeks to use the data contained in this clinical information system on all patients admitted to ICU since 2005 for the purpose of this study. The applicant outlines reasons why it is not possible to obtain consent including the number of participants. The processing activities include extracting personal data from the ICU clinical information system and subsequently pseudonymising and using the extracted data for the purpose of this study. The extracted data will be cleansed of identifying information using specialist software. Analysis undertaken by third parties outside the data controller is on irrevocably anonymised data.
HRCDC Comments:	The HRCDC noted that ethics approval had been granted by the Research Ethics Committee for the study where the design, methodology and ethical aspects of the study, including consent protocols are considered. Only studies that have ethical approval, or provisional ethical approval, can be considered by the HRCDC to consider if the public interest outweighs the requirement for explicit consent.

	The Chair 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 decision should be deferred pending receipt of further information: **Public Interest** • The HRCDC was of the view that the research has a strong degree of public interest. **Replica Database** • The HRCDC discussed the development of an extensive replica database of all patients admitted to the ICU that will exist in parallel with the ICU clinical information system. • The HRCDC noted the Applicant's response as to why data on all patients admitted to the ICU will be extracted for the purpose of this study, which is to allow for access to an unbiased data set and relevant comparator groups It was also noted that the study had begun in September 2019, focusing on a smaller sub-group of patients who required treatment with prone positioning. • The HRCDC discussed that the ICU clinical information system, called 'Metavision', should allow users to search for and extract the personal data they need for their research study. Therefore, and having regard to the volume of data that will be collected, the HRCDC queried why it was necessary to develop and maintain such an extensive replica database that will exist in parallel with Metavision, to answer the research question. • It was also commented that the National Office of Clinical Audit (NOCA) could provide an alternative data source to answer the research question and possible mitigate the need to collect such a large volume of data directly from the Metavision system. **Future Research** • The HRCDC discussed that the replica database may be linked with other HSE data sources in the future and questioned why this was necessary. It was also discussed that the replica database may be retained and used for future research studies. • The Secretariat noted the Applicant's response confirming that no other data linkages had occurred to date. Furthermore, the Secretariat has highlighted to the Applicant that the scope of the declaration, if made, is limited to the processing of personal data for this specific study only. It was commented that any future linkages or processing of the personal data in the replica database in other research studies would require an amendment or a new consent declaration. • However, given the number of participants and volume of data involved, the HRCDC was of the view that more information is required from the Applicant with regard to the secure storage and governance arrangements that will be in place for the longer-term retention and potential broader use of the replica database once the study has concluded.

	Consent and Transparency • The HRCDC discussed the feasibility of obtaining consent or next-of-kin assent from both retrospective and prospective patients. • There was a consensus that it would very difficult to obtain consent or next-of-kin assent from the retrospective patients due to the number of admissions made to the ICU since 2005. • On the prospective patients, the HRCDC noted the Applicant's response that, for future entries into the clinical information system, a system for obtaining consent will be developed within the hospital system. • The HRCDC discussed the feasibility of obtaining prospective consent or assent, but more information is required from the Applicant regarding the number of expected participants required for the study. • The HRCDC was of the view that all participants should be made aware of this study and of their data protection rights, including the right to withdraw if they wish to do so. A number of proposed transparency measures were outlined by the Applicant. The HRCDC discussed that additional information would be required to clarify what transparency measures can be immediately implemented to inform participants and the public about this specific study. **Public and Patient Involvement:** • The Applicant outlined some PPI activities, including seeking the opinion of patients and family members who have had experience in the ICU. The HRCDC queried if this PPI activity was undertaken specifically for this study or for research undertaken in Galway University Hospital more generally. • In addition, other PPI activities to be developed were noted including PPI in the development of a specific research patient information leaflet. However, it was noted that this is not guaranteed as it is subject to funding. • The HRCDC was of the view that PPI could be further enhanced and therefore more information should be requested from the Applicant on what could be done in this area. **Other:** • The HRCDC noted that research ethics committee approval (REC) was granted in 2017. It was queried whether the REC approval in place remains valid.
HRCDC Decision:	The consensus of the HRCDC was that a decision would be deferred pending receipt of further information.
Further Information Requested:	**Query 1 - Public Interest:** The HRCDC recognise the public interest in this specific research study, however it is not clear why the study needs to create an extensive replicate ICU database that will exist in parallel with Metavision to answer the research question.

