HRCDC
Health Research Consent Declaration Committee

Date: 11th December 2020
Location: Videoconference

Minutes of the Meeting

HRCDC Attendance

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

Quorum for Decisions ☒YES

Returning Applications - For Consideration

Applicant	Ref No.	Title
Fintan Sheerin	20-029-AF1	Models of Care for people Ageing with an Intellectual Disability

New Applications for Amendments to current Consent Declarations- For Consideration

Applicant	Ref No.	Title
Alistair Nichol	19-003-AF2/AMD1	Treatment of Invasively ventilated adults with Early Activity and Mobilisation (TEAM) Trial

New Applications - For Consideration

Applicant	Ref No.	Title
Alistair Nichol	20-036-AF1	EPO-TRAUMA
Deirdre Broderick	20-033-AF1	Epidemiologic study of LGV
Deirdre Broderick	20-032-AF1	Molecular Epidemiology of Mumps in Dublin Ireland
Emer Doheny	20-037-AF1/COV	Home monitoring of respiration in COVID-19 patients using smartphone technology: analysis of retrospective data
Ivan Perry	20-034-AF1	A Capture-Recapture Study to Estimate the Prevalence of Problem-Opiate Use in Ireland (2015 - 2019)

HRCDC
Health Research Consent Declaration Committee

Meeting Items

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

2. **Apologies**
   Barry O'Sullivan, Malcolm Kell, Simon Furney, Sheelah Connolly, John Ferguson

3. **Disclosure of Interest**
   - Aideen Hartney declared her interest in application 20-029-AF1 and was absent for this part of the meeting.
   - Kathy Brickell declared her interest in 19-003-AF2/AMD1 and 20-036-AF1 and was absent for these parts of the meeting.
   - Zubair Kabir declared his interest in 20-034-AF1 and was absent for this part of the meeting.

4. **Minutes of the last meeting**
   Draft minutes of the 12th November 2020 meeting were circulated in advance of the meeting and were agreed by the HRCDC.

5. **Returning Applications:**

Reference ID:	20-029-AF1
Lead Applicant:	Fintan Sheerin
Lead Data Controller:	Trinity College Dublin The National Disability Authority
Title:	Models of Care for people Ageing with an Intellectual Disability
Research Objective:	See HRCDC Meeting minutes of 13th October 2020
Reason for Declaration:	The HRCDC considered the Applicant's response to the HRCDC's request for further information in the decision letter of 21st October 2020. See HRCDC Meeting minutes of 13th October 2020.
HRCDC Comments:	The Chair introduced the agenda item and reminded members of the further information that was requested from the Applicant. The Chair invited members to comment on the Applicant's responses and requested each HRCDC member to indicate whether a consent declaration should be made. The consensus of the HRCDC was that no Declaration should be made. The decision was based on the following discussion points: **Study Impact and Scale** • When considering the degree of public interest in this study, the HRCDC discussed the Applicant's most recent responses which aimed to further describe and clarify the public interest, the research question and the type of data that will be collected from interviews with participants with an intellectual disability. • It was acknowledged that the responses did provide further detail and clarity on these important elements. • However, the HRCDC queried whether the design and small scale of the study, specifically the interviews and the relatively low number (~12) of participants with an intellectual disability who will be interviewed, would be adequate to sufficiently address the

	study's research question. In particular, it was not clearly outlined by the Applicant, given the small scale of the study how the research outputs, if significant enough, would contribute to, or inform changes to health policy and services, and budget requirements. • The HRCDC further discussed that alternative approaches could be explored to gather information required to address the research question. **Assent/Consent and Interview Process** • In general, the HRCDC was of the view that the assent/consent process was more clearly outlined in the Applicant's responses, however some elements were still not clear, for example what is meant by a 'guardian' providing assent. The HRCDC also commented that the participants appear to be receiving a number of study documents. • It was also noted that the consent/assent process and research interviews will be conducted virtually due to the ongoing restrictions due to COVID-19. • When considering the participant cohort who lack decision-making capacity, it was discussed that virtual engagement via videocall could make the assent/consent and interview process more challenging. **Public and Patient Involvement (PPI)** • The HRCDC acknowledged the Applicant's response regarding PPI, including reference to members of the steering committees for IDS-TILDA and the National Intellectual Disability Memory Service as well as the intention to engage with PPI representatives in the future. It was discussed that PPI activities should be carried out throughout the lifetime of the study and built upon where possible by engaging with many of the advocacy groups in this area **Public Interest** • The HRCDC acknowledged that there was a degree of public interest in this research area. • However, when weighing up the aforementioned points of discussion, in particular the relatively small scale of and uncertain impact of the study on public health policy and funding, in conjugation with the small cohort of participants that lack-decision making capacity, for which the declaration is being sought - the HRCDC consensus was that the public interest in the study did not significantly outweigh the participant's data protection rights and interests.
HRCDC Decision:	The consensus of the HRCDC was that No Consent Declaration should be made

