HRCDC
Health Research Consent Declaration Committee

Date: 12th July 2022
Location: Zoom

Minutes of the Meeting

HRCDC Attendance

Name
Brigid McManus
Evelyn Mahon
Alyson Bailey
Kathy Brickell
Sheelah Connolly
Aideen Hartney
Zubair Kabir
Barry O' Sullivan
Dan Rea
Cornelius Cooney
John Woods
Jonny Barrett (Secretariat)
Caroline Byrne (Secretariat)
Marta Pisarska (Secretariat)

Quorum for Decisions
☒**YES**

New Amendments – For consideration

Applicant	Ref No.	Title
Jack Laffan	20-001-AF1/AMD1	A retrospective analysis of the Irish national Acute Coronary Syndrome (ACS) programme database)

New Applications - For Consideration

Applicant	Ref No.	Title
Denis O'Mahony	22-007-AF1	OPTImization of Medication by Transdisciplinary Assessment of Drug Treatment in Elderly Hospitalized Patients (OPTIMATE)
Frank Moriarty	22-008-AF1	Evaluation of policies and practices to support safe and appropriate controlled drug prescribing
Tomás Barry	22-009-AF1	Linking and harnessing health and population data to improve outcomes in Out-of-Hospital Cardiac Arrest

Meeting Items

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

2. **Apologies**
   Simon Furney, Claire Collins, Barry Lyons, Mary Tumelty, Noreen O'Brien (Secretariat)

3. **Disclosure of Interest**

- **22-007-AF1 (OPTIMATE study).** Barry O'Sullivan (BoS) and Zubair Kabir (ZK) disclosed an interest in this application and were absent for this part of the meeting
- **22-009-AF1 (Linking and harnessing health and population data to improve outcomes in Out-of-Hospital Cardiac Arrest).** Kathy Brickell (KB) disclosed an interest in this application and was absent for this part of the meeting.

4. Minutes of the last meeting

Draft minutes of 14th June 2022 were circulated in advance of the meeting and were approved by the HRCDC.

5. Amendments:

Reference ID:	20-001-AF1/AMD1
Lead Applicant:	Jack Laffan
Lead Data Controller:	Royal College of Surgeons in Ireland
Title:	A retrospective analysis of the Irish national Acute Coronary Syndrome (ACS) programme database)
Research Objective:	Please see HRCDC minutes of 26th May 2020
Purpose of Amendment:	The purpose of this amendment request is to extend the duration of the consent declaration. In addition, the Applicant outlines that they wish to expand the study from the initial 2013-2014 participant cohort to include participants up to 2018 and to include additional hospital sites to the 5 sites that were noted in the original HRCDC application form.
HRCDC Comments:	The Chair introduced the amendment request and invited the Secretariat to provide an overview of the correspondence and engagement that has occurred with the Applicant. It was highlighted that the consent declaration expired in November 2020 and that the data controller was continuing to store pseudonymised data. The Applicant stated that the data currently held can be anonymised and that pseudonymised data continues to be stored to allow participants the opportunity to withdraw. The HRCDC were also informed of the progress made to meet the conditions that were attached to the consent declaration. Based on the information provided by the Applicant, it was noted that Condition 5, appropriate data agreements/arrangements, had not been progressed since the consent declaration was made. The HRCDC discussed the amendment request. Based on the information provided it was the consensus of the HRCDC that an amendment for extending the duration of the consent declaration or expanding its scope to include new participant cohorts and hospital sites should not be made: **Expiration of the consent declaration** • The HRCDC discussed the correspondence and engagement that had occurred with the Applicant. • It was noted that, at the time of their first Annual Review, the Applicant was informed that the consent declaration had already expired, and that the Applicant was to submit an amendment request to extend the duration of the consent declaration for the personal data it currently holds. It was commented that following