	Please **i)** elaborate on the public interest for creating this extensive database to answer the research question and **ii)** outline whether the required data can be collected in another way that does not result in a replica database being created. Correspondingly, it is also noted that the replica database will be retained for a number of years and maybe used in future research studies. Considering its voluminous nature and that it will be created for research purposes without consent, **iii)** why is this replica database needed for future research and can future research studies extract the data required directly from the Metavision system or other data sources, eg NOCA? Further detailed information is also required to understand **iv)** what security, access and governance arrangements will be in place regarding the retention and use of the replica database in future research. **Query 2 - Prospective consent:** In order to consider the scope of the consent declaration, if made, and the feasibility of obtaining consent going forward, the HRCDC requires **i)** further information on the anticipated number of prospective participants that could be entered into the clinical information system as a result of being admitted to the ICU. The information can be an estimation based on historical data of ICU admissions over a specific timeline. The HRCDC further requires **ii)** information as to how a consent/deferred consent protocol could be implemented in the future, as is referenced in the application submission documentation. **Query 3 - Transparency**: Further details are required as to how all patients can become aware of the research study and the existence of the replica database that contains their data, and how they may exercise their data protection rights, including withdrawing from the study. **Query 4 - PPI engagement**: Further detailed information is required to understand how the Applicant is committed to implementing robust and ongoing PPI for the duration of the study. A timeline and roadmap for this activity should be considered as part of the response. **Query 5 - Ethics Approval:** Please confirm that the ethics approval granted in 2017 is still valid for the research activities outlined in the application to the HRCDC.

Reference ID:	19-060-AF3
Lead Applicant:	Austin Stack
Lead Data Controller:	University of Limerick (UL)

Title:	National Kidney Disease Surveillance System (NKDSS) and Quality Assurance (QA) Programme
Research Objective:	Chronic Kidney Disease (CKD) affects at least 1 in 10 persons in Ireland and may if untreated progress to kidney failure and premature cardiovascular disease and death. Early identification of kidney disease and treatment of underlying risk factors can slow the progression and prevent or delay the need for dialysis treatment. For those who develop kidney failure, the outcomes are even poorer with an average life expectancy of 5 years or less despite advancements in dialysis and introduction of evidence-based guidelines. While the epidemiology of kidney disease is well characterized in many countries, there is a major lack of information on kidney disease in Ireland. Whilst some progress has been made to expand the understanding of kidney disease in Ireland, available data are limited in scope and representation. The major goal of the NKDSS and QA Programme, is to provide meaningful high-quality information on the frequency of kidney disease (acute and chronic) and its complications in the Irish health system. The information consists of demographic (name, medical record number etc.) and clinical information from different data sources such as Laboratory Information Systems, dialysis registers, the Hospital In-patient Enquiry Scheme (HIPE) and the CSO. Using personal identifiers, UL is then able to link the data from each source to a single, unique individual to provide as complete a profile as possible of the participant's health status. The programme will also: - assess the quality of care provided to patients with kidney disease - assess the effectiveness of different treatments for kidney disease - help identify areas or regions where the burden of disease is high - help identify areas of good clinical practice and areas where clinical care is suboptimal in the health system By capturing information over several years, the study aims to get a better picture of how common the disease is and examine whether strategies for prevention are working.
Reason for Declaration:	A consent declaration is requested for the collection, transfer, pseudonymisation, storage and subsequent linking/merging of the personal data from all data sources. The data is irrevocably anonymised before any analysis is undertaken.
HRCDC Comments:	The HRCDC noted that ethics approval had been granted by the Research Ethics Committee for the study where the design, methodology and ethical aspects of the study, including consent protocols are considered. Only studies that have ethical approval, or provisional ethical approval, can be considered by the HRCDC to consider if the public interest outweighs the requirement for explicit consent. The Chair 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 conditional declaration should be made:

Public Interest

- The HRCDC was of the view that the study had a strong degree of public interest.

Consent

- The HRCDC discussed if it would be feasible to obtain consent for future participants who are diagnosed with kidney disease and who may be included in the study. Considering the high degree of public interest, coupled with the diversity of data sources and the number of participants who will likely meet the criteria for inclusion in the study, on balance it was the consensus of the HRCDC that obtaining prospective participant consent would not be feasible.
- The HRCDC also discussed that it would not be feasible to obtain the consent of retrospective participants.