6. New Amendments to current Consent Declarations

HRCDC
Health Research Consent
Declaration Committee

Reference ID:	19-003-AF2/AMD1
Lead Applicant:	Alistair Nichol
Lead Data Controller:	St Vincent's University Hospital, Dublin Monash University, Melbourne
Title:	Treatment of Invasively ventilated adults with Early Activity and Mobilisation (TEAM) Trial
Research Objective:	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 assent/consent protocol has been amended to include telephone consent/assent. • The study wishes to include two additional research sites: Galway University Hospital and Beacon Hospital.
HRCDC comments:	The Chair requested each HRCDC member to indicate whether the request for the amendment should be approved. It was the consensus of the HRCDC that the amendment to the consent declaration decision could be made. **Research Ethics Committee (REC) Approval** • It was discussed that the declaration will only cover the hospital sites where REC approval is in place. and that evidence of REC approval for the other sites must be forwarded to the HRCDC when available. • It was noted that REC approval for the amended consent protocol has been obtained from St. Vincent's University Hospital and the Beacon Hospital, with approval for the updated consent protocol pending from Tallaght University Hospital and Galway University Hospital (GUH). • The HRCDC also discussed the date of the original REC approval for GUH site and the date the study commenced processing data at that site. • The HRCDC was of the view that the Applicant should consult with the relevant data protection officers with regards any data protection matters that may have arisen since the commencement date of the study up until the date of the amendment to the declaration, and provide any relevant feedback to the HRCDC. **Telephone consent/assent process** • It was noted that the wording used in the script to obtain telephone assent contains references to both assent and consent and should be revised for consistency and accuracy.
HRCDC Decision:	The consensus of the HRCDC was that the conditional declaration could be amended as requested by the Applicant
Amendment Duration	The Amendment is made commencing 11th December 2020 and shall be valid 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 duration of the consent declaration)
Conditions Attached:	**Condition 1.** The Applicant is requested to consult with Data Protection Officers at St. Vincent's University Hospital and Galway

	University Hospital in relation to any data protection matters that may have arisen since the commencement date of processing personal data for the study, until the date that this amendment to the declaration has been made and to provide any relevant feedback to the HRCDC. **Condition 2.** The amendment to this declaration only covers the research sites that have Research Ethics Committee (REC) approval in place. Confirmation of REC approval for the amended consent protocol from Tallaght University Hospital and Galway University Hospital, that currently remains pending, must be provided to the HRCDC once it is available.
Additional Comment	**Comment:** Please ensure the wording used in the telephone script and accompanying assent/consent form is consistent and accurate. The HRCDC notes that the terms 'assent' & 'consent' are both used in this document.

7. New Applications

Reference ID:	20-036-AF1
Lead Applicant:	Alistair Nichols
Lead Data Controller:	Monash University University College Dublin
Title:	EPO-TRAUMA
Research Objective:	The World Health Organization has forecast that, by 2030, trauma will become the third leading cause of disability and death globally. Erythropoietin is a hormone that is essential for red blood cell production. Drugs with a similar function are available for use in the treatment of humans and are called erythropoiesis stimulating agents (ESAs). Erythropoietin has many effects beyond increasing red blood cell numbers. Studies in animals have shown erythropoietin can have protective effects following injury to vital organs including the brain, kidney, liver and heart. Previous research suggests the use of the ESA called epoetin, increases the number of patients surviving severe trauma and reduces the risk of disability in those who survive. An analysis which pooled all relevant studies evaluating the use of ESAs in critically ill trauma patients showed a reduced mortality by at least 20%. This finding may have important implications for patient management. The study aims to conduct an international multicentre trial of the ESA epoetin alfa in 2,500 critically ill trauma patients in Australia, New Zealand and Europe.
Reason for Declaration:	For the purpose of processing, including review, collecting, pseudonymising, sharing pseudonymised data, storing, analysis, archiving, destruction of personal data of participants who lack decision-making capacity. The scope also includes the storage only of personal data for future research purposes.
HRCDC Comments:	The HRCDC noted that ethics approval had been granted by the Research Ethics Committee (REC) 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. **Patient and Public Involvement (PPI)** • The HRCDC discussed that PPI had been undertaken by way of only one consultation with a past ICU attendee, to seek views on the study. It was further discussed that additional and broader PPI could be undertaken to ensure wider representative views are captured. **Patient Information Leaflets (PILs)** • The HRCDC discussed that the PILs were quite technical and should be revised for readability for the benefit of the participants who may regain capacity to consent and individuals providing assent on behalf of participants. It was noted that a similar request was made by the Research Ethics Committee (REC). • HRCDC noted that the assent 'by phone' form provides an option for the storage of data for future research for 15 years; however, the assent 'in person' form does not provide a specific timeline. **Data Minimisation and Storage** • The HRCDC discussed the extent of personal data being collected such as name, date of birth, hospital number and Patient study Number (PSN). It was discussed whether additional data minimisation measures could be implemented to reduce the data protection risks. • It was noted that the role of the contractor 'Research Path' was to collect and store data in a pseudonymised and encrypted form for 15 years from the date of final publication, or longer if required. The HRCDC commented that the principle of data minimisation should be applied to the data held by Research Path over the course of the retention period. **Reconsent/Assent affirmation** • The HRCDC discussed that as an additional safeguard, where participants lack decision-making capacity for a prolonged period of time, assent should be reaffirmed from the individual who provided it on behalf of the participant. • From the information provided, it was also noted that participants would be followed up at 6 months to evaluate the success of the

	treatment. The HRCDC discussed that this offered an opportunity to obtain deferred consent, if possible or to reaffirm relative assent if not already reaffirmed.
HRCDC Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made.
Duration of Declaration:	The Declaration is made commencing 11th December 2020 and shall be valid until consent can be obtained from the participants once decision-making capacity is regained and shall cover the duration of the study (4 years) and for 15 years after the study concludes i.e. December 2039.
Conditions Attached:	The following conditions are attached to the declaration made by the HRCDC: **Condition 1**. The HRCDC have requested that further, broader PPI should be carried out for the study and not limited to the single representative individual. **Condition 2.** The HRCDC request that the Applicant implement further data minimisation measures where at all possible. Specifically, consider if age, date of birth, full address and contact number, medical record number are all required in addition to the Patient Study Number. Similarly, for all data being stored and archived with Research Path, data minimisation measures should be implemented to reduce data protection risks over the lifetime of the retention period. This is a reporting requirement of the Annual Review. **Condition 3:** 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: **i)** 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. **ii)** 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. This includes determining capacity to consent at the 6-month follow-up visit. The Applicant must report on this condition as part of the Annual Review, including the number of participants where deferred consent has and has not been obtained.
HRCDC Recommendations:	The following recommendation has been made to the Applicant: **Recommendation 1.** To ensure clarity, transparency and consistency of information for participants and/or those providing assent, the HRCDC requests that the study information leaflet and

	assent/consent forms are reviewed. The following points are highlighted by the HRCDC for consideration by the Applicant: **(i)** The HRCDC considered the Patient Information Leaflets (PILs)/Research Study information leaflets to be quite technical in parts and should be readable from the perspective of the participant and those providing assent. This recommendation is in line with the feedback from the Research Ethics Committee. **(ii)** Section 10 of the Study Information Leaflet further outlines for the individual providing assent, how the study participant may lodge a complaint with the data protection authority. The Applicant is requested to review this form to ensure it is clear how the individual providing assent may lodge a complaint if necessary. **(iii)** The study information leaflets should clearly outline the participant's data protection rights, including information on any limitations/derogations to these rights; the use of broad statements such as 'you may have data protection rights' should be avoided. **(iv)** In the option for permitting the storage of data for future research, the telephone assent form provides a specific timeframe of 15 years, however this is not outlined in the other assent/consent forms.

Reference ID:	20-033-AF1
Lead Applicant:	Deirdre Broderick
Lead Data Controller:	St James's Hospital
Title:	Epidemiologic study of LGV
Research Objective:	Lymphogranuloma venereum (LGV) is a sexually-transmitted infection caused by Chlamydia Trachomatis. It is endemic in some areas of Africa, Southeast Asia, India, the Caribbean and South America. In the past 10 years it has been increasingly recognized in industrialised countries including North America, Europe and the UK. It causes genital ulceration followed by swelling of lymph nodes and if untreated can result in disfiguring ulceration and enlargement of the external genitalia. It is diagnosed using nucleic acid amplification techniques to detect the presence of viral DNA. The study aims to examine the LGV isolates collected in St. James's Hospital since the introduction of NAAT testing and, using the clinical patient records, identify common risk factors and symptoms, which may help identify interventions to reduce spread. The study will also look at molecular typing data, to determine the genotypes circulating in this population.
Reason for Declaration:	For the processing of personal data, which includes the access and collection, analysis and pseudonymisation of clinical data associated with biosamples.
HRCDC Comments:	The HRCDC noted that provisional ethics approval had been granted by the Research Ethics Committee (REC) for the study where the design, methodology and ethical aspects of the study 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 no Declaration should be made.

Patient and Public Involvement (PPI)

- The HRCDC noted from the information provided that no PPI had been considered for the study.
- It was discussed that PPI is an important safeguarding element, where no explicit consent is being sought, to ensure a PPI perspective is reflected in the overall study.
- The HRCDC discussed that there are many support or advocacy groups that could be approached to discuss the study and understand the views and perspectives that would be representative of individuals whose data is being sought for the study. The HRCDC was also of the view that PPI was especially important considering the sensitive nature of the data that would be processed.

Transparency

- The HRCDC was of the view that insufficient transparency measures were to be implemented. It was not evident from the information provided how participants would be informed about this specific study, how their personal data is to be processed and how they could withdraw from the study, should they wish to exercise that right to do so.
- The HRCDC discussed that the privacy notices provided by the applicant were generic hospital privacy notices and not specific to this study. It was unclear how a participant would know of the existence of the study and have an opportunity to exercise their data protection rights.

Data and Biosample collection

- The HRCDC noted the data that will be collected includes Medical Record Number, co-infections with HIV and Hepatitis, year of birth, and sexual history. It was discussed that the extensive data being collected was of an extremely sensitive nature. It was further queried whether the medical records of the individuals and small number of participants would inform enough about disease prevalence and patient history.
- The HRCDC also queried if consent had been obtained initially, or any information provided to individuals who presented at the GUIDE/STI clinic for their biosamples and data to be stored for future use, beyond care and treatment. This is particularly relevant for participants whose data was collected after the General Data Protection Regulations in 2019.

	Consent/Contact • The HRCDC noted that attempts to consent or contact participants were not carried out. Considering the sensitive nature of the data to be collected and the relatively small numbers of participants, it was discussed that it would be possible and appropriate to contact and consent participants, especially if individuals were receiving follow up care. **Public Interest** • It was unclear from the information provided by the Applicant how the research questions, including the proposed risk factors for the disease to be identified, would contribute to the public interest. • When weighing up the aforementioned points of discussion, in particular the sensitive clinical data being sought in conjugation with the biosamples and the lack of data protection safeguards such as transparency measures and PPI in the study, the HRCDC was of the opinion that the public benefit and interest in the research study did not significantly outweigh the public interest in the requirement to obtain the explicit consent of the participant.
HRCDC Decision:	The consensus of the HRCDC was that No Declaration should be made.
HRCDC Feedback:	The HRCDC discussed that although no declaration was made, this does not preclude the Applicant Data Controller from submitting a new application in the future for this study, where significant and material changes have been made to the application seeking a consent declaration. Where best endeavourers have been made to seek consent from participants and where no response was provided, a consent declaration may be applied for in this scenario. All of the points outlined above must be fully considered and addressed, including the transparency measures and enhanced PPI. Any HRCDC decision would be made on the basis of the new application. This would be in line with Section 7 of the HRCDC Standard Operating Procedures

Reference ID:	20-032-AF1 ***[SUBSEQUENTLY WITHDRAWN, JANUARY 2021]***
Lead Applicant:	Deirdre Broderick
Lead Data Controller:	St James's Hospital, Dublin
Title:	Molecular Epidemiology of Mumps in Dublin, Ireland
Research Objective:	Mumps is an acute viral illness affecting the salivary glands, which can spread to glands in the reproductive system e.g. testes in men and ovaries in women, and the brain. Whole genome sequencing allows detailed examination of the genetic material of the virus, and comparison with other mumps strains to determine if the strains circulating in this patient group are all similar or different. The aim of the study is to perform whole genome sequencing on samples positive for mumps from the past 2 - 5 years, in order to examine if the mumps viruses are similar or different genetically.

Reason for Declaration:	For the purpose of receiving pseudonymised biosamples with an associated sample identifier from the National Virus Reference Laboratory (NVRL) in University College Dublin and carrying out subsequent anonymisation and analysis of the samples.
HRCDC Comments:	The HRCDC noted that provisional ethics approval had been granted by the Research Ethics Committee (REC) for the study where the design, methodology and ethical aspects of the study 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 discussed that there was a potential public interest in the study, however it was not clear from the limited information provided by the Applicant, if the public interest case in the study was sufficiently strong on balance with other data protection measures, specifically transparency measures and patient and public involvement. **Patient and Public Involvement (PPI) & Transparency** • The HRCDC noted that the Applicant had not considered PPI for the study and was of the view that, while PPI may not be necessary from individual perspective, it is nonetheless important for transparency purposes and to help ensure that there is patient and the public awareness and interest in the study. • The HRCDC discussed that the transparency measures in place for the study were inadequate and noted that the St. James's Hospital general privacy and data protection policies were being relied upon. **Data Protection Risks** • It was discussed that the data protection risks to the participants were extremely low given that only an individual sample identifier number, and no other data, was being transferred with the biosamples from the NVRL. **Analysis of biosamples & associated data** • The HRCDC noted that a relatively moderate number of biosamples sample identifiers were being accessed. • It was queried if the study could be carried out prospectively with consented participants, as opposed to carrying out analysis on retrospectively collected biosamples. It was discussed that there would be a benefit in analysing existing biosamples and data, from an epidemiological perspective, to understand disease incidence and prevalence.

	• The HRCDC discussed whether St. James's Hospital were receiving the entire biosample collected from patients who presented with mumps, or just an aliquot portion. From the information provided, it was noted that any remaining biosamples post analysis would be destroyed by the Applicant. **Consent** • From the information provided, the HRCDC discussed that it was not clear if any consent had been obtained, or information provided to the patient, for the storage and use of their biosamples and data for purposes outside of care and treatment at the time their sample was collected. It was discussed that information on what previous consent was obtained, or information provided, should be requested from the Applicant.
HRCDC Decision:	The consensus of the HRCDC was that a formal decision would be deferred pending receipt of further information.
Further Information Requested:	The HRCDC request further detailed information on the following queries: **Query 1.** For the purpose of determining the public interest case in the study, the Applicant is requested to provide the HRCDC with further information as to how the findings of the study may in practice influence, impact or result in changes to public health policy and services. **Query 2.** The HRCDC requests further detailed information from the Applicant as to what specific transparency measures can be implemented in advance of the study commencing and throughout the lifetime of the study, to ensure there is public and patient awareness regarding the existence of and subsequent outputs of the study. Consideration should be given to the use of appropriate websites, notices and any relevant groups/platforms to promote and disseminate the outputs of the study. It is advisable to consult with the Data Controller's DPO on this matter and provide substantiating documentation to the HRCDC, where relevant, when responding to this query. **Query 3**. The HRCDC request further information from the Applicant regarding the scope of consent that was obtained, or information provided, if any, when the biosamples and data were initially collected from the patient. Specifically, it should be clarified if the biosamples and data were consented for future storage and use at the NVRL, at that time. The original consent documentation should be provided, if available.

Reference ID:	20-037-AF1/COV
Lead Applicant:	Emer Doheny
Lead Data Controller:	University College Dublin
Title:	Home monitoring of respiration in COVID-19 patients using smartphone technology: analysis of retrospective data

Research Objective:	The patientMpower for COVID-19 app has been used in Irish hospitals to remotely monitor COVID-19 patients following discharge since March 2020. The app prompts users to monitor their oxygen saturation, breathlessness, temperature and heart rate, four times daily, and automatically generates clinical alerts using these data. The resulting database has enormous value in improving the understanding of symptom presentation and progression in COVID-19. The study aims to investigate the temporal characteristics and correlations between symptoms monitored using the app and to predict symptom progression in Covid-19 patients.
Reason for Declaration:	The data processing activities include the transfer, analysis and storage of pseudonymised, retrospective data of the app users for the purpose of this study. The users are limited to those who have already consented to the use of their data in research.
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 discussed the innovative use of the pre-existing data for research purposes and, overall, was of the view that there is a strong public interest case for this study. **Existing consent** • It was noted that the study will only process the de-identified data of app users who have already agreed via the app to the use of their data for research purposes; a declaration is sought by the Applicant as the consent obtained did not explicitly detail this study. • It was further discussed that processing the data of participants who have already provided consent for research purposes provides an additional data protection safeguard. **Transparency** • The HRCDC noted the transparency measures that will be implemented as referenced by the Applicant, specifically providing information about the study and the participant's data protection rights via the UCD and patientMpower websites. • The HRCDC discussed whether this information would be uploaded in a prominent and easy-to-access section of the

	websites so that participants and the public can be made aware of the study. It was also discussed if other communication platforms beyond the two websites could be utilised. • The HRCDC was of the view that the transparency measures should be enhanced so that the published study information is clearly visible and accessible to participants and the public. • In addition, it was re-emphasised that transparency measures should clearly outline how participants can exercise their data protection rights, including the right to withdraw and by providing relevant contact information. **Public and Patient Involvement (PPI)** • The HRCDC discussed the Applicant's response that no PPI has been undertaken for this specific study. • It was the view of the HRCDC that PPI provides an additional data protection safeguard in situations where it is not possible to obtain explicit consent and that PPI could be undertaken at any stage of a study, for example engaging with PPI groups from the research design to informing the dissemination of findings. **Data minimisation** • It was noted that 'clinical site' is a data field that will be obtained by the data controller, UCD. Considering the principle of data minimisation, the HRCDC queried if this data field was required to achieve the research objective. **Other** • Noting the transfer of data from patientMpower to UCD, the HRCDC queried the controllership of the research study and whether the data that is transferred to UCD is de-identified. • Based on the Applicant's response it was clarified that UCD are the sole data controller of the study and that UCD do not have access to identifiable personal data. • The exit strategy was discussed by the HRCDC and it was noted that the reference was made to archiving the data for future research purposes. It was clarified by the Applicant that the data will be fully anonymised 2 years after the study concludes. • The HRCDC discussed the Applicant's reference to a 'balancing rights document' that they are currently developing. It was discussed that it would be beneficial to request this document as part of the first Annual Review.
HRCDC Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made
Duration of Declaration:	The Conditional Declaration is made commencing 11th December 2020 and is valid until 1st January 2023 or upon confirmation that the data has been rendered anonymised or destroyed, or whichever occurs sooner.
Conditions Attached:	**Condition 1.** The HRCDC notes that information on this study will be published on the UCD and patientMpower websites. To ensure that participants and the public are made aware of this study and the use of their personal data, Information should be posted on a

	prominent and easy-to-locate section of both organisation's websites. - Consideration should be given to providing information on the study via other suitable platform including the COVID-19 app, social media and other relevant websites. - Transparency measures should clearly outline how participants can exercise their data protection rights, including the right to withdraw from the study and have their data deleted; - A relevant contact point for the study and data protection matters should be provided. This is a reporting requirement as part of the Annual Review **Condition 2.** 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 and to create a more patient-centred approach. The Applicant is requested to undertake public and patient involvement (PPI) in this study through, for example, direct engagement with representative COVID-19 patient and advocacy groups to inform the development of the study, dissemination of research findings and enhance the level of transparency for this study. This is a reporting requirement as part of the Annual Review. **Condition 3.** The Applicant is requested to submit a copy of the completed balancing rights document referenced in the HRCDC application form as part of the first Annual Review.
HRCDC Recommendations:	**Recommendation 1.** In line with the principle of data minimisation and to reduce the risk of re-identifying the patient, the Applicant is requested to consider if obtaining 'clinical site' is a required data point for the purpose of this study.

Reference ID:	20-034-AF1
Lead Applicant:	Ivan Perry
Lead Data Controller:	University College Cork (UCC)
Title:	A Capture-Recapture Study to Estimate the Prevalence of Problem-Opiate Use in Ireland (2015 - 2019)
Research Objective:	This research study aims to estimate the number of problematic opiate drug users in the Republic of Ireland from 2015-2019. Problematic opiate use is a significant problem in Ireland and across the globe. Opiates include drugs such as heroin, morphine, methadone, codeine, hydrocodone, fentanyl and tramadol. While some of these have valid medical purposes, their misuse as "street drugs" can lead to many health and social issues for users and society. The study aims to estimate the number of problematic opiate drug users in the Republic of Ireland from 2015 – 2019. This data will be used to compare trends in opiate use over time and inform government and policy makers regarding the scale of the problem. As measuring the prevalence of drug users is difficult, the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) recommend the use of indirect methods such as the

	capture-recapture method or the multiplier method to estimate the prevalence of high-risk drug users.
Reason for Declaration:	A declaration is required to process (access, obtain, match, consolidate and subsequently anonymise prior to analysis) the personal data previously collected by other agencies, for the purpose of this study.
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 and obtaining consent** • The HRCDC noted the extent of sensitive personal data that will be collected for this study and the vulnerable cohort involved. It was discussed whether participants would expect their data to be used in this way and whether it would therefore be appropriate to try and obtain the participant's explicit consent for the use of their data. • The HRCDC also queried the extent to which the research findings will impact areas such as policy and treatment. • However, the HRCDC noted the Applicant's response that personal data on up to 20,000 participants will be included in this study. It was the consensus of the HRCDC that obtaining consent from this number of participants, many of whom will be very difficult to trace and contact, is not practical or feasible. • The Applicant's reference that obtaining consent would be likely to critically undermine the capture-recapture methodology was also discussed. It was noted that this methodology is described as the most suitable technique to achieve the research objective and has been used in previous studies in Ireland examining this area. • It was further noted that the study is undertaken for the purpose of European reporting. • On balance, whilst recognising the sensitive nature of the data to be processed, the HRCDC was of the view that it would not be feasible or appropriate to obtain or attempt to obtain explicit consent and that the public interest in the study outweighed the requirement for explicit consent. **Public and Patient Involvement (PPI)** • The HRCDC noted the Applicant's response that there will be no engagement with individual participants about this study but that

	they will inform advocacy and patient groups with specific reference made to the National Drugs Forum. • However, the HRCDC was of the view that further PPI activities should be undertaken as an important data protection safeguard and to create a more participant-centred research approach. PPI was considered an important activity due to the cohort of participants and the sensitive nature of the data. It was also discussed that it should be feasible to effectively engage with some of the many groups that represent and support people with addiction issues. **Transparency** • The HRCDC noted the Applicant's response that they will publish notices on the Health Research Board (HRB) and UCC websites. • It was discussed that robust transparency measures are particularly important in the context of this study due to the sensitive nature of the personal data and the study cohort involved. • Therefore HRCDC was of the view that enhanced and broader transparency measures should be implemented to inform participants and the public about this study and their data protection rights, which could be achieved in part through enhanced PPI activities such as engagement with relevant representative and advocacy groups and communication channels. • In addition, information published on organisational websites, including the HRB and UCC websites, should be posted in prominent and easy-to-access sections. • The HRCDC commented that transparency measures should also reference and provide information on the previous versions of this study that have been conducted. • Furthermore, the HRCDC commented that enhanced transparency measures should be implemented in advance of the study commencing. **Anonymisation** • It was noted that the study will aim to fully anonymise the personal data it receives within one year of the study commencing. The HRCDC commented that the data should be anonymised as soon as possible once it has been matched and consolidated. **Data Transfer Agreements** • It was noted that data sharing agreements will be in place between data providers and the data controller/UCC of the study, prior to any data transfer. • It was further commented that, in limited circumstances where the data provider is unable to transfer the data to UCC, the study's co-investigator may be given direct access to the data on site in order to complete the dataset required for the study.

	• The HRCDC discussed that any agreements between the parties should include terms and conditions setting out obligations of confidentiality for direct access to the data. **Other** • The HRCDC commented that this decision does not create a precedent for future HRCDC applications seeking a declaration for similar studies investigating the prevalence of opiate use in Ireland. Therefore, future applications for equivalent versions of this study will be considered on their own merit. • If future studies should be undertaken, the HRCDC discussed that consideration should be given as to how patients who are receiving treatment and accessing services may be provided with information on the study, and could provide consent, where possible. • In addition, for future HRCDC applications the Applicant is expected to consider and address the issues of transparency measures, PPI and should discuss how future patients might be consented, in their application form.
HRCDC Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made.
Duration of Declaration:	The Conditional Declaration is made commencing 11th December 2020 and is valid for 1 year (until 11th December 2021) or upon confirmation that the data has been rendered anonymised or destroyed, or whichever occurs sooner.
Conditions Attached:	**Condition 1.** It is a condition that this declaration is not effective until confirmation has been received by the HRCDC that the required data transfer agreements are in place between UCC (the data controller of the study) and the providers of the personal data. Correspondingly, the agreements in place should include appropriate terms and conditions setting out obligations of confidentiality for researchers with direct access to the data on-site, where relevant. For the avoidance of doubt, no transfer of personal data and/or direct access to personal data can occur until the appropriate agreements are concluded. **Condition 2.** The Applicant is requested to implement enhanced transparency measures in order for participants and the public to be made aware of the study and the use of their personal data. It is a condition of this declaration that enhanced transparency measures are implemented prior to the commencement of the study. Specific transparency measures for consideration are as follows; - In addition to using the UCC and HRB websites and the National Drugs Forum as a platform for communication, the Applicant should consider publicising the study on websites of relevant representative and advocacy organisations and social media. Where possible the Applicant should engage with the data providers for publicising on its websites.

	- Information on the study should also be posted on prominent and easy-to-access sections of websites. - The information provided should also clearly outline to a participant their data protection rights and how they can exercise these rights, where applicable. A point of contact for the participant to engage with regarding the study and data protection rights should be provided. The Applicant is requested to report on the efforts made to enhance the level of transparency as part of the Annual Review *Note for context:* The HRCDC notes the Applicant's response outlining why participants may be unable to withdraw their data from the study. However, the HRCDC is mindful of an individual's data protection rights as provided for under the GDPR. Therefore, enhanced transparency measures should clearly outline the participant's data protection rights including any limitations/derogations of these rights as provided for in the GDPR. Please discuss with your Data Protection Officer. **Condition 3.** The Applicant is requested to enhance the level of PPI through direct engagement with representative participant support and advocacy groups. Engagement should be undertaken to inform and seek views from representative groups regarding the research design, dissemination of research findings and enhance the level of transparency within this study. The Applicant is requested to commence PPI activities within 3 months of the date of this declaration and confirm details of such in writing for the HRCDC. This is also a reporting requirement as part of the Annual Review. **Condition 4.** The HRCDC acknowledges that future studies on the prevalence of problematic opiate drug users in Ireland may be conducted. For the avoidance of doubt this declaration only applies to the '2015-2019' prevalence study and should not be construed as setting a precedent for future applications that may be made to the HRCDC.
HRCDC Comment:	**Comment.** Future applications to the HRCDC seeking a declaration must demonstrate that the safeguards set out in the conditions attached to this declaration, will be applied to future studies prior to commencement; specifically, robust transparency measures and PPI activity. Consideration should also be given as to how future patients can be consented to and/or informed of the research when they engage with health care services.

8. Annual Reviews

The Secretariat has received 3 Annual Reviews in advance of the meeting of which all 3 where deemed to be complete.

- 19-002-AF1: A retrospective case analysis of serious untoward incidents in super catchment mental health services in the HSE South East
- 19-012-AF3: Breast Cancer Proteomics and Molecular Heterogeneity
- 19-084-AF1: 1 Year post-sepsis study

9. Any other Business

- The HRCDC were informed of the latest updates with regards to new members of the Committee. It is expected that new members will be formally appointed by the Minister for Health shortly.
- The Chair updated the HRCDC on the proposed dates and times for HRCDC meetings in 2021. Members were also informed that an updated Doodle Poll will be circulated to finalise the meeting dates for 2021. It was confirmed that the next meeting of the HRCDC will be on Tuesday 26th January 2021.
- The Secretariat provided an overview of the activities of the HRCDC in 2020, including the number of meetings, applications submitted, decisions made and pending applications.
- The Secretariat provided an update that the amendments to the Health Research Regulations are due to be signed shortly and that guidance material to accompany the amendments have been developed.
- The Secretariat provided a briefing document regarding the CSO COVID-19 Data Hub for the HRCDC's information.
- The Chair thanked the HRCDC and Secretariat for their work throughout 2020, noting it was a particularly challenging and busy period.

*** The Chair closed the meeting***