	the first Annual Review, an amendment request was not submitted for almost a year during which time a valid consent declaration was not in place for the data controller to continue to store the pseudonymised data. • The HRCDC acknowledged why pseudonymised data continued to be stored and noted that, prior to submitting an amendment request, the Applicant was seeking REC approval to include new participant cohorts and hospital sites. However, notwithstanding this, it was the view of the HRCDC that it would not be appropriate to make an amendment to extend the duration of the consent declaration and/or expand its scope given the prolonged period that has passed since the consent declaration expired in November 2020, as well as given the delay in submitting an amendment request to extend the duration of the declaration. **Data agreements/arrangements.** • Following subsequent Annual Reviews and previous correspondence with the Applicant, it was noted that progress had not been made to sufficiently progress and meet Condition 5 (data agreements/arrangements) that was attached to the consent declaration. • While the reasons for not progressing Condition 5 were noted, it was the view of the HRCDC that the lack of progress to put in place the formalised data agreements/arrangements was unsatisfactory given the length of time that has passed. Correspondingly it was the view of the HRCDC that it would also not be appropriate to extend the duration or expand the scope of the consent declaration for this reason. The HRCDC re-emphasised that data agreements/arrangements are important and essential data protection measures that need to be in place. **Other** • With a consent declaration not in place, the HRCDC commented that it is up to the data controller, RCSI, to determine how they should proceed with regards the existing pseudonymised data the Applicant currently holds. • While the amendment has not been made, the HRCDC discussed that the Applicant can submit a new consent declaration application form with regards the expanded study scope of new participant cohorts and hospital sites for consideration. The HRCDC emphasised that prior to submitting any future new application, the Applicant must first provide evidence to the satisfaction of the HRCDC that suitable data agreements/arrangements are formalised with the parties sharing personal data, as was required under Condition 5. • The HRCDC was concerned about the issues that had arisen with regards the expiration of the consent declaration and that the agreements/arrangements, as required under Condition 5, had not been progressed. The HRCDC was of the view that these matters should be drawn to the attention of the DPO in RCSI for consideration of the appropriate actions that may need to be taken with regards to data protection compliance.

HRCDC Decision:	The consensus of the HRCDC was that no amendment to the consent declaration should be made.

6. New Applications

Reference ID:	22-007-AF1
Lead Applicant:	Denis O'Mahony
Data Controllers:	University College Cork
Title:	OPTImization of Medication by Transdisciplinary Assessment of Drug Treatment in Elderly Hospitalized Patients (OPTIMATE)
Research Objective:	This study is being done to find out if a multi-faceted intervention designed to optimize medication in hospitalized older people with multiple chronic medical conditions exposed to multiple medications can reduce unplanned hospital readmission and emergency department attendance compared to current usual medication management. The study intervention aims to minimize potentially inappropriate medications in a structured way and involves follow up with patients and GPs. Patients will be allocated equally to (i) standard medication management (control arm) or (ii) trained physician-delivered intervention or (iii) clinical pharmacist-delivered intervention.
Reason for Declaration:	A consent declaration is requested for the processing of personal data (collection, analysis, storage etc.) for the purpose of the OPTIMATE study where participants lack decision-making capacity due to their dementia or the effects of delirium. A consent declaration is requested for both the pilot and main OPTIMATE study. Proxy assent on behalf of the participant will be sought. At the end of the study fully anonymised datasets and results will be made available in data sharing repositories.
HRCDC Comments:	The HRCDC noted that ethics approval had been granted 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 discussed the aims and objectives of this study. While it was commented that further detail could have been provided on each of the three study interventions, it was discussed that the matter of polypharmacy and unsuitable prescribing are important areas of research. It was also discussed that this study may have a direct benefit to the study participants themselves. • On balance, based on the information provided, the HRCDC was of the view that there is a public interest case in this study. **Decision-making capacity and assent/consent process**

	• It was noted by the HRCDC that participants may lack decision making capacity due to the impact of their dementia and due to the effects of delirium. It was further noted that decision-making capacity is to be determined using the Mini-Mental Status Examination (MMSE) score. • The HRCDC discussed that decision making capacity should be determined using a functional assessment of capacity, as opposed to a medical model of assessment such as an MMSE score. • The HRCDC also discussed the importance of obtaining deferred participant consent where possible. • For participants with dementia, the HRCDC noted the Applicant's response that such individuals are not expected to regain capacity during their participation in this study if they lacked capacity upon study enrolment. The HRCDC discussed that while some participants with dementia may not regain decision-making to provide deferred consent, this should not be assumed for all individuals. Correspondingly for the cohort of participants who have dementia, it was the view of the HRCDC that their decision-making capacity should be re-assessed at appropriate points in the study to determine if they have regained capacity and to seek their deferred consent. • Further, for participants who lack decision-making capacity due to delirium, it was noted that the study will seek their deferred consent if they regain full cognitive function and mental capacity. The HRCDC discussed that this appeared to be a high threshold and that participants with delirium may regain decision-making capacity to provide deferred consent without having regained full cognitive function or mental capacity. It was therefore commented that decision-making capacity of participants in this cohort should also be determined based on a functional assessment of capacity. **Pilot and main OPTIMATE study** • It was discussed that participants enrolled at the pilot phase will continue to be included in the main phase of the study. The HRCDC also noted that the study information leaflet and consent/assent form did not provide details of a pilot phase. • It was commented that information on the pilot phase should be outlined in the information leaflet and that the participant and/or their proxy should be informed whether their enrolment has occurred at the pilot or main phase. Where they have been enrolled into the pilot study, individuals should correspondingly be informed that that they will also be included, and their data processed, in the main OPTIMATE trial. **Study Information Leaflet** • It was discussed that separate, specific information leaflets and consent/assent forms should be developed and employed when seeking participant consent or proxy assent. • It was also discussed that the study documentation should be reviewed and amended to ensure it provides clarity and consistency of information on various areas including withdrawing

	from the study, the collection of follow-up data from GPs and pharmacists and other data protection matters. **Research ethics committee (REC) approval** • The HRCDC queried if the study had undergone review by the full research ethics committee that covers University Hospital Waterford. It was discussed that the Applicant should ensure that the study had undergone review by the full REC for this site. **Other** • It was noted that data agreements and arrangements will be in place between the various parties in this study. It was commented that the necessary agreements must be in place prior to the study commencing data processing. • The HRCDC discussed the volume of data that will be processed in the study. It was commented that it is important that only the minimal amount of data is processed for the purpose of this study. • The HRCDC also noted and agreed with the observations made by the Secretariat regarding technical and more standard safeguards that may need to be considered by the Committee. These observations included clarifying the scope of the consent declaration made and ensuring that the proxy providing assent on behalf of the participant is the most suitable person to understand their will and preferences.
HRCDC Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made.
Duration of Declaration:	The Declaration is made on 12th July 2022 and is valid until 30th September 2024 and for 15 years thereafter until 30th September 2039, or until the personal data has been destroyed or irrevocably anonymised, whichever occurs sooner.
Conditions Attached:	**Condition 1.** Aligned with the principles of the Assisted Decision-Making Act 2015, it is a condition of this declaration that participant decision making capacity should be determined from a functional perspective and assessment, rather than from a primarily medical perspective. The Applicant is required to report on how decision-making capacity to consent is determined from a functional perspective as part of the Annual Review. **Condition 2.** - For participants who lack decision making capacity and have been enrolled based on proxy assent, it is a condition of this declaration that their level of decision-making capacity is re-assessed during the study at appropriate points in time. - Correspondingly, where it is determined that a participant has regained decision-making capacity, and can provide explicit consent for the study and the processing of their data, then their deferred consent should be sought. - As per Condition 1, participant decision making capacity should be reassessed from a functional perspective. - For the avoidance of doubt this condition applies to participants who initially lacked decision-making capacity at the time of their enrolment due to either dementia or delirium.

	Condition 3. - the Applicant must ensure that the individual identified to provide proxy assent on behalf of an individual who lacks decision making capacity, is the most appropriate person to understand their will and preferences. - where a participant lacks decision-making capacity, the study should continue to engage with the participant to the best extent that is possible, both during the consent/assent process and the study activities. The Applicant is requested to report on both points as part of the Annual Review. **Condition 4.** The Applicant is requested to provide confirmation that the study has received approval from the full research ethics committee that covers University Hospital Waterford. Evidence that the study has been reviewed and approved by the full research ethics committee for the University Hospital Waterford site must be provided as soon as is practicable and within 2 months of receipt of this consent declaration. For the avoidance of doubt, the consent declaration will not be in effect for the University Hospital Waterford site until this Condition is met. **Condition 5.** Appropriate agreements and arrangements governing the sharing and processing of personal data must be in place between the relevant parties in this study, including relevant agreements between the controller UCC and the data processors. Personal data should not be transferred, shared or processed prior to the necessary data agreements being in place. Confirmation should be provided to the HRCDC when the appropriate agreements are in place. **Condition 6.** Separate and specific study information leaflets and consent/assent forms should be used when obtaining (a) consent/deferred consent from the participant and (b) proxy assent from a suitable individual where the participant lacks decision-making capacity. For the avoidance of doubt a single version of the study information leaflet and consent/assent form should not be used. Separate, specific, and tailored study documentation should be utilised when obtaining either participant consent or proxy assent. Further, to ensure clarity and transparency for participants and/or their proxy/relatives, the HRCDC requests that the study information leaflet and assent/consent forms are reviewed and amended. The following observations should be addressed: (i) Clear information should be provided to participants and/or their proxy that the OPTIMATE study involves both a pilot phase as well as a main study phase. At the time of obtaining proxy assent or participant consent, individuals should be clearly informed if the participant has been enrolled at the pilot phase. Further, if enrolled at the pilot phase it should be made clear that the participant will continue to be included, and their data processed, in the main phase of the OPTIMATE trial.

	(ii) it should be ensured that the study information leaflets sufficiently and clearly describe the three intervention arms of this study and what the interventions will practically entail for the prescribing of the participant's medications and their care and treatment. (iii) it should be clearly outlined that follow-up data will be sought from the participant's GP and/or pharmacist. Proxy assent/participant consent should be requested for the collection of this follow-up data within the assent/consent form (iv) the information leaflet should inform participants and the proxy that anonymised datasets and results will be made available in data sharing repositories (v) the UCC Clinical Studies Data Protection Notice (pgs 5-8 of the study information leaflet) should be provided to the participant and/or proxy as a separate appendix that accompanies the information leaflet and assent/consent form. It should not be incorporated into the main body of the study information leaflet. (vi) reference to the processing of racial and ethnicity data should be removed from the UCC Clinical Studies Data Protection Notice, as this data is not collected for this study. More generally the Applicant should ensure that the information leaflet clearly and accurately reflects the data that will be collected and processed for this study (vii) Pg 4 of the information leaflet references that pseudonymised data may be shared/released to third parties if requested. It should be clear in the study documentation that where such pseudonymise data is shared, that the participant's identity will not be disclosed and that the link/master key remains at the hospital site or with UCC. (viii) the study information leaflets must provide clear and consistent information with regards withdrawing proxy assent/consent and what will happen the personal data already collected in such a scenario. It should also be clear if there is a point in time where data cannot be deleted or if there is a particular location where data cannot be deleted from. If an explicit request to delete data must be made after assent/consent is withdrawn, then this too must also be clearly outlined in the consenting documents. The study information leaflets, and assent/consent forms must be reviewed and amended as described above prior to the enrolment of participants in the study.
HRCDC Recommendations:	**Recommendation 1.** Aligned with the principle of data minimisation the study should ensure that it only obtains and processes the minimal amount of personal data required for this study.

Reference ID:	22-008-AF1
Lead Applicant:	Frank Moriarty
Data Controllers:	Royal College of Surgeons Ireland
Title:	Evaluation of policies and practices to support safe and appropriate controlled drug prescribing
Research Objective:	While all medications can pose benefits and risks, some are particularly of concern for reasons of misuse/harm, including opioid

	medications, used as analgesics to treat pain, and benzodiazepines, used as sedatives to treat sleep troubles and anxiety. The aim of this project is to evaluate prescribing of analgesic and sedative medications. It will examine time trends in volumes and patterns of prescribing in Ireland, to understand how the use of these medications has increased over the last number of years. It will also consider how changes in health policies may have affected prescribing of these medication as well as harm to patients (in the form of drug poisonings and deaths). Lastly it will examine how much difference there is between regions and GP practices in the level and way they prescribe these medicines, to help understand where and how they may be over- or under-prescribed. Publicly available, non-personal data from NHS England and monthly data from the National Poison Information Centre and the National Drugs Related Deaths Index will also be processed as part of the study's work packages, including for comparison purposes.
Reason for Declaration:	The consent declaration is requested to process the personal data (obtaining, analysing, storing etc.) from the Primary Care Reimbursement Service (PCRS) for the purpose of this research study. The Applicant states that due to the number of participants and for reasons of scientific integrity, it is not feasible to obtain explicit consent.
HRCDC Comments:	The HRCDC noted that ethics approval had been granted 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 case** • The HRCDC discussed the aims and objectives of this study. • It was noted that the data is already highly pseudonymised prior to transfer to the data controller. • The HRCDC queried the level of impact that this study will have given that it is not seeking to follow-up patients to determine their health outcomes. However, it was discussed that this is a research area that is of growing importance. The HRCDC commented that understanding the trends in prescribing of these medications within Ireland will likely provide some important insights and information. In addition, while it was noted that there maybe limits to comparing the data in Ireland with data from NHS England, this benchmark comparison would also be of research value. • On balance it was the view of the HRCDC that there is a public interest case in this study. **Security measures**

	• The HRCDC discussed the methods employed to de-identify the data and limit the ability of the data controller to identify a participant, including removing directly identifiable data from the dataset and the use of quasi-identifiers that do not link back directly to the participant. • Nonetheless, while strong pseudonymisation methods will be employed it was acknowledged that the Applicant states that the data will be considered pseudonymised for the duration of the study. The HRCDC also commented that should any linkages with other data sources occur in the future, that this would likely increase the risk of re-identifying the participant. It was noted that any data linkages to the PCRS data by this study will require an amendment to the consent declaration. • The use of OneDrive, with two-factor authentication and access restrictions as the method for storing the personal data was also noted. Where data is saved in the cloud, the HRCDC discussed the importance of ensuring that secure encrypted systems are used. It was queried whether there were other secure methods that could be utilised to store the data. **Transparency and withdrawing from the study** • It was noted that the study will create and launch a project website prior to its commencement, where information about the study and data processing will be provided. The HRCDC discussed the importance of implementing sufficient transparency measures so that the GPs and pharmacists, in addition to the wider public, can be made aware of this research and the processing of data. It was commented that the website and any other transparency measures should be in place before the study commences and clearly outline what data is processed for this study and by whom, and further outline the participant's data protection rights. • The Applicant's response on the ability to withdraw data from the study was also noted. Specifically, the Applicant outlined why participant data cannot be removed from the study if this was to be requested. The highly pseudonymised nature of the data and technical abilities were noted as reasons why a participant's data cannot be withdrawn. **Public & patient involvement (PPI)** • The HRCDC discussed the level of public and patient involvement that has and will be undertaken in this study and that PPI activities will continue as the study progresses, including inviting PPI representatives onto the study's advisory group. It was noted that interviews had been held with some PPI representatives, however it wasn't clear if PPI engagement to date mentioned or discussed the seeking of a consent declaration, where the data will be obtained from, and which cohorts will have their data processed. • It was commented that future PPI engagement should be structured on the specifics and details of this research study including the pseudonymised nature of the data, the data sources to be used and the role of the consent declaration process, among others.

	Data sharing agreement • It was commented that the study must ensure that appropriate data sharing agreements/arrangements are in place prior to the transfer and processing of personal data. **Other** • It was noted that Art 9(2)(g), substantial public interest, was the relevant condition identified by the Applicant for the proposed processing of the personal data. It was commented that Art 9(2)(j), scientific research, maybe more appropriate, however this is a matter for the data controller to determine. • It was noted that the data from the PCRS is limited to individuals who were eligible for the General Medical Services (GMS) scheme only. While it was noted that this creates a level of study biasness, it was discussed that personal data from this cohort is used as it provides the most complete dataset on the prescribing of such medications in Ireland. • From the information provided, the HRCDC also noted that the PCRS privacy statement outlines that individuals will be contacted for their consent if their PCRS data is used for research but if it cannot be anonymized. It was noted that consideration should be given to amending this section of the PCRS privacy statement given that a consent declaration, not participant consent, may be sought. It was noted that this information appeared to be in an older version of the Privacy statement that precluded the Health Research Regulations. • The HRCDC also noted and agreed with the observations made by the Secretariat regarding technical and more standard safeguards that may need to be considered by the Committee.
HRCDC Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made.
Duration of Declaration:	The Declaration is made on 12th July 2022 and is valid for two years until 31st July 2022 and for 5 years of data archiving thereafter until 31st July 2027, or until the personal data has been destroyed or irrevocably anonymised, whichever occurs sooner. The consent declaration will only come into effect when the Applicant has received confirmation from the HRCDC of a satisfactory response to Condition 1.
Conditions Attached:	**Condition 1.** it is a condition of this consent declaration that robust transparency measures are implemented prior to the commencement of this study. As part of this condition the Applicant is requested to explore what other measures and communication channels can be developed and utilised beyond the soon to be established study website that is noted in the HRCDC application form. The Applicant must also ensure that the measures implemented clearly outline the aims and objectives of the study, the source of and type of data and the cohort of participants included (i.e, PCRS and GMS scheme data), the methods in place to protect the identity of individuals and the comparisons of data with the UK. It should also outline the participant's data protection rights, including any restrictions or derogations to such rights. In this context the limitations

	to withdrawing data from this study should be clearly highlighted. Such transparency measures should aim to provide information to GPs and pharmacists, as well as the wider public. The Applicant is required to report to the HRCDC on this Condition within 3 months of receipt of this consent declaration. For the avoidance of doubt this consent declaration will not be in effect until this report is furnished and is considered satisfactory by the HRCDC. **Condition 2.** The scope of this consent declaration is made to RCSI for the purpose of this specific study only, as described in HRCDC application form. The further processing of personal data beyond this scope, including the transfer of pseudonymised data, linkage of the PCRS data with other data sources etc. is not covered by this consent declaration and will require the submission of an amendment request form or new HRCDC application form for consideration, whichever is most appropriate. **Condition 3.** The Applicant must ensure that the appropriate data sharing agreement is in place between the data controller RCSI and the provider of personal data for this study, the HSE PCRS. The sharing and processing of personal data cannot occur until this condition is met and confirmation should be provided to the HRCDC when the necessary agreement is in place. **Condition 4.** The Applicant must ensure that sufficient security measures, including encryption and two-factor authentication, is employed with regards the storage and processing of the data in this study. Should the use of OneDrive not provide sufficient encryption, authentication or other data security measures, then alternative solutions should be implemented by the study. **Condition 5.** The HRCDC notes the following statement in the PCRS Privacy Statement '*The HSE PCRS ensures that you cannot be identified by anonymising the information. If it is not possible to anonymise the information, you will be contacted for your consent*'. Given that participants may not always be contacted for their consent with regards the use of their PCRS data, the Applicant is requested to highlight this section of the Privacy Statement to the PCRS for their consideration and amendment in the context of the Health Research Regulations and the consent declaration process.
HRCDC Recommendations:	**Recommendation 1.** If not previously undertaken, future PPI activities with representatives should ensure that discussions and engagements are structured in the context of this study, including that the study has undergone the consent declaration process, the sources and volume of data to be used, the participant cohort that is included and other relevant important details that are specific to this particular research.

Reference ID:	22-009-AF1
Lead Applicant:	Tomás Barry
Data Controllers:	University College Dublin

Title:	Linking and harnessing health and population data to improve outcomes in Out-of-Hospital Cardiac Arrest
Research Objective:	Out-of-Hospital cardiac arrest (OHCA) affects more than 2,500 people in Ireland every year. Survival remains low at 7%. Treatment is very time sensitive. Survival depends on the actions of the community where OHCA occurs and the emergency medical system. The 'chain of survival' includes early recognition and activation of emergency medical services, care provided by bystanders, dispatched first responders, the ambulance service and hospital. To improve survival this research will study the entire chain of survival from community to hospital for the first time in Ireland. It will link existing national data from first responders, ambulance services, hospitals and the national census. It will explore why different groups of patients do or do not survive cardiac arrest and ultimately use this data to develop specific health system interventions that can increase survival in Ireland. A consent declaration is required as individual level consent would be impossible to obtain.
Reason for Declaration:	A consent declaration is sought for the processing (collection, linkage, analysis, storage) of personal data (coded by study ID) from the OHCAR and HIPE for the purpose of this study. If possible to achieve, the data will be irreversibly anonymised at the end of the study and this data will be made available for future research via a repository. If this is not possible then the data will be stored by UCD for 10 years and then deleted.
HRCDC Comments:	The HRCDC noted that ethics approval had been granted 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 discussed the aims and objectives of this study. It was discussed that the study involved the processing of a large volume of data and a high degree of data linkage across different data sources. It was further noted that, due to the nature of out of hospital cardiac arrests, the majority of participants would be deceased. • While it was commented that the study's processing activities and overall objectives and research questions are ambitious, the HRCDC was of the view that this is an important area of research and that there is a strong public interest case in this study. **Data controllership and data agreements** • It was queried who is the data controller for this study given that data is sourced from a number of parties. It was clarified that University College Dublin (UCD) is the data controller of this study.

	• It was further discussed that it is important that the necessary data agreements and arrangements are in place between UCD and the relevant parties who will be providing personal data. **Scope of the consent declaration** • The HRCDC discussed the response from the Applicant that it will explore whether the data can be irreversibly anonymised at the end of this study, and if this anonymised data can then be made available for future research, subject to stakeholder approvals. • The HRCDC noted the response from the data protection officer and Applicant that irreversible anonymisation of the data is challenging and unlikely in the context of this study but that nonetheless this matter will be examined. • It was highlighted that if it is not possible to irreversibly anonymise the data then the consent declaration will be made for the duration of the study and a 10-year period of data archiving. It was further commented that the consent declaration will not extend to the further processing of personal data, including the transfer of pseudonymised data, beyond this specific study. • The HRCDC was of the view that the Applicant should provide updates on the potential for anonymising the data as part of the Annual Review process. **Transparency and withdrawing from the study** • The HRCDC noted the Applicant's response with regards the transparency measures that will be implemented for this study, including the provision of information via the UCD and other relevant websites. A privacy notice document was submitted outlining the information that will be provided. It was commented that it is important that the websites and other transparency measures are sufficiently publicised and signposted and that other methods of communication are explored. • It was also discussed that sections of the privacy notice are relatively technical and detailed in nature and therefore maybe confusing to some individuals. It was the view of the HRCDC that the notice should be reviewed, including to ensure that lay-person's terminology is used where possible. It was highlighted that terms such as 'aggregated' and 'granular' should be avoided. • From the privacy notice, it was further noted that participants who wish to withdraw their data from the study will be assisted by the Applicant to liaise with the Out of Hospital Cardiac Arrest Registry (OHCAR), as the OHCAR holds the information linking the participant to their data. The HRCDC was of the view that the process of withdrawing from the study should be streamlined as much as possible from the perspective of the participant. **Research ethics approval** • The Applicant outlined that, in addition to research ethical approval from the Irish College of General Practitioners which had already been obtained, local research ethics approval may be needed from some hospital sites. The HRCDC commented that where local REC approval is required then it should be obtained by the study.

	Other • It was commented that the measures in place to protect the participant's data appeared reasonable. • It was noted that Art 9(2)(g), substantial public interest, was the relevant condition identified by the Applicant for the proposed processing of the personal data. It was commented that Art 9(2)(j), scientific research, may be more appropriate, however this is a matter for the data controller to determine. • The HRCDC noted the level of PPI activities. It was commented that the Applicant should be advised to provide further detailed information on their PPI engagement in future HRCDC applications. • The HRCDC also noted and agreed with the observations made by the Secretariat regarding technical and more standard safeguards that may need to be considered by the Committee.
HRCDC Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made.
Duration of Declaration:	The Declaration is made on 12th July 2022 and is valid until 30th September 2025 and for 10 years of data archiving thereafter until 30th September 2035, or until the personal data has been destroyed or irrevocably anonymised, whichever occurs sooner. *Note:* in line with the principle of data minimisation, the duration of the consent declaration may be amended should the personal data be irreversibly anonymised. *Note:* as per the attached conditions, the consent declaration will not be in place prior to meeting certain conditions.
Conditions Attached:	**Condition 1**. It is a condition of this declaration that the proposed transparency measures (i.e., information on the UCD and other relevant websites) are implemented prior to the commencement of the study. The consent declaration will not be in effect until such measures are in place prior to the study's commencement. Further, the Applicant is requested to explore and consider what other transparency measures and communication channels could be utilised to inform the public about this study, the processing of personal data and their data protection rights, including information on how to withdraw. Examples can include communicating and providing information via other relevant third-party representative organisations such as the Irish Heart Foundation. As part of this Condition, it is also important that the transparency measures implemented are sufficiently publicised and signposted so that the public can be made aware of their presence. **Condition 2.** Further to Condition 1, the Applicant is requested to review the content of the privacy notice document that outlines the information to be provided on the UCD and other relevant websites to ensure that it provides information in clear and lay-person's terms, In this regard, technical terminology such as 'granular' and 'aggregated' should not be used, and the section describing the data to be processed, including CSO data, should be reviewed and amended where appropriate to ensure that it is clear and concise.

	Condition 3. It is noted that should a participant wish to withdraw their data from the study that they should contact the Applicant who will then assist them in liaising with the OHCAR. It is a condition of this declaration that the process for withdrawal is as streamlined as possible from the perspective of the study participant. Correspondingly, where a participant wishes to withdraw their personal data from this study, the steps that need to be taken should not rest with the participant and should be undertaken by the Applicant and the data controller, wherever possible. Only the minimal amount of effort and actions should need to be taken by the participant as part of the withdrawal process. **Condition 4.** The Applicant must ensure that the appropriate and necessary data agreements and arrangements are in place between UCD and the relevant parties who will be providing personal data for this study, including the data from HIPE and the OHCAR. Personal data must not be shared, transferred or processed prior to the necessary data agreements being put in place and confirmation should be provided to the HRCDC once the agreements and arrangements have been put in place. The consent declaration will not be in effect until this condition has been met. **Condition 5.** Where necessary to do so, the Applicant must attain local research ethics committee approval for this study and provide confirmation to the HRCDC when such approval has been obtained. For the avoidance of doubt a consent declaration cannot cover data processing activities that are not covered by the requisite REC approval. **Condition 6**. As part of the Annual Review the Applicant is requested to provide updates with regards the potential to irreversibly anonymise the data which is to be explored as part of this study.
HRCDC Recommendations:	**Recommendation 1.** The Applicant is requested to examine and consider the use of Art 9(2)(j) 'scientific research' as an appropriate condition for the proposed processing of personal data in this study. **Recommendation 2.** Should the Applicant submit a future application to the HRCDC, it is recommended that further detailed information on the PPI engagement undertaken is outlined in the HRCDC application form. General statements outlining that PPI engagement has been undertaken should be avoided.

7. Annual Reviews

The Secretariat has received 2 annual reviews in advance of the meeting which were deemed satisfactory:

- **Ref ID:** 19-021-AF3; Eve Griffin, Paul Corcoran: National Self Harm Study
- **Ref ID:** 19-041-AF3-COV; Bairbre McNicholas-John Laffey: The role of T-Regulatory and Mononuclear Phagocyte Cells causing Immune Dysfunction in Sepsis (A study on the role of immune dysfunction in sepsis and COVID-19)

8. Activities report and events of interest

The following publications of interest were noted to the HRCDC:

- NREC Annual Report: https://www.nrecoffice.ie/wp-content/uploads/National-Office-Annual-Report-2021_Digital.pdf
- IPPOSI Citizen's Jury Witness Presentations: https://www.youtube.com/playlist?list=PLeArG_0tTqep6ih_NwL0HmnEwyfpMx2Ql
- Opinion piece on journal.ie on patient advocacy and engagement: https://www.thejournal.ie/readme/chief-patient-officer-idea-opinion-5780336-Jun2022/?utm_source=shortlink

9. Any Other Business

- The Chair reminded the HRCDC that a HRCDC meeting has been scheduled for 9th August 2022. The HRCDC will be informed in due course if this meeting will occur.

****The Chair closed the meeting****