Transparency

- The HRCDC was of the view that enhanced transparency measures should be implemented to inform and support prospective participants. These measures should also clearly outline to participants how they can withdraw their data from the study if they wish to do so. Specifically, the study website should position more prominently the research activities and use of participant data and how participants could withdraw from the study.

Public and Patient Involvement (PPI)

- Regarding PPI, the HRCDC noted the efforts that have been made which include the presence of patients on the study's Steering Committee and Scientific Advisory Group.
- The HRCDC discussed that PPI could be enhanced further through more explicit engagement with individuals and patient representative groups who could support the dissemination of the research findings and the implementation of further transparency measures.

Research Ethics Approval & Scope of Declaration

- Although the study is described as a '*National Surveillance System*' it was noted that research ethics committee approval is in place for a select number of hospitals/regions.
- The Applicant confirmed that the addition of any other hospitals and regions will require the appropriate ethical approval and amendments to the consent declaration.

Other

- The HRCDC noted that study collaborators, including those outside of Ireland are not receiving or otherwise processing data.
- It was commented that although the data collected is irrevocably anonymised before conducting any analysis. It further discussed that further safeguards are employed to protect the identification

	of the participant. This includes legal undertakings not to attempt to re-identify any individual when analysing the data. • The HRCDC also discussed the length of the declaration requested by the Applicant. An indefinite declaration was requested, however in line with previous HRCDC decisions it was determined that a declaration for 10 years should be made with the Applicant having the right to request an extension via an amendment application. • It was discussed that further clarity could have been provided on the data linkage activity.
HRCDC Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made.
Duration of Declaration:	The Declaration is made commencing 8th August 2018 and shall be valid until 13th October 2028; a period of 10 years after the decision of the HRCDC to make a conditional declaration. The Applicant may apply for an extension to this duration before the current declaration period expires.
Conditions Attached:	**Condition 1:** The Applicant is requested to implement enhanced transparency measures so that participants, in particular prospective participants, are made aware of the study and the use of their personal data. Transparency measures should clearly outline to a participant how they can exercise their data protection rights, including the right to withdraw from the study and have their data deleted. As part of these measures, consideration should be given to improving the level of information provided on the study's website, such as posting details on a more prominent and easy-to-access section of the website. The Applicant is requested to report on the efforts made to enhance the level of transparency as part of the Annual Review. **Condition 2:** The Applicant is requested to further enhance PPI by more explicit engagement with representative patient groups in areas such as the dissemination of research findings and to help enhance the level of transparency within this study. The Applicant is requested to report on the efforts made to enhance the level of PPI as part of the Annual Review.

7. Annual Reviews

The Secretariat has received 6 Annual Reviews in advance of the meeting. Of these 5 were deemed to be complete by the Secretariat.

One Annual Review (Ref ID:19-013-AF2) was brought to the HRCDC for consideration, as a condition had not been met for reasons outlined by the Applicant. The Applicant highlighted that a controller-processor agreement was no longer required. The Secretariat prepared a response letter for consideration by the HRCDC. The response was approved with some edits.

It was the view of the HRCDC that the Applicant should be requested to draw the response letter to the attention of their data protection officer for any institutional wide policies that need to be considered.

8. Activities report

EV gave an overview of the Activities Report which was provided to the HRCDC in advance of the meeting. Activities included;
i) Secretariat feedback to a consultation process on a European Data Protection Board Opinion guidance document '*Guidelines 07/2020 on the concepts of controller and processor in the GDPR*' (https://edpb.europa.eu/our-work-tools/public-consultations-art-704/2020/guidelines-072020-concepts-controller-and-processor_en)
ii) engagement with the Health Research Data Protection Network to discuss data protection matters within Data Controller organisations;
iii) engagement with the Irish Platform for Patient Organisations, Science & Industry (IPPOSI) to highlight the work of the HRCDC and understand topics of mutual interest.

EV notified the HRCDC that IPPOSI was carrying out a national mapping exercise inviting Irish health partners to share PPI activities. EV has completed this survey on behalf of the HRCDC, in the context of PPI in the decision-making role of the HRCDC. This ensures that the HRCDC is now included in this national exercise as providing an opportunity for PPI within the Irish Health sector.

9. Any other Business
The HRCDC briefly discussed additional membership of the HRCDC, the amendments and the need to consider scheduling HRCDC meeting dates for 2